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Introduction

**Chirantan Chatterjee, Anindya S. Chakrabarti and
Anil B. Deolalikar**

1. Introduction

As of April 23, 2022, the COVID-19 pandemic has caused 6.2 million deaths worldwide, with 507 million globally reported cases. China, among some other countries, is still struggling to contain it with a zero-covid strategy. The top 10 impacted countries include both rich and poor economies, including the United States, India, Brazil, France, Germany, and the United Kingdom.

This once-in-a-century pandemic has also caused many debates in science and evidence-based policy between scholars within and across disciplines, be it epidemiologists, clinicians, virologists, biostatisticians, economists, sociologists, political scientists, and management scientists, among others. This itself could be the focal point of another book around how the pandemic may have impacted Mertonian norms (of communism, universalism, disinterestedness, and organized skepticism) of science. One core debate, was around the distributional implications in economics of trade-offs between *health and wealth* (Bloom and Canning, 2000; Deaton, 2002; Glover *et al.*, 2020). In response to the pandemic, this translated into countries pondering strong nationwide lockdowns to

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protect vulnerable populations but at the cost of economic adversity versus focused containment strategies to minimize economic damages.

The accompanying hard policy choices made dynamically over the last two years by social planners in developed and developing countries resulted in debates between those espousing the John Snow Memorandum (<http://www.johnsnowmemo.com/>) and others who signed up for the Great Barrington Declaration (<https://gbdeclaration.org>).

2. Coverage

Our book is an attempt to learn from these debates for future pandemics. In the process, we cover some pivotal issues societies grappled with during COVID-19, in particular health, innovation, and the economy. We are fortunate here to have been able to assemble a geographically and scientifically diverse group of interdisciplinary scholars who discuss a range of topics, starting from the history of pandemics, exponential SIR growth models in epidemiology, to the pandemic's macroeconomic and adverse effects on health systems, apart from deliberating normatively on the future of global public health and confidence around health provisioning. We also have chapters discussing the emergence and reinvigoration of telemedicine as an alternative way to provide healthcare, the related challenges and benefits, and adaptive clinical trial protocols for pharmaceutical interventions. In one of the chapters, the role of seroprevalence and testing strategies in guiding federal and provincial lockdown policies is also discussed.

While the above chapters were about non-pharmaceutical interventions, within the ambit of pharmaceutical interventions, we have chapters covering the role of intellectual property for a one-world perspective on access to vaccines, the reshaping of global biopharmaceutical supply chains and conversations around national healthcare supply chain resilience herein, and the role of evidence-based medicine facilitated through digital health and electronic medical records. We also have a chapter on the effect of the COVID-19 pandemic on recombination innovation and Indian science, which should provide insights for the future into the science of science and innovation policy during a pandemic, especially under

resource-constrained settings, like in many low- and middle-income countries (LMICs).

Besides causing unintended consequences, the pandemic also resulted in global alarms over a silently rising epidemic in mental wellness, with disturbing impacts, especially on women, and vulnerabilities therein, and the learning losses in education, despite virtual teaching efforts worldwide. Our book pays careful attention to these questions as well with specific chapters from thoughtful scholars who are experts in their fields. The pandemic in addition caused concerns around food insecurity and prices that relates to the debates around inflation we are now seeing worldwide in 2023, and this is another focus in this book.

3. Health, Innovation, and the Economy

Surely, our book is not the first in the emerging literature on this aspect of COVID-19, nor will it be the last. Several other issues, such as the impact of the pandemic on misinformation, labor markets, the emergence of work-from-home standards worldwide and its effects on tools for virtual work (e.g., Zoom), remain not so forcefully discussed, though they have been touched upon in some of the chapters indirectly, and researchers are still trying to understand them better. Another key area was the role of the digital divide that impacted vulnerable populations during the pandemic within and across countries, especially impacting them during work or study from home. Similarly, discussions around the non-COVID effects of COVID-19 (such as on tuberculosis detection, antibiotics consumption, and cancer treatment) within healthcare that remained but are only indirectly discussed in this book.

That said, we do see value in our efforts resulting in a standard book for master's and doctoral studies given the way we have organized its layout. In the first section, we cover the core issues around protecting health worldwide, which starts with epidemiological exponential models, discusses the history of pandemics, deliberates on the normative role of health systems, and ponders on the unintended consequences of the pandemic on mental health. All this is meant to be a direct discussion about the confidence in providing healthcare in LMICs. The normative

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design of public health systems of tomorrow is also covered in the first section.

The second section is primarily focused on the consequences of innovation that came out of the pandemic, be that in trying to contain its spread or in responding to it with *ex post* interventions. With chapters on the role of seroprevalence tests guiding national and provincial lockdown policies, the role of the pandemic in spurring recombinant science and inventive work, the debates over intellectual property and access to vaccines for the Global South, the role of disruptive business models such as telemedicine to enable continued provision of healthcare, all related more broadly to a conversation around the economics and public policy of technological change and innovation in the second section. In addition, the pandemic unexpectedly spurred discussions about making clinical trials for medicines nimbler using adaptive trials and about maintaining electronic health record systems to enable evidence-based medicine. A final important conversation was on national healthcare and pharmaceutical supply chain resilience, which we address with focused chapters in our second section on innovation.

The concluding section on economy-wide effects includes chapters on the macroeconomic consequences of the pandemic, the impact of the pandemic on a developing economy, such as India, in the context of education, and its adverse consequences for food prices, inflation, and gendered effects.

4. Discussion and Policy Implications

The broad idea across the chapters is to use the reflections in the chapters to take away policy lessons for tomorrow's pandemic. The interested reader is encouraged, of course, to survey studies beyond the book, for example on the role of the pandemic in the shifting global geopolitical equilibrium. Overall, *Flattening the Curve* should offer a compilation of key topics for master's, doctoral, and postdoctoral students of pandemics in public policy, public health, management, and global health departments of universities to learn about what was done right and what was done not so right with the COVID-19 pandemic. The book should also be

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of interest to politicians, policy makers, and bureaucrats in office should they be interested in looking back and reflecting on their lives over the last couple of years, wherever they may be.

We ardently hope that the book will offer questions for future research and doctoral dissertations to better understand the COVID-19 pandemic and prepare the world for pandemic prevention in the future. This will be especially important given the United Nations Sustainable Development Goals of 2030 (which one can safely assume to have been severely impacted) amidst rising zoonotic diseases in the Anthropocene (Carlson *et al.*, 2021). While it is clear that much more remains to be done, we nonetheless wish the reader an enjoyable reading experience.

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Part I

Health

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Chapter 1.1

Modeling-Informed Policy, Policy Evaluated by Modeling

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Abstract

The coronavirus disease 2019 (COVID-19) pandemic that has had the world in its grip since the beginning of 2020 has resulted in an unprecedented level of public interest and media attention focusing on the field of mathematical epidemiology. Ever since the disease came to worldwide attention, numerous models with varying levels of sophistication have been proposed; many of these have tried to predict the course of the disease over different timescales, ranging from attempting to project the number of active cases over successive days and weeks to attempts at forecasting the date(s) on which subsequent “waves” of the pandemic will purportedly emerge. Other models have examined

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the efficacy of the various policy measures that have been adopted (including the unparalleled use of “lockdowns,” i.e., extremely stringent restrictions on travel, social interaction, and access to public spaces) by countries around the world in an attempt to contain and combat the disease. This multiplicity of models may have given the impression of an apparent overabundance of distinct mathematical approaches to investigate how pandemics evolve over time. More importantly, some of the more extravagant claims made by a few modeling groups about their ability to predict future outcomes, which went hand in hand with the occasional abuse of models by agencies with vested interests, have led to bewilderment in many quarters about the true capabilities and utility of mathematical modeling. Here, we provide a brief guide to the epidemiological modeling enterprise, focusing on how it has emerged as a tool for informed public health policy-making and has, in turn, influenced the design of interventions aimed at preventing disease outbreaks from turning into raging epidemics. We show that the diversity of models is somewhat illusory, as the bulk of them are rooted in the compartmental modeling framework that we describe here. While its basic structure may appear to be a highly idealized description of the processes at work, we show that features that provide more realism, such as the community organization of populations or strategic decision-making by individuals, can be incorporated into such models to make them behave in accordance with empirical observations. We conclude with the argument that the true value of models lies in their ability to test *in silico* the consequences of different policy choices in the course of an epidemic, a much superior alternative to trial-and-error approaches that are highly costly in terms of both lives and socioeconomic disruption.

Keywords: epidemiology; SIR models; COVID-19

1. Introduction

Every new pandemic brings about renewed interest in understanding the factors responsible for the rapid spread of diseases and the possible means by which they can be contained and subsequently eliminated. Apart from spurring developments in research into pathogen biology and advances in the medical practice of handling infections, the epidemics that broke out

in the 20th and 21st centuries have brought to the attention of public authorities the role that mathematical modeling can play in identifying key drivers of spread and suggesting methods to break the chain of infection (Anderson and May, 1992; Keeling and Rohani, 2008). Modeling also helps in analyzing the effectiveness of possible remedial measures, which may be either pharmaceutical in nature, e.g., designing the most efficient strategy for vaccinating the population if a vaccine is available but can only be given to a limited number of people within a specific timeframe owing to resource and personnel constraints, or involve non-pharmaceutical means, such as quarantining, travel restrictions, and workplace and school closure. Indeed, it is arguably a mathematical understanding of herd immunity, conferred upon vaccinating only a part of the population, that made it possible to aim for the complete elimination of life-threatening diseases, as was achieved for smallpox in 1980 when WHO declared it to have been eradicated from the entire world (Henderson, 1976, 2011). Unfortunately, this success could not be emulated with other vaccine-preventable diseases as yet — although much of the world has been made polio-free through sustained vaccination campaigns (Larson and Ghinai, 2011). More alarmingly, childhood diseases, such as measles, for which effective vaccines have existed for decades are appearing to make a comeback even in affluent countries as a result of vaccine hesitancy (Hotez *et al.*, 2020). As this potentially threatens to reverse the great gains made in public health over the previous century through mass vaccination, mathematical modeling to identify the factors that may reduce vaccine uptake in the population serves a very important purpose in preventing future pandemics (Bauch and Bhattacharyya, 2012).

Thus, modeling has played multifarious roles in shaping epidemiological policy for several decades before the COVID-19 pandemic broke out in early 2020. However, what appears to be different this time, as we struggle with the pandemic even after two years since the initial outbreak in Wuhan, China in December 2019, is the prominent part that modeling has played in driving the various policies adopted by countries around the world to contain further spread and reduce mortality (Hale *et al.*, 2021). Unlike epidemics in the recent past, such as the SARS outbreak in 2003 (see, e.g., Hufnagel *et al.*, 2004; Chen *et al.*, 2007) or the more widespread 2009 swine flu pandemic (Jesup *et al.*, 2010), which were also occasions

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when modeling was extensively employed, during this pandemic, modeling (and modelers) has been prominently featured in the media and mathematical epidemiological terms, such as R-nought, have become common household terms. Moreover, results from model simulations have been cited by the authorities to support the roll out of different measures or at least justify them afterward. Of course, the real-time use of model simulations to understand the course of an ongoing epidemic and test the efficacy of possible countermeasures which are then applied in the field is not in itself new. For example, during the 2001 epidemic of foot-and-mouth disease (FMD) among livestock in the United Kingdom, modeling was used to compare the effectiveness of country-wide preemptive vaccination against a policy that combined reactive vaccination and culling in affected farms (Ferguson *et al.*, 2001). Also, detailed agent-based models, taking into account information about the movements throughout the day of individuals residing in a city, have already been used earlier to determine strategies that would be the most effective response to a sudden outbreak of an infectious disease, possibly via deliberate release of pathogens within an urban environment by hostile forces (Barret *et al.*, 2005).

The current pandemic has, however, dwarfed previous efforts at using models to devise policy by the sheer volume of literature that has been produced over such a short time, and the attention that has been given to various scenarios described by the models by the public, the media, and governmental agencies is possibly unprecedented. It has highlighted, as never before, the role that data-driven quantitative analysis (and specifically, epidemiological modeling) can play in arriving at crucial decisions affecting public health (Van Kerkhove *et al.*, 2010). It has also revealed the limitations of modeling when it comes to making accurate forecasts of a future outbreak, an inherently stochastic event which is affected by a multitude of factors, not all of which are well-understood or for which data are available. Indeed, while models that involve a large number of variables and mechanisms can be developed to describe a pandemic, these typically also involve fitting many parameters from data that are inherently noisy and often incomplete so that, in practice, simpler models with fewer parameters may be more useful. Furthermore, modeling allows performing *gedankensperiments*, whereby the impact of different policy decisions on the future progress of a pandemic can be gauged without

having to go through a costly (both in terms of resources and lives lost) trial-and-error process. In this chapter, we first provide an outline of the early connection between modeling and public health policy design (indeed modeling itself arose from the need of providing convincing arguments for specific policies) before proceeding to describe how mathematical epidemiology has helped in designing vaccination policies, which has been the cornerstone of the giant strides made in epidemic management since the latter half of the past century. We go on to describe how developments in network theory has helped bring about a new age of data-informed public health policy design, and finally, we show how the use of game-theoretic models is helping us understand the complex process by which individuals choose (or not) to adhere to the directives of public health authorities, which dictate the success or otherwise of such policies. We conclude with a short discussion of the future outlook based on the experience with managing the COVID-19 pandemic.

2. The Beginnings

Surprisingly, the mathematical modeling of epidemics was pioneered not by a mathematician but by a medical doctor, Ronald Ross, who of course gained international renown for establishing the critical role that mosquitos play in transmitting malaria from one infected individual to another (for which he was awarded the second ever Nobel Prize for Physiology and Medicine in 1902). However, elucidation of the path of disease transmission was only the means toward an end for Ross, whose principal goal was the prevention of malaria. He continued to work toward this end with a single-minded focus using the insights he had gained from his laboratory work to inform methods for controlling the spread of malaria (*Nature*, 1948). Ross had decided that controlling the population of mosquitos (the vector for malaria) is the key to this, and in 1899, he was provided an opportunity to test his ideas for promoting public health when he headed a three-member team sent in 1899 by the Liverpool School of Tropical Diseases to Sierra Leone, then a British colony in West Africa, to investigate the causative factors of malaria and suggest means of controlling the spread of the disease (Bockarie *et al.*, 1999). This was prompted by the extremely high mortality of the colonists infected by malaria, with the disease-induced death rate

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among European soldiers stationed in Sierra Leone being more than eight times higher than among the soldiers recruited from the local population (Wilson, 1898). The team identified two native mosquito species as being responsible for transmitting malaria to humans, a definitive demonstration that mosquitos are responsible for human malaria (Austen, 1899).¹ The team's recommendation for reducing the incidence of malaria involved antilarval measures, such as applying tar to large, stagnant waterbodies and the removal of containers including bottles, cans, and tires, as well as filling potholes in roads, which can function as storage for rainwater (and hence potential breeding grounds for mosquitos). However, only limited funds were made available for these activities, so they could not be continued for any extended period of time. Not surprisingly, after the measures were stopped, mosquito breeding continued once more. Thus, as the measures did not appear to have had achieved a lasting reduction in malaria incidence, the authorities concluded that the results of the trial did not justify the expenses of carrying out a regular program for controlling mosquito breeding.

This first effort was subsequently followed by additional experimental trials in malaria prevention by controlling mosquito breeding, such as by the US Army officers W.C. Gorgas and J.A. LePrince in Cuba in 1899 — which they followed up in collaboration with S.T. Darling in the Panama Canal Zone during 1904–1914 (Gorgas, 1906) — and Ross himself in Ismailia, Egypt during 1901–1903 (Ross, 1903) and subsequently in Mauritius in 1908 (Ross, 1908). Ross had argued that the fact that malaria was widespread even in places where people used personal prophylaxes, such as mosquito nets and treatment using quinine, indicated that these measures will not by themselves be effective in eradicating malaria unless accompanied by control of the population of mosquitos that carry the disease (Ross, 1903). He had pointed out that reduction in mosquito numbers by even a modest amount should have a substantial impact on the

¹In India, Ross had demonstrated the role of mosquito in transmitting avian malaria. The crucial step that showed humans could contract malaria on being bitten by mosquitos that had previously bitten malaria-infected humans could not be experimentally established during this time because of a number of factors, including, perhaps understandably, the lack of volunteers willing to be bitten by infected mosquitos.

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incidence of the disease. Rather than draining of marshes or large pools, this involved preventing mosquitos breeding in stagnant water that may have collected in much smaller tanks or even pots and holes. Based on his experiences with authorities who were unwilling to continue devoting funds and manpower in a sustained manner into programs whose effectiveness they were unconvinced of,² Ross realized that a “proof” that such methods work will be difficult to provide based on field data alone. He therefore turned to modeling.

Ross had understood that for new cases of malaria to occur, the parasite must be present in a large number of individuals and mosquitos that are capable of carrying it also will have to be numerous. If these conditions are not met, the chain of infection can be broken. This insight formed the basis for his public health program aimed at controlling malaria, which he described using a simple quantitative argument (Ross, 1910). To begin with, Ross considered a single individual infected with malaria in a population of 1,000 individuals and asked, what is the probability that a mosquito will be able to transmit the infection to another individual. Ross argued that because not every mosquito can bite a human, we can assume a one in four probability for such an event. Furthermore, such an event will have to involve the single infected individual, who is randomly chosen from the total village population of 1,000, yielding a probability of 1/4,000 that a mosquito will bite the infected person. As a mosquito does not immediately become infectious upon ingesting the parasite, we need to consider a probability (one in three, say) that it survives for the number of weeks required for the parasites to mature and then factor in the probability that it will bite a human (one in four, as mentioned previously). Thus, the probability that a single mosquito will be able to infect another person from the index case is 1/48,000. Thus, for the expected number of mosquitos that can continue the infection to be even of the order of unity, the population of the mosquitos will need to be

²As Ross put it in what he referred to as the sanitary axiom: “Widespread diseases … cause much pain, poverty, sorrow, expense and loss of prosperity … and the rule is to grudge spending a hundred pounds for disease which costs thousands…[Therefore] “for economic reasons alone, governments are justified in spending for the prevention of [malaria] a sum of money equal to the loss which the diseases inflict on the people” (Ross, 1910).

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at least tens of thousands. Thus, in order to control or eliminate malaria, one need not have to achieve complete extermination of mosquitos, but bringing their numbers down to levels that are practically achievable can potentially break further progress of the infection so that once the infected person has recovered, there will be no further risk of malaria. This is a truly remarkable thought experiment that shows how quantitative reasoning can help guide public health policy.

These arguments were put in a more formal mathematical form by Ross in 1911 by describing the evolution of the number of infected individuals in a population using a system of coupled differential equations (Ross, 1911). It is interesting that he framed this in terms of a very general process by which a certain event (which could be, among other things, death or marriage or even bankruptcy) can occur to members of a population and was not restricted to only the transmission of pathogens. Given a certain probability of such an event occurring to any one individual, Ross asked how many would be affected at any particular instant.³ During 1916–1917, in collaboration with the mathematician Hilda Hudson, Ross developed a general theory of epidemics building upon this foundation. It was termed “*a priori* pathometry” by Ross, as instead of trying to understand *a posteriori* the reasons for the observed behavior of an epidemic, the theory was aimed at describing the process by which an epidemic spreads in order to predict how such an event will develop over time (Ross, 1916; Ross and Hudson, 1917a, 1917b). To realize its full potential though, it had to be connected with parameters that could be measured from empirical data such that the output of the model could be made to quantitatively fit the field observations for a specific epidemic. This was done by George MacDonald in the 1950s, when he revised the model for the spread of malaria devised by Ross in order to include metrics for key components determining the nature of spreading by mosquitos, such as their death rate and feeding rate (Smith *et al.*, 2012). This allowed one to

³This “theory of happenings” by Ross can thus be seen as a precursor of attempts to understand social and economic behavior in terms of how an event occurring to an individual can often be seen as an outcome of her interactions with other members of the population, an endeavor that has in recent times been often referred to as econophysics or sociophysics (Sinha *et al.*, 2011).

extract results with important public health implications, most importantly, allowing identification of the most vulnerable link in the chain of transmission which could be targeted using control measures to arrest further spread of a disease.

3. Compartmental Models of Epidemics

While Ross' model is considered to be a pioneering effort in the quantitative description of an epidemic, the work done by his protégé Anderson McKendrick (a military doctor, McKendrick had accompanied Ross to Sierra Leone and had been influenced by Ross' mathematical arguments) in collaboration with William Kermack, a chemist by training, has arguably been more influential in the development of mathematical epidemiology to its current stage (Kermack and McKendrick, 1927). While Ross had focused on the phenomenon of transmission of infection, Kermack and McKendrick considered the entire course of an epidemic, in particular, asking why and how does it end. In trying to answer this question, they developed a mathematical model for describing the dynamics of epidemics in general (i.e., not limited to a specific disease, such as malaria) and showed that depending on the values of certain key parameters, an outbreak can either quickly die out spontaneously or result in an epidemic — thus pointing to the existence of an epidemic threshold. Furthermore, their model could explain why an epidemic dies out even when a part of the population is yet to be infected and the pathogen has not lost any of its ability to infect. For simplicity, they assumed the population to be *well mixed*, in the sense that any given individual could be in contact with any other individual at any time. This allowed them to approximate the expected number of new infections at a particular instant to be proportional to the number of infectious individuals and the number of those whom they can infect upon coming in contact (this latter category is termed as susceptible). Taking into account that those who have already been infected and have subsequently recovered develop a resistance or immunity to further infection allows partitioning the population into a finite number of *compartments*, viz., those comprising individuals who are susceptible (S), infected (I), or recovered (R) (see Figure 1).

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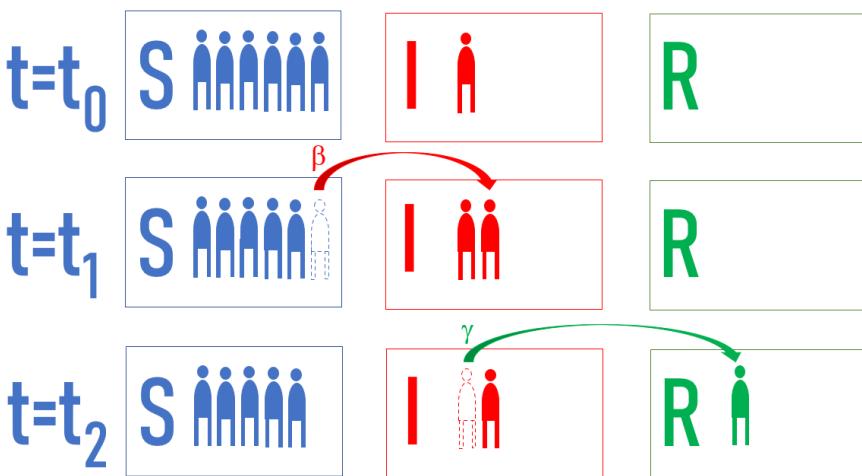


Figure 1. Schematic diagram of a susceptible–infected–recovered compartmental model for epidemic progression. The rows represent the situation at successive time periods, with $t = t_0$ corresponding to the initial state when the first infections appear, with almost the entire population being susceptible. At subsequent times, susceptible individuals move to the infected category and infected individuals move to the recovered category. The corresponding rates are indicated on the arrows representing these inter-compartment transfers.

The resultant SIR model is the simplest of the compartmental models, which sees the progress of the epidemic as a transfer of part of the population successively from S to I to R compartments. The probability that any individual in S compartment will get infected (and hence be moved to the I compartment) upon coming in contact with an infected individual for time interval dt is given by βdt , where β is the rate of spread. On the other hand, an infected individual can recover with a rate γ , and this recovery rate determines the rapidity with which individuals move from compartment I to compartment R. Under the well-mixed assumption, if i is the fraction of the population that is infected, then an individual having k contacts is likely to find ki of these to be with individuals who are infected. As each of these contacts has a probability βdt of successfully transmitting infection, the probability that at least one of these gives rise to a new infection is $1 - (1 - \beta dt)^{ki}$, which in the limit of extremely small time interval such that $\beta dt \ll 1$ simplifies to $\beta k i dt$ (retaining only the leading

order in the power series expansion). If we also approximate the number of contacts k of each individual with its mean value $\langle k \rangle$ across the entire population, the resulting time-evolution equations for the fractions of population s , i , and r residing in the compartments S, I, and R, respectively, are (Barrat *et al.*, 2008)

$$\begin{aligned} ds/dt &= -\beta\langle k \rangle is, \\ di/dt &= \beta\langle k \rangle is - \gamma i, \text{ and} \\ dr/dt &= \gamma i. \end{aligned}$$

It has been implicitly assumed that the epidemic occurs at a much faster timescale compared to that at which demographic changes take place such that the total population summed over the compartments is constant, i.e., $s + I + r = 1$. Thus, only two out of the three variables are independent. As by definition, an epidemic is said to occur when $di/dt > 0$ (i.e., the infected population grows over time), the threshold condition needed to be satisfied for an epidemic to take place is $\beta\langle k \rangle s - \gamma > 0$. Noting that the recovery rate is the reciprocal of the average period t for which an individual is infectious, we can rewrite the condition as

$$\beta\langle k \rangle \tau_s > 1. \quad (1)$$

For a disease against which no vaccine is available, at the time of an initial outbreak, almost the entire population can be assumed to be susceptible such that $s \approx 1$. Under this circumstance, the infected fraction will evolve as $di/dt = (\beta\langle k \rangle - \gamma)i$. Thus, if $\beta\langle k \rangle > \gamma$, the fraction of infected will increase exponentially; conversely, it will rapidly decay to zero if $\beta\langle k \rangle < \gamma$. As the solution of the equation provides a quantitative measure of the rate of growth of the infected population, it can be connected to one of the most important metrics for an epidemic, viz., the basic reproduction number (R_0). This measures the mean number of infections that result from contacts with a single infected individual in a wholly susceptible population (Heesterbeek, 2002) and can be expressed in terms of the parameters of the SIR model as $R_0 = \beta\langle k \rangle / \gamma$.

It is easy to see from Equation (1) that the rate of progress of an epidemic is essentially influenced by the following four different factors: (i) the ease with which a contact between infected and susceptible

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individuals result in a successful transmission of infection (β), (ii) the mean number of contacts between individuals ($\langle k \rangle$) which is an attribute of the social network that they are part of, (iii) the duration for which a person is able to infect others (τ), and (iv) the proportion of the population which is susceptible (s) (Anderson and May, 1992; Kucharski, 2020). As it is the product of these four quantities that yields the epidemic growth rate, it suggests a multipronged approach toward controlling an epidemic, whereby any combination of these factors can be targeted by public health policy interventions to stop the epidemic. Thus, public hygienic practices, such as use of masks and disinfection, attempts to decrease β , while a lower $\langle k \rangle$ is sought by quarantining, school or workplace closure, and physical distancing — and in extreme cases, by imposing shelter-in-place or lockdown. Measures put in place for rapid detection through mass testing and isolation of the identified infectious individuals aim at reducing τ . Finally, if a vaccine is (or becomes) available, it can reduce s by transferring individuals from the S directly to the R partition, without having to enter the intervening I compartment. As some of the factors may be more amenable to reduction through the means available at hand, the usefulness of the expression of the growth rate in this product form is enormous, allowing us to determine by how much the achievable reduction in the different factors can slow down the spread of an epidemic. In this context, it is important to note that even small reductions in each of the factors can result in a relatively large decrease in the growth rate, possibly bringing it below the epidemic threshold. Thus, the public health policy implications of even such a simplified model are far-reaching.

Moving our focus away from the beginning of an epidemic, if we now consider its entire trajectory, we observe that the initial exponential rise of i eventually slows down, plateaus, and then declines (Figure 2). This is entirely consistent with the fact that the total population is conserved, and with time, the number of individuals remaining in the susceptible compartment will decline. Thus, after the epidemic has continued for some time, an infectious agent will mostly encounter individuals who are either already infected or have recovered from it (and are therefore immune). While there may still be susceptible individuals remaining, if they are screened from the pathogen by the majority that are in the I or R compartments, the number of new successful transmissions will be few and far

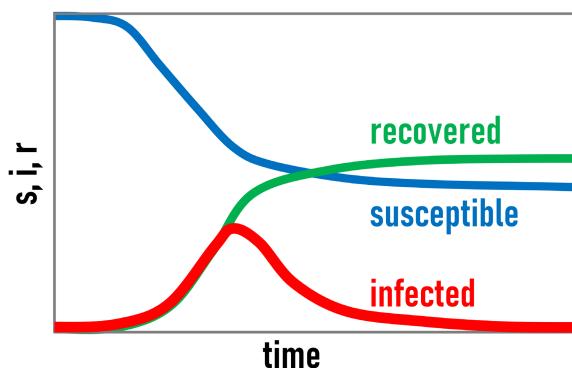


Figure 2. Typical time-evolution (shown schematically) of the susceptible, infected, and recovered population fractions in a simulated epidemic in the SIR model.

between. Eventually, when the pathogen can no longer find a susceptible individual over the time period during which all remaining infected individuals recover, the chain of transmission will be broken and the epidemic will come to an end even though there will still be susceptible individuals remaining in the population (see Figure 2). This situation is usually referred to as one in which the population has reached *herd immunity* such that even though there may be individuals who may still acquire the infection, collectively, the population is able to resist an epidemic.

The size of the susceptible population remaining at the end of an epidemic turns out to be a function of the basic reproduction number and is given by the implicit equation $s(\infty) = \exp(-R_0 [1 - s(\infty)])$ (Diekmann and Heesterbeek, 2000). Its complement, i.e., $1 - s(\infty)$, yields the final size of the epidemic, i.e., the total fraction of the population who would have been infected at one time or another before the epidemic runs its course *if no measures are taken to mitigate it*. Needless to say, this is also an important metric from the perspective of public health. In the context of the COVID-19 epidemic, for which R_0 has been calculated to be between 2 and 3 for most countries, this translates to about 80–94% of the population being eventually infected before herd immunity is achieved.⁴ This has

⁴In reality, the exact value of the fraction of population that needs to be infected before reaching herd immunity for COVID-19 is hard to calculate owing to a number of factors,

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obvious bearing on the discussions about the nature of measures that ought to be adopted to counter the epidemic. During the early stage of the COVID-19 pandemic in 2020, several countries were debating whether it would be more beneficial to not introduce socioeconomically costly lockdowns and just allow the population to achieve herd immunity by having the infection spread, albeit in a controlled manner (Khalife and VanGennep, 2021). Among advanced economies, the United Kingdom (to some extent) and, most notably, Sweden chose this path, arguing that by shielding the most vulnerable segment of the population from getting infected and assuming that the younger population, despite getting infected in large numbers, will be less likely to suffer life-threatening manifestation of the disease, the epidemic can be managed with minimum disruption. However, in practice, the policy not only led to more infections but also a higher level of hospitalization and greater number of deaths than what was seen in the neighboring countries of Norway, Denmark, and Finland, which had adopted more interventionist approaches (Orlowski and Goldsmith, 2020). More worryingly, high levels of mortality persisted in Sweden for a longer period than in its neighbors, running counter to the assumption underlying its strategy. This was that trying to “flatten the curve” by adopting stricter measures to prevent infections would only prolong the epidemic, whereas allowing the disease to spread among the population would result in herd immunity being quickly achieved (thereby protecting the vulnerable population from infection).

While our discussion of the compartmental modeling framework has only considered in detail the basic SIR model, the framework is general enough to accommodate additional compartments that may be necessary to adequately describe the specific features of the progression of a disease whose epidemic is being investigated. Indeed, it appears that for describing the COVID-19 epidemic, it is important to take into

which has led to many different estimates being publicized at different times (McNeil, 2020). Some of these factors complicating the estimation include the different mitigation measures that have been undertaken at various stages, variation in the degree of susceptibility among individuals, presence of several strains of the virus to which a population may exhibit different resistances, and the possibility of reinfection among those who had previously been infected.

account the latency period between the transmission of the pathogen to a susceptible individual (exposure) and the pathogen starting to multiply within the individual (infection, which may be either symptomatic or asymptomatic). This is incorporated by inserting an additional compartment E, corresponding to the category of individuals who are exposed, between the S and I compartments of the model (which is thus termed as SEIR model). Comparison between different models suggest that the projections of disease incidence made using such SEIR models tend to be relatively more accurate (Friedman *et al.*, 2020), and they have indeed been used widely to fit the evolution of the COVID-19 pandemic in different countries and regions (see, for example, IHME COVID-19 Forecasting Team, 2021, for forecasts of COVID-19 scenarios in the United States).

It is of course possible to introduce other compartments into an epidemic model, e.g., distinguishing between symptomatic and asymptomatic infected individuals. This may be an important distinction to include in the model if one is aiming to study the role that rapid identification and subsequent isolation of infectious individuals may play in containing the epidemic. While it may be difficult to identify asymptomatic cases — who may be themselves unaware that they are infected and thus will not seek medical attention — in the absence of widespread (and repeated) testing, these individuals are often just as likely to transmit the infection to others as symptomatic cases (Gao *et al.*, 2021). It has been estimated that more than a third of all COVID-19 infection cases are asymptomatic (Sah *et al.*, 2021), which could be silently contributing to the chain of propagation of the infection, making surveillance-based control of the pandemic particularly challenging. Indeed, it has been reported that more than half of all COVID-19 infections could have been caused by individuals not showing any overt signs of being infected, i.e., who were either presymptomatic (i.e., yet to show clinical symptoms) or asymptomatic (Moghadas *et al.*, 2020).⁵

⁵Distinguishing between presymptomatic and asymptomatic individuals may also be necessary in some cases. This can possibly be implemented by having the flow from the exposed (E) compartment bifurcate into two streams, one going over to the asymptomatic

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Other additional compartments may be included by further dividing the infected compartment into those who developed only mild symptoms and those for whom the disease manifested in an extremely severe form, which would be necessary if one is using the model to project hospital occupancy or ICU requirement. Again, to estimate deaths arising due to the infection, the R compartment may be divided into sub-compartments corresponding to those who recovered and those patients who were removed from the population through death. The possibility of reinfection among those who had already been infected earlier (Stokel-Walker, 2021) can also be investigated in this modeling framework by assuming that individuals in the recovered category may, with a certain rate of immunity loss, reenter the susceptible category, thereby allowing them to be infected once again. Such SIRS dynamics, when simulated on a social contact network, can exhibit persistently recurring outbreaks resembling multiple “waves” of epidemics (Jesan *et al.*, 2016). However, one must keep in mind that increasing the complexity of the model by introducing many compartments does not necessarily lead to more accurate description of the actual epidemic. This is because of the much larger number of parameters governing the dynamics of these more complex models, each of which needs to be fitted from the data and are hence susceptible to problems associated with parameter estimation (Basu and Andrews, 2013). Therefore, in practice, a simpler model having fewer compartments may be easier to calibrate with empirical data (and in a more robust manner) and hence be capable of providing a more accurate picture of an epidemic than one which has many more compartments in order to conform more closely with reality. Ultimately, which model is best for one’s purpose depends on the questions that are being asked.

The compartments could be further subdivided according to the innate characteristics of individuals (e.g., their age) if the resulting subpopulations differ in terms of the various rates that govern the epidemiological dynamics. Given the differential effect of COVID-19 according to age, with older patients forming the bulk of the severe cases with an increased mortality risk (Davies *et al.*, 2020), several models, including ones

compartment while the other successively passes through the presymptomatic and symptomatic compartments, both eventually converging again in the R compartment.

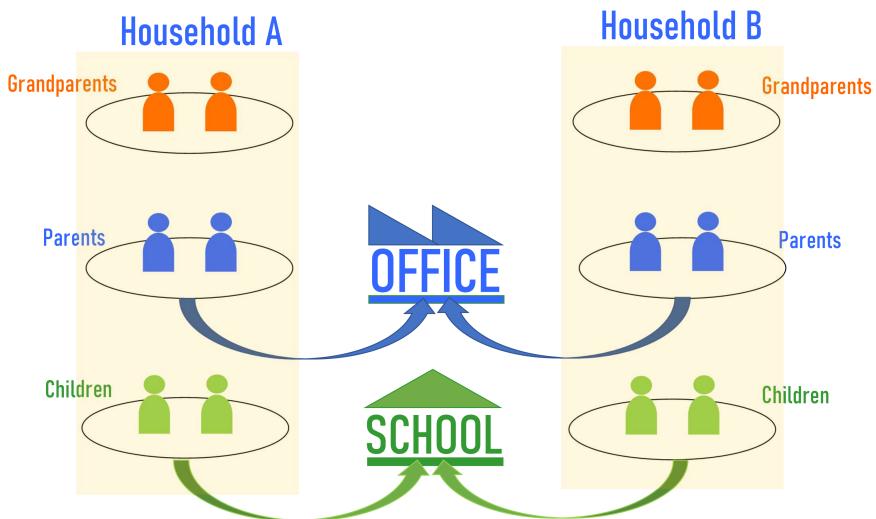


Figure 3. Considering the age structure of a population is important in analyzing the spread of an epidemic not only because the effect of the disease on different age groups may differ drastically but also because the frequency of contacts (resulting in potential exposure) may differ remarkably between, as well as, across individuals belonging to different age groups. Within the same household, senior citizens may have much more limited contact with individuals outside their home, compared to adults and children, who will come into contact with others at offices and schools, respectively.

modeling the epidemic in India (Hazra *et al.*, 2021), have considered the age structure of the population. The mobility pattern and contact rates of individuals in different age groups can be considerably different (Figure 3) and are affected differently by targeted containment strategies, such as school closure or workplace closure. Thus, it is expected that by considering the different rates of transmission within and between distinct age categories, a more accurate picture of disease progression can be obtained (Wilder *et al.*, 2020). Indeed, such studies suggest specific policies as regards optimal containment, taking into account the economic impact of such policies. For example, it has been suggested that making half of the population of a particular age group to shelter in place (i.e., undergo lockdown) while ensuring only physical distancing for the rest can substantially reduce both infections and deaths (Wilder *et al.*, 2020). As this will

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have a much more limited social and economic cost compared to a complete lockdown, it does seem like a welcome alternative to the global lockdown policies followed by many governments around the world. In particular, modeling the spread of COVID-19 on a simulated social network has led to the suggestion of implementing an alternating quarantine procedure, whereby at any time, half the workforce works for one week while the other half shelters in place, with the roles being exchanged on alternate weeks (Meidan *et al.*, 2021).

4. Vaccination

The idea of herd immunity for preventing an epidemic, originally conceived in terms of the critical fraction of the population that needs to be resistant against contracting the disease by prior infection, also applies when vaccination can be performed to make individuals immune without having them go through the infected stage (i.e., direct passage from the S to the R compartment). Assuming that the vaccine has a 100% effectiveness (i.e., anyone receiving it is completely immune and will never get infected), then if p is the fraction of the population that is vaccinated, the fraction of the population that is still susceptible to the disease is $s = 1 - p$. From the condition for an epidemic to occur (Equation 1), it is easy to see that in order to prevent an epidemic, we will need to vaccinate more than $p_c = 1 - (1/R_0)$ fraction of the population. Thus, for a disease like COVID-19, for which R_0 is reportedly mostly between 2 and 3, more than 50–66% of the population needs to be vaccinated to prevent any local outbreaks from spreading. Note that this is a lower bound, as none of the vaccines that have been introduced so far against the disease has 100% effectiveness, ranging instead from 95% down to 67% (Evans and Jewell, 2021); moreover, their efficacy appears to decrease with time (Katella, 2021). If a vaccine is only partially able to confer protection, it is intuitively clear that the threshold percentage of population needed to be vaccinated will need to be higher. Indeed, if we assume that a vaccine prevents infection in only ϵ fraction of the recipients (i.e., ϵ is the vaccine effectiveness in the field — which may differ from the efficacy observed in clinical trials), then at least $(1 - 1/R_0)/\epsilon$ fraction of the total population must be vaccinated in order to keep an outbreak localized. This implies that if the

effectiveness is less than $(1 - 1/R_0)$, then the epidemic cannot be terminated even after the entire population has received the vaccine (Fine *et al.*, 2011). The important implication of this result is that any COVID-19 vaccine that has less than 66% effectiveness may not be worth introducing for public use, an important input for taking decisions on vaccine policy.

A useful comparison may be made with the worldwide vaccination program for the eradication of smallpox that was carried out by the WHO during 1966–1977. As estimates of R_0 for smallpox vary between 3.5 and 6 (Gani and Leach, 2001), the strategy was to achieve in every country more than 80% coverage through mass vaccination. This was obviously difficult to achieve in poorer economies, as is also seen in the present for COVID-19 vaccination.⁶ However, in places where there were insufficient vaccines to achieve the critical vaccinated fraction, an alternative strategy involving identifying every new case of smallpox and then containing the infection by vaccinating all primary as well as secondary contacts (i.e., the contacts of primary contacts) turned out to be successful in eradicating the disease even in areas where the coverage was substantially lower than the threshold (e.g., in Nigeria it was less than 50%) (Belongia and Naleway, 2003). Indeed, such ring vaccination became the dominant strategy in the latter stages of the WHO smallpox eradication campaign. While this may suggest the use of similar methods for countering the poor coverage of the COVID-19 vaccines in several countries, it has to be noted that the strategy worked so well for smallpox even when there were delays in identifying cases partly because every infected person eventually manifests clinical symptoms of the disease and partly because it is transmitted only after relatively prolonged contact with the infected person (Deen and von Seidlein, 2018). In contrast, a large number of COVID-19 cases are asymptomatic even when they are infectious, and the pathogen spreads fairly easily, for example, via aerosols that can be inhaled even by persons not in close proximity to the infected individual (Jarvis, 2020).

⁶As of December 6, 2021, while 72% of the population in the US and Canada have received at least one dose of a vaccine against COVID-19, this is only 11% for Africa. For comparison, India during the same time has had 35% of the population fully vaccinated and 59% had received at least one dose. Globally, 56.5% have received at least one dose (Holder, 2021).

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However, there are other characteristic features of COVID-19 that could be considered to design optimal vaccine strategies. For example, the differences observed in the epidemic dynamics in different age classes can be exploited. This is not unique to COVID-19, as such age-structure effects can be seen, for instance, in influenza, for which modeling has shown that the most effective reduction is achieved by preferentially vaccinating school-age children and young adults, as this is more likely to break the chains of infection (Medlock and Galvani, 2009). Although there are similarities between these two diseases, it turns out that this is not true for COVID-19, as the success of a strategy also depends on the effectiveness of the vaccine being used (Bubar *et al.*, 2021). If a vaccine has lower efficacy, the indirect benefits of vaccination in protecting unvaccinated individuals from being exposed to the pathogen would also be reduced. In this case, the transmission may continue onward even when younger, more mobile individuals are vaccinated, so it may be more effective in terms of mortality reduction to vaccinate the older population who have a higher risk of suffering from severe forms of the disease (possibly leading to death), especially since, unlike influenza vaccines, there is little evidence of age dependence in the efficacy of COVID-19 vaccines (Bubar *et al.*, 2021).

5. Networks

We have so far considered transmission in populations that are well-mixed (i.e., any pair of individuals in the population has the same probability of being in contact). This presumes a homogeneous contact structure, with every individual having more or less the same number of contacts that are randomly distributed among the population. While this may be interpreted in terms of random graphs, i.e., networks in which every pair of nodes has an equal probability p of being connected, such a contact network structure does not accord with reality, even though it makes the models mathematically tractable (Andersson and Britton, 2000). Developments in our understanding of the complex networks that underlie real-world systems (see Newman, 2010, for a comprehensive review) has therefore also led to a better appreciation of how the structure of the connection topology affects the progression of epidemics (Newman, 2002). In particular, many

studies have focused on the role of degree heterogeneity, i.e., variations in the number of contacts that each individual has with others in the population (Barrat *et al.*, 2008). This is particularly relevant for the spread of COVID-19, in which the bulk of the infections are believed to have been driven by relatively few superspreading events (Lee *et al.*, 2020; Chen *et al.*, 2021).⁷ Superspreading has also been implicated in the genesis of variants of concern of the SARS-CoV-2 pathogen (i.e., genetic mutants that have higher transmissibility or virulence compared to the dominant strain) by facilitating genetic drift (Gómez-Carballa *et al.*, 2021). Modeling of epidemics in which superspreading plays a prominent role has suggested that in such processes, most infections do not give rise to sustained chains of transmission and outbreaks are relatively uncommon, unlike in well-mixed models (Lloyd-Smith *et al.*, 2005). However, a few rare events can lead to the cases amplifying to large numbers relatively quickly, as has indeed been borne out during the COVID-19 pandemic (Wong and Collins, 2020). Given the high individual variation in transmissibility, the results suggest that the measures targeting specific people or places for intervention may be more efficient in controlling the pandemic than instituting general population-wide measures (Lewis, 2021).

An intriguing possibility underlying the high variation of transmission ability that has been explored via modeling is the potential role of hubs in the contact network (Figure 4), i.e., individuals having extremely large number of links compared to the average (Newman, 2010). A theoretical study on their effect during the COVID-19 pandemic concluded that such hubs result in an increased spread, at least initially, but that they also tend to lower the threshold for attaining herd immunity (Großmann *et al.*, 2021). Intriguingly, for networks having a heterogeneous degree distribution, it can be shown that the condition for the outbreak of an epidemic (instead of $\beta \langle k \rangle / \gamma > 1$, as in the case of homogeneous networks) is given

⁷For example, a study based on contact-tracing data during the SARS-CoV-2 outbreak in Wuhan, China, between January and April, 2020, concluded that as many as 80% of the cases could be attributed to only 15% of the infected individuals (Sun *et al.*, 2021). This is consistent with the findings from a study of COVID-19 outbreaks in several counties of Georgia, USA, that the top 2% (in terms of the spread of the epidemic) directly transmit the infection to as much as 20% of the total number affected (Lau *et al.*, 2020).

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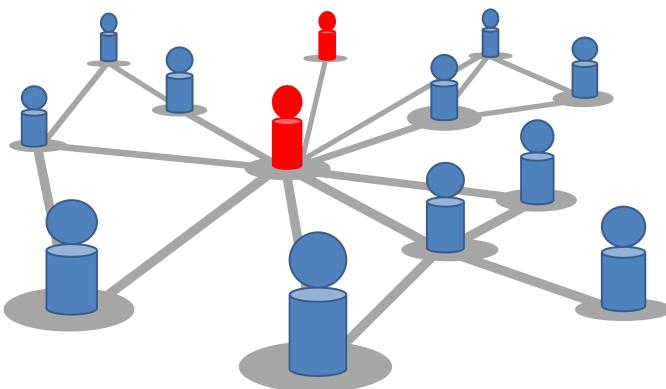


Figure 4. (Color online) Social networks through which infections propagate from one individual to another are a more accurate reflection of the heterogeneity of contacts in a real population. The central node (indicated in red) with a high *degree* (number of connections) can play a key role in the rapid spread of an epidemic through the population shown once it gets infected by another node (also shown in red) that is otherwise peripheral to the network.

by $\beta/\gamma > \langle k \rangle / (\langle k^2 \rangle - \langle k \rangle)$ (Barrat *et al.*, 2008). This result suggests that as the heterogeneity increases, the epidemic threshold will be lowered (Pastor-Satorras *et al.*, 2015), making it easier for infections to develop into large outbreaks and also making them harder to prevent by vaccinations, as a much larger fraction of the population would need to be immunized against the disease. Even more intriguing possibilities arise if the network is scale-free,⁸ with the degree distribution decaying as a power law such that the second moment is diverging ($\langle k^2 \rangle \rightarrow \infty$). For networks of arbitrary size, a consideration appropriate for example in the context of computer viruses spreading over the Internet, the condition implies that there are no thresholds to constrain epidemics from occurring (Pastor-Satorras and Vespignani, 2001). In other words, regardless of the fraction of the population made resistant to infection, herd immunity will never be

⁸Scale-free degree distribution was first introduced in the context of citation networks (de Solla Price, 1965). The properties of such networks have been extensively investigated in recent times, although empirical evidence for any social network being scale-free is weak at best (Broido and Clauset, 2019).

achieved. While alarming, it has also been pointed out that as individuals rarely have close contact during the relatively brief period in which they are infectious with an extremely large number of people, the results may not apply to the transmission of diseases, such as COVID-19. On the other hand, it has ramifications for sexually transmitted diseases, such as HIV, which may reside in individuals for a long time without apparent symptoms and spread through the activity of a few highly promiscuous individuals (Lloyd and May, 2001).

Another feature of real-world networks distinguishing them from random graphs that is likely to play a role in shaping the evolution of an epidemic is the existence of strongly clustered neighborhoods, i.e., individuals known to a person would also be extremely likely to be mutually acquainted (Newman, 2003). Typically, such cliques co-occur with a short average path length, which characterizes random graphs — a combination which is a hallmark of the so-called “small-world” networks (Watts and Strogatz, 1998). High clustering is expected to decrease the size of the epidemic, as transmission from each infected person can only occur in their local neighborhood; in contrast, spreading can occur extremely rapidly over random networks, as a pathogen can travel between any two individuals in only a few hops. Studies on Watts–Strogatz (WS) model networks, which are generated from maximally clustered, regular graphs by rewiring p fraction of the total number of links to randomly chosen individuals in the network, show that even a few random connections (i.e., very low p) is sufficient to make the average path length comparable to that of an equivalent random network. Thus, in a clustered social network, the existence of a few connections between neighborhoods that are otherwise far apart will make an outbreak spread through it almost as rapidly as in a random graph. Thus, identification of such links in a specific network and rendering it incapable of transmitting the pathogen (e.g., by quarantining or vaccinating the nodes connected by these links) can provide efficient means of suppressing an epidemic.

It is intriguing that the characteristic features of small-world networks are also seen in networks exhibiting community organization (Pan and Sinha, 2009). Such networks, which capture several empirical features of social networks (Sinha, 2014), are characterized by the existence of modules, subnetworks that have a significantly higher density of connections

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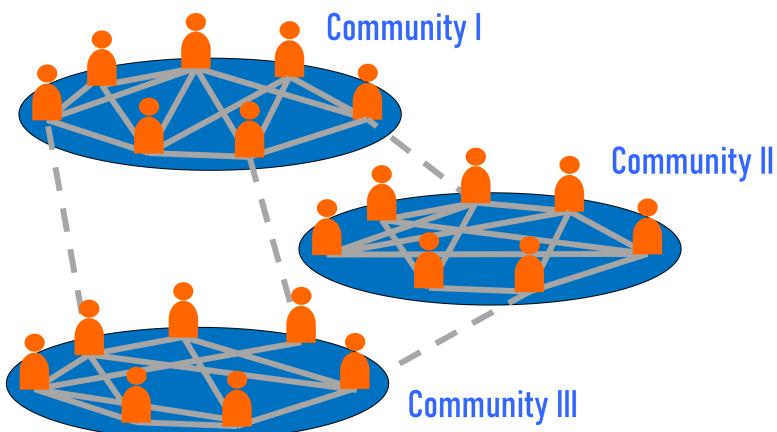


Figure 5. Epidemic spreading over a contact network are shaped to a large extent by its mesoscopic structure, which could, for example, be organized into communities or modules (shown as disks).

within members of each module and relatively sparse connectivity between different modules (Figure 5). It has been suggested by modeling studies that the segregation of different subpopulations (each of which are highly cohesive) can delay the spreading of infection from one module to another, thereby reducing the disease burden (Sah *et al.*, 2017). Conversely, it has been shown that such networks can actually promote the long-term persistence of a disease, when individuals lose immunity from prior infection (or vaccination) after a period of time (Jesan *et al.*, 2016). As this is now known to be the case for COVID-19, it is relevant to note that the model shows recurrent outbreaks of the disease to be the norm over an extended range of modularity and epidemiological parameters. The reason for this is that as the disease takes a relatively long time to “jump” from one community to another, the modular organization allows the epidemic to be long-lasting. We note that evidence of such highly nonuniform spreading behavior has been reported for SARS-CoV-2 infections (Thomas *et al.*, 2020). Thus, by the time the epidemic is about to be extinguished through a lack of susceptible individuals, the first individuals to be infected will be just about entering the susceptible compartment once more, which will allow the epidemic to be sustained for a longer period.

The structure of the network allows even relatively small isolated populations to exhibit repeated outbreaks, when an equivalent well-mixed population would have shown the extinction of the disease. Thus, the critical community size required for an epidemic to become recurrent can be lowered by the occurrence of mesoscopic structures⁹ in the contact network, such as community organization.

6. Games

In the models discussed so far, individuals have almost exclusively been treated as passive recipients of infection. However, to evaluate policy implications of containment measures, one will need to take into account how different individuals will respond to (or adhere to) the specific directives put in place to control an epidemic. A case in point is the use of mass vaccination in an effort to remove the threat of any further outbreaks. Although it may seem intuitive that every individual will choose to vaccinate themselves in order to reduce the risk of infection and disease and thus implementing the policy is just a matter of logistics (ensuring that there is enough vaccine and trained personnel to administer the shots), in practice, the situation could be far more complex. Individuals may be tempted to forego the cost or effort involved in getting vaccinated by free riding on others who have already received the vaccine. This is because herd immunity is a public good, as the immune status conferred by vaccination not only protects the individual receiving it but also benefits the community by screening the unvaccinated individuals from the pathogen. A similar situation also arises for non-pharmaceutical interventions, such as quarantining, travel restrictions, workplace or school closures, and most important from the perspective of COVID-19, shelter-in-place (lock-down) mandates. Assuming that the behavior adopted by individuals can be modeled as an implementation of strategies adopted by rational agents trying to maximize their personal utility or benefit, based upon

⁹Mesoscopic refers to features that appear neither at the global or macro scale of the network as a whole (such as average path length or diameter) nor at the micro scale of individual nodes (such as their degree) of the network but at an intermediate level.

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information available to them, we can investigate the collective response or adherence using the theory of games.

In this setting, each individual is assumed to receive a payoff depending upon the strategy choice made by all agents including herself. Each agent in turn makes her choice knowing this payoff matrix and with the understanding that all other agents are also attempting to maximize their utility. In case of collective action aimed at controlling an epidemic, a higher payoff would correspond to reducing the risk of infection while simultaneously minimizing one's cost in doing so. While, in general, this would be a game involving many agents simultaneously, for simplicity, we can focus on the payoff matrix for two agents, each having to choose between adherence (cooperation) or not (defection) at each round (Figure 6). Thus, if both adhere to the

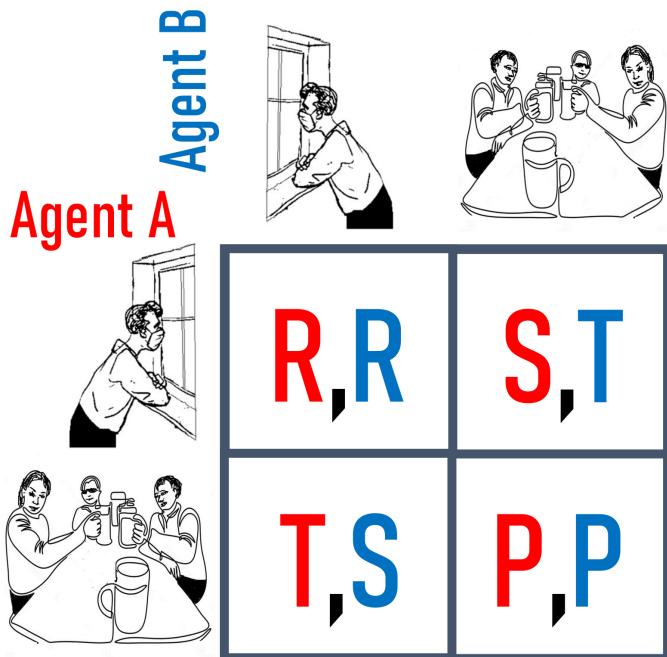


Figure 6. Agents deciding on whether to adhere (or not) to restrictions put in place to contain the pandemic viewed as a game with a symmetric payoff matrix.

Source: Line art adapted from stock images.

epidemic control policy put in place, they each receive a reward payoff R for cooperating, while if both choose not to adhere, the corresponding payoff P is the penalty for mutual defection. If one adheres while the other does not, the former receives the “Sucker’s payoff” S, while the payoff T of the latter quantifies the temptation to cheat. For different choices of the relative ordering of the payoffs, situations corresponding to various well-known games, such as Prisoners’ Dilemma ($T > R > P > S$) or Hawk–Dove ($T > R > S > P$), will be realized (Rapoport, 1966). These games illustrate *social dilemmas*, in which actions chosen by agents to maximize their individual payoff can have the paradoxical effect of making the situation worse for everyone (Rapoport and Chammah, 1965). In the case of epidemic control, if every agent believes that everyone else is adhering to the policy imposed (adhering to which involves a personal cost, e.g., restriction of their freedom of movement or being inoculated with a vaccine that may have possible side effects), they may be tempted to not incur the cost themselves by arguing that as others are all doing it, one person not adhering is unlikely to reduce the efficacy of the policy. This may result in the majority choosing non-adherence, resulting in failed implementation of the policy and consequently an increased risk of infection for everyone.

Such arguments have been advanced to explain vaccine hesitancy, a key issue of concern in controlling COVID-19 through pharmaceutical means (Solís Arce *et al.*, 2021). Earlier studies have shown that the success of vaccination programs in reducing the incidence of various childhood diseases may have paradoxically created opportunities for people to consider foregoing it. When a substantially high fraction of the population is already resistant to the disease, the reduced risk of infection makes any perception of even a low risk associated with the vaccine outweigh its benefit (Bauch and Earn, 2004). The myopic focus on only one’s immediate payoff can lead individuals to avoid getting vaccinated, creating susceptible pools that provide opportunity for the pathogen to renew its attack and escape eradication. Indeed, the past few years have seen a resurgence of several vaccine-preventable diseases, including measles that had been almost eliminated in developed economies, such as the US (Phadke *et al.*, 2016). By simulating epidemic propagation in a social network that is simultaneously used by individuals to estimate the risk of

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infection by obtaining information on disease incidence and the number of neighbors vaccinated to decide on optimal action (whether to get vaccinated or not), it has been observed that the information source for disease prevalence is decisive in shaping public response to vaccination (Sharma *et al.*, 2019). In particular, the availability of real-time information about disease incidence in the immediate network neighborhood can lead to higher vaccine acceptance, a potential policy goal for managing COVID-19.

A similar analysis can also be carried out to understand the effectiveness of non-pharmaceutical interventions. For example, it has been shown using models that social distancing, which reduces disease transmission by decreasing the rate of contact between individuals, is most likely to be beneficial for diseases that spread at an intermediate rate, specifically, those having the basic reproduction number $R_0 \approx 2$ (Reluga, 2010). The current pandemic has seen extensive use of it to buy time (by delaying the progress

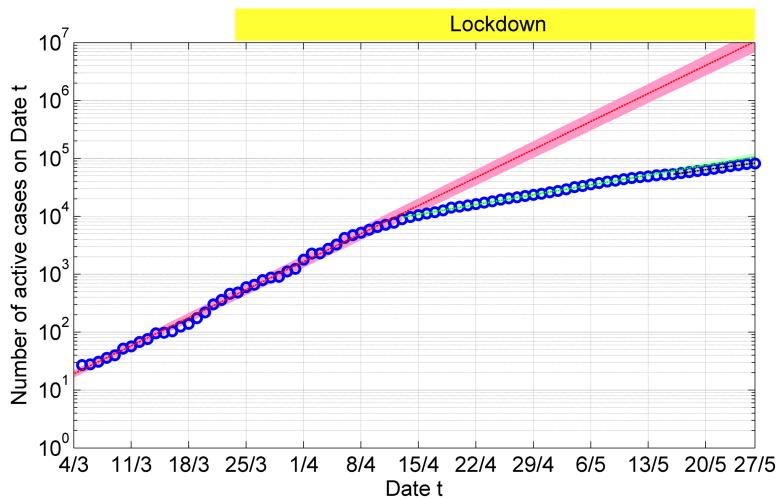


Figure 7. The progress of the COVID-19 pandemic in India in the period immediately following its outbreak. The circles represent the actual incidence while the broken line denotes the projection of the number of active cases if the initial rate of spread had continued unchanged. The shaded interval represents the confidence intervals of the projection. The period during which shelter-in-place was imposed on the entire country is indicated by a horizontal bar above the figure.

of the epidemic) to develop a vaccine. However, the most strikingly novel feature of COVID-19 management is the widespread imposition of shelter-in-place (lockdown) policies. It has been credited with substantially reducing the burden of the disease, including in India (Figure 7). However, this measure has a major cost associated with it, as it causes widespread psychological, social, and economic disruptions (Every-Palmer *et al.*, 2020; Mandel and Veetil, 2020). As the cost of lockdown may be vastly different across socioeconomic classes, it is important to understand how the success (or otherwise) of such policies may be tied to the behavior of individuals who may have differing incentives to circumvent such policies. For example, preliminary studies carried out by our group suggest that less than complete adherence to lockdown can lead to multiple resurgent peaks in the disease incidence, resembling the several waves of COVID-19 that have occurred so far.

7. Challenges and Prospects

The COVID-19 pandemic has been a very instructive episode for the design of public health policy using mathematical modeling. While the period since the worldwide outbreak in early 2020 has seen a veritable explosion in the number of published modeling studies using an unprecedented range of modeling tools and techniques to study various aspects, it has also revealed the limitations of modeling. While modeling studies have been widely cited to justify one policy or another, it has now become clearer how sensitively such results depend on the specific assumptions underlying the modeling. It has also been revealed that epidemic progression depends on many different factors, some of which may not even be apparent — a humbling experience for epidemiological modelers who may have imagined that the level of sophistication achieved by the field could finally make it a predictive science. Indeed, there is now greater appreciation that instead of trying to predict the exact time of occurrence of the next outbreak (which, being a result of many chance factors coming together, is essentially a stochastic event), the true value of modeling lies in providing a testing ground for comparing various remedial measures without having to go through a costly (both in terms of money and lives) trial-and-error process in the field. This has also permeated to the public

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consciousness, as observed by the fact that in many cases, the acceptance of epidemic control policy measures has been contingent on the reported results of epidemiological models and the understanding that such modeling has informed the design of optimal intervention procedures.

Modeling successes and failures during the pandemic have also thrown up important questions that would need to be addressed in the future. For one, the utility of simple versus complex models has been debated with respect to their respective performances in describing the progress of the epidemic. The importance of parameter estimation from noisy data has been appreciated more, as it has been seen that models with a large number of parameters do not necessarily give a more accurate description of the real-world process. It has also been a puzzle as to why the first wave of the pandemic saw a much lower spread rate in the poorer countries of South Asia compared to the developed countries of Europe and North America. The initial facile explanations for this, such as the unfounded speculation about the supposed genetic resistance of South Asians to the pathogen, were patently wrong, as shown clearly by the disastrous consequences of the so-called second wave in India. As the disease continues to evolve, with new variants of concerns emerging, increasingly, people are wondering about how the epidemic will eventually end. An important question is whether mutant strains, such as Omicron (i.e., the B.1.1.529 strain of the SARS-CoV-2 virus first detected in November 2021 in South Africa), will find it harder to spread because of the partial resistance offered by large sections of the populations being either infected earlier (with different strains) or being vaccinated. Finally, the use of lockdown has emerged as an unprecedented weapon in the arsenal of public health interventions. As its impact had not been known before, the pandemic has served as an unintended lab for looking at the role of large-scale perturbations to the spread of an epidemic, which are, however, not cost-free. We have to take into account how individuals will weigh the risk of being infected (and potentially dying) against the loss of livelihood if we are to use variants of such measures successfully in the future. Possibly, one of the most important questions from a policy perspective that future modelers may be called to answer is whether it is possible to have a shelter-in-place intervention plan that is socio-economically less damaging while having the same effectiveness as the lockdown

that has been implemented during the current pandemic. The results of such studies promise to usher in a new age of modeling-driven public health policy design.

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Chapter 1.2

The Economic History of Pandemics

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Abstract

COVID-19 has brought the attention to the study of past pandemics to ascertain if there are common trends across pandemics and what one might anticipate in the future. This chapter reviews pandemics through the lens of economic history to see their linkages with income, inequality, migration, and globalization. Pandemics tend to be supply-side shocks that depress incomes, either through lockdowns or mass mortality, by constraining the supply of labor. Pandemics also tend to increase inequality in the short run due to the disproportionate impact of economic and mortality dislocations on the poor. However, when mortality shocks have been large, the aftermath of the pandemic could also reduce inequality due to the rising bargaining power of scarce labor. Migrant flight from cities is one of the most stylized facts of pandemics, leading to supply-side disruptions and delayed economic recoveries. Globalization may not have caused more frequent pandemics, but the occurrence of a pandemic has often led to restrictions on the movement of people and slowed down globalization. The COVID-19 pandemic shares some of these features of past pandemics but also differs in its

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mortality profile, and hence, the economic repercussions also differ to some extent.

Keywords: economic history; pandemic; global health

1. Introduction

While history does not necessarily repeat itself in exact manner, it is said that it often rhymes. The COVID-19 pandemic has certainly brought this out in a stark manner, with a growing appetite among researchers and the public to understand various aspects of the history of pandemics. COVID-19 has evoked memories of past pandemic diseases, such as plague, smallpox, cholera, and influenza, and specific episodes, such as the horrific 14th-century “Black Death” plague and the 1918 “Spanish Flu” influenza. People are interested in knowing the ways in which past pandemics evolved, were managed, and eventually ended either with human ingenuity or without. Furthermore, the long-term consequences of pandemics have also attracted attention, as they have tended to mark a sharp disruption in the way in which societies and economies operated.

In this chapter, we look at similarities and differences that past pandemics share with the current one from the lens of economic history. It thus deals with questions such as the following: How do pandemics affect incomes? How do they affect labor migration? Did past pandemics represent demand-side or supply-side shocks to the economy? How do pandemics affect the labor market and inequality? Is there a link between pandemics and globalization?

These questions go beyond academic interest, as policymakers are increasingly acknowledging the value of reading pandemic history to understand plausible scenarios. The word “unprecedented” was often used in 2020–2021 as policymakers grappled with the epidemiological and economic challenges presented by COVID-19, and yet, historians will point out that many of the challenges were not “unprecedented” but simply forgotten. COVID-19 may be different from previous pandemic diseases in terms of its mortality profile, but the economic challenges it presents, as this chapter will show, can still be like those of the past.

The rest of this chapter is structured as follows: It begins by providing an overview of past pandemics by pointing out their magnitude and

geography in absolute and proportional terms. It then provides an overview of the emerging literature on pandemic history, written by economic historians and economists, with a particular focus on the 1918–1920 influenza pandemic, the deadliest pandemic in modern history and the one most like the COVID-19 pandemic. It concludes by pointing out the relevance of these themes in the COVID-19 era.

2. Pandemics of the Past

Compared to other events of mass mortality, such as wars, earthquakes, floods, and famines, pandemics are usually not well described or documented by the people affected by them. In terms of visual imagery in a pandemic, buildings don't fall and cities are not plundered. In pandemics, people die without a trace of such destruction unless the pandemic itself sparked a war or a riot. In economic terms, pandemics, in theory, destroy labor, not capital.

Nor are pandemics commemorated with memorials and remembered in the same way as wars are. The lack of clearly identifiable enemies and the willingness to forget a raging pandemic tragedy and move on with life are important considerations as to why pandemics can be erased so quickly from collective memory. What we do know about the pandemics of the past is thus extremely limited and based on the work of historians who have tried to reconstruct the events from death registers, burial records, memoirs, diaries, traveler accounts, and the like.

What constitutes as a “pandemic” as opposed to an “epidemic” or “endemic” phenomenon is also sometimes hard to strictly classify in history. Today, the notion of a simultaneous transmission of a disease across the world is used to define a pandemic, not in terms of severity but in anticipation of it (Harrison, 2017). Historians find it difficult to uncover past pandemics that did not cause mass mortality because they left little traces of the event. Furthermore, important communicable diseases, such as malaria, which arguably has led to the greatest number of human deaths in history (Shah, 2010), are usually considered as being endemic in certain regions or as localized epidemics stretching over a few years; historians have never referred to a malarial pandemic. Typhus, measles, and tuberculosis are some of the other significant diseases that are typically not characterized as pandemics (Kiple, 1993).

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Given these limitations of definition, Table 1 shows six diseases that have evoked scholarly attention in the realm of pandemic history, i.e., diseases that spread over large geographies, meaning continents, and more recently, the entire world: plague, smallpox, cholera, influenza, HIV/AIDS, and COVID-19.

2.1 Plague

Until the 20th century, the plague was the best known and remembered disease, even if it was less understood. Bubonic plague, which may have had a case mortality rate of over 80%, left clear marks on the bodies — the buboes — that made it a dreaded disease. Medical traditions varied around the world, but in many, the “miasma” theory of disease origins was very popular, which attributed diseases to impure air. In the late 19th century, the bacteriological revolution led to a new understanding of diseases, one that identified plague as a bacterial disease (now named *Yersinia pestis*), and by the first decade of the 20th century, the transmission of plague from rodents to humans via the bite of rat fleas was unearthed.

Historians identify three epochs of plague pandemics in history. The first plague pandemic occurred between the 6th and 8th century CE, centered around the Mediterranean region, though recent research suggests that earlier claims of mass mortality in the tens of millions were vastly exaggerated (Mordechai *et al.*, 2019). The second plague pandemic is characterized by the “Black Death” tragedy in the middle of the 14th century, followed by more localized outbreaks all the way up to the early 18th century in Europe. The plague devastated Europe, with estimates suggesting tens of millions of deaths, wiping out over a third of the population and perhaps 10–20% of the global population (Alfani and Murphy, 2017). This large demographic shock has generated a lot of interest in the field of economic history, as will be seen in the next section.

The third plague pandemic from the middle of the 19th century to the middle of the 20th century affected Asia, causing millions of deaths, over 90% of them occurring in the Indian subcontinent alone. In each of the three epochs, evidence of human ingenuity in ending the pandemics is limited; the epidemiological literature suggests an intricate host–parasite relationship among rodents in plague reservoirs located in some

Table 1. Major documented pandemics of the past.

Disease	Period	Mortality Estimate (Millions)	Mortality of Estimated Global Population	Key Regions Affected	Common Reference
Plague	1340s–1350s	25–50	10–20%	Europe	Black Death
Cholera	1817 – Early 20th c.	20+	1%	India, Egypt, Russia	
Plague	Late 19th c. – Early 20th c.	13+	1%	India, China	3rd Plague Pandemic
Influenza	1918–1920	40+	2% +	India, Iran, South Africa	Spanish Flu
HIV/AIDS	1980s – Till date	30+	0.4% +	Sub-Saharan Africa	
COVID-19/ SARS-CoV-2	2020 – Till Date	15+	0.2% +	Americas, India, Russia	
Other Notable Pandemics					
Plague	6th c. – 8th c. CE	-	-	Mediterranean Region	1st Plague Pandemic
Plague	15th c. – 18th c. CE	-	-	Europe and Asia	2nd Plague Pandemic (post-Black Death)
Smallpox	16th c. – 19th c. CE	-	-	Americas	
Influenza	1957–1958	1	0.03%	East Asia	Asian Flu
Influenza	1968	1	0.03%	East Asia, the US	Hong Kong Flu
SARS-CoV	2002–2004	Few thousands	Negligible	China	
Influenza	2009–2010	0.2	Negligible	North America	Swine Flu

Source: Alfani and Murphy (2017), Kilbourne (2006), Simonsen *et al.* (2013), Tumbe (2020a, 2020b), The Economist Excess Mortality Database for COVID-19.

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parts of the world (McNeill, 1976). That is, herd immunity among rodents could explain the falling incidence of plague among humans. Plague cycles are still poorly understood, but the means of transmission to humans are now known well enough that plague prevention and curative measures appear to be powerful. Antibiotics and vaccines have been developed that now make plague a relatively less dangerous disease. Apart from Madagascar, few places in the world witness regular outbreaks of plague today.

2.2 Smallpox

Smallpox is a viral disease that props up in the literature on pandemic history because of its catastrophic impact on the native population of the Americas, facilitated through European migration between the 16th and 18th centuries. By some estimates, well over half the population was wiped out in the Americas, though as a share of the global population, it was probably less than 2%. Mortality among children was particularly severe. If the disease was not fatal, it left its mark in the form of pustules, which would erupt and fall off from the bodies of the survivors a few weeks after the onset of the disease. Smallpox was also widely prevalent in Asia and Europe, and modern vaccination drives emerged to eradicate this disease, which reduced in intensity in the 20th century.

Inoculation and vaccination efforts related to smallpox go back several centuries. In the 19th century, vaccination drives against smallpox picked up steam around the world, facing stiff resistance from social and religious taboos. “Vaccine hesitancy,” an oft-used phrase today, was rife, and the vaccine slowly derived its legitimacy over time only because its effects were measurable by scientists and observable to the public. Smallpox-related morbidity and mortality began to fall in the 20th century. A global public health response was instrumental in coordinating efforts to quicken the elimination of the disease. The World Health Organization’s monitoring efforts paid dividends, and no cases have been reported after the 1970s. It is a rare case in which vaccination played a vital role in bringing about the eventual eradication of the pandemic.

2.3 Cholera

Cholera is a bacterial disease that was well known before the 19th century and particularly endemic in Eastern India. It led to dehydration of the body, sunken faces, and eventually death if not treated properly. In 1817, a particularly virulent strain of cholera broke out in Eastern India and spread across the Indian subcontinent within two years, much of Asia over a decade, and became the most talked about disease around the world by the 1840s. Case fatality rates were over 50% until the early 20th century, though better prevention techniques halted its course in Europe and North America after the 1860s. Once the water-borne nature of the disease transmission was understood, better investments in clean water supplies served as an effective measure of disease prevention. Nevertheless, cholera continued to haunt large parts of the world well into the early 20th century, as the adoption of the new scientific paradigm on cholera prevention was slow. Apart from India, countries such as Egypt and Russia were ravaged by cholera in the 19th century. In Egypt, nearly 10% of its population was wiped out due to the disease. Overall, between 1817 and 1920, cholera accounted for around 20 million deaths worldwide, or around 1% of the global population. Of this total, 8 million deaths were in the Indian subcontinent alone in epidemic-ridden places. Another 30 million deaths in India could be attributed to its endemicity (Tumbe, 2020b). The cholera pandemic subsided primarily due to effective measures of disease prevention, considering the water-borne nature of the disease. Eventually, better treatment methods brought down the case fatality rates, first by the intravenous (IV) method and then, in the late 20th century, through the extremely cost-effective oral rehydration therapy (ORT). Antibiotics and better vaccines also helped in the latter part of the 20th century, but prevention techniques ruled supreme.

2.4 Influenza

Pandemic waves of viral influenza sweeping across the world have been identified across centuries, but it struck especially hard in 1918–1920, popularly referred to then as the “Spanish Flu.” This was the worst pandemic in modern history and ranks only next to the Black Death in its

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demographic impact — killing over 40 million people, or 2% of the global population. It was more widespread than the 14th-century Black Death, tormenting every part of the world except for a few isolated islands that practiced strict quarantine for two years. It appeared in two waves in most places, the first in early 1918 and a more lethal one in late 1918, while some places also received a third wave. Its impact was particularly harsh in India (15–20 million deaths, or 6% of the population) and in Iran and South Africa (3–6% mortality). Unlike plague, smallpox, and cholera, which were seen to be diseases originating in Asia, the 1918 flu waves appear to have emerged from the US and Europe and spread around the world, facilitated by massive troop movements against the backdrop of World War I. One of the stylized facts of the pandemic was its W-shaped age–mortality signature — high among the very young, then among those aged 20–40, and then among those aged 60 and above. Many young working people succumbed to the pandemic. The science of virology had not yet developed then, and people were clueless as to what actually hit them and why the pandemic eventually ended. Herd immunity or strain mutation to less lethal forms, rather than human ingenuity, are possible explanations for how that pandemic ended (Crosby, 1993).

Two other flu pandemics were notable in the 20th century, one in 1957–1958 (the so-called “Asian Flu”) and one in 1968 (the so-called “Hong Kong” flu), collectively killing around 3 million people, mainly in East Asia, but also hundreds of thousands of people in the US. As a share of the global population, the mortality rate was only 0.03%, compared to the 2% figure of the 1918–1920 pandemic. More recently, the flu outbreak of 2009–2010 (popularly known as “Swine Flu”), was characterized as a pandemic, leading to around 200 thousand deaths, many again in North America. But as a share of the global population, it was negligible.

All the four influenza pandemics mentioned here are said to have started from animal–human disease crossovers. As the science of virology and vaccination developed over the 20th century, “flu shots” became popular in some places to protect oneself against the disease, which also shows high seasonality. However, the danger of the next influenza pandemic is always lurking around the corner.

One reason for this is that scientists understand bacteria-based diseases far better than virus-based ones. As the Nobel Prize-winning scientist Joshua Lederberg (1925–2008) once pointed out:

We have a reasonable lead on bacterial intruders; we grossly neglect the protozoan parasites that mainly afflict the third world; we are dangerously ignorant about how to cope with viruses.

(Lederberg, 1988, p. 343)

2.5 HIV/AIDS

Human immunodeficiency virus and acquired immunodeficiency syndrome (HIV/AIDS) was the deadliest pandemic before COVID-19, killing over 30 million people since the 1980s, almost all in sub-Saharan Africa. The sexual transmission of the disease makes it slow moving as compared to influenza; nevertheless, the disease has spread across the world. It generated a lot of attention in global health policy circles, and cheaper anti-viral drugs have lessened the blow of the disease, significantly enhancing the longevity of people affected by it. Like cholera, the efforts to curb the HIV/AIDS pandemic have focused more on prevention than cure.

Just like the 1918 influenza pandemic, HIV/AIDS has had a disproportionate impact on the prime working-age population, leading to severe economic repercussions (Bell *et al.*, 2006). It limited the transfer of human capital from one generation to the next and reduced childcare support systems when the parents were infected. South Africa's macroeconomic performance over the past two decades was undermined by the high prevalence of the disease and its drawbacks on productivity.

2.6 COVID-19

Over the past two decades, there have been two coronavirus (CoV)-led pandemics. The first, labeled as severe acute respiratory syndrome (SARS)-CoV, broke out in China and spread to several countries in 2002–2004, claiming a few thousand deaths. The more recent outbreak from Wuhan in late 2019, quickly spread around the world in early 2020. The

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most stylized fact about SARS-CoV-2, or COVID-19, is the mortality gradient against age, as the disease so far has affected only older people in greater propensity. At the end of 2020, the reported death rates across the world were skewed higher in the relatively richer countries of the world due to older populations, better reporting standards, and for other reasons not fully known (Deaton, 2021). However, in 2021, with the outbreak of the Delta variant, the virus took on a deadly turn, especially in India, Indonesia, and parts of the world that were relatively unaffected in 2020. While five million deaths were officially reported due to the pandemic, excess mortality estimates suggest that the number may be well over 15 million, with India, Russia, the US, and Brazil badly affected in absolute terms and much of Latin America in per capita terms (*Economist*, 2021).

COVID-19's global toll so far stands at around 0.2% of the global population, marking it out to be the deadliest airborne pandemic since 1918. In its transmission mechanism, it is closer to influenza and smallpox rather than cholera, plague, or HIV/AIDS. Unlike the 1918–1920 influenza pandemic, COVID-19's toll is disproportionately higher among the aged. But like most pandemics of the past, COVID-19 is rolling across the world in waves. What sets COVID-19 apart from any pandemic of the past is the near perfect synchrony of national lockdowns in early 2020 that arguably limited its spread to some extent. This, however, also led to a massive economic crisis. It is the interaction of pandemics with economic phenomenon that we turn to next.

3. The Economic Aspects of Past Pandemics

3.1 How do pandemics affect incomes?

A core dilemma revealed by the COVID-19 pandemic is the seeming trade-off between lives and livelihoods while crafting public policies for pandemic management. Extreme lockdowns may curb the spread of the disease in the short run but lead to mass unemployment, especially in sectors where work cannot be done from home. No lockdowns, on the other hand, may keep the economy chugging along but allow the spread of the disease and lead to high mortality.

What is less appreciated in this debate is that without some curbs on economic activity, a deadly pandemic with a high mortality rate will also cripple economic activity because people will simply not show up for work due to fright, morbidity, or death. Table 2 presents the major episodes of global per capita income contractions over the past century to illustrate this point. Of the six episodes, two were associated with financial crashes (1930s Great Depression and the 2009 Global Financial Crisis), two were associated with World War-led disruptions, and two were associated with pandemics.

In 2020, national lockdowns triggered by the COVID-19 pandemic ground the global economy to a halt for a few months such that per capita incomes fell by 4.4%. Curiously, a similar effect was observed during the 1917–1921 period, which combined the effects of World War I and the influenza pandemic, but it was a period with limited government-mandated lockdowns. Research, exclusively on the 1918 flu pandemic period, shows that the average country faced declines in gross domestic product (GDP) and consumption to the tune of 6% and 8%, respectively (Barro *et al.*, 2020). In India, real GDP fell by 10% in 1918–1919, its steepest fall in any year between 1901 and 2019 (Tumbe, 2020b). These disruptions were primarily induced by a raging pandemic without any major lockdowns.

On the other hand, the other pandemics of the past century with lighter mortality (the flu pandemics and SARS) did not affect too many countries or affect economic activity greatly. The evidence shows that

Table 2. Major episodes of contraction in global per capita income, 1910–2020.

Period	Global Per Capita Income Growth (%)	Significant Event
1930–1932	-17.6	Great Depression
1945–1946	-15.4	World War-II
1914	-6.7	World War-I
2020	-4.4	COVID-19 Pandemic
1917–1921	-4.4	World War-I & Influenza Pandemic
2009	-2.5	Global Financial Crisis

Source: World Bank Development Indicators and World Bank Blog. <https://blogs.worldbank.org/opendata/understanding-depth-2020-global-recession-5-charts>.

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pandemics can take a heavy toll on incomes — either through lockdowns in anticipation of the event or through mortality-led disruptions in the absence of lockdowns. Economic disruptions and income declines were also noted all through the era of the cholera and plague pandemics in the 19th and early 20th centuries (Tumbe, 2020a) due to an elaborate quarantine system that limited labor mobility and trade.

3.2 How do pandemics affect labor migration?

“Migrant flight” is one of the stylized facts about pandemics, from the Black Death to COVID-19. This occurs due to various reasons. First, migrant workers receive information about the disease and make a rational decision to escape the destination region in search of safer pastures. This was duly noted during the plague pandemics, as information on the disease was easily available and rumor mongering heightened the sense of the crisis (Arnold, 1993). It was noted during the cholera outbreaks in the 19th century from places as varied as India and the US (Tumbe, 2020a).

Second, labor migration is often circular in nature with migrants straddling two places at the same time — the village and the city or two countries — such that health crises make them want to go home to secure the comfort of their families. This may not be possible due to travel bans on international migration, where means of transport by air or water are blocked out. Historically, this would mean the closure of ports subject to quarantine laws, and today, it would reflect the shutting down of air space for international traffic. But travel bans for internal migration or land-based options were often not enforceable as people could always walk back home. That is why when China stopped railway services for migrants in 1911 during a plague outbreak and India suddenly stopped its railway services in 2020 as part of its national lockdown strategy, both these actions led to a humanitarian crisis as migrants began to walk home (Tumbe, 2020a). It does not seem pragmatic to deliberately block internal migrants from returning home in a pandemic when the borders are porous and private transport options are in plenty.

Finally, there could also be cultural reasons, such as attachment to the native place, that make migrants want to flee even when conditions are not all that dire. In India, the notion of preferring to die in one’s place of birth was observed in the migrant flights during the 19th-century plague as well as during COVID-19 in 2020.

For all these reasons, cities have tended to hollow out during pandemics, temporarily bringing down rents (Figure 1 illustrates this through the medium of a cartoon published during the cholera outbreak in the US). This was also well documented in 2020 in the US, where people moved out of cities toward suburbs and rents in inner cities declined (Gupta *et al.*, 2021).

These reverse migrations are temporary, and workers do go back to their employers eventually as conditions improve, but in the interim, the labor shortfall hurts the prospects of production. That is, labor flight in a pandemic, apart from mortality, is an important supply-side disruption that constrains economic activities.

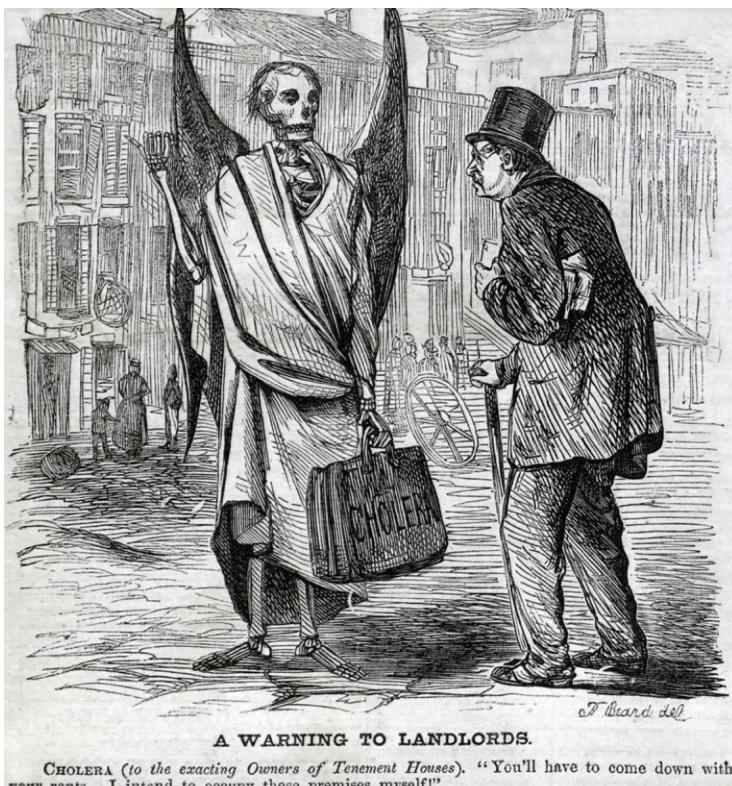


Figure 1. Cholera, migrant flight, and housing rents in 19th-century US.

Source: From “House Divided: The Civil War Research Engine at Dickinson College: A Warning to Landlords,” cartoon, Harper’s Weekly, March 24, 1866.

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3.3 Are pandemics demand-side shocks or supply-side shocks?

In a pandemic, the loss of income and purchasing power represents a demand shock, while the disruption of supply chains, especially because of the loss of labor through mortality or migration, represents a supply shock. Demand-side shocks are instantly enforced by national lockdowns, as daily-wage jobs dry up and incomes decline. Supply-side disruptions can occur because people migrate back to their villages from the cities and do not show up on the factory floor. In episodes of mass mortality, production ceases because of worker deaths or deaths in the worker's family because he or she has to take leave from work. People also voluntarily drop out of the labor force as pandemics create anxiety and mental health issues that force people to take a break from work. And in a national lockdown, when trucks carrying goods are not allowed to cross international or internal boundaries, supply lines get choked. Whether the supply-side or demand-side shock is greater in a pandemic is typically reflected in wages and prices.

The evidence from past pandemics strongly suggests that pandemics tend to be supply-side shocks. This, of course, depends on the extent of the mortality shock. For two of the deadliest pandemics in history — the 14th-century plague and the 1918 Influenza — the upward pressure on prices and wages have been clearly documented (Alfani, 2022; Tumbe, 2020a). India experienced its worst bout of inflation between 1870 and 1940 during the influenza pandemic years of 1918–1920, with rates as high as 30%. The absence of labor was documented in various reports, hurting farm operations and factory shop floors. Those pandemic-linked supply-chain disruptions contributed to inflationary pressures rather than deflationary pressures, which were experienced during the 1930s Great Depression.

COVID-19 is different from previous pandemics due to the simultaneous global lockdowns enforced by governments across the world. While this translated into instant income declines, it also led to global supply chain disruptions as trade flows came to a halt. As workers shifted to online modes of transactions, there was a massive demand for computer-related equipment and a resulting “chip” shortage in the semiconductor

industry, as supply lines were stalled by the lockdowns. The abrupt switch in demand preferences combined with disruptions in global trade led to a price surge in some sectors of the global economy.

So far, the evidence on inflationary pressures during the COVID-19 pandemic is mixed, though by late 2021, it was tending toward being significantly more inflationary than deflationary. The reduction in global trade and economic activities initially caused a sharp fall in fuel prices in 2020, and migrant flight in some places led to rent reductions. But as the mortality increased and lockdowns stayed on, the inflationary pressures from the supply-side disruptions seem to have dominated the demand-side disruptions. Inflation rates in several countries in 2021 were at record highs over the past decade. As with past pandemics, COVID-19 has thus far exhibited more of a supply-side shock to the global economy than a demand-side shock, even though the global mortality rate is still only a fraction of that observed during the 1918–1920 pandemic.

This observation has one important policy lesson. If pandemics tend to be supply-side shocks, economic policies should ease the supply constraints in creative ways to bring the economy back on track. This could involve new ways of sourcing materials and expanding partnerships with a wider set of countries to diversify trading risks.

3.4 How do pandemics affect labor markets and inequality?

Pandemics affect labor markets through selective mortality and migration. While migration was discussed earlier, the mortality impact should be understood along the standard identities analyzed in any labor market, such as class, gender, age, race, caste, religion, and region. In general, research shows that pandemics are not “socially neutral” and have adverse consequences on the underprivileged (Mamelund, 2006; Herring and Korol, 2012; Li and Li, 2017; Mamelund, 2018; Økland and Mamelund, 2019).

The mortality rates in most pandemics of the past, especially plague and cholera, tended to be much higher among the poor than the rich. The biggest pandemic in modern history, the 1918 influenza, hit poorer countries much harder than the rest (Murray *et al.*, 2006). This is because the rich tend to have better levels of nutrition and also access to decent

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healthcare. Paradoxically, this differential mortality, if large enough, could also alter the balance of power between labor and capital in the long run and improve the condition of laborers through higher real wages. That is, if too many workers die, the surviving workers could benefit from more bargaining power.

Regions which faced large demographic shocks, such as Europe during the 14th-century plague or India during the 1918 influenza pandemic, clearly witnessed higher real wages after the pandemic for laborers (Alfani, 2022; Tumbe, 2020a). Debates on the existence of surplus labor and related wage movements in agriculture also used the 1918 influenza pandemic shock in India to test claims, but the limited nature of data precluded any definitive conclusion (Schultz, 1964, 1967; Sen, 1967).

Yet another channel of pandemic impact is via fertility reductions. South Africa was badly affected by HIV/AIDS in the late 20th century, but one study found that this could actually improve the welfare of future generations (Young, 2005). The paper, evocatively titled, “The Gift of the Dying,” argued that while the disease could have lowered the human capital accumulation of orphaned children, there were gains through fertility reduction induced by the pandemic, which raised the future per capita consumption possibilities of the country.

In utero exposure to pandemic diseases could have adverse long-term labor market consequences, as documented by one study for the 1918 pandemic in the US (Almond, 2006), though this result did not hold in several other countries (Vollmer and Wojcik, 2017).

Pandemics could also alter female labor force participation rates due to selective mortality. This was observed in India during the 1918–1920 influenza pandemic as female labor force participation rates shot up in the Census of 1921, but the rise was short lived and reversed by 1931 (Fenske *et al.*, 2020).

Discrimination in the labor market due to gender, race, caste, or religion could also be heightened during a pandemic. In 14th-century Europe, plague outbreaks led to Jewish persecution as they were blamed for the onset of the disease, just as a woman belonging to a low-ranking caste in India was killed on suspicion of bringing cholera to her village in the 20th century (Tumbe, 2020a). Discrimination in access to healthcare could also influence the variation in mortality rates in a pandemic.

The distributive aspects of pandemics have evoked substantial attention from historians over the 14th-century Black Death episode. It has been shown, using data on property tax records, that wealth inequality reduced in the aftermath of the pandemic (Alfani, 2022). The rise in real wages for unskilled workers suggests that even income inequality may have fallen. These effects were not uniform across Europe and held only in the immediate aftermath of the pandemic.

As Guido Alfani points out, past pandemics have dented poverty in two ways: “redistribution *towards* the poor or extermination *of* the poor” (Alfani, 2022, p. 1). The redistribution may have occurred during a large demographic shock, such as that of the Black Death, but there is little evidence on the same for other pandemics.

The evidence so far suggests that only with large mortality shocks (global mortality rate $> 1\%$) does the labor market get substantially affected. There could of course be localized shocks with important changes effected in those regions. As noted earlier, one of the unique aspects of pandemics is that they represent a shock to labor rather than the physical stock of capital. As a result, labor–capital ratios can change and so can the bargaining power of laborers versus capitalists.

The COVID-19 pandemic though is unlikely to decrease inequality. The global mortality impact is higher than that of recent flu pandemics but relatively lower than the 1918–1920 pandemic and much lower than the 14th-century plague. On the contrary, the use of lockdowns, which seem to disproportionately affect the poor, who often cannot work from home, suggests that inequality may have even increased during the pandemic. Indeed, in India, labor market surveys show a steady gradient of income decline during the lockdown period, with the poorest decile witnessing the largest percentage reduction in incomes (APU, 2021). The long-term repercussions of COVID-19 on inequality are yet unknown, but they are unlikely to be similar to those witnessed after the Black Death plague or 1918 influenza pandemics (Sayed and Peng, 2021).

3.5 Is there a link between pandemics and globalization?

A tour through the history of pandemics does not suggest an automatic connection with globalization. The worst pandemic noted till date, the

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14th-century plague, worked its way around Europe at a time of pre-modern transportation and communication technologies and in a world of little globalization. Over the course of the 19th century, as globalization intensified, the spread of diseases did become faster and faster but after the 1918–1920 pandemic, it took nearly a century for the next pandemic to arise. Lethal pandemics have so far occurred rarely in history, and their timing does not suggest a direct link with globalization. The spread of COVID-19 took only a few weeks compared to the spread of cholera around the world in the late 19th century, which took decades, but prevention techniques, such as lockdowns, and better scientific knowledge through global cooperation could also limit its spread.

More substantively, pandemics could lead to nativism and the *reversal* of globalization on some dimensions, especially migration. In the 19th century, India and China were seen as generators of pandemics (cholera and plague, respectively), and this prompted a series of immigration laws that effectively blocked their entry into Western labor markets for several decades of the 20th century. Even in the COVID-19 era, travel advisories are based on the perception of pandemic threats, effectively blocking migration. In such cases, pandemic-related insecurities hasten a move to close borders of certain nationalities. Pandemics can also lead to a short-term collapse in global trade due to synchronous quarantines or lockdowns, as witnessed in the past and present. That is why, pandemics are more likely to affect globalization in the short run than vice versa.

4. Conclusion: COVID-19 in Light of the Past

As compared to earlier pandemics, there are three distinctive aspects of the COVID-19 pandemic. First, the age–mortality gradient slopes upward, and the death rates are highest among the aged. This was not observed in most of the previous pandemics, which also affected the young in large numbers. Second, the COVID-19 pandemic is unique in the widespread use of lockdowns to curb the spread of the disease, which was not observed with similar intensity in any of the previous pandemics. Quarantine measures were in place then, but most firms were free from government mandates to remain shuttered during the pandemic. As a result, most countries have faced a recession in 2020 and substantial

economic dislocation, even when the mortality impact was little. Finally, for the first time, an effective vaccine against COVID-19 has been developed in record time in a pandemic due to global collaborative efforts, and many countries had achieved near-universal vaccination coverage by the end of 2021. Most countries, especially those in Africa, were far from achieving this target though and were susceptible to lethal COVID-19 waves in the immediate future. If this pandemic does indeed subside due to vaccination, that would be a remarkable achievement, but most pandemics of the past did not or took an extraordinarily long time to do so.

In its economic aspects, the COVID-19 era has so far followed the path treaded by lethal pandemics of the past with income declines, migrant flight, and inflationary pressures creeping in. At the same time, we are also witnessing a reordering of worker preferences in terms of location of work for the professional elite and even a withdrawal from the workforce for noneconomic reasons. This reordering was seldom seen in past pandemics because people did not have to face extended lockdowns nor did they have the technology to work effectively from home. The large-scale shutting down of schools done in the past only for brief time periods could also have long-term consequences that are as yet unknown.

Paradoxically, by limiting mortality through lockdowns, whose economic impact is disproportionately felt by the poor, the COVID-19 pandemic could also be increasing income inequality, a feature not observed in lethal pandemics of the past because of an effective change in capital-labor ratios that ultimately benefited workers.

What then are the key takeaways from the study of the past and the present for the future? First, pandemics have an immediate impact on the mobility of labor, either crushing it through a lockdown or enabling it through migrant flight or a combination of both. While it is easy to curtail international mobility, it is not easy to do so with internal mobility, as the humanitarian crises of China in 1911 or India in 2020 displayed. Pandemic management in the future must take this into account and anticipate migrant flight at the time of a lockdown. Policies that restrict mobility need to be balanced with policies that enhance social protection of those affected.

Second, since pandemics tend to be supply-side shocks, policymakers have to focus on easing the supply constraints to keep prices in check.

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While income support to the poor could help reduce the slide in incomes, it is only by overcoming the supply chain disruptions that the economy can be brought back on track at the earliest. This requires new sourcing options for materials and wider partnerships to reduce trading risks. Finally, since pandemics are not “socially neutral,” expanding good quality healthcare facilities across the board is the only way to minimize the social fallout of pandemics.

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Chapter 1.3

Rethinking the Indian Health System for the Post-COVID-19 World

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Abstract

The pre-pandemic Indian health system had made some progress in providing healthcare, but there were inherent weaknesses in addressing public goods and institutional capacity. The pandemic has exposed the weaknesses of the system, which led to limited options for all actors in responding to the pandemic. A study of the sources of difficulty when faced with the pandemic offers the following four lessons in health policy strategy in India: (1) strengthening policy community and institutions, (2) harnessing the energy of private markets, (3) establishing measurement systems to create feedback loops, and (4) not regressing back to the pre-pandemic status quo.

Keywords: health systems; India; pandemic

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1. Introduction

Many developing countries suffered significantly during the COVID-19 pandemic. This was in part owing to the weak starting point of the health systems even prior to the pandemic. There should be concerted efforts to strengthen the health systems in the post-pandemic world in developing countries in order to be better prepared for future pandemics.

Before COVID-19, the Indian health system had made significant progress in outcomes of IMR, MMR, NMR, and infectious diseases, such as polio and HIV/AIDS, through concerted efforts by the government and expansion of the private sector. However, relative to other developed countries and well-performing developing countries, there were capability gaps in both public goods (insufficient public health) and private goods of health (market failure).

There is a considerable pending agenda in public health. Most of this work lies outside the traditional boundary of the ministries of health. The cost-effectiveness of these interventions is high, particularly when healthcare works poorly. As an example, particularly when healthcare works badly, improving air quality yields high bang for the buck. Historically, there has been a bias in favor of the government providing healthcare at the expense of public health. Public goods under the purview of the ministries of health, e.g., vaccines, surveillance, and pandemic preparedness, were not the best in class compared to those in Asian countries, such as Vietnam, Thailand, and Singapore.

In the field of healthcare, private healthcare providers with out-of-pocket transactional expenditures dominate. These private markets are rife with market failures. In developing countries, state intervention to address such market failures is largely absent. The complex and comprehensive healthcare systems that are seen in developed countries are largely infeasible in developing countries owing to limitations in fiscal and administrative capacity. Hence, there are challenges of undersupply of healthcare, variable quality of care, and large inefficiencies.

The Indian health system was thus in a vulnerable state and was not prepared for the pandemic. Understanding the inherent weaknesses of the health system, the government's response to the COVID-19 pandemic was a national lockdown to give the health system time to prepare

for it. This was a costly but logical path. After the first wave, the system did not focus on fixing the inherent challenges of the health system, and it began reverting to pre-pandemic functioning. This again left India unprepared for the second wave, which was even more damaging. After the second wave, there has been some incremental efforts for strengthening oxygen supply, vaccines, and overall preparedness. However, there is a need for health system strengthening beyond the specific point efforts.

There were many heroic efforts by individuals and institutions during the pandemic, which helped overcome the worst of the pandemic. However, there is a need to reflect and incorporate learnings of this episode into the future. There are four lessons to be learnt from the pandemic. These lessons should be addressed by the health system of India in the post-pandemic world.

First, strengthening policy-making community and institutions is a critical action needed in the post-pandemic world. Institutions are flag-bearers of change. Without strong institutions across government, non-profit, and private, the momentum of change will be difficult to sustain. Public health institutions (like Public Health England, RKI Germany), along with government institutions across different levels, need to be strengthened to address market failure. System thinking and institution building are about a policy community that operates through evidence, design thinking, and feedback loops. India needs to foster a strong policy research community.

Second, harnessing the energy of private markets can strengthen the health system. For this, there is need for avoiding policies and practices which hamper the private sector, such as price caps, slow approvals of new diagnostics and labs, and excessive and cumbersome regulations. At the same time, it is important to create mechanisms to address the market failure of the private sector through information disclosures, the development of standards, and encouragement toward the development of insurance systems. Lastly, the private sector is like a river, and its speed and efficiency can be accelerated through instruments such as advanced commitments (e.g., the US deployed Operation Warp Speed). India should build policy instruments for such mechanisms.

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Third is establishing measurement systems to create feedback loops for the health system. This will help cut through the fog of confusion and steer the system toward more effective and efficient paths. While Ayushman Bharat Digital Mission (ABDM) establishes standards and is adopted over time, there is a need for building stronger health data sets, surveillance, and measurement ecosystem in India. These data should be developed as a public good and released into the research community to inform policy.

Fourth is not regressing back to pre-pandemic status quo. Many countries are undertaking systematic reform in the health system post COVID-19. This includes countries such as South Korea and the UK, which had good health systems even before the pandemic. There is always room for improvement. India should also reflect on the past and use COVID-19 as an opportunity to revamp the health system. It should avoid becoming complacent like in the period after the first wave.

2. Health System in Developing Countries

Leo Tolstoy wrote: “Happy families are all alike; every unhappy family is unhappy in its own way.” In a similar fashion, while advanced economies are relatively homogeneous liberal democracies, underdeveloped countries are strikingly diverse in terms of politics, social structure, economy, and state. Yet, we can describe some broad regularities that characterize underdevelopment.

In developing countries, the foundations of politics and economics are in flux and hotly contested. There are grand debates and rival views on fundamental features of the society and state. As an example, in India, women’s participation in the labor force is very low, and there are conservative and progressive camps in society with rival views about the present state of affairs. The basic features of the state, such as law and order, infrastructure, international relations, military affairs, and the judiciary, tend to dominate the prioritization of policymakers and political actors. Conversely, health policy tends to be less important. As an example, the fraction of work hours devoted to health by the head of state is likely to be higher in Sweden than in Sri Lanka. Under such conditions,

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the share of GDP or public spending that is channeled toward health and related areas tends to be small. Thinking from the viewpoint of public expenditure, in developing countries, both legs are weak: the *magnitude* of resourcing and the *efficacy* in translating expenditure into outcomes. Health expenditure (across both public health and healthcare) thus induces a relatively modest impact upon the health of the people.

While the infectious disease burden has subsided in developed countries, developing countries face the twin problems of infectious and chronic diseases. So, while the problem is larger, the resources and capability are more limited.

For both infectious and chronic diseases, the main agenda for public health lies in areas such as water and air pollution, nutrition and the food system, road safety, disaster risk resilience, mental health, economic well-being, the level of interpersonal violence, and the control of communicable diseases. A diverse array of government initiatives — largely outside the traditional ministries of health — are required in order to foster well-being. These initiatives demand complex intersectoral coordination. As an example, *health* concerns need to be brought into the construction of *infrastructure* in order to increase safety and disaster risk resilience, thus reducing the disease burden. Developing countries have gaps in many of the sectoral efforts that create an environment of health. At the same time, intersectoral cooperation is much harder to achieve in developing countries, with each of the sectors focused on reaching a minimum threshold.

Public health interventions are defined as those which act at the level of a *population* rather than at the level of an *individual*. They tend to be about prevention rather than cure. In the language of economics, these interventions produce “public goods” — those that are non-rival and non-excludable. The cost efficiency of these interventions tends to be particularly high if the state capability and political economy permit sound implementation. As an example, controlling air pollution is cheaper for society than dealing with the consequential disease burden.

Two classes of incentive problems hamper state interventions of a preventive nature. In the principal-agent problem between citizens and state, the state is more able to take credit for involvement in healthcare, whereas public goods in (say) the control of communicable diseases are invisible. Alongside this are the political interests and intellectual

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influence of healthcare workers upon health policy, who tend to prioritize healthcare over public health.

Turning to the private goods of healthcare, the developing country landscape is different from that seen in many developed countries in the role played by private healthcare providers with out-of-pocket transactional expenditures. A great deal of medicines, diagnostics, primary care, and hospitalization is done with voluntary market-based transactions between paying customers and private providers. These private markets are riven with market failure given the high extent of asymmetric information.

Healthcare inherently involves complex issues of incentives as well as checks and balances. In advanced economies, public systems help induce the right behavior from private producers under conditions of high asymmetric information. The internal systems of management in each healthcare facility have design elements that contain malpractice. Underdevelopment implies low institutional capacity at private firms and in the state. As a consequence, under conditions of underdevelopment, policy influences on incentives are likely to be imperfect, and private responses to those incentives are also likely to be partial.

The comprehensive and complex healthcare systems that are seen in most advanced economies are essentially infeasible in developing countries. The pathways to addressing market failure that are conventionally seen in advanced economies — sophisticated large-scale buyers in either the government or in private insurance companies — are generally absent in developing countries. Alongside the private system, there tends to be a public sector healthcare system, with limited capacity, which tends to be a free provider (funded by general tax revenues) that competes with the for-profit private sector healthcare system. However, both the government and private sector care suffer from lack of incentives for high levels of quality and productivity improvement largely due to information asymmetry. As a result, the patient welfare and wellness suffers.

The field of health in developing countries thus suffers from a combination of two problems: weak public goods in health (through low resourcing and poor execution) and weak private goods (a combination of poor incentives in public sector healthcare and a different kind of wrong incentives in private healthcare). These problems have come together to induce poor health outcomes across a variety of metrics, such as

disability-adjusted life years, infant mortality, multi drug resistance, TB prevalence, maternal mortality, or cardiovascular burden.

In this kind of setting, a pandemic, such as COVID-19, can become a major shock to the health system and to the health of the people. As an example, the Spanish Flu of 1918 showed up in India with a lag and is estimated as having killed 5% of the population from 1918 to 1920. This pandemic induced a remarkable outcome where the population of India declined from the 1911 to the 1921 census — the only experience of a population decline over a 10-year period in India's history. It was similarly particularly important in South Africa and Indonesia. For these reasons, in late 2019 and early 2020, health thinkers in India were extremely concerned about the rumors emanating out of China about a potential new pandemic.

In this chapter, we closely examine the pre-existing conditions in India and the experience of the pandemic and draw lessons for health policy in India.

3. The Indian Health System Before the Pandemic

India has had improvements in outcomes over the years but continues to lag many other developing countries, such as Bangladesh, Sri Lanka, China, and Malaysia, on health outcomes and financial protection.

India faces a high burden of infectious diseases as well as noncommunicable diseases (NCDs). The world's largest count of TB patients and diabetes patients are found in India. Most of India has no health insurance or are covered poorly — choosing to pay out of pocket to access services and health inputs from the private sector, exiting the government-built care delivery system. Most households are one health shock away from poverty. Quality of care is highly diverse and overall poor. Even in the biggest cities, knowledge of and adherence to best-practice clinical protocols is low. As a consequence, the outcomes of care are low. Multiple systematic studies by Jishnu Das have demonstrated quality challenges in India across government and private sector.

There are direct connections between poverty, a weak health system, and unsatisfactory health outcomes. High GDP growth will undoubtedly help. But at the same time, at every level of income, there are features of

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the health system, as follows, that lie at the root cause of low performance: (i) weaknesses in public health (public goods), (ii) market failure in the (largely) private healthcare system, and (iii) weak institutional structures with low political accountability systems, which hamper improvements in public health or useful intervention in healthcare. Conversely, in this article, we will not bemoan the areas where India lagged the advanced economies in aspects that merely reflect lower per capita income. We will focus on the aspects of organization, policy, and incentives which held back the public and private pandemic response.

3.1 Weak public goods, i.e., public health

Public health addresses externalities and public goods at the population level. This is distinct from private goods of healthcare, e.g., a surgery is a rival and excludable good even if it is produced by a government facility.

Public goods in health can broadly be categorized into two elements. The first part is the elements that fall into traditional conceptions of a ministry of health and are common horizontal activities across disease areas: vaccines, vector control, surveillance systems, drug approval, pandemic preparedness, and assembling and releasing health statistics. The second are the class of activities that lie outside a health ministry, e.g., food/nutrition, clean water, clean air, urban planning, road safety, and secondary education for women. There are also called “social determinants of health.”

There have been several successes in India in public health — polio, AIDS, and vaccination, especially in rural areas for basic vaccines. These are critical achievements. However, India was not the best in class in public goods. This is corroborated through the still high prevalence of vector-borne diseases, malnutrition, as well as NCDs.

The social determinants of health are organized across many ministries. Health considerations do not adequately play out either in the budget process (e.g., the positive impact of rural roads for health should encourage greater funding) or in operational aspects (e.g., health as a consideration in the design of roads). Despite periodic calls for inter-sectoral task forces, there has been limited all-of-government thinking on health. Why

has India struggled to make progress on public goods when a few developing countries have been able to do so (e.g., Thailand, Sri Lanka)?

3.2 Weaknesses in the private goods of health care

In the private goods of healthcare (insurance, hospitals, clinics, labs, drugs, pharmacies, and ambulances), there is one large budget-financed public sector organization alongside the dominant force, which is private firms.

The government participates in healthcare through two mechanisms: ownership and management of some healthcare facilities and government-sponsored health insurance schemes (GSHIs).

The National Health Mission (NHM) is an agglomeration of central government vertical programs (maternal child health, TB, family planning, and NCDs), which run programs for care delivery in a mission mode in partnership with state governments. The operations of NHM are designed by the union government and partly funded by the state governments. Given the narrow disease focus lens, there has been some success achieved in areas with the possibility of narrow execution at defined points in the lifecycle, e.g., child health and family planning. However, diseases that require engagement with broader health system (e.g., TB, diabetes, and CVD) are not amenable to mission mode. In TB, for example, the patient's diagnosis needs are not distinctive from those of other diseases, and often, the first port of call for such patients is the private sector primary care provider. Without an overarching engagement model between government and private primary care providers, interventions on TB are often piecemeal, delayed, or insufficient. In addition, verticalization in health policy, with special work for each disease, is also cost inefficient. Each vertical program builds its own supply chain, monitoring system, training module, budget line, and incentive structure — trying to outcompete the other. This is a sub-optimal system design.

State governments also own facilities, hospitals, clinics, labs, and procure drugs. These are provided free of cost to all those who seek them. There are several challenges with this model, the primary one being low accountability. Governments face little feedback on healthcare performance

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from elections, and the civil servants working in these facilities have a fixed wage and face no accountability from their employers.

Across all levels of a government, substantial amounts of money is being spent on public sector healthcare facilities. Owing to the weaknesses of public management, there is poor bang for the buck. The response from the citizenry has been to exit the Government health system. Faced with a choice between a free public sector healthcare provider and a non-free private sector healthcare provider (who may often be unfair in their dealings), many people are voting with their feet in favor of the private provider.

The market share of the public system has been declining. It is estimated that more than 70% of outpatient consultations and hospitalizations are in the private sector. Most pharmaceuticals are produced by the private sector and sold through private pharmacies. Most of the testing is done in private labs. Private health is largely funded by out-of-pocket expenditures by individuals who are not able to discern quality of care and nor do they have bargaining power with hospitals, especially during emergencies. In the international experience, in countries with large private sector care providers, there are three pathways to address the market failure of asymmetric information: government purchasing, commercial insurance, or regulations.

By the late 1990s, it became increasingly clear that intensification of public expenditures into direct management and operation of healthcare facilities was not going to work well. Politicians saw poor bang for the buck in putting budgetary resources into expanding public healthcare facilities. This led to the rise of a public-private partnership approach of government-sponsored health insurance (GSHI), where the government is the funder and healthcare services are purchased from private healthcare facilities.

State and national governments have a government-sponsored health insurance program, which intends to provide free hospitalization for the 600 million plus low-income population. At present, these programs are more of an aspiration: If citizens actually used them, the budgetary consequences would be daunting. With low spending and weak processes/tools and delay in payments, GSHIs have not been able to live up to their promise of improving the cost and quality of private healthcare yet. The model however continues to evolve and become stronger. The evolution of GSHIs is an important aspect of the health system.

The second pathway through which market failure in private healthcare could be addressed is private health insurance. So far, private health insurance companies have not achieved the scale or processes to influence private healthcare providers. The regulator of insurance, the IRDA, is more oriented toward the financial aspects of insurance and has not developed domain knowledge in health systems thinking.

The third pathway through which market failure in private healthcare could be addressed is regulation. The legal and institutional foundations for health regulation are largely absent. As a consequence, the regulatory capacity to understand and address market failure does not exist in health.

The present behavior of regulation emphasizes bans, licensing requirements, and price caps. Price caps are used in order to improve access for the poor, but as is well known in public economics, price caps reshape the incentives of firms with unintended consequences. The Clinical Establishment Act imposed a set of stringent infrastructure and operations requirements for providers. It has been implemented for over a decade with limited compliance or impact. In many respects, the state system is now in a process of trying to achieve detailed control of private healthcare providers. As with the previous experience in India with central planning systems, this may be challenging.

While state and national governments struggle to build capabilities to address this gap, the private sector is beginning to innovate with many models, e.g., second opinions, managed care, value-based care, rating models, and IOT devices for real-time/remote monitoring of sugar level. These are nascent, but if consumers demand better quality care and affordable health, the market forces may rise to cater to the needs of the citizens. There may be some hope. Other policy and regulatory levers may yet be not sufficiently explored — collaborative planning with private sector, data collection and sharing, effective support of innovation in private sector for long-term R&D and innovation (like the NIH and CDC in the US), etc.

3.3 Weaknesses of institutions

The Indian Health system has multiple gaps and market failures which have been brought to focus due to the pandemic. Table 1 captures a summary of the health system before the pandemic. There were limited mechanisms for

population-level disease surveillance and acquiring data sets, which can help with identification of problems, design, and rapid response. The National Center for Disease Control is supposed to be the focal point of communicable diseases and is a union government agency. It was not institutionally ready for the pandemic. While there is substantial vaccine manufacturing capacity in India, there is limited upstream R&D capacity for vaccines, therapeutics, and tests. There is a limited innovation ecosystem to enable rapid responses to local population-level challenges, with a process of posing authentic questions and rapidly obtaining sound answers.

Natural disasters always have an important health component, and the Indian disaster response has been weak on controlling the health fallout of natural disasters. The Indian National Disaster Management Agency

Table 1. Summary of Indian health system before the pandemic.

	Element	Status Pre-pandemic	Impact
Public goods	Health driven: vaccines, pandemic preparedness, vector control, surveillance, etc.	Weak–moderate	Highly infectious diseases and NCDs burden
	Social determinants of health: urban planning, food, water, air, secondary education, etc.	Weak	
Private goods	Government: Hospitals, primary care, pharma, diagnostic, etc. produced or financed by the government	Weak–moderate	Access utilization but low-quality care, low financial protection. Large market failure
	Private: Hospitals, primary care, pharma, diagnostic, etc. produced or financed by private institutions	Weak–moderate	
Institutions	National: Undertaking common activities across geographies	Weak–moderate	Selective mission-mode effectiveness.
	Local: Undertaking local activities with local context and accountability	Very weak	Limited complex and adaptive design and execution success

(NDMA) came to prominence in the pandemic response owing to the infirmities of the institutional structure in mainline public health, and NDMA had no experience or institutional capacity on health.

The heart of a successful health system is impersonal, rules-based institutional capacity — in the public and private sectors — that steadily reshapes incentives. As an example, the health system in Israel is dominated by four large private HMOs and works well through the institutional capacity of these organizations. The Indian predicament lies in low institutional capacity in both the public and private sectors.

Each part of the Indian health system is shaped by incentives to emphasize the wrong directions. There is a need for a thinking community that spans policy and practice, which can reimagine the health system in original ways, in ways that harnesses the strengths of each side.

4. Lessons from the Pandemic

There have been heroic efforts on the part of individuals, governments, frontline workers, and nonprofit and private sectors that has enabled India to come through to the other side of the initial waves of the pandemic. These efforts are to be acknowledged and lauded. However, there is also a merit in reflecting on the past and synthesize lessons for the future, so we could prepare better for future pandemics.

It is useful to subdivide the pandemic period into four phases. Phase 1 was roughly from the WHO announcement on COVID-19 to the end of national lockdowns in May 2020. Phase 2 ran till March 2021 and essentially covers Wave 1 of the disease. Phase 3 is the Wave 2 of April–June 2021. Phase 4 started in July 2021 and is presently ongoing. At this time, we can reflect on what happened in these four phases of the pandemic and what lessons we can draw.

4.1 Phase 1 (mid-January – end of May, 2020)

This phase was marked by uncertainty, centralized action, and slow preparation. The virus was new to India and the world. Despite multiple models, there were no certainty about the epidemiologic progression and health impact. There was uncertainty about the appropriate tests,

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treatment, and population behavior. Given the weak health systems and the unlikelihood of a fast ramp up on adequate preparedness, there was a fear about the outcome. The union government embarked on a relatively extreme lockdown.

This was in contrast to many South East and East Asian countries that had strong health systems in place (public goods, private goods, and institutions), which enabled them to take a milder social-distancing approach. With a weak health system (public goods, private goods, and institutions), the nature of the Indian lockdown was extreme and covered the entire country. The lockdown likely helped in slowing the progression of the infection and gave precious time to beef up the preparation for public awareness and behavior change (wearing masks, washing hands, etc.), strengthening testing, isolation/quarantining, treatment (ventilators, oxygen). However, there may have been adverse economic and health impacts (especially for non-COVID-19 care, which saw a large utilization dip during the lockdown) of the sudden onset of the lockdown and of the one-size-fits-all approach for a large and diverse country.

In the absence of institutional capacity for contact tracing in local governments, there was a search for technological solutions. The mobile app “Aarogya Setu” was tried by the union government.

With the lockdown and initial fear, the private healthcare sector took a back seat. Most of the preparation was led by the state and utilized the state-owned healthcare system: government testing labs, government PHCs, and hospitals. Few private care providers volunteered, and even if they did, licensing and government processes did not enable them to participate. As an example, initially, private testing labs were not permitted to test for COVID-19, thus idling the substantial capacity for testing in the private sector. This was in contrast to South Korea, Germany, and South Africa, which actively sought collaboration with the private sector in innovating on local testing, ramping up testing, and care provision. There were gaps in capabilities in government contracting, which hampered policymakers in being able to harness the enormous size and scope of the private healthcare system. Working with the private sector is seen as difficult, and faced with urgency, policymakers chose to use the healthcare system that they owned as the only lever. This is the reminder of the importance of developing conceptual and policy frameworks in

peace time, which can then be brought to bear when faced with a crisis.

This phase was also marked by shortages of inputs — masks, PPEs, reagents, testing machines, ventilators, etc. Local supply ecosystems were not set up for the surge in global and Indian demand. In other countries, we saw a role for governments (e.g., Operation Warp Speed in the US) in helping private producers solve choke points and obtain scale through advance contracting, subsidies, faster approvals, etc. This did not happen in India; the Indian private sector did scale up capacity, but it was on its own. The state often responded in measures familiar to them, with price limits and bans. This would lead to reduced interest of the private sector in investing in these fields in the future. Ayushman Bharat, which was a tool for contracting with private labs and hospitals for COVID-19, was largely not used.

This was the phase of the pandemic where knowledge was in short supply. Basic knowledge about treatment protocols, correlates of morbidity and mortality, and the extent of spread of the disease in India: these things were not known. The health statistical system in India showed its limitations. Rational, evidence-based debate in a community of experts was, as a result, lacking.

4.2 Phase 2 (beginning of June 2020–March 2021)

This phase was marked by a decentralized policy, focusing on adapting to the COVID-19 waves with the realization that an indefinite nationwide extreme lockdown imposed too high an economic cost. The scale of testing improved, partly through improvement of global availability of materials and partly through easing of government restrictions. There was a greater realization that India is a continental economy, more like the European Union, and there is a unique epi curve across 100 regions of the country.

State governments became much more important in this phase, where the sick required treatment, as opposed to the first phase in which the disease burden was low. State governments dealt with the pandemic in a mission mode, with dedicated teams and a focus on production of services through the government healthcare system. Government had limited

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engagement with the larger private health system. Local state governments (government funded) and private sector (providing services out of pocket or through commercial insurance) provided care to the sick. State governments continued to engage with the private sector through the tools of price caps on testing and care delivery and selective purchasing through government-sponsored health insurance schemes for treatment (not testing). Policymakers did not undertake actions that would help scale up the healthcare output of the private sector, unlike a few other countries (e.g., Germany).

Some innovations emerged — low-cost ventilators, vaccines, local tests, masks, and concentrators — supported by government institutions and private nonprofit initiatives. While these were good initiatives, their impact on the overall state of the pandemic was less than desired. Slow licensing, lack of rigorous assessments, and lack of support in scale up (advance contracting, capital expenditure support) were some of the barriers. India primarily rode on global innovation and capacities on vaccines, pharma, testing, and ventilators to meet the bulk of its needs. There was no Indian operation warp speed. Vaccine production took place in India through private and philanthropic initiatives (the partnership between AstraZeneca and Serum Institute). COVAXIN was given a quick approval. However, it was not able to scale up and contribute a large share to vaccination.

Official data about testing were not useful in understanding the disease on a population scale owing to heterogeneous constraints on the testing process. A few research papers started survey-based measurement of the footprint of the disease, and this was the only way to track the spread of the disease. Longitudinal household survey data were repurposed to develop estimators of excess death, thus overcoming a gap in the health statistical system, which does not count deaths correctly. Limited genomic surveillance was undertaken.

Toward the end of Phase 2, the health system started returning to more normal conditions. Many elements of the health system, which had been put on the back seat, started returning to normal. These included nutrition, maternal child healthcare, routine immunizations, and TB.

Given the shortage of domestically available vaccines, the vaccination strategy adopted was a staggered approach that targeted frontline workers and the high-risk group consisting of 350 million people over 4–5 months.

There was no announcement on the plan for the remaining population. Import of vaccines was not encouraged nor expedited by the government. Initially, private healthcare organizations were prohibited from engaging in vaccination, but this was reversed. The union government set out to build a computer system — CoWIN — through which it would control and track every vaccination in the country.

In the FY 2021–2022 budget presented in February 2021, the minister of finance proposed only a marginal increase in the funding allocated to the ministry of health, largely for vaccination of the prioritized 350 million population. There was no announcement of a health system or institutional reform. India was ready to put COVID-19 in the rearview mirror, with little course correction in light of Wave 1. The health system began to switch back to its pre-pandemic mode.

4.3 Phase 3 (April–June, 2021)

Wave 2 was a rude shock to the system. We were largely where we were in early 2020 when the epidemic first began. There was more knowledge about the virus and a better health system but with a less than robust response mechanism. This time, the pandemic spread simultaneously across multiple states.

Much of the population was unvaccinated. If 3 million vaccinations per day had taken place in the first three months of the year, this would have created 270 million people vaccinated with one dose by March 31, which could have altered the disease trajectory in Wave 2. Through the peak months of April, May, and June, if another 270 million vaccinations had taken place, it could have altered events.

With the sudden spike, there were huge shortages of beds, oxygen, medicines, and tests. Both the population and the healthcare system were overwhelmed. There was firefighting on every front. Data systems continued to be weak, with no clarity on the full impact of Wave 2 across urban and rural India. We may never know what happened in those terrible months, what worked and what did not.

There was a renewed focus on vaccines. However, policy tools did not aid the speed or diversity of the vaccination rollout — with limited advance payments, union government's control over all aspects of

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vaccination, and vaccine monoculture (almost all vaccines in India were the AstraZeneca vaccine).

4.4 Phase 4

The second round of normalization began in July 2021. There was greater push for vaccination over time. When the Omicron wave began, there was a fresh sense of the need for more distributed intelligence in booster doses and in the benefits from a diverse array of vaccines in the country.

The two-year roller-coaster ride of COVID-19 has seen many ups and downs. Many heroes emerged who averted disasters. Many horrors occurred which could not be averted. The picture of corpses in the Ganga — the holy symbol of India — is very stark in the memory of citizens.

How can we do better? There are four important lessons which India should hold on to as it builds the path ahead.

4.5 First, we need to establish sound institutional capacity and a policy community

There is an important distinction between the sustained capabilities of institutions and the hurried work done in an emergency, in “mission mode.” It is particularly hard to achieve state capacity in the latter.

To make an analogy from the world of firms, a small bunch of 20-year-olds can do remarkable things for a few months in a startup. But mobilizing a large scale of resources and manpower to overcome complex problems requires a large complex organization with organizational design, processes, and training. Startup culture is fueled by the promise of extreme financial payoffs, which are absent in the world of policy. All too often, in India, mission mode is firefighting and hasty decisions, which are not based on evidence, political considerations in policy-making that are fostered through the lack of public debate, and arbitrary power.

The very reliance upon mission mode in India points to the weaknesses of institutions. But we should resist the temptation of doing complex things in mission mode, where the institutional capacity has not been built, as the probability of policy failure is higher. As an example, consider

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dealing with an epidemic. A large number of epidemics, large and small, are currently coursing through the country. What is important is to establish institutional capacity that works on epidemics at all times. The regular work on small outbreaks will create the muscle that will then be able to rise to the occasion when a bigger pandemic appears.

This institutional capacity needs to be flexible. As an example, consider contact tracing. Contact tracing is a critical element of controlling communicable diseases. It requires intensive human engagement and cannot be replaced by an app. Every city in India requires processes and skilled staff that would do contact tracing. However, right from the design stage, the processes should be designed in a way that a small permanent crew is in place, as a “standing army,” but this has the ability to rapidly hire, train, and control contract workers so as to be able to scale up rapidly when faced with a big problem. This will create the ability to deal with a plague outbreak in Surat or a COVID-19 outbreak as and when these arise.

In mission mode, there tends to be an emphasis on a small leadership, which gives orders to a large number of people. System thinking, as well as institution building, is instead a tale of thinking about incentives. The idea should be to establish incentives that reshape the behavior of a large number of actors on a sustained basis. This makes possible a bigger response to a crisis.

As an example, consider the problem of medical oxygen. When faced with Wave 2, there were great shortages of medical oxygen all over India. The peak load was very high, and the government commandeered all possible sources of oxygen (regardless of the magnitude of the economic impact) in trying to find a response. How will the Indian health system think more effectively about medical oxygen in the future?

If a state system occasionally expropriates private actors and grabs oxygen when it feels this is required, this would hamper private confidence and investments in the overall oxygen industry. It is better to work through the price system and not through state power that expropriates. What is required is a network of contracts through which strategic reserves of medical oxygen are held all across the country, and the cost of this infrastructure is charged to the healthcare industry as the price of optionality.

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System thinking, as well as institution building, is about a policy community that operates through evidence with feedback loops. A capable research community needs to be in place, which studies the data, diagnoses problems, and measures the impact of recent policy initiatives. This research would result in creative problem solving by the policy community. Health policy would get better through a process of iterative refinement. What is important are the feedback loops and a bottom-up process of discovery of problems and solutions, rather than the top-down imposition of an *idée fixe*, a grand design.

The institutions and actors in healthcare need to work toward deeply understanding the system and improving outcomes with as little state intrusion as possible. This requires a keen understanding of the purpose of each element of the state institutional apparatus. The highest impact will be obtained by focusing on a few questions. How can we build resilient public goods (health focused, social determinants of health) across the levels of community (local, state, national, and global), how can we address market failures while imposing the lowest cost upon society, and what is the design of incentive-compatible institutions which will enable these two objectives?

Institutional design holds the key. The analogy between the US CDC and the Indian NCDC is apparent, and the NCDC has low capabilities when compared with the US CDC. The public goods of water and sanitation are best organized in a highly decentralized way, but in India, the union government plays a dominant role. We see pockets of India with better public health, such as Jamshedpur, Kerala, Tamil Nadu, and Bombay, and each of these is a reflection of the role of the triumvirate of local control, local financing, and local accountability in achieving cost-efficient and sustained gains.

In advanced economies, we see important institutional elements for public health, such as the Robert Koch Institute (RKI) in Germany or Public Health England (PHE) in the UK. These are absent in India. In most states, departments of public health, which were present under colonial rule, were replaced by departments of health, which are healthcare focused.

Public institutions work well through iterative refinement, the establishment of processes, accountability mechanisms, and feedback loops.

4.6 Second, one of the most important forces to harness is the private health sector

The Indian state system has severe capacity constraints, and the private sector has the potential to achieve speed, scale, and cost efficiency. Year after year, we have seen the rising role for the private healthcare industry in meeting the needs of the people. Just as people are exiting from government schools and going to private schools, people are exiting from government healthcare and going to private healthcare. In India there are significant market failures in the private sector. At the same time the vast potential of private innovation is not leveraged sufficiently.

The energy of the government is primarily focused on its own delivery of healthcare and vertical disease missions. This has created a competitive view of the private sector rather than collaboration. Few policymakers have been able to think about the overall Indian health system, where the private sector contributes innovation and competitive hunger, and the institutional capacity in the public and private sectors combats market failure in private healthcare provision.

The private sector, in turn, is sub-scaled and focused on the near term. Most management teams are consumed in working within the present incentive arrangements and meeting short-term ROE targets. Firms with the scale and time horizons to think strategically have yet to emerge.

The private health sector is like a wild river. Channeled correctly, it can produce energy, food, and life but unchecked, it may cause damage. Smart institutions (national and local) should seek to harness its power. In India, during COVID-19, the private sector was ignored by policymakers. Policymakers periodically sent a ban or a restriction to the private sector, e.g., doctors were prohibited from buying vaccines and vaccinating people. However, it was not actively leveraged.

This led to the slow ramp up of testing, critical care, vaccination, and innovation in India. The private sector that was left to its own devices also did not cover itself in glory. There was also price gouging and poor-quality care. As the bulk of the specialist health workers, lab experts, and ventilators were in the private sector, this had important adverse consequences.

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This was in contrast to South Korea, the US, Germany, Israel, the EU, etc., where private sector innovation, speed, and capital was proactively harnessed by the governments to great benefit. In South Korea, the government worked with private labs to develop local testing kits in record time, which were scaled up in private labs to undertake scale testing and keep COVID-19 under check. In Germany, the government provided subsidies to private hospitals to keep beds free for COVID-19 patients and also to ramp up critical care beds. They also rapidly decentralized test licensing to enable more private sector and overall scale up of testing. Operation Warp Speed in the US engaged in faster approvals, advance contracting, and subsidies, thus dramatically accelerating the private sector innovation for vaccines, pharma, and tests, which not only benefited them but also the world. Israel's private HMOs were critical in achieving one of the fastest vaccinations of an entire population among countries. Most of these countries used data/transparency, subsidies/purchasing/advance contracting, and accelerated regulations to enable the private sector. None used price caps.

There should be deliberate effort through committees to lay down effective policy approach with respect to private sector. These committees should have representation from both the government and private sectors as well as international experts from other countries with mixed health systems. There should be effort to leverage lessons from other sectors in India, such as telecom and airports, where private and public collaboration is more effective.

Systems thinking for overall health system, including private sector, also needs institutional capacity. There needs to be national and local bodies to address market failure as well as to unlock the potential of the private sector. No such dedicated body exists today. Given the nature of competition between the government-led and private healthcare systems, this role is not done by anyone. This needs to be changed in the post-pandemic world.

4.7 Third, data and measurement matters

The lack of knowledge creates misdirection about where the system is and where the system needs to go.

India's weak data, surveillance, and measurement hampered the ability to adapt all across the country. Policymakers, healthcare firms, employers, and citizens: everyone needed data on the pandemic in order

to make better decisions, and these data were lacking. This could have been addressed through investing in smart measurement systems, such as measurement of seroprevalence and excess deaths from longitudinal survey data, greater use of private labs in testing and genomic surveillance, release of government data sets, and systematic death audits.

Ayushman Bharat Digital Mission (ABDHM) is one step in the direction toward setting up standards and enabling adoption of information systems. However, this will take time to be adopted at the levels of the UK health system — insurance and financing systems will over time bring incentives for adoption. In the interim, there is a need for statistical surveillance systems to track, analyze, and understand the health system.

The brain behind the discovery process in public policy is the feedback loops created by the research community. The possibilities of this community are defined by the data availability. The sustained construction and release of trusted large-scale health data sets is a prerequisite for the next stage, i.e., research.

4.8 Fourth, beware the natural mean reversion to the pre-pandemic health system

Many other countries, such as South Korea, China, and the UK, even those which fared relatively well in the pandemic, are using this as a moment to review their health system and undertake modifications.

India regressed back to the pre-pandemic status quo after Wave 1. There is a risk of the health system slowly reverting back to pre-pandemic status after Wave 2 as well. This would be a big disaster. The anguish in our hearts about the death and disease of the pandemic should be channeled into building back better.

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Chapter 1.4

Confidence in Healthcare During Pandemics: A Developing Country Perspective

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Abstract

In this chapter, we study the role of individuals' confidence in healthcare institutions on curative and preventive demand for healthcare during the COVID-19 pandemic in India. Specifically, we collate data on pre-pandemic self-reported measures of confidence in healthcare institutions in the private and public sectors and correlate these measures to aspects of demand for healthcare during the pandemic. We find that confidence in healthcare is positively correlated with demand for healthcare, which implies that policymakers must seek to establish credible health care institutions for COVID-19 care to tackle this major public health problem. This is because, in the absence of such credible institutions,

which are perceived to be better service providers, the demand for health care is likely to be low, which can mask the actual infection rates leading to underreporting of infections and low vaccine take-up. We present a conceptual framework based on a simple microeconomic theoretical model that can help understand such behavior and use historical data on self-reported confidence measures from a large nationally representative household survey, along with rapidly incoming COVID-19 data, to perform our empirical analysis.

Keywords: India; hospitals; confidence; global health

1. Introduction

Healthcare is a credence good, ascertaining the quality of which is generally difficult due to unobserved heterogeneity (Dulleck and Kerschbamer, 2006; Das *et al.*, 2016; Bhattacharya and Chatterjee, 2020). In general, if the quality of healthcare is perceptively better with available perks and signals of quality, then this might affect the demand for healthcare (Adhvaryu *et al.*, 2019). It is, however, more challenging to understand whether public or private healthcare facilities are relatively more efficient, as it is not obvious how to compare the quality of outcomes across these providers. In a rare instance, Das *et al.* (2016) use an audit study to show the relative efficiency and competence of private healthcare in the context of India. Despite the fact that gauging the quality of these institutions is rather difficult, this question is of particular interest to policymakers, more so in the wake of a raging pandemic, such as COVID-19. This is because critical policy decisions, such as allowing private facilities to provide COVID-19 care, whether to expand vaccination through private facilities and to what extent, and whether the acceleration of testing should be implemented through the private sector or government laboratories, depend on *ex ante* understanding of the efficiency of the private sector over the public sector and realizing the costs and benefits of such policies.

While these are essentially supply-side decisions, part of the success of these policies would likely depend on demand-side factors, such as citizens' perceptions about the relative efficiencies inducing their relative

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preferences for private and public healthcare given the unobserved quality. Along these lines, recent research on COVID-19 seems to suggest that confidence in healthcare institutions can affect mobility and compliance (Chan *et al.*, 2020), and higher confidence in private healthcare is highly correlated with higher number of reported COVID-19 cases (Bhattacharya and Chatterjee, 2020).

In this chapter, we attempt to study the role of confidence in private hospitals and public health facilities in greater detail, with a focus on understanding what could shape citizens' preferences and also its eventual consequences. The chapter primarily focusses on the aspects of curative healthcare and correlates the reporting of COVID-19 infections and other demand-side outcomes, such as seeking hospital care when diagnosed with COVID-19, with historical levels of confidence in healthcare providers. In the latter half of the chapter, we also present some analytical results on the possible correlation between confidence in healthcare and the demand for preventive healthcare, such as take-up of vaccines for COVID-19. The dissemination of information regarding COVID-19 precautions as well as targeting vaccinations for the entire population are major public health concerns. This chapter provides insights into factors that may be potentially beyond the control of the policymaker, such as idiosyncratic tastes and preferences based on perceptions of healthcare providing institutions, which may affect achieving this target. To avoid confounding with current policy efforts not being sufficient to create adequate confidence in healthcare during the COVID-19 pandemic, we use historical measures of confidence.

We choose India as the context of our study. This is motivated by two main reasons. First, India was one of the worst affected countries in terms of COVID-19 cases reported, and particularly, during the second wave in 2021, the country had to go through massive household agony and overall an extensive healthcare crisis. There was a huge spike in cases reported, with daily numbers sometimes exceeding the population of some other countries in the world.¹ As a result, a study on India is representative of a large fraction of the people affected by this pandemic. Second, healthcare

¹<https://www.sciencenews.org/article/coronavirus-covid-india-crisis-social-distancing-masks-variant>.

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infrastructure in developing countries like India has already been stressed before the pandemic, and therefore, understanding the demand-side factors that may drive critical decisions related to policy and infrastructure is of utmost relevance and significance.

We rely on a mixed-methodology approach for this study, namely, using theoretical insights, primary data analysis, as well as secondary data evidence. The larger objective of this study is to understand the veracity of the numbers that are released in the public domain with respect to COVID-19 statistics from various sources. If there exists an unobserved heterogeneity in the measures of confidence, this can potentially mask the actual efficiency of these institutions, and as a result, the self-reported numbers should be interpreted with caution. This is a very important issue because misinformation may either lead to widespread panic among citizens, which may overwhelm the healthcare systems unnecessarily or, conversely, may lead to widespread irresponsible behavior due to a sense of relaxation. The latter is heavily detrimental during a pandemic, such as COVID-19, which requires coordinated citizen actions, such as masking and social distancing and therefore can lead to major public health crises.

2. Public and Private Healthcare in India

The COVID-19 pandemic has in many ways translated a healthcare crisis into an economic and social crisis. The interlinkage between healthcare and other sectors of the economy has deepened, stressing the need for a critical focus on the healthcare system and expenditure across all developing countries. Based on pre-pandemic data — India, among the developing countries, has one of the lowest public health spending of just INR 3 (in USD equivalence, this is approximately 4 cents) per person per day that counts for 1.02% of the GDP (National Health Profile, 2018). Therefore, the private medical sector remains the primary source of healthcare for the majority of households in urban (70%) as well as rural areas (63%) (National Family Health Survey III, 2005–2006).

Although the poorer sections of the society depend on the public health system more than the rich, even in the poorest income class, only the bottom 36% quintile opts for public hospitals for treatment (NSSO, 2017).

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Despite healthcare being a credence good, this heterogeneity is perhaps related to the perception among the citizens about the efficacy and quality of healthcare received and also potentially on past experiences. This revealed preference for private hospitals is reflected by the India Human Development Survey (IHDS) -II data across most of the states in India. In Figures 1 and 2, we provide a snapshot of this relative consumer preference by the states of India based on the IHDS-II of 2011–2012.

Against this backdrop, it is also notable that the average expenditure per hospitalization case in private hospitals is seven times higher than in public hospitals. Although, economic theory suggests that the working of free market is efficient under “normal” circumstances — health services being an essential commodity, the need for intervention seems to be important. Anecdotal evidence and news reports in the wake of the COVID-19 pandemic suggests that the private health institutions had largely withdrawn their medical services and it resulted in overburdening the government hospitals. Consequently, these public facilities were left to tackle with both COVID-19 and general non-COVID-19 patients. In any crisis, the government is expected to act first and stabilize the market operation, and this is no different for COVID-19-related health crises.

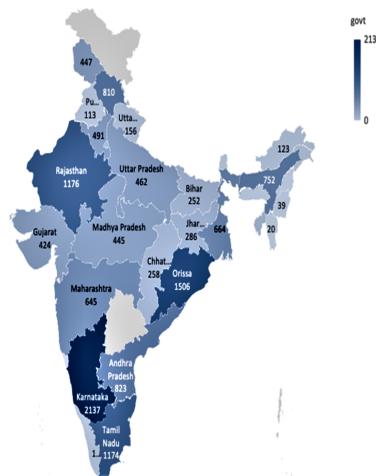


Figure 1. State-wise number of government hospitals opted by consumers in India.

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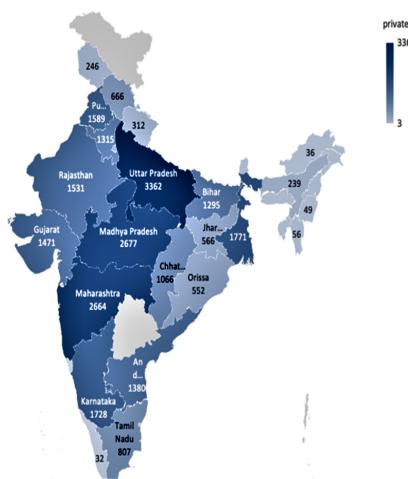


Figure 2. State-wise number of private hospitals opted by consumers in India.

Here, the perception of the citizens regarding the role of the government healthcare institutions becomes crucial in determining the degree of effective management of the crises at hand.

For a developing country like India with a large population, the risk associated with the spread of infection during pandemics is rather large, as noted by Bhattacharya and Chatterjee (2020), who go on to suggest that popular opinion on the implementation of the lockdown in India may have been initially favorable, but eventually, sharp criticism of the policymaking as well as potential underreporting of the rate of infection were made. Bhattacharya and Chatterjee (2020) further add to the large body of literature on behavioral anomalies and take-up during pandemics and disease breakouts (Mesnard and Seabright, 2009; Mullahy, 1999; Schmitz and Wubker, 2010; Nuscheler and Roeder, 2015; Maurer and Harris, 2016) to show that with higher levels of confidence in private healthcare, if COVID-19 care is available at private health facilities, the reporting of COVID-19 infections seem to go up. The key finding here is that citizens' average level of confidence in the healthcare facility is highly correlated with the incidence of the number of diagnosed cases, which cannot rule out a hypothesis that there exists a bias in the reporting masked by idiosyncratic preferences for healthcare providers.

3. Conceptual Framework

While the advent of heterodox ideas in economics has been rather fast paced over the past few decades, it is interesting to note that despite biases and fallibilities exhibited by human factors, some of which we discussed above, the core idea of responding to incentives can still remain relevant. In this section, we attempt to present a brief conceptual framework to understand the rationale behind some of the choices and decisions of citizens under the COVID-19 pandemic using a very simple textbook micro-economic framework. It is worth mentioning that not only does our model consider that individuals respond to incentives, but also the fact that the incentives are a function of the institutions depending on which they make their decisions.

Let us begin with the issue of underreporting of COVID-19 cases. This can be critically explained by the perception about the quality of service provided by public spaces. In other words, we can closely look into the issue of underreporting through the trust or confidence in an institution. We first proceed with the situation under which an individual intends to go for a diagnostic test (D). The individual will undergo a diagnostic test if she perceives that the test reports will help to cure her faster and more effectively. Put differently, the patient needs to *feel* that the test is meaningful and essential, which is dependent on her trust in the institution (τ). Also, the cost of undergoing the test is a critical factor influencing the decision. The cost of a diagnostic test can be explicit, i.e., the per unit cost of the test, C_τ , or the cost of waiting in the queue, and other institutional as well as procedural costs are accounted by the implicit cost C_I . Therefore, the total cost of the diagnostic test would be a sum of the explicit cost ($C_\tau \cdot D$) and the implicit cost (C_I). The net gain from taking the test will then depend on the trust in the institution and cost, where the net gain will increase with trust and will decrease with cost. In other words, an increase in trust in the institution increases the utility of the test undergone, but if the cost increases, then the benefit is dampened. It is crucial to understand the relationship between trust in the institution and the cost of the tests taken. The standard utilitarian approach helps us to derive a positive relationship between the cost of the test and trust in the healthcare center, which can be justified by patients' willingness to pay more for services since they perceive the quality

of the service to be high. This, in turn, entails inducing greater trust in the system. However, the behavior of patients in public and private spaces is different. In private hospital, consumers feel that they are paying a high explicit cost for improved quality of service. In public hospitals, the services are subsidized, so the increased cost primarily accounts for the increased waiting time, adding to the implicit cost (increase in the increase in unit explicit cost would more adversely affect the decision of choosing a diagnostic test vis-à-vis an increase in unit implicit cost). We can show with the help of a diagram (see Appendix) that when the cost of tests is substantially high, then consumers perceive that they are paying for higher quality in the private healthcare sector, thus inducing elevated trust. But a higher cost in government hospitals indicates that there is leakage in the system, which results in reduced trust. Interestingly, in the lower cost range, trust is greater in public health spaces due to the presence of subsidies. The quality of services is questioned in the lower cost regime in private healthcare centers, as often the provisions are in terms of alternate medicines.

During the early phases of the COVID-19 pandemic, private hospitals were not equipped with the testing kits and the treatment protocols were absent, leading to a complete market failure. The reliance on public hospitals was massive then. The restricted flow of information about the disease led to the emergence of paternalistic interventions by the public domain and also nurtured a bottom-up paternalistic demand for such interventions, which eventually did not lead to efficient correction of market failure (Boettke and Powell, 2021). The paternalistic demand emerged due to sparse information, which increased the trust in public healthcare. Therefore, we can conjecture that trust in public institutions are not exogenous, rather it is developed on the basis of the availability of information about the disease. When information about a disease is available, say for chronic diseases like diabetes, hypertension, anemia, etc., trust in private healthcare is greater than in public ones. But for less-known diseases like COVID-19, trust in government hospitals is greater. This suggests that with an increase in the availability of information about a disease, there would be an increase in the number of diagnoses in private hospitals as well. It is essential to acknowledge that structuring the institutional environment in the wake of a pandemic is critical, as human beings' decisions or choices are bounded by the realms of the institution.

4. Data

We use both primary and secondary sources of data for our analysis in this chapter. For the primary data, we conducted a survey in early 2021 to understand the confidence of Indian nationals in government institutions, particularly as a resort during an unexpected crisis. The year 2020–2021 was marked by the COVID-19 pandemic and associated with multiple phases of lockdown leading to an economic crisis. Also, during this time, there were quite a few major calamity-related crises (including cyclones,² floods,³ forest fires, and locust infestation), and the response of the government and people's expectations appeared unaligned (Dey and Chakravarty, 2021). This survey records the expectations and confidence in public institutions, particularly the healthcare system, in the time of COVID-19.

The survey was conducted online, using a snowball sampling technique. The survey received responses from 115 respondents belonging to urban, digitally literate, and educated group. The participants of the survey were given the option to opt out at any time point of the survey so that biased and erroneous responses can be minimized. The survey was carried out with a detailed questionnaire,⁴ designed and formulated based on our findings from previous field survey data collected through focus group discussions and semi-structured interviews with stakeholders. There were six major questions related to trust in institutions, in addition to sections dealing with the identification of the participants and their personal details to evaluate the socioeconomic status of the individual. The initial questions in the questionnaire were framed to understand the general perception about an institution during a crisis. The later section of the questionnaire contained more specific questions on the pandemic and healthcare, such as which type of institution works more effectively in a crisis, how they manage their finances, and what kind of facilities institutions must provide during a crisis.

²Cyclone Amphan and Yaas in West Bengal, Orissa; Nisarga and Tauktae in Maharashtra.

³Hyderabad floods, Kerala floods, Vidharva floods, Surashtra Floods, Maharashtra floods.

⁴Questionnaire can be shared upon request.

For the secondary data, we relied on multiple sources. First, we collected historical data on the measures of households' self-reported levels of confidence in public and private healthcare from the India Human Development Survey (IHDS)-II of 2011–2012. This was a joint survey carried out by the National Council of Applied Economic Research (NCAER), India, and the University of Maryland, USA. It is a nationally representative household survey, consisting of data from over 41,000 households in the rural and urban areas of India. For the data on COVID-19 indicators, we relied on the sources used by Bhattacharya and Chatterjee (2020) who use rapidly disseminated early data on COVID-19 during the first stage of lockdowns in India in 2020 from the five states of Jharkhand, Karnataka, Odisha, Rajasthan, and West Bengal. The original source of data comes from the website, covid19india.org, a crowdsourced initiative, which collated data from official bulletins and handles of government departments and made it available for public use. Like Bhattacharya and Chatterjee (2020), we match these two data sets for the secondary data analysis part of this chapter.

5. Analysis

We begin by focusing on one of the most important aspects of this research, namely, the interlinkage between confidence in private and public healthcare facilities and the demand for healthcare services from these facilities. In the context of the pandemic, this can have important ramifications, as *demand* could imply a desire to get tested or, during later stages of the pandemic, a desire to get vaccinated. These decisions are critical in improving the overall public health standards of the economy.

From the primary survey, it is evident that during a calamity-related crisis, 46% of the respondents expect the government to provide relief and around 40% believe that civil societies, such as independent community clubs or nongovernmental organizations, would take lesser time to reach out with relief. These numbers are shown in Figure 3. The chart implicitly reveals that the institutional services rendered by both the systems (public or private) are unequivocally important. We also asked respondents about their perception regarding the mode of finance of the relief program. The results reveal that 84% of people would want the relief fund to be factored into the government budget so that, primarily, it can be financed from the taxpayers' money, as presented in Figure 4.

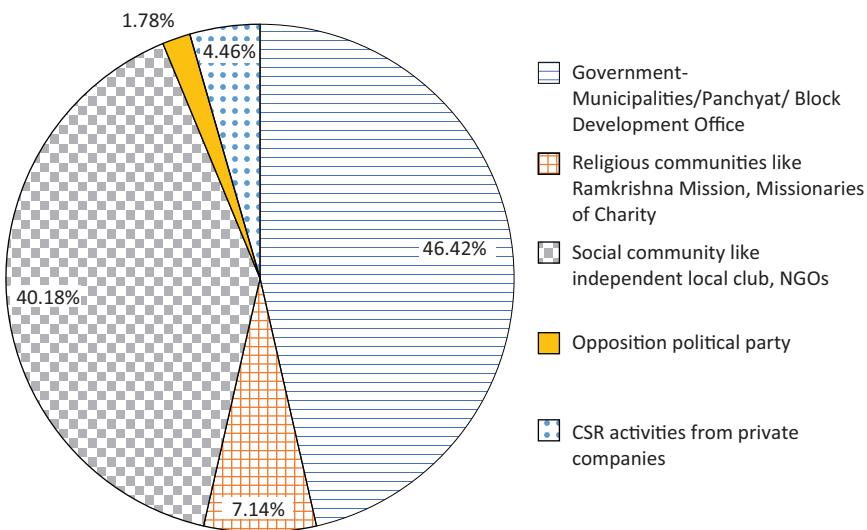
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Figure 3. Distribution of relief expectations of different institutions during a crisis.

Nearly 54–55% of the respondents also believe that financing the relief work should include voluntary contributions by citizens, constituency development funds (such as the ones earmarked for the Members of Legislative Assemblies, or MLAs), and voluntary contributions by big corporate houses, as evident from Figure 4.

This analysis broadly suggests that people do have higher expectations of the government and public facilities in terms of taking the requisite actions during crises, such as COVID-19. While we do seem to find that private providers are also considered important, much of people's relief expectations are placed on the government, and it would be interesting to understand what consequences this might have in terms of the actual behavior of individuals when seeking healthcare services, or in other words, how this may affect the demand for public healthcare as opposed to private healthcare.

5.1 *Ex ante* confidence in healthcare and actual number of reported cases

Further to the above discussion, we attempt to correlate the measures of pre-pandemic confidence in public and private healthcare facilities with

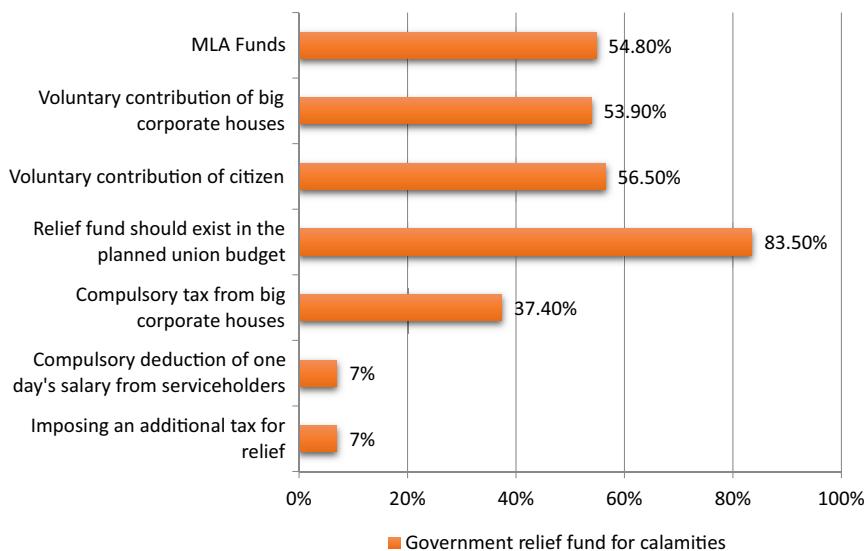
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Figure 4. Expected mode of relief funding by the government.

the number of reported cases of COVID-19 in the early stages of the pandemic. This exercise has two potential advantages. First, it allows us to look at the confidence levels of citizens in private and public healthcare that is not a function of their performance or perceived performance during COVID-19. Second, we focus on the early stages of the pandemic and restrict the analysis to data up to May 2020, when India was still experiencing the first wave and was under the first extended lockdown. This allows us to look at the associations without the potential confounding of dynamic changes in the confidence levels during the pandemic, which may affect reporting.

We use the rapidly disseminated COVID-19 data from the crowd-sourced platform and match it with that from the IHDS-II. From the IHDS-II data, we create indices of confidence in private and public healthcare. We create two dummy variables based on the responses of individuals and households. The first one measures confidence in private healthcare, and the second is about public healthcare facilities. These variables take the value 1 if individuals report a great deal of confidence in the healthcare provider and 0 if they report only some or no confidence at all.

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Table 1. Number of diagnosed COVID-19 cases at district level by pre-pandemic levels of confidence in private and public healthcare facilities.

	Low Confidence (1)	High Confidence (2)	Δ (2) – (1)	$H_0: \Delta = 0$ <i>p</i> values
Private healthcare	148.11	150.88	2.77	0.68
Public healthcare	121.35	168.77	47.42	<0.01

Note: Each cell in column (1) represents the average number of cases of COVID-19 diagnosed and reported in the district of the respondent per million population as of May 2020 for low levels of confidence in private and public healthcare and in column (2) the same numbers for those who report high confidence.

In Table 1, we report an interesting facet coming out of this data analysis. We compare the average number of COVID-19 cases diagnosed in the districts of the respondents who report low confidence in private healthcare to the ones who report higher confidence, as per IHDS historical data from 2011–2012. The data on diagnosed cases is the cumulative numbers in India as of May 2020. We break this analysis down by reported levels of confidence in private and public healthcare separately. We find that for private healthcare facilities, there is very little difference in the numbers of diagnosed cases per million population in the district of the respondents, and the difference is statistically indistinguishable from zero. However, for public healthcare, there does exist a stark contrast. It is clear that in regions which report historically higher confidence in public healthcare, the total number of diagnosed cases is very high at 168 per million population, whereas for low-confidence regions, this turns out to be only 121 cases per million population. This difference of 47 cases per million population is statistically significant at the 99% level of confidence, and we are able to reject the null hypothesis in column 4, i.e., the difference between the two is zero.

Table 1 provides another very interesting insight. In general, if we look at the columns independently, it is clear that diagnosed cases are relatively higher for low-confidence in private healthcare regions compared to those for low confidence in public healthcare regions. This implies that when confidence in public healthcare is low *ex ante*, there could be a

potential bias where diagnosed cases would only spike if there is access to private facilities. This in spirit is the story of Bhattacharya and Chatterjee's (2020) study. Relating to Figure 13, we can say that, potentially, the situation is similar to that on the right of point E, where for the same level of trust (above point E), the cost of private healthcare is lower than that of public healthcare. The explicit cost cannot be high for services provided by public healthcare, but the implicit cost can certainly be high enough for individuals to indulge in services from private hospitals. If we compare the numbers in column (2), we find that for high confidence in public healthcare, the diagnosed cases are even higher than those in districts where confidence in private healthcare is high. This suggests an inherent preference toward public healthcare in general but only if the quality of care is perceptibly higher, indicating the situation on the left of point E in Figure 13. This provided us with the motivation for understanding the *ex post* levels of confidence in public healthcare. Specifically, we are interested in exploring and speculating whether the higher number of cases reported in India in the later stages of the pandemic, particularly during the second wave, can also be partly explained by changes in perceptions of government health facilities.

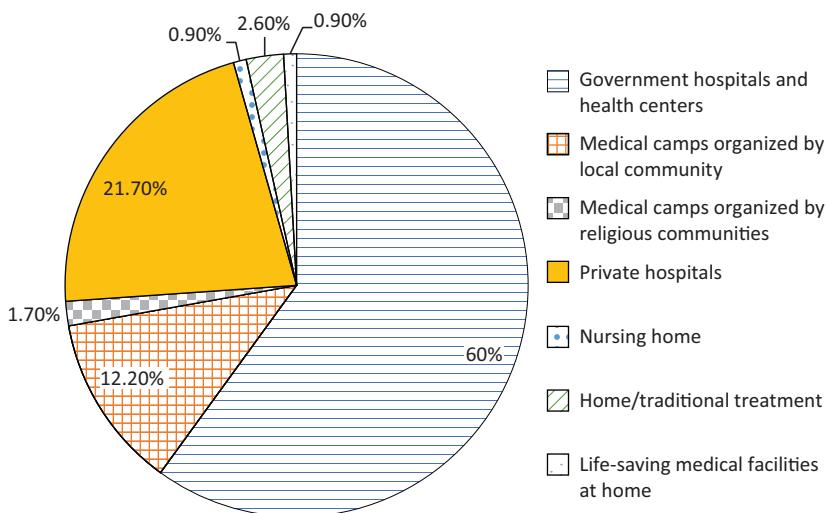


Figure 5. Trust in institutions for provision of reliable medical facilities during the COVID-19 pandemic.

5.2 *Ex post* confidence in healthcare facilities

To explore this idea further, in the next section, we rely on our findings from the primary survey again, which was conducted in early 2021. It appears that the trust in government medical facilities is recorded to be high at 60% during the COVID-19 pandemic, followed by 22% trust in private medical care, as depicted in Figure 5.

This is in line with our hypothesis that perceptions of government healthcare may have changed with the progress in the pandemic, and as such, the number of cases reported would have gone up. Our theoretical framework proposed that the lack of dissemination of knowledge about a less-known disease like COVID-19 could possibly explain the change in confidence levels. From Table 1, we expect that with higher confidence in public health facilities, the number of diagnosed cases would be high. With the higher average levels of confidence in public healthcare in early 2021, the rising number of cases of COVID-19 diagnosed and reported is consistent with the central idea of this chapter. This is notwithstanding the fact that there was obviously an increase in the actual rate of infection, but just to point out that part of the reason for a massive difference in numbers from the early period to the later period could be correlated with the dynamic levels of confidence in the government's ability and the infrastructure for provision of COVID-19 care.

5.3 Healthcare infrastructure during the pandemic and its association with confidence levels

In this section, we try to provide an overview of the early healthcare infrastructure dedicated for COVID-19 treatment in India and how it compares with *ex ante* confidence levels in private and public healthcare facilities. Further to this, we look at *ex post* confidence levels in healthcare and policy expectations of citizens from the government toward providing quality COVID-19 care.

In Figure 6, we present a snapshot of the infrastructure earmarked for COVID-19 care in Indian districts and breakdown the analysis by historical levels of confidence in healthcare facilities in those districts. The objective of this exercise is to understand the distribution of

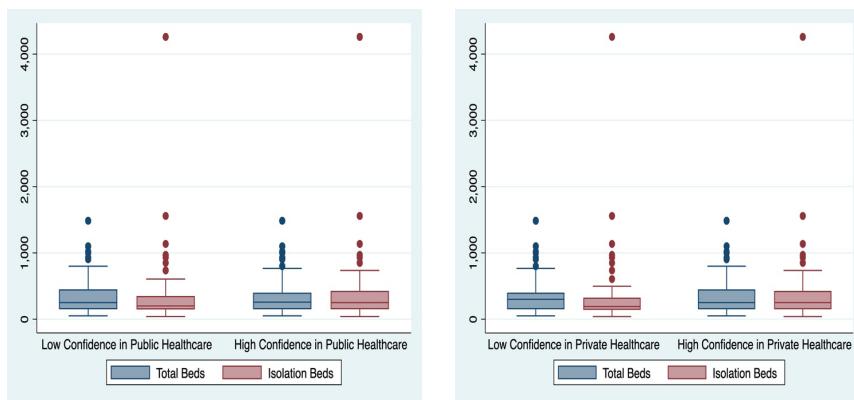


Figure 6. COVID-19 care infrastructure in May 2020 by confidence in healthcare during 2011–2012.

Source: IHDS-II and covid19india.org databases.

healthcare infrastructure dedicated to COVID-19 treatment and whether these vary by *ex ante* levels of confidence. Reassuringly, there does not seem to be a lot of variation in the infrastructure depending on the levels of confidence, suggesting that the *supply* of healthcare was not necessarily driven by consumer preferences during the early stages of the COVID-19 pandemic. This reinforces the hypothesis that any variation arising in the reporting of COVID-19 infections and number of diagnosed cases that can be correlated with consumer confidence levels in healthcare infrastructure should purely be attributed to *demand*-side factors, such as individual perceptions, tastes, and preferences or, potentially, as our model points out, asymmetric or incomplete information.

However, Figure 6 does point out something interesting about the pattern on the supply side. For low confidence in both private as well as public healthcare, the average numbers of isolation beds are strictly lower than the total number of beds, suggesting that only a part of the overall infrastructure was dedicated to very specialized COVID-19 care in these regions. However, in the high confidence regions, the distributions almost overlap, suggesting that very specialized COVID-19 care, as indicated by the requirement for isolation beds, almost entirely coincides with the total COVID-19 care infrastructure. This is consistent with the idea that lower

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levels of confidence in healthcare facilities would disincentivize reporting of mild infections where households may prefer to home isolate instead of seeking specialized care at a facility in which they do not have much confidence.

However, it is not clear whether the infrastructure was adequate or at least perceived as adequate. Our primary survey helps us address this issue. It turns out that there is an overwhelming consensus on the lack of adequacy of government facilities, and this is acknowledged by the respondents. Consequently, they seem to recommend interventions, such as setting a ceiling on prices charged for treatment and diagnosis in private medical facilities (77%) and/or partially subsidizing private hospitals for treatment and diagnosis (58%), as shown in Figure 7.

Only a small minority of our respondents felt that the treatment should be entirely free everywhere, as evident from Figure 6, although much of it has to do with the demography of our respondents chosen in the sample. About half of our respondents felt that the treatment in public facilities should be free of cost. However, a large majority felt that there should be some sort of regulation on prices charged for COVID-19 care by private facilities.

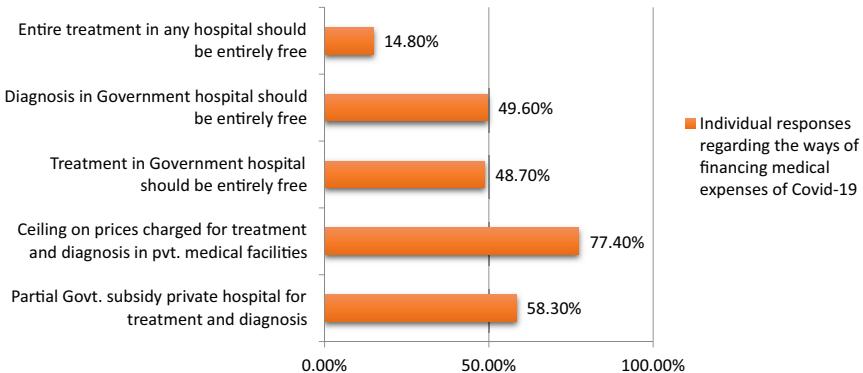


Figure 7. Individual responses regarding the ways of financing medical expenses due to COVID-19.

5.4 What determines confidence?

Our theoretical framework alluded to the fact that asymmetry of information could be an important factor determining confidence in healthcare systems. In this section, we explore other potential determinants using data from our primary survey as well as the IHDS-II. Our primary survey suggests that confidence in public institutions may be captured through issues such as perceptions about the optimal utilization of funds. We find that majority of the respondents feel that only less than 40% of the funds raised for government relief programs reach the beneficiaries despite India having substantial voluntary contributions toward government relief funds in response to appeals from the heads of states. During the initial months of the pandemic, this was particularly relevant as the prime minister personally made repeated appeals for donations, and a large corpus was created out of it by the name of “PM CARES.” Our survey casts aspersions on the general perception regarding the utilization of such funds. It is important to clarify here that the data are not sufficient to claim any evidence on the actual utilization, but the survey simply reflects an average perception. In contrast, respondents believed that 60% of the funds raised by social communities are effectively used. These results are seen from the graph presented in Figure 8.

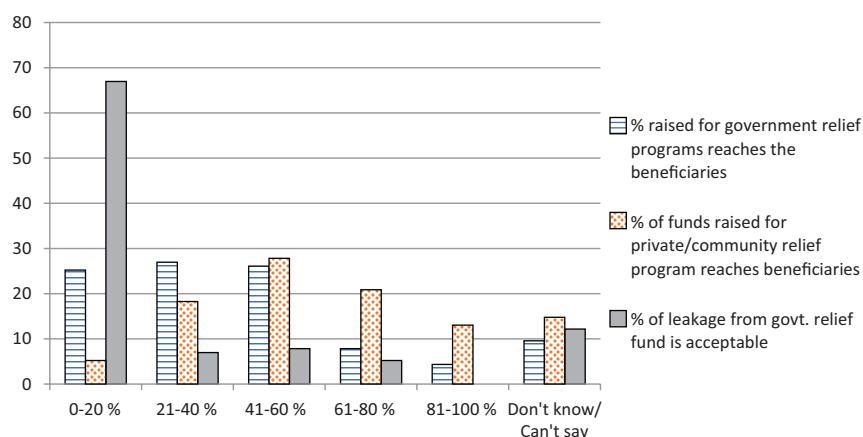


Figure 8. Acceptable percentage of inefficiency of the institutions.

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Some of these results also reinforce the idea that a lack of information on actual usage can lead to mis-perceptions or biased beliefs about the government's functioning, if the perceptions indeed are flawed, and therefore, it may be in the best interest of policymakers who care about trust and confidence among citizens to make information available to a great extent to avoid such issues.

We use secondary data from IHDS-II to examine some additional associations that may provide an insight into potential determinants of confidence in healthcare systems. First, we check if there are statistically significant associations between confidence in healthcare systems and receipts of government benefits. The underlying hypothesis is that people who have benefited from government transfers may be more likely to have a positive opinion about government facilities, including health facilities. The results reported in Table 2 are consistent with this idea.

We see that the mean levels of confidence in public healthcare seem to be higher for households that have received some sort of government benefit compared to the ones that have received no such benefit. The difference between the mean levels of confidence for the two groups is statistically significant at the 99% level of confidence. However, there seems to be no such difference in the confidence levels for private healthcare, which is unsurprising because the transfers from government should not actually affect the rating of private healthcare services. It is also interesting to note that, on average, the confidence for both these groups are higher in private healthcare and lower for public healthcare. Although, for the group that does not receive any benefit, the confidence in public

Table 2. Confidence in healthcare systems conditional of receiving government benefits.

	Received Transfers (1)	Never Received Transfer (2)	Δ (2) – (1)	H0: $\Delta = 0$ <i>p</i> values
Private healthcare	0.732	0.734	0.002	0.82
Public healthcare	0.637	0.589	-0.048	<0.01

Note: Each cell represents the mean level of confidence in the relevant healthcare system for the groups identified by the columns.

Source: IHDS-II.

healthcare is much lower. This analysis provides further insight that some of the factors determining confidence in public healthcare can actually be correlated with the reach of other government programs.

It would be interesting to investigate if expenses incurred on healthcare are correlated with confidence levels. This might help us understand some of the other potential determinants of confidence in healthcare systems. In Figure 9, we provide some descriptive evidence that this might actually be true. It turns out that the individuals who report high confidence in public healthcare are usually from households that have had to incur lower expenditure on healthcare, particularly in terms of in-patient medical bills. The ones who have had to incur larger in-patient expenses usually appear to have reported lower confidence in public healthcare. Interestingly, this difference does not seem to appear for out-patient expenditure nor for confidence in private healthcare. In line with

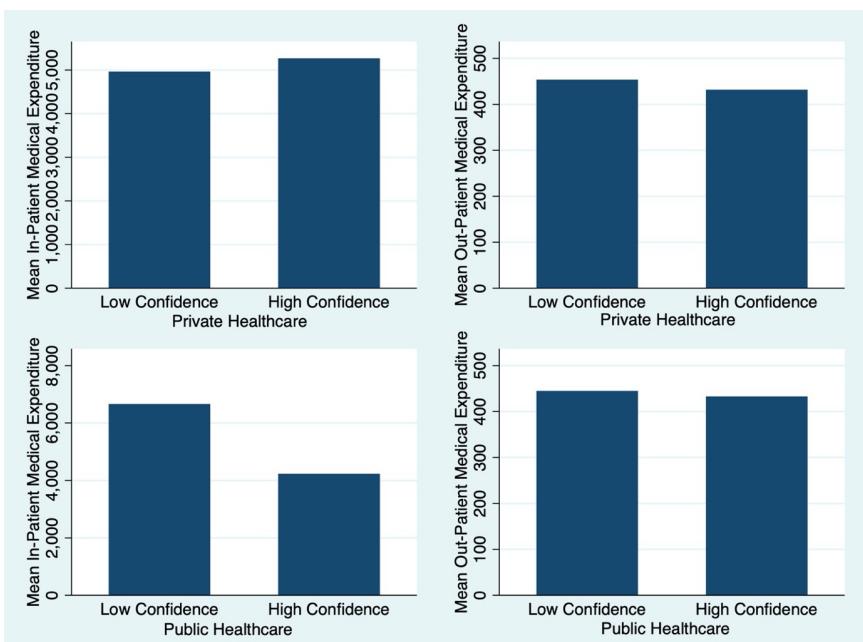


Figure 9. Does confidence vary with medical expenditure incurred?

Source: IHDS-II.

Chatterjee (2021), this suggests that idiosyncratic biases may play a role in explaining the heterogeneity in the confidence measures, particularly when confidence is self-reported.

5.5 From curative to preventive care: Does confidence influence vaccination?

For the major part of this chapter, the focus has been on the role of confidence in healthcare service providers and healthcare infrastructure in explaining the take-up of curative healthcare, which can be used as a proxy measure of reporting the incidence of COVID-19. However, with the passage of time and as the pandemic matures through ebbs and flows, another pertinent question to ask is whether a similar argument can be put forward for preventive healthcare practices, such as vaccine adoption.

Most of the developed economies, as well as some emerging economies, have been performing extraordinarily in vaccinating their population. Trust in the vaccines is crucial, and the role of government in convincing the effectiveness of vaccines has been discussed widely⁵ (e.g., Centers for Disease Control and Prevention (CDC) Report, 2021; OECD report, 2021; Madad *et al.*, 2022). While some countries, such as India, instilled trust by enforcing mobility restrictions without vaccines, some developed countries, such as Canada, failed miserably in communication, leading to declaration of an emergency situation.⁶ Therefore, confidence does seem to play an important role in the preventive aspects of COVID-19 infections. Essentially, this further strengthens our analytical approach to the problem from the demand side of the market for healthcare during the COVID-19 pandemic. We are able to show that the demand-side factors not only affect curative healthcare, such as seeking care at designated COVID-19 hospitals and reporting of infections, but can also potentially explain the

⁵<https://www.oecd.org/coronavirus/policy-responses/enhancing-public-trust-in-covid-19-vaccination-the-role-of-governments-eae0ec5a/>. <https://www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence.html> <https://www.liebertpub.com/doi/10.1089/hs.2021.0180>.

⁶<https://www.theguardian.com/world/2022/jan/30/thousands-join-protest-in-canada-against-covid-vaccine-mandates>.

heterogeneity in vaccine take-up as well as provide a novel explanation for understanding vaccine hesitancy.

Figure 10 provides the relation of government effectiveness with the vaccination rates in less-developed and developing economies. If we can proxy the confidence in public institutions for government effectiveness, it shows a positive correlation coefficient of 0.7 with the vaccination rate across economies.

Even the free availability of vaccines is not often reflected in the uptake outcomes, which may result from lack of awareness or lower levels of confidence. In India, we find that confidence in private and public health institutions has an effect on the rate of vaccination and the wastage of vaccines across different states.

Interestingly, we find that there is a very low correlation between the number of vaccinations and the confidence in healthcare centers; however, the correlation is lower for public institution as compared with private hospitals. This indicates that higher confidence in private hospitals may induce more vaccination vis-a-vis public hospitals across the different states of India. Figures 11 and 12 shows the state-wise COVID-19 vaccination and vaccine wastage distribution for Indian states, depicting a weak relation (correlation coefficient of 0.019) between the two. We try to understand the how confidence in healthcare institutions can drive the wastage of vaccines. Striking are the numbers in the bottom row of Table 3, showing a negative correlation between the percentage of wastage of

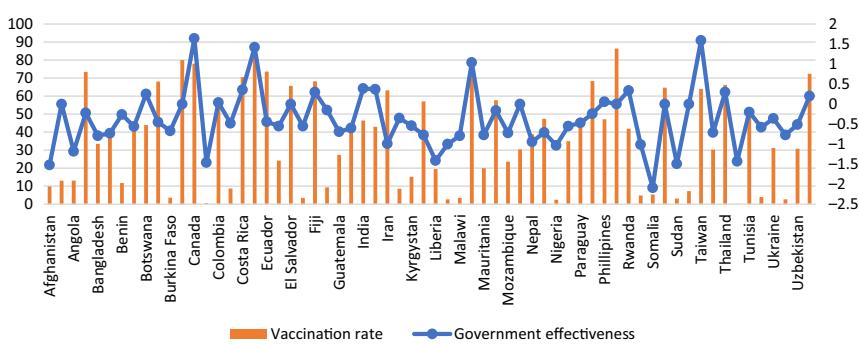


Figure 10. Does vaccination rate vary with government effectiveness?

Source: World Bank and WHO databases.

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vaccines and confidence in government hospitals, indicating overuse of vaccines in government hospitals and increased wastage with confidence in private one.

Can we then interpret that an individual perceives wastage as affluence and hence confuses it with the idea that quality is not compromised in private hospitals? To answer, we need more information that can provide insights behind the numbers.

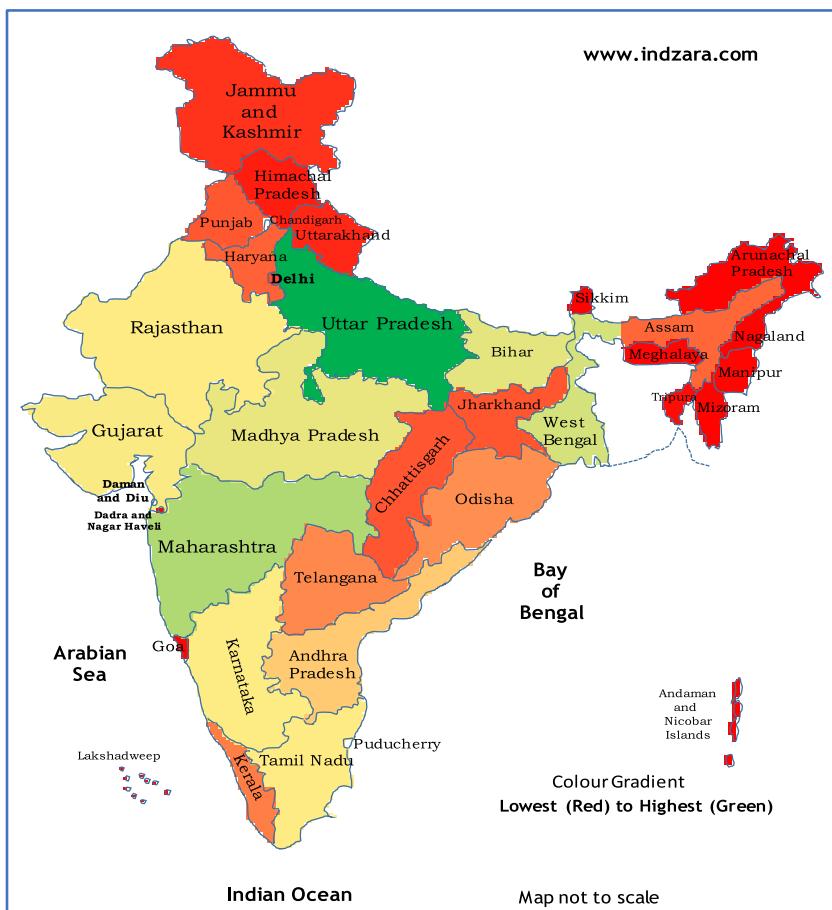


Figure 11. (Color online) State-wise COVID-19 vaccination status in India.

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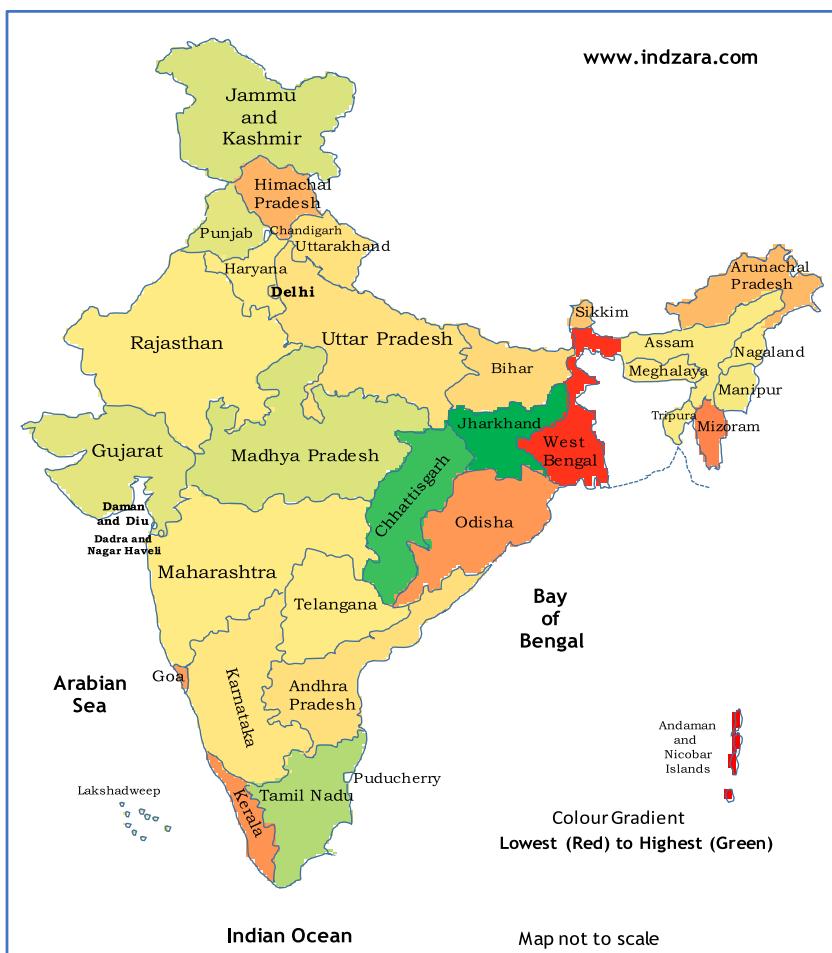


Figure 12. (Color online) State-wise COVID-19 vaccine wastage status in India.

Table 3. Correlation coefficient between confidence in public and private health institutions and vaccination and wastage of vaccines in India.

	Confidence in Government Hospitals	Confidence in Private Hospitals
Total number of vaccinations	0.168073	0.239193
Percentage of wastage of vaccines	-0.11331	0.194145

6. Conclusions

In this chapter, we explored the role and impact of citizens' confidence in healthcare on important public health issues, particularly during the COVID-19 pandemic. The major motivation for this study was the fact that the reported number of COVID-19 infections in India had enormous heterogeneity in the early stages of the pandemic. We investigated potential factors that can explain this and focused on the role of idiosyncratic confidence levels of individuals in the healthcare sector. There is evidence in the recent literature on public health during the pandemic that suggests that low trust and confidence in healthcare service delivery can actually mask the take-up of tests, investigations, and potentially vaccines.

We provided some descriptive evidence of interesting correlations between historically recorded measures of pre-pandemic confidence in private and public healthcare in India and the reported levels of COVID-19 infections during the early stages of the pandemic. We found that there appears to be significant differences in the number of diagnosed cases based on these historical confidence measures. We also provide preliminary evidence that, with the maturing of the pandemic, confidence ratings of government health facilities potentially changed. This could have been a natural consequence of the disaster response of the government or due to potential asymmetric information about a new disease, where citizens may prefer to rely on administrative guidelines for health as opposed to alternative private providers. We showed that there does not, however, seem to be any supply-side response to these historical confidence measures, i.e., the government does not allocate health infrastructure differentially based on consumer confidence. Therefore, the biases in the measures and under-reporting of infection, if any, should largely be attributed to demand-side factors. We further analyzed the potential impacts of such heterogeneity in confidence measures for health institutions on the demand for preventive healthcare measured by the take-up of vaccines. In general, this creates a potential policy issue where active steps would need to be taken to stimulate demand for healthcare to manage the public health problem at hand generated by the pandemic.

We attempt to summarize the potential determinants of confidence using both primary and secondary data, given that these measures turn out

to be very important for public health policy-making. We find that a lot of the confidence measures may rely on individual experiences with government facilities, either in the past or concurrently. This relation between reporting confidence and previous experience is not necessarily limited only to medical services but may be extended to any government benefits that citizens expect to receive. We also find a strong descriptive preference among our primary survey respondents regarding expectations from the government to regulate the expenses incurred for availing medical services. This is corroborated by the evidence from pre-pandemic secondary data, where confidence in public healthcare seems to vary based on the in-patient medical expenses incurred by households.

In sum, the chapter brings out two very important aspects of public health during pandemics. First, the measures of confidence in healthcare facilities are likely to be biased by individual heterogeneity arising out of a wide range of circumstances that the respondent is experiencing. As such, these self-reported measures should be interpreted with caution. Second, despite the problems with the self-reported measures, it is evident that a lot of the demand for healthcare is correlated with these confidence levels. This creates a problem for the policymaker interested in stimulating demand for important health products, such as COVID-19 vaccines, as the take-up of such programs could be low if the citizens do not have enough confidence in the healthcare system. Therefore, it is crucial for health policymakers to invest in instilling confidence in the consumers of healthcare. One way is to improve transparency through proper dissemination of information, as identified by the theoretical model. The overall policy recommendation of the chapter is to influence the demand side of healthcare by paying heed to the factors that shape the confidence of the citizens on the public healthcare system and to avoid biased evaluation or misperceptions by providing accurate and timely information.

Our basic findings are comparable with other work on the subject, such as recent publications in *Nature Medicine*, which show that vaccine hesitancy in low- and middle-income countries (LMICs) can be analyzed through demand-side factors, and the take-up rate can be affected by health workers, and the trust that consumers seem to have in them is critical in determining this.⁷ Research acknowledges that the major concern

⁷<https://www.nature.com/articles/s41591-021-01459-7>.

about preventive healthcare in LMICs is still the supply-side factors, but the demand-side factors, such as the ones we presented in this chapter, can actually help understand the equilibrium based on which welfare planning and policy-making is done.

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Appendix

Connecting our analysis with a basic microeconomic analytical framework, we can write utility from a diagnostic test as

$$u(D) = U(\tau, C(D)), \quad (1)$$

where $\frac{\partial u}{\partial \tau} \geq 0, \frac{\partial u}{\partial C} \leq 0$, and we assume that the utility increases at a decreasing rate for an increase in trust $\left(\frac{\partial^2 u}{\partial \tau^2} < 0\right)$ due to the law of diminishing marginal utility and $\frac{\partial^2 u}{\partial C^2} > 0$, for which the utility decreases sharply due to an increase in cost. Then, we can derive the relation between τ and C , for which the utility from the diagnostic test is constant by taking the total derivative of Equation (1) to get

$$d\bar{u} = \frac{\partial u}{\partial \tau} \cdot d\tau + \frac{\partial u}{\partial C} \cdot dC,$$

$$\text{or } \frac{d\tau}{dC} = -\frac{\frac{\partial u}{\partial C}}{\frac{\partial u}{\partial \tau}} > 0. \quad (2)$$

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Equation (2) shows a positive relation between the cost for the test and trust in the healthcare center. This justifies the observation that patients pay higher for services according to the perceived notion of the quality of the service, which in turn entails trust in the system, is high. The second-order derivative in Equation (2) shows that the increase in the cost of the test would increase trust in the institution at an increasing rate,

$$\text{as } \frac{\partial^2 \tau}{\partial C^2} = -\frac{\partial^2 u}{\partial \tau^2} > 0.$$

Since the behavior of patients in public and private spaces is different, we can write that the effect on trust due to change in cost is lower in government health institutions as compared to private ones such that

$$\left. \frac{d\tau}{dC} \right|_{govt} < \left. \frac{d\tau}{dC} \right|_{private}.$$

We plot this relation in Figure 13. In Figure 13, the steeper curve is the trust–cost relationship for private healthcare centers (P) and the flatter one is for government hospitals (G). At E, the utility of diagnostic tests from both types of health centers is the

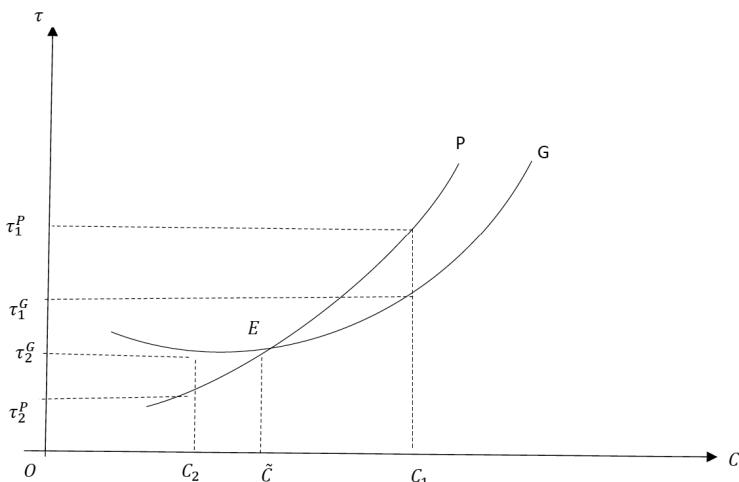


Figure 13. Indifference curve of diagnosis in government and private hospitals.

same. So, \tilde{C} is the critical point beyond which, if the cost increases to C_1 , the trust level is elevated to τ_1^P , as the consumers perceive that they are paying for higher quality in a private hospital. But a higher cost in a government hospital induces a lower degree of trust such that $\tau_1^G < \tau_1^P$. Intuition suggests that this may be because of the presence of corruption, which is partly responsible for the increased cost. However, for $C < \tilde{C}$, $\tau_2^G > \tau_2^P$, accounting for the low quality of service in private hospitals that include private medical clinics for alternative medicines, such as Ayurveda or voodoo.

In normal times, we observe that $\tau^G < \tau^P$. But when information about a disease is unavailable, the trust equation between government and private health institutions changes. Therefore, we can write that trust in public institutions is not exogenous, rather it is developed on the basis of the availability of information about the disease (I), i.e., $\tau^G(I)$ and $\frac{d\tau^G}{dI} < 0$, indicating that the greater the availability of information, the lesser the trust in government healthcare services. Connecting this idea to the situation of underreporting, we find that the utility of undergoing a COVID-19 test in a government hospital is $u(D_G) = u(\tau^G(I), C)$ and $\frac{du}{dI} = \frac{\partial u}{\partial \tau^G} \cdot \frac{\partial \tau^G}{\partial I} < 0$, indicating that increased information will induce more reporting via private health institutions.

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Chapter 1.5

The Future of Public Health Investments: Lessons from the COVID-19 Pandemic

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Abstract

Public health practice is only possible when different stakeholders, from policymakers to civil society representatives, come together to tackle health problems to improve people's health, protect people from falling sick, and confront the catastrophic health expenses that the illness entails. The chapter looks at whether such collaborations were successful during the COVID-19 pandemic and what more is needed to increase the resilience of the health systems and populations to face any future health risks.

An assessment of recent public health indicators shows that though a lot of gains have been made in India, many indicators still do not compare favorably with other low- and middle-income countries. There is also a lot of disparity between different states. The Indian Public Health

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Standards set the template for investment in infrastructure and skills, but there are gaps that need to be addressed to improve functioning.

In the initial stages of the pandemic, there was a lack of coordination and collaboration between the different arms of the government responsible for a concerted, evidence-based response. There was a lack of trust in the decision-making capabilities of the primary-level health workforce, and the local communities and civil societies were not supported adequately. There was no shared responsibility in tackling the pandemic. This improved toward the end of 2020, but the deluge of cases during the Delta wave in 2021 once again incapacitated the health systems, leading to extremely high morbidity and mortality. The COVID-19 pandemic has reemphasized the need for establishing a public health cadre that could be tasked with the responsibility of managing health emergencies and routine planning equally effectively. Investment in infrastructure for rapid response surveillance systems, skilling of existing human resources, and giving authority to plan and act at district and sub-district levels is essential, and the return of investment on such interventions will be evident through improved life expectancy and health-related quality of life in the near future.

Keywords: public health; pandemics; India

1. Public Health in the Modern World

1.1 Responsibility for public health

Distilling the various definitions, the common thread for conceptualizing public health is that it represents collective action for sustained population-wide health improvement. Collective action needs authority and accountability to large population groups. A government usually has the administrative authority and the legal support to make things happen by coordinating and directing the efforts of all those involved in improving health. Therefore, for public health efforts to succeed, the government is the fulcrum around which all other partners coalesce.

1.2 Mission of public health

The mission of public health is to reduce ill health and disability and preserve health to maintain and improve the quality of life of people.

The World Health Organization (WHO) emphasizes that public health should work toward providing maximum benefit for the largest number of people.

The mission of public health can be achieved only if dedicated investments are made. The investments include establishing and skilling a public health workforce, providing financial resources and infrastructure to support the workforce, and setting up surveillance systems for early identification and rectification of potential outbreaks and a policy framework for action.

The health status of populations across the globe have shown impressive gains over the past century, especially over the past three decades. People are living longer and are in a better frame of health than populations in the past. A considerable proportion of this gain can be attributed to the ascendancy of public health philosophy and measures with increasing attention being paid to the needs of populations rather than only individuals seeking clinical care. At the same time, existing gaps need to be identified and addressed to make healthcare accessible to the most vulnerable populations so that nobody is missed out.

Public health, therefore, strives for accessibility, availability, affordability, and appropriateness of services for all while ensuring accountability of the health system to achieve quality of care.

1.3 Public health interventions

Public health looks at identifying community-based or community-directed interventions that can improve health outcomes at a population level. A community intervention is a cost-effective strategy that attempts to prevent diseases and promote health by instituting technologically sound and scientifically proven strategies at the community level to the largest number of those in need. In this dispensation, the community is the “patient,” as each individual can be adequately cared for within the confines of the community. Such an intervention need not be the “costliest” one but needs to be the “optimal” one. This means that it should be a strategy that is acceptable to the community and makes a difference in preventing spread of a disease condition among a significant proportion of those affected at an affordable cost. The safety of an intervention is even

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more critical in public health practice compared to clinical practice, as a large number of people will be administered the intervention.

1.4 Public health indicators

Public health has made many gains in the past century, but despite these gains, there are still wide disparities in health status indicators within and across countries (Table 1).

When we compare health indicators across some countries in Asia and other parts of the world, we find that the life expectancy in India is lower than that of her neighbors, such as Bangladesh and Sri Lanka, and when we compare the same with that of Japan, there is a 15-year difference. India's other mortality indicators and disease prevalence are also worse compared to those of her neighbors, including Sri Lanka and Bangladesh (Table 1). The current expenditure on health as a proportion of gross domestic product (GDP) is also one of the lowest in India.

Sustainable improvement in health indicators is only possible when 70–80% of care (and appropriate funding) is provided for primary health-care and only around 10–15% is provided at the tertiary levels of care. Unfortunately, the emphasis in India has been on ramping up tertiary and secondary care facilities, with more allocation for these levels compared to primary care levels. In Sri Lanka, only 13.2% of the curative care expenditure by publicly funded hospitals is on tertiary care, while 37.9% is on primary care and the remaining on secondary care (Alliance for Health Policy and Systems Research & WHO. Primary Health Care Systems (PRIMASYS): Case study from Sri Lanka, 2017).

In India, the current health expenditure (CHE) data for 2017–2018 showed that 8.2% of CHE was spent on primary health centers, dispensaries, and family planning centers as against 17% for government hospitals and 29.2% for private hospitals. Hospitalization curative care expenses account for 34.4% of CHE, while 19.3% is spent on outpatient curative care (National Health Systems Resource Centre, Ministry of Health & family Welfare, Government of India: National Health Accounts – Estimates for India 2017–2018, 2021). Though officially 47% attribution is shown on primary care, 34% on secondary care, and only 6.4% on tertiary care, when this is analyzed more carefully, the primary care expense

Table 1. Comparison of health indicators (2020).

Indicators	India	Sri Lanka	Brazil	China	Bangladesh	Egypt	Thailand	Canada	Japan
Health Status									
Life Expectancy at birth (yrs)	69.4	76.98	75.88	76.91	72.59	71.99	77.15	82.1	84.4
Infant Mortality Rate per 1,000 live births	29.7	6.1	13.9	6.8	25.6	17.3	7.7	4.2	1.8
Crude death rate per 1,000 population	7.3	6.75	6.5	7.1	5.5	5.78	7.79	7.6	11.1
Mortality from CVD, diabetes, or CRD at 30–70 years (%)	21.9	13.2	15.5	15.9	18.9	28.0	13.7	9.6	8.3
Diabetes prevalence (% among 20–79 years)	10.4	10.7	10.4	9.2	9.2	17.2	7.0	7.6	5.6
TB incidence per 100,000	199	64	46	58	221	12	150	5.5	1.3
Malaria incidence per 1,000 population	5.33	0.0	5.1	0.0	0.7	0.0	0.4	0.0	NA
Prevalence of anemia in non-pregnant women 15–49 y (%)	53.0	34.6	16.0	15.4	36.5	28.3	23.8	10.2	18.9
Risk Factors for Health									
Prevalence of current tobacco use (% adults)	42	22.9	16.5	24.7	39.1	21.4	22.8	17.5	21.9
Financial Protection									
Government health expenditure (% of GDP)	0.95	1.54	3.96	3.02	0.4	1.4	15.03	7.93	9.2
Current health expenditure (% GDP)	3.54	3.76	9.51	5.35	2.34	4.94	2.89	10.79	10.95
Out-of-pocket expenditure as % of current health expenditure	62.7	50.65	27.54	35.75	73.87	62.3	11.01	14.7	12.7
Health System									
Physicians per 1,000 population	0.86	1.0	2.16	NA	0.58	0.45	0.8	NA	NA
Nurses/ midwives per 1,000 population	1.73	2.18	10.12	NA	0.41	1.93	2.76	9.94	NA

Source: World Bank (2022).

Table 2. Comparison of some health indicators across selected states.

State	IMR/1,000 Live Births (SRS Bulletin, Government of India, 2021)	Households Covered Under Health Insurance/Health Financing Scheme (National Family Health Survey Health Survey (NFHS- 5), 2019–2020)	Under 5 Mortality Rate (National Family Health Survey (NFHS-5), 2019–2020)	Non-pregnant Women with Anemia % (National Family Health Survey (NFHS- 5), 2019–2020)
Andhra Pradesh	25	70.2	35.2	59.0
Assam	40	60.0	39.1	66.4
Bihar	29	14.6	56.4	63.6
Gujarat	25	39.0	37.6	65.1
Kerala	6	51.5	5.2	36.5
Maharashtra	17	20.0	28.0	54.5
Goa	8	66.0	10.6	38.9
Mizoram	3	46.4	24.0	34.8
Nagaland	3	20.5	33.0	29.3

shown also includes a substantial cost on curative care, including medicines.

A recent report showed that the governments spend more on tertiary care compared to primary care. In Mumbai, the corporation spent 74% of the budget on hospitals (Health Budget: Delhi, Mumbai spent more on tertiary than primary healthcare, 2022). Even the proposed National Health Protection Mission looks at providing increased coverage for hospitalization at the secondary and tertiary levels of care.

A comparison of health indicators across different states in India also shows wide variation (Table 2).

2. Public Health Systems

With increasing emphasis on the social determinants of health, the current thinking differentiates between the “biomedical” delivery of health services (the public health systems, or the micro environment) and the macro environment, which promotes health and prevents diseases looking at all

factors that impact on health status and health behaviors. Distilling various definitions, public health was described as a multidisciplinary area of practices, concepts, and values viewed from a population perspective (Jarvis *et al.*, 2020). Initially, public health systems were conceptualized as only pertaining to the national, state/provincial, and local health agencies tasked with providing public health services to a population (Wall, 1998). Public health systems are aptly defined as “the collective capacity of governmental, private and other public sector entities that support the mission and core functions of public health. It is the cumulative arrangement of resources, infrastructure and policies impacting health that exist to support public health within communities” (Jarvis *et al.*, 2020). Still, many believe that the primary responsibility for public health service delivery was with the government and that it was their role to seek to partner with nongovernmental agencies to deliver services (Wall, 1998; Mays *et al.*, 2004).

A public health system can be envisaged to have three major task components:

1. Delivery of public health services across all levels of the health system, from primary to tertiary care.
2. An institutional structure for education, training, and research. This is essential to provide the required public health personnel and to provide evidence for health systems evaluation and action research for strengthening implementation and bring in new knowledge.
3. Policy formulation and planning at the national and regional levels.

2.1 Public health systems in India

Looking at the broader concept of public health systems in India, health-care is delivered by an asynchronous medley of players from the publicly funded institutions and the private for- and not-for-profit entities. Most times, there is no coordination between the health service players of different sectors, leading to skewed services concentrated in larger urban agglomerates, while formal services in the rural hinterlands are mostly served by public entities or informal or self-trained personnel.

The public health system in the formal sector in India is a three-tiered system composed of primary, secondary, and tertiary health care

institutions/facilities. The primary level is the first point of contact in the formal health system for individuals needing services. This level is supported by community-level personnel called the Accredited Social Health Activist (ASHA) who is the bridge between the community and the health system. The primary health services consist of subcenters (SCs), primary health centers (PHCs), community health centers (CHCs), area hospitals, rural family welfare centers, urban health posts, urban family welfare centers, district postpartum centers and subdistrict postpartum centers funded by the department of family welfare, dispensaries and clinics, urban health services provided by municipalities, healthcare for central government employees provided by the Central Government Health Scheme (CGHS), hospitals and dispensaries of railways, defense and similar major departments providing healthcare services for their personnel, medical infrastructure, and Employee's State Insurance Scheme (ESIS) hospitals and dispensaries providing healthcare to employees of industries. The "Ayushman Bharat" scheme was launched in 2018 as a health assurance scheme for the population below the poverty line and now covers almost the entire country. Under the scheme, 150,000 existing SCs and PHCs are being transformed into health & wellness centers (HWCs) to deliver primary health care services (National Health Mission, Government of India. Rural Health Statistics, 2019–2020). Specific staffing patterns have been formulated for the different levels. Additionally, another component of the Ayushman Bharat scheme is the Pradhan Mantri Jan Arogya Yojana (PMJAY), which is geared to provide health protection for the poor to avail secondary and tertiary health care services, primarily diagnostic and surgical services. As of 2020, 157,921 SCs, 30,813 PHCs, and 5,649 CHCs are functioning in the country and are mostly located in rural areas. There are 212,593 female health workers/auxiliary nurse midwives (ANMs), 28,516 medical officers at PHCs, 4,957 specialists at CHCs as of 2020, along with supportive care human resources, such as nursing personnel, laboratory technicians, and radiographers (National Health Mission, Government of India. Rural Health Statistics, 2019–2020).

The district health center/hospital, along with the CHC, provides specialist care and is part of the secondary level of public healthcare in India. The tertiary level comprises super-specialty care, which is mostly based at publicly funded medical colleges.

2.2 Indian Public Health Standards

The Indian Public Health Standards (IPHS) provide the framework for human resources and infrastructure at all levels of care in the public health system. The IPHS is used to benchmark the achievements across the country and helps in upgrading plans for infrastructure.¹⁻⁵ The objectives of the IPHS are to:

- ensure the provision of a minimum package of publicly funded healthcare services;
- assure quality of care by ensuring provision of services of good quality;
- promote responsiveness of the health system to the needs of the country.

In terms of provision of infrastructure and minimum personnel, the IPHS has identified norms for different levels (Table 3).

The National Health Policy was revised in 2017 and has set the country's goals of enhancing life expectancy at birth from 67.5 to 70 years, reducing under-five mortality to 23 by 2025, and reducing infant mortality rate to 28 by 2019 (Gauttam *et al.*, 2021).

¹Department of Health & Family Welfare, Ministry of Health & Family Welfare, Government of India. Indian Public Health Standards (IPHS) Guidelines for Sub Centres. http://mohfw.nic.in/NRHM/IPHS_Revised_Guidelines_2012/Sub_Centers.pdf

²Department of Health & Family Welfare, Ministry of Health & family Welfare, Government of India. Indian Public Health Standards (IPHS) Guidelines for Primary Health Centres. http://mohfw.nic.in/NRHM/IPHS_Revised_Guidelines_2012/Primary_Health_Centres.pdf.

³Indian Public Health Standards (IPHS) Guidelines for Community Health Centres. http://mohfw.nic.in/NRHM/IPHS_Revised_Guidelines_2012/Community_Health_Centres.pdf.

⁴Indian Public Health Standards (IPHS) Guidelines for Sub-District/Sub-Divisional Hospitals (31–100 Bedded). http://mohfw.nic.in/NRHM/IPHS_Revised_Guidelines_2012/Sub_District_and_Sub-divisional_Hospital.pdf.

⁵Indian Public Health Standards (IPHS) Guidelines for District Hospitals (101–500 Bedded). http://mohfw.nic.in/NRHM/IPHS_Revised_Guidelines_2012/District_Hospital.pdf.

Table 3. The IPHS norms for human resources and infrastructure in India.

Facility	Population Covered Tribal areas	Population Covered Non-tribal Areas	Personnel
Subcenter	3,000	5,000	1 ANM/female health worker (2 in HWCs); female health assistant monitors 6 subcenters
Primary health centre	20,000	30,000	Medical officer supported by 14 paramedical personnel
Community health center	80,000	120,000	4 specialists (surgeon, physician, gynecologist, and pediatrician) supported by 21 paramedical personnel; 30 inpatient beds available

2.3 Functional status of the public health system in India

In theory, India has a robust public health system in place, but the functioning is not optimal as there are gaps in the system. There are five domains where gaps are evident. These domains are governance, human resources (health workforce), infrastructure (physical and drugs/equipment), financing, and community engagement (trust and perceptions).

2.3.1 Governance

India's health system is a mixed system with the formal private for-profit sector dominating in urban areas and the publicly funded health system and the informal for-profit private practitioners dominating the rural landscape. The public health system in the country follows a federated hierarchy, where the national government is responsible for policy formulation and part funding of services, and the respective state governments are responsible for legislation and implementation. Earlier, the national government, in a mission mode, funded most programs and the state governments provided the operational machinery to implement

them in their territories. But, over the past five years, the financial contributions from the national government have reduced significantly and the states have been asked to find additional resources to fund healthcare. Since health is not a top priority for most states, they have been lethargic in their response to providing financial support. At the same time, many states had a state-financed health insurance scheme targeting hospitalization care, which accounted for a significant proportion of their finances. This consequently affected the health programs at the district level.

2.3.2 *Financing*

As mentioned in an earlier section, financing mechanisms are not adequate to protect and promote the health of populations. Tertiary- and secondary-level care has now been subsumed under the Ayushman Bharat scheme in most of India, and the national government's contribution to other existing public health programs has diminished over the past five years. The concept of private insurance is very new with very low penetration, especially in rural India. Therefore, the "missing middle" in the lower-middle and middle income segments of the population caused catastrophic health expenditures at the family or individual level. Primary care, preventive care, and outpatient diagnostic care are mostly paid for out of pocket by families or individuals. Out-of-pocket expenses have reduced marginally in recent years but are still sufficiently high to cause concern. At the same time, financial allocation for health from the government, though showing an increase in absolute numbers, is still very low in terms of relative proportionate allocation.

2.3.3 *Human resource*

There are vacant positions against sanctioned posts (the more rural or remote the area, the more the absenteeism or non-recruitment), inadequate skills to tackle the prevalent health problems in the country, lack of continued upgrading of professional competence, lack of promotions or retention policies, poor motivation, and lack of incentives. Skills for maternal and child health are generally updated but professional competencies for planning and tackling communicable and noncommunicable diseases

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(NCDs) are not optimal. Decision-making based on locally collected evidence is critical for a rapid response to outbreaks, but the health workforce neither has the authority nor the initiative to act at their catchment area level. This became evident during COVID-19, where the health workforce at the district and subdistrict levels was waiting for inputs from the state rather than immediately initiating action based on the local situation. Accountability is almost nonexistent in India. Most states allow private practice by government doctors, and this makes these doctors spend more time in their private clinics rather than in the government hospitals, as their private clinics are more lucrative financially.

2.3.4 *Infrastructure, medicines, etc.*

At all three levels of the health system, there is a shortage of essential equipment and medical supplies along with poor maintenance of available equipment. Security of the premises and personnel is also of concern. Though equipment may be available, many a time, they are not functional, and there is either no skilled personnel or fund allocation for even minor repairs. Though over the years, accommodation facilities have been provided, they are suboptimal in utility, which means that most of the staff prefer to stay in rented premises. All these factors impact on the delivery of quality healthcare, especially at the primary and subdistrict levels.

2.3.5 *Community engagement*

Studies show that the utilization of primary-level public health facilities is patchy. For antenatal care, immunization, and postnatal care, the PHC network is popular among the population, but when it comes to acute or chronic medical care, only around half the population visits a PHC, and there is more “trust” or “acceptance” of the informal private practitioners in the rural areas (Rushender *et al.*, 2016; Joseph and Anal, 2017).

3. COVID-19 and the Public Health Response

Though the first case of COVID-19 was detected in January 2020, indigenous transmission of the disease was manifested only in April 2020. Though cases

were recorded in March 2020, they were mostly among people with a history of travel. Therefore, the government of India started taking serious notice and enforced mitigation and containment strategies in March 2020. The COVID-19 outbreak is a reality check on the state of public health and pandemic preparedness in India and highlighted the concerns about the efficiency and effectiveness of the existing public health system components in India.

3.1 The politics of COVID-19 response

In the initial stages of the pandemic, there was confusion and chaos as public health personnel and the scientific community faced such a rapidly spreading outbreak with no specific prevention or treatment protocols. Public health professionals used the knowledge gained over the past century of dealing with influenza and other major diseases that spread through the respiratory route. Most of the measures used were generic in nature and were seen to halt the spread with earlier outbreaks, such as SARS or MERS. However, due to the lack of any specific measures, across the globe, politics and politicians came to the forefront. In some countries, they listened to scientific reasoning, but in many others, scientific or public health counsel was not sought and decisions were taken without looking at the wider socioeconomic consequences for the civil society. Sudden lockdowns, lack of transparency in sharing information, fudging of numbers of reported cases or deaths, and a lack of confidence or vested autonomy in frontline health personnel, ceding space to sooth-sayers and promoting formulations/concoctions without any evidence, were seen in formulating a response. This led to confusion, indignation, and frustration in the general population. Religious fervor was used by some to paint COVID-19 as a demon and a fight between the “good” forces and the “evil demons.” This manifested in irrational steps, such as part-time curfews, night curfews, and closure of all establishments, including hospitals. On the other hand, half-baked modelers scared both governments and populations with their outrageous predictions. Supplies were ramped up without a plan in mind, and in many cases, the items procured were never used or sparsely used and later consigned to garbage. This happened in relation to equipment, testing kits, and medicines alike. Many governments procured test kits which had poor sensitivity and

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specificity, and later, these kits had to be discarded. Panic buying led to unnecessary expenditure. Politicians were telling the professionals what the course of action should be rather than the public health professionals advising the political leaders on what the evidence-based actions were.

In India, on the governance front, there was confusion as to who should lead the response. India has multiple agencies, including the National Disaster Management Authority, the National Centre for Disease Control, the Indian Council for Medical Research, and the Niti Aayog (the policy think tank). All of them were involved, some to a greater degree than the others. However, there was a lack of coordination mechanism with the delineation of specific responsibilities for each agency in the fight against the pandemic. The National Centre for Disease Control (NCDC) is the equivalent of the Centers for Disease Control in the US or Public Health England in the UK, but right through the pandemic, NCDC played more of a supporting role rather than the lead role.

3.2 Need for strengthening the public health response

The COVID-19 pandemic highlighted the need for strengthening the public health system as people thronged to publicly funded facilities to access care at an affordable cost. Over the decade, from 1991 to 2001, the central government slashed the capital investment on publicly funded hospitals from 25% to 6%, forcing state governments, already reeling under fiscal stress, to generate their own financing for these hospitals (Roy, 2021). This hazardous decision affected the capacity of publicly funded hospitals to provide care during COVID-19.

Another area of concern was the lack of confidence in the huge public health workforce at the primary and community level to play a more effective role. The entire workforce responded superlatively to tackle the pandemic but were fighting the battle with their hands tied. They followed directions passed to them in a top-down fashion, but no effort was made to enhance their skills, provide feedback, or give them the autonomy for public health measures that may be more appropriate to their context. The pandemic needed a clinical response at the hospital level and a public health response at the community level, but unfortunately, both were led by specialist clinicians who were out of their depth in dealing with

population-wide actions. This is something that needs introspection for an improved response in the future.

3.3 The evolution of the pandemic in India

The first wave in India started in March 2020 and peaked by September 2020 (Sarkar *et al.*, 2021). The second wave started in March 2021 and peaked by May 2021. The third wave seemed to have started in December and peaked by January 2022 in India. The curves of the three waves show that the amplitude of the curve and the duration of the waves have reduced over the past two years (Figure 1). This is a positive sign, provided that unexpected, more virulent variants do not appear.

The pandemic trajectory in India debunked some of the theories of climate and transmission, as unlike in the temperate regions of the world, the maximum intensity of cases in India occurred in the spring and summer months. It was observed that the peak in May 2021 compared to the

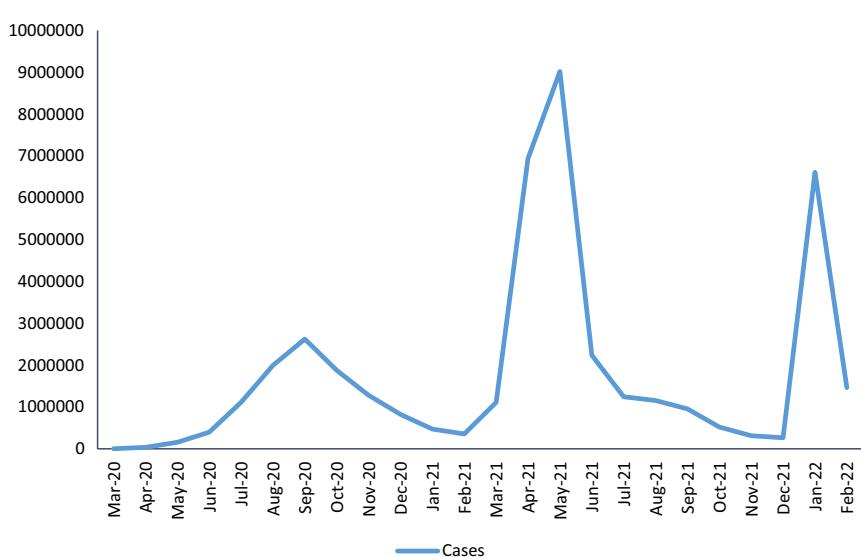


Figure 1. Monthly reported COVID-19 cases in India.

Source: COVID Today: Tracking India's Pandemic Response, <https://covidtoday.github.io/backend/>; Covid Statistics India, <https://ourworldindata.org/coronavirus/country/india>.

peak in September 2020 was 71% higher and that the peak was achieved over a short span of three months in 2021 compared to nearly six months in 2020 (Figure 1). The exact reason why the second wave was so devastating is not very clear, but it seems that the appearance of the Delta variant as the predominant strain and quickly discarding COVID-19-appropriate behavior and protocols without adequate attention to the available evidence is the likely reason for this.

The impact on mortality was even more catastrophic (Figure 2). Comparing the peaks in September 2020 and May 2021, there was a 261% increase. Once again, this increase occurred over a very short span of 8–10 weeks, which inundated and overwhelmed the health system, both in the public and private health sector in India. Incidentally, though the spike in cases came down by January 2022, reported mortality continued to increase late into February 2022. This again is interesting, as against the perception that Omicron was mostly asymptomatic and “mild,” the reported deaths kept increasing (Figure 2).

One of the principal measures to combat the COVID-19 pandemic is testing, tracking, and treating COVID-19 suspects and cases. Toward this

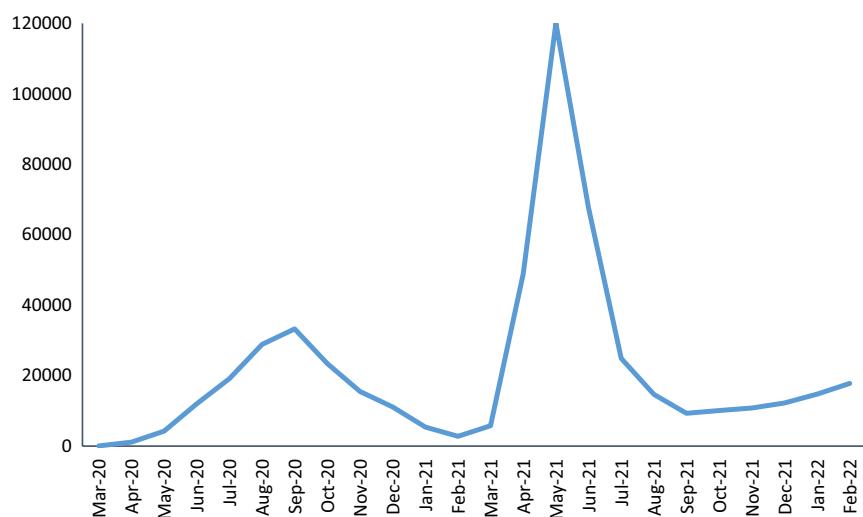


Figure 2. Mortality data during the COVID-19 pandemic in India.

Source: COVID Today: Tracking India's Pandemic Response, <https://covidtoday.github.io/backend/>; Covid Statistics India, <https://ourworldindata.org/coronavirus/country/india>.

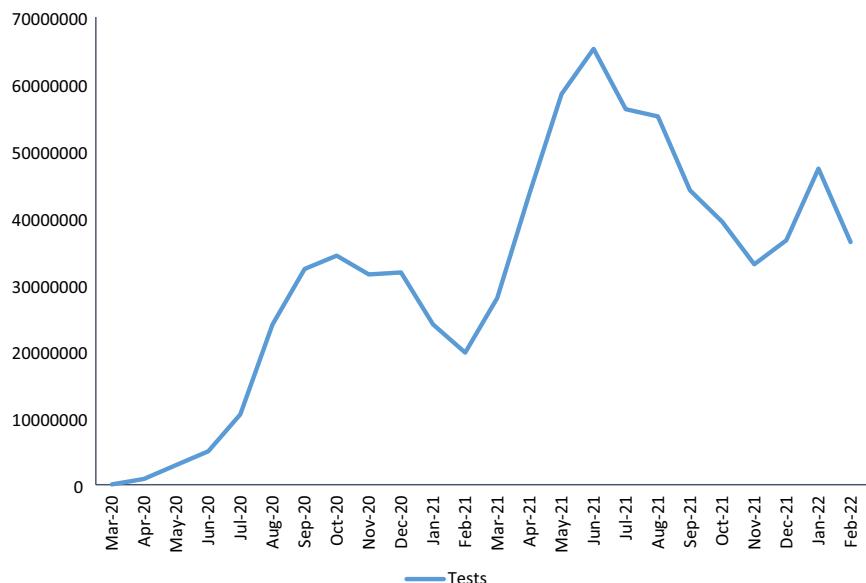
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Figure 3. COVID-19 testing patterns in India.

Source: COVID Today: Tracking India's Pandemic Response, <https://covidtoday.github.io/backend/>; Covid Statistics India, <https://ourworldindata.org/coronavirus/country/india>.

end, there was a need to ramp up the capacity for testing in the country. But it took time to initiate the process of testing, and even then, the testing numbers were not optimal to tackle the COVID-19 case identification and isolation effectively (Figure 3). Though there was a 261% increase in mortality, the peak of testing in May 2021 was only 81% higher compared to the peak seen in September 2020. Data also showed that there was renewed testing when caseloads increased but then dropped down very quickly when the magnitude of cases dropped significantly (Figure 4).

This can be a dangerous trend as testing would need to continue for longer to monitor any sudden change in the trends in the country. The number of laboratories testing for COVID-19 was only one in January 2020, which increased to 1,065 by July 2020 and 2,504 in May 2021.⁶ This geometric increase in laboratory capacity was built up very quickly

⁶ICMR. Availability of COVID testing laboratories in the county. <https://www.icmr.gov.in/COVIDTimeline/cindex.html>

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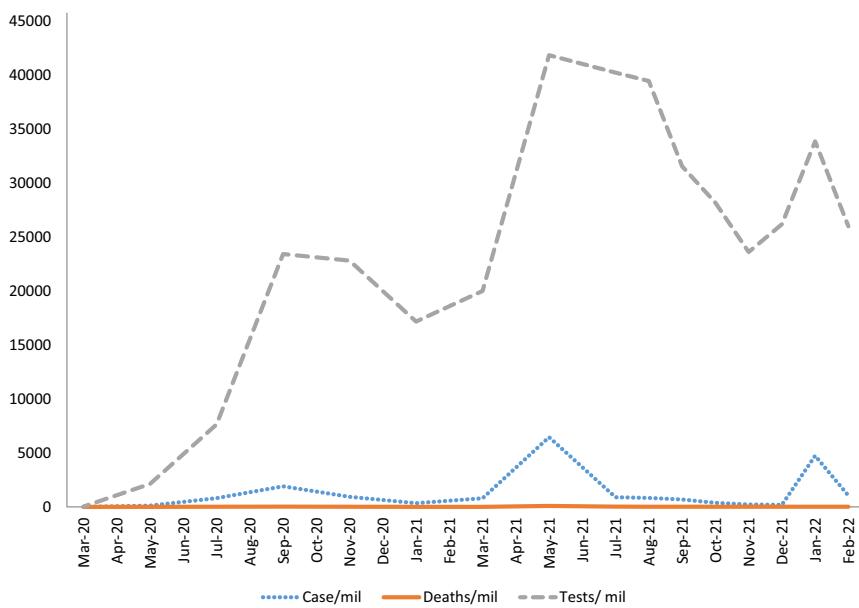


Figure 4. Comparison of cases, deaths, and tests per million population.

Source: COVID Today: Tracking India's Pandemic Response, <https://covidtoday.github.io/backend/>; Covid Statistics India, <https://ourworldindata.org/coronavirus/country/india>.

in the country; therefore, there should have been no problem in maintaining an optimal testing protocol in the country.

Public health does not give much credence to absolute numbers except when a health event is of short duration and there are no changes in the macro environment during that period. An absolute number is only a "numerator." One needs a "denominator" to make sense of data. This is because of the different sizes of populations and other demographic characteristics in a country. The denominator allows comparisons between countries and within regions. Only with a denominator can one understand trends and the impact of public health measures in a population.

Though in terms of absolute number of COVID-19 cases, India ranks only next to the US, when a denominator, such as the population in different countries, is considered, the scenario changes dramatically (Table 4). When cases per million population are considered, the US is followed by the UK and Spain, while India and Sri Lanka are very similar. When

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Table 4. Comparison of COVID-19 situation in different countries (as of March 11, 2022).

Countries	Reported COVID-19 Cases	Cases Per Million Population	Reported COVID-19 Deaths	Deaths Per Million Population	Total Tests for COVID-19	Tests Per Million Population
USA	81,108,786	242,642	991,260	2965	962,617,214	2,879,729
India	42,984,261	30,640	515,745	368	776,894,810	553,791
Brazil	29,249,903	135,979	654,147	3041	63,776,166	296,448
UK	19,457,976	284,112	162,624	2462	489,082,431	7,141,249
Russia	17,242,043	118,064	359,585	2462	273,400,000	1,872,091
Germany	16,636,606	197,501	125,669	1492	104,701,826	1,242,967
Turkey	14,488,373	168,728	96,094	1119	147,556,339	1,718,406
Spain	11,204,125	239,480	101,077	2160	471,036,328	10,068,042
Iran	7,113,591	82,905	138,572	1615	48,036,013	559,833
Indonesia	5,864,010	21,063	151,703	545	88,544,248	318,050
Peru	3,531,075	104,638	211,364	6263	27,785,664	823,386
Bangladesh	1,948,798	11,638	29,100	174	13,600,387	81,219
Pakistan	1,517,512	6652	30,298	133	28,825,303	117,595
Bulgaria	1,109,581	161,740	36,028	5252	9,339,153	1,361,334
Sri Lanka	654,916	30,370	16,374	759	6,368,159	295,307
Egypt	494,519	4684	24,269	230	3,693,367	34,980
Singapore	901,758	152,122	1116	188	23,315,251	3,933,156

Source: (Worldometer, 2022).

deaths per million population are considered, Peru is the worst with 6,363 deaths per million population, followed by Bulgaria (5,252), Brazil (3,041), the US (2,965), and the UK (2,4629) among the countries listed in Table 4, while India, Pakistan, Bangladesh, Egypt, and Singapore have better profiles. In terms of tests per million population, most countries in South Asia, including India, lag behind other countries. Test per million or absolute number of tests should be inferred cautiously, as it does not indicate the number of people tested as against cases or deaths, which refer to the number of people.

Serosurveillance has played a major role in tracking the COVID-19 pandemic in India. A population-based sero-epidemiological study can

Table 5. Seroprevalence surveys in India.

Period	Seroprevalence	Reference
May–June 2020: ICMR First round	0.73% among those aged >18 years	(Murhekar <i>et al.</i> , 2020)
August–September 2020: ICMR second round	6.6% among those aged >10 years	(Murhekar <i>et al.</i> , 2021a)
December 2020 – January 2021: ICMR Third round	24.1% among those aged >10 years	(Murhekar <i>et al.</i> , 2021b)
June–July 2021: ICMR Fourth round	67.6% among those aged >6 years; 85% healthcare workers	(Murhekar <i>et al.</i> , 2021c)

measure the extent of the population that has antibodies against SARS-CoV-2. Such studies can estimate the proportion of the population exposed to the virus and the proportion of the population that remains susceptible to the virus. The antibodies developed in the population can act as a marker of total or partial immunity (Kshatri *et al.*, 2021). The Indian Council for Medical Research (ICMR) has been conducting repeated serosurveys in randomized samples across the country (Table 5).

The ICMR serosurveillance surveys show that there has been an exponential increase in the positivity rate across the country from June 2020 to July 2021 (Table 5). In this one-year period, from 0.73% of the sample being COVID-19-antibody positive, it increased to 67.6% of the sample being positive. The first round only covered adults aged 18+ years (Murhekar *et al.*, 2020). The next two rounds covered all those aged 10+ years (Murhekar *et al.*, 2021a, 2021b), while the most recent survey included all those aged 6+ years (Murhekar *et al.*, 2021c). Evidence shows that the pandemic has affected all age groups and has slowly transitioned from the urban areas into the rural parts of the country. The data from the fourth round conducted in June–July 2021 is not strictly comparable to the earlier rounds, as COVID-19 vaccination was offered to the population from January 2021, and the high seropositivity of 67.6% also includes antibodies developed due to the vaccines in addition to direct infections. However, even if we discount for the vaccine, there is still a significant increase in number of

people infected with COVID-19 in India. There was a wide variation in seropositivity across the states, with the lowest in Kerala (44.3%) to the highest in Madhya Pradesh (80.0%) (Murhekar *et al.*, 2021c). From this data, one can discern that higher literacy and developmental indicators in a state like Kerala compared to a state like Madhya Pradesh leads to higher compliance with COVID-19-appropriate behavior, and a widely dispersed population and housing conditions can act as a barrier to rapid transmission. However, it also means that a significant proportion of the population is still vulnerable under such conditions, and surveillance and care will be needed for a long time, especially with rapidly spreading variants like Omicron.

A series of three repeat surveys on the same surviving sample in Bhubaneshwar, India, showed that the peak of the first wave was seen mid-September in that city (Kshatri *et al.*, 2021). It was also seen that in the initial round, seropositivity was higher among the elderly, while in the later rounds, middle-aged population had the highest prevalence. Interestingly, in the first round, males had significantly higher proportion who were seropositive compared to females, but during the later rounds, these sex differences were not observed. It was also observed that seroprevalence was higher among those who hailed from families with larger household size (Kshatri *et al.*, 2021). This information charts the natural progression of COVID-19 in India and would reflect what has probably occurred in all densely populated urban areas of the country.

The COVID-19 outbreak in India seems to have reversed some of the public health gains made over the past 20 years. Some experts have indicated that the life expectancy for both males and females may have decreased by 2–3 years, with males facing a more severe impact (Yadav *et al.*, 2021). This is not a good sign for the realization of Sustainable Development Goals (SDGs) by 2030 as time is ticking away.

4. Justification for Strengthening of Public Health Systems After COVID-19: India as an Exemplar

Data show that the public health system did not respond optimally to the pandemic because of inherent weaknesses in the system and the lack of

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decentralized decision-making capacity and authority. The pandemic has exacerbated the weakness of the fragile public health system in India.

Even in the pre-COVID-19 period, evaluations of the public health system, especially at the primary level, showed suboptimal functioning. A study in Central India revealed that 67% of patients needing healthcare bypassed the publicly funded PHC network and sought services from private hospitals due to perceived lack of competencies of the PHC personnel, despite out-of-pocket expenditure being 50% lower in the public health system (Rao and Sheffel, 2018). This study highlights that in addition to structural reinforcement, competency augmentation is important. Another study evaluating maternal and child health services in the public health system in Bihar found that only half the essential drugs were available at PHCs and district hospitals and that adequacy of staffing had a positive correlation with quality of care (Kaur *et al.*, 2019). Weaknesses in quality, skilled human resources, and accountability at the PHC level were identified as important determinants of maternal care services in India (Sharma *et al.*, 2018).

The SC is the lowest rung of the organized public health system in India. It is usually the first contact for people seeking care for maternal and child health, communicable diseases, and NCDs. An evaluation of SCs in the state of Andhra Pradesh revealed serious deficiencies in terms of physical facilities, availability of drugs and equipment, and communication access, and it was opined that the SCs lacked the requisite human resources and vital infrastructure to function and deliver services effectively to the rural population and that the stated norms in the IPHS guidelines were not adequately met (Sriram, 2019). Similar observations were recorded at the PHC level too, in Andhra Pradesh, where nonavailability of trained personnel and lack of critical essential drugs as well as equipment (Sriram, 2018).

4.1 Routine health service delivery during COVID-19

Available data from the country show that there has been a significant drop in utilization of health services during the lockdowns in 2020 and

that the patient load has not yet returned to pre-COVID-19 levels in most specialty hospitals.

It has been reported that non-COVID-19 healthcare services, such as screening and elective procedures, have been adversely affected in the country. The sudden disruption of healthcare services and access in March 2020 caught many off guard. Patients who suffered most were the newborns who needed constant care, children with disability due to causes such as cerebral palsy, and the elderly with diabetes, hypertension, kidney diseases needing dialysis, etc.

Studies have reported a significant decrease in ophthalmic services, including screening for retinopathy of prematurity, a condition seen in prematurely born low-birth-weight babies, where the retina is not fully developed, and if not treated in time, the baby goes blind. One study reported that screening decreased by 73–90% and treatment by 63–89% (Kaur *et al.*, 2021). This study found that, contrary to the popular perception, the second wave lockdown was also very disruptive. Similar concerns were expressed in a study looking at pediatric cardiac services (Choubey *et al.*, 2021). The first wave saw a two-thirds reduction in hospital admissions and cardiac surgeries, and the uptake had not yet come back to normal pre-COVID-19 levels even in October 2021 (Choubey *et al.*, 2021).

Emergency department attendances decreased by 35% during the first lockdown in two large London hospitals in the UK (Vollmer *et al.*, 2021). Data from a large multispecialty hospital in Delhi in India showed that there was a significant impact on non-COVID-19 caseload in the hospital. There was a 55.36% decrease in new hospital outpatient consultations and a 34.07% decrease in hospital admissions. In the first lockdown, the services were affected even more with an 89.31% decrease in new outpatient consultations and 59.8% decrease in admissions (Vaishya *et al.*, 2021).

4.2 Impact of COVID-19 on the marginalized: People with disabilities in India

We undertook a study across 14 states in India in 2020. We observed that 42.5% of people with disability reported difficulty in accessing

routine medical care, and among those with a pre-existing health condition, the situation was even worse (Tetali *et al.*, 2022). Therefore, persons with disabilities (PWDs) with antecedent medical problems suffered significantly more than those who did not have an antecedent health condition. Nearly a quarter reported difficulty in getting their medications, while 28% reported postponing their scheduled medical appointments because of the lockdown. More than half of the PWDs perceived that a continuous lockdown would have a deleterious effect on their health (Murthy *et al.*, 2022). Of the 35.7% needing medicines during the lockdown, nearly half (46%) stated that they faced problems in accessing the same, and 58% of those who needed regular blood pressure monitoring could not get it done during the lockdown. A third of those who stated needing regular blood sugar estimation expressed their lack of access to this service. Among the 17% needing rehabilitation services, 59.4% failed to access the same, and 81.6% reported experiencing moderate to high levels of stress (Murthy *et al.*, 2022). These observations highlight the need for adequate planning and preparedness of the public health system to tackle health concerns of the entire population, with a special emphasis on structured targeted services for vulnerable groups, such as the elderly and the disabled.

A multi-country analysis looking at pandemic responses observed that most countries, including India, enforced rigorous lockdowns to contain the spread of COVID-19. However, gleaning the epidemic curves and time series analyses, it was documented that the containment measures were successful in high-income countries and not in low-income countries like India (Jang *et al.*, 2021). This analysis highlights the need to consider the local context in developing and delivering public health interventions rather than blindly adopting strategies from countries with different socio-demographic milieus.

Pandemic preparedness envisages that all efforts should be made before an outbreak and in the inter-pandemic period to ramp up the public health systems. COVID-19, though a catastrophe for the human race, is an opportunity for public health. For the first time, the value of investing in public health systems has been realized and so this is the opportune time to develop a blueprint to improve public health services in the country.

5. Specific Investments in Public Health

5.1 Benefits of investment

Public health yields rich dividends for a population's health status. The gains are incremental based on the inputs into public health systems. Patchy knee-jerk responses do not result in sustainable benefits. This is because there is a need for long-term planning for the benefits to accrue. The COVID-19 pandemic has made people realize that if we do not invest in the health sector today, then the vaccine-preventable and other chronic diseases of today can result in epidemics and increased magnitude of concerns, such as drug-resistant diseases, which will inflate the need for financial resources by 10–100 times in the future (Vyas *et al.*, 2021).

Unlike clinical health services, which yield returns immediately, the return of investment in public health takes a long time, perhaps even generations. Therefore, the yardstick to measure success for public health measures has to be different. Patience and perseverance are the key determinants of public health success. In recent memory are the eliminations of polio in India and malaria in Sri Lanka. Sustained investments over nearly half a century in evidence-based interventions paved the way for elimination. Partnerships were forged and resources were provided on a mega scale to achieve the aim of elimination. The private for-profit and not-for-profit sectors, the civil society, and the public health machinery joined hands to achieve the impossible under the overall coordination of the public health apparatus. The same was the case with small pox 50 years ago and with guinea worm 40 years ago.

5.2 Public health investment and Sustainable Development Goals

With the global focus on achieving the SDGs by 2030 and sustained improved health after that, the need for focusing on public health is of paramount importance. Public health needs to provide valid evidence for interventions to be identified and systematized for roll out at population level. It needs to consider the scientific basis of health and disease on the one hand, client needs and perceptions in a cultural context on the other,

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and a consideration of logistics and uninterrupted supply chain and skills to deliver services. Technological breakthroughs in a laboratory need to be translated into need-based and affordable interventions benefiting populations to add value and improve quality of life. Any new intervention is only relevant if it is accompanied by a “social breakthrough,” i.e., how to adapt the innovation to reach the maximum number of people possible. Unless the social and technological breakthroughs go hand in hand, they can’t be of any benefit to the population’s health status.

5.3 Need for multidisciplinary approach

Public health needs involvement of many disciplines, including those outside the health sector, due to the impact that social determinants have on health status of both individuals and populations. To improve health of communities, substantial investment is needed in preventive health programs and campaigns. Seeking investment in preventive programs is an uphill task, as it is a challenge for policymakers as allocation for health needs to compete with other major governmental expenditures (Vliet *et al.*, 2020). Therefore, there is an urgent need to generate and share evidence on economic evaluations to provide policymakers with justification to invest in public health by presenting information of both the costs and returns and the cost savings that would accrue due to the returns (Vliet *et al.*, 2020).

5.4 Public health preparedness

Investments in public health should also consider the level of public health preparedness of countries to face the challenges of future pandemics. Though the WHO has consistently asked its member states to assess their preparedness, many countries did not pay serious attention, as overall there was a decrease in infectious disease outbreaks globally. COVID-19 has made countries rethink public health preparedness, and now is the time to strengthen public health systems to make them more responsive to timely and appropriate actions. Efforts have been made recently to define the core principles of public health emergency preparedness (Belfroid *et al.*, 2020). An extensive consultation among experts in the European

Union listed 42 priority recommendation as core preparedness principles. The recommendations were categorized in seven domains — governance, capacity-building and maintenance, surveillance, risk assessment, risk and crisis management, post-event evaluation, and implementation of lessons learnt (Belfroid *et al.*, 2020). These recommendations can be used as a template to augment/enhance investment in public health systems in other countries also.

5.5 Importance of social determinants

There is a strong case that has been made for public health investments to be measured in social terms rather than looking at the investments only from a monetization perspective of return on investment. Showcasing the social, economic, and environmental values of public health interventions is important. It has been suggested that the social value should be captured using indices such as social return on investment (SROI) and social cost–benefit analysis (SCBA), which have been developed over the past few decades (Ashton *et al.*, 2020). Social value is unlocked by the experience people have after partaking in an intervention, such as increased confidence or residing near a park (Ashton *et al.*, 2020).

5.6 Public health expenditure and accrued impact

A recent analysis from India observed that the mortality due to COVID-19 varied across the states, and the difference could be attributed to the level of public expenditure on health (Balakrishnan and Namboodhiry, 2021). The paper highlights the observation that states that have spent more on health have lower mortality from COVID-19 and that more critical was the expenditure in relation to GDP and not per capita health expenditure (Balakrishnan and Namboodhiry, 2021). The authors also showed that the share of the state budget allocated to health is important for the public health landscape. They opine, and rightfully so, that a share of less than 5% could be construed as very low, given the current state of health infrastructure in the country. Half of the states in India fell into this category, and it was also seen that for a significant section of India, the expenditure on law and order exceeds that on the health of the population.

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(Balakrishnan and Namboodhury, 2021). The authors state that the richer states spent less of their GDP on the public health sector. From a public policy point of view, this has the implication that lower spending is a policy choice (Balakrishnan and Namboodhury, 2021). Since health is a state subject in India, there is a need to advocate with the different state governments the perils of suboptimal investment in health.

5.7 Future public health investments

Public health has evolved over the years and more so in the past 20 months due to the COVID-19 pandemic. The strategies today need to harness the power of digital technology coupled with the existing public health infrastructure and consider “hybrid” solutions to deliver care rather than the conventional health services delivered in person. Digital public health, big data, and precision public health are new additions to the public health lexicon. Digital health and big data can revolutionize the practice of public health by increasing access, enhancing decision-making capacity, and enabling prioritization in a cost-optimal manner. Precision public health has been referred to as the modernization of surveillance mechanisms by integrating multiple data sets to respond more efficiently to control an outbreak and identify and mitigate risks to health (Keney and Mamo, 2020). In that sense, precision public health harnesses the benefits of big population-based, multifaceted data (epidemiological, social, and environmental) and newer health technologies together.

The practice of public health has changed over the past two decades as has healthcare in general, with the advent of digital technology. The process of adoption of digital technology has been accelerated due to the COVID-19 pandemic. Therefore, investments for the future need to support this new reality, which can work toward improving the quality of service delivery as well as surveillance and training capabilities. Today's investments in public health therefore have the potential to reduce overall costs of care and improved access (Table 6).

Investments in public health should consider both the direct provision of public health services and the support services, such as digital technology, surveillance, monitoring, analytics, and modeling skills, which have

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Table 6. Specific public health investments for enhancing public health system in India.

Domain	Strategies
Health workforce adequacy & competency	<ul style="list-style-type: none"> • Numbers should resonate with IPHS norms • Skills commensurate with quality outcomes • Shortages/leave of absence should not exceed 5% at any given time • Enhance use of digital technology for upgrading skills & competencies by reaching large number of trainees in a short time with standardized training modules • Innovative mentorship with designated supervisors
Infrastructure availability	<ul style="list-style-type: none"> • Physical facilities as per IPHS norms should be available across the country • Urban infrastructure for primary care should be augmented along with the rural infrastructure
Diagnostic support services	<ul style="list-style-type: none"> • Rapid diagnostic kits for common infectious diseases should be available • Point-of-care diagnostics for early detection of NCDs and MCH problems • Functioning lab and X-ray unit as per IPHS standards
Equipment	<ul style="list-style-type: none"> • Functional equipment to cover all prevalent health conditions should be available. • Need for building capacity for equipment maintenance and troubleshooting at public health facilities
Essential drugs	<ul style="list-style-type: none"> • Essential drugs should be available in adequate quantity all through the year • Essential drug lists should be based on prevalent health conditions
Service delivery	<ul style="list-style-type: none"> • Quality of services to be improved to build confidence and trust among facility users • Optimizing use of tele-health to promote consultations from home when facility visit is not required • Use of health drones for logistic support
Surveillance systems	<ul style="list-style-type: none"> • Real-time trends and changes captured using digital technology and GPS to identify and contain new outbreaks • Promote and use a digitally networked health management and information system

(Continued)

Table 6. (*Continued*)

Domain	Strategies
Big data analytics	<ul style="list-style-type: none"> • Build capacity for using big data analytics, machine learning, and artificial intelligence to assess emerging challenges, plan effectively, and monitor implementation • Merging health and social determinant/development, environmental data for analysis
Modeling skills	<ul style="list-style-type: none"> • Invest in capacity-building of research scientists to develop predictive models for disease transmission and workforce requirements
Health financing	<ul style="list-style-type: none"> • Health budget should exceed 5% of the country's GDP • At least 70% of funding should be dedicated to primary care services and strengthening of public health facilities • Out-of-pocket expenses should be progressively reduced <25% • Promoting health insurance for the lower-middle- and middle-income populations
Community partnership	<ul style="list-style-type: none"> • Community engagement to facilitate civil society participation in decision-making and planning of public health services • Community ownership and financing models to be validated and promoted • Communication technology used extensively to share risk perception and reduction with community
Governance	<ul style="list-style-type: none"> • Decentralization of authority to district and sub-district levels • Build capacity for local decision-making and activity planning • Evidence-based public health legislation customized to the country's health needs and problems
Creation of evidence hubs and public health think tanks	<ul style="list-style-type: none"> • Inculcate and incentivize research culture in public health and health sciences • Include only evidence-based interventions in policy • Regional network of public health evidence hubs to be developed
Public health emergency preparedness	<ul style="list-style-type: none"> • Orienting all stakeholders, including the civil society, to emergency preparedness, including disaster preparedness. • Regular mock drill to be conducted • Formation of planning and implementation groups at all administrative levels

to go hand in hand. Investing in one domain and not in the other will not help build a robust public health environment.

5.8 Public health workforce

At the heart of any public health system is the availability of health personnel with requisite competencies and motivation. Digital technology can be harnessed effectively to roll out massive online courses for personnel already engaged in public health services. The initial development of the course material will be resource intensive, but the yield will be very high. The IPHS act as the benchmark for public health services and improved quality and access. One of the concerns with the public health workforce is the lack of adequate numbers of skilled personnel. COVID-19 has taught us that this will be perilous. Therefore, this needs to be redressed. Setting up designated mentorship with online support on a monthly one-to-one basis can make a difference for the future and increase the confidence in public health system personnel.

“Quality drives demand” is a well-recognized dictum, but unfortunately, this aspect is not given due attention. Patchy availability or non-availability of human resources at a public health facility or lack of skills or competencies discredits the system. Recruiting personnel with basic skills and then building their competencies aligned with the existing public health system is very important.

5.9 Public health infrastructure

There has been a focus on developing the rural healthcare infrastructure to the detriment of urban health services under the premise that urban residents can access services more easily. Though this is true, it is also true that the urban poor and marginalized are unable to access care. COVID-19 started off as an urban-centric phenomenon, and the lack of an urban public health service had a catastrophic effect on COVID-19 transmission, as there were not enough personnel to undertake public health functions, such as tracing, tracking, and testing people exposed to the risk of COVID-19, especially in urban areas.

5.10 Diagnostic services

Diagnostic services, especially rapid diagnostics, is another lacuna in the existing public health system. Conditions like COVID-19 and dengue can be controlled more effectively if rapid kits are available. Though the dengue rapid kit is very sensitive, its availability in the public health system is limited, and its absence puts more and more people at risk of more severe dengue, which can be fatal. Point-of-care diagnostics have been revolutionized by digital technology, and many of these have been validated for use but have not yet found due recognition. Early detection is an important function of public health, and more attention is needed for affordable point-of-care diagnostics. They can play a very crucial role in the detection of NCDs. This is important since more than 60% of mortality in India is due to NCDs, and detection at the “golden hour” can save many premature deaths.

5.11 Equipment

Equipment availability and functionality are critical for the success of public health interventions. Unfortunately, public health systems rarely invest in maintenance contracts or skilling personnel to manage small repairs. There are instances where, because of a lack of AAA cells, torches were not working, or because of a wire getting chewed up by a rat, the generator was not functioning. Monitoring such situations is important if public health systems are to become credible.

5.12 Service delivery

Though the vast majority of India’s population is in the rural areas, the penetration of organized public health services in rural India is poor. Most people access care from private self-trained nonformal practitioners in rural India due to the paucity or lack of trained health personnel. The economic survey of 2018–2019 showed that 60% of primary health centers in India had only one medical officer posted, while 5% had none. In Jharkhand, more than 10% of PHCs did not have a doctor, while in

Chhattisgarh, more than 20% did not have a doctor.⁷ The survey indicated that states where there was one or no doctors in more than 70% of facilities, such as in Bihar, UP, Rajasthan, Kerala, Karnataka, and Gujarat, there was a higher infant mortality rate and maternal mortality ratio (see footnote 7). The survey also found that only 20% of PHCs met the IPHS norms. In Haryana and Uttar Pradesh, less than 5% met the IPHS norms, while at the other end of the spectrum were Tamil Nadu (80% adherence) and Andhra Pradesh (100% adherence).

Social entrepreneurship or social responsibility ventures have also developed models of change with the private sector entering into viable partnerships for improved public health service delivery (Bhattacharyya *et al.*, 2010). Out-of-the-box innovations will culminate in successful models.

5.13 Surveillance

A white paper with a road map for public health surveillance was recently enunciated in India (Niti Aayog, 2020). Till date, surveillance services have been patchy and unstructured or were functioning in disease-specific silos. The Indian Public Health Surveillance plans to change the landscape. The intention is that surveillance will be cutting across all levels of healthcare from primary to the tertiary levels and that anonymized data will be used for immediate action. The impetus has been provided by the COVID-19 outbreak when the lack of structured surveillance systems was observed to be working toward the detriment of the public health system. The blueprint suggests building on the gains from the National Digital Health blueprint and the rolling out of the Integrated Disease Surveillance Program. It also recognized the need for a skilled workforce to support surveillance activities. The penetration of smartphone technology offers an excellent opportunity to augment existing surveillance systems. The prosed integrated system will incorporate re-emerging and emerging communicable diseases, noncommunicable diseases, and anti-microbial

⁷Economic Survey 2018-19: Healthcare still inaccessible in rural India. <https://www.downtoearth.org.in/news/health/economic-survey-2018-19-healthcare-still-inaccessible-in-rural-india-65443>.

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resistance (Niti Aayog, 2020). Private sector involvement is also recognized as important. One Health is also emphasized as many of the emerging vector-borne conditions jump from animals to humans.

Medical service data is important for surveillance functions and helps in early detection of new outbreaks (Pilot *et al.*, 2017). However, skills and delegation of authority to local levels are necessary ingredients for a vibrant surveillance system. Local levels at district and sub-district levels should be empowered and supported to act upon local disease data and share the data rapidly to the next levels for immediate response.

Participatory surveillance with active engagement of the community can play an effective role in the future due to the widespread use of smart-phone technology. During the COVID-19 pandemic, structured protocols were developed for the same and were effective in making the community a partner in early detection. Many countries, including India, developed applications to promote early detection (Garg *et al.*, 2020). Many resident welfare societies also made efforts to share information on positive cases with other residents, thereby reducing the risk of interaction with infected persons. A similar approach was followed in the surveillance of google trends on influenza. Though an attractive idea for rapid identification of disease clusters, initial efforts resulted in erroneous interpretations. However, more recently, improved analytics have reduced errors by more than 44% for recent data and by 80% for data from 2012–2013 (Kandula and Shaman, 2019). A similar approach for dengue surveillance was also promising, with better results seen in areas with higher incidence (Strauss *et al.*, 2017). Combining improved data analytics with participatory surveillance can yield good returns.

5.14 Big data analytics

Population-based big data analytics has the potential to revolutionize decision-making for public health interventions by providing the rigor of delving through a large amount of data and determinants from different regions, thereby increasing the validity. Patient medical records, population dynamics, health, nutrition, and social survey data can all be

synthesized and their trends dissected. High-end computing systems provide inferences rapidly; therefore, the speed at which inferences are available can provide a near real-time intervention. Artificial intelligence (AI) and machine learning (ML) have provided a major fillip to analyzing big and diverse data sets (Dash *et al.*, 2019). Big data analytics in public health is in its nascent stages, but there is bound to be accelerated use in the next decade. Every level of the publicly funded health system in the country collects an enormous amount of data. Most of this data is in paper format, though recently, there is an increased use of computerized or electronic data management systems (Gupta *et al.*, 2021). Unfortunately, this data is hardly ever used to analyze disease trends or setting priorities or planning for healthcare. Big data analytics can help both with structured and unstructured data. It helps in the ease of data retrieval and archiving (where large amounts of data can be stored) and provides leads rapidly, unlike the present systems of health data analysis, which takes years before being available for use. Therefore velocity, volume, variability, veracity, and variety characterize big data and adds value due to the use of data visualization techniques in a short span of time (Batko and Slezak, 2022). Big data also allows synchronization of varied data sets. For example, health facility utilization data can be merged with demographic data or financial data sets to get a better understanding of cost of care, out-of-pocket expenditures, profiling of population using publicly funded facilities, etc. Big data can be effectively used for improving the quality of care for patients, understanding which medicine is more appropriate for an identified population subgroup, which diagnostic procedures are more predictive of disease or progression or prognosis, etc. Big data helps evidence-based practice of public health, as more appropriate and timely decision-making is facilitated.

Availability of big data could have revolutionized the speed of response to an outbreak like COVID-19, as decisions on repurposing of drugs could have been aided by archived data from the use of such a medicine or diagnostic procedure in a short period of time. Therefore, skills for managing and analyzing big data is a necessity today for improved public health practice in future.

5.15 Modeling

Public health needs extensive use of modeling techniques whether to predict outbreaks, improve health status, or project the future needs of the health system for human resources and infrastructure. Unfortunately, these domain skills have not been harnessed adequately in the past. There is now an urgent need to add these skills to the public health practitioner's armamentarium. Modeling is a powerful and effective tool, the potential of which has not yet been fully utilized in public health. Statistical modeling can be used for a range of benefits at a much lower cost than primary data collection and can play a crucial role by using available data and trend analyses to help in evidence-based planning. The initial leads on what could be the impact of COVID-19 and non-pharmaceutical interventions to prevent COVID-19 were all based on modeling of the pandemic. During the COVID-19 pandemic, a number of predictive models were developed and used to forecast the magnitude of the COVID-19 cases, the speed of transmission, the need for equipment such as ventilators, etc. (Mishra *et al.*, 2020; Song *et al.*, 2021). A number of mathematical models have been used to predict the trajectory of the COVID-19 pandemic in the South Asian region, including susceptible infection recovery, exponential growth, sequential Bayesian, maximum likelihood, and time dependent models (Singh *et al.*, 2021).

5.16 Public health emergency preparedness

The frequency of natural disasters as well as infectious disease outbreaks have increased over the past two decades due to deforestation, trade, and speed of international travel. Thirty previously unknown infectious diseases have emerged in the last 30 years. More than 75% of these have jumped from the animal kingdom to human beings.

Pandemic preparedness refers to all the policies formulated before an outbreak, risk assessment of similar outbreaks in the future, managing/mitigating risk by public health interventions, and decreasing the vulnerability and increasing the resilience of the society. COVID-19 is not the first nor the last pandemic the world will see; therefore, health emergency preparedness is important. The COVID-19 pandemic has

spurred the world to join hands to draft an international pandemic agreement (Gostin *et al.*, 2021). Researchers have recently developed a new indicator called the Epidemic Preparedness Index (EPI) to assess national-level preparedness (Oppenheim *et al.*, 2019). The indicator cumulated scores across domains, including public health infrastructure, physical infrastructure, institutional capacity, economic resources, and public health communications. Therefore, it is an inclusive comprehensive indicator, which countries can use to see where they are and what resources they need to commit to improve the ecosystem. Countries in South East Asia were ranked among the least prepared. Emergency preparedness also needs to consider how confidence can be generated in public health facilities (Yadav, 2021) and how to build resilience in populations. These aspects are discussed in other chapters in this compendium.

Emergency disaster or health or pandemic management can only be effectively managed if there is a lead coordinating agency that works in partnerships with other public health agencies to mount an effective response. During COVID-19, there were multiple voices emerging from national-level think tanks in India — The ICMR, the NCDC, the National Disaster Management Agency, the National Institute of Communicable Diseases, and the Niti Aayog. There was duplicity of functioning with a lot of overlap. Coordinated preparedness would have defined the roles and responsibilities of each of the professional agencies involved, i.e., the role of the ICMR being limited to medical research initiatives, while the NCDC is tasked with being the face of managing the pandemic under overall policy guidelines of the Niti Aayog. Unless clear lines and roles are delineated, health personnel within the health system will be faced with conflicting directives, which is not conducive to an appropriate timely response.

5.17. Epidemiological research, implementation and operational research

Evidence is the foundation on which a public health response or intervention can be planned. Just like one talks about evidence-based medicine (EBM), there is a need for developing systems and protocols for

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evidence-based public health (EBPH). A conceptual basis for EBPH and how it differs from EBM has recently been elucidated (Gerhardus *et al.*, 2008). Since criteria for decision-making at the population level differ from criteria for treating individual patients in a hospital, one cannot directly adopt the same protocols or algorithms as EBM. Therefore, there is a need to invest in the skilling of personnel to build expertise to advise the governments on what interventions should be implemented. EBPH also needs to look at what works and at what cost and what would be the most optimal intervention given the resources in a particular country. Therefore, in addition to epidemiological research methods, such as community intervention trials, there is an urgent need to plan for implementation and operational research. Funding for such an initiative needs to come from a dedicated allocation in the national and state health budgets. Without dedicated funding and the appropriate research skills, EBPH practice in India will not get due recognition and importance.

5.18. Innovation and augmenting life sciences and pharmaceutical sectors

The COVID-19 pandemic has clearly demonstrated that the governments need to invest in innovation in the implementation and strengthening of life sciences and pharmaceutical research and discovery platforms. Most countries exhibited parochial nationalistic tendencies to pander to their local constituencies, especially countries with advanced industry in these sectors. Despite the promises made by some countries to support the COVAX initiative launched by Coalition of Epidemic Preparedness Innovations (CEPI), WHO, GAVI, and UNICEF, countries that lacked production capacity could not ramp up their vaccine coverage or provide generic drugs at an affordable cost. Though today more than two-thirds of the eligible population has received at least one dose of a COVID-19 vaccine, there are huge disparities in fully vaccinated proportions. In Africa, the coverage with two doses as of March 14, 2022 is 14.17% as against 65.77% in Asia, 64.9% in Europe, 62.2% in North America, and 71.55% in South America.⁸ At country level, at the top of the vaccine coverage

⁸Coronavirus (COVID-19) Vaccinations. <https://ourworldindata.org/covid-vaccinations>.

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ladder are the UAE (95.63%), followed by Portugal (92.6%), Singapore (90.46%), Brunei (91.61%), and Malta (90.07%). At the other end are countries such as Burkina Faso (5.36%), Burundi (0.08%), Cameroon (2.99%), Chad (0.87%), Democratic Republic of Congo (0.48%), Haiti (0.93%) Madagascar (3.56%), Malawi (4.13%), Mali (4.35%), Nigeria (4.15%), Papua New Guinea (2.56%), and Sudan (5.2%). India's fully vaccinated proportion is 54.81% (see footnote 8).

In addition to life sciences and pharmaceutical agents, innovation is also required for healthcare service delivery. During COVID-19, we have seen that the initial response during the first surge in 2020 was not dependent on the strength of the health system in a country, as even the most sophisticated well-funded systems found it difficult to respond. This was the stage when all countries were overwhelmed, as there was no historical evidence to support targeted public health interventions. Though the learning curve was steep, by the end of the first quarter of 2021, a significant amount of learning from shared evidence from across the globe became available and networks and collaborations were forged. This led to more successful management of hospitalized patients and the use of drugs to prevent critical disease or mortality. The biggest game changer was the availability of effective vaccines — an innovation that can be called the greatest wonder of the modern world in 2021. This was followed up by innovations in vaccine delivery systems by triaging and prioritizing population groups that needed vaccines first. This enabled us to quickly vaccinate large numbers. Innovation in communication techniques reduced vaccine hesitancy. Innovations in digital technology smoothed the COVID-19 response, with new applications, such as tele-consultations and monitoring of caseload in the community. So, innovation was the key to success in combating COVID-19.

We now need innovative thinking, along with innovation, to reduce inequities in vaccine coverage today and availability of affordable drugs and devices in the future. Everybody knew that the pandemic would end only if people across the globe were quickly vaccinated, but innovative thought on how this could be operationalized were not on the agenda. Countries rushed to provide boosters to their population even when significant numbers were unvaccinated in most of the low- and middle-income countries. The Omicron wave infected a significant proportion of

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those who were already “boosted,” so the benefit of potent effective vaccines could have been passed on to those who did not get a single dose so that the world could have been a better place for everyone concerned.

6. Restructuring Public Health Architecture

Implementation of public health activities is a state responsibility, while policy formulation and the template for public health services is determined by the union government. Therefore, though the policy framework for restructuring public health services will be a prerogative of the union government, it does not preclude states from additional initiatives over and above the union’s recommendations and directives. Unfortunately, most states have not shown adequate fiscal prudence and therefore find it difficult to even add to the union government’s directives are, leave alone think of local initiatives.

One of the main strategic investments in restructuring public health services in India is the creation of a dedicated public health cadre. As of now, especially at the senior level, health professionals occupy public health positions without any prior skilling or experience and lack competencies that can result in successful outcomes, including visioning, planning, implementation, or monitoring. It has been opined that creation of a public health cadre will help in addressing the major health challenges in specific regions (Salunke and Lal, 2017). Such a cadre will be able to ensure multisectoral convergence that will benefit all domains of public health (Salunke and Lal, 2017).

At the policy level, many major committees (National Knowledge Commission, 2005; High Level Expert Group on Universal Health Coverage, 2012; Steering Committee for the 12th five-year plan, 2012; National Health Policy, 2017) have emphasized the need for a public health cadre (Salunke and Lal, 2017).

A public health professional is a multidimensional manager of health programs who improves the effectiveness and efficiency of health programs. Since the focus of attention for a public health professional is the quality of the health of populations, it will not be prudent to club clinical and public health activities under the responsibility ambit of the same person, as clinical health looks at an individual’s well-being while public health emphasizes population health.

Most high-income countries have made concerted efforts to invest in public health. Low- and middle-income countries, such as Sri Lanka in our immediate neighborhood, has also invested strongly in public health and this has paid rich dividends to the country. Sri Lanka's health indicators are one of the best in the South Asian region and compare favorably with many high-income countries.

A dedicated public health cadre is needed for the following reasons:

1. The training in public health of the personnel is utilized.
2. The personnel gain experience, which is optimally utilized as they move up the service ladder.
3. There is an assurance of professional progression, so the personnel are attracted to and retained in the health system.

6.1 Need for reorganization of the health system

There is an urgent need to reorganize the public health system in the country for harnessing benefits of a skilled workforce and available infrastructure for the following reasons:

- (a) The quality of delivery of healthcare services needs to be improved.
- (b) The workload of the staff in the Department of Health & Family Welfare has increased several folds in recent times. The number of national programs have increased over the years.
- (c) With increased number of programs and demands, the quality of supportive supervision has to be enhanced. With this, the restructuring can enable adequate levels of supportive supervision and provide hand-holding support to implementers in the field.
- (d) The motivation and commitment of staff improves when they have clear-cut professional pathways and career progression pathways depending on specific responsibilities.

The combination of experienced public health professionals at all levels of the state health system and the greater autonomy they have will result in speedier allocation and more effective use of resources, thus enhancing access to healthcare. Greater access implies better protection from conditions that lead to adverse health outcomes.

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A dedicated public health cadre will also be able to develop better linkages with the veterinary and agricultural scientists and strengthen the “One Health” approach, which will be critical for early detection and management of new emerging infectious diseases.

Restructuring should not lead to dismantling of the existing systems but should build on the gains of the existing infrastructure and human resources. Such disruptions have been cautioned against by others too (Salunke and Lal, 2017). This is particularly important at the sub-district levels, where innovative approaches can be used to skill the existing human resources and offer them an opportunity to join a dedicated cadre. It should be ensured that once a professional moves from a clinical to a public health cadre, they should be mandated to work in this cadre. If the cadre has to perform efficiently, a dedicated protected budget line is essential so that funds are not moved to some other program if that program suddenly needs funds. This will be demotivating for the personnel who have committed their services to the cadre.

Though a number of states have been deliberating on the need for a public health cadre, two states — Tamil Nadu and Maharashtra — have already invested in a public health cadre (Kumar *et al.*, 2016). Of these, Tamil Nadu invested in a public health cadre first and the return on this investment is discernable in the excellent improvement in the health indicators of the state (Kumar *et al.*, 2016). In addition to the states with an established public health cadre, there are states, such as West Bengal and Kerala, where there has been advances in working toward a public health cadre, while advocacy efforts have been going on in Karnataka, Madhya Pradesh, Haryana, Assam, etc. (Kumar *et al.*, 2016).

A public health cadre should be developed at three levels — block, district, and state. Some states may also wish to add a component at the divisional level. Building a public health cadre should involve a judicious mix of employing doctors with pre-existing public health qualifications and/or providing in-service public health training to existing doctors. Initially, states may wish to sponsor in-service doctors interested in joining the public health cadre to quality-assured public health training programs. In the medium and long term, it should be made a prerequisite

that doctors joining public health need to possess a relevant higher qualification, e.g., degree/diploma in public health or a master's in public health.

The states should consider adopting a comprehensive public health act to provide regulatory powers for enforcement to its functionaries.

7. Funding Public Health

In most countries, public health is funded from the government revenues, which is calculated as a proportion of GDP. This is nearly 10–15% in most high-income countries and below 5% in low- and middle-income countries. In India, this has varied between 1.5 and 3% since independence, with a decline rather than an increase over the years.

To boost spending on education, the government started collecting an education “cess” (tax) on income tax. Unfortunately, only 1% of the Indian population pays income tax. Therefore, something like a health “cess” added to the income tax will not generate the scale of revenue that can help build a viable infrastructure. Therefore, alternative funding mechanisms will have to be thought of.

Nearly all individuals below the poverty line in all the states in India are covered by either the Ayushman Bharat scheme or a state-sponsored insurance scheme, where the premium is paid by the government. There is also an urgent need to cover the other segments of the population, especially the middle-income segment when the country is committed to universal healthcare.

One way to increase the funding for public health is by earmarking a dedicated proportion of GST collections solely for developing public health services. Since everybody pays GST on products purchased, using a dedicated amount from such collections may be a solution. In this manner, the proportion of the expenditure on health as a proportion of GDP can be raised quickly, and this can provide the needed resources for supporting the growth of public health in the country.

Another option could be tax incentives for corporates or philanthropists who may contribute to public health. A similar incentive exists for income tax deductions for funds supporting research.

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8. Conclusions

There is an urgent need to scale up investment in public health to meet the SDGs and to improve the health status of the population rather than improving outcomes for a minuscule proportion of the population who can pay for services. The need has increased dramatically after the COVID-19 pandemic, as it has been realized that countries can only face the threat of pandemics and other disasters when the public health system is robust and responsive to the needs of the population.

Public health is concerned with the modalities for improving population health, preventing disease, and enhancing the quality of life of people and communities. It employs a set of interventions for assessing the health status and problems and providing assurance to populations that their health needs will be taken care of. These interventions need to be cost-effective and align with the community's perceptions and needs.

Available evidence shows that the health status indicators in India need to be improved to be on par with other countries in South Asia and other parts of the world. Out-of-pocket expenditure needs to be reduced, and financial protection should be ensured for the population to prevent catastrophic health expenditures. There also needs to be a rethinking of what health expenditures should be prioritized in the health budget and how primary healthcare can be supported substantially more than what is seen at present.

The public health system has shown tremendous gains over the past 50 years, but much more is possible as the system is working at suboptimal levels due to gaps in the functionality of the health system, especially at the sub-district level. The IPHS should be the guiding document to improve the system with appropriate investments.

Many countries have suffered from a political response to the COVID-19 pandemic instead of an evidence-based public health response. Though all countries were equally ravaged in the initial stages, countries which relied and trusted their appropriate public health professionals and agencies were able to turn things around quickly, while others who relied extensively on a political solution faced significant losses and catastrophic consequences.

The COVID-19 pandemic showed the world, and especially India, that there was a need to strengthen public health systems urgently. The trajectory of some aspects of the COVID-19 pandemic, such as mortality, could have been effectively tackled if strong public health systems were in place and governments had invested in developing these systems.

Unlike clinical health services, the return on investment in public health services takes a much longer time. Investments are needed in the public health workforce, infrastructure, service delivery modalities, monitoring and surveillance, data analytics, research, technology, and innovation.

The debate has been raging for too long, and now, it is time to take wise decisions in the backdrop of COVID-19.

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Chapter 1.6

Mental Health and the COVID-19 Pandemic

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Abstract

This chapter provides an overview of the research produced so far on the effects of the COVID-19 pandemic on mental health. A preponderance of largely observational evidence suggests that the disease hurts mental health both directly and indirectly. Direct effects include damage to the brain and nervous system, as well as psychological trauma from near-death experiences. Indirect effects operate through the fear and guilt of infecting loved ones, the loss of loved ones and major life experiences, social isolation and loneliness, school closures, job loss, and burnout from increased caretaking responsibilities. Particularly acute effects on specific groups of people, from children and adolescents to healthcare workers, are highlighted. The chapter concludes with lessons and silver linings that can help us reduce the negative effects future pandemics have on mental health.

Keywords: mental health; COVID-19; pandemic; global health

1. Introduction

The COVID-19 pandemic has ravaged the world since the end of 2019. Through waves that have hit their peaks at different times in different parts of the world, it has, as of this writing, officially killed over 5 million people. Over 280 million more people have found themselves in overburdened hospitals and makeshift care centers, in bed with fever, cough, aches, and loss of smell for days, and with long-term health issues now known as “Long COVID.” The physical trauma caused by the invisible killer has come with serious psychological damage, either as a result of neurological damage caused directly by the disease or by the emotional shock of falling deathly ill. Still others, even those never infected, faced the psychological challenges of prolonged isolation, social distancing from loved ones, loss of employment and financial struggle, disruption of schooling, the fear of unwittingly infecting those around us, and many other forms of trauma.

This chapter describes what we know so far about the mental health consequences of the pandemic and highlights lessons that citizens and policymakers alike should keep in mind for the future. As of this writing, the SARS-CoV-2 virus is continuing to spread, mutate, and ravage in countries where only a small percentage of the population has been vaccinated, as well as in those where existing vaccines provide only limited protection against new variants. As a result, the research discussed here is work that has been done essentially in real time. It will be incomplete because the pandemic is not yet over, because the rush for knowledge is almost surely resulting in errors in the analyses, and because we still do not know so much about the long-term effects of this pandemic. This chapter should thus be viewed as an effort to focus our attention on key ongoing mental health consequences of the pandemic, to remind us of the areas that require future monitoring and inquiry, and to help us prepare now for future pandemics that are likely on the horizon.

2. Direct Effects

More than two years into the COVID-19 pandemic, we are still grappling with all the ways the disease affects the human body. In addition to its attack

on the respiratory system, the virus also generates neurological and psychiatric issues that we are only beginning to understand. In the six months following a COVID-19 diagnosis, patients were 2.5 times more likely to experience their first intracranial hemorrhage, 2.3 times more likely to be diagnosed with dementia, 2.2 times more likely to receive their first diagnosis of psychosis, and 1.8 times more likely to receive their first anxiety disorder diagnosis than comparable individuals who had been afflicted with influenza in the past (Taquet *et al.*, 2021a). Another work has suggested that, although possibly confounded by socioeconomic factors, a prior diagnosis of a psychiatric disorder is a risk factor for COVID-19 (Taquet *et al.*, 2021b).

Motivated by these findings and evidence that those with severe psychiatric disorders were more likely to die from COVID-19 complications, the U.S. Centers for Disease Control and Prevention (CDC) designated mood disorder as a condition, on par with age and immunocompromising disease, that qualified individuals for a booster shot of the vaccine (Wu, 2021). Though research is nascent, there is growing understanding that the disease is having a direct effect on the mental health of those afflicted with it. There is less clarity on which aspects of the disease drive damage to our health through neurological and psychological channels.

2.1. Trauma

How much of the damage comes from the fear and uncertainty that accompanies infection, especially for those with pre-existing health issues, immunocompromised loved ones who might also have been exposed, or those who experienced hospitalization? While no study yet offers a concrete answer, we know that the effect is nonnegligible. Although lacking a proper control group, a study of those who were hospitalized in Italy for COVID-19 at the beginning of 2020, for example, found that 30.2% of the survivors were suffering from post-traumatic stress disorder (PTSD) in subsequent months (Janiri *et al.*, 2021). Those with PTSD were also more likely to report having experienced delirium or agitation during the course of their severe illness.

A study of patients in Norway concluded that “anxiety and depression might be more a consequence of the severity of initial disease and the trauma of hospitalisation, rather than a direct consequence of the viral

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infection itself” (Caspersen *et al.*, 2021). As the following sections will show, this is likely an understatement of the consequences of the viral infection itself for mental health, but existing research makes clear that the negative effects from trauma are substantial. Studies showing that areas hardest hit by the virus also experience the largest increases in depression and anxiety (Santomauro *et al.*, 2021) and others that point to declines in anxiety and depression after vaccination (Blanchflower and Bryson, 2021; Agrawal *et al.*, 2021) all provide ample evidence that fear generated by the pandemic played a key role in worsening mental health around the world.

2.2. Neurological and autoimmune issues

How much of the damage comes from the virus’s direct attack on the neurological system or from the immune system’s destructive overreaction to the virus? Here too the exact role played by this channel is unknown, but it is significant enough for researchers and doctors to call it a crisis (Belluck, 2021a). The body’s inflammatory response to the virus has been shown to affect the brain, causing symptoms that are often seen in patients with concussions or traumatic brain injuries: headaches, dizziness, muscle pain, blurred vision, and difficulty focusing, among others (Graham *et al.*, 2021).

Ongoing research suggests that those who lose their sense of smell, especially for a prolonged period of time, are more likely to experience some of the same issues with memory and cognition as patients who are later diagnosed with Alzheimer’s disease (Hamilton, 2021). And a study of patients treated at University Hospital Heidelberg in Germany found that only 22.9% of patients were completely symptom-free after 12 months, with neurocognitive issues with fatigue, concentration, sleep, and speech among the most common persistent symptoms (Seefle *et al.*, 2021).

2.3. “Long COVID”

A testament to the complexities of the virus and our immune response, these so-called Long COVID symptoms are not only present in those who have a severe course of the disease. A seemingly mild bout of COVID-19 could still result in these neurological issues weeks and even months later

(Belluck 2021a, b; Graham *et al.*, 2021). Declines in episodic memory and rapid vigilance that last up to six months and declines in white matter that last for at least seven weeks are among the issues measured by scientists so far (Fernández-Castañeda *et al.*, 2022; Zhao *et al.*, 2022).

The full long-run implications of these phenomena will not be known for some time, but the sheer fact that almost 300 million people worldwide have had COVID-19 as of this writing suggests that the prognosis of a mental health crisis is accurate. Even if the significant decline in mental well-being facing millions of adults lasts weeks or months and does not increase the probability of mental health issues down the road, the costs to quality of life and economic productivity will be high. Worrisome still is research suggesting that children are not immune from Long COVID and its particular damage to mental health: 11–15% of infected children are estimated to be struggling with these long-run consequences after surviving the virus (Belluck, 2021c). All of these findings underscore that the direct effects of infection are not limited to severe flu-like symptoms and loss of taste and smell. How the virus affects the neurological system and brain function will debilitate a large percentage of infected children and adults for weeks, months, and, for some, even years.

Sans immediate public health attention to these quietly destructive mental health consequences of COVID-19, countries around the world are likely to be faced with rising healthcare costs, as well as losses in productivity, educational attainment, and economic growth (e.g., Layard and Clark, 2014; Ridley *et al.*, 2020). The world was already facing a mental health crisis prior to the pandemic, so calls for addressing the root causes of poor mental health and for expanding the provision of mental healthcare must now be heeded all the more (Santomauro *et al.*, 2021; Case and Deaton, 2021). While we do not know whether the next pandemic will be caused by a virus that also attacks our mental health directly, the investments we make today in our mental health and in service delivery should be considered part of an effort to improve pandemic preparedness around the world (Dong and Bouey, 2020). As the following section on COVID-19's indirect effects on mental health will show, these investments will protect not just those who are infected but also those who suffer from the inevitable loss, fear, disruption, and isolation with which pandemics hammer societies.

3. Indirect Effects

Despite significant technological advancements, the pandemic caught the world largely unprepared for a virus as deadly, debilitating, and transmissible as COVID-19. As a result, many of the measures employed by countries to gain control over the crisis were blunt instruments, such as lockdowns, closures, and bans. A lack of pandemic preparedness, poor transparency about the nature of the crisis from China, the World Health Organization (WHO), and subsequently other governments, and the genuine seriousness of the threat led to measures that created significant disruptions across societies. All but one US public school district was closed by the end of March, 2020 (Zviedrite *et al.*, 2021), and UNESCO estimates that over 100 million additional children will fall below the minimum proficiency level in reading as a result of the pandemic (UNESCO, 2021; Hanushek and Woessmann, 2020). Over 90% of countries saw disruptions in their ability to provide essential health services (WHO, 2021). India had an unemployment rate as high as 21.7% in May 2020 as a result of lockdowns (Beniwal, 2021), and the global supply chain experienced crushing backlogs across goods and modes of trade (e.g., Barman *et al.*, 2021; Pak *et al.*, 2020; Young *et al.*, 2021). Concerns about the virus necessitated social distancing of at least six feet, generating a sudden wall between friends, families, and social organization, while making large indoor social gatherings untenable altogether.

The forced and phobia-driven separation of people that resulted from the pandemic has likely taken a significant toll on mental health around the world. Prior work has shown a strong interplay between isolation, loneliness, and social connections and mental health issues, such as depression, anxiety, and suicidality. Social beings by nature, people derive meaning from quality social connections and activities, which in and of themselves act as protection against many mental health issues. With the onset of the pandemic, this key human characteristic became dangerous, with the fear and guilt of unwittingly infecting loved ones likely driving up anxiety rates (e.g., Rich and Hida, 2021). The omnipresence of the virus means that no studies currently exist or are likely to come out that provide a convincing causal analysis of the effects of the fear, isolation, and social and economic hardship caused by the pandemic on mental

health. However, the observational evidence, coupled with prior research in psychology, paints an overwhelming picture of how COVID-19 has indirectly attacked mental health around the world.

3.1. Children and adolescents

Children and adolescents around the world have seen among the largest negative effects on mental health from disruptions caused by the pandemic. Research from the beginning of the pandemic hinted that fear, uncertainty, and loss would hit young people hardest, showing that perceived personal health risks from COVID-19 declined with age (Bordalo *et al.*, 2020). One hypothesis for this finding is that the sudden salience of death and disease was a particular shock to the young, for whom such issues are normally many years away and therefore normally peripheral. While this psychological effect does mean that most young people overestimate the risk they face from contracting COVID-19 (the unknown long-run consequences of Long COVID notwithstanding), it also means that young people's mental health is heavily strained by fear.

Fear of the virus has not been contained to fear for one's own health. On average, a COVID-19 death in the US leaves approximately nine bereaved family members, many of whom are children (Verdery *et al.*, 2020). With childhood trauma known to have pernicious long-run effects on development and well-being in adulthood, bereavement and social support are thus especially important for children at this time. The nature of the pandemic — in the way it has forced the cancelation of social events, closed schools, increased fear of infection from hospital visits, and forced isolation and separation — is making it harder to access exactly these forms of care.

Loss has also manifested itself in many ways for children and adolescents. Loss of time with family and loved ones, loss of existing and unformed friendships, loss of knowledge and social skills developed in school, the inability to mark major milestones such as graduations and convocations, and the difficulty of developing romantic relationships all took a toll on young people's mental health during the pandemic. Already alarming before the pandemic, the prevalence rates of serious depression and anxiety symptoms have about doubled during the pandemic, to 25%

and 20% of all children, respectively (Racine *et al.*, 2021). Suicidality has also increased in children, with US emergency department visits for mental health issues increasing by 31% in 2020 relative to 2019 for those aged 12–17 (Yard *et al.*, 2021). UNICEF and International Labor Organization surveys have found similar trends around the world (Kwai and Peltier, 2021). Such prevalence rates have prompted the American Academy of Pediatrics and its partner organizations to declare a national emergency in child and adolescent mental health in October 2021 (Mayne *et al.*, 2021; AAP *et al.*, 2021).

As many children have spent more time at home with their parents, behavioral issues and intergenerational conflict have become a growing concern. Schools have seen an increase in bullying and are in demand for counseling services upon opening up (Vestal, 2021). A study in Italy and Spain found significant increases in irritability and restlessness among children aged 3–18, with quarantine increasing tensions within the family (Orgilés *et al.*, 2020). Physical exercise has also declined, likely contributing to the behavioral issues being documented (Giuntella *et al.*, 2020). More time at home has also meant more potential for tension and conflict between children and parents. A 2021 CDC survey of high school students revealed that 55.1% of them experiencing emotional abuse and 11.3% experiencing physical abuse while in isolation at home (CDC, 2022). These rates were 2–4 times those recorded in a similar survey in 2013.

On top of the direct neurological effects experienced by children afflicted with COVID-19 (LaRovere *et al.*, 2021), the disruptions and isolation caused by the pandemic have created unprecedented mental health struggles for millions of children around the world. This crisis demands the attention of parents, healthcare professionals, educators, and researchers, with an eye toward mitigating short-run pain and minimizing negative long-run consequences. The sheer scale of the problem will require increased investments in the personnel and services available to children. Given how important quality friendships and social interactions are for mental health, using every public health tool at our disposal to bring children back to in-person learning and interaction will be an important step toward ameliorating this mental health crisis.

3.2. College and graduate students

College and graduate students have also experienced large negative shocks to their mental health. Already in a bad state (e.g., Evans *et al.*, 2018; Bolotnyy *et al.*, 2021), college and graduate student mental health has continued to worsen (e.g., Narita *et al.*, 2021; Eisenberg, 2020). Studies consistently point to loneliness and isolation worsened by the pandemic as key drivers of these trends, with the effects particularly pronounced for students, like those in their first year of study, who had unformed or weak ties to their college community when the pandemic hit. One study of first-year college students, for example, found that the prevalence of moderate–severe anxiety rose from 18.1% just before the pandemic to 25.3% in the first four months of the pandemic (Fruehwirth *et al.*, 2021). Moderate–severe depression symptoms rose from 21.5% to 31.7%. Consistent with other work, the study found women and LGBTQ students to be particularly affected (Dench *et al.*, 2020; Browning *et al.*, 2021). Additional work has shown that students who were mandated to leave campus in the middle of the pandemic were also disproportionately affected, reporting more grief, loneliness, and PTSD symptoms (Conrad *et al.*, 2021). While distance and online learning have undoubtedly smoothed the educational shock from the pandemic, they have come with their own sources of stress and have not been an adequate substitute for in-person social connections (Ramachandran, 2021).

3.3. Adults

Adults have not been immune from the pandemic’s toll on mental health. As childcare, schools, and colleges closed and children returned home, parents have seen significant declines in their own mental health (Moyer, 2022). Alcohol use and abuse have increased, resulting in increases in liver disease, transplants for alcohol-associated liver disease, and emergency department visits for alcohol withdrawal (Julien *et al.*, 2021; White *et al.*, 2022). In the US, alcohol-related deaths increased by 25% between 2019 and 2020, outpacing the increase in all-cause mortality of 16.6% (White *et al.*, 2022). Job loss, housing insecurity, school closures, and overwhelming caretaking responsibilities have compounded the mental

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health strain from isolation, loneliness, uncertainty, and the loss of loved ones.

Dubbed “Long Social Distancing,” a phenomenon is also emerging where 10–15% of the adult US population consistently say that they plan to maintain social distancing and will not return to pre-COVID-19 activities once the pandemic has ended (Barrero *et al.*, 2021). Time will tell just how persistent the pandemic disruption will be to social behavior, in the US and elsewhere, but preliminary data suggest that the effects might be significant. As with the increase in working from home, the net effect on adult mental health from spending more time at home and with close family and friends rather than in restaurants or in large social gatherings will also become clear with time. We do know, though, that in the midst of a shock like the COVID-19 pandemic, our coping mechanisms, along with our existing social structures and social safety nets, are maladaptive. Short-run damage to mental health is significant.

3.4. Healthcare and essential professionals

Healthcare professionals, especially those just starting out in their careers, have seen work dynamics that were notoriously bad for mental health get even worse (Schwenk *et al.*, 2010; De Kock *et al.*, 2021). Trauma from constant exposure to the virus and to death, along with the exhaustion of long hours and overwhelmed facilities, has resulted in significant increases in depression, anxiety, and other mental health issues among nurses, doctors, and other frontline workers (De Kock *et al.*, 2021). Moral injury has also been a factor driving mental distress, a product of having to make life-or-death decisions that violate one’s moral or ethical code (Greenberg *et al.*, 2020).

Others who have also been on the front lines, as essential workers keeping society’s basic functions going, have been among the professionals most likely to experience burnout and to fall victim to the virus’s attack on their physical and mental health (Wolfe *et al.*, 2021). The Great Resignation, where millions of people in the US and other advanced economies are leaving their jobs, is likely one manifestation of the burnout and mental health strain caused by the pandemic.

3.5. The elderly

The effect on the mental health of the elderly has been pronounced. Facing the greatest direct risk from COVID-19, the elderly have also experienced isolation from family and friends at levels higher than any other demographic. Nursing homes became epicenters of transmission in many countries, while also shutting out friends and family from regular visits and worsening patient mental health (Levere *et al.*, 2021). With less oversight and more isolation came an increase in the incidence of abuse, with elder abuse in the US rising from 10% before the pandemic to 20% during the pandemic (Chang and Levy, 2021). In Turkey, lockdowns and the consequent declines in mobility significantly worsened the mental health of those over the age of 65 (Altindag *et al.*, 2022).

Still, one encouraging sign has been the fact that the mental health of the elderly has worsened much less than the mental health of young people. Researchers have pointed to a phenomenon called “crisis competence,” the resilience and hope that comes from many years of overcoming difficulties and shocks (Leland, 2021). One, thus, has reason to hope that increased resilience across demographic groups will be one of the silver linings of the pandemic and, along with other tools of preparedness, will serve us well in future pandemics.

4. Conclusion and Silver Linings

The pandemic has exacerbated existing issues across societies, making painfully clear where our vulnerabilities lie. A large, and growing, literature has given us a wealth of information on the direct and indirect effects of a deadly pandemic on people across countries and demographics. While crucial mistakes, from the prolonged closure of schools to the inadequacy of psychiatric resources, have resulted in intense psychological pain, they have also provided us with a roadmap for the next inevitable pandemic. Learning the right lessons, encouraging innovation, and emphasizing preparedness for future direct and indirect negative consequences of pandemics will be crucial for policymakers and citizens alike.

More reliable systems of childcare and senior care, for example, should now be considered critical aspects of pandemic preparedness.

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Innovations in ventilation systems and investments in reliable testing infrastructure should continue in order to ensure that in-person activities, especially educational ones, can continue with minimal disruption. Doctor shortages must be addressed, and psychiatric hospitals should be more agile and able to avoid the kinds of bed shortages we have seen in this pandemic. Mental health support for frontline and essential workers must also be made a priority.

Encouragingly, we are already seeing the kinds of social attitudes and innovation that should lessen the negative mental health consequences of future pandemics. Telehealth treatments and mental health services are booming, enabling more people to receive care and firming up an infrastructure for the rapid deployment of care in circumstances where leaving the home is ill-advised. While the effectiveness of many digital mental health interventions is still an open question, digital Cognitive Behavioral Therapy (CBT) initiatives appear to be working well and further research promises to give us more effective tools (Lehtimaki *et al.*, 2021). We are also seeing innovations in remote work technologies that are increasing the flexibility that many have in their lives. Coupled with an increased appreciation for family and quality social connections, more balanced lifestyles could lead to significant improvements in mental health.

Crises like the COVID-19 pandemic, while deeply traumatic and deadly, can be moments of recognition and change, of silver lining that make societies more resilient and better prepared for future shocks. If we follow the rigorous research while resisting temptations to move on and procrastinate on essential investments, we will ensure that we see less psychological suffering in the future.

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Part II

Innovation

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Chapter 2.1

The Role of Seroprevalence in Evidence for Policy-Making During COVID-19

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Abstract

Seroprevalence studies estimate the share of population that has been infected by a virus and can provide valuable information for policymakers as they respond to a pandemic, especially in its early stages. The spread of COVID-19 globally, as measured by seroprevalence studies, has been considerably more extensive than what is perceived from the case numbers reported by governments worldwide. The inability to incorporate evidence from such studies in a timely manner contributed to missed opportunities in the policy response to COVID-19. In this chapter, we discuss the potential role that seroprevalence studies can play

in providing timely evidence for policy-making as well as the factors that lead to impediments in the adoption of such evidence. Building on our own experience with conducting some of the earliest seroprevalence studies in India, we describe the challenges of policy-making in crises and of incorporating uncertainty into this process, and we also examine some of the technical challenges in conducting these studies. In addition, we discuss policy responses that could be informed by evidence from such studies and highlight the lessons learned that might inform efforts in a future crisis, should it ever occur.

Keywords: seroprevalence; pandemics; global health

1. Background

At the time of this writing, in April 2022, the COVID-19 pandemic had already changed course a few times, with the emergence of new variants with vastly varying patterns of spread and severity. These new variants have made this pandemic an unprecedented challenge in almost unimaginable ways. As we write, a third wave of COVID-19, driven by the Omicron variant of SARS-CoV-2, has started after an astonishingly rapid spread among populations around the world. While the severity of the Omicron variant was considerably lower relative to Delta, which was the primary concern in the summer of 2021, the pace of its spread revealed potential threats to health systems around the world when faced with such variants (Ahmad *et al.*, 2021). Looking back at the past two years, despite incredible scientific achievements in the response to COVID-19 (who could have imagined a suite of vaccines being developed and deployed — even if imperfectly — in such a short time), the public policy response to the pandemic and its variants appears to suffer from an inability to rely on evidence.

This chapter focuses specifically on evidence-based policy during COVID-19 and the role of seroprevalence studies. In many parts of the world today, although clearly not all, it is almost too late to conduct seroprevalence studies — at least in part because a significant share of the population in those parts has already been infected with one or more

variants of SARS-CoV-2 and vaccination campaigns have been rolling out globally. Despite huge inequalities in the availability of vaccines globally, with some of the poorest parts of the world unable to procure vaccine supplies, the largest vaccination campaign in human history has already delivered over 9.5 billion doses across 1,840 countries (Bloomberg News, 2021). (As a result, large proportions of the population in some parts of the world now are seropositive. In Delhi, India, for instance, the results from the sixth round of seroprevalence surveys released by the government showed that over 90% of the population that had not been vaccinated had antibodies (among those vaccinated, over 97% had antibodies) (Press Trust of India, 2021).

Although seroprevalence studies might not inform public policy response to COVID-19 in 2022 during the ongoing Omicron wave in many countries, such evidence can be very valuable in countries with low levels of vaccination or low levels of exposure to previous waves of COVID-19. Furthermore, it is essential to document and review what we have learned from the attempts to generate evidence on the spread of a novel disease. Governments worldwide varied dramatically in their willingness to rely on evidence to inform policy — *this was particularly stark in the case of seroprevalence studies*. Some governments actively promoted studies to generate evidence on seroprevalence, while others scuttled such efforts. In contrast to thousands of seroprevalence studies that have been conducted in specific populations over the last two years (for instance, among cancer patients and among nurses, doctors, and other professionals), relatively fewer studies present population-based estimates, although this strand of the literature continues to grow rapidly. A recent (2021) meta-analysis of seroprevalence studies worldwide, for instance, identified 47 studies conducted until August 2020 (essentially covering the first wave of COVID-19) (Rostami *et al.*, 2021). Other reviews of seroprevalence studies have found a vast variation in the number of studies included, ranging from 10 to 338 studies, depending on the eligibility criteria employed in the selection in such reviews (Ioannidis, 2021b). Overall, seroprevalence studies have documented consistently that the spread of COVID-19 has been considerably more extensive than what is perceived from the case numbers reported by governments worldwide.

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We start with an overview of the challenges for policy-making in crises and the importance of evidence in the context of uncertainty. We then present a summary of research on COVID-19 seroprevalence, including some of the technical challenges in conducting serological testing in survey research and the implications of uncertainty that plagues decision-making during a pandemic. We then focus attention on policy responses that evidence from seroprevalence could inform (*or more accurately could have informed*) during various phases of the pandemic — including mobility, reopening, and vaccine policy. The chapter concludes with a section on lessons learned that might inform efforts in a similar future crisis, should it ever occur.

2. Evidence, Uncertainty, and Policy-making

In early 2020, when reports of a new coronavirus infection started trickling in from Wuhan in China, there was very little evidence to inform public policy responses globally (Zhou *et al.*, 2020). The Centers for Disease Control in the US confirmed the first nontravel-related cases of COVID-19 on 26 and 28 February (Jorden *et al.*, 2020). India, meanwhile, had detected its initial cases in January in Kerala — a state which had one of the most effective public health systems in the country (Andrews *et al.*, 2020). By early March, 22 new cases were reported, many of them among tourists. While officially reported cases of COVID-19 (based on confirmed RT-PCR tests) were still slowly rising, India (like many other countries at the time) imposed increasing restrictions on international travel. On March 24, the Prime Minister of India announced one of the strictest domestic lockdowns in the world. The prime minister announced that, according to experts whom they had consulted with at the time, a lockdown of 21 days would be necessary to stem the transmission. Despite the harsh lockdowns (and possibly abetted by the same lockdowns which forced people into small, enclosed spaces for extended periods of time), India's reported case numbers grew dramatically.

By mid-June 2020, India ranked fourth globally in the number of *officially reported* cases and eighth in the number of *reported* deaths (Malani *et al.*, 2020). Subsequent seroprevalence studies (including those

conducted by us together with colleagues) showed that COVID-19 had traveled far and wide in India. The migration of low-wage workers, who lost incomes in urban centers due to the lockdown, brought large numbers of COVID-19-positive (and infectious) individuals to rural areas, contributing to the epidemic across the country (Malani *et al.*, 2020). For instance, among the 1.6 million workers who returned to Bihar from all over the country during May 4–June 10, the state tested 2.7% of the returnees. At that time, the prevalence of COVID-19 among the returning workers ranged from 6.3% to 11%, as seen in Table 1, reproduced from Malani *et al.* (2020).

As reported by Malani *et al.* (2020), there were large differences between the test positivity rates that were being reported by states and the positivity rate among workers from those states, with worker samples being on average more than 2 percentage points higher. This early study had one of the first indications that poorer communities in urban areas in India might have had higher levels of COVID-19 exposure in the first wave (which was consistent with the evidence from a number of subsequent seroprevalence studies in India).

It was expected that the official statistics on the number of cases would be an underestimate based on (a) the government's data showing that the vast majority of cases in India at the time were asymptomatic and (b) the severe restrictions being imposed at the time on access to tests that were initially necessary due to unavailability of reagents and tests. The stunning and consistent finding from the seroprevalence studies (see next section for details on numbers), however, was the vast gap between the cases reported in official statistics and the estimated number of people who had been infected based on population samples.

2.1 Uncertainty in number of cases

A critical policy challenge that faced India (and many countries) at the time was the lack of evidence to inform policy decisions. In the absence of seroprevalence studies in the early months of COVID-19, governments had to make preemptive decisions based on the number of reported confirmed cases (based on molecular testing that rely on PCR) or on the

Table 1. COVID test positivity rates among workers returning to Bihar, May–June 2020

State	(1) May 4–May 21			(2) May 22–May 31			(3) June 1–June 10			Change from Period (1) to (2)	Change from Period (2) to (3)		
	Returning Worker			Returning Worker			Returning Worker						
	Positive Rate	95% CI	Positive Rate	95% CI	Positive Rate	95% CI	Positive Rate	95% CI	Positive Rate				
Andhra Pradesh	1.1%	[1.1%, 2.1%]	5.9%	[2.5%, 9.3%]	3.1%	[1.1%, 6.1%]	4.8%		-2.8%				
Chandigarh	2.8%	[4.4%, 5.2%]	8.2%	[2.7%, 13.6%]	5.5%	[−5.0%, 11.5%]	5.4%		-2.7%				
Chhattisgarh	3.8%	[1.2%, 6.3%]	4.0%	[−3.7%, 11.7%]	0.0%	[0%, 0%]	0.2%		-4.0%				
Delhi	13.3%	[11.9%, 14.7%]	16.1%	[14.3%, 17.9%]	12.9%	[11.6%, 14.2%]	2.8%		-3.2%				
Gujarat	5.8%	[5%, 6.5%]	8.9%	[7.7%, 10.1%]	9.1%	[8%, 10.2%]	3.2%		0.2%				
Haryana	7.0%	[5.7%, 4.4%]	10.8%	[8.6%, 13.1%]	12.1%	[10.1%, 14%]	3.8%		1.2%				
Jammu and Kashmir	7.7%	[−2.6%, 17.9%]	4.5%	[−1.6%, 10.7%]	6.3%	[.3%, 12.4%]	-3.1%		1.8%				
Jharkhand	1.2%	[0%, 2.4%]	4.2%	[.9%, 7.5%]	6.3%	[1.8%, 10.8%]	3.0%		2.1%				
Karnataka	1.7%	[1.8%, 2.7%]	7.5%	[4.4%, 10.6%]	4.6%	[2.8%, 6.5%]	5.8%		-2.9%				
Madhya Pradesh	3.2%	[1.4%, 5.1%]	4.3%	[.9%, 7.6%]	3.3%	[−4%, 6.9%]	1.0%		-1.0%				

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Maharashtra	9.6%	[8.6%, 10.6%]	18.1%	[16.3%, 19.9%]	9.4%	[8.2%, 10.5%]	8.5%	-8.8%
Odisha	2.1%	[1%, 4.1%]	1.2%	[-1.1%, 3.4%]	0.0%	[0%, 0%]	-0.9%	-1.2%
Punjab	2.1%	[1.2%, 6.7%]	4.8%	[3.1%, 6.4%]	4.9%	[3.4%, 6.4%]	2.7%	0.1%
Rajasthan	3.1%	[2.2%, 3.9%]	5.0%	[3.1%, 6.9%]	4.8%	[2.8%, 6.9%]	1.9%	-0.1%
Tamil Nadu	4.5%	[2.2%, 6.7%]	6.9%	[3.9%, 9.9%]	3.7%	[2.3%, 5.1%]	2.5%	-3.2%
Telangana	4.7%	[3.6%, 5.6%]	5.5%	[2.6%, 8.5%]	1.9%	[-2%, 4%]	0.8%	-3.6%
Uttar Pradesh	4.2%	[3.6%, 5.1%]	14.5%	[11.5%, 17.4%]	10.2%	[7.8%, 12.6%]	10.3%	-4.3%
Uttarakhand	0.0%	[0%, 0%]	5.2%	[.5%, 10.2%]	2.0%	[-1.8%, 5.8%]	5.2%	-3.2%
West Bengal	6.8%	[5%, 8.5%]	4.3%	[2.1%, 6.5%]	3.8%	[2%, 5.6%]	-2.5%	0.5%
Total	6.3%	[5.9%, 6.6%]	11.0%	[10.4%, 11.6%]	8.8%	[8.3%, 9.3%]	4.7%	-2.2%

Notes. Only states from which at least 25 returning workers were tested by Bihar in each period are included in this table. Prevalence is defined as the number of confirmed positive tests divided by the total number of workers tested during the relevant time period. 95% CIs the 95% confidence interval using a normal approximation to a binomial distribution. Asterisks(*)/**/*** are used to mark statistical significance (at the 10/5/1% level).

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projected estimates from models. Both these inputs have significant challenges that lead to significant uncertainty.

The total number of reported cases is a function of the number of people who are infected, the share of them who are symptomatic, the subset that arrive at the health center, implementation of the PCR test including how well the swab was collected, the quality of labs, and administrative challenges (including delays) in reporting, as well as incentives faced by ground-level staff to accurately report these numbers. In addition, structural bottlenecks, such as lack of adequate testing centers across the states in India, further reduced the number of cases tested and reported. During the pandemic lockdown, individuals who developed symptoms had little incentive or motivation to get themselves tested voluntarily — governments were attempting to seal the residences of those who tested positive or send individuals to ill-equipped COVID-19 isolation centers. The subsequent expansion of testing capacity also resulted in global challenges with the availability of reagents and supplies, in addition to staffing during the pandemic (Peeling *et al.*, 2021). Consequently, laboratories across India were also unable to correctly implement protocols to save scarce resources early in the epidemic, such as pooled testing, even after the government's approval of the process. It is also important to note that as the epidemic becomes more widespread, there are no gains from implementing such pooled testing, so this was only a factor in the early stages of the epidemic. For example, at 20% positivity and pool sizes of five, almost every pool would need to be deconvoluted and retested, thus eliminating all efficiency gains from pooling.

2.2 Uncertainty in modeling

In the absence of accurate and timely data on cases or the spread of COVID-19, the debates on mitigation versus suppression of the pandemic relied almost entirely on modeling estimates. Without reliable evidence, the challenge of model specification and estimation of a fast-moving pandemic is almost insurmountable. The results from modeling to inform policy solutions rely entirely on the assumptions made by the model and the (limited) availability of data to estimate parameters that

are then used to build projections. The main problem with such projections is that they often yield an estimate that is taken at face value by policymakers who do not fully understand the amount of uncertainty that surrounds the estimate (Manski, 2020). The problems with data quality and testing mentioned in the previous section contribute directly to the uncertainty in any prediction of the time path of an epidemic (Manski and Molinari, 2021). The uncertainty of the models used to drive policy often conflicts with the certainty that policymakers (and public health advocates) project in making the case for strict suppression strategies. Over time, especially during the first wave, this discrepancy contributed to debates that contrasted public health goals and the catastrophic economic effects of non-pharmaceutical interventions and lockdowns in particular (Schneider, 2020). The vast incongruence between the predictions of competing models, along with the failure of predictions from many models, led to spirited debates in the media, in addition to an overall distrust in mathematical models. At the root of such debates and distrust was the underlying uncertainty that was inherent in every model that stemmed from problems of data and model specification (Holmdahl and Buckee, 2020).

2.3 Policy-making in the time of COVID-19 uncertainty

The challenge faced by a policymaker in the face of a new devastating pandemic has parallels to the “goalkeeper’s dilemma” in soccer. The pandemic, like the soccer ball kicked from the penalty line and traveling rapidly — so fast that if the goalkeeper waits to observe the motion of the ball and then decide which way to jump, it is too late already. But standing still runs the risk of being perceived as not having taken a chance at saving the goal. Policymakers, during the unprecedented, fast-moving pandemic, also faced a similar challenge. There was little information or certainty to predict which way the pandemic would move, but waiting to decide runs the risk of huge political consequences and the lost opportunity to have taken any step when it was possible. It is thus not surprising that

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governments decided to act when the pandemic broke. They really had no choice but to act and act decisively.

More complex decision-making challenges arrived as time went by and information overload became an issue. The uncertainty about all the moving parts of the pandemic and the resulting uncertainty in the model predictions complicated the policymakers' decision. Instead of picking one model that the decision-maker "knew" was the right one, the appropriate strategy was one that needed the policymaker to acknowledge that each model had its own brand of uncertainty and that it was necessary to consider various (often competing) recommendations in making decisions. Berger *et al.* present an excellent summary of rational policy-making during a pandemic, including the challenges of communication of uncertainty faced at every step of the way (Berger *et al.*, 2021). A central and recurring argument in the discussion in this section has been the need to acknowledge the uncertainty and to communicate that uncertainty both by academics to policymakers and by policymakers to the general public.

What role do seroprevalence studies have to play in this debate? These studies, as we explain in the following section, can provide timely and critical input about the state of the epidemic. Such evidence can be used to not only address the data problems mentioned in this section but also to inform policy decisions, as governments responded to the early stages of COVID-19.

3. Seroprevalence Studies

3.1 What is seroprevalence?

Seroprevalence, in a nutshell, refers to the prevalence of antibodies (of a specific type) in a population. Prevalence, in epidemiologic terms, is defined as the proportion of a population who have a specific characteristic in a given time period. The "sero" in seroprevalence comes from the word "serology," which refers to the study of blood serum — the clear fluid that remains when blood clots. The serum contains antibodies, which are proteins that the body has produced in its fight against foreign proteins, such as a virus. While the study of serology can include a broad set of topics

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related to serum, antibodies, and immunology in general, seroprevalence studies typically refer to the studies in a population that seek to estimate the proportion that has antibodies of a certain type in a given time period.

The objective of prevalence studies, in general, is to measure the proportion of the population that is currently or was previously infected by an illness. While prevalence studies technically include seroprevalence studies, the former term typically refers to studies that estimate the fraction of a population that currently has an illness (in this case, infected with the COVID-19 virus). Since infection leads to antibodies and antibodies remain in the blood stream even after the infection has been cleared, seroprevalence studies measure past infection. Since past infection confers immunity, a key advantage of seroprevalence studies over current prevalence studies is that they measure immunity in the population better than (current) prevalence studies. Furthermore, by testing for antibodies from past infections, serological tests can detect both clinical as well as sub-clinical infections retrospectively (Tang *et al.*, 2020). This is especially salient in the case of COVID-19, where a very large share of those who were infected were asymptomatic.

A seroprevalence study focused on antibodies to the SARS-CoV-2 virus faces unique challenges that are driven by the biology of the virus and by the nature of the pandemic, as well as policy responses to the pandemic. Because antibodies are produced by the body in response to proteins (antigens) in the virus, it is critical to recognize that any given virus could have multiple antigen proteins. For instance, the SARS-CoV-2 antigens could include spike protein (S), including the receptor-binding (RBD), S1 and S2 domains, and the whole protein (S1 + S2), nucleocapsid protein (NP), and the papain-like protease (PLpro) (de Assis *et al.*, 2021). Some of these proteins, however, such as the nucleocapsid protein, are shared by a number of viruses in the coronavirus family that includes the SARS-CoV-2, MERS-CoV, as well as viruses that cause the common cold (Centers for Disease Control, 2020). Consequently, different serology studies might yield differing results based on the type of antibody they might be focused on and also the stage of the underlying epidemic. At low levels of *true* prevalence, relying on tests that are more susceptible to cross-reactivity runs the risk of high false positive rates.

Although evidence from early in the pandemic — as early as the summer of 2020 — clearly pointed toward the high proportion of asymptomatic infections, governments in most parts of the world focused on the number of cases that showed up in health centers with symptoms and tested positive. This led to a predictable gross underestimation of the spread of the pandemic, which in turn led to further missteps in policy responses.

Our study, conducted on six slum communities and six non-slum communities in Mumbai in July 2020, found seroprevalence estimates in excess of 55% in slums and over 12% in non-slum areas (Malani *et al.*, 2021). This study had tested for presence of IgG antibodies to the nucleocapsid protein of the SARS-CoV-2 virus and yielded evidence suggesting dramatic asymptomatic transmission in community settings in India at the time. Our subsequent study, conducted in a sample drawn from a representative population across the state of Karnataka in June–August 2020, revealed that 44% (95% CI, 40.0–48.2%) of rural populations and 54% (95% CI, 48.4–59.2%) of urban population in Karnataka already had IgG antibodies to the RBD spike protein (Mohanan *et al.*, 2021). Estimates of the seroprevalence found in our study in Karnataka suggested that the officially reported case numbers were approximately 10% of the total number of persons infected at the time.

Similarly, Malani *et al.* (2021) report findings from a study jointly conducted with the state government of Tamil Nadu, where seroprevalence estimates from samples collected in October–November 2020 were roughly 36 times the number of confirmed cases reported by then (Malani *et al.*, 2021). In contrast, seroprevalence estimates conducted in nationwide surveys around the same time yielded significantly lower estimates (Murhekar *et al.*, 2021). Reviews of seroprevalence studies from across multiple countries show similarly large variation in the range of estimates (Ioannidis, 2021b). The differences in estimates of seroprevalence seen across regional- or state-level studies versus national studies are often driven by a number of factors, including sample size, data analysis method, and measurements including choice of tests, and response rates (Franceschi *et al.*, 2021).

This gap, between what the seroprevalence studies and the government testing data showed, was a product of bad sampling design. If the

government had conducted PCR tests on a representative population and not just on individuals who showed up at healthcare facilities, they would have learned the extent of asymptomatic infection. As to why the government did not test a representative sample, it is unclear whether because they did not want to alarm the population about asymptomatic spread or because testing policies were developed by clinicians rather than public health experts, and clinicians tend to focus on diagnosing people in a healthcare setting. Lack of test kits could not be the explanation because the government conducted a tremendous number of tests. Nor is the lack of a representative sample the explanation; we were able to constitute representative samples, often with the aid of state governments, for our seroprevalence studies.

It is unsurprising that seroprevalence studies conducted in India yielded varying results; these studies were, after all, conducted among different populations, using different sampling designs, conducted by different research groups (government versus academic), and using different testing methods and sample collection methods. These varying factors point to not only the critical challenges faced by teams conducting COVID-19 seroprevalence research (especially in India) but also to sources of uncertainty in the estimates that such studies might produce. For instance, the heterogeneity across population subgroups presents a significant challenge. As our own research within a large city (Mumbai) and across a large state (Karnataka) found, there are large differences across urban and rural as well as slum and non-slum populations. Similarly, logistical challenges abounded, with strict mobility restrictions in place during lockdown, impeding the teams' ability to conduct fieldwork and data collection. In addition to logistics, it is a daunting challenge to find the human resources needed to conduct fieldwork that includes collecting potentially COVID-19-positive specimens.

4. Potential for Policies Based on Seroprevalence Data in Pandemic Response

The data from seroprevalence studies, despite limitations, can be a very valuable part of the policy response toolkit. In theory, with appropriate level of government support, it is possible to collect random samples from

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carefully constructed representative population samples on a regular basis. Ideally, in a fast-moving epidemic, governments could rely on a sustained seroprevalence study to understand the dynamics of the disease in various parts of the population.

Early in the pandemic, the notion of immunity passports found considerable attention stemming from the hope that detectable antibodies would confer immunity to subsequent infection (Phelan, 2020). Furthermore, there was hope that if such immunity might have in fact been conferred, seroprevalence data could form the basis of easing restrictions on distancing, mobility, and return to work. There was a chance to mitigate the devastating consequences to the global economy with data from serological testing if such immunity might have persisted. However, as we now know, during the time of the Omicron wave, the emergence of variants of SARS-CoV-2 turned much of that hope into wishful thinking — neither vaccines nor prior infections provided full immunity to subsequent infection from Omicron (although the severity from the latter, relative to Delta or Alpha variant, appears to be significantly lower) (Ahmad *et al.*, 2021).

Another area for potential policy innovation was around the prioritization of vaccination. Especially after the first wave of the pandemic had started subsiding and prior to the emergence of Delta, there was a window when some governments had actively started making plans for vaccinating their population. India had this unique window as well — despite the many missteps during the first wave and surges of COVID-19 cases across the country, India had largely escaped the proverbial bullet in 2020 rather fortuitously. The apparently (relatively) low number of deaths in India during the first wave of the epidemic was due to the epidemic having been relatively concentrated among the urban poor (as seen in our seroprevalence study in Mumbai, for instance) and also due to factors such as survivorship bias and age structure. In fact, Malani and Ramachandran (2021) find evidence of large increases in excess deaths in the older age groups (Malani and Ramachandran, 2021). Part of the reason why India didn't see large aggregate numbers of deaths in the first wave was that the wave largely hit urban poor areas, where the population pyramid had relatively few individuals in that older age group.

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In early 2021, as vaccines started being manufactured and distributed, India announced its ambitious immunization drive (Srivastava, 2021). The lack of availability of adequate number of vaccines to be supplied nationally presented a potential opportunity to rely on data from seroprevalence to target sections of the population with low levels of seroprevalence. An alternative policy that would have been more targeted was to test individuals for antibodies and delay vaccination for those who were seropositive. However, this policy was not pursued by the government for a number of reasons ranging from ethical to political. Because poorer populations were more likely to have contracted the illness in the first wave, this policy would have vaccinated higher-income segments before lower-income ones.

One area where some local governments were able to use seroprevalence data effectively in the policy response was related to local mobility and lockdown decisions. The city of Mumbai, for instance, had supported and facilitated some of the long-standing seroprevalence studies in India. Because the city administration had also appointed team members to the research team as collaborators, findings from these studies were available to the administration in real time and were used by the city in making policy decisions. Similarly, city governments, such as Delhi, also had commissioned multiple seroprevalence studies that provided timely information to help the administration make decisions about release from lockdown.

5. Hindsight is 2020

The events of 2020 point to many lessons that can be learned from the efforts to conduct seroprevalence studies as well as from efforts to inform policy. It is true that hindsight is 2020 and even literally so in this case. However, it is also true that some of the pain and suffering caused during the second wave of Delta in the summer of 2021 could have been avoided if it were not for the hubris of policymakers in India (Krishnan, 2022). Seroprevalence data from 2020 from a range of sources had shown that although a large share of the Indian population had antibodies, these were not uniformly distributed. Older individuals living in apartments

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(or non-slum areas), who had largely escaped the first wave, were at the highest risk. The hubris of policymakers that led them to ignore these findings entirely and encourage large cultural and religious gatherings based on political priorities was one of the driving factors for the large number of deaths in India in 2021.

In the current state of the pandemic, with Omicron having outcompeted Delta in most parts of the world, conducting seroprevalence studies is no longer a priority. However, countries that did not experience large waves of infections during 2020 and 2021 and also have low rates of vaccination might find seroprevalence studies to be very informative in estimating the share of population already infected and the share at risk. This approach is distinct from alternative approaches, such as conducting wastewater surveillance. The latter is a highly cost-effective way to collect information on the concentration of the virus in fecal matter in sewage systems, allowing researchers and policymakers to track community prevalence by proxy (Paterson and Durrheim, 2022; McMahan *et al.*, 2021). While wastewater surveillance can provide a quick read on the current level of infection and changes over time, seroprevalence studies can provide a cumulative view of the total share of the population that has antibodies from having been exposed in the past. These approaches are not substitutes and should ideally be used in parallel to inform policy-making.

Employing evidence from seroprevalence for policy-making in a pandemic is sadly not without its own share of challenges. Seroprevalence studies showing large numbers of people being infected could lead to panic and fear among members of the public and, in turn, could drive governments to claim that such studies are flawed and not consistent with the true numbers released officially. Ironically, over time, the same numbers indicating high levels of seroprevalence can lead to hubris, with governments claiming credit for managing the epidemic well. Indeed, this is what happened in India — by the time the first wave had passed, the central government and various state governments had started celebrating how well their policy responses had managed the pandemic and encouraged large mass gatherings and political rallies (Krishnan, 2022). Instead, what was (and is) necessary is clear science communication. Only by clearly communicating key lessons from such studies to the general public

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can strategies featuring non-pharmaceutical interventions succeed (especially those requiring large-scale social adoption).

A second challenge for seroprevalence studies is that, while antibodies linger even after an infection has been cleared, the concentration of antibodies decline over time. But this decline does not mean that a person loses immunity because t-cells remember what antibodies to produce if the virus — or a close mutation — returns. As a result, even seroprevalence studies conducted after a period of exposure may underestimate the degree of prior infection and population-level immunity to the virus. This means that even with seroprevalence studies, governments might underestimate the spread of infection early in the pandemic and underestimate protection against future risk later in an epidemic.

More broadly, governments need to build capacity to gather intelligence about infections to protect against future pandemics. This requires maintaining names and contact information for population-representative samples that are kept updated with periodic population health surveys. This requires labs with the ability to develop tests and to process those test samples. This also requires being open to even imperfect tests and having statisticians on hand to make statistical adjustments for imperfect tests. Finally, it means having the capacity to quickly report prevalence and seroprevalence results to policymakers and the public. It is critical to learn from the missteps in the COVID-19 response so that when faced with new pandemics in the future, governments will be equipped to leverage valuable intelligence from seroprevalence surveys.

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Chapter 2.2

COVID-19 and Intellectual Property Issues

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Abstract

The aim of this chapter is to explore the stakes at play in relation to the proposed COVID-19 IP waiver, assess what other factors affect access to COVID-19 vaccines, diagnostics, and therapeutics worldwide, and briefly discuss initiatives taken at different levels to improve access to countries lagging behind. With 458 million cases of COVID-19

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diagnosed worldwide and more than 6 million deaths by March 2022, the question is whether lifting intellectual property rights (IPRs) restrictions is the solution to unlock the sanitary crisis in developing countries. Policymakers need to be attentive to the impact and role of patents as incentive mechanism and be open to address patent system reforms, but attention should also be paid to IP-related voluntary initiatives and the advantages conferred by other factors, such as first mover advantages, reliance on prior scientific advances, market exclusivity provided by regulatory approvals, advanced purchase agreements, “vaccine nationalism,” data exclusivity from clinical trials, and know-how protected by secrecy. A global approach and more empirical evidence are needed to address the inequalities derived from this pandemic in order to be prepared for the next.

Keywords: intellectual property rights; pharmaceuticals; pandemics; global health

1. Introduction

In early October 2020, 10 months after the World Health Organization (WHO) declared COVID-19 a pandemic, India and South Africa called for a temporary waiver of intellectual property rights (IPRs) provisions in trade agreements to enable World Trade Organization (WTO) members to not grant or enforce intellectual property rights related to COVID-19 products and technologies.² Shortly after its publication, the IP waiver received strong support from humanitarian organizations worldwide and the governments of a large number of low- and middle-income countries, and by the end of 2021, more than 100 WTO members had supported the waiver, including China and the United States (US), as well as the WHO. There were also some opponents, including the United Kingdom, Germany, Switzerland, and Norway; the European Union (EU) published a statement with caveats and alternatives in June

² [https://www.europarl.europa.eu/RegData/etudes/ATAG/2021/690649/EPRS_ATA\(2021\)690649_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/ATAG/2021/690649/EPRS_ATA(2021)690649_EN.pdf) (Accessed March 15, 2022).

202, and high-level negotiations at the WTO were still ongoing as of March 2022.

The aim of this chapter is to explore the stakes at play in relation to the proposed COVID-19 IP waiver, assess what other factors affect access to COVID-19 vaccines, diagnostics, and therapeutics worldwide, and briefly discuss initiatives taken at different levels to improve access to countries lagging behind. With 458 million cases of COVID-19 diagnosed worldwide and more than 6 million deaths by March 2022,³ the question is whether lifting IPR restrictions is the solution to unlock the sanitary crisis in developing countries.

Opponents to the IP waiver claim that IPRs are not the blocking point for access to tests, therapeutics, and vaccines but rather supply and distribution of raw materials, know-how, and manufacturing and distribution capacity. They also claim that the waiver and other compulsory measures could discourage innovation to fight future pandemics and other diseases and that priority should be given to voluntary initiatives, such as licensing agreements, non-enforcement pledges, and investments in infrastructure, which will be more effective.

Moreover, defenders of the IP waiver argue that a health crisis of this magnitude needs radical solutions to provide access to solutions to billions of people. The few companies selling COVID-19 vaccines and therapeutics are obtaining extraordinary profits thanks to the advanced purchase agreements (APAs) signed with governments in developed countries, and developing countries do not have enough resources to have equal access. They also argue that exclusive rights conferred by patents to vaccine manufacturers prevent production at a larger scale and more competitive pricing schemes. A final claim from this perspective is that solutions for COVID-19 have only been possible because of decades of research funded with public money, and in addition, governments have provided further support since early 2022 and APAs which have reduced risks for pharmaceutical companies by securing markets.

In this context, high-level discussions on the IP waiver linger at the WTO while the situation gradually improves in developed countries, but

³<https://www.statista.com/topics/5994/the-coronavirus-disease-covid-19-outbreak/#dossierKeyfigures> (Accessed March 15, 2022).

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inequalities persist with respect to developing countries.⁴ In October 2021, only 3% of people in low-income countries had been vaccinated. Six months later, in March 2022, this share had increased to 14% of people in low-income countries but was still insufficient.⁵ The international COVAX facility, which relies on donations from developing countries, has helped deliver more than 1.4 billion vaccines to 144 countries that could not afford them.⁶

The remainder of the chapter is organized as follows. Section 2 reviews briefly economic studies on patents and innovation. Section 3 provides some relevant information about the COVID-19 pandemic. Section 4 presents information on the IPRs protecting COVID-19 technologies, with a subsection focusing on mRNA vaccines. Section 5 describes the history of the IP waiver proposal. Section 6 is dedicated to other initiatives, and Section 7 concludes by setting out some lessons for future pandemics.

2. Patents and Innovation

Patents give temporary exclusion rights to the producer of the innovative knowledge, who may decide to grant others permission to use the protected knowledge via licensing or transfer agreements and sue for infringement those who use the knowledge without permission. In the extreme case, when there are no substitute products in the market, the owner of the intellectual property can recover the R&D costs by charging monopoly prices. But in exchange for this exclusive right, inventors must describe their invention in the patent application so that a person skilled in the art could replicate it. During the patent term, others may be able to use the knowledge for research purposes under the so-called research or experimental use exemption in patent law (OECD, 2006), and once the

⁴ There are also some differences in vaccine rates in developed countries due to hesitancy and reluctance to get vaccinated, but the highest inequalities are between low-income and high-income countries.

⁵ <https://ourworldindata.org/covid-vaccinations> (Accessed October 30, 2021 and March 15, 2022).

⁶ <https://www.gavi.org/covax-vaccine-roll-out>.

patent has expired, the knowledge would be in the public domain for others to use it with no restriction.

The classic economic argument behind the rationale for patents is the public good character of innovative knowledge (Arrow, 1962; Nordhaus, 1969; Romer, 1990). According to this view, the non-rival and non-excludable features of public goods cause a market failure because of the impossibility to recoup R&D costs at market prices when invention becomes available because once known, rivals could replicate the invention “at no additional costs,” preventing the inventor from obtaining competitive rents in the market.

This view of patents has been contested, however, by noting that the investment needed to replicate inventions can be very high in some technology fields, including pharma and medical technologies, where having the know-how and complementary assets is very relevant. In these sectors, as pointed out by Cohen and Levinthal (1989, 1990), firms need to invest in order to build absorptive capacity to identify, assimilate, and exploit knowledge, and the cost of such capacity building invalidates the argument that imitation can happen costlessly.

Several scholars have proposed reforms of the patent system, arguing that it exceed its benefits for a large number of inventions and technology fields (e.g., Nelson and Winter, 1982; Bester and Petrakis, 1998; Hellwig and Irmens, 2000; Quah, 2002). Encaoua *et al.* (2006) provide insight from economic theory to guide such reforms, concluding that not all inventions deserve the same treatment and the patent system should not be based on one-size-fits-all principles. They posit that when imitation is costly and first mover advantages are important, patents may not be the best means to protect inventions and argue that an optimal patent system could be based on a menu of different degrees of patent protection, allowing self-selection by inventors. Indeed, patents are more important in the pharmaceutical sector than in other sectors, as several surveys and data on number of patent filings by sector confirm. In other sectors, firms report other protection means, such as market lead or complementary assets, as more relevant than patents (Mansfield, 1986; Levin *et al.*, 1987; Cohen *et al.*, 2000; Sampat, 2018).

If patents are a policy instrument, policymakers need to be attentive to their impact and their role as incentive mechanism and be open to

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address patent system reforms (Jaffe and Lerner, 2004; Encaoua *et al.*, 2006; Bessen and Meurer, 2008). Ouellette and Williams (2020) identify the following three failures of the current patent system: (i) insufficient knowledge disclosure, (ii) lack of transparency about ownership, and (iii) heterogeneity in effective patent terms due to differences across sectors and within sectors (e.g., because of different length of clinical trials across pharma segments).

As put by Edith Penrose, “If national patent laws did not exist, it would be difficult to make a conclusive case for introducing them; but the fact that they do exist shifts the burden of proof and it is equally difficult to make a really conclusive case for abolishing them” (Penrose, 1951). A similar argument was put forward by Machlup: “If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it” (Machlup, 1958). The key in Machlup’s argument is the call to improve knowledge about the impact of patents and the need to do it before taking any action in order to avoid undesired effects.

Along these lines, in a recent literature review, Sampat (2018) concludes that patents are unlikely to have a strong effect on high social value investments without significant markets, as research to date points to heterogeneous effects of patents on cumulative innovation. In addition, he argues that “understanding the costs of patent protection better is particularly important since, as Machlup himself noted, the important question is not whether patents are good for innovation but whether they get us the innovation we want at lower cost than other alternative S&T policy instruments (e.g. prizes or public funding).”

Boldrin and Levine (2008, 2013) made a strong case against the “intellectual monopolies” conferred by patents and copyright and have argued that the only solution was to simply abolish the IPR systems as we know them.

Trade-Related Aspects of Intellectual Property Rights (TRIPs) is the international legal agreement between all the member nations of the WTO, which came into force in 1995 and establishes minimum standards for IP national regulations, with exceptions for least developed countries.

Before TRIPS, the rule in many countries was to treat pharmaceutical products differently by excluding them from patentability in national patent laws.⁷ This was the case for Spain until 1992 (Martinez, 2009) and France until (Clavier, 1959). As put by Clavier (2010): “the idea that medicines are not patentable on public health grounds can be strongly supported as long as there is no efficient pharmaceutical industry, because patenting or denying patent protection for drug inventions reveals the economic policy orientation of a state.” Indeed, countries tend to refuse patent protection to pharmaceutical products when they do not have the innovative capability to develop their own inventions or when the country is specialized in the production of generic drugs. When a country does not grant patent protection, replicating the invention based on information from patents granted elsewhere cannot be qualified as infringement (Clavier, 2010).

Lerner (2002) analyzed the changes in the strength of patent protection in 60 countries over 150 years and found that “wealthier nations are more likely to have patent systems, to allow patentees a longer time to put their patents into practice and to ratify treaties assuring equal treatment of other nations.”

Only one country seems to have ever abolished its patent system for a few years: the Netherlands. The Netherlands fully abolished patents in all technology fields for a few years, more precisely for four decades in the 19th century, between 1869 and 1912. As explained by van Gompel (2019), “the decision to abolish patents was not made overnight, but took roughly thirteen years. Indeed, the Dutch legislator acted consciously and cautiously not to upset international affairs. However, as it expected other states to follow suit, it was confident that its international relations would not be hurt (...) One reason why the Netherlands restored patents in 1912 was the international pressure to that effect by parties to the 1883 Paris Convention for the Protection of Industrial Property, to which the Netherlands was one of the first signatories.”

⁷The WTO TRIPS agreement requires patents to be available for any invention, product, or process in all fields of technology in signatory countries, although it includes some special provisions for developing countries.

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Would countries ever agree to suspend patents related to COVID-19 for a given period of time? As observed by the Netherlands in the 19th century, such a measure would make sense if taken collectively by all countries. In the meantime, individual motivations, social pressure, ongoing negotiation, as well as the threat of compulsory licensing are triggering voluntary measures by patent owners. Abi-Younes *et al.* (2020) hold that “the first best solution would be for private actors to act responsibly by providing a broad and affordable access to tests, drugs, and vaccines. Government intervention is certainly an option to consider — if only because the threat of compulsory licensing encourages patent holders to act responsibly.”

3. The COVID-19 Pandemic

It is not the first time that patent system reforms are urged, claiming that unlocking patented knowledge would guarantee access to medicines at affordable prices. But the COVID-19 pandemic is different from previous health crises, above all because of its global scope, number of infections, deaths, and rapid propagation. The response from scientific institutions, firms, and governments has also been record-breaking: enormous amounts of public funding devoted to finding solutions, moved fast to rely on collaboration and open science, rapid diffusion of knowledge to society, clinical trials and vaccine production at unprecedent speed, and APAs signed by governments worldwide for vaccine deployment only a few months after the outbreak.

In early 2020, it was hard to imagine that only a few months after the official declaration of the pandemic, vaccines would be available and approved by regulatory agencies. Two years later, almost all the adult population in developed countries had received at least one dose of a COVID-19 vaccine, but what many had been warning about since the first vaccines were approved has proven to be true: Economic and development disparities have led to *vaccine inequity* across countries. According to official data gathered by Our World in Data (Mathieu *et al.*, 2021), as of March 15, 2022, 63.8% of the world population has received at least one dose of a COVID-19 vaccine (Figure 1): 10.94 billion doses have been administered globally, but only 14% of people in low-income countries have received at least one dose, compared to 58% in

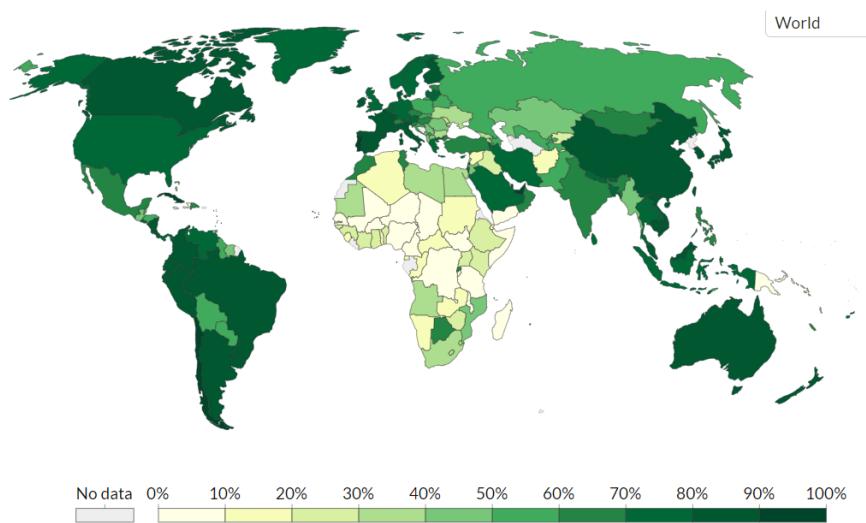


Figure 1. Share of people who received at least one dose of COVID-19 by March 15, 2022.

Note: Total number of people who received at least one vaccine dose divided by the total population of the country.

Source: Official data collated by Our World in Data. Retrieved March 15, 2022, <https://ourworldindata.org/covid-vaccinations>.

lower-middle-income, 81% in upper-middle-income, and 79% in high-income countries.⁸

Public support for pharma companies during the pandemic has taken many forms, with all of them going in the direction of reducing risks. As argued by Frank *et al.* (2021): “the government essentially removed the bulk of traditional industry risks related to vaccine development: (a) scientific failures, (b) failures to demonstrate safety and efficacy, (c) manufacturing risks; and (d) market risks related to low demand.”

⁸As reported at <https://ourworldindata.org/covid-vaccinations> (March 15, 2022). To compare with the situation six months earlier, 49% of the world population had received at least one dose of a COVID-19 vaccine by October 30, 2021, and 7.04 billion doses had been administered globally, but only 3.6% of people in low-income countries had received at least one dose, as reported at <https://ourworldindata.org/covid-vaccinations> (Accessed October 31, 2021).

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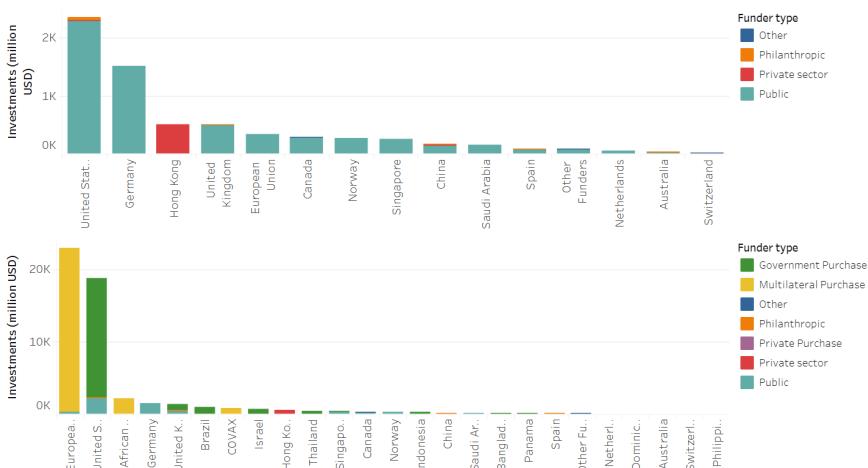


Figure 2. (Color online) Source of COVID-19 vaccine R&D investments, by source country, funder type, and type of investments by March 15, 2022.

Source: Global Health Centre (2021), COVID-19 Vaccines R&D Investments. Graduate Institute of International and Development Studies. Retrieved March 15, 2021, from: knowledgeportalia.org/.

Figure 2 shows that the US and Germany are by far the largest investors in vaccine R&D, and public funding represents 90.69% of the USD 6.6 billion tracked. Data include APAs, as these were made before there was certainty in safety and efficacy of the vaccines and could be understood as an additional incentive that reduces business risk in the R&D stage. When considering APAs, the US and the EU account for the majority of the funding: USD 41.6 billion of the USD 52 billion tracked.⁹

Success rates are low, and even for those who achieve regulatory approval, the degree of effectiveness of vaccines differs, so the higher the number of active research lines, the more the likelihood of finding better vaccines and treatments (Azoulay and Jones, 2020). The rapid response from developed countries has only been possible because of decades of previous research funded largely with public funds, the efforts from pharma companies and hospitals to do the clinical trials and to produce and distribute the vaccines faster than ever, and the commitment from the

⁹knowledgeportalia.org/covid19-r-d-funding.

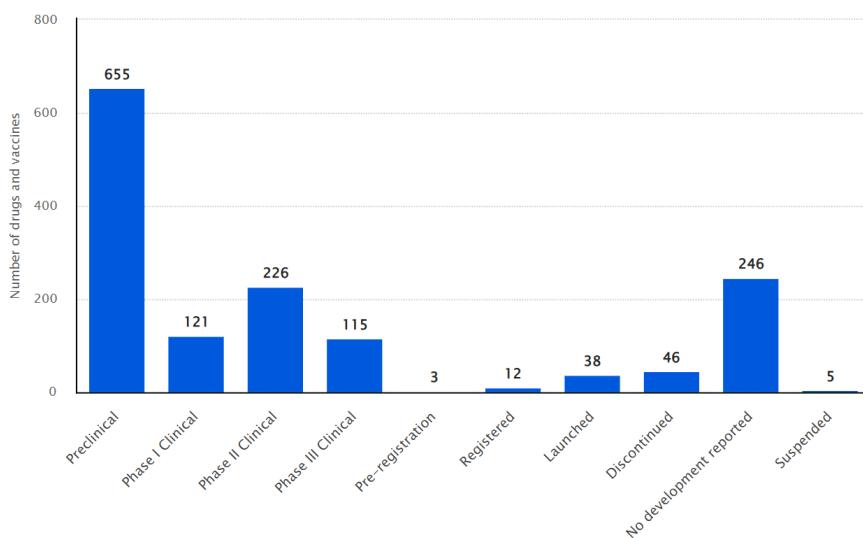
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Figure 3. Number of coronavirus (COVID-19) drugs and vaccines in development worldwide as of March 11, 2022, by phase.

Source: Pharma Intelligence (Pharmaprojects), as reported by Statista. Retrieved March 11, 2022, from: <https://www.statista.com/statistics/1119060/coronavirus-drugs-in-development-by-phase-worldwide/>.

governments that signed APAs for their deployment, when the vaccines were still in the pipeline.

Public research funding prior to the pandemic has been key to the development of the messenger ribonucleic acid (mRNA), a technology that teaches cells to create proteins that will trigger immune responses, and has made possible the Pfizer/BioNTech and Moderna vaccines. Decades of research at universities and public research organizations have had a strong role in the research leading to the development of the COVID-19 vaccines currently in the market and others in progress.¹⁰

The WHO landscape of novel coronavirus candidate vaccine development reported 149 vaccines in clinical development and 195 in preclinical development, as of March 15, 2022.¹¹ Beyond vaccines, when

¹⁰<https://www.nature.com/articles/d41586-021-02483-w>.

¹¹<https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>.

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COVID-19-related drugs are also included, the number of ongoing initiatives is much larger (Figure 3).

The stakes are huge when the target is the world population, 7.9 billion people by the end of 2021,¹² and more so when the market can be secured with APAs from governments that reduce risks for leading firms. In this context, early movers can obtain very substantial profits. Pfizer made almost USD 7 billion in COVID-19 vaccine sales in 2021, with more than 3 billion doses of the Pfizer/BioNTech vaccine manufactured in the year.¹³

The members of ActionAid, a federation of humanitarian initiatives, with headquarters in South Africa, defending the IP waiver, claim that the profit margins obtained by vaccine manufacturers are excessive and difficult to justify given the large amount of public support received.¹⁴

Information on profit margins and prices is very difficult to obtain, as not all arrangements are reported and those reported tend to lack basic information, such as number of doses and price per dose, or terms and conditions, such as timelines and liability. According to the Global Health Center of the Graduate Institute Geneva reports (on its website called Knowledge Portalia) that price estimates are unavailable in their database gathering information from public sources for about 63% of the confirmed purchase agreements.¹⁵ Transparency about prices agreed in APAs paid

¹²<https://ourworldindata.org/world-population-growth#population-of-the-world-today>.

¹³<https://www.theguardian.com/business/2022/feb/08/pfizer-covid-vaccine-pill-profits-sales>.

¹⁴“Moderna, BioNTech, and Pfizer are reaping astronomical and unconscionable profits due to their monopolies of mRNA covid vaccines — upwards of 69% profit margins in the case of Moderna and BioNTech (...) Thanks to their patent monopolies for successful vaccines against the coronavirus, development of which was supported by \$100 billion in public funding from taxpayers in the US, Germany, and other countries, the three corporations earned more than \$26 billion in revenue in the first half of the year, at least two-thirds of it as pure profit in the case of Moderna and BioNTech. The Alliance also estimates that the three corporations are over-charging, pricing vaccines by as much as \$41 billion above the estimated cost of production.”(<https://actionaid.org/news/2021/pharmaceutical-companies-reaping-immoral-profits-covid-vaccines-yet-paying-low-tax-rates>)

¹⁵<https://www.knowledgeportalia.org/covid19-vaccine-arrangements> (Accessed March 15, 2022).

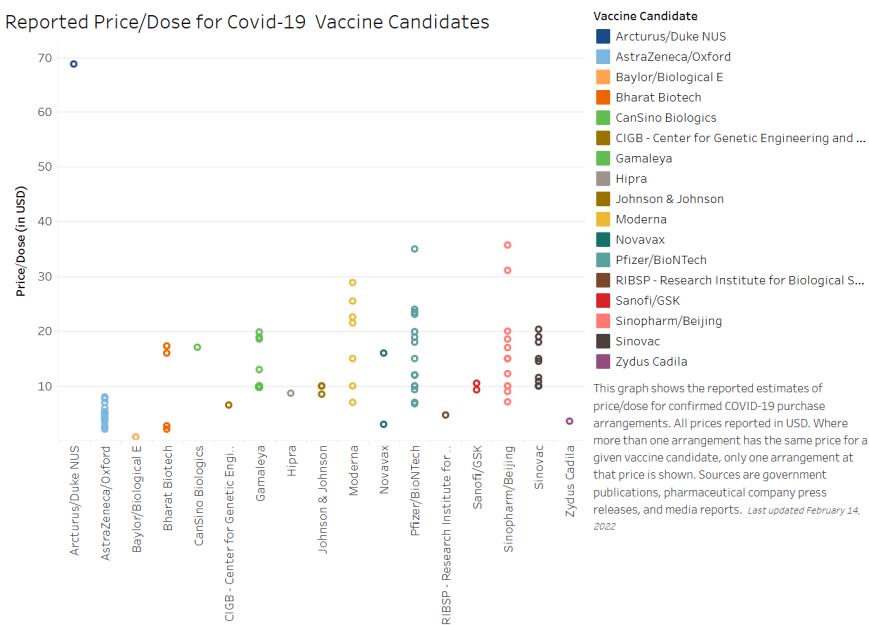


Figure 4. (Color online) Reported price/dose for COVID-19 vaccine candidates by February 14, 2022.

Source: Global Health Centre. (2021). COVID-19 Vaccine Purchases and Manufacturing Agreements. Graduate Institute of International and Development Studies. Retrieved from: www.knowledgeportalia.org/ (Accessed March 15, 2022).

with public funds should be the rule, especially during a pandemic. The reported prices per dose and the number of doses purchased by vaccine manufacturers, as reported by the Graduate Institute Geneva in February 2022, are shown in Figures 4 and 5, respectively.

The fact that there are so many manufacturers with vaccine candidates who have signed APAs with different countries worldwide indicates that no single firm holds a *monopoly* over COVID-19 vaccines in the market. In addition, the large number of clinical trials in progress confirms that there will probably be even more alternative vaccines to choose from in the future, provided they get regulatory approval.

However, even if approved, there is also competition between vaccines in terms of safety, effectiveness, and capacity to adapt to new variants of the virus. The vaccines relying on the mRNA technology seem to

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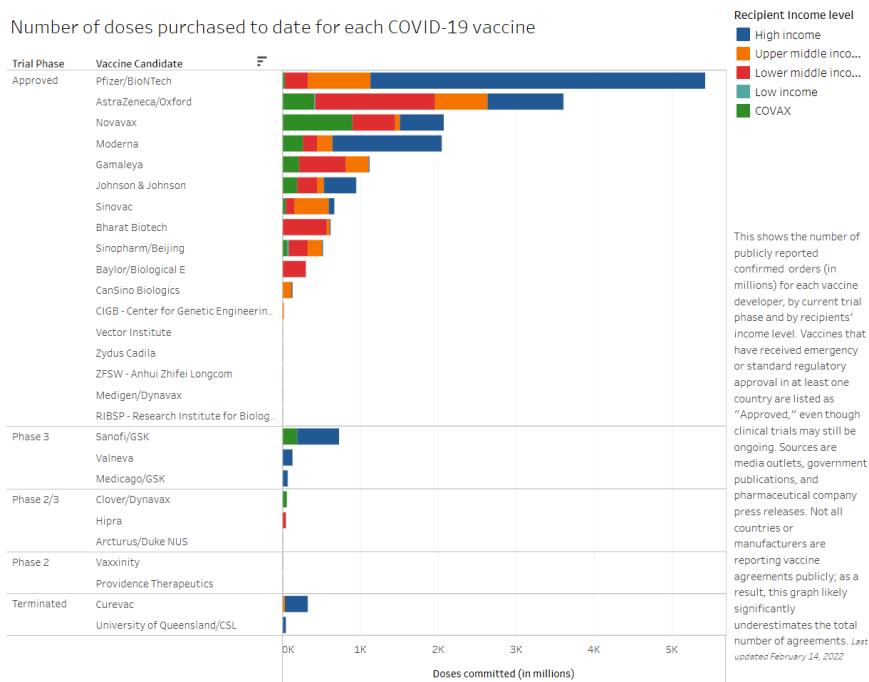


Figure 5. (Color online) Number of doses purchased for each COVID-19 vaccine as of February 14, 2022.

Source: Global Health Centre. (2021). COVID-19 Vaccine Purchases and Manufacturing Agreements. Graduate Institute of International and Development Studies. Retrieved from: www.knowledgeportalia.org/ (Accessed March 15, 2022).

be winning the race in those three dimensions, and Moderna and the joint venture between Pfizer and BioNTech have a competitive advantage on the COVID-19 mRNA vaccines, as they were the first to produce them. They believed in the technology and invested earlier and more than others. This first mover advantage enabled them to secure APAs and test the effects of their vaccines on the population, which allowed them to accumulate know-how and experience to improve their vaccines with further research.

Evidence of the importance of market lead in the vaccine race was Sanofi's abandonment of the development of their own COVID-19 vaccine based on mRNA technology. On September 28, 2021, Sanofi announced that it had abandoned the development of its COVID-19

mRNA vaccine, despite positive progress, acknowledging that it was too late to be useful when rivals BioNTech/Pfizer and Moderna had already captured the market.¹⁶ The company said it would continue to develop another COVID-19 vaccine, based on a more traditional manufacturing technique with GlaxoSmithKline, using recombinant protein molecule to deliver the antigen.¹⁷ Sanofi did not have an mRNA technology platform of its own in 2020, when the pandemic started, but had signed a cooperation agreement with the mRNA therapeutics company Translate Bio in 2018 (acquired by Sanofi in August 2021).¹⁸ The company declared that it will not have its own COVID-19 mRNA vaccine but will focus efforts on the application of mRNA to other diseases, including cancer.¹⁹

4. Intellectual Property Rights on COVID-19 Technologies

The debate on IPR issues related to COVID-19 often focuses on vaccines, but prevention, contention, and treatment innovations occur in many different fields, from 3-D printing technologies to sensors or artificial intelligence. It is difficult to draw the line between COVID-19-related technologies and the rest in order to distinguish those protecting essential knowledge from others. Tietze *et al.* (2020) referred to the COVID-19 essential knowledge as “crisis-critical technologies,” making a distinction that reminds of a well-known problem in telecommunications where procedures to declare standard essential patents are well established and patent pools with fair, reasonable, and nondiscriminatory licensing practices are the norm.

In addition, most of the time, analysts and the media concentrate on patents, and patents related to COVID-19 vaccines to be more precise, but

¹⁶ <https://reliefweb.int/report/world/msf-urges-sanofi-hand-over-abandoned-mrna-vaccine-candidate-who-mrna-vaccine-tech>.

¹⁷ <https://www.ft.com/content/22ec6b9f-d007-41a9-8ab9-a76d17c73a3f>.

¹⁸ <https://www.sanofi.com/en/media-room/press-releases/2021/2021-08-03-07-00-00-2273307>.

¹⁹ <https://www.connexionfrance.com/French-news/French-pharmaceutical-company-Sanofi-stops-work-on-French-Covid-vaccine-as-it-is-no-longer-needed>.

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there is a wide range of IPRs protecting COVID-19 technologies, from copyright to industrial design, without forgetting industrial secrets covering know-how. The lack of comprehensive information on other IPRs and the higher stakes and visibility of patents often leads to focus on patents and very often on patents related to vaccines.

Identifying what patents are relevant to fight against COVID-19 is not an easy task. First of all, because patent information comes with a delay and since patent applications are published 18 months after filing and the virus was discovered at the end of 2019 and its first sequence was publicly available in January 2020, many COVID-19-specific patents will only start to become public in 2021–2022. Second, as argued by Jefferson *et al.* (2020), because “virtually all the strategies being used to develop interventions will be based on existing technologies and platforms, and for these legal rights and practical use know-how must be dealt with. Also, the close relationship between the current pandemic virus and previous outbreaks of coronavirus disease will illuminate and inform actions being taken now, by improved practices and public health measures.”

Several patent offices²⁰ and information providers²¹ have tried to improve the transparency of COVID-19-related inventions by aggregating data with predefined keyword search strategies and visualization of

²⁰Two examples of patent offices with dedicated websites to COVID-19 resources are the European Patent Office (EPO) and the US Patent and Trademark Office (USPTO). The EPO provides search scripts for patent applications related to COVID-19 on its website: “EPO patent examiners and data analysts have compiled until now about 300 data sets to support the important work of clinicians, scientists and engineers. Arranged into four broad themes and updated regularly, charts show which countries have the most patent filings and which applicants and inventors are most prolific in the relevant fields.” The four themes are: (i) vaccines and therapeutics, (ii) diagnostics and analytics, (iii) informatics, and (iv) technologies for the new normal. See <https://www.epo.org/news-events/in-focus/fighting-coronavirus.html>. The USPTO has a website called USPTO COVID-19 response resource center available at <https://www.uspto.gov/coronavirus/uspto-covid-19-response-resource-center>.

²¹Two examples of bibliometric information providers with freely available data on COVID-19 are Lens.org and Digital Science. Lens.org has a website dedicated to Sars-CoV-2: navigating the information overload, available at <https://www.lens.org/lens/report/view/SARS-CoV-2-Navigating-information-overload-with-Lensorg/1584/page/1583>. Digital Science has a website with COVID-19 resources, available at <https://www.dimensions.ai/covid19/>.

pre-calculated data in specific reports. Some of these strategies focus on relevant technologies for COVID-19 vaccines with no time limit in order to capture all patents covering all related knowledge (e.g., mRNA), whereas others focus on the specific coronavirus that triggered the pandemic, Sars-Cov-2, and the name given to the disease caused by the virus, COVID-19, which is by definition limited to a period of time starting in early 2020.

Based on the latter, Figure 6 shows the number of filings having keywords related to COVID-19 or Sars-Cov-2 in the full text by jurisdiction and for priority years 2020–2021, as reported in March 2022 in the Dimensions.ai web application, based on official information from patent offices.²²

By far, the patent office that has received the highest number of filings on COVID-19 inventions is China (more than 11,598 patents and utility models), followed by WIPO via the International Patent Cooperation Treaty (PCT) patent filings (5,373), the US (2,907), and Korea (1,324). Among the European jurisdictions, Germany (430) and Spain (421) stand out, together with the EPO (434), ahead of Japan (420), Taiwan (415), and Australia (319). This country-wise distribution reflects efforts of domestic universities, public research institutions and companies to find solutions to fight COVID-19, but also the importance of these jurisdictions for foreign inventions. It also reveals that efforts have been widespread, as the list of countries with at least one COVID-19 related patent filing in their territory is much longer than what is shown in the figure, which is limited to the top 20 jurisdictions.

International PCT patent filings have 30 months to choose the countries for national entries, so the number of COVID-19 foreign patent filings in low and middle-income countries without domestic patents will likely increase in the future, more so if the patent owners from more developed countries want to open manufacturing plants in those territories or enter into licensing agreements with local producers.

The latter refers to the most recent patents, but many of the patents protecting relevant COVID-19 technologies today were filed many years

²²Keywords used include “2019-nCoV,” “COVID-19,” “SARS-CoV-2,” “HCoV-2019,” “hcov,” “NCOVID-19,” “severe acute respiratory syndrome coronavirus 2,” “severe acute respiratory syndrome corona virus 2,” “coronavirus disease 2019,” and “coronavirus & Wuhan/China/novel.”

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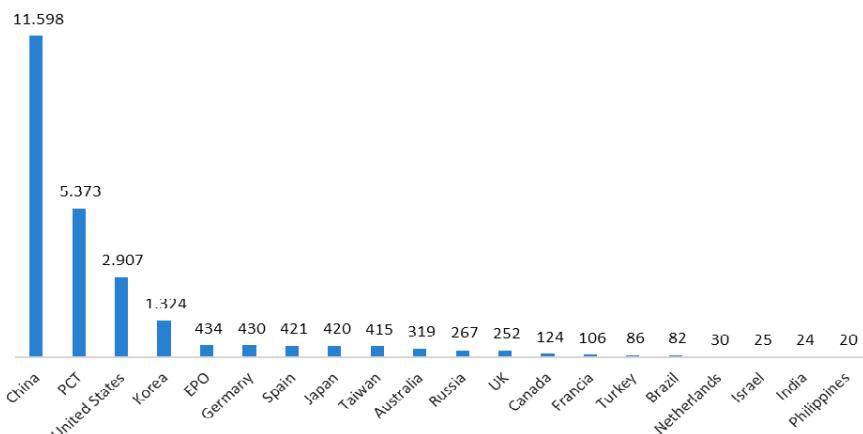


Figure 6. Top 20 jurisdictions in terms of number of COVID-19-related filings for priority years 2020–2021.

Notes: Number of patent filings per jurisdiction for priority years 2020–2021 using COVID-19-related keyword patent search. Dimensions.ai data adds up patents and utility models for offices offering both. This mostly affects data for China. WIPO (PCT), United States and EPO only include patent filings.

Source: Own elaboration based on data from Digital Science, app.dimensions.ai, retrieved March 15, 2022.

ago, and since they were not extended to those countries back then, they cannot in principle do it now because international extensions can only be filed shortly after the priority filing.²³ For those inventions, foreign patent owners will not have patents to enforce, since patents are only enforceable in the jurisdictions where they are eventually applied and granted.²⁴ The IP waiver will therefore be irrelevant in jurisdictions where there is no IP granted to COVID-19 technologies.

The next section focuses on patents related to COVID-19 mRNA vaccines, which rely on decades of research, and the relevant knowledge necessary to develop a vaccine may be a mix of old and recent scientific publications and patented inventions, together with know-how gained with experience of trial and error.

²³Twelve months for international extensions with the Paris Convention for the national filings route, 30 months with the Patent Cooperation Treaty for the international filings route.

²⁴<https://rapidreviews covid19.mitpress.mit.edu/pub/3540kznp/release/1>.

4.1 Patents related to COVID-19 mRNA vaccines

The vaccines that were the first in the race were those relying on mRNA, a technology that was the result of a cumulative research process, building on decades of previous research that had not always received sufficient public support but for which a number of patents had been filed over the years (Shores *et al.*, 2021).

Katalin Kariko, a Hungarian-American biochemistry researcher, had dedicated her career to developing the mRNA technology, convinced that “mRNA could be used to instruct cells to develop their own medicines, including vaccines,”²⁵ but for large part of it, she was in a precarious situation because many of her grant applications were rejected. In 2005, Katalin Kariko and Drew Weissman published a technique that allowed the therapeutic-use mRNA without inducing an immune response. They also filed two patents on their invention in 2006 and 2013 with the University of Pennsylvania, where they worked at the time, that they later licensed non-exclusively to Moderna and BioNTech.²⁶

Many other researchers had tried to develop mRNA vaccines, including the founders of the German company Curevac who also had an mRNA COVID-19 vaccine in the pipeline that did not reach the market.²⁷

The companies that finally succeeded and produced highly effective vaccines with this technology were Moderna and BioNTech. They licensed the patents of Kariko and Weissman and continued to do research and patented new inventions. Back in 2015, Stéphane Bancel, the CEO of Moderna, said that their technology had advanced to the point that the company’s initial patent filings were “irrelevant”: “This is Moderna generation 1.0, and we’re at 6.0 now.”²⁸

Moderna published the following statement in early October 2020: “As a company committed to innovation, Moderna recognizes that intellectual property rights play an important role in encouraging investment

²⁵<https://www.nytimes.com/2021/04/08/health/coronavirus-mrna-kariko.html>.

²⁶Kariko joined BioNTech in 2013, and she is now senior vice president.

²⁷Curevac did not succeed with its first attempt to develop an mRNA vaccine, and although it had signed APAs, it did not deliver and refocused efforts to increase efficacy.

²⁸https://www.nature.com/news/polopoly_fs/1.17674!/menu/main/topColumns/topLeft-Column/pdf/522026a.pdf?origin=ppub.

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in research. Our portfolio of intellectual property is an important asset that will protect and enhance our ability to continue to invest in innovative medicines (...) Beyond Moderna's vaccine, there are other covid-19 vaccines in development that may use Moderna-patented technologies. We feel a special obligation under the current circumstances to use our resources to bring this pandemic to an end as quickly as possible. Accordingly, while the pandemic continues, Moderna will *not enforce our covid-19 related patents against those making vaccines intended to combat the pandemic*. Further, to eliminate any perceived IP barriers to vaccine development during the pandemic period, upon request we are also *willing to license our intellectual property* for covid-19 vaccines to others for the post pandemic period.”²⁹ As reported on the website, by the end of October 2021, Moderna has been granted more than 240 patents in the US, Europe, Japan, and other jurisdictions, protecting fundamental inventions in the mRNA therapeutics space, with several hundred additional pending patent applications covering key advances in the field. They state the following: “We have augmented their internal patent estate with several in-licensed patent estates, including licenses to pioneering discoveries from Harvard University and the University of Pennsylvania. We continue to invest aggressively in science and technology to build a broader patent portfolio and ensure Moderna is in the strongest possible position to deliver on the promise of mRNA to bring a new class of transformative medicines to patients in the decades to come.”

BioNTech also states on its website how important intellectual property is for the company: “A strong intellectual property position based on ground-breaking science. We maintain a future-looking view, continuously expanding our patent estate. We pursue a *layered intellectual property strategy to protect our various technology platforms* and their application to the treatment of cancer and other serious diseases. One focus of our intellectual property strategy is to provide protection for our platforms and product candidates currently *in development*. We also pursue intellectual property protection for assets that may be used in *future development* programs and/or that may be of interest to our collaborators,

²⁹<https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19>.

or otherwise may prove valuable in the field.”³⁰ BioNTech defines its patent portfolio as having 200 overall owned patent families, including in-licensed patent portfolio, more than 100 patent families that are exclusively or jointly owned, all including at least one filing in Europe or the US, several pending or granted in multiple jurisdictions. But more importantly, in another section of the website, BioNTech sets out all the products they have in the pipeline, for which intellectual property is key and intertwined, including cancer, infectious diseases, and rare diseases.³¹ On February 16, 2022, the CEO of BioNTech declared that the company would not enforce its patents against African manufacturers trying to copy its COVID-19 vaccine, along the lines of what Moderna announced in October 2020.³²

Both Moderna, founded in 2010, and BioNTech, founded in 2018, have a strong IP stance. They are relatively young firms with many products and treatments in the pipeline for cancer and infectious diseases, for which the IP waiver represents a real threat. Both have shown willingness to enter into licensing agreements (Moderna) and expand production (BioNTech) voluntarily, possibly affected by the IP waiver threat.³³

³⁰<https://biontech.de/how-we-translate/intellectual-property>.

³¹https://biontech.de/sites/default/files/2021-10/20211006_BiontechPipeline_without_milestones-1.pdf.

³²<https://endpts.com/as-patent-debate-swirls-biontech-ceo-promises-not-to-enforce-covid-vaccine-ip-rights-in-africa-report/>.

³³In May 2021, the CEO of BioNTech said: “We have now scaled the manufacturing capacity up to 3 billion doses in 2021, and more than 40% of these doses are expected to go to middle- and low-income countries,” Waiving patents would not ease supply shortages in the coming months, he said, citing the complexity of producing the mRNA-based shot his company developed last year. His company is working to further expand its manufacturing network with its own sites, such as one now planned in Singapore, and through cooperation with other manufacturers to ensure greater supply while maintaining the quality of the vaccine. But he also noted that rival manufacturers have their own shots either on the market already or in the pipeline. “We believe, together with the other vaccine developers, in the next 9 to 12 months, that there will be more than enough vaccine produced and there is absolutely no need for waiving patents.” <https://apnews.com/article/europe-coronavirus-vaccine-coronavirus-pandemic-health-business-2a03ff6d794f6e6b92a58c1403683e7b>.

5. The IP Waiver

The IP waiver proposal presented by India and South Africa in October 2020 aimed to enable WTO members to *not grant or enforce* patents or other IP obligations on copyright, industrial designs, and the protection of undisclosed information related to COVID-19 products and technologies. The waiver proposal affects sections 5 (*patents*), 1 (*copyright*), 4 (*industrial designs*), and 7 (*undisclosed information*).³⁴

The objective was to eliminate barriers in a context of global emergency because of the pandemic: (i) to *timely access* to affordable medical products, including vaccines and medicines and (ii) to *scaling up* of research, development, manufacturing, and supply of medical products essential to combat COVID-19.³⁵ However, the claim that IPRs were hindering timely provision of affordable medical products to patients was very weak in the proposal. Although it mentioned “several reports about intellectual property rights hindering provisioning of affordable medical products to patients” the only source referred to was some news in the press about Kentucky Gov. Andy Beshear calling on 3M to release patent for N95 respirator amid pandemic, which included a supporting tweet by President Trump saying “I believe it’s their patriotic duty, and they [3M] should put it out there so everybody else can manufacture it.”³⁶ The proposal also mentioned that some WTO members were considering to expedite compulsory licensing within their territories, without giving any further detail.

On May 25, 2021, a revised proposal was presented by a number of WTO members (the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the least developed countries (LDC) group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela, and Zimbabwe) supporting the IP waiver in order to specify its scope, stating

³⁴ <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>.

³⁵ LDC members are exempt from applying most of the TRIPS agreement until July 2034 or until their graduation from the LDC category.

³⁶ <https://eu.courier-journal.com/story/news/2020/04/03/beshear-calls-3-m-release-patent-n-95-respirator-amid-pandemic/5112729002/>.

that it would apply to health products and technologies, which include diagnostics, therapeutics, vaccines, medical devices, and personal protective equipment to tackle COVID-19. It was also specified that the IP waiver would be in force for a minimum of three years and be reviewed annually.³⁷

On June 4, 2021, the EU presented a counterproposal in the form of a strong multilateral trade response to the COVID-19 pandemic. It consisted in limiting export restrictions, supporting expanding vaccine production, and facilitating the use of existing licensing flexibilities in the TRIPS agreement in particular articles 31 and 31bis on compulsory licensing by member states.³⁸ More precisely, the EU called on governments to: “(i) Ensure that COVID-19 vaccines, treatments and their components can cross borders freely; (ii) encourage producers to expand their production, while ensuring that those countries most in need of vaccines receive them at an affordable price, and; (iii) facilitate the use of compulsory licensing within the WTO’s existing Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement already provides this flexibility, which is a legitimate tool during the pandemic that can be used swiftly where needed. (...) As regards the *broad waiver* proposed by a number of WTO members, the European Commission, while ready to discuss any option that helps end the pandemic as soon as possible, is not convinced that this would provide the best immediate response to reach the objective of the widest and timely distribution of COVID-19 vaccines that the world urgently needs. Today’s proposals aim at achieving that objective in a swift and effective manner.”³⁹

TRIPS allows WTO members some flexibilities, in particular with articles 31 and 31bis related to compulsory licensing in emergency situations, and although they have rarely been executed, the mere threat of imposing them have had important effects in the past. The TRIPS flexibilities database launched in 2018, created and maintained by Ellen t’Hoen

³⁷ <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True>.

³⁸ <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W681.pdf&Open=True>.

³⁹ https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2801.

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and her team at the website called “Medicines, Law and Policy,” includes a historical record and information of the times when these flexibilities have been invoked, planned to invoke, or asked to invoke, whether or not they have been executed.⁴⁰

The positive stance of the US announced in May 2021 was unexpected and attracted a lot of attention.⁴¹ As explained by Price *et al.* (2021),⁴² the US support came as a surprise to all, but the waiver, if implemented, would not be the end but the beginning of a long process. It will simply ensure that WTO members could not use the TRIPS enforcement mechanisms to prevent countries from diminishing trade secrets, issuing compulsory licensing, or changing their national IP laws. That is, the waiver would not automatically abolish IP rights everywhere. Moreover, it needs consensus from all 164 members, but major countries are opposed to it, and negotiations take time, both at the international level at WTO and eventually later nationally, to implement the changes domestically. Lastly, they note, following Contreras, that the main benefit of the waiver would not be related to patents but to trade secrets, and if it goes through, it would be the first time in history that mandatory

⁴⁰“The TRIPS Flexibilities Database contains instances when authorities have invoked, planned to invoke, or have been asked to invoke a TRIPS flexibility for public health reasons, in particular to assure access to medicines. The flexibilities reported in the database are compulsory licensing, including public non-commercial use (TRIPS art. 31), patent exceptions (TRIPS art. 30), the Least Developed Country transition provisions (Paragraph 7 of the Doha Declaration on TRIPS and Public Health) and parallel import (Paragraph 5(d) Doha Declaration. The TRIPS Flexibilities Database provides instances starting from 2001, the year in which the World Trade Organization adopted the Doha Declaration. It includes cases from low, middle, and high-income countries, and incorporates instances that are both executed and instances that are, pending, not executed or suspended. It includes non-executed instances to capture the fact that also the mere threat of a TRIPS flexibility can have an effect.” <http://tripsflexibilities.medicineslawandpolicy.org/>.

⁴¹Among the critics, Mossoff (2021) requests retraction of the support to the IP waiver by the US government and proposes to focus instead on eliminating trade barriers, release the millions of doses that have not been used in the US so that they can be used in other countries, and marshal international support for investment in developing countries.

⁴²<https://writtendescription.blogspot.com/2021/07/whats-happening-with-proposals-for-wto.html>.

trade secret transfer would be implemented. In the words of Jorge Contreras:

The unprecedented U.S. support of the proposed WTO IP waiver is an important national gesture toward global solidarity in a time of crisis. Yet it is important to remember the limited scope of such a waiver — it simply provides that countries will not be able to bring trade-related claims in the WTO against countries that issue compulsory IP licenses in the context of COVID-19. The impact of such a waiver on international vaccine supplies will depend in large part on how other countries elect to implement compulsory licensing rules under the waiver, and whether they can effectively require the transfer of confidential manufacturing, testing, and safety information to supplemental producers. Alternatively, the threat of such governmental action around the world could encourage companies to engage in voluntary knowledge transfer to alleviate global supply shortages, which might be the greatest benefit of the WTO IP waiver.⁴³

The coalition called the “People’s vaccine” published two demands for firms and governments in May 2021. First, that pharma companies openly share vaccine know-how, e.g., through the WHO COVID-19 technology and access pool (C-TAP). Second, that governments suspend patent rules at the WTO on COVID-19 vaccines, treatments, and testing during the pandemic.⁴⁴

According to the latest news on the IP waiver negotiations at the WTO, a compromise was reached between South Africa, India, the US, and the EU in mid-March 2022, after a deadlock of 18 months.⁴⁵ The main features of this compromise include the following, as reported only unofficially:

- (1) Focus on vaccines (and commitment to decide on extension to therapeutics and diagnostics within six months from the decision on vaccines);

⁴³ <https://blog.petrieflom.law.harvard.edu/2021/05/07/wto-waiver-intellectual-property-covid/>.

⁴⁴ <https://peoplesvaccine.org/take-action/>.

⁴⁵ <https://www.politico.eu/article/compromise-reached-on-covid-19-vaccine-intellectual-property-rights-waiver/>.

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- (2) Short term (three or five years);
- (3) Limited to developing countries;
- (4) Compulsory licensing, executive orders, emergency decrees, and judicial or administrative orders;
- (5) Including all the patents needed to develop the product;
- (6) Access to data produced through previous clinical trials;
- (7) Remuneration for patent holders would follow good practices in national emergencies, pandemics, or similar;
- (8) Exports to other eligible countries allowed, in addition to production for the domestic market.

6. Other Initiatives: Pledges, Voluntary Transfers, and Capacity Building

Contreras *et al.* (2020), the group of academics behind the initiative to create a platform for the open COVID-19 pledge in 2020, argued at the beginning of the pandemic that “voluntary pledges to make intellectual property broadly available to address urgent public health crises can overcome administrative and legal hurdles faced by more elaborate legal arrangements such as patent pools and achieve greater acceptance than governmental compulsory licensing.”⁴⁶

Thus, as regards intellectual property, there are alternative ways to accelerate the sharing of patented knowledge other than by temporarily waiving international agreements. On the other hand, the promise to develop a Pandemic Treaty at WHO⁴⁷ will help to be prepared for the future, but this will again require consensus and international negotiations.

Indeed, as negotiations on the IP waiver continue, a large number of voluntary transfer initiatives have been implemented without waiting for that decision to be taken, although the threat of the IP waiver helped to

⁴⁶ Antonelli *et al.* (2021) have examined the patents included in the open COVID pledge <https://onlinelibrary.wiley.com/doi/10.1111/radm.12493>.

⁴⁷ <https://www.consilium.europa.eu/en/press/press-releases/2021/05/20/eu-supports-start-of-who-process-for-establishment-of-pandemic-treaty-council-decision/>.

accelerate some of them. These include the Open COVID Pledge,⁴⁸ the Medicines Patent Pool,⁴⁹ the WHO COVID-19 Technology Access Pool (C-TAP),⁵⁰ the WHO mRNA Technology Transfer Hubs,⁵¹ the voluntary licensing agreements signed by specific firms,⁵² the non-enforcement commitments from individual firms, such as Moderna,⁵³ and the mobile manufacturing facility by BioNtech to help increase manufacturing and distribution capacity in Africa.⁵⁴

Another initiative is the plan announced by CEPI with a budget of USD 3.5 billion, aiming to (i) cut vaccine development time to 100 days; (ii) create an all-in-one coronavirus vaccine for protection against multiple variants and betacoronaviruses; and (iii) build vaccine libraries, where we can use information learned about a whole virus family to rapidly respond to a novel disease threat.⁵⁵

7. Conclusions and Lessons for Future Pandemics

The implicit question throughout this chapter has been whether there is a causal link between patents and the lack of equitable access to COVID-19

⁴⁸<https://opencovidpledge.org/>.

⁴⁹<https://medicinespatentpool.org/who-we-are/about-us/>.

⁵⁰<https://www.who.int/initiatives/covid-19-technology-access-pool#:~:text=C%2DTAP%20was%20launched,Technology%20Bank%20and%20Unitaid>.

⁵¹<https://www.paho.org/en/news/16-6-2021-pahowho-calls-expression-interest-contribute-establishment-covid-19-mrna-vaccine>.

⁵²<https://www.merck.com/news/the-medicines-patent-pool-mpp-and-merck-enter-into-license-agreement-for-molnupiravir-an-investigational-oral-antiviral-covid-19-medicine-to-increase-broad-access-in-low-and-middle-income-countri/>.

⁵³<https://www.fiercepharma.com/pharma/leading-vaccine-player-moderna-won-t-enforce-patents-against-other-companies-during-pandemic>.

⁵⁴<https://www.dw.com/en/covid-digest-germany-s-biontech-unveils-mobile-vaccine-units/a-60805059>.

⁵⁵CEPI is a global partnership between public, private, philanthropic, and civil society organizations launched in Davos in 2017 to develop vaccines to stop future epidemics, see more information about its plan here: https://cepi.net/news_cepi/survey-launched-by-cepi-to-track-multinational-vaccine-manufacturing-capacity-for-use-in-future-epidemics-and-pandemics/.

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vaccines, diagnostics, and therapeutics for all, particularly vaccines, and if there is one, suspending patents would lead to more equitable access.

Most of the evidence presented and the studies and expert opinions reviewed indicate that the competitive advantage of the top vaccine manufacturers comes mainly from first mover advantages, reliance on prior scientific advances, market exclusivity provided by regulatory approvals, secure markets via APAs, “vaccine nationalism,” data exclusivity from clinical trials and know-how protected by secrecy.

There are other, more important barriers to producing COVID-19 technologies than patents, and these include lack of access to raw materials, know-how, absorptive capacity, and complementary assets.

Moreover, if a patent waiver is implemented, it will be difficult to discern which patents are essential, and solutions will have to be found country by country, knowing that the waiver will be in principle limited to developing countries, and pharmaceutical companies rarely file their patents in low-income countries without manufacturing capacity.

In the words of Maskus (2021), “countries were caught unprepared and without a plan for dealing with cross-border supply externalities. It is time to build a comprehensive framework that anticipates these problems for the next outbreaks.” With that aim, it is time to set up a coordinated international response to resolve supply bottlenecks and ensure sufficient resources to incentivize increases in licensed production and distribution.

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Chapter 2.3

Pharma Supply Chain and Globalization in the Face of the COVID-19 Pandemic: A Review

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Abstract

With the COVID-19 pandemic, governments around the globe discovered the vulnerability of the pharma supply chains (PSCs). In this review, we describe the nature of disruptions that occurred and the political debates. Then, we examine some features of the demand in pharmaceuticals: the evolution of the health market, drug supply shortages, and the access to essential medicines. After some reminders about the organization of the pharmaceutical industry and drug manufacturing, we analyze the characteristics of the supply of pharmaceuticals and the trends of the pharma globalization value chain (GVC). Finally, we discuss policy proposals to circumvent the disruption of PSCs in times of crisis, including stockpiling, improving the resilience of the PSCs, protecting the industrial commons, and relocating manufacturing plants. In conclusion, we draw a research agenda for economists and a political agenda for governments.

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Keywords: global value chain; supply chain; pharmaceuticals; COVID-19; drug shortage

1. Introduction

With the COVID-19 pandemic, the economies of developed countries, as well as those of emerging and developing countries, have discovered their great dependence on health supplies, whether it be for drugs, vaccines, or medical devices.

In this review, we start by describing the nature of health product supply disruptions and the nature of the political debates that occurred during the pandemic. Then, we examine the demand for pharmaceuticals, its evolution, and the drug supply shortages, distinguishing them from the debate on access to essential medicines. Next, we address the characteristics of the supply of pharmaceuticals and the trends of the pharma globalization value chain (GVC), after some background on the organization of the pharmaceutical industry and drug manufacturing, in order to understand the nature of supplies and the economic dimensions for pharmaceutical companies. Finally, we discuss policy proposals to circumvent the disruption of pharma supply chain (PSCs) in times of crisis, including stockpiling, improving the resilience of the PSCs, protecting the industrial commons, and relocating manufacturing plants. In conclusion, we draw a research agenda for economists and a political agenda for governments.

It should be noted that for, reasons of clarity, we focus primarily on drug supply shortages, and we will not address the problem of medical devices, which are subject to a rather different industrial organization, business model, and regulations. Furthermore, we will not directly address the topic of vaccines, which during this crisis was primarily a problem of access to innovation.

1.1. Lessons from the COVID-19 pandemic

1.1.1 Vulnerability of medical product and pharma supply chains

As soon as the epidemic of COVID-19 began to spread outside of China, the first signs of disruption in the supply of health products appeared in March 2020.

Supply disruptions in health goods concerned four main categories: personal protective equipment (PPE), intensive care unit (ICU) medical care, diagnostic tests, and finally drug shortages. The appearance and the importance of the supply disruptions varied with time and according to the country, the impact of the first epidemic wave, the country's state of public health, and the lockdown measures.

A number of these supply disruptions have already been the topic of scientific publications in different countries.

At the end of April 2020, a survey of doctors across the UK highlighted shortages of antibiotics, anesthetic drugs, and painkillers (Rimmer, 2020). Acute respiratory distress syndrome is a major complication in patients with severe COVID-19 disease and requires invasive ventilation, which led to a surge in the use of sedatives, analgesics, and paralytics (Ammar, 2021). For example, the stock of drugs, such as propofol, atracurium, and norepinephrine, was less than one month's consumption in Singapore (Siow, 2020). In Canada, a shortage of salbutamol inhalers needed by patients with respiratory comorbidities was reported (Elbeddini, 2020). The pandemic has affected the availability of treatments for other diseases. Between 2019 and 2020, the number of drug shortages in the US increased by 37%, while that in Australia increased by 300% (Cameron, 2020). India's lockdown in March 2020 raised concerns about the procurement and supply of antiretroviral (ARV) drugs (Rewari, 2020), and the ability of India's generic drug manufacturers to meet regional and global demand for generic ARV therapy in low- and middle-income countries where AIDS is endemic, such as in Nigeria (Oladele, 2020). During the second wave of COVID-19 in India, a rare lethal fungal infection called "black fungus" caused by *Mucormycetes* revealed a shortage of the antifungal drug amphotericin B (Arun, 2021). Drug shortages have significantly affected the ability to provide care at pediatric hospitals (Moss, 2021). Finally, the pandemic led to an important increase in demand for drugs that have been tested for repurposed therapies. Two examples illustrate this situation: the highly publicized hydroxychloroquine (Shuman, 2020), which demonstrated to be finally ineffective, and the immunosuppressive drug Tocilizumab, which improves slightly the prognostic of severe COVID-19 patients (Verma, 2021).

Disruptions in the supply of health goods have been followed by various responses from health professionals, civil society, and governments, such as stockpiling, restricting surgical mask usage, encouraging

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recycling, or avoiding waste, 3-D printing manufacturing, test pooling, drug compounding, and export restrictions. The pandemic hit so many countries at the same time that many governments imposed export restrictions on PPE, ICU medical devices, and drugs. The COVID-19 outbreak led India to restrict the export of dozens of drugs, including paracetamol and various antibiotics, leading to fears of a global shortage of essential medicines.¹ Pauwelyn (2020) reported at least 75 countries that had implemented such restrictions as of April 26, 2020.

1.1.2. Political debates to promote strategic autonomy and increase supply security

The pandemic has raised again US protectionism, with US lawmakers concerned about protecting their supply chains (SCs) from exogenous disruptions,² in the context of the trade war between China and the US.

In parallel, the European Commission has engaged to reduce European industry dependence from nonmember state suppliers. The issue of the relocation of the pharmaceutical industry has been undertaken by the European Commissioner for Internal Market, rethinking the free trade doctrine of the EU.³

In June 2020, the French government announced an action plan for the relocation of healthcare industries in France.⁴ This policy plan has been followed by strategic proposals from the French Pharmaceutical

¹ Reuters (March 2, 2020), Global supplier India curbs drug exports as coronavirus fears grow. <https://www.reuters.com/article/us-health-coronavirus-india-idUSKBN20Q0ZZ>.

² Bird, M. (April 22, 2020). Globalized Commerce Might Prove Resilient to the Pandemic. The Wall Street Journal Online. <https://www.wsj.com/articles/globalized-commerce-might-prove-resilient-to-the-pandemic-11587549813>.

³ Bulletin Quotidien Europe, (May 15, 2020), EU response to COVID-19 competitiveness: issue of Union's strategic autonomy on EU ministers' agenda n°12487. <https://agen-ceurope.eu/fr/bulletin/sommaire/12487>.

⁴<https://www.entreprises.gouv.fr/fr/actualites/industrie/filières/plan-d-actions-du-gouvernement-pour-relocaliser-industries-de-sante>.

Companies Association⁵ on areas covering policy, regulation, manufacturing incentives, and supply disruption.⁶

In the UK, a publication in *The Telegraph*, in August 2020, highlighted the fact that more and more companies are considering relocating their production because of rising air freight prices and shortages. UK firms were planning to replace cheap Chinese labor with increased automation, but the complexity of SCs and the uncertainty about the future of trade relations were still obstacles.⁷

In Ireland, where the pharmaceutical company Gilead has set up one of its two production units outside North America to produce remdesivir, the country's dependence on American multinationals became a weakness when US pharma companies switched all their production to meet the needs of the US health market in priority, including Gilead, which received market authorization for its antiviral drug remdesivir for the treatment of hospitalized COVID-19 patients.

Despite India's excellence in the pharmaceutical sector, the over-reliance on active pharmaceutical ingredients (APIs) from China created vulnerabilities in the drug SC.⁸ In this context, India launched an initiative with Australia and Japan on SC resilience.⁹

However, relocation of firms was already a major topic of discussion prior to the COVID-19 pandemic. It became an issue after the 2008 financial crisis, but the issue of reshoring the pharmaceutical industry dates back to 2012, when the US faced a major drug shortage.

⁵Les Entreprises du Médicament, <https://www.leem.org>.

⁶<https://www.leem.org/sites/default/files/2020-09/PR%202020-09-10%20%28Kearney-Leem%20...%2012%20recommendations%20...%29.pdf>.

⁷Burden, L. (2020, 28 august), Companies look to reshore after Covid decimates supply chain, *Telegraph* Online. <https://www.telegraph.co.uk/business/2020/08/28/companies-look-reshore-covid-decimates-supply-chains/>.

⁸Chinoy, S. R. (2020, 30 December), Resilient supply chains as a pandemic lesson. *The Hindu* Online. <https://www.thehindu.com/opinion/lead/resilient-supply-chains-as-a-pandemic-lesson/article33447988.ece>.

⁹<https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1714362>.

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2. Demand for Pharmaceuticals

The demand for healthcare goods has increased significantly worldwide. During the past half-century, the world population has doubled and life expectancy¹⁰ increased significantly from 60 years to 72–73 years in OECD countries and almost doubled in Africa from 36 to 54 years.¹¹ This improvement in life expectancy is concomitant with an increase in the GDP per capita in the world.¹² As a result, per capita health expenditure has increased significantly both in OECD countries and in the BRICS.¹³ All these factors have contributed to a strong increase in pharmaceuticals demand around the world, especially for essential medicines. This has been partly met by the emergence of a strong pharmaceutical industry in China and India, focusing on generic drugs.

2.1 Drug shortages increase

Drug shortages has been reported worldwide with an important increase in recent years. However, formal definitions of drug shortages vary from country to country, and the characteristics of the shortages, including their range, duration, and frequency are difficult to assess in cross-country analysis (Bochenek, 2018). Unfortunately, scientific studies on drug shortage are scarce.

Trends in US shortages have been studied from 2001 to 2016 (Mazer-Amirshahi, 2017). An update of the data shows that the problem continues to grow, culminating in the COVID-19 crisis (Gorry *et al.*, unpublished results). Half of the shortages reported were for drugs used in critical care. The majority of drugs in short supply were parenteral (71.7%) and more than a third (39.1%) were single-source drugs. Infectious disease drugs were the most common drugs on shortage, (19.9%). A complementary

¹⁰<https://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates/ghe-life-expectancy-and-healthy-life-expectancy>.

¹¹<https://population.un.org/wpp/>.

¹²<https://data.worldbank.org/indicator/NY.GDP.PCAP.KD.ZG>.

¹³<https://data.oecd.org/healthres/health-spending.htm>.

study on antibacterial agents run between 2001 and 2013 measured a rate of 0.35 additional drug shortage every month since 2007 (Quadri, 2015).

Shortages affected essential medicine, such as cardiovascular drugs (Reed, 2016). In a survey, US oncologists experienced drug shortages annually, which induced medication errors and disturbed the conduct of clinical trials (McBride, 2013). For example, the first-choice oncology drugs, such as liposomal doxorubicin and 5-fluorouracil, are affected by shortages, and it explains why clinical trials evaluating novel agents in combination with standard-of-care drugs are also being affected by drug shortages (Li, 2015).

In France, the number of international nonproprietary names (INNs)¹⁴ reported in shortage quadrupled between 2012 and 2018 (Benhabib, 2020). Once again, the drugs most affected by these shortages are generic injectables.

While non-parenteral drug shortages are common, they have generally received less attention in academic research. The therapeutic classes most affected remain similar over time. But, the COVID-19 crisis has led to shortages of new therapeutic classes (Ammar, 2021).

There are multiple causes for these drug shortages: The origins or aggravating factors can be found at all levels of the drug manufacturing chain. The accumulation of hazards along this chain leads to the multiplication of these shortages. These include global tension between demand and production capacity, unforeseen market fluctuations, production-related problems, raw material supply problems, and regulatory or economic constraints (Tucker, 2020).

In the US, the Food and Drug Administration (FDA) established an action plan in 2012 to combat these shortages with significant impact.¹⁵ It aimed to improve the agency's ability to address drug shortages by focusing on the following two objectives: (i) strengthening the FDA's ability to respond to supply disruption notices and (ii) addressing the underlying causes of supply disruptions to prevent them, while recognizing that manufacturers have an important role to play. The FDA's approach has been echoed at the European level: The European Medicines Agency

¹⁴<https://www.who.int/teams/health-product-and-policy-standards/inn>.

¹⁵<https://www.congress.gov/bill/112th-congress/senate-bill/3187>.

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(EMA) has set up an online consultation in 2018 on the subject of non-compliance with good manufacturing practices in the context of stockouts.

2.2 Access to essential medicines

The concept of “essential medicines” dates back to military tradition and the discovery of penicillin, which was essential to soldiers. Since then, ensuring access to essential medicines has been considered a basic human right. The Essential Medicines List (EML) was implemented by the World Health Organization (WHO)¹⁶ in 1977 as a core list of 186 drugs necessary to satisfy the priority health needs of a population. It contains the most cost-effective drugs in regard to disease prevalence (Laing, 2003). The EML includes, in particular, opioid analgesics and anxiolytics, which are essential to palliative care. These drugs are regulated under United Nations Convention (Pettus, 2020). The 22nd list of WHO EML, published in 2021, includes 479 active substances. Of note, if drugs on the WHO EML list are available as generic products, being under patent does not preclude inclusion.

In 2016, more than 155 countries, including developed and developing countries, have created national lists of essential medicines based on WHO EML. However, the definition of “essential” is not implicit, as Duong and colleagues (2015) showed in their analysis of the EML in Australia, while an EML could play a role in drug pricing and drug shortages even in high-income countries.

Inclusion of a drug in the WHO EML and by individual countries has stimulated the entry of new firms into the market to respond to shortages and to improve affordability and access (Chivukula, 2018). But the identification of a drug as essential is not always sufficient to improve availability and affordability, as Kaur and Mahajan (2020) have documented in India. They found that regional governments are procuring essential medicines at a fair price, but the low availability of medicines in public

¹⁶<https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists>.

health facilities forces poor patients to buy drugs from the private sector at relatively high prices.

3. Supply Side of Pharmaceuticals

3.1 Pharmaceutical industry and drug manufacturing

The pharmaceutical industry has built its business model around important investment in research and development, with returns guaranteed by patent monopoly. Since the late 1990s, pharmaceutical firms have been evolving in a changing world under numerous challenges. After decades of drug discovery, they faced a drying “drug pipeline” (Mullard, 2012). Since the 2000s, “Big Pharma” has been facing a patent cliff; the end of patent monopoly for many blockbuster drugs has brutally exposed them to generic drug competition with a fall in turnover (Harrison, 2013). Concomitantly, the sector has seen the opening of “pharmerging country” market with fast-growing drug markets in BRICS countries, with China becoming the third largest drug market in 2011.¹⁷ At the same time, governments have sought to save money in healthcare systems by using health technology assessment and cost-effective drug pricing (Benoit and Gorry, 2017). Then, the whole sector started to move from the blockbuster to the niche-buster business model, following the path opened by the regulators with the Orphan Drug legislation in the US (1983) and EU (2000) (Gorry and Useche, 2019). It has been accompanied by a financialization of the pharmaceutical industry, with consolidation of global companies through outsourcing clinical trials, offshoring manufacturing, merger and acquisition, and therefore concentration of the industry (Montalban and Sakinc, 2013).

The synthesis of pharmaceutical drugs is a complex industrial process that can be broken down into several manufacturing operations organized in two major steps, the synthesis of fine chemicals or APIs and the formulation giving rise to the final formulation dose (FFD).

Fine chemicals are produced in batch reactors and sold as starting materials for pharmaceuticals. The synthesis of a pharmaceutical

¹⁷ <https://fici.in/spdocument/20174/PHARMERGING%20SHAKE-UP.pdf>.

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molecule can produce a large volume of waste. All these operations require quality controls and are subjected to control by drug regulatory agencies in many countries, such as the FDA or EMA. They are produced on a large scale to satisfy the industry's demand. It costs 10 times less for a plant based in China or India. This fact, coupled with a low labor cost, explains why, in recent decades, APIs production has been outsourced to China and India.

The market for APIs was valued in 2010 at USD 23 billion, while the world drug market generated a USD 835 billion turnover, which is a 36-fold increase in value. The industry is fragmented between 2,000 and 3,000 API companies, of which the top 20 are divisions of large chemical or pharmaceutical companies, often subsidiaries of generic drugs (Ciriminna and Pagliaro, 2013).

3.2 Pharma supply chain

If SC management is a major research topic in process operations and management, few research addresses the specificities of the pharmaceutical industry. Indeed, the PSC is lagging behind SCs in other industries in terms of performance and best practices (Beaulieu, 2021). The PSC is complex and involves many countries and numerous companies, ranging from large multinationals to mid- and small-size operations. The PSC is largely production centered and far from patient demands and healthcare outcomes (Settanni, 2017). Pharmaceutical firms need to balance future capacity with anticipated demands due to the uncertainty in clinical trials and competition. As a result, pharmaceutical companies must be prepared to produce large volumes of drugs to meet healthcare market demand (Reinholdt, 2015). In addition, the PSC management has to deal with product perishability all along the SC, from manufacturers to patients (Chung, 2016).

Historically, the PSC was fully integrated and owned by the company: This vertical integration allowed the control of subsidiaries, e.g., the synthesis of APIs or bulk chemicals, in the pharmaceutical industry.

Apart from works in the research field of pharmaceutical chemistry, the literature on APIs is weak or even nonexistent in the economic field.

The only data available are those of international business consulting firms; it is true that the PSC is covered by business secret. But it is possible to take advantage of the requirement for importers to register and/or be audited by drug agencies. In the US, Americans have become totally dependent on Asia. In 2001, 140 manufacturing sites in China were registered by the FDA, and that number had grown to 815 in 2007. Manufacturing sites in China and India now account for nearly 40% of all foreign manufacturing sites registered with the FDA (Woo, 2008). Nowadays, the US health market relies essentially on non-domestic manufacturing, in India and China, for APIs (intermediate products) as well as formulated medicines (FDD) (Kaygisiz, 2021).

The manufacture of APIs has thus become a major sector of the Indian industry. India ranks third in terms of volume of drugs produced and has become the world's leading supplier of generic drugs. In 2008, India accounted for a quarter of all generic drug applications (ANDAs¹⁸) in front of the FDA. India's exports of final formulations to the top 28 regulated countries surpassed exports of APIs, demonstrating an upward shift in the quality of the Indian pharmaceutical industry (Jena, 2009). However, India's dominant position is accompanied by weaknesses: The country is heavily dependent on imports from China for several raw materials used to produce some of these drugs (Vyas, 2020; Cherian, 2021).

Moreover, experts say that many Indian drug manufacturers produce substandard drugs for markets where regulation is lacking, especially Africa. One-tenth of APIs fail quality control, often with an underdose of the active ingredient. The explanation is that Indian pharmaceutical companies and/or their export intermediaries differentiate the quality of medicines according to the destination of consumption (Bate, 2016).

Regarding China's place in drug manufacturing, we can focus on the example of a key drug in the fight against malaria in developing countries, artemisinin. China became a major producer, and India was its largest buyer of API, while FDD end forms were mainly exported to Africa. Exports of artemisinin derivatives produced in China shifted from being API-dominant to FDD-dominant (Huang, 2016).

¹⁸<https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda>.

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3.3 Global value chain and pharmaceutical industry

Since the Doha round of the World Trade Organization, the GVC has been restructured englobing emerging countries. The trend toward globalization has extended to the SCs of finished pharmaceuticals and APIs. Then, the movement in the industry has been toward outsourcing and offshoring.

Pharmaceutical export data from the COMTRADE database¹⁹ can be used to measure the respective weight of the different countries. Depending on the indicators used, the statistics give a contrasting view of international trade (Gorry *et al.*, unpublished results). The limitation of the interpretation of these export data is that they are measured in monetary values rather than in unit values. Insofar as there could easily be a factor of 1–100 in the cost of manufacturing an innovative drug compared to a generic drug, this measure will give an advantage to countries specializing in pharmaceutical innovation compared to countries specializing in production.

The globalization of trade in pharmaceuticals had a positive impact on achieving the health-related Millennium Development Goals, such as vaccination against measles or antiretroviral therapies (Yuana, 2020).

Grossman and his colleagues (2008) have identified among the determinants of outsourcing/offshoring the size of the domestic and foreign market for suppliers, the cost of searching a supplier, the cost of coordination, and the nature of the contracting environment in each country.

There are numerous examples of outsourcing or offshoring activities among the firms in the pharmaceutical sector, including sometimes core business activities, such as drug testing, clinical trials, or manufacturing (Adobor, 2012; Nogueira, 2018). These strategies have been driven by the competition, the race against time to market, and the increasing domestic cost. Finally, the search for a higher margin or gain results in optimization of trading and transfer price structures, if not tax heavens (Sha, 2004).

Outsourcing comes with a transaction cost, especially for the pharmaceutical industry with the quality control requirements of the drug agencies, such as the EMA or FDA. It has been demonstrated that offshore

¹⁹<https://comtrade.un.org>.

plants are exposed to higher quality risk than domestic plants (Grava, 2011).

Among the destination countries for pharmaceutical offshoring, India has historically taken a central place, becoming the “world’s drug factory,” even if today it is being overtaken by China. The literature shows that Western companies that engage in offshoring to India have access to trained workers, infrastructure, and a huge market. But inadequate protection of intellectual property rights (IPRs), scarcity of highly skilled labor, and institutional gaps pose serious problems and impede further development in India (Mohiuddini, 2017).

More recently, regulatory barriers for chemicals have created rising pressure for global regulatory harmonization.

In 2006, the European Union has introduced a new chemical regulation called Registration, Evaluation and Authorisation of Chemicals (REACH). Chemical firms must ensure that they control, along the production chain, the dangers to health and the environment. In 2016, the US congress enacted a revision to the Toxic Substances Control Act (regulatory law applicable to industrial chemicals (Graham and Illés, 2018). If pharmaceutical products are exempted from the application of the REACH, the intrants of pharmaceutical manufacturing, such as solvents, are concerned in large volumes. Therefore, an unintended consequence of the implementation of environmental regulation has been the offshoring of production to countries with less regulations, as has been demonstrated by Tang (2015).

Major export-oriented Asian economies, such as South Korea, Taiwan, and China, have adopted new REACH-compliant chemical regulations and have successfully increased their exports to the European chemicals market (Yoojin and Koo, 2020).

3.4 The pharmaceutical GVC and the pandemic stress test

The COVID-19 pandemic had a *ripple effect* on the GVC by disturbing the whole system with a multiplier effect. It has served as a *stress test*, revealing pre-existing weaknesses with subsequent shocks in the PSC.

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It has been highlighted that downstream countries and sectors suffered more from China's production disruption than upstream ones (Qin, 2020).

At the macroeconomic level, politicians and academics have defended the idea that GVCs have been the main transmission channel of "economic contagion" (Coveri, 2020). At least, it is an opportunity to rethink national industrial policy in a globalized world.

At the microeconomic level, the pandemic had the merit of revealing that companies with different localization strategies (international diversification vs. reshoring) or different governance of their SCs (internalization vs. externalization) were more or less resilient (Strange, 2020).

Academic researchers have started to study the factors of the SC resilience. Analysis reveals that adaptation capabilities play a key role in the SC management under pandemic disruptions (Ivanov, 2021). Rajak and colleagues (2021) identified, in India, the three most successful factors: social distancing, emergency logistics systems, and emergency backup facilities. Using a knowledge-based approach, Orlando and colleagues (2021) found that the most resilient SCs were those that had previously introduced innovations in the SC management. However, no analysis is available on the resilience factors of the PSC.

The pharmaceutical firms have many opportunities to build a more sustainable SC based on innovation. They could focus on improving coordination, facilitating autonomous decision and proactive recall product, and mitigating waste. Indeed, pollution control has already become a key focus in the global PSC (Mukherjee, 2020).

4. Policy Issues

Following the COVID-19 health crisis, what policies could improve the drug SC? A number of academic researchers, consulting firms, and politicians have put forward various proposals. These include the following: (i) drugs stockpiling, (ii) improving the resilience of the SC, (iii) protecting the industrial commons, and (iv) relocating manufacturing companies.

4.1 Stockpiling

The outbreak of the highly pathogenic avian influenza virus (H5N1) between 2006 and 2007 served as a warning to the world of the threat of

influenza pandemic. The WHO encouraged countries and pharmaceutical firms to prepare ahead of time. Several pharmaceutical companies have developed H5N1 vaccines, and the idea of storing vaccines has been developed for use in an emergency and implemented by various countries, including the US and France.

In the US, the Strategic National Stockpile²⁰ is in charge of stock antibiotics, vaccines, antitoxins, and other medical supplies (Jennings, 2008). This strategic drug stockpiling was born in the context of the Cold War, then fell into disuse in the 1970s, before coming back to the forefront, initially as part of the prevention of bioterrorism in the US, before being rehabilitated in the face of the influenza pandemic in the early 2000s. Then, the Centre for Disease Control (CDC) recommended purchasing new antiviral drugs and being prepared for the emergence of resistance to antiviral drugs (Patel, 2009).

In France, the strategic stock of medicines and PPE followed an opposite trajectory. In 2007, the French government created an Emergency Preparedness and Response Unit (EPRU) and a stockpile of millions of masks, vaccines, drugs, and other medical equipment was built up in a few years. But in 2016, the doctrine was abandoned: It was useless to keep billions of masks, the authorities said.²¹

The limits of the storage strategy soon became apparent with the constitution of stocks that were largely insufficient to cover the needs of the population, even to protect hospital employees. As a result, the rapid and massive production of medicines or vaccines in the event of a health crisis appeared to be the solution. Japan had been studying the development of new antiviral drugs of the neuraminidase inhibitor class. But the firms and the authorities faced the difficulty of stockpiling a drug that does not have a marketing authorization (Sugita, 2009).

Another alternative has been considered: the development of stocks by hospitals or even firms, with different incentives, including mandatory stocks or contracts on predetermined supply (Harrington, 2010). Different scenarios have been evaluated from a cost perspective, which show that there are many drawbacks (Li, 2010). However, an antiviral stockpiling

²⁰<https://www.phe.gov/about/sns/Pages/default.aspx>.

²¹https://www.lexpress.fr/actualite/societe/sante/coronavirus-comment-la-france-a-sabordé-ses-stocks-stratégiques-de-masques_2125901.html.

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modeling based on a Monte Carlo simulation has shown that, at the scale of a hospital, having a stock, even if it is relatively modest, is most important (Abramovich, 2017).

In recent years, a controversy has arisen among the public regarding the stock of drugs, for example in Denmark, with the oseltamivir and the role of the pharmaceutical lobby (Vilhelmsen, 2018). However, public opinion has reversed with the COVID-19 crisis, and the populations of EU countries, in particular the *in-need* countries, are more in favor of cooperation at the EU level than a national policy (Beetsma, 2021), knowing that there is no EU common health policy and that the construction of the European drug market is incomplete (Gorry, 2014).

4.2 Resilience of pharma GVC

Although the concept of “resilience” has been used for some time in ecology and psychology, it has entered the political discourse only in recent years and has since gained importance in several areas of research. However, the definition of this concept is far from unanimous. The resilience can be defined as the ability of an organization to adapt or recover from a disruptive event. But it has taken on different meanings depending on the field of research, management sciences, or economics. In economics, the concept has taken a central place in the economic study of ecological systems, especially since development agencies and other militant associations have appropriated the concept with the 2008 financial crisis. Thus, the concept of resilience is considered either as a capacity, or as a normative condition, or as a return to equilibrium. In a review of the literature, Barrett and colleagues (2021) found that the theoretical framework is not very consistent between the different published analyses. Quantitative analyses are few and divided between different methods, limiting the comparison of results. Moreover, most of the results focus on the impact on natural shocks and a few countries. In geographical economics, the concept of resilience has taken another direction, with an interest in the resilience of regional or local economies. But this concept remains rather ambiguous, in particular how it relates to long-term regional development (Martin and Sunley, 2015).

Companies and SC managers did not wait for the COVID-19 crisis to take an interest in the resilience of SCs. Supply disruptions can have serious consequences on business. Therefore, companies have been interested in SC risk management to assess the resilience of SCs and to determine where vulnerabilities exist.

But it must be acknowledged that despite the increase in drug shortages, the subject of resilience of PSCs has remained a marginal topic in academic research. At a minimum, it is proposed to set up an optimal inventory level by modeling the drug manufacturing process in order to minimize the effects of a disruption and to develop agility capabilities and rely on dual sourcing (Lücker and Seifert, 2017). From a logistical point of view, the flexibility of PSC is a key element: It must be based on flexibility of orders, networking, and collaboration with suppliers (Ward and Hargaden, 2019).

A PSC can be considered in its complexity as a dynamic network of interactions, and management researchers have proposed to use the theoretical framework of the complex adaptive system, which takes into account various determinants, such as the PSC characteristics, the PSC weaknesses, its environment, and the resilience measures implemented (Yaroson *et al.*, 2021). The past literature has emphasized on micro- and macro-level supply network resilience: At the micro level, the resilience is the result of collaboration between buyers and suppliers on risk prevention, and at the macro level, the resilience is the result of collaboration between firms and institutions, such as governments or trade associations, to regulate long-term risks. Along this line, Azadegan and colleagues defend the idea of meso-level resilience when multiple SCs collaborate with short-term risks.

4.3 Industrial commons

In 2012, Pisano and Shih published their book, *Producing Prosperity*, in which they highlighted the importance of the link between manufacturing and innovation: One cannot go without the other. They declare: “When a country loses the ability/capacity to manufacture, it loses the ability to innovate.” Thus, they developed the concept of *industrial*

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commons: “the set of manufacturing and technical capabilities that support innovation across a broad range of industries.” They argue that US firms have been ceding the American industrial commons by outsourcing manufacturing for decades, and the country has lost its ability to produce high-tech products. Corporate management has overestimated the competitive benefits of outsourcing by ignoring the dangers of outsourcing production, and they call the US government for an American manufacturing renaissance to face economic challenges.

By contrast, the Korean government successfully upgraded domestic firms’ innovation capabilities and reduced the possibility of deindustrialization in the course of globalization by moving from classical developmentalism to a new form of development based on inclusive and collaborative networks (Kim, 2017).

In the face of the supply disruptions caused by the COVID-19 pandemic, some authors have argued the need to develop such “commons” in our society so that companies become more efficient in normal times and more resilient in the event of health, economic, or climate crises. The implementation of public policies of “*industrial commons*” can reduce the cost for companies adopting resilience-building SC strategies (Chopra, 2021).

4.4 Reshoring

Although the term relocation is synonymous to reshoring, the latter refers to the process of returning the product manufacturing back to the firm’s original country. It is the opposite of outsourcing or, more precisely, offshoring.

In the context of globalization, the international relocation of firms has been studied by economists, and it has been found that labor-intensive firms are more prone to relocate to other countries. But size of the firm, access to network, or innovation rates are also positive determinants (Pennings and Sleuwaegen, 2000).

For some time now, firms are reconsidering reshoring their offshore activities to domestic locations. The determinants of this strategy depend on the location, the firm, the manufacturing process, the governance, and the transaction cost (McIvor and Bals 2021).

Pharmaceutical supply has been exposed to increasing drug shortages during the past decade and the pandemic has shown how fragile the PSCs are in both developed and developing countries. It is urgent to improve the resilience of these SCs, and the reshoring of PSCs might be a solution. This vital national security need has been expressed by politicians all around the globe, including in the US as well as in India. However, this solution cannot be implemented with the same drug manufacturing processes for two reasons: one is related to price competition and the other to the environmental constraints imposed on the manufacturers. Reshoring will have to rely on innovation to redesign PSCs (Gurvich, 2020).

Green chemistry could offer drug companies improved chemical processes, reducing the environmental impact of the industry while remaining economically competitive (Gupta and Mahajan, 2015). Many Western pharmaceutical companies are adopting these processes and moving back their manufacturing capacity. These evolutions also concern emerging countries. As a matter of fact, the increase in contaminated drug products in China and India led local authorities to increase quality controls. Remarkably, the Indian pharmaceutical company, Dr. Reddy, is adopting green chemistry processes (Ciriminna and Mario Pagliaro, 2013).

5. Conclusions

5.1. In a nutshell

In the aftermath of the first wave of the COVID-19 epidemic, our societies have realized the vulnerability of the SCs of medicines and medical equipment in both rich and poor countries. This led to a political debate on the stakes of a renewed industrial policy willing to turn its back on globalization. The pandemic acted as a stress test, revealing a situation that had existed for many years: the problem of access to essential medicines in poor countries and the increase in drug supply shortages in rich countries.

The pharmaceutical sector is characterized by a complex production chain that is strongly regulated by numerous mechanisms to ensure safety and quality for patients. This industrial sector, which experienced strong growth in the past century, has been exposed to new scientific and

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economic challenges in recent decades, which it has faced through financialization, concentration, and relocation.

At the same time, the demand for health goods has increased significantly worldwide due to the economic growth of emerging countries (especially China and India) and an increasing share of the wealth produced devoted to health, resulting in a doubling of life expectancy over the past 50 years.

In this context, the pharmaceutical industry has not escaped the globalization of the economy, many Western companies have relocated their production, and new champions have emerged along the SCs of pharmaceutical production.

If today, the main pharmaceutical markets are in the US and Europe, the majority of APIs and generic medicaments are produced in China and India.

It is obvious that the relocation of pharmaceutical production has been carried out for reasons of low production and labor costs. It is likely that new environmental regulations in Europe and the US have played a role, even if this is not well documented. They gave the opportunity to India first and then to China to specialize in this industrial sector.

However, this description is too simplistic ; a mapping of API producers shows a more heterogeneous geographical diversity, and trade reveals the complexity of the SCs, explaining why even India, the world's supplier, was not immune to supply disruptions during this crisis.

Apart from the nationalist reflex of protectionism, which is not a viable solution in times of crisis, whether in the short or long term, many other solutions are available to politicians.

The most obvious solution is a public health policy measure that can be implemented in any country: the constitution of stocks of medicines and strategic medical equipment to face any crisis, health or armed conflict. This simple idea is in reality much more difficult to implement: It requires defining a list of essential medicines, a particular logistic organization, and adequate incentives, and it has a cost. This strategy could be implemented in a rich country, but with much more difficulty in a poor country in the absence of strong institutions, governance, or health legislation.

More prosaically, the pharmaceutical industry, led by governments, could improve the resilience of the drug SCs. Based on the academic

literature, there is clearly room for improvement. But it is not certain whether this opportunity will be seized by industry, which in truth has been little affected by the crisis and which would be more inclined to implement lean management as a source of savings.

Finally, the issues of industrial relocation have appeared or reappeared in the political discourse of governments of many countries. This idea is exposed to the same problems as the solution of the strategic stock: which drug production to privilege, API or FDF manufacturing, at what cost, and with which incentive for the manufacturers? But this policy of going backward in relation to the globalization in recent decades has the merit of making our leaders understand the importance of the industrial commons and perhaps of innovation.

5.2 A research agenda

Throughout this literature review, our bibliographic searches on the topics of drug shortages, essential medicines, the PSCs, and the globalization of the value chain have been confronted with a small number of academic works, mainly published in management sciences, with little or no work in economics. Transnational studies on drug shortages, exploring the characteristics of the market (price, volume, and competition) and of the firms (size, positioning, product portfolio, etc.) are some suggestions which would be most useful in order to explore the impact of competition and prices on generic market sustainability for essential medicines. Another avenue of research could be to analyze the network of API suppliers and the international pharmaceutical product trade. Finally, the impact of the European REACh legislation on the trade of pharmaceutical products and offshoring could be tested, or the environmental impact of pharmaceutical manufacturing could be modeled to shed light on the future economic challenges of green innovation in the drug industry.

5.3 A political agenda

Today, access to medicines is not only the problem of developing countries, it is also the problem of developed countries, with skyrocketing costs and recurrent drug supply shortages. For a long time, there have been

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arguments about the benefits or disadvantages of the IPR on medicines around the North–South divide. But the economic problem may lie elsewhere.

With the need to control their healthcare expenditures, developed countries have focused on price control measures in the generic market. While this policy has favored the emergence of new specialization and geographic concentration of the industry, making it possible to satisfy the demand of low-income countries, it is at the origin of an exacerbated competition and finally of the abandonment of the production of numerous molecules by numerous firms, weakening the pharma GVC. This model is not viable in the long term: Our world must probably rethink the economic model of drug value renumeration where society overpays for new innovative drugs and underpays for old but essential drugs. Within the evolutionary economics framework, one should reconsider that therapeutic innovation is not always a matter of drug substitution; public health still needs some “old” molecules of our pharmacopoeia, provided that they are sold and produced above marginal cost.

With climate and environmental issues, there may be new opportunities for pharmaceutical supply independence, both for rich and poor countries, based on innovation. In the years to come, the pharmaceutical industry will not be exempt from efforts to save energy and reduce environmental pollution, since this industry belongs to the fine chemicals sector and is closely dependent on the oil economy.

Innovations in green chemistry, with continuous flow production, lower volumes of chemical intrants, and the reduction of polluting effluents at a lower energy cost can be an opportunity to re-localize pharmaceutical production if governments know how to manipulate the right policy incentives. The return to vertical integration of the pharmaceutical industry will then guarantee quality and security of supply.

Facing this new paradigm, China and India will have to adapt their industry by improving the quality standard of their pharmaceutical production. In doing so, these countries will also gain in pharmaceutical independence by developing drug production capacities from APIs to FFD, for the benefit of their domestic market and population health. This perspective will be the condition for a smart specialization and to meet the challenge of therapeutic innovation in the years to come. In the absence of

adjusted incentives, the risk is for India, as is for developed countries, to be totally dependent on China in terms of both API and FFD sourcing at the risk that the Chinese pharmaceutical industry will turn first to its domestic market driven by a strong demand for healthcare.

In conclusion, improving health security around the globe in the face of the next health crisis cannot be reduced to the adjustment of economic variables or a few incentives but will require new compromises between the different stakeholders (Coris, 2021).

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Chapter 2.4

COVID-19 and Recombinant Innovation in Indian Science

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Abstract

Has the COVID-19 pandemic nudged the scientific establishment and biotech ecosystem in India to focus on social impact and translational biology in the human health space? We address this first by reexamining the promise of science to society, namely, can and should the pursuit of knowledge be harnessed for the improvement of human life (utility)? We emphasize the possibility of pursuits that both expand the frontiers of the known and are useful, namely the “Pasteur’s quadrant.” Overlay this position with the conditions that support recombinant growth, which is the ability to combine existing knowledge into forms and products that are more valuable or in synchrony with what is needed, and you are likely to zoom in on where India is today. We use anecdotes and vignettes of how scientists, scientific institutions, and the biotechnology industry responded to the COVID-19 pandemic to illustrate the fertility

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of the Pasteur's quadrant, supplemented with inklings of recombinant growth. Based on these data, we offer an optimistic view that Indian science and industry are poised to find the sweet spot in the landscape of knowledge and usefulness — such that both human creativity and human societies can flourish. Such developments are likely to stand us in good stead, particularly as we rise to the challenge of emerging diseases and antibiotic resistance.

Keywords: pandemics; COVID-19; recombinant science; India

COVID-19 prompts particularly sharp doubt about India's future. The second wave of infection was so sweeping and its impact so graphic, that it deeply affected both the reality and perception of life in India. This was a once-in-a-century event; it was epochal How do we square this experience with India's long-term future? A diverse culture, a young and aspirational population and a varied and entrepreneurial private sector are the foundation of our promise.

— Naushad Forbes, *The Struggle and the Promise: Restoring India's Potential*, Harper, 2022

1. Introduction

In the context of the extraordinary crisis that the world is experiencing with the COVID-19 pandemic, we are going to need a “reset.” It seems natural to assume that science and technology will have to drive the agenda. Our collective pandemic experience in India exposed the weakness in our civic and health systems to respond to infrequent but high-impact disasters. It also revealed our lack of focus on disaster sciences and that we would do well to learn from our East Asian neighbors.

The COVID-19 experience not only underlined the need to accelerate efforts toward better healthcare but also demonstrated radically new ways to achieve that goal. It broke down barriers and made possible what were earlier thought impossible: telemedicine adoption in remotest areas; doctors monitoring patients in home care; unprecedented community participation and coordination enabled by modern communications; and

data-driven pandemic response at various levels. But most impactful of all is the development of vaccines at record speed.

As the then Director General of the Indian Council of Medical Research states (Bhargava, 2021), “India detected its first case of COVID-19 on January 30th 2020 in Kerala; by March 20th the National Institute for Virology, Pune had isolated the SARS-CoV2 virus strain brought in by a tourist from Italy; by May 18th 2020 India was performing 100,000 COVID-19 tests a day; and on 16th of January, the country began its rollout of COVAXIN®, a home-grown vaccine, manufactured at Bharat Biotech in Hyderabad and then taken through rigorous clinical trials to meet global standards of approval culminating in the WHO approval in November of 2021, that has, as of this writing, delivered approximately 14% of the 1.72 Billion vaccinations in the country which amounts to approximately 240 Million doses. A remarkable triumph of homegrown science and technology.”

We may not have perfected all of these, but the progress made in two years in biopharmaceutical innovation is remarkable, nevertheless. Similarly, though not yet deployed widely in public view, there have been some impressive accomplishments by the scientific community behind the scenes: AI-powered screening via cough sounds and x-rays; genomic surveillance; and molecular diagnostics kits and reagents. The challenges of access during the pandemic gave us new ways to provide on-demand healthcare for anyone, anywhere, using digital solutions. The blueprint for national digital health was accelerated in deployment.

Will this be an inflection point for Indian science and create a new cadre of scientists driven by a genuine interest in translation and impact in society? It would be difficult to answer such a sweeping question within the limitations of this chapter. However, we examine a few anecdotes that suggest a movement in a positive direction prompted partly by the response to the pandemic but enabled by a foundation that has been laid over some time now — ever since the push for innovation in science and technology began to drive policy in 2010 under the then Prime Minister Manmohan Singh.¹

¹<https://www.hindustantimes.com/delhi/pm-calls-innovation-game-changer/story-uIQLXWf5wBUKerAEgloIN.html>.

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Independent India was born in the middle of the 20th century, and we were led to believe in the early decades that the United States (US) had figured out its innovation advantage in the post-war years by tapping into centers of excellence in higher education and growing innovation clusters around them. We acknowledged the important role that Professor Vannevar Bush, the legendary MIT electrical engineer, entrepreneur (founder of Raytheon), and science administrator par excellence, had played in enabling this in the post-World War II era. In his classical declaration, “Science the endless frontier,” penned in 1945 when tasked by President Roosevelt to come up with a plan for scientific advancement building on and suited to the post-war period, Prof. Bush, the then director of the Office of Scientific Research and Development, included the following lines in the conclusion of his cover note to President Truman:

Scientific progress is one essential key to our security as a nation, to our better health, to more jobs, to a higher standard of living, and to our cultural progress.

The institution building that resulted (including the setting up of the National Science Foundation in the US), Prof. Bush left to others. He went back to Cambridge to work with Raytheon and the MIT Corporation.

In post-independence India, Prime Minister Nehru had similar tasks cut out for the “Rocket Boys” Homi Bhabha and Vikram Sarabhai and of course many others, such as Meghnad Saha, Mahalanobis, and Raman. Sir CV Raman proclaimed in 1947 that “vast powers are placed in the hands of man by successful research which opens up a vista of possibilities for its beneficial application in the relief of the fundamental ills of humanity, namely hunger, poverty and disease.” As noted by many, we did experience a great period of development well into the 1970s, motivated by the ethos of nation-building and achieved by channeling creative energy and innovation toward “material advancement.”

Science and higher education in the US were going through a major realignment in the late 1970s and 1980s. The pivot was to place the bet on translation and commercialization of federally funded research output. The remarkable bipartisan Bayh–Dole Act had opened the doors for individual researchers (and universities) to leverage funded research as intellectual property that could be taken forward — licensed or

commercially exploited to create new products, solutions, and private companies. Clusters around the hotspots of scientific research formed, and “regional advantage” in Saxenian (1996) terms had taken root with variations in the innovation culture of competition. The role model for US entrepreneurs has always been Thomas Alva Edison — except for recent times when Steve Jobs and now Elon Musk seem to have become popular icons.

In the 1980s, India, in contrast, seemed to choose a new alignment, which might be considered a conservative and almost retrograde pivot. We were now driven by the objectives of “excellence in research.” The higher educational institutions were quickly bound much more tightly to purist academic metrics. Publish in high-quality journals and conferences, place your postgraduate students in other centers of excellence, and ensure that the admissions process brought in the most tutored young scientists into the campus — these were the rules of thumb that served most of us well. Those of us who were positioned to contribute toward this form of pursuit of excellence were rewarded, lauded, and encouraged with promotions and awards. It is not surprising then that the academic community aligned with these new incentives, and we learned to game the metrics and the system. In essence, we had been nudged.

As has been often debated, there is a tension between basic research, which is driven by goals of extending the frontiers of fundamental understanding, and applied research, which is directed toward some individual, group, or societal need or use. The tried and tested method of dealing with research and innovation that takes a dichotomous approach of basic versus applied has not yielded great results in recent years. We need a framework(s) to evaluate an innovation that adds value to our society as both an application of large impact and a contribution of a qualitative leap in knowledge and understanding, thereby laying a foundation upon which edifices can be built.

2. The Innovation Ecosystems

A century ago, physicists and engineers combined forces and symbiotically produced technologies, such as the telegraph, telephone, radio, aircraft, radar, electromechanical calculator, and power systems, thus completing the agenda of the first machine age. The post-World War II era,

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the middle of the 20th century, saw the role again of physicists and mathematicians, fresh out of the war effort, looking for new frontiers and aiding in the birth of computers and digital hardware, along with the beginnings of molecular biology. The digital hardware was a little further along and was soon laying the foundations that would usher in the next revolution.

We are truly climbing at a steep incline toward instant communication and an anthropomorphic and superior machine intelligence. Data scientists today have access to an amazing scale of hardware at their beck and call. Software has been playing catch-up with hardware since the 1970s, when DARPA announced its first personal computing project, Project on Mathematics and Computation, or Project MAC, to bridge this gap. So, if you are amazed by Alpha Go, Alpha Fold, Watson, and autonomous vehicles, you haven't seen anything yet. Work, progress, and prosperity with brilliant technologies are the promises of the second machine age (Brynjolfsson and McAfee, 2014).

Genomics, the software of biology, in combination with the advances in molecular biology, has positioned biology now to progress toward a quantified science that can open up great synergies with the engineering disciplines of materials research and micro- and nanotechnologies that can help biotechnology reach its long-standing promise of improving human health, food and energy security, and environmental sustainability. If so, this will certainly be the century of the life sciences and the foundation of an industry that will have a qualitatively different environmental footprint with unforeseen levels of automation using precision robotics.

We are entering the "Age of Living Machines" (Hockfield, 2019). The obvious question to ask is whether India has a strategy that can help us ride the steep advances in bioengineering to build a bioeconomy. What are the right levers to push this sector of Indian biotechnology onto the world stage and has the COVID-19 pandemic and the national response accelerated our entry into the new age?

3. Models of Innovation and Evaluation Frameworks

We are going to posit three different models of innovation that appear to be useful in understanding and classifying a lot of the innovations that we

have witnessed and necessitated during these incredibly tense and event-filled 24 months of the COVID-19 crisis.

3.1 Vannevar Bush's thesis: Science the endless frontier (Bush, 1945)

Professor Vannevar Bush based his plan for the endless frontier on a very linear model of innovation: Basic Research → Applied Research → Development → Production/Operations.

This model led Prof. Bush to reveal what he believed strongly to be “a perverse law governing research” under which “applied research invariably drives out pure.” Historians have written that this led Bush to insist upon the principle of federal patronage for the advancement of knowledge in the US, a departure that came to govern the federal science policy after World War II.

One immediate consequence was the creation of the National Science Foundation (NSF) in 1950, and the stark dichotomy of applied and fundamental research, as presented by Professor Bush, was soon recast as “programmatic research” versus “uncommitted research.” The gradual emphasis on programmatic research perhaps got a boost in the late 1950s as a consequence of the competitive challenge caused by the launch of *Sputnik*, and suddenly, there was a strong push toward a military industrial complex, as observed also by President Eisenhower in his departing address to the nation.

The die was cast, and by the 1970s, the NSF was being celebrated for its extraordinary success in collaboration with Advanced Research Projects Agency (ARPA) in new materials research, the proclamations in the 1980s on the equivalence of importance accorded to the sciences and to technology. Finally, in 1993, the report of the National Science Board on a foundation for the NSF in the 21st century made it clear that technology that remains in the lab provides almost no economic benefit. Applications in government provide some benefit, but those that succeed in larger commercial markets, including global markets, should be the focus of policy (Bloch and Cheney, 1993).

All these currents of science policy debates led Donald E. Stokes, the dean of the Woodrow Wilson School, to posit a dynamical representation that extended the linear representation of innovation that had been

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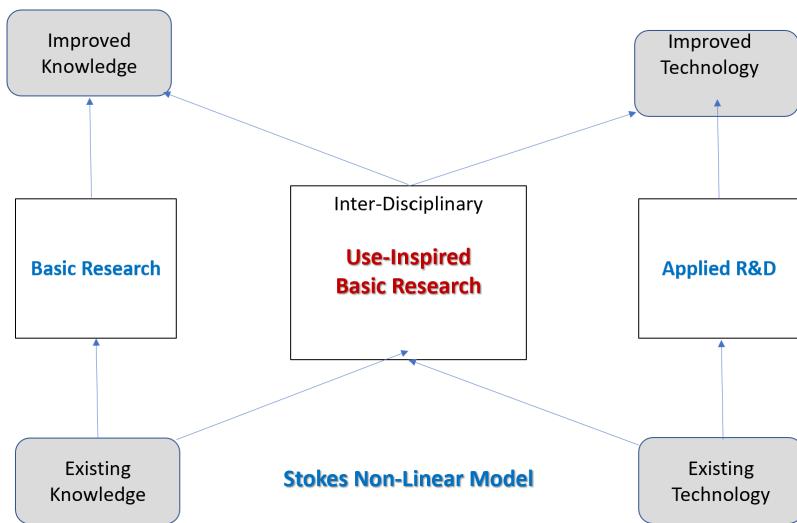


Figure 1. Stokes' nonlinear model of innovation and scientific advancement.

formulated by Vannevar Bush in the post-war years. The new perspective was expressed as shown in Figure 1.

In this formulation, the left vertical path was that of a purist, a basic-research journey epitomized by a scientist like Niels Bohr. The rightmost vertical path was that of an engineering-driven innovator epitomized by Thomas Alva Edison, and finally, the paths going across use inspired basic research epitomized by Louis Pasteur and his amazing innovations based on his understanding of microbiology but with a view toward meeting the needs of society. The idea of Pasteur's quadrant had taken shape by the mid-1990s.

3.2 Pasteur's quadrant: Basic science and technological innovation

Donald E. Stokes at the Brookings Institution penned a classic book on innovation, which in some ways was a critique of Vannevar Bush's framework, which equated basic science and technological innovation. Stokes proposed an intriguing diagram (Figure 2) in which he suggested that

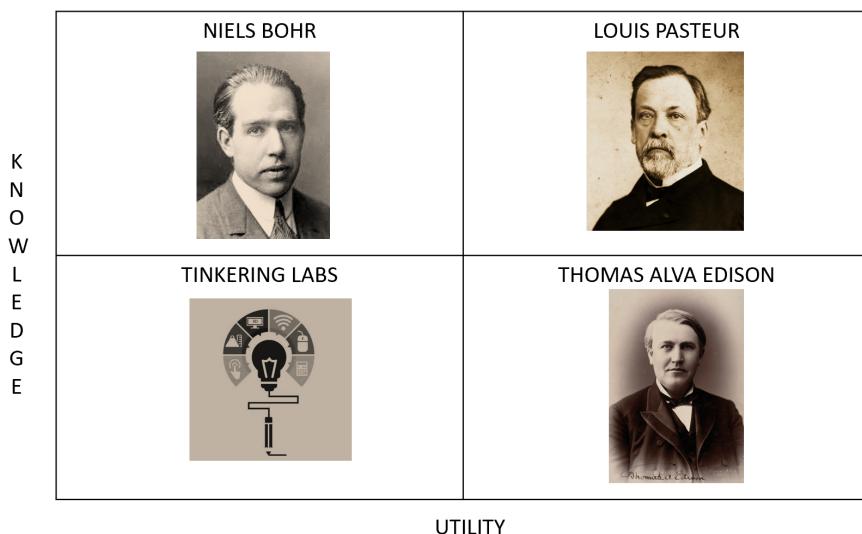


Figure 2. A two-by-two matrix of knowledge versus utility to define Pasteur's Quadrant.

the university scientist, driven by the paradigm that Niels Bohr represented — namely, new basic knowledge in science being the motivation — defines a quadrant that is high in the quest for fundamental understanding but poor on the considerations of utility. The professional engineer goes in an orthogonal direction, emulating Edison, in the pursuit of utility with less regard for the advancement of knowledge. The technologist researcher (in university or industry) today would attempt a middle path but will perhaps fall short of reaching the full potential which, in Stokes' description, is Pasteur's quadrant — advancing both knowledge and utility. Big science or systems engineering is the modern approach to making this happen. Donald Stokes unfortunately perished too soon, after publishing his tome, to see this emergence. But it is Pasteur's Quadrant that now drives us.

The American people remained deeply convinced that science and technology would elevate their lives, and this commitment only grew stronger in the 1980s and 1990s when the famous market research company Harris poll recorded in early 1994 (The Harris Poll, 1994) that 68% of the sample agreed (and only 29% disagreed) that science would solve many of the world's problems.

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We would urge the reader to think about the IT/ITES industry in India, which was seeded by government-led policy (Saraswati, 2013) for enabling software as an export industry. Where in the quadrant framework of Stokes would we place our IT/ITES industry? It is well known that the R&D investments in this sector stay at very low levels — possibly no more than 1.5% of its sales (China, by contrast, is at 8–9% of sales). It is focused on human capital, of course, since it is entirely driven by services. To its credit, the information technology services sector has continued to scale at a breakneck speed, and perhaps, the global market is still so open that the incentive for innovation is not strong. So, moving out of Edison's quadrant into Pasteur's has perhaps not been of interest.

Is the biotechnology and pharmaceutical industry in India different from infotech? It appears so. Again, the indicators from 2019 data, as presented in the CTIER Handbook, puts the R&D figures just under 10% of sales in this industry. At this level of commitment, we are possibly on track to transition from the paradigm of innovation set by Edison to that of Pasteur in the framework of Don Stokes. Also, since Pasteur is often considered the real pioneer of vaccine science, the COVID-19 pandemic seems the right trigger for the national quest in India to move its innovation focus into Pasteur's Quadrant.

3.3 Weitzman's recombinant growth theory and innovation ecosystems

In order to keep pace with the disruptive technologies that are changing the world and to truly understand their impact on our collective future, we must engage with the scientific and technological paths that have led us here. With the remarkable advances in technology, at an exponential scale, which we have witnessed over the last 100 years toward the digital revolution and the second machine age, we are now poised to enter the age of living machines (Chandru, 2020).

Paul Romer tells us that the countries that take the lead in the 21st century will be the ones that implement innovation ecosystems that more

effectively support the production of new ideas in the private sector. Using the phraseology of bioengineering, new recombinant innovation ecosystems has to be the focus of our national strategy. Weitzman describes it well as an idea-based production function driving a growth model:

Economic growth occurs whenever people take resources and rearrange them in ways that make them more valuable. Possibilities do not merely add up; they multiply... Production of new ideas is made a function of newly reconfigured old ideas in the spirit of the way an agricultural research station develops improved plant varieties by cross-pollinating existing plant varieties. The model shows how knowledge can build upon itself in a combinatoric feedback process that may have significant implications for economic growth. (Weitzman, 1998)

This formulation suggests that the ability to grow would be bolstered by recombining existing ideas into usable forms and may be limited not for the lack of ideas themselves but for our inability to meld them into utility.

This new paradigm of innovation might well suit India in the years to come. We have an extremely well-trained and creative science and technology workforce. The nation has seen an extraordinary scale of human capacity-building through our higher educational institutions, national labs, and emerging multinational corporate research institutions. The Internet and increased mobility, while on a pause during the pandemic, has been in high gear for decades now.

Major breakthroughs by Indian scientists in fundamental research may seem yet out of reach since the R&D support in domestic institutions have not reached the critical levels; however, the ability to process the pool of ideas into potentially novel combinations addressing internal and global markets seems imminently possible, and we have possibly seen glimpses of this as responses to the pandemic. The rest of this chapter will be devoted to describing a few of such exciting case studies that the authors have chosen to herald the arrival of the recombinant innovation age of Indian science.

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4. Case Studies of Science Innovation: Circa COVID-19 Pandemic

We have chosen four examples to illustrate the innovation responses in the biotechnology sector that we have witnessed during the pandemic. The examples are related to vaccines, diagnostics, genomic surveillance, and computational epidemiology.

4.1 Case 1: The story of COVAXIN® and vaccine innovation

In mid-January 2021, less than a year after the detection of the first case of COVID-19 in the country, India began the rollout of COVAXIN®, a vaccine made in India, manufactured by Bharat Biotech, and developed in partnership with the Indian Council of Medical Research (ICMR). Of the first 1.72 billion vaccinations in the country, 14% were doses of COVAXIN® (240 million doses). This is undoubtedly an example of science delivering for society. The vaccine was taken through clinical trials, met the global standards, and was approved by the WHO in November 2021. A commemorative stamp was issued by the president of India, together with national awards to the scientists and entrepreneurs involved in the program (Figure 3).

The partnership between the ICMR and Bharat Biotech brought out once again the ability of a public–private partnership in the vaccine space. This was an extraordinary learning experience for the nation in taking a vaccine from first principles through to GMP manufacturing, the entire clinical development process, and approvals for global use by the WHO Strategic Advisory Group of Experts on Immunization (SAGE).

The WHO's conclusions included a statement that COVAXIN®'s efficacy against COVID-19 of any severity, 14 or more days after a second dose, is 78%. The vaccine's efficacy against severe disease is 93%. In adults aged less than 60 years, the efficacy is 79%, and in those aged 60 years and over, it is 68%.

As with any high-complexity innovation that is home grown in a lower- and middle-income country (LMIC), there would be a contingent of doubters and detractors. So, it becomes important to present technical evidence and credibility of the invention.

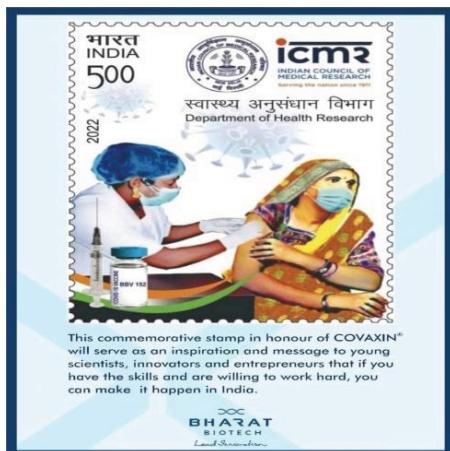


Figure 3. The public–private partnership between the ICMR and Bharat Biotech was an extraordinary learning experience for the nation in taking a vaccine from first principles through to GMP manufacturing, the entire clinical development process, and approvals for global use by the WHO SAGE. The commemorative stamp signifies the remarkable coming together of healthcare workers, scientific community and vaccine manufacturers during the COVID19 pandemic. The stamp shows a healthcare worker vaccinating a senior citizen, together with an image of a vial labelled ‘COVAXIN’.

Source: Bharat Biotech website.

We would be remiss to not mention a few of the advanced vaccine initiatives in the country:

- The **COVISHIELD®** vaccine, manufactured by the Serum Institute of India (SII) in Pune, under license from the Oxford-Astra Zeneca vaccine’s construct, was a massive manufacturing and delivery success. The remaining 86% of vaccine delivery in India was made by this impressive ability to scale up in response to the pandemic crisis. The extraordinary vision of the late Cyrus Poonawala and the agile business leadership by his son Adar Poonawala brought out once again the best in India’s famed prowess as the pharmacy of the world.
- The SII is a world-famous contract manufacturing enterprise for vaccines, as has been demonstrated over the years. This was driven home during the pandemic when the vaccine developed by NOVOVAX Inc in the US was contracted to SII. When it was finally approved by

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WHO in late 2021, it was the Novavax/SII vaccine that made the cut. The vaccine has been approved now under EUL in several countries, including India, under the label COVAXON™ and should be soon an option in India.

- mRNA vaccine **HGCO19** Gennova — license from HDT Bio (USA) (innovations: stable at 2–8 degrees and is being reengineered for Omicron).
- Biological E Limited and **CORBEVAX** licensed from Dynavax Technologies (innovation: recombinant vaccine). This has just been launched in March 2022 for 12–18-year-olds.
- Zydus Cadila DNA Vaccine **ZyCov-D** (innovations: nucleic + needle-free delivery) in trials.
- IISc and Sree Chitra Tirunal **Mynvax** (innovations: recombinant vaccine for influenza and COVID-19 and heat tolerant) in trials.

The Western media pronouncements and the scientific community were broadly led to believe that the mRNA vaccine technology is a special province of only the most technologically advanced societies (the US and Germany). However, as Achal Prabhala of IBSA and Alain Alsahani (*Médecins Sans Frontières*) have argued (Prabhala and Alsahani, 2022):

In the nearly two years that we have lived through the coronavirus pandemic, we have thought of mRNA vaccines as a luxury that only a few can make and have. But an examination of the evidence will force us to acknowledge that the opposite is true, and this conclusion has the potential to end the pandemic everywhere. Prolonging the delusion that companies in countries of the developing world are not ready to make mRNA vaccines may serve a handful of corporations, but it harms the world.

In the same article, Prabhala and Alsahani also provide a list of 120 pharmaceutical manufacturers across LMICs with the interest and ability to manufacture mRNA vaccines. As India builds the capacity for pandemic preparedness and disaster sciences, the capacity for rapid development of nucleic vaccines should match our demonstrated

capabilities with manufacturing affordable traditional vaccines for the world.

In summary, the progress that the Indian vaccine industry sector made in the context of the pandemic was remarkable. The public–private partnership in the creation of the novel COVAXIN® was also noteworthy. However, it is important to not lose sight of some ways in which we could have been even more effective:

- The protection received by mass vaccinations might have been even more effective if the government had not delayed in making funding available for manufacturing through an advanced procurement policy, as adopted by several other manufacturing nations. It may have lessened the deadly blow that the second wave (Delta wave) wreaked on the nation if vaccine stocks had been available early in 2021 for a larger section of the vulnerable population. While we had demographic factors (a young nation) in our favor, we had extreme unrecognized co-morbidities, which were the likely cause of the havoc wreaked by the Delta wave in the second quarter of 2021.
- Our attention to quality in manufacturing of pharmaceutical products is exceptional when the units are driven by export markets. We need our regulators of biopharma manufactured for internal consumption to be just as alert and demanding as the international regulators are. Dual standards will invariably cause challenges, as were recently faced by COVAXIN® manufacturing units and WHO suspending procurement through UN agencies until process and facility upgrades are made to address deficiencies.
- Cuba has demonstrated how an LMIC with limited resources of financial and human capital could respond with alacrity in developing three protein subunit vaccines that were rapidly rolled out to serve their population and offer to the world. Making their technology open source and available to humanity was an exceptional gesture. It seems that you can get to Pasteur's Quadrant with frugal means if there is a will.

4.2 Case 2: Innovation in diagnostics

In a recent compilation of the Indian bioeconomy for the calendar year 2021, the industry's Association of Biotechnology Led Enterprises (ABLE) of India presented data to indicate that the biopharmaceutical contribution for the year was approximately USD 40 billion out of a total of around USD 80 billion. The surprising insight was that of the contribution, around 54% was from diagnostics. Vaccines, for example, was around 20% of biopharma. So, the real impact of COVID-19 was perhaps the innovation in diagnostics, although since it was quite fragmented, the business journalists did not seem to pick up on this.

It was clear that RT-PCR quickly became the gold standard test. Early in the pandemic, the focus was on quickly building capacity at molecular biology labs in academic centers across the country and turning them into testing centers (CIDR IISc, inStem, NIMHANS Neurovirology Lab, etc.). Soon, the capacity in public labs was unable to keep pace with the demand as the infections increased despite the lockdown, and qualified private labs with NABL (ISO-15189) certification were roped into action. As the volume of testing picked up, the costs were brought down almost a third of the initial price.

The private sector was being directed to address the early challenges of shortage of imported kits. Several groups stepped forward, and MyLab Discovery Solutions from Pune stood out as the first local kit to get regulatory approval and launch. They also quickly scaled up manufacturing with contract manufacturers in the country and rapidly brought down the price of an RT-PCR test to under USD 50 per sample. According to current records, around 769 million tests have been conducted till March 2022. This would also include a substantial number of rapid antigen tests (RATs), including the popular CoviSelf® test created by MyLab as well. The newspapers reported that during the third wave (Omicron variants driven), the city of Bengaluru alone was selling 2,000 self-tests of RAT a day through retail channels.

An important development during this period was the realization that creating a marketplace that could coordinate the supply chains for indigenous diagnostics would make a difference to the *AtmaNirbhar* call by the leadership and help us reach the target of one million tests a day. The InDx

program, hosted at C-CAMP and supported by the Rockefeller Foundation, has put India on track to roll out large-scale diagnostics to cater to the needs of the great aspiration of the nation to achieve universal healthcare. The InDx program also demonstrated an interesting use of a digital marketplace to create infrastructure for recombinant innovation on a mission-critical footing.

The innovation potential of the biotechnology sector to deliver on the diagnostics challenges of the pandemic became visible in spades over the last two years. Here is a shortlist of deep science and technology innovation products and services that became available:

- Molbio's Truenat, a closed and portable PCR platform, which had been developed for TB drug resistant strain testing, was redeployed for SARS-CoV-2, and over 1,200 test centers became functional. At a busy international airport, a 16-rack Molbio Quattro system was deployed, which could do rapid turnaround (less than 60 min) of around 500 samples in a single run.
- The FELUDA and RAY CRISPR-based detection systems for SARS-CoV-2, which made the regulatory cut for diagnostics, came out of the IGIB-CSIR labs and was licensed by TATA MD to be commercially launched.
- Tapestry pooling (based on an ingenious adaptation of compressed sensing) for obtaining great cost reduction by using pooling methods with clever algorithmic inversion of pooling to retrieve quantitative detection of positive sample was developed at Indian Institute of Technology (IIT) Bombay in Mumbai, and a startup, Algorithmic Biologics, was launched by one of the inventors, Professor Manoj Gopalkrishnan, to take this forward. In the latest communication, we were informed that over 25,000 samples have been analyzed using this platform. Tapestry was the only technology from India to qualify for the X-Prize competition finals for novel work on COVID-19 response.
- When the third wave hit India (Omicron was first detected on November 29, 2021 and uploaded on GISAID soon after on December 2), India was readily prepared with two new RT-PCR tests that seemed to work in identifying Omicron infection. The first to be out was the

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GenePath CovDelta developed by GenePath (Pune) and manufactured at Achira Labs (Bengaluru). The ICMR test Omisure, licensed to TATA MD and brought out soon after, cleared the certification in its second attempt and was put into action. The much vaunted ThermoFisher test was unable to detect the BA.2 sub-lineage of Omicron that swept India by late January 2022.

With all these developments, it seems to call out to the molecular diagnostics sector in India to join the vaccine sector to make the cut of Pasteur's Quadrant. As the legendary chairperson of the biotech industry body ABLE, Dr Kiran Mazumdar Shaw likes to paraphrase, "necessity is the mother of innovation."

4.3 Case 3: Pathogen genomics/genomic epidemiology

What is pathogen genomics and what was its early contribution to the understanding of SARS-CoV-2?

The ability to read the genome of a potential pathogen by sequencing opens up ways of predicting its behavior by leveraging knowledge based on the similarity to known pathogens and classification into pathogen families. This is the promise of pathogen genomics. The sequencing of the first SARS-CoV-2 genome from a cluster of cases in China in late 2019 informed us that we were faced with a respiratory virus of the coronavirus family related to the SARS and MERS coronaviruses, which were known to infect and cause epidemics in humans (Zhu *et al.*, 2020). This sequence from Wuhan was shared and allowed the entire global community to make molecular diagnostics for detection of the virus and, in time, the mRNA-based vaccines for SARS-CoV-2.

So, had SARS-CoV-2 emerged in India, would we have been able to sequence and share this information in a timely manner?

The tools and resources for doing this — namely the ability to perform sequencing and the expertise to analyze such data was only present in a few institutes in the country at the end of 2019, and even within these,

a small subset had worked with pathogen genomes. Most of these laboratories had only worked with such data in research mode for projects on known pathogens. The ICMR center, National Institute of Virology (NIV), was probably among the few institutions with the mandate for outbreak investigation, sequencing technology, and expertise required to do this work. The first sequences of SARS-CoV-2 from samples collected in late January were submitted to GISAID (a database for influenza surveillance that has been co-opted for SARS-CoV-2) (Elbe and Buckland-Merrett, 2017) by NIV in early March 2020.

Traditionally, pathogen discovery has been done after an outbreak and relied on culturing the organisms together with molecular methods for identification. The use of sequencing as a tool that circumvents this step, i.e., the isolation/culturing of the organism, is still not a universally accepted practice at this point in time. It also requires public health institutions to either develop relatively sophisticated molecular diagnostic and analytics capabilities or work with some level of transparency with research institutions that have these tools and resources. From the other end, it requires institutes whose primary mandate is basic research or fundamental science to extend their interest into an area where their skills and expertise have immediate value. The cost from their end is that time spent on and developing the skills for solving the immediate problem may take time away from established career paths, goals, and tenure tracks. There may be no mechanism in place for such institutions to reward or encourage young researchers who pursue this kind of interest away from their area of research in a non-pandemic situation. Such a system of collaboration would then necessarily rely on resources being available to facilitate them.

Thus, the way things would have played out in India is not very different from other LMICs, where the resource distribution and priorities in health spending before the COVID-19 pandemic would not have eased or supported the development of genomics capacity within public health institutions. Also, there wasn't enough support nor incentives for individuals in research institutions (with their focus on fundamental/basic research) in the country to use or test and develop their skills in genomics or sequencing and apply it to problems in outbreak situations.

4.3.1 Where are we now?

In order to address the need for genomic surveillance of SARS-CoV-2, a national consortium for sequencing was formed in India, initially composed of 10 national institutes for concerted sequencing and sharing of sequencing information with the global community in a transparent and timely manner. In this, India followed the lead of the UK in detecting the first SARS-CoV-2 variant of concern (VoC), now known as Alpha in December 2020, less than a year after the detection of the virus in Wuhan (Figure 4). The COG UK, a consortium of laboratories across the UK, had been set up early in the pandemic (April 2020) and sequenced at speed, with transparency and commitment to information sharing via timely and public reports available via UK Health Security Agency. This model has served as an example for the rest of the world. It must however be remembered that COG UK, their funders, and collaborating networks have a unique history of investment in pandemic preparedness and using genomics for pathogen surveillance and outbreak response. Multiple labs within this framework had experience developing and deploying protocols for sequencing pathogens — mainly viruses in many parts of the world — with partnerships such as the ARTIC network (Real-Time Molecular Epidemiology for Outbreak Response) and the CADDE Project (Brazil–UK Centre for (Arbo)virus Discovery, Diagnosis, Genomics, and Epidemiology). Adding to this is the real-time sequencing experience of the Ebola outbreak in West Africa 2014–2016 (Quick *et al.*, 2016) and Zika outbreak in Brazil in 2015 (Giovanetti *et al.*, 2020). Supported by the Wellcome Trust, the MRC UK and the decades of work at the Sanger Institute and University of Edinburgh on pathogen sequence data generation, sharing, and analysis, particularly methods for phylogenetic analysis of viruses. These groups had both the expertise and experience of working in outbreaks and across domains and a history of international collaboration on pathogen genomics with researchers across the world. The ARTIC Primer sets for SARS-CoV-2 — now almost universally used for SARS-CoV-2 sequencing, the mutation detection system in CoV Glue, and the lineage detection system PANGOLIN (O'Toole *et al.*, 2021) are tools that have emerged from this ecosystem. It is important to keep this in mind as we use this template to assess the effort in India.

The India SARS-CoV-2 sequencing consortium, INSACOG, was set up on December 30, 2020, as a multi-agency (Department of Biotechnology,

Centre for Scientific and Industrial Research, ICMR, and Ministry of Health and Family Welfare) network of laboratories called Regional Genomic Sequencing laboratories (RGSL). The effort was facilitated by the National Centre for Disease Control (NCDC) under their Integrated Disease Surveillance Programme (IDSP). Initially, this included 10 laboratories which had either sequenced SARS-CoV-2 during the pandemic or had the capacity to do so based on their deep experience in other fields of human genetics or oncology or rare genetic diseases. The network currently includes more than 38 labs, and the effort is expanding in order to track SARS-CoV-2 variants. There were some important things to note about this consortium.

India now has well over 120,000 sequences of SARS-CoV-2 available on GISAID; while a fraction of these are from individual efforts, INSACOG is responsible for a large proportion of these sequences (Figure 4). We need to compare this to other viruses sequenced in the country: only a few hundred genomes of all Dengue serotypes and less than a hundred full genomes of viruses, such as Japanese Encephalitis Virus, have been sequenced since 1947 to the present. So, there is no doubt that SARS-CoV-2 has allowed sequencing capacity and knowledge to scale, and this is likely to flow into many other pathogens in the near future.

This is the first time that academic labs or institutions not directly involved or mandated to participate in the outbreak response have been

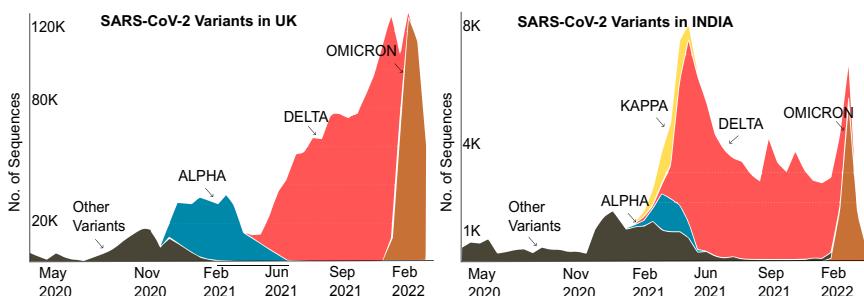


Figure 4. SARS-CoV-2 variant sequence analysis from the UK (left) and India (right) showing proportion of variants – relevant Variants of Concern (Alpha, Delta, Kappa and Omicron) are labelled. Figure is adapted from Our World in Data, based on SARS-CoV-2 sequencing data deposited to GISAID by sequencing laboratories across the world.

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brought in as active partners. The pandemic has also provided an unprecedented opportunity for different agencies to come together and share genomic, clinical, and epidemiological data. This integration of multiple data streams has been challenging all over the world.

The WHO recommends continuous sequencing of SARS-CoV-2 cases in order to detect variants of concern early. This means a further increase in sequencing capacity in India. In parallel to the diagnostic efforts in the country, sequencing may need to be opened up to the private sector to adequately address this issue. In fact, private labs with sequencing expertise have been encouraged to submit their expression of interest to join INSACOG, and several proposals for scaling sequencing are currently in review. The bottleneck for sequencing may then become the availability of sequencing reagents, which are almost exclusively imported from outside India and are currently in high demand all over the world.

Despite its challenges, this effort has encouraged several agencies to come together to address genomic surveillance in the country and build capacity. The consortium has also contributed to scientific understanding of SARS-CoV-2 (Mlcochova *et al.*, 2021), especially the Delta variant (Dhar *et al.*, 2021), which was first detected in the country. It is critical to retain the talent and know-how that has been built in this space and channel it to other pathogen sequencing activity in the post-pandemic world. Even as the future of this effort and if and how it will be expanded into a long-term program is unclear, it may be useful to understand some of the challenges in the translation of genomic sequences into actionable information. To understand these challenges, we need to make the distinction between pathogen genomics and genomic epidemiology.

4.3.2 Introduction to genomic epidemiology

The idea that changes in the sequence of SARS-CoV-2 can help us understand the spread of the virus was appreciated in early 2020 (Hodcroft *et al.*, 2020). At that time, it was unclear if these changes would lead to a change in the properties of the virus — the way it spreads, escapes from the immune response (both from natural infection and from vaccines), and the severity

of disease. In order to fully unleash the power of sequencing, genomic data needs to be combined with epidemiological information at two levels. The first is at the level of the individual — who got infected, when, and where. The second is that at the local epidemiological context — positivity rate, hospitalization rate, composition of variants circulating in that location, vaccination status, demographics, population density, contact within the population, etc.

The superimposition of sequence/variants/mutant data on the above data is the most powerful path to detecting variants early (Rambaut *et al.*, 2020). The promise of genomic epidemiology is the ability to provide actionable insights in a timely manner to decision-makers. This includes scenarios such as a correlation between a new mutation/variant with higher transmission and severe disease or reinfection despite vaccination.

The challenges include logistics of sample transport to sequencing labs and timely flow of sequence information back to surveillance networks and policymakers. The other issue with the increasing number of sequences is that of scaling informatics infrastructure and real-time data analysis.

Apart from the INSACOG efforts, sequencing efforts driven largely by the states have also been a part of the pandemic response in India. Kerala was one of the first states to implement a comprehensive genomic surveillance program in collaboration with CSIR-IGIB. This model of timely sequencing and data sharing is important to enable genomic data to impact policy. The genomic surveillance efforts highlighted spread from a limited number of introductions into the state (Radhakrishnan *et al.*, 2021). Studies on SARS-CoV-2 genomes and their local variations have also been reported from Andhra Pradesh (Roja Rani *et al.*, 2021), Telangana (Gupta *et al.*, 2021), and Gujarat (Joshi *et al.*, 2021).

The state of Karnataka also benefited from two early RGSLs being in the state. At the National Institute of Mental Health and Neurosciences, we started sequencing early and carried out a comprehensive analysis of the first 1,500 cases in Karnataka — providing insights about the introduction and spread of SARS-CoV-2 in the state (Pattabiraman, Habib, *et al.*, 2020). Our second study looked at the introduction of variants of concern into the state (Pattabiraman, Prasad, *et al.*, 2022). Both studies were able to

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demonstrate the utility of containment efforts. They highlighted the fact that introduction of SARS-CoV-2 occurred both by international and domestic travel. When the VOC Alpha was detected in a traveler to Karnataka from UK, the containment activities that were initiated seem to have effectively limited its initial spread in the state. A more intensive sequencing is probably warranted at a city scale in India, and several efforts are now underway in multiple cities to ensure good background data, which would be invaluable for the assessment of variants. Such data are critical for understanding how VOCs are introduced, emerge, and spread in a population in the context of vaccination and waning population immunity.

An alternative to sequencing human cases is environmental surveillance for variants. In the case of SARS-CoV-2, many initiatives across the world are taking advantage of the fecal shedding of the virus to identify variants in wastewater (Safford *et al.*, 2022). Prior to SARS-CoV-2, polio has been the main disease for which wastewater surveillance was in place and done routinely as part of the eradication efforts (Garg *et al.*, 2018). In India, wastewater surveillance is being carried out in some cities, such as Bengaluru, Hyderabad, Pune, and Delhi, with support from the Rockefeller Foundation and as part of the COVIDActionCollab.

4.3.3 How is India preparing for pandemic X in the context of genomic sequencing?

A system of laboratories under the aegis of ICMR — namely the VRDL network — was envisioned as a way of dealing with outbreaks of a pathogen with pandemic potential. This complements the epidemiology work of the NCDC-IDSP network, which currently performs outbreak investigation and surveillance in the country. If both these networks work together, they will be able to detect emerging pathogens in a timely manner. Private sector contribution in this can be envisioned for the development of tools for data collection, clean-up and validation, analysis and interpretation, and sequencing as a service, as needed by the surveillance network. SARS-CoV-2's legacy may be that of a massive expansion of sequencing capacity in India. This will need to be matched with our ability to convert sequence data into useful information.

In order to do this, countries like India need to balance the needs of pandemic response while making a case for the use of this relatively expensive tool in the midst of a crisis. All over the world, the case for genomic epidemiology is being developed, and the WHO has emphasized this as a capacity that needs to be built as part of the response to this pandemic. However, this occurs in the background of resource limitation, vaccine inequity, and the discriminatory travel bans imposed by rich countries when new variants are detected in other parts of the world. To actually reap the benefits of this envisioned expansion in genomic surveillance of pathogens, we need to recognize the disproportionate challenges faced by scientists in LMICs in the generation and sharing of genomic information of pathogens and potential pathogens in the context of an unequal world.

4.4 Case 4: Data science and epidemiology in pandemics

Epidemiology is a classical discipline of the study of population health. It took a biostatistical shape in the early 20th century with the adoption of “Compartment Models” of susceptible, infected, and recovered subpopulations in a lumped compartment. The dynamics of transition between these SIR states of infections are captured through simple ordinary differential equations. Surprisingly, after 100 years, this is broadly how epidemiology modeling is still taught in many clinical and public health programs.

The idea of bringing modern data science to bear on modeling, forecasting, and surveillance has been an important trend since the early part of this millennium that was perhaps triggered by the Anthrax scare in the US and an acute awareness of vulnerabilities to biological weapons and terrorism. Not surprisingly, the work was rapidly brought into military research on biodefense at places such as Los Alamos in New Mexico. However, the methodologies are applicable to public health and the surveillance of epidemics as well. Biodefense and public health are two faces of the same coin — dealing with epidemics that might be either deliberately man made or unwittingly formed through ecological disruptions.

As might be expected, there were researchers from the Indian diaspora involved in this early work.² In fact, one of the teams led by Professor Madhav Marathe has established the Biocomplexity Institute and the division of Network Systems Science and Advanced Computing (NSSAC) with a number of investigators based at the University of Virginia. Another group is led by Dr Ramanan Laxminarayanan at the Center for Disease Dynamics, Economics & Policy (CDDEP), with offices in Washington DC and New Delhi. The Virginia group has excelled in bringing the cutting edge of data science and agent-based systems to bear on the next generation of epidemiological platforms, while the CDDEP team is known for its exceptional work in epidemiology from a *One Health* perspective. Both these teams have been actively engaged in collaborations in India with academics and state health agencies in the context of the recent COVID-19 pandemic.

A simple explanation for the change in approach is that the dynamics of infection spread is modeled with *synthetic agent-based populations*, and the details of the interactions at home, on the streets, at workplaces, and in shopping malls are actually modeled using detailed interaction graphs. With the addition of mobility tracking and contact tracing with GPS and Bluetooth or QR codes, the detailing becomes even more accurate. To run the simulations and forecasts and use them for surveillance and intervention decisions requires some computational heft, which is why you need data science expertise. Possibly, the best illustration of this was the “city scale” agent-based model (Agrawal *et al.*, 2020) with 13 million agents to represent the actual population of the city of Bengaluru.

The first challenge with data-science-driven “computational epidemiology” is the access to data. The state agencies collect data and archive them in a massive population-scale infrastructure that India has now become adept at through the famous *Aadhaar*, or unique citizen ID project, rolled out in the past decade (more on this later).

²Chandru, V. (2020 December). Exponential technologies and the perfect storm for digital health, editorial, special issue on digital health. *Journal of Indian Institute of Science*, Springer. http://eprints.iisc.ac.in/66846/1/jou_ind_ins_sci_100_4-593-595.pdf.

However, for strategic reasons, the access to these data has been quite restricted and the computational epidemiology community would not have flourished in the past two years but for the valiant community-driven (crowdsourced) efforts to wrangle and ingest data on a near real-time basis. A shout-out to the extraordinary group that built the crowdsourced COVID-19 India portal, which kept this going till October 31, 2021. Fortunately, at least two more groups have now been created: in COVID-19 portal (anchored by the faculty of the Indian Institute of Science (IISc), Indian Statistical Institute (ISI) Bengaluru, and IIT Madras) and COVID-19 Bharat portal (anchored at DataKind also in Bengaluru and supported by Data Development Lab), taking on the onus of keeping the open data updated since November 2021 and accessible to all.

The former's continued effort, in COVID-19, also provides a tab on models and forecasts, which illustrate the power of computational epidemiology in action that is building on this data repository. For example, on the Omicron forecasts, this portal presents the models and forecasts made by the IISc-ISI team, the SUTRA modeling effort (which is a government-sponsored effort out of IIT Hyderabad and IIT Kanpur), as well as the international effort anchored at the Institute for Health Metrics and Evaluation (IHME). The INDSCI-Sim efforts as well as the CSIR forecasts can also be found here.

As a testimony to the veracity of these efforts, we should note that the Karnataka government's recent decisions on curfews in Bengaluru during the Omicron wave that just subsided were on the basis of forecast scenarios presented by the IISc-ISI investigators in collaboration with the team at the University of Virginia. At IISc in Bengaluru, the core group in computational epidemiology now offers a popular elective course in the division of interdisciplinary research that the authors of this chapter have given lectures in. These capacity-building efforts will surely help us in prepare for the next pandemic.

There were a lot of innovative approaches taken by communities to use modeling, testing, and monitoring technologies for their safety. This was mostly evident in technology parks, factories, and larger multinational offices but also in academic institutions and even some residential communities. As we saw with Omicron and the third wave, if the virus

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mutates and negates the gains made with therapeutics and vaccines, screening and testing will again become the most important weapons to battle the epidemic.

The need for a localized decision-support platform suitable for our campuses led the Department of Science and Technology through its national mission on interdisciplinary cyber physical systems (NMiCPS) to support the integrated Campus RAKSHAK project³ in September 2020 at IIT Jodhpur. Two prototypes of Campus RAKSHAK have presently been deployed at IIT Jodhpur and IIIT Hyderabad. The consortium-based project saw IIT Jodhpur collaborate with IISc, IIT Kharagpur, IIIT Hyderabad, IIT Bombay, Algorithmic Biologics Pvt. Ltd., Health Badge Pvt. Ltd., and Prithvi AI Lab to build, integrate, and test to ensure safety on campuses through this initiative.

Campus RAKSHAK is based on four components:

- *Tapestry pooling* is a clever compressed sensing method that achieves cost savings in testing without compromising safety. This innovation made it to the final round of the X-Prize for COVID-19-related innovations in testing, the only entry from India to make the grade.
- *Go Corona Go* is a contact-tracing app that builds a primary, secondary, and tertiary contact graph of students, which can be used in both monitoring and mitigation of risk on campuses.
- Three simulators called the *Campus Modeler*, *CampusSim*, and *EpiSimmer* with complementary predictive power for modeling safety control and mitigation strategies form a central component of the solution.
- *HealthBadge* is an information management and badging system. It categorizes campus residents based on the seriousness of the infection and issues red, amber, and green badges to them following an investigation of the infection. There are interesting game theoretic and information privacy nuances that HealthBadge incorporates.

These together form a single integrated decision-support platform that monitors, predicts, and can recommend mitigation strategies for campuses against COVID-19 and can be of great value in the context of future infections for campuses and various community settings.

³<https://www.nationalheraldindia.com/india/campus-rakshak-to-check-coronavirus>.

At state and national population scales, technology solutions had to be built from scratch to address India's needs for her billion-plus citizens. India has, of course, now a track record of building some of the world's best digital platforms at an enormous scale. The clever idea that drove India to take a leadership position in this technology space derives from a simple idea — scaling up existing solutions often fails while building solutions for scale have a better chance of success.

Aarogya Setu,⁴ the national contact-tracing and test-monitoring application that works on mobile phones with chatbots fluent in all Indian languages, saw rapid adoption in the early days of the pandemic for personal safety use and later also became an important monitoring mechanism for high-risk spreaders of infection, travelers, and residents in hot spots. There were perhaps some compliance challenges in reaching full population scale the first time around, but we have had about 215 million downloads of the application and the monitoring of close to 800 million tests that have been tracked. This has given the nation the capability in future disaster situations for rapid deployment at population scale.

The second application at population scale to be deployed in India during the pandemic was Co-WIN,⁵ which grew out of an early realization that the way out of the pandemic was through mass vaccination. By mid-2020, the technology leadership that had created the national ID, Aadhaar, made a presentation to the Prime Minister's Office, that the underlying platform could be repurposed for the massive logistical challenges that lay ahead with the roll out of vaccination for a population of 1.3 billion people. The Co-WIN platform, rolled out by the National Health Authority in January 2021 for vaccine registration and certification for eligible citizens, is perhaps India's greatest success story during this pandemic. The platform had many outstanding design features:

- It addresses the problems of information asymmetries — mobile OTP as simple CRM capture for vaccination registration.
- Compliance (vaccination protocols, spacing between doses, etc.).

⁴<https://www.aarogyasetu.gov.in/>.

⁵<https://www.cowin.gov.in/>.

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- Accessibility (it is multilingual) and minimal data (name, gender, year of birth, and phone number) collection from citizens with consent.
- Co-WIN can be accessed from 110 apps of various kinds that citizens already had installed on their mobiles.
- Easy access to vaccination certificates for any citizen on their phones with encryption QR codes that need a public key from the government to unlock — privacy by design.

The Co-WIN platform is a digital public good that is being adapted now for pediatric vaccinations, blood donation, and organ donor registries and will eventually play an important role in the national Ayushman Bharat Digital Mission (ABDM), which is India's vehicle for addressing the challenge of attaining universal healthcare in the coming years. India is now looking to empower other countries with the Co-WIN portal technology as a strategy for pandemic preparedness.

5. Conclusion: A Brief History of the Next Pandemic in India

Wars and pandemics are usually the drivers for major shifts in science and technology. In a recent book called *2034*, Elliot Ackerman and Admiral James Stavridis speak about the history of the next world war. When asked why they wrote this book, Stavridis answered that he thought a book like *2034* might prevent the next world war given that we are at the verge of a cold war between the US and China. As George Santayana famously said, “Those who cannot remember the past are condemned to repeat it.”

When we speak about “a brief history of the next pandemic,” I think the horrors of the one we are in — and it isn’t over yet — are fresh enough that we shouldn’t need a *2034*-type remedy. But there does seem to be a pandemic that is already afoot; clinicians and public health scholars are aware of the challenges that anti-microbial resistance (AMR) poses to the world, and the LMICs in particular need urgent attention. India is in a precarious position, as has been recognized by the ICMR. We need to take the threat seriously and make sure that all stakeholders understand the dire

need for stewardship because “when antibiotics stop working, the next pandemic is already here.”

We do hope that the recombinant innovation that has been unleashed through the COVID-19 pandemic in India for vaccines, diagnostics, pathogen surveillance, and computational epidemiology, along with the many important contributions within Edison’s Quadrant, has put India on a path to be better prepared for pandemics in years to come. While the huge tragedies and suffering that the nation has faced will remain etched in our memories for a long time, we are also filled with hope for a new translational and collaborative intent among the scientists and technologists of the nation and indeed the world.

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Chapter 2.5

Innovations in Clinical Trial Design: Lessons from the COVID-19 Pandemic

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Abstract

COVID-19 has shown that clinical trials need to be efficient, adaptable, and provide high-fidelity data that are actionable for public health officials and clinicians to deliver safe and effective interventions. Traditional fixed design trials, such as prospective randomized, double-blind clinical trials, need large sample sizes, are subjected to multiple study protocols for every interventional arm, take time to complete, and are expensive. In addition, they are not flexible enough to add or delete study arms during the course of the trial. Standard clinical trials are performed through sponsor-specific networks of clinical sites, with each

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trial and sponsor essentially competing with others for trial subjects to validate their therapeutic platform. Adaptive trials are more flexible and dynamically adjustable based on the accumulated results. This approach focuses on the best treatment, individual drug, or a combination among various options for a disease instead of focusing on the best single drug for a disease. Adaptive trials are often more efficient, cost-effective, and need fewer trial participants as futile treatment arms may be stopped early. Fewer patients may need to be randomized to a less promising treatment, and smaller study cohorts may be required to address the trial's questions. Global health consortiums, governments, and multilateral institutions have the opportunity to collaborate and conduct adaptive trials, via established global clinical trial networks, to study and identify disease-outcome-driven interventions.

Keywords: pandemics; COVID-19; clinical trials; global health

1. Context of Trials in a Pandemic

Prospective double-blind, randomized clinical trials are the gold standard for regulatory approvals of drugs and therapies, guiding healthcare providers, regulators, and drug manufacturers. These trials need large sample sizes, are subjected to multiple study protocols for every interventional arm, take time to complete, require complex infrastructure to execute, and are expensive (Ajmera *et al.*, 2021).

The COVID-19 pandemic has forced the global life science and healthcare community to realize that the issues of safety and efficacy of novel therapeutics and vaccines need to be addressed much faster and in a much more cohesive fashion to quickly bend the curve and reduce the human toll of the pandemic. Among many of the learnings from the pandemic, it has become apparent that global public health emergencies need efficient, integrated, rapidly implementable, cost-effective, and flexible clinical trial designs that will rapidly lead to valid data about a novel vaccine or a therapy's efficacy and safety. The pandemic has provided an opportunity for clinical researchers to learn from the experience of various trials to better respond to future global contagions.

The fundamental inefficiencies and shortcomings that surround the traditional approaches to clinical trials became apparent in the pandemic as governments and other entities rushed to conduct trials on various drugs

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as monotherapy or combinations of interventions. COVID-19 has shown that trials need to be efficient, fast, adaptable, and provide high fidelity data that are actionable, acceptable by regulators, and allow public health officials and clinicians to deliver safe and effective interventions. Traditional fixed design trials, such as the prospective randomized, double-blind clinical trials, need large sample sizes, are subjected to multiple study protocols for every interventional arm, time take to complete, have rigid and defined trial structures, require complex infrastructure, and are costly. In addition, for each potential COVID-19 vaccine or therapeutic agent, standard clinical trials are performed through sponsor-specific networks of clinical sites, with each trial and sponsor essentially competing with others for trial subjects to validate their therapeutic platform.

The pandemic also saw the emergence of weak and ineffectively structured clinical trials. An analysis of over 2,000 COVID-19 trials by the FDA demonstrated that only 5% of the clinical trials were adequately randomized or statistically powered to prove safety and efficacy (Bugin and Woodcock, 2021). Even though many of these trials did not effectively prove safety and efficacy, their results still influenced many clinicians, governments, and COVID-19 patients to consider these treatment options. Ivermectin and colchicine are examples of two such repurposed therapeutic agents that were widely prescribed based on inadequate trial designs and unproved results.

Properly structuring of trial protocols for novel diseases, where the pathogenesis, natural history, and outcomes are still unknown, takes time. However, this luxury of time is not available in a rapidly spreading disease, such as in a pandemic, forcing a compressed timeframe to obtain the necessary trial results and institute global prophylactic or therapeutic measures. Design flexibility in a trial is a major, necessary attribute to provide a feedback loop to get accurate results. Information gained during a trial needs to inform the trial's ongoing design in an adaptive manner (Figure 1). Flexible trials allow new treatment arms, new dosage, change of allocation ratios, and dropping of "failing" treatment arms without undermining the statistical power of the trial. Finally, responding to a global pandemic requires public, private, and social entities to expeditiously come together in a cohesive fashion to conduct pivotal cross-border trials to achieve the speed, efficiency, and global health applicability of the trial's result.

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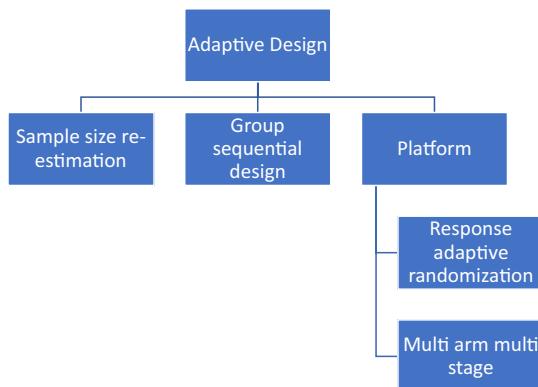


Figure 1. Advantages of adaptive trial design.

This chapter does not provide a comprehensive review of all COVID-19 trials; rather, it aims to provide an overview of new flexible and faster study designs while maintaining their scientific integrity.

2. Adaptive Trial Design

Adaptive clinical trials have been around for over two decades. These trial designs depart from the traditional fixed-design clinical trials, where the trial design is linear and the results are measured based on a determined statistical methodology. Adaptive trials are more flexible, i.e., dynamically adjustable based on the accumulated results. This approach focuses the trial on the best approach to address a disease instead of focusing on the best single drug for a disease.

Essentially, an adaptive trial adds a “review–adapt–modify” loop to the traditional linear trial design, as shown in a simple schematic in Figure 2.

This regular analysis of the evolving data to modify and adapt an ongoing clinical trial without compromising the scientific integrity or the statistical validity of the trial is the hallmark of adaptive trials. Hence, data need to be properly collected, stored, and analyzed based on acceptable standards, the integrity of trial processes needs to be maintained at all stages, and the objective of the trial can't be compromised. Adaptive trials allow pre-planned changes as part of the adaption process. Examples of

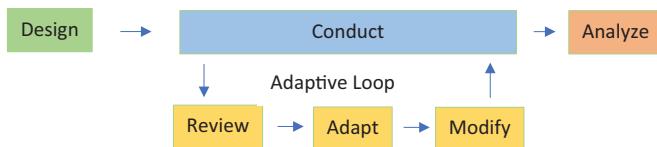
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Figure 2. Adaptive loop in trial design.

Source: Adapted from Pallmann *et al.* BMC Med 16, 29 2018.

this include adjusting the sample size, abandoning treatments or doses, stopping the whole trial at an early stage for success or lack of efficacy, modifying the allocation ratio of patients to trial arms, and focusing recruitment efforts on patients most likely to benefit from the trial (Chow and Chang, 2008).

Adaptive trials are often more efficient, ethical, cost-effective, and need fewer trial participants as futile treatment arms may stop early, fewer patients may be randomized to a less promising treatment, and smaller study cohorts may be required to address the trial's questions. As a result, these trials reduce the need for multiple redundant clinical trials, estimated treatment effects, and conclusions may be known quickly, allowing effective treatments to be rapidly deployed to respond to a global contagion (Pallmann *et al.*, 2018).

Experience and expertise related to adaptive trials need to be expanded, and there needs to be a greater regulatory acceptance of adaptive trial designs for these trial designs to expand in their use.

The Consolidated Standards of Reporting Trials (CONSORT) guidelines provide a structure for the reporting of randomized controlled trials (RCTs), enabling readers to assess the validity of a trial's results. CONSORT guidelines were developed through collaboration and consensus between clinical trial methodologists, statisticians, and journal editors (Schulz, Altman, and Moher, 2010). The recent CONSORT guidelines have been extended to include adaptive trial designs (Dimairo *et al.*, 2020). Adaptive designs have decision rules made *a priori* for adapting the study methodology as the study evolves over the course of time, with preliminary data allowing for modification of study entry criteria, treatment arms, study assignment, sample size, or dosage of the drug. The *a priori* decision rules are necessary to preserve the validity and integrity of

the trial. The focus on disease outcomes, rather than the intervention, requires that evolving information be allowed to be factored in the trial design. This also reduces the need for multiple redundant clinical trials and the cost of the trial and provides the best approach for a disease instead of the best single drug for a disease. The challenges are the new approach to statistical design, testing of results, and their interpretation.

The PREVAIL II trial for the Ebola virus outbreak in West Africa in 2014 used a Bayesian design (Dodd *et al.*, 2016) and is an example of adaptive trial design. In a Bayesian design, the aim is to provide decision rules after analyzing the observed responses in the trial to modify or drop certain ineffective arms and retain effective arms (Jacob *et al.*, 2016). A response adaptive design can be used for phase 1/2 dose-finding study as well as large phase 3 efficacy trials. Any dose arm can be dropped for futility and toxicity, or the randomization of patients can be increased to 2:1 in favor of the treatment arm for doses showing promising results (Stallard *et al.*, 2020). A specific concern relating to type 1 error, the false rejection of an actually true null hypothesis, is a major challenge.

3. Master Protocol Trials

Master protocol trials were initially designed for oncological drugs to simultaneously evaluate more than one drug or cancer type within the same structure. Structured as a single trial design and protocol that can evaluate multiple drugs in parallel and disease populations in sub-studies, master protocol trials are efficient and enhance the drug development and therapeutic validation process.

There are three types of master protocol trials: basket, umbrella, and platform trials.

A study designed to evaluate a single drug in different disease populations is a basket trial, as shown in the schematic in Figure 3(a).

A study evaluating multiple interventions in a single disease population is known as an umbrella trial, as shown in the schematic in Figure 3(b).

For example, the Diabetic Retinopathy Clinical Research (DCRC) network trials evaluating various interventions in diabetic retinopathy is

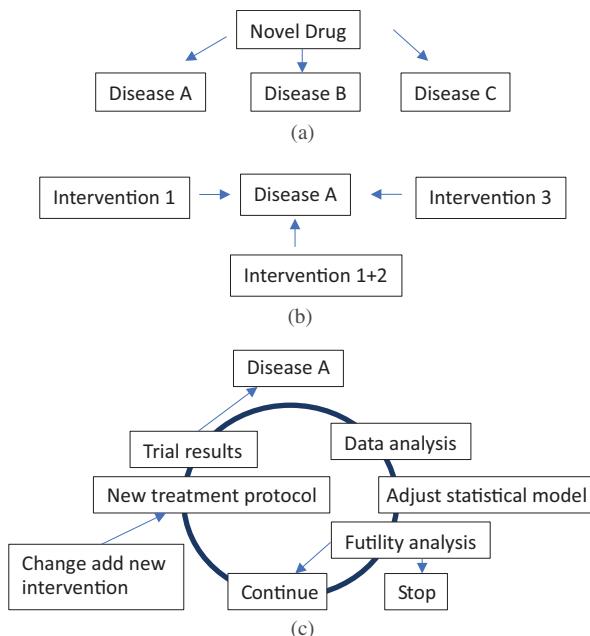
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Figure 3. Schematics of (a) basket, (b) umbrella, and (c) platform trials.

Source: Adapted and simplified from Beglin (2020), <https://doi.org/10.1016/j.conc.2020.100568>.

an umbrella trial. The mission of the DRCR retina network is to conduct multicenter clinical trials focused on retinal disorders. The DRCR network was formed in 2002 and is funded by the National Eye Institute.

A platform trial is a type of adaptive trial, which involves multiple interventions being evaluated for a single disease using decision algorithms to modify treatment arms, as illustrated in a schematic in Figure 3(c) (Beglin, 2020).

Interim analyses are a part of the design feature, which may include surrogate markers to identify early indicators of outcome. Multiple interventions can be evaluated in a perpetual manner under a single protocol using the same pool of administrative resources as well as trial procedures. Multiple arms have the same target for sample size, as well as new treatment arms that are added in the interim. The maximum number of arms in a platform trial are decided *a priori* based on the operational feasibility of the study. Flexible multi-arm, multi-stage (MAMS) trials use inputs from

Table 1. Differences between traditional and platform trials.

Characteristic	Traditional Trials	Platform Trials
Objective	Focus on single intervention	Focus on disease outcome, which may include combination of treatments
Treatment arms	Fixed, small	Flexible, arms may be added or dropped
Duration	Finite	Perpetual, as long as the disease is of public health importance
Treatment assignment	Fixed randomization	Response adaptive randomization
Support	Pharmaceutical industry	Global Health Consortiums, Government Agencies, Institutes

interim analyses to modify treatment arms and protocols without increasing type 1 and type 2 errors. MAMS appears to be efficient when there is no “clear winner” among different treatment arms. Bayesian response adaptive randomization (BRAR) is better than MAMS if one treatment arm appears more effective, and the probability of an ineffective treatment arm being dropped from the trial increases. BRAR increases the allocation of subjects to the treatment arm that appears effective (Lin and Bunn, 2017).

Platform trials provide numerous advantages over the more traditional trial designs (Table 1). Platform trials are focused on the disease outcomes and hence provide an opportunity to change the protocol’s design based on interim analyses (Park *et al.*, 2020). There is an opportunity to drop an ineffective treatment arm and bring in a new, more effective treatment arm in a perpetual trial. COVID-19 is increasingly being recognized as a perpetual disease, with variable clinical features coupled with new mutations of concern and a long-haul symptom complex. Most of the treatments for COVID-19-affected patients have been with repurposed drugs, and multiple such drugs have been evaluated. Traditional two-arm studies would be inefficient to decide the effectiveness. MAMS, with its flexible design, would be the most efficient trial design to identify a single drug or combination of drugs for the best outcome. The SOLIDARITY trial of the World Health Organization (WHO) (Repurposed Antiviral Drugs for COVID-19 — Interim WHO Solidarity Trial Results, 2020), and the AGILE trials are examples of platform trial (Griffiths *et al.*, 2021). It is the outcome of such MAMS trials that uncovered the therapeutic benefit of dexamethasone in advanced COVID-19.

There is increasing interest in platform trial designs, as they are perpetual, efficient, and focused on the disease. However, it has not been given enough consideration among clinicians and, especially, the biopharmaceutical industry. Platform trial designs pose a particular challenge for the pharmaceutical industry, as platform trials involve combination treatments and are perpetual. Unlike a traditional trial design, platform trials are not targeted to obtain data to achieve regulatory approval for market commercialization. With the availability of numerous treatments for various diseases, such as cancers, chronic heart diseases, diabetes, and autoimmune diseases, many of which need to be treated by drug combinations, as well as nondrug interventions, platform trials provide the most effective trial design to evaluate them.

4. Global Clinical Trial Networks

Establishing robust global health networks that include multiple pre-accredited clinical trial sites, with trained investigators connected through a robust trial technology platform, built around block-chain-driven data pipelines that can respond to all types of sponsors, is critical to build a future in a global clinical research ecosystem. Such a system promises to be dynamic, flexible, and have the scale to conduct multiple trials simultaneously during a pandemic. This will allow future clinical trials to be driven by large health consortiums, organizations, networks, and societies, with industry collaboration. Critical to such a network would be to accredit the sites and the system based on the standards set out by the Alliance for Clinical Research Excellence and Safety (ACRES) consortium.

5. Regulatory Considerations and Challenges

Traditional trials are efficient to assess a single therapeutic agent and obtain regulatory approval. The COVID-19 pandemic has expanded the role of regulatory authorities to support treatment decisions by healthcare providers based on evidence for new as well as repurposed drugs which may be of off-label use. All drugs may not require a label (Narayanan and Honavar, 2017), but evidence provided by large trials during pandemics

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helps save millions of lives. Health organizations could suggest guidelines based on evidence, which may include combinations of drugs and other interventions. The New England Journal of Medicine has published an editorial by the Directors of Drug Evaluation and Research on platform trials (Woodcock and LaVange, 2017).

The US Food and Drug Administration (USFDA) and European Medicines Agency (EMA) have laid down requirements for platform trials.

6. Conclusion

Flexible and responsive adaptive designs in clinical trials can help in faster identification of effective treatments as well as futile drugs which can harm patients. In a pandemic setting, rapid testing of drugs in trials and incorporating effective interventions in treatment guidelines is sought after by healthcare professionals. Adaptive trial designs also help in rapid identification of ineffective treatments. Industry sponsored clinical trial models are structured to support a particular therapy's regulatory process for approval and commercialization. Global health consortiums, governments, and multilateral institutions have the opportunity to collaborate and conduct adaptive trials, via established global clinical trial networks, to study and identify specific disease-outcome-driven interventions. While most clinicians are generally unaware of these new design strategies, the clinical trial landscape is changing rapidly, with many new adaptive trials, such as platform trials, being performed during the COVID-19 pandemic. While COVID-19 has forced care providers to think differently, clinicians need to take a greater leadership role in generating efficient trial designs to identify the best therapeutic interventions for various diseases. However, challenges remain in adopting such new clinical trial designs on a large scale.

7. Key Messages

- Flexible and responsive adaptive designs in clinical trials can yield faster results.
- Platform trials are focused on the disease outcomes.

- Adaptive designs have rules made *a priori* for modifying the study methodology.
- Multiple hypotheses can be tested in a single trial.
- Establishing global clinical trial networks is urgently required.
- The clinical trial landscape is changing rapidly, with many new platform trials being performed.

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Hyperlinks

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Chapter 2.6

Lessons from Pandemic: Teleophthalmology in LV Prasad Eye Institute

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Abstract

Access to healthcare is a key challenge facing people around the world during the COVID-19 pandemic. Many innovative telemedicine solutions have been implemented to enhance access to healthcare during the pandemic. An ecosystem of telemedicine with adequate infrastructure and country-specific practice guidelines has been developed. An exponential increase in teleconsultations, corresponding to the pandemic surges, has been observed around the world. This chapter focuses on a comprehensive teleophthalmology solution developed during the pandemic by the LV Prasad Eye Institute. The infrastructure and resources required to develop a mobile teleophthalmology solution are

outlined. Lessons learned in delivering care through teleophthalmology during the pandemic are shared.

Keywords: telemedicine; pandemics; global health; digital health

1. Introduction

The COVID-19 pandemic has brought with it a variety of challenges impacting access to healthcare. These barriers include travel restrictions, strict quarantines, minimal face-to-face encounters, and economic hardship. There were also barriers related to the adoption of technology, reimbursement of teleconsultations, insurance coverage, licensing requirements of physicians, etc. (Grewe, 2022). These barriers have greatly affected all branches of healthcare, and the field of ophthalmology is no exception (Saleem *et al.*, 2020).

The first recorded teleophthalmology project was conducted in 1987, when retinal images from astronauts on the Columbia mission were beamed back to Earth through a video fundoscope. The aim of the project was to better understand the effect of unique gravity conditions (such as zero gravity) on the human eye (Zwart *et al.*, 2017). Since then, teleophthalmology has proven itself to be a cost-effective alternative to in-person examinations, particularly in the treatment of conditions such as diabetic retinopathy and glaucoma. A systematic review of teleophthalmology has found it to be especially efficient and cost-effective in conjunction with other positive factors, such as screening numbers, older patient age, regular patient screening, and the comprehensive utilization of telemedicine equipment (Sharafeldin *et al.*, 2018).

Despite its accuracy, cost-effectiveness, and reported levels of patient satisfaction (that have been repeatedly proven through various studies over the past three decades), telecare models have not been routinely integrated and optimally utilized in regular patient care systems. The barriers to such integration were attributed to a lack of familiarity with these technologies among both patients and providers, technical challenges, time constraints, reimbursement concerns, doubts about its accuracy, and irregular patient satisfaction (Scott Kruse *et al.*, 2018).

However, the disruption caused by the COVID-19 pandemic in access to healthcare has led patients and medical providers to look for immediate teleophthalmology solutions to provide the necessary care virtually

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(Sharma *et al.*, 2020; Sommer and Blumenthal, 2020). There has been a sharp increase in the use of telehealth platforms to access virtual healthcare. In India, an online teleportal survey showed that online consultation for healthcare had increased by 500% during the pandemic (80% of the new incoming patients were first-time users). This was accompanied by a 44% drop in in-patient visits.¹

In response to the health crisis caused by the pandemic, the government of India put various measures in place to encourage more institutions to adopt and take up telemedicine:

- (1) Telemedicine practice guidelines were released to provide uniform standard telemedicine care.²
- (2) Health Insurance Portability and Accountability Act (HIPAA) restrictions for transmission of patient information have been relaxed (e.g., use of media such as WhatsApp, e-mail, Google Meet, and Zoom) to facilitate easy access to eye care.
- (3) A nationwide eSanjeevani platform has been launched as a part of the digital India Initiative to provide necessary care and advice. Sanjeevani, Government of India's telemedicine initiative, completed 1.2 crore consultations, and around 90,000 patients use eSanjeevani daily to seek health services remotely as on September 21, 2021.³ All registered medical practitioners who want to practice telemedicine in all specialties must obtain an online certification in accordance with the new telemedicine guidelines of India.

2. Telemedicine Lessons During COVID-19 by LV Prasad Eye Institute

LV Prasad Eye Institute (LVPEI) is a comprehensive pyramidal-model eye health facility (Figure – LVPEI map). The entire LVPEI system is digitized, with the integration of ophthalmic electronic medical record

¹<https://indianexpress.com/article/lifestyle/health/500-increase-in-healthcare-teleconsultation-in-india-80-are-first-time-users-report-6483212>. 2021.

²Ministry of Health and Family Welfare TPG, 2020 (Mar. 25, 2020), <https://www.mohfw.gov.in/pdf/Telemedicine.pdf>. Telemedicine Practice Guidelines. 2020.

³eSanjeevani GoIsti, completes ..., PressReleasePage hpgi. (2021). eSanjeevani, Govt. of India's telemedicine initiative, completes; <https://pib.gov.in>, PressReleasePage.

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(eyeSMART EMR) from primary to tertiary levels. Before the pandemic, primary eye care was delivered solely through teleophthalmologic means (Das *et al.*, 2019). After the pandemic, teleophthalmology connected the entire LVPEI pyramid (Das *et al.*, 2020).

Lesson 1: Digitalization and EMR infrastructure are the best investments for developing effective telemedicine systems.

3. Pandemic Impact on Eye Care: LVPEI Case Study

During the national lockdown and the accompanying strict quarantine measures, the footfall of patients fell drastically across the entire institute network, from the primary to tertiary level. Strengthening teleophthalmology systems across the network has since become a priority. To introduce the concept of different levels of eye care, we use the LVPEI model of eye care and examine how teleophthalmology is conducted at each level.

At the primary level, a single vision center can provide eye care for a population of nearly 50,000. Ten such vision centers are linked to one secondary center, collectively referred to as a village vision complex (VCC). Community eye care (CEC) services facilitate effective screening of the local population and their referral, as patients traveled from remote villages to the vision centers.

A trained vision technician manages a vision center, screening individuals with eye ailments, providing services (such as corrective eyeglasses), and referring persons with complicated conditions to an ophthalmologist in the nearest secondary center, where comprehensive ophthalmic care is then provided. Patients needing specialty eye care are further referred to a tertiary care center, and particularly complex eye conditions are then sent to a center of excellence if required.

4. Primary Care Level

The steps for teleconsultation at the primary level include an initial patient visit to a primary care vision center in a rural area. Consent for teleconsultation, medical history, slit lamp eye examination, intraocular pressure details, and anterior and posterior segment photographs are all recorded by a vision technician in the EMR on a tablet and then sent through the cloud

network to an ophthalmologist at a tertiary care center. Vision technicians are primary eye care providers with a high school diploma who have been trained for two years to provide primary eye care. They fulfill the three Rs of eye care: refraction and prescribe corrective lenses, recognize vision-threatening eye problems, and refer them to the next level of eye care as required. The ophthalmologist located at the command center in the tertiary center reviews the case details and pictures and then communicates the management/treatment plan with the vision technician and the patient via a video call on Skype Lite. The ophthalmologist's advice and e-prescriptions are recorded online at the vision center location and provided to the patients.

5. The COVID-19 Pandemic and Teleophthalmology at Primary Level of Eye Care

The COVID-19 pandemic has significantly impacted rural patient care in the LVPEI primary care network (Marmamula *et al.*, 2020; Rathi *et al.*, 2020). At the primary level, more than 100,000 phone calls were made by vision technicians to patients in remote rural locations. These phone numbers were obtained from electronic medical records. These patients from rural locations could then avail teleconsultations with ophthalmologists located at the secondary level. This teleconsultation process was managed by vision technicians who posted patient pictures and case details in a social media group (WhatsApp). More than 750 primary eye care teleconsultations were done during the lockdown through this WhatsApp group. Prior to the pandemic, 2,000 primary care teleconsultations, on average, happened in the primary eye care network. During and after the pandemic, this number had doubled to an average of 4,000 primary care teleconsultations. The majority (>80%) of these primary care teleconsultations are managed at the vision center itself, thus reducing unnecessary travel, saving time and money for the patients and, in turn, reducing the associated carbon foot print. Only 20% of patients required referral to higher centers for medical/surgical management (figure showing case example collage of primary eye care teleconsultations).

Lesson 2: 80% of the problems at the primary care level can be addressed by teleophthalmology alone, with only 20% requiring an additional referral.

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Lesson 3: Teleophthalmology systems were responsible for continuity of care at the primary level during the height of the pandemic.

5.1 Innovation for capturing good quality images during teleconsultation

Additional tools to capture a usable and quality anterior segment photograph help supplement the information gathered during teleconsultation. One such tool that we have devised is a smartphone anterior segment image capture attachment called Grabi, which can be easily used by a patient, caregiver, or eye care practitioner on any smartphone. This device has the ability to capture clinical-quality details, thus facilitating an effective tele-consultation (Joshi *et al.*, 2021).

5.2 Innovations in visual acuity measurement during teleophthalmology

Visual acuity measurement is crucial in providing an effective teleconsultation. In a validation study, we found that a smartphone visual acuity app, PEEK acuity, showed comparable results with standard in-clinic COMPLOG visual acuity measurements (Satgunam *et al.*, 2021). We also found that such apps are easy to download and can be used effectively by a patient's caregiver (unpublished data).

Lesson 4: The pandemic has compelled teleophthalmology systems to grow, accompanied and encouraged by various innovations (e.g., image capture apparatus, validation of visual acuity applications, mobile applications for teleconsultation, etc.).

6. Secondary Eye Care Level

At the secondary level, teleconsultations take place between fellows and residents with experts at the tertiary level. This communication is captured in an EMR that can be accessed at both ends. The necessary investigative reports are sent through social media applications, such as WhatsApp. Our next goal would be to embed these referrals through a referring physician portal into a central teleconsultation portal to allow for seamless data collection.

7. Tertiary Eye Care Level

Innovations in development of mobile applications for teleophthalmology consultation (Connect Care)

Recognizing the importance of teleophthalmology during the COVID-19 pandemic, a mobile teleophthalmology application (ConnectCare) was developed in-house at the LVPEI in June 2020. A prior survey was done to understand patient and physician perceptions toward telemedicine. The patient-side application has helpful features, such as onboarding with mobile number, a way to book appointments, uploading necessary investigation reports and case records, etc.

The physician-side application gives one the ability to view appointment slots and virtual outpatient history, upload reports, and treatment advice. It also allows for easy cross-specialty consultation, administration of e-prescriptions, etc. Teleophthalmology consultation can be performed through both audio and video calls. All physicians have completed the mandatory registration telemedicine certificate course offered by the Telemedicine Society of India. For each specialty, specific teleconsultation indications have been prepared.

Teleconsultations were provided to the following three major categories of patients: (1) postoperative follow-up patients, (2) triage to assess the need for in-person visit for new patients, and (3) second opinions with the help of investigation reports. The teleconsultation system has been integrated into the mainstream regular patient care model. A dedicated teleconsultation schedule has been allotted to all physicians. Approximately 10% of all consultations take place via the ConnectCare online platform daily.

Lesson 5: Teleophthalmology consultations have become an integral part of the regular patient care system.

A total of 43,052 online teleophthalmology consultations took place between June 2020 and September 2021. Patients from 10 ophthalmic subspecialties from 13,202 locations across the country received online consultations from 138 ophthalmologists through the LVPEI network (Figure 1). Figure 1 clearly shows that there was an increase in the number of patients

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making use of the teleconsultation facility corresponding to the peak periods of the pandemic (e.g., October 2020: 3,353 and May 2021: 4,231).

Lesson 6: The online teleconsultation feature has helped to care for the vulnerable populations (elderly, children, and nonpaying patients) by saving time and money and diminishing our carbon footprint.

A majority of the people availing teleconsultation were male (54.2% versus 45.8%; Figure 2).

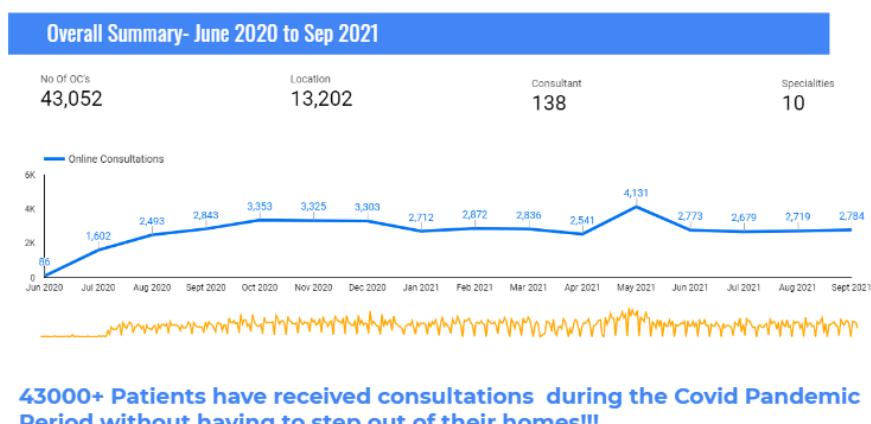


Figure 1. Online consultation data at LVPEI network.

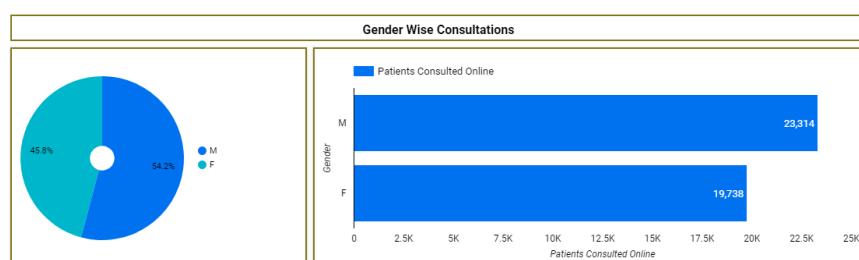


Figure 2. Gender distribution — Online consultations at LVPEI network.

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In total, 4,198 patients over the age of 70 received teleconsultation — advice without the need for travel (Figure 3).

A total of 6,757 children received teleconsultation, reducing the need for the children and parents to have to travel to the hospital or vision center (Figure 4).

In total, 9,407 nonpaying patients received online teleconsultation without the need to spend money on transportation (Figure 5).

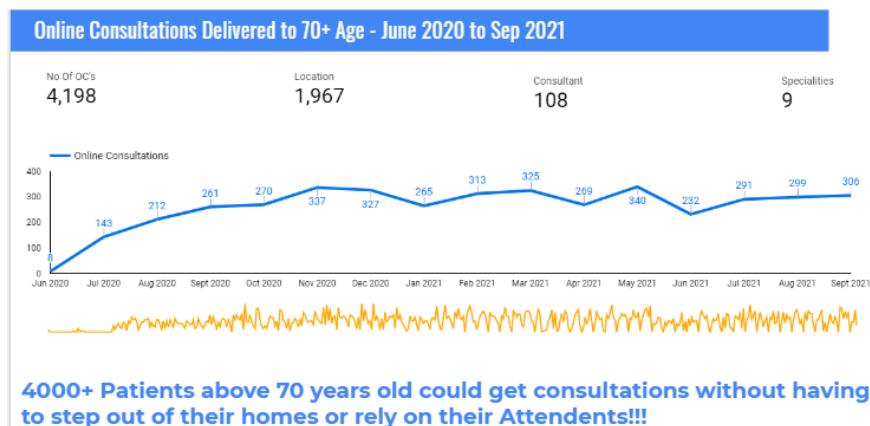


Figure 3. Elderly patients — Online consultation data.

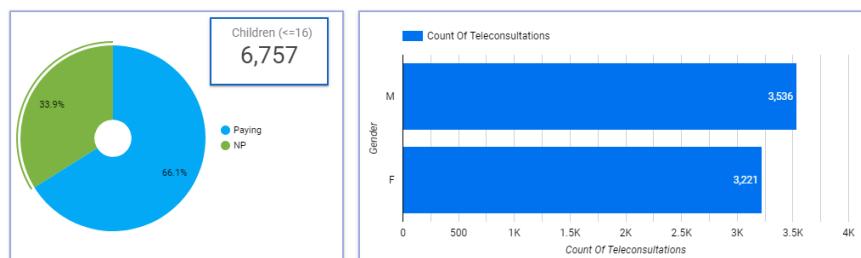


Figure 4. Children — Online consultation data.

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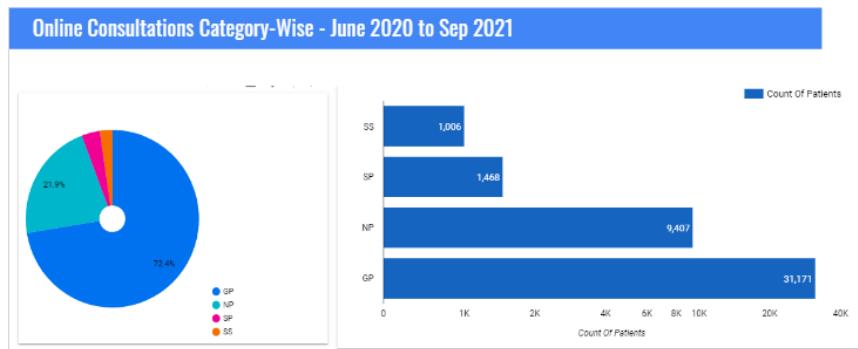


Figure 5. Nonpaying patients — Online consultation data.

8. The Future

Telemedicine has the potential to create a carbon-free (health-free) healthcare system by reducing travel-related carbon emissions. In a systematic review by Purohit *et al.*, it was found that the carbon footprint savings ranged from 0.70 to 372 kg CO₂e per consultation (Purohit *et al.*, 2021). These values are regional and context specific, and the majority of the data relate to secondary and tertiary healthcare levels in developed countries, such as the UK and the US. There is an immediate need to conduct similar studies regarding the beneficial role of telemedicine impact in reducing the carbon footprint in primary, secondary, and tertiary levels of eye care and healthcare in India. Apart from its direct impact on the carbon footprint, there are multiple other beneficial effects in the form of cutting costs and saving time for patients and healthcare providers through the implementation of telemedicine systems.

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Chapter 2.7

Electronic Health Records and Health Efficiency Post Pandemic

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Abstract

Catering to the healthcare needs of seven billion people poses unique challenges and opportunities globally. The provision of the basic right to healthcare is the moral responsibility of the government toward its citizens. Although access to health information is crucial, the emphasis must be on the quality of the data being collected that will guide the decisions of our policymakers. We must and should adopt the best technology frameworks that are relevant to our geography without compromising the volume of care that is currently being delivered. With the changing landscape of both lifestyle and the trend of diseases over the years, it is imperative that we need to have the right information at the right time to make the right decision for the right individual. The implementation of digital health is a key step in the direction that

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ensures the availability, accessibility, affordability, and acceptability of healthcare for the masses. There has never been a more opportune time such as this to lay down a strong foundation to enable the collection of “good quality” digital health data points to guide us in the future to prepare for any challenge, such as the COVID-19 pandemic.

Keywords: digital health; big data; electronic medical records; COVID-19 pandemic; health economics

1. The COVID-19 Pandemic

“It was the best of times, it was the worst of times, it was the age of wisdom, it was the age of foolishness, it was the epoch of belief, it was the epoch of incredulity, it was the season of light, it was the season of darkness, it was the spring of hope, it was the winter of despair” wrote Charles Dickens in *A Tale of Two Cities*, which has a profound relevance to the current COVID-19 pandemic that has claimed countless lives and continues to rage in different parts of the world. The COVID-19 pandemic brought in unprecedented challenges that the world had not foreseen. With over 245 million infected worldwide, the pandemic relentlessly claimed the lives of over 5 million people (Dong *et al.*, 2020). Nothing prepared us for the pace at which the virus spread across the world in the initial few months, fueling mass hysteria and fear psychosis in the population. Entire populations were locked up in their homes to prevent the spread of the virus, which led to national lockdowns and a humanitarian crisis around the world. The use of personal protective equipment (PPE) was mandated, while the mode of transmission of the virus was still being understood by scientists. The forced social distancing and work from home brought in new challenges on the physical and mental health fronts. The healthcare frontline workers were overwhelmed by the load of patients and were ill-equipped to handle this rapidly growing pandemic, both on the equipment front and knowledge about the disease and its treatment. Various protocols were defined for treating the patients affected with COVID-19, and there was a massive surge in physicians contributing to literature around the world in the hope of sharing their experiences for others to learn from. An analysis of the initial three months of the COVID-19 pandemic revealed that 2,482 articles were published, half of which were secondary.

The majority of the early publications on COVID-19 did not provide new information, and only a negligible number of published articles reported a limitation in their abstract (Di Girolamo and Meursinge Reynders, 2020). A majority of the insights that could have been generated in the initial phase of the pandemic through structured data input into electronic medical records (EMRs) were lost due to the nonavailability of the same. The right insight provided at the right time to the right individual aids in efficient clinical decision-making.

2. Electronic Medical Records

The world today is currently navigating through the fourth industrial revolution, where the barrier between man and machine is dissolving.¹ Data are being generated exponentially on who we were, who we are, and where we need to be. A data point is a discrete unit of information. It is generated from various sources, such as the Internet, financial sector, healthcare, mobile data, and others (Lei and Kong, 2020). The magnitude of data produced by humans every day is 2.5 quintillion bytes, about 1.72 MB of data is created every second by every person, and an astonishing 90% of the world's data have been created in the last two years alone.² There is an increasing trend over the past couple of decades among nations around the world to digitize healthcare processes to improve the quality of delivery and optimize the costs (Health Information and Management Systems Society. Electronic Health Records: a global perspective, 2010). The Global Health Observatory (GHO) data reported a steady growth in the adoption of EMRs over the past 15 years and a 46% global increase in the past five years. More than 50% of the upper-, middle-, and high-income countries have adopted national EMR systems. The adoption of EMRs is lower in the lower-middle (35%) and low-income (15%) countries. The most frequently cited barriers to going digital were lack of infrastructure,

¹https://en.wikipedia.org/wiki/Fourth_Industrial_Revolution (Last accessed on October 15th, 2021).

²<https://techjury.net/blog/how-much-data-is-created-every-day/#gref> (Last accessed on October 15th, 2021).

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capacity, funding, and legal frameworks.³ There is reasonable progress among 56% of the World Health Organization (WHO) member countries in implementing legislation governing the EMR systems; however, a large proportion of the countries lack appropriate legislation. At the end of 2016, an analysis by the Healthcare Information and Management Systems Society (HIMSS), Asia Pacific, of the adoption model of EMR reported only 2.6% of hospitals had achieved a Level 6 certification in India, which required physician documentation (templates), full clinical decision support system (CDSS), and closed loop medication administration.

3. The Indian Scenario

Approximately 1.5% of the hospitals in India are measured at Level 7 of functioning, which involves complete EMRs and data analytics to improve care by the end of 2020. Currently, a larger proportion of hospitals (31%) are measured at Level 3 certification, which include nursing/clinical documentation, CDSS (error checking), and availability of PACS outside radiology (Sharma and Aggarwal, 2016). In April 2013, the Ministry of Health & Family Welfare, Government of India, launched their recommendations for EMR standards in India and updated them in 2016.⁴ The activities in EMR adoption include creation of the basic information & communication technology (ICT) infrastructure, following the prescribed standards of development to ensure interoperability, and adhering to the national policy and regulations. The data consciousness of India as a nation has evolved significantly over the past decade. The Open Government Data (OGD) Platform, India, or data.gov.in, supports the vision of the open data initiative of the government of India.⁵ The portal is a single-point access to documents, datasets, tools, services, and applications published by the ministries, departments, and organizations of the government of India and was launched in October 2012. The initiative is in compliance with the National Data

³https://www.who.int/goe/publications/global_diffusion/en/ (Last accessed on October 21st, 2021).

⁴https://www.nhp.gov.in/ehr_standards_mtl_mtl (Last accessed on October 17th, 2021).

⁵<https://data.gov.in/> (Last accessed on October 17th, 2021).

Sharing and Accessibility Policy (NDSAP) of India, gazette notified in March 2012.⁶ The Department of Health and Family Welfare has over 301,054 resources, 511 catalogs, and 30,534 application programming interfaces (APIs). Some of the datasets pertaining to ophthalmology on the portal include reports of cataract operations performed, pilot surveys on causes of blindness, school screening programs, prophylaxis against blindness due to Vitamin A deficiency, number of eye donations, states/union territories information of eye mishaps, annual record of eye surgeries performed at the National Institutes of Health (NIH), and disabled population among main workers, marginal workers, and nonworkers. The National Health Systems Resources Centre (NHSRC) publishes the HMIS Data Analysis, which is based on the data uploaded to a national web portal (nrhm-mis.nic.in) encompassing all the states and districts of India. The healthcare data are analyzed on an annual basis, and the latest available data are from 2015–2016 which is post-dated.⁷ Here lies an opportunity to collate information from EMR related to the eye disease burden and outcomes both from the public and private sectors. As a nation, India has taken a step forward to provide the data in a transparent manner to its citizens through the data.gov.in platform.

4. Evidence-Based Medicine

David M. Eddy first began to use the term “evidence-based” in 1987 during workshops, and in a manual commissioned by the Council of Medical Specialty Societies to teach formal methods for designing clinical practice guidelines. The manual was eventually published by the American College of Physicians (Eddy, 1992; Institute of Medicine, 1990). Eddy first published the term “evidence-based” in March 1990 in an article in the *Journal of the American Medical Association* that laid out the principles of evidence-based guidelines and population-level policies, which Eddy described as “explicitly describing the available evidence that pertains to a policy and tying the policy to evidence instead of standard-of-care

⁶<https://dst.gov.in/national-data-sharing-and-accessibility-policy-0> (Last accessed on October 17th, 2021).

⁷<http://www.nhsrccindia.org/hmis-data-analysis> (Last accessed on October 17th, 2021).

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practices or the beliefs of experts. The pertinent evidence must be identified, described, and analyzed. The policymakers must determine whether the policy is justified by the evidence. A rationale must be written" (Eddy, 1990). Evidence-based medicine (EBM) is the conscientious, explicit, judicious, and reasonable use of modern, best evidence in making decisions about the care of individual patients (Wilson, 2000). EBM integrates clinical experience and patient values with the best available research information. Evidence-based practice includes the integration of best available evidence, clinical expertise, and patient values and circumstances related to patient and client management, practice management, and health policy decision-making. All the above three elements are equally important. The practice of EBM involves five essential steps (Brownson *et al.*, 2003; Sackett, 1997). First is converting information needs into answerable questions; second, finding the best evidence with which to answer the questions; third, critically appraising the evidence for its validity and usefulness; fourth, applying the results of the appraisal to clinical practice; and fifth, evaluating performance. Data is at the heart of understanding insights into the presentation of diseases, natural history of progression, and identifying the most efficient treatment protocols yielding better outcomes for the patients. The lack of structured digital health data is a major constraint to helping develop guidelines to adapt to the current scenario on the ground. Digital health data enables tracking the evolving trends of the disease burden in question and helps to monitor outcomes, which eventually helps to bring down the cost of healthcare. Applying the knowledge gained from large clinical datasets to patient care promotes consistency of treatment and optimal outcomes, helps establish national standards of patient care, and sets criteria to measure and reward performance-based medical practices. The need for EBM was at its highest during the COVID-19 pandemic where treatment protocols that worked reliably had to be widely disseminated. Without the foundation of structured digital capture of health data, we will always be left wanting in the future!

5. Lessons from the Pandemic

The lessons that the pandemic has taught us can be broadly classified into the following segments: *access, care, evidence, and policy*.

5.1 Access

The pandemic brought to the fore the biggest challenge due to the national lockdowns and restriction on the movement of the people. Access to health-care services became a major challenge for the population who were unable to follow up with their care providers. The rise of telehealth platforms, despite certain limitations such as the inability to perform a detailed remote clinical examination, provided some solace to patients as they could continue to be in touch with their physicians. Governments rallied to establish guidelines to define the scope of the disease and treatments that physicians could advise patients through the remote teleconsultation process. At moments of such gravity, we all need to understand and support public health professionals and governments in their efforts to develop and implement strategies to protect human health and human life. The fundamental and non-derogable right to life is at stake, and governments are obligated to ensure its protection. Human health depends not only on readily accessible healthcare but also on access to accurate information about the nature of the threats and the means to protect oneself, one's family, and one's community. The right to access health information, which includes the right to seek, receive, and impart information and ideas of all kinds, regardless of frontiers, through any media, applies to everyone, everywhere.

5.2 Care

The COVID-19 pandemic has had a major impact on the capacity of health systems to continue the delivery of essential health services. While health systems around the world are being challenged by an increasing demand for care of COVID-19 patients, it is critical to maintain preventive and curative services, especially for the most vulnerable populations, such as children, older persons, people living with chronic conditions, minorities, and people living with disabilities. Countries need to achieve the optimal balance between fighting the COVID-19 pandemic and the maintenance of essential health services. Countries around the world are facing the challenge of increased demand for care of people with COVID-19, compounded by fear, misinformation, and limitations on movement that disrupt the delivery of healthcare for all conditions.

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5.3 Evidence

The COVID-19 pandemic can drive positive changes with evidence-based medicine. The pandemic has spawned too many uninformative clinical trials and reviews, and reform is needed to ensure that the world gets high-quality evidence to treat patients in need. The COVID-19 pandemic has been one of the biggest tests yet of evidence-based medicine and has shown that the current system falls short in a fast-moving global emergency. There have, of course, been huge wins in the form of randomized controlled trials, which have been crucial to testing the safety and efficacy of drugs, as well as the vaccines that will bring the pandemic to an end. It's important that researchers, doctors, and global leaders assess what worked, what didn't, and why and make recommendations for change. They must fix the evidence pipeline so that it is stronger and better able to supply timely, high-quality evidence — not just for the next pandemic but for everyday health emergencies, from tuberculosis to noncommunicable diseases.

5.4 Policy

The pandemic forced governments to take policy decisions on many fronts with no time to spare. Every single day was a learning from the last to modify, retain, or revoke policies being launched that affected populations at large across various countries around the world. There was an unprecedented effort to develop access tools and guidance for healthcare facilities to plan and prepare, manage surges, and operate effectively during COVID-19. Strategic workforce planning, support, and capacity-building are required to guarantee health system operations. The pandemic further impacted the availability and capacity of health workers to deliver essential services and meet the needs arising from unforeseen surges.

6. The Data Point

It is important to define data quality to ensure value in its analysis. The five characteristics of data quality are accuracy, completeness,

consistency, uniqueness, and timeliness.⁸ Data *accuracy* ensures that the information that is being input into a database is correct and acceptable for future analysis. *Completeness* ensures a comprehensive collection of the information. *Consistency* ensures the uniformity of the generated data, either in structured, semi-structured, or unstructured formats. *Uniqueness* ensures whether the data captured is relevant for analysis, and *timeliness* ensures that the data is up to date and can be used for real-time reporting. In just eight years, the estimated worldwide digital healthcare data grew from 50 petabytes in 2012 to 2,500 petabytes in 2020 (Manyika *et al.*, 2011). Healthcare information systems (HIS) have evolved into an institutional backbone, running its entire operations and clinical processes (Kaur and Rani, 2015). Healthcare data is unique in the fact that it is complex, relational, and comprises various formats, including text, images, and media. Data quality in healthcare is of paramount importance to creating best practice patterns, ensuring continuous quality improvement, and delivering personalized medicine to patients. User input variance is an important factor to be considered in healthcare data, and the use of structured clinical examination forms using EMRs can greatly enhance the quality of a dataset (Das *et al.*, 2020). Outcomes in healthcare vary across the different disciplines, which range from an immediate improvement in visual outcome after cataract surgery to a prolonged rehabilitation and recovery after orthopedic surgery. It is important to understand that documentation of healthcare outcomes is a function of time, and not all disciplines are similar. Research is a snapshot in time and evolves with the growing experience of delivering patient care and reporting the same. Data visualization tools allow the creation of real-time data pipelines from EMRs to capture trends in disease burden, disease progression, and treatment outcomes, which presents the most up-to-date insights beyond the duration of the study (Das, Rath, *et al.*, 2019; Das, Kammari, *et al.*, 2019). The creation of "*continuous healthcare data pipelines*" from EMRs is a reality and must become the norm to benefit from the latest insights from the analysis of big datasets. The ability to discover patterns in big data that are beyond human comprehension poses the most exciting aspect of

⁸<http://www.computerbusinessresearch.com/Home/database/five-characteristics-of-high-quality-information/> (Last accessed on October 17th, 2021).

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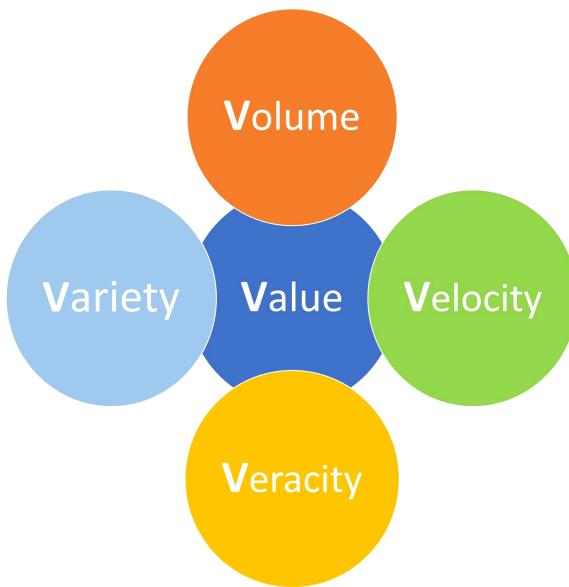


Figure 1. The five Vs of big data.

research into large datasets. Such unseen patterns can help in clinical decision support, disease surveillance, and population health management (Liang and Kelemen, 2016). The common ending for big data and the traditional sampling-based inference is that as the sample size grows larger, the insights get stronger, and the longer the real-time follow-up, the closer the results are to clinical significance and relevance. Big data science is an important and inevitable complement to evidence-based medicine. There is a need to generate continuous, consistent, and connected big datasets in healthcare to enable automation of insights using technology tools. Generation of a “*Good Quality*” data point is the first important step in our quest for new knowledge. The five characteristics of big data are illustrated in Figure 1.

7. Real-World Data and Real-World Evidence

The use of computers, mobile devices, wearables, and other biosensors to gather and store huge amounts of health-related data has been rapidly

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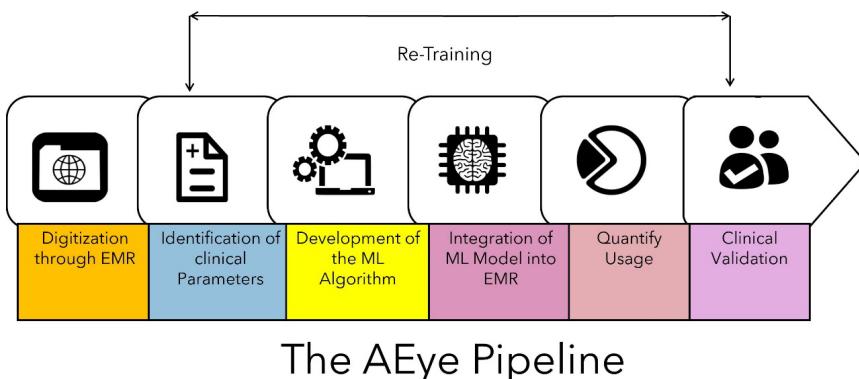
accelerating across the world. Such data hold the potential to allow us to better design and conduct clinical trials and studies in a healthcare setting to answer questions previously thought infeasible. In addition, with the development of sophisticated, new analytical capabilities, we are better able to analyze these data and apply the results of our analyses to medical product development and approval for the benefit of the patients. Real-world data (RWD) are the data relating to patient health status and/or the delivery of healthcare routinely collected from a variety of sources. RWD can come from a number of sources, such as EMRs, claims and billing activities, product and disease registries, patient-generated data, including in home-use settings, and data gathered from other sources that can inform health status, such as mobile devices. Clinical data from EMRs and case report forms (eCRFs). These data provide patient demographics, family history, comorbidities, procedure and treatment history, and outcomes. Patient-generated data from patient-reported outcome (PRO) surveys provide data insights directly from the patient, and they help researchers understand what happens outside of clinic visits, procedures, and hospital stays. Cost and utilization data from claims and public datasets provide information regarding healthcare services utilization, population coverage, and prescribing patterns. Public health data from various government data sources add critical information to enable stakeholders to best serve the needs of the populations they serve. Real-world evidence (RWE) is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD. RWE can be generated by different study designs or analyses, including, but not limited to, randomized trials, including large simple trials, pragmatic trials, and observational studies (prospective and/or retrospective). The creation of RWE requires a combination of high-powered analytics, a validated approach, and a robust knowledge of available RWD sources. This process includes the following steps: (1) defining a study protocol that answers relevant clinical questions; (2) defining which data elements can be collected from which RWD sources; (3) establishing data capture arrangements and protocols with existing RWD sources; (4) blending disparate data sources through probabilistic record-matching algorithms; (5) validating and supplementing blended data through editable eCRFs; (6) defining and calculating clinically relevant outcomes and measures;

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and (7) appropriately assessing and controlling for variability in data quality, availability, and confounding patient factors that affect measured outcomes. RWE can provide a holistic view of patients that, in many cases, cannot be studied through traditional clinical trials. RWE plays an important role in research across the product lifecycle for both pharmaceutical and device companies. It can inform pre-trial study design by helping researchers identify potential patients and create proper inclusion criteria for clinical trials. Once a product is approved and marketed, RWE can help a pharmaceutical or medical device company understand their products' relative safety, effectiveness, value, off-label use, and more. This post-market surveillance, or post-marketing surveillance, is valuable to stakeholders across healthcare. Through advanced analytics, RWE can provide individualized decision-support tools that can facilitate shared decision-making between a patient and physician. Through comparing the outcomes of different treatment options, it might become evident that particular drugs or dosages are better optimized for different individuals, and treatment guidelines can be refined and optimized accordingly. With large real-world datasets, researchers can perform observational, retrospective, and prospective studies that help academia advance its understanding of current therapies and technologies. RWE can track outcomes and quality measures across organizations. For administrators, RWE can provide information about how their entire health system is performing relative to others and how their individual physicians are benchmarking relative to their peers. This information can help inform coverage discussions with payers and refine quality-based reimbursement strategies that reward solid outcomes. The potential for us to harness the power of RWD and RWE is dependent on the availability of good quality healthcare data from EMRs, and we must work toward establishing systems that enable us to effectively mine this information in times of need, such as in a pandemic.

8. The AEye Pipeline

The application of data science to big datasets in healthcare can be summarized using the *AEye Pipeline* (Verkicular and Das, 2019). The pipeline comprehensively describes seven steps in the application of technology to



The AEye Pipeline

Figure 2. The AEye Pipeline.

clinical datasets for the generation of newer insights to care providers. The steps are detailed in Figure 2. Step 1 details the *digitization of data through EMRs*, which is the primary step for any kind of research based on big datasets. The Intelligent Research in Sight (IRIS) Registry is the largest national clinical specialty data registry, with nearly 50 million patient visits and 14 million unique patients in the United States (Parke II *et al.*, 2017). The *Système national d'information inter-régime de l'assurance maladie* (SNIIR-AM) database covers nearly 65 million people and consists of medical and administrative data from 1,546 French private or public healthcare facilities catering to the general population (Daien *et al.*, 2017). The National Ophthalmology Database (NOD) from the United Kingdom was initiated by the Royal College of Ophthalmologists to collate anonymized clinical data from contributing hospitals of the National Health Service (NHS) (Jackson *et al.*, 2013). The UK DR EMR Users Group has published their comprehensive experience in analyzing big data on patients with diabetic retinopathy from 20 United Kingdom hospital eye services on the real-world prevalence and progression data (Catherine *et al.*, 2015), the impact of cataract surgery on diabetic macular edema (Denniston *et al.*, 2017), the progression of diabetic retinopathy (Lee *et al.*, 2017), and the impact of deprivation on the presentation of diabetic eye disease at hospital services (Denniston *et al.*, 2019). The eyeSmart EMR database implemented in a multitiered ophthalmology network in India has

reported an eight-year experience describing 4.7 million patient visits and 2.2 million unique patients seen on EMRs. The Ophthatome™ system is an integrated knowledge base of ophthalmic diseases and has collected data from 0.5 million unique patients in India (Raj *et al.*, 2020). The implementation of EMR systems in large ophthalmology institutions (Scholl *et al.*, 2011), and the use of big data to understand endophthalmitis prophylaxis have been described in India (Haripriya *et al.*, 2017). It is evident that the digitization of clinical data helps to generate large datasets for further analysis. Step 2 details the *identification of clinical parameters* as well as the benefits of structured datasets and the challenges with unstructured ones. It is important to structure the input of clinical information in a standardized format as much as possible to ensure uniformity of the data for analysis. The use of drop-down menus, multiple selection, and standard forms enables the user to input data in a repeatable manner. The use of free-text boxes in EMRs contributes to unstructured data and missing information that will lead to challenges during analysis (Bowman, 2013). The use of deep learning techniques in natural language processing (Ting *et al.*, 2019) and finite state modeling to extract information from unstructured data entered in free-text boxes (Sai Prashanthi *et al.*, 2020) can lead to increased information integrity. Step 3 is the *development of machine learning (ML) algorithms* and the application of data science techniques to big datasets. Research using ML models, such as linear regression, logistic regression, support vector machine, classification and regression trees (CART), ensemble methods, and artificial neural network (ANN), has the potential to improve ocular disease diagnosis, disease progression, and risk assessment (Lin *et al.*, 2020). Deep learning algorithms (DLAs) focus on three major aspects: classification, segmentation, and prediction using static images generated from an ocular diagnostic device, such as fundus photography, optical coherence tomography (OCT), and visual fields (Tong *et al.*, 2020). Step 4 details the *integration of an ML model into the EMR* to complete the loop at the point of care. While a significant amount of research has advanced in the development of algorithms, it is important to integrate the insight into EMRs for efficient care of the patient. The entire purpose is to enhance the provision of care by providing the edge of superior clinical decision-making by the care provider, which otherwise would not have been possible (Sagkriotis *et al.*, 2021; Lin *et al.*, 2018).

Step 5 details the *quantification of the usage* of insights provided by a machine. This is a crucial dynamic at the intersection of man and machine that evolves with time. How will a clinician with decades of experience trust the insight from an artificial intelligence (AI) system? How can trust in the AI system be optimized to improve decision-making? Interpersonal trust is a human belief based on the three main dimensions of benevolence, integrity, and ability (Mayer *et al.*, 1995). The reputation of the system, the integrity of the insight, and the user perception of the ability of the AI all influence the reliance of a clinician on the technology (Lee and See, 2004). Step 6 is *clinical validation* of the algorithm or the software as a medical device (SaMD) in a real-world setting. Outcomes in healthcare are influenced by many patient-related factors that may or may not be quantifiable. Hence, tracking the performance of an algorithm over a period of time is important to build the trust among clinicians using this technology. Clinical evaluation can either be a *valid clinical association*, which generates evidence to demonstrate an association between SaMD output and the SaMD-targeted clinical condition, or an *analytical validation*, which generates evidence that the SaMD correctly processes input data to generate accurate, reliable, and precise output data, or a *clinical validation*, which generates evidence that the SaMD's accurate, reliable, and precise data output achieves its intended purpose in its target population in the context of clinical care.⁹ There is a need for assurance of the safety and effectiveness of any SaMD by ensuring high data quality for training, algorithm correctness (verification), performance testing (validation) and generalizability (addressing bias), and reliable interpretability. Step 7 completes the cycle by incorporating *retraining*, or continuous learning, in real time. The SaMD must be capable of capturing real-world performance data to understand user interactions with the SaMD and must be able to monitor its technical and analytical performance to evolve into a more efficient and reliable tool for the clinicians. This continuous feedback will connect back to Step 2 to include or exclude relevant parameters as an input into the ML model to further refine the SaMD. We need to avoid any unintended consequences to the patient due to a wrong insight that may precipitate due to a break in any of the above seven steps of the AEye pipeline. The key to

⁹<https://www.fda.gov/media/143303/download> (Last accessed on October 19th, 2021).

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improving healthcare delivery lies in digitization through EMRs, the implementation of SaMD, and continuous learning.

9. The LV Prasad Eye Institute Experience

Established in 1987, LV Prasad Eye Institute (LVPEI), a World Health Organization Collaborating Centre for Prevention of Blindness, is a comprehensive eye health facility situated in India, as shown in Figure 3. The Institute has 10 active arms in its areas of operations: Clinical Services, Education, Research, Vision Rehabilitation, Rural and Community Eye Health, Eye Banking, Advocacy and Policy Planning, Capacity Building,

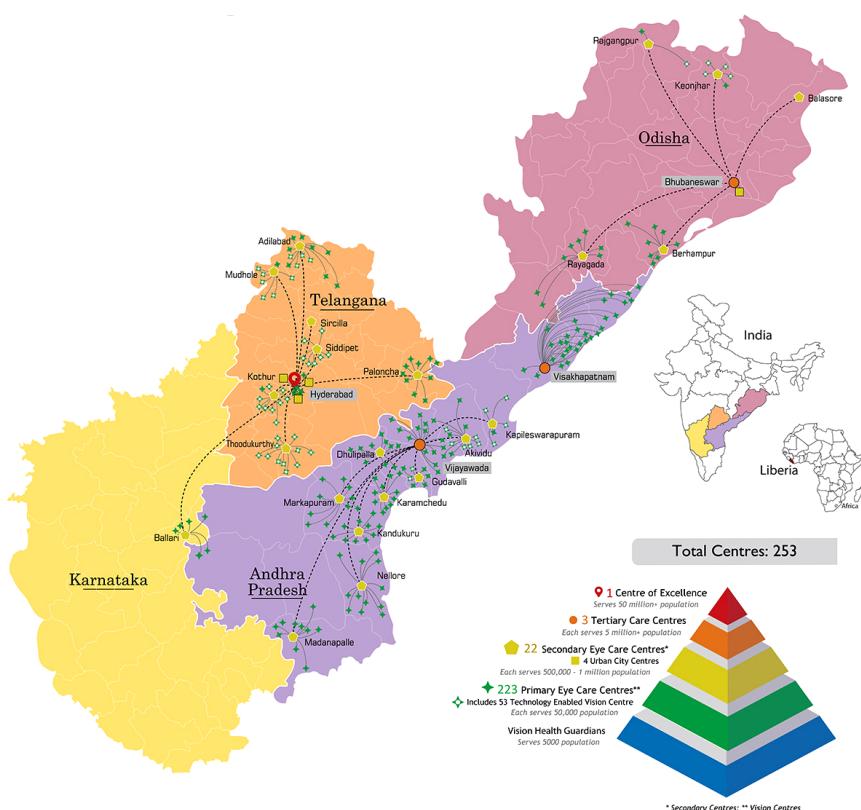


Figure 3. The LV Prasad Eye Institute (LVPEI) Network.

Innovation, and Product Development. The mission of L V Prasad Eye Institute is to be a center of excellence (CoE) in eye care services, basic and clinical research into eye diseases and vision-threatening conditions, training, product development, and rehabilitation for those with incurable visual disability, with a focus on extending equitable and efficient eye care to underserved populations in the developing world. The vision is to create excellent and equitable eye care systems that reach all those in need. The institute, over 34 years, has reached over 32.11 million individuals through the delivery of eye care services, with over 50% of the services provided free of cost, regardless of the complexity of care. The institute had to rapidly adapt to the COVID-19 pandemic and the attending challenges in a short span of time. In India, the first case of COVID-19, a traveler from Wuhan, was reported on January 30, 2020, in the southern state of Kerala. COVID-19 was reported in Hyderabad a month later, on March 2, 2020, in a traveler from Dubai. A sharp increase in numbers then followed. India went into a countrywide strict lockdown on March 23 for three weeks, which was further extended by another three weeks until May 3, 2020.¹⁰ Subsequently, from May 4, 2020, India was divided into three zones at the district level, red, orange, and green, based on the presence of active cases in the community. Red zones included areas with high numbers of new active cases, orange zones with no new cases reported in the previous two weeks, and green zones with no active COVID-19 cases (see footnote 10). While the lockdown continued in the red zones, there were some relaxations given in the orange and green zones (see footnote 10). The lockdown, while saving lives and flattening the curve by reducing the number of patients reporting to hospitals, continued to have a detrimental effect on the Indian economy. The healthcare industry was also badly hit, and the institute had to prepare guidelines at short notice to take care of its patients and staff. Hospitals needed to rapidly develop new operational guidelines and an exit strategy for implementation after the lockdown. Based on the available evidence, the following provides a summary of the experience of LVPEI in India, which manages a network of tertiary, secondary, and primary eye health centers

¹⁰https://en.wikipedia.org/wiki/COVID-19_pandemic_lockdown_in_India. (Last accessed on 17th October 2021).

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through its unique eye health pyramid (Rao *et al.*, 2012). Our response to COVID-19, pre-lockdown, during lockdown, as well as the exit strategy after the lockdown are detailed. It based its strategy plan on the level of threats as was done in Singapore.¹¹ The Hospital Infection Control Committee (HICC) held the first meeting on January 10 (the first case was reported to the World Health Organization on December 31); gave serious attention to this threat and initiated steps on February 20 and a more detailed action plan on March 2 (after the first case was reported in Hyderabad, where our main campus is situated). Steps were taken to consolidate actions, and at each step, importance was given to: clear evidence from literature and protocols; clear instructions and communication; monitoring and auditing of compliances; getting feedback and improving; and daily meeting of nodal and strategy teams with updated data and actions. The LVPEI response to COVID-19 can be divided into the following steps: (1) administrative control; (2) patient triaging and clinical protocols; (3) staff protection; (4) environmental protection; (5) social distancing measures; (6) communication strategy; and (7) monitoring. The response was based on the principles of social distancing, hand hygiene, following respiratory etiquette, surface disinfection protocol, and rational use of appropriate personal protective equipment (PPE). The response was also aligned with the core values of the institute — patient first, excellence, equity, togetherness, and integrity. Data-driven decisions were at the heart of all policy decisions that were taken in the network. The establishment of the eyeSmart EMR system in 2010 greatly enabled the assessment of the patient care trends and also helped to triage patients who needed emergent care. Actionable insights were possible due to the faster retrieval of clinical and operational data from the eyeSmart EMR system. A cross-sectional hospital-based study was conducted, which included all patients who presented to the emergency department between March 23, 2020 and April 19, 2020. The data were collected using the eyeSmart EMR system. Overall, 1,192 patients (mean: 42.57 per day) presented to the ocular emergency department and were included for analysis. The median age of the patients was 35 years (interquartile range,

¹¹ <https://www.gov.sg/article/what-do-the-different-dorscon-levels-mean>. (Last accessed on 17th October 2021).

IQR: 20–52 years), and they were mostly adults (77.85%). The majority of the patients were male (62.16%) and presented from the local metropolitan region (56.21%). On triaging based on the ocular disorders at presentation, the majority of the patients were emergency related (65.02%), followed by urgent (8.14%) and routine (26.85%) in nature. The most common emergencies were microbial keratitis (23.74%), followed by corneal trauma (16.39%). There was an increasing trend seen in emergency patients (46.11% in week 1 to 71.78% in week 4) and a decreasing trend seen in routine patients (45% in week 1 to 21.20% in week 4). A subset of patients (23.49%) underwent surgery where indicated, and the most commonly performed procedures were vitreo-retinal (32.86%) followed by trauma-related procedures (31.43%) (Das and Narayanan, 2020). The first lockdown had significantly impacted patient care in rural areas. As compared to the pre-lockdown period, during the lockdown, there was an issue with access to services by females. Despite a higher number of specialty patients (including emergencies) visiting during the lockdown, 91% of the patients who visited rural centers could be managed locally, avoiding long-distance travel (Rathi *et al.*, 2020). Data from the EMRs were collected on patients seen between June 2019 and June 2020, which included age, gender, total patients seen (new or follow-up), and socioeconomic status (paying and nonpaying). A comparative study was done on the data for outpatients and surgeries performed between the period before COVID-19 and during “Unlock I” in the COVID-19 period. There was a 36.71% reduction in the number of overall outpatients seen in June 2020 ($n = 83,161$) compared to June 2019 ($n = 131,395$). The reduction was variable across different levels of the pyramid, with the highest reduction in the CoE (54.18%), followed by tertiary centers (TCs) (40.37%), secondary centers (SCs) (30.49%), and vision centers (VCs) (18.85%). A similar pattern was seen for new, paying patients with the highest reduction in the CoE (54.22%), followed by the TCs (25.86%) and SCs (4.9%). A 43.67% reduction was noted in the surgeries performed in June 2020 ($n = 6,168$) compared to June 2019 ($n = 10,950$). Reduction in paying services was highest in the CoE (47.52%), followed by the TCs (15.17%) and SCs (4.87%). There was no significant change in the uptake of services by gender in the LVPEI network (Rathi *et al.*, 2021). The use of teleophthalmology consultations

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using EMRs helped to continue offering advice to the patients who could not reach the network due to the lockdown restrictions imposed on account of the COVID-19 pandemic. The cross-sectional hospital-based study also included 7,008 teleconsultations presented between March 23 and April 19, 2020. A three-level protocol was implemented to triage the calls. The data from patient queries were collected using a Google Form/ Sheets, and the tele-calls were returned using the patient information retrieved from the EMR system. Overall, 7,008 tele-calls were addressed, of which 2,805 (40.02%) patients whose clinical-related queries were answered were included for analysis. The most common queries were related to redness/pain/watering/blurring of vision (31.52%), closely followed by usage of medications (31.05%). The majority of the queries were directed to the department of cornea (34.15%), followed by retina (24.74%). Less than one-fifth of the patients were from the lower socio-economic class (16.08%), and one-fourth were new patients (23.96%). The most common advice given to the patients was related to the management of medications (54.15%), followed by appointment-related information (17.79%). Emergency requests requiring further evaluation by an ophthalmologist accounted for a small percentage (16.36%) of the patients (Das *et al.*, 2020). The tracking of patient trends enabled the identification of vulnerable patients with ocular diseases that cause severe visual impairment. Data from the EMRs helped to identify patterns in cataract surgery (Das and Reddy, 2021), diabetic retinopathy (Das, Narayanan, *et al.*, 2021), infective keratitis (Das, Chaurasia, *et al.*, 2021a), keratoplasty (Das, Chaurasia, *et al.*, 2021b), ocular oncology, glaucoma, endophthalmitis (Das and Dave, 2021), and ocular surface disorders (Das, Rao, *et al.*, 2021). The institute has been able to navigate through the pandemic using data to guide decisions that have affected patient care services across the LVPEI network.

10. Conclusion

Catering to the healthcare needs of the 7 billion people on the planet poses unique challenges and opportunities globally. The provision of the basic right to healthcare is the moral responsibility of a government toward its

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citizens. While the access to health information is crucial, the emphasis must be on the quality of the data being collected that will guide the decisions of our policymakers. The three “I” concept of *integrate, insights, and impact* can help bring the mandate together. There is a need to *integrate* the various sources of data being generated from EMRs or data registries, health insurance and administrative databases, diagnostic centers, biobanks, epidemiology consortia, and crowdsourced data. The *insights* generated from the integration of the data will help to identify areas of unmet need and also track the progress of interventions and guide policy decisions. The greatest impact of data-driven informed decisions, for the first time ever, will be the shift toward citizen- and wellness-centric policy-making globally. The integration of data and the insights generated will catalyze *impact* on people’s lives. The way forward is described in Table 1. There is a need for governments to bring together healthcare providers who have currently digitized their data to show the potential of collating this standardized information to impact healthcare delivery for the population. We must and should adopt the best technology frameworks that are relevant to our geography without compromising the volume of care that is currently being delivered. With the changing landscape of both lifestyle and the trends of diseases over the years, it is imperative that we need to have the right information at the right time to make the right decision for the right individual. The investment in taking the bold step of digital transformation by

Table 1. The way forward with healthcare data for the globe: people to policy.

INTEGRATE	Federated Databases (EMR/Data Registries) Diagnostic Centers/Biobanks Epidemiology Consortia
INSIGHTS	Citizen Centric Wellness Centric Informed Decision-making
IMPACT	Identify Unmet Needs Track Metrics Monitor Feedback

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healthcare institutions globally will pay rich dividends in the long run. The implementation of digital health is a key step in the direction that ensures the availability, accessibility, affordability, and acceptability of healthcare for the masses. There has never been a more opportune time such as this to lay down a strong foundation to enable the collection of “good quality” digital health data points to guide us in the future to take on and conquer greater challenges than the COVID-19 pandemic!

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Part III

Economy

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Chapter 3.1

Pandemics and Macroeconomics: Insights from COVID-19

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Abstract

In this chapter, we talk about the macroeconomic and health impacts of the COVID-19 pandemic in India. We begin by providing evidence on the evolution of aggregate income and active infections during the first wave of the pandemic. We then discuss a macro-SIR model that provides an integrated framework for studying both the economic and health ramifications of the pandemic. Finally, we quantify the economic costs associated with two government policies implemented during this time, lockdowns and income transfers, and analyze how successful they were in slowing down the disease spread.

Keywords: macroeconomics; pandemics; COVID-19

1. Introduction

The COVID-19 pandemic has caused a severe humanitarian crisis across the world, and India is no exception to this. Millions of people battled through infections and lost their lives over the past couple of years. In addition to the health crisis, the COVID-19 pandemic also led to severe economic pain among the people. In order to control the pandemic, governments across the world imposed containment measures (lock-downs) of varying intensities, which added to the economic suffering of the population.

India went into one of the harshest lockdowns in the world on March 24, 2020. Almost all sectors, except essential services, were shut, and people were instructed to stay in their homes. A stringency index developed by Hale *et al.* (2021), which measures the strictness of lockdowns across the world, shows that India had reached the maximum possible lockdown stringency by the end of March and April, followed by calibrated easing over the subsequent months.¹ This inflicted a tremendous economic cost on the people, as many of them lost their jobs and suffered drastic decline in their income.

In order to quantify the decline in income, I make use of individual data from Consumer Pyramid Household Survey (CPHS). This is a household-level panel data from around 236,000 households, and it features data on income at a monthly frequency.² This helps us in finding the change in average income over the various stages of the pandemic. Figure 1(a) shows the average income of workers in the year 2020 compared to that in the previous year. As can be seen, there was a gradual decline in income even before the start of the pandemic. But in the month of March, when the lockdown started, the income was 20% below the benchmark levels. The months of April and May, during which the country was subjected to an almost complete lockdown, saw a drastic decline, with income falling by 53% and 42%, respectively. There was a gradual recovery starting from June, as the lockdown was relaxed, but the

¹More information on this index for India and other countries across the world can be found at <https://www.bsg.ox.ac.uk/research/research-projects/coronavirus-government-response-tracker>.

²More details on this data can be found at <https://consumerpyramidsdx.cmie.com/>.

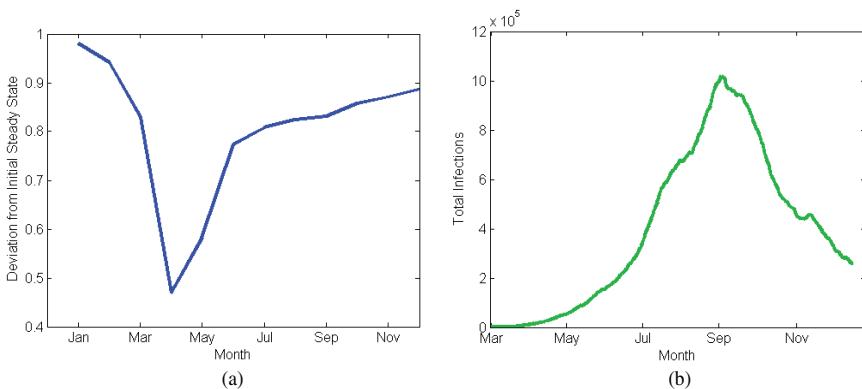


Figure 1. Economic and health impacts of COVID-19: (a) aggregate income; (b) active infections.

recovery was not complete, as even at the end of the year, the income was 10% below the pre-pandemic levels.

To study the infection dynamics of COVID-19, I obtained data from www.covid19india.org, a crowdsourced initiative. The total number of active infections hit its peak on September 17, 2020, when around a million people were infected, according to this source.³ Figure 1(b) shows the evolution of active infections over time.

Since a pandemic has both economic and health impacts, it is important for us to study both these dimensions together in an integrated framework. The existing macroeconomic models, though able to shed light on the decline in income, do not explicitly consider the evolution of a pandemic in an economy. On the other hand, the benchmark SIR models used by epidemiologists to study disease dynamics do not factor in economic interactions. Hence, in this chapter, I discuss the macro-SIR model that brings together both the macroeconomic and SIR models in a single framework. This would be of immense value to a policymaker who has to implement policies after considering both the economic and health aspects of a pandemic.

Following the work of Eichenbaum *et al.* (2020), we integrate an SIR epidemiological model into a macroeconomic, general equilibrium

³Care should be taken while interpreting this data. Only a very small fraction of the infected patients were tested. Hence, this number is an underestimate of the actual number of infections in the country.

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framework. The model has a unit measure of workers who supply labor and consume final goods produced by the firms. Individuals can contract the disease from other infected people through three different channels: while purchasing consumption goods or at their workplace or during any other social interaction. The same individuals take the risk of infections into account while deciding on their consumption and labor supply. These individual consumption and labor supply decisions, in turn, determine the aggregate infection rates in the economy. This framework enables us to jointly determine the economic and disease dynamics in equilibrium and hence analyze both the economic and health impacts of the pandemic.

Calibrating this model to the Indian data, we analyze the effects of the COVID-19 pandemic and of the two government policies implemented during this period: lockdowns and income transfers. Under a benchmark scenario with no policy intervention, our model simulations show that the pandemic generates a peak infection rate of around 16%, and it takes 218 days to reach this peak. It also leads to a 4.7% decline in income. During a pandemic, even without any policy action, individuals cut down their consumption and labor hours to reduce the chance of getting infected, and this in turn leads to a decline in income.

Next, I introduce two different kinds of lockdown policies into our model simulations to study the impact of these policies on economic and disease outcomes. We find that a very stringent policy reduces the peak infection rate from 16% to 8.4%, while a less stringent one reduces it to 10.4%. They also increase the days to peak from 218 days to 295 and 286 days, respectively. Thus, both the severe and less severe lockdowns are successful in flattening the curve and also in significantly slowing down the disease transmission, with the more severe lockdown performing better in controlling the pandemic. On the economic front, both the lockdown policies have significant costs, with the more severe policy leading to a 26.7% decline in income while a less severe lockdown causing a 20.9% decline. Thus, we do see that there is a trade-off between controlling the pandemic and the cost imposed on the economy, with the more severe lockdown doing a better job on the health front and also inflicting more cost on the economic front.

Finally, we show that income transfers by the government are also effective in slowing down the spread of infections in the economy.

Experimenting with two different kinds of transfer policies, we find that both the transfer policies are successful in reducing the peak infection rates from 16% to 8.4% and 11.3%, respectively. They also slow down the disease spread by pushing the peak date from 218 days to 293 and 280 days, respectively. These income transfers enable workers to stay at home more and not venture out for work, thus curtailing the disease transmission and reducing the peak infection rate. Thus, economic transfers can double up as a health policy during a pandemic, slowing down the spread of infections in the economy.

There is a growing body of literature that studies the economic impacts of a pandemic using computable general equilibrium (CGE) modeling. Keogh-Brown *et al.* (2010) and Smith *et al.* (2011) use a CGE model to analyze the GDP loss suffered by the UK under different pandemic and containment policy scenarios. More recently, Keogh-Brown *et al.* (2020) use a similar framework to predict the potential impact of the COVID-19 spread in the UK. There is also rapidly emerging literature of integrating SIR epidemiological models into a macroeconomic framework. Eichenbaum *et al.* (2000) embed a benchmark SIR model into a simple general equilibrium setup to study the interaction between economic and health dynamics. Glover *et al.* (2020) build in heterogeneity into this setup, where individuals differ by age, sector, and health status, to analyze the distributional consequences of the pandemic. Kaplan *et al.* (2020) integrate the epidemiological framework into a heterogeneous agent new Keynesian model to talk about the sectoral impact of the pandemic. Acemoglu *et al.* (2020) derive optimal lockdown policies using an SIR model, where the risks of infection and fatality vary across different groups of people.

This chapter also contributes to a large literature analyzing the impact of transfers on various economic outcomes. For instance, Fiszbein and Schady (2009) show that transfers can have a positive effect on poverty reduction, Galiani and McEwan (2013) talk about their impact on school enrollment, and Gertler (2004) studies their effect on child health. We add to this literature by showing that transfers, on top of being an economic policy, can also serve as a health policy during a pandemic.

The rest of the chapter is organized as follows. Section 2 gives a description of the framework that integrates the macroeconomic and SIR

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models, while Section 3 presents the calibration of the model for India. The economic and health impacts of the pandemic and the government policies are discussed in Section 4, while the policy implications are presented in Section 5. Section 6 concludes.

2. Model Framework

I start by introducing a very simple macroeconomic model of households and firms. I then discuss a basic SIR model used by epidemiologists to understand disease dynamics. Finally, following the work of Eichenbaum *et al.* (2020), I set up the macro-SIR model which combines the macroeconomic and SIR frameworks.

2.1. A simple macroeconomic model

Consider an economy housed with a unit measure of agents who have infinite lifetime. We make the assumption that the agents live for an infinite lifetime as it simplifies our analysis. In every period, the agents choose their consumption and labor supply to maximize their lifetime utility, which is given by

$$U = \sum_{t=0}^{\infty} \beta^t u(c_t, n_t),$$

where $u(\cdot)$ is the utility an agent derives from consuming c_t amounts of goods and supplying n_t amounts of labor at time period t . β is a discount factor which captures the value the agent places on the future.⁴ The agents maximize the lifetime discounted utility U subject to the budget constraint

$$(1 + \mu_t)c_t = w_t n_t + \Gamma_t,$$

where w_t represents the real wage and $w_t n_t$ is the income earned from the labor market. μ_t denotes the tax on consumption, while Γ_t is the lumpsum

⁴The specific utility function we use for our quantitative experiments is $u(c_t, n_t) = \log c_t - \frac{\theta}{2} n_t^2$, where θ captures the disutility the agent suffers from supplying labor.

transfers from the government. Once this macroeconomic model is integrated into the SIR framework, μ_t is treated as a way to capture lockdown policies of the government during the pandemic.

This economy also features a continuum of perfectly competitive firms, where the agents work to produce consumption goods consumed by the household in return. The firms hire labor to maximize their profit (Π) given by

$$\Pi = An_t - w_t n_t,$$

where An_t refers to the total production with n_t amounts of labor, while $w_t n_t$ is the total wages paid to the workers. In equilibrium, the wages adjust so that both goods and labor markets arrive at the equilibrium. The details of the model and the equilibrium conditions are given in Appendix A.

2.2. A basic SIR model

One of the benchmark models used by epidemiologists to study and forecast disease dynamics is the SIR model proposed by Kermack and McKendrick (1927). With the emergence of a pandemic, the population gets subdivided into four groups: susceptible (those who have not been infected yet), infected (those who are currently infected), recovered (those who have survived the infection), and deceased (the infected who did not survive). They are denoted by S_t , I_t , R_t , and D_t , respectively (and hence the name SIR model).

Let T_t refer to the total number of new infections occurring at time t . A susceptible person could potentially get infected by coming into contact with an infected person. Not all contacts between a susceptible and an infected person will turn into infections. The classic SIR model assumes that the rate at which a susceptible person gets infected is given by πI_t , where π determines the rate at which contact turns into infections. The total number of new infections at time t is given by

$$T_t = \pi S_t I_t. \quad (1)$$

$S_t I_t$ captures the total number of meetings between susceptible and infected people, and π fraction of these meetings develop into new infections.

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Thus, the higher the infected or susceptible population, the more the contact between these two groups of people and hence the higher the number of new infections in the economy.

We can now understand how these population groups evolve over time. Given the number of new infections in the economy, the number of susceptible people in the next period ($t + 1$) is the number of susceptible people in this period minus the people newly infected in the current period:

$$S_{t+1} = S_t - T_t \quad (2)$$

The number of infected people in $t + 1$ is equal to the number of infected people at the start of period t plus new infections T_t minus those who either recovered or died in the current period:

$$I_{t+1} = I_t + T_t - (\pi_r + \pi_d)I_t, \quad (3)$$

where π_r is the rate of recovery while π_d is the fatality rate of infected people. Consequently, the number of recovered people in the next period is the total recovered as of today (R_t) plus any new recoveries in the current period ($\pi_r I_t$):

$$R_{t+1} = R_t + \pi_r I_t. \quad (4)$$

Similarly, the total number of deceased people in $t + 1$ is the total number of deceased in t (D_t) plus any new deaths ($\pi_d I_t$):

$$D_{t+1} = D_t + \pi_d I_t. \quad (5)$$

The total population of the economy reduces with deaths according to

$$Pop_{t+1} = Pop_t - \pi_d I_t. \quad (6)$$

At the start of the pandemic (when $t = 0$), it is assumed that a small fraction of the population (ε) are exposed to the virus and hence infected, while the rest are not infected but susceptible, with no recoveries or deaths yet. Since we normalize the total population to be 1 at the start of the pandemic, the total number of susceptible and infected population is given by

$$I_0 = \varepsilon, \quad S_0 = 1 - \varepsilon. \quad (7)$$

Even though the standard SIR model described above is an elegant framework to understand the dynamics of disease spread, it doesn't take into account the interactions between economic decisions of people or the government and the infection dynamics. For example, with the advent of a pandemic, people might not venture out to work to reduce their chance of getting infected. This might reduce the severity of the pandemic but could potentially increase the economic cost arising due to the decline in income. Another aspect that is of potential importance is to jointly understand the costs and benefits of government policies on both economic and health dimensions. In order to study this rich interplay between economic factors and disease dynamics, we need to integrate the SIR model with the macroeconomic framework introduced earlier. Eichenbaum *et al.* (2020) construct such a macro-SIR model, which is discussed in the following section.

2.3. A macro-SIR model

In the canonical SIR model discussed so far, everyday decisions of people do not play any role in influencing the evolution of the pandemic. The transition rates between different stages of a pandemic were assumed to be exogenous, unaffected by economic decisions of the people. The model by Eichenbaum *et al.* (2020) relaxes this assumption by making the infection spread depend on consumption and labor decisions of the people. As before, during a pandemic, there are four groups in the population: susceptible (S_t), infected (I_t), recovered (R_t), and deceased (D_t). The major distinction from the classic SIR model is that the susceptible population can now get infected in three different ways.

First, susceptible people can meet infected people in places where they are purchasing goods for consumption, such as supermarkets, malls, and theaters. The total number of infections arising out of this consumption channel is given by $\pi_1(S_t c_t^S)(I_t c_t^I)$, where $S_t c_t^S$ is the total consumption of the entire susceptible population, $I_t c_t^I$ is the total consumption of the infected population, and π_1 is the rate at which these interactions turn into new infections. Both susceptible and infected people decide whether

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they want to head out for their consumption purchases. Hence, the consumption decisions of an individual affect the probability of infections and hence the evolution of the pandemic.

Second, infected people can transmit infections to susceptible people at their workplaces. The total number of infections occurring through this channel is given by $\pi_2(S_t n_t^S)(I_t n_t^I)$, where $S_t n_t^S$ is the total working hours of susceptible people and $I_t n_t^I$ is the total labor hours of the infected population, with π_2 capturing the rate of new infections in the labor channel. Similar to consumption decisions, individual labor supply decisions influence the propagation of infections in the economy.

Finally, infections can also spread through any random meetings between susceptible and infected individuals, other than consumption- and labor-related activities. The total number of such meetings is given by $S_t I_t$, and this will lead to $\pi_3 S_t I_t$ new infections. This channel is analogous to the standard SIR model, where there is no role for individual economic decisions in determining the disease dynamics.

Thus, the total number of new infections in period t is the sum of the infections arising from all the three channels and is given by

$$T_t = \pi_1(S_t c_t^S)(I_t c_t^I) + \pi_2(S_t n_t^S)(I_t n_t^I) + \pi_3 S_t I_t. \quad (8)$$

Comparing this with Equation 1, which captures the evolution of new infections in a simple SIR model, we can see that the macro-SIR model explicitly models the impact of individual consumption and labor choices in determining the new infections in the economy. This will help us in studying the relationship between economic decisions and propagation of new infections and also the impact of different policies on these indicators.

I now describe how individuals optimally make their consumption and labor supply decisions amidst the pandemic. All individuals take the evolution of new infections (8) and the laws of motion of the SIR framework (2)–(5) as given and choose their consumption and labor supply every period. As in our simple macroeconomic framework, individuals live for an infinite lifetime unless they don't survive the pandemic. In each period, they choose their consumption and labor supply to maximize the lifetime utility. Next, I describe the decision problem of different types of individuals in the economy.

2.3.1. Susceptible people

Susceptible workers choose their consumption (c_t^S) and labor hours (n_t^S) every period to maximize their lifetime utility U_t^S , which is given by

$$U_t^S = u(c_t^S, n_t^S) + \beta[(1 - \tau_t)U_{t+1}^S + \tau_t U_{t+1}^I],$$

subject to the budget constraint

$$(1 + \mu_t)c_t^S = w_t n_t^S + \Gamma_t$$

and the probability of infection τ_t :

$$\tau_t = \pi_1 c_t^S (I_t C_t^I) + \pi_2 n_t^S (I_t N_t^I) + \pi_3 I_t.$$

U_t^S represents the lifetime utility of a susceptible individual in period t . It has two components, namely, the utility obtained through consumption and labor supply in the current period, ($u(c_t^S, n_t^S)$), and the discounted lifetime utility starting next period. U_{t+1}^S is the lifetime utility of a susceptible person starting tomorrow, while U_{t+1}^I is the lifetime utility of a person who is infected starting tomorrow. In the next period, the susceptible individual either gets infected with probability τ_t or stays susceptible with probability $1 - \tau_t$. Importantly, the susceptible person, while making consumption and labor decisions in this period, knows that they would get infected in the next period with probability τ_t . Additionally, their economic decisions in this period will affect this infection probability through both consumption and labor channels. Thus, susceptible people would aim to reduce their consumption and labor supply in order to reduce the risk of getting infected tomorrow.

2.3.2. Infected people

An infected worker chooses their consumption (c_t^I) and labor (n_t^I) to maximize their lifetime utility:

$$U_t^I = u(c_t^I, n_t^I) + \beta[(1 - \pi_r - \pi_d)U_{t+1}^I + \pi_r U_{t+1}^R],$$

subject to

$$(1 + \mu_t)c_t^I = w_t \phi n_t^I + \Gamma_t.$$

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Similar to susceptible workers, U_t^I represents the lifetime utility of infected workers. It has two components, namely, the utility enjoyed in the current period through consumption and labor, $u(c_t^I, n_t^I)$, and the future discounted lifetime utility. U_{t+1}^R is the lifetime utility of a person who recovers in the next period. The infected worker while making their economic decisions in this period realizes that they will recover with probability π_r , die with probability π_d , or stay infected with remaining probability.⁵ We also assume that infections reduce the productivity of labor. $\phi \in (0,1)$ captures the decline in productivity of labor due to infections.

2.3.3. Recovered people

A recovered worker chooses consumption (c_t^R) and labor (n_t^R) to maximize their lifetime utility:

$$U_t^R = u(c_t^R, n_t^R) + \beta U_{t+1}^R,$$

subject to

$$(1 + \mu_t)c_t^R = w_t n_t^R + \Gamma_t.$$

Here, we assume that once a person has recovered, there is no chance of reinfection and hence they stay recovered throughout their lifetime.

In this framework, individuals choose the optimal mix of labor and leisure as well as how much to consume every period. The susceptible, infected, and recovered individuals take the infection probabilities and the aggregate laws of motion of infections as given while making their consumption and labor decisions. That is, individuals internalize the risk of getting infected while making their economic decisions. In equilibrium, these individual decisions, in turn, determine the probability of getting infected and hence the total number of infections in the economy. Thus, this framework enables us to study the interplay between the economic and health outcomes of a pandemic, as both are determined

⁵The lifetime utility of a dead person is taken to be zero, which is the usual assumption in macro and health economics literature.

simultaneously in equilibrium. A detailed description of the model and equilibrium conditions is given in Appendix A.

Using this model, we next analyze the economic and disease dynamics together. We study the impact of two different government policies, lockdowns and transfers, on both economic and health indicators. In our framework, lockdowns are modeled as taxes (μ_t) on consumption. Lockdowns make consumption decisions more difficult and hence act as a tax on consumption. Transfers are modeled as lumpsum payouts (Γ_t) from the government, and they contribute to the income of the individuals. Before we perform different quantitative experiments with our model, we have to choose values for the model parameters to reflect the Indian economy, which we turn to next.

3. Calibration

We choose the values for different model parameters to match the various data moments of the Indian economy. We have two sets of parameters to calibrate: economic parameters and disease parameters.

3.1. Economic parameters

We have three economic parameters to calibrate. Each period in the model represents a day. In order to reflect that, we set the discount factor, β , to be $(0.96)^{1/365}$, which corresponds to a yearly real interest rate of 4%. We choose the total factor productivity, A , of the economy to be 26.47 to capture the pre-pandemic average daily income of INR 138.75.⁶ Finally, the parameter governing the disutility of labor, θ , is set to 0.034 to target the pre-pandemic labor supply of 5 hours per day.

3.2. Disease parameters

We need to calibrate five transmission probabilities that govern the disease dynamics in the model. Following the epidemiological studies on

⁶INR is Indian Rupee.

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COVID-19, I assume that after infection, it takes 18 days for a case to close (i.e., for an infected individual to recover or die). Setting the mortality rate of infections at 0.33%, we obtain the probabilities of recovery (π_r) and death (π_d) to be 0.0553 and 0.0002, respectively.

Following the work of Wang *et al.* (2020), we choose R_0 , the expected number of secondary infections ensuing from a single infection, to be 2.2. Combining this with our choice of recovery and death probabilities, the total probability of getting infected is 0.12. To distribute this total probability across the three different channels of infection, we use Time Use Survey data for India (1999) to find out how much time an average Indian spends on these activities. The data suggest that, on average, people spend about 68 hours per week outside their homes, out of which 2 hours are spent on consumption-related activities, 35 hours on work, and the rest on social interactions. Using the proportion of time spent to weight our different channels, we find that the probability of getting infected through the consumption channel is 6.5×10^{-8} , the labor channel is 0.0023, and the social interaction channel is 0.0557. Finally, we assume that a fraction of the population, i.e., 10^{-6} , were initially infected in period 0.⁷ The details of the calibration are provided in Appendix B.

4. Quantitative Analysis

Now that we have calibrated the model for India, we can use our framework to study the economic and health impacts of the COVID-19 pandemic and also the policies implemented by the government to counter the disease spread. Economic impact is measured using the decline in aggregate income (compared to pre-pandemic levels) and cost of transfers, if any. Health effects are measured using peak infection rate and the number of days it takes for the infections to reach the peak. A lower peak infection rate and a higher number of days to peak are preferred by policymakers, as these impose less strain on the health facilities during a pandemic. First, we start with the benchmark scenario with no policy intervention. We then introduce two different government policies — lockdowns and income

⁷With the population of India at 138×10^7 people, this amounts to 1,380 infections at the starting period.

Table 1. Policy impact of lockdowns.

Impact	No Policy	Sustained	Staggered
Economic Impact			
Output Loss (%)	4.72	26.68	20.90
Health Impact			
Peak Infection Rate (%)	16.00	8.40	10.41
Days to Peak	218	295	286

Note: Loss of output refers to the total decline in aggregate output as a percentage of initial steady state over a period of 300 days (from day 101 to 400) when the lockdown is in place. Peak infection rate reports the maximum infection as a percentage of the initial population. Days to peak measures the number of days it takes for the infections to peak.

Table 2. Policy impact of transfers.

Impact	No Policy	Sustained	Staggered
Economic Impact			
Output Loss (%)	4.72	31.34	21.79
Cost of Transfers (% GDP)	—	4.45	2.67
Health Impact			
Peak Infection Rate (%)	16.00	8.42	11.26
Days to Peak	218	293	280

Note: Loss of output refers to the total decline in aggregate output as a percentage of the initial steady state over a period of 300 days (from day 101 to 400) when the transfers are provided. Total transfers are measured as a percentage of GDP. Peak infection rate reports the maximum infection as a percentage of the initial population. Days to peak measures the number of days it takes for the infections to peak.

transfers and study their impact on economic and health outcomes. The effects of different lockdown policies are given in Table 1 while that of transfer policies are given in Table 2.

4.1. Benchmark (no policy)

We first simulate our model assuming that there is no policy implementation on the ground. This will serve as a benchmark for analyzing the impact of policies on different economic and health aspects. In this

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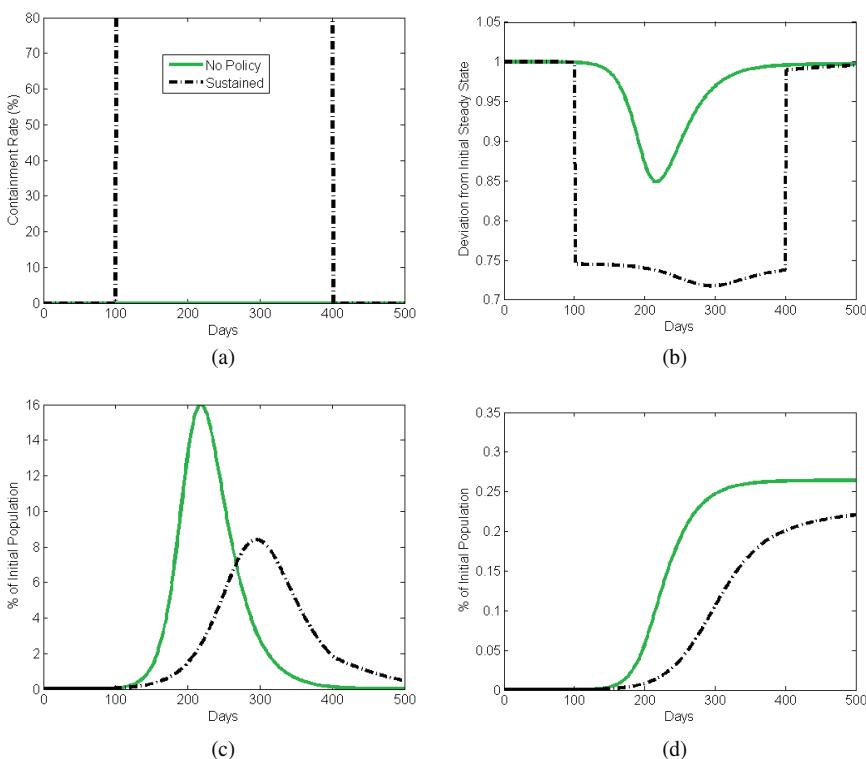


Figure 2. Impact of sustained lockdown: (a) lockdown policy; (b) aggregate labor/output; (c) infections; (d) deaths.

scenario with no policy intervention, we find that the total number of infections reach a peak of 16% of the initial population on day 218 from the start of the pandemic. Figures 2(c) and 2(d) show the dynamics of active infections and deaths in our model economy. Importantly, we find that, even without any policy action, individuals factor in the risk of getting infected and optimally choose to reduce their consumption and labor supply, as seen in Figure 2(b). This causes a reduction in aggregate output of 4.72% compared to the pre-pandemic level. Thus, even without any containment policies, the emergence of the pandemic drags the economy into a recession, as people cut back on their consumption and labor supply, which in turn generates a decline in output. This is an important insight we get from our integrated macro-SIR model, which a pure

macroeconomic or a simple SIR model wouldn't give. Thus, for a policymaker, it is important to realize that a pandemic in itself can lead to a decline in the income of the population. Any policy interventions, such as lockdowns, might worsen this scenario, as can be noted from the following section.

4.2. Lockdown policies

We now introduce two different lockdown policies in our model setup. In the first policy scenario, called sustained lockdown, the government imposes a severe lockdown on 80% of the economy for a sustained period of 300 days. The second policy we consider is called as staggered lockdown, where the government imposes a severe lockdown for the first 100 days and then gradually relaxes the lockdown every 100 days. Figures 2 and 3 show the sustained and staggered lockdown policies, respectively.

Compared to the no policy scenario, both sustained and staggered lockdown policies are successful in slowing down the infection spread and reducing the deaths. The sustained lockdown reduces the peak infection rate from 16% to 8.4% and slows down the pandemic by increasing the days to peak from 218 days to 295 days. Compared to the sustained policy, the staggered lockdown is less intense and hence less successful in controlling the pandemic. It brings down the peak infection rate to 10.4% and increases the days to peak to 286 days. It also results in more deaths compared to the sustained containment policy.

On the other hand, when we look at the economic cost imposed by these policies, both the lockdown policies impose much more economic strain compared to the no policy case. The sustained lockdown causes a decline of around 26.7% in income compared to a 4.7% decline in the benchmark case. The staggered lockdown also imposes a huge cost, with income reducing by 20.9%, but it is less compared to that in the sustained case. The economic and health dynamics of both the sustained and staggered containment policies are shown in Figures 2 and 3, respectively.

As can be seen from the analysis of these two different lockdown policies, there is a clear trade-off between containing the pandemic and the cost imposed on the economy. The sustained lockdown performs the best in slowing down the disease spread, but it also imposes the maximum

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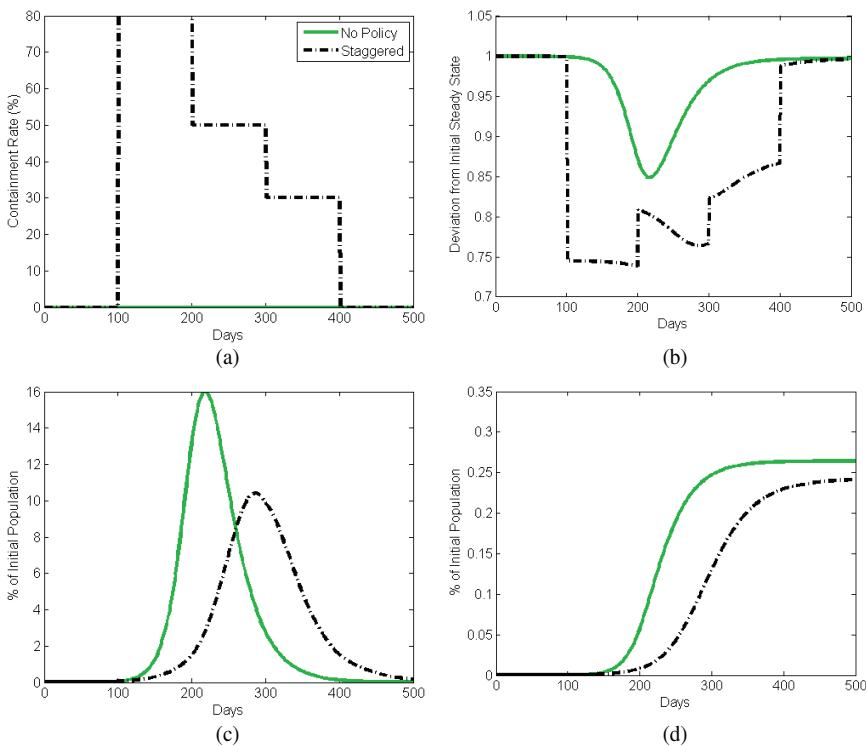


Figure 3. Impact of staggered lockdown: (a) lockdown policy; (b) aggregate labor/output; (c) infections; (d) deaths.

economic cost. The staggered lockdown, even though it inflicts less pain on the economy, is not as successful in controlling the pandemic. Finally, doing nothing is economically cheap but disastrous on the health front. Thus, policymakers are faced with an array of choices, and they have to strike a balance between the economic and health fronts during a pandemic.

4.3. Transfer policies

As we just saw, lockdown policies implemented to control the pandemic impose a lot of financial strain on individuals. Hence, a number of countries, including India, implemented income transfers to support the

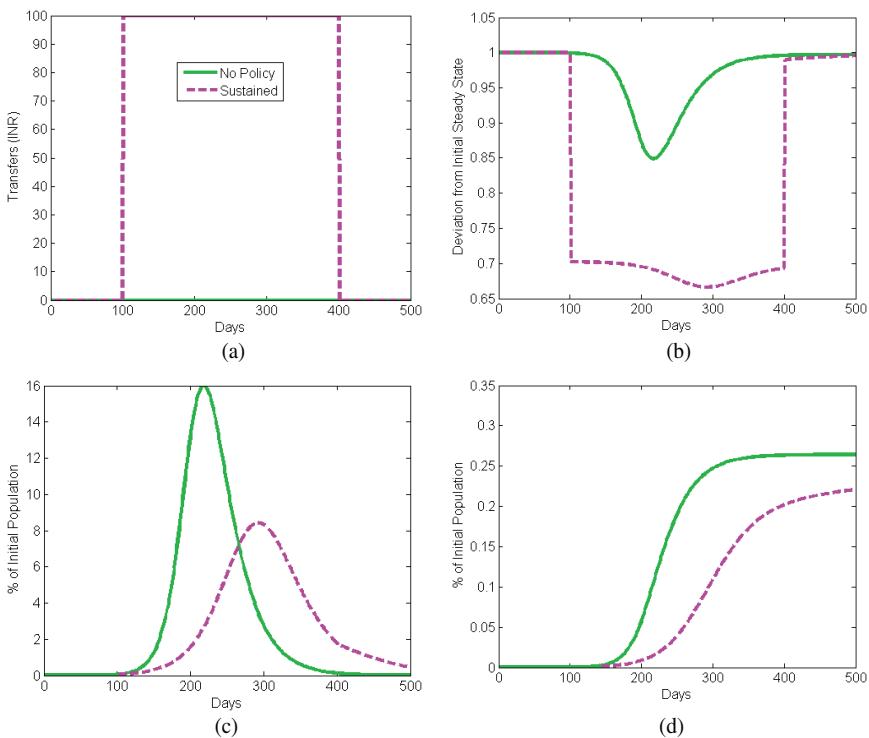


Figure 4. Impact of sustained transfers: (a) transfer policy; (b) aggregate labor/output; (c) infections; (d) deaths.

households during these extraordinary times. We now analyze the economic and health impacts of such a policy. Just like in the case of lockdowns, we consider two different kinds of transfer policies: sustained and staggered. Sustained transfers involve a government providing INR 100 every day to every nonagricultural worker for 300 days. The staggered transfers policy starts by paying INR 100 for the first 100 days and then reducing it to INR 50 and INR 30 over the next 100 days. Figures 4(a) and 5(b) show the effects of sustained and staggered transfer policies,

Even though these transfers were primarily provided to alleviate the economic hardships of the individuals, both the sustained and staggered transfers are successful in reducing the infection spread. Sustained

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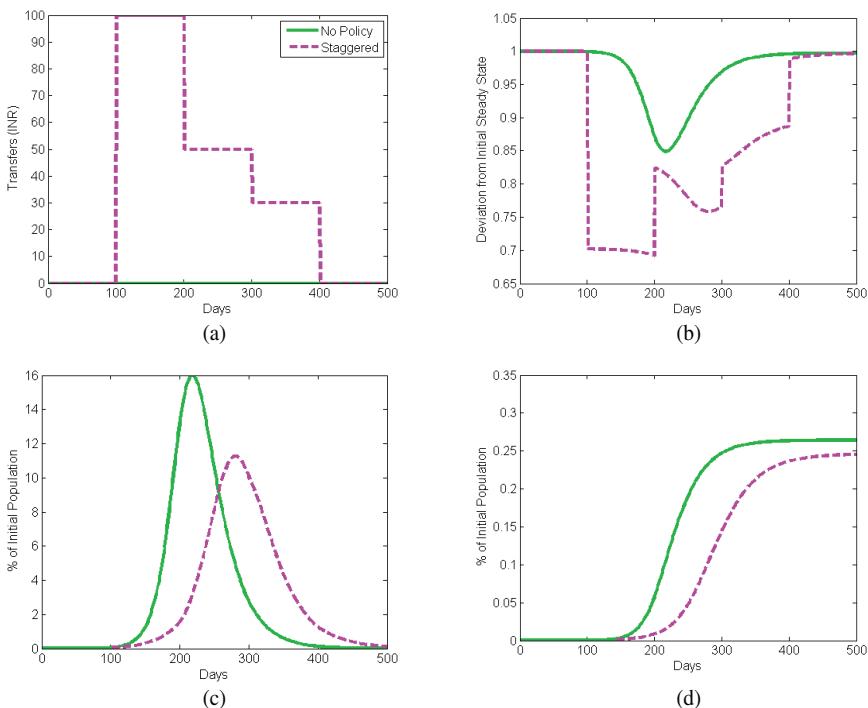


Figure 5. Impact of staggered transfers: (a) transfer policy; (b) aggregate labor/output; (c) infections; (d) deaths.

transfers reduce the peak infection rate from 16% to 8.42%, while staggered transfers bring it down to 11.26%. They also slow down the pandemic, with the sustained policy pushing the days to peak from 218 days to 293 days, while the staggered policy increases it to 280 days. Just like in the case of lockdowns, there is a trade-off between economic and health outcomes. The sustained transfer, which costs 4.45% of the GDP to implement, is more successful in containing the pandemic compared to the staggered transfer, which amounts to 2.67% of the GDP.⁸ Figures 4 and 5 show the economic and health dynamics of the sustained and staggered transfer policies, respectively.

⁸According to World Bank statistics, the total nonagricultural labor force of India is 296 million and the total GDP is INR 200 trillion (USD 2.69 trillion approximately).

Transfers provided by the government increase the income of the households. These transfers enable households to reduce their labor supply further, causing the aggregate output to decline by around 31.3% in the sustained case and 21.8% in the staggered case, compared to a 4.7% fall in the benchmark case. But this cutback in labor supply helps in reducing the spread of infections through the labor market channel, thus having a large positive effect on both peak infection rates and days to peak. This exercise shows that income transfers, though primarily an economic policy, can double up as a health policy to combat the spread of a pandemic. Governments all over the world have used varying degrees of lockdown to control the spread of COVID-19 while using transfers to mitigate the negative economic effects of such lockdowns. Our results show that economic transfers can reduce both economic and health distress during these extraordinary times.

5. Policy Implications

One of the difficult quandaries facing policymakers is regarding the intensity and length of lockdowns in order to control a raging pandemic. One school of thought called the John Snow Memorandum⁹ argues that policymakers should prioritize controlling the community transmission of the virus by implementing population-wide mandates and measures. It argues that, even though lockdowns are disruptive and have economic costs, countries that have weak policy responses end up facing prolonged restrictions due to the pandemic, which in turn exacerbate the socioeconomic inequalities and deficiencies. The Great Barrington Declaration,¹⁰ on the other hand, raises concerns about the physical and mental health impacts of COVID-19 policies, and it advocates for “Focused Protection.” The supporters of this declaration argue that implementing population-wide measures will end up causing irreparable damage to the population and could disproportionately affect the underprivileged.

⁹The John Snow Memorandum: <https://www.johnsnowmemo.com/john-snow-memo.html>.

¹⁰The Great Barrington Declaration: <https://gbdeclaration.org/>.

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The findings we obtained from simulating the macro-SIR model resonate with both the viewpoints, as outlined above. Through our model framework, we do find that the pandemic policies, such as lockdowns, succeed in slowing down the disease spread but are costly in economic terms. Importantly, these quantitative models will help policymakers to simulate different policy scenarios and arrive at a policy that could potentially achieve large health benefits for a given amount of economic cost.

Another important insight obtained from our model simulations is the role played by economic transfers. Even though transfers are primarily treated as an economic policy to help people tide over the pandemic, we find that the transfers also have beneficial impacts on the health front. For a policymaker fighting the pandemic, transfers are an attractive option, as they reduce the immediate suffering of the population and at the same time help in controlling the disease transmission. Combining policy interventions like lockdowns with transfers will reduce the economic costs of the policies and improve the potential health benefits that could be achieved. Economic transfers as a policy tool also help in bridging the gap between the two different policy viewpoints, i.e., the John Snow Memorandum and the Great Barrington Declaration. Combining lockdowns with economic transfers helps in reducing the trade-offs characterized by these policy proposals and could help policymakers in achieving a balance between economic and health dimensions during a pandemic.

6. Conclusion

The emergence of the COVID-19 pandemic and the subsequent containment policies have led to a sharp decline in the average income. In order to jointly analyze the economic and disease dynamics of the pandemic, we introduce a macroeconomic-SIR framework. Calibrating this model for India, different lockdown policies impose significant economic costs, and there is a trade-off between controlling the infections and the costs inflicted on the economy. Finally, we introduce economic transfers in our model framework to find that transfers can be used as a health policy to flatten the pandemic.

The macro-SIR framework discussed in this chapter would be a valuable guide for policymakers, as it would help them to simulate various policies and find their economic and health impacts before implementing them. This would enable policymakers to choose the policy that best controls the disease spread but at the same time inflicts manageable economic costs. It would also be extremely rewarding to use this framework and analyze the different facets of the pandemic in the context of India. Dasgupta and Murali (2020) extend this benchmark model to talk about the increase in income inequality in India during the pandemic. Hopefully, this chapter would introduce the macro-SIR framework to a wider audience and spur more research in this area.

Acknowledgments

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Appendix A: Model

The model closely follows the work of Eichenbaum *et al.* (2020). I present the simple macroeconomic framework followed by the macro-SIR model.

A.1. A simple macroeconomic model

A.1.1. Households

Households choose consumption (c) and labor (n) to maximize the life-time utility:

$$U = u(c, n) + \beta U,$$

subject to

$$c = wn + \Gamma,$$

where w is the wage and Γ represents the transfers.

A.1.2. Firms

Firms produce consumption goods and maximize profit:

$$\Pi = AN - wN,$$

where N is the labor demand and A is total factor productivity.

A.1.3. Market clearing

In equilibrium, both goods and labor markets clear:

$$c = AN,$$

$$n = N.$$

A.2. Macro-SIR model

We embed the SIR model into the macroeconomic framework. Let S_t , I_t , R_t , and D_t be the total number of susceptible, infected, recovered, and deceased people at time t , respectively.

A.2.1. Aggregate laws of motion

A susceptible person can get infected through three different channels. So, the total number of newly infected people in time t is given by

$$T_t = \pi_{s1}(S_t C_t^S)(I_t C_t^I) + \pi_{s2}(S_t N_t^S)(I_t N_t^I) + \pi_{s3} S_t I_t,$$

where the three terms capture the three channels of infection. The various groups evolve according to

$$S_{t+1} = S_t - T_t,$$

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$$I_{t+1} = I_t + T_t - (\pi_r + \pi_d)I_t,$$

$$R_{t+1} = R_t + \pi_r I_t,$$

$$D_{t+1} = D_t + \pi_d I_t,$$

where π_r and π_d refer to the probability of recovery and death, respectively. Assuming ε as the fraction of the population infected in period 0,

$$I_0 = \varepsilon, \quad S_0 = 1 - \varepsilon.$$

Individuals take these laws of motion as given and make their decisions.

A.2.2. Susceptible people

Susceptible workers choose their consumption and labor to maximize their lifetime utility:

$$U_t^s = u(c_t^s, n_t^s) + \beta [(1 - \tau_t) U_{t+1}^s + \tau_t U_{t+1}^i],$$

subject to

$$c_t^s = w_t n_t^s + \Gamma_t,$$

and the infection rate τ_t is given by

$$\tau_t = \pi_{s1} c_t^s (I_t C_t^I) + \pi_{s2} n_t^s (I_t N_t^I) + \pi_{s3} I_t.$$

A susceptible person takes the aggregate consumption and labor supply of infected people as a given while making their choices.

A.2.3. Infected people

An infected worker maximizes

$$U_t^i = u(c_t^i, n_t^i) + \beta [(1 - \pi_r - \pi_d) U_{t+1}^i + \pi_r U_{t+1}^r],$$

subject to

$$c_t^i = w_t \phi n_t^i + \Gamma_t.$$

where ϕ captures the loss in productivity due to infections.

A.2.4. Recovered people

A recovered worker maximizes

$$U_t^r = u(c_t^r, n_t^r) + \beta U_{t+1}^r,$$

subject to

$$c_t^r = w_t n_t^r + \Gamma_t.$$

A.2.5. Market clearing

The markets for both consumption and labor clear:

$$\begin{aligned} S_t n_t^s + I_t n_t^i + R_t n_t^r &= N_t, \\ S_t c_t^s + I_t c_t^i + R_t c_t^r &= AN_t. \end{aligned}$$

Appendix B: Calibration

Value for the probabilities of recovery and death: Every period, a fraction of the infected individuals either recover or die. We refer to them as “closed” cases. The probability that an infected person dies in a period, π_d , is then given by

$$\pi_d = m \times Pr(closed),$$

where m , the mortality rate, measures the fraction of closed cases who have died, while $Pr(closed)$ is the probability of a case getting closed.

Evidence from China WHO (2020) suggests that for COVID-19, it takes about 2 weeks on average from onset to clinical recovery for mild cases, while the corresponding number for patients with severe or critical disease is 4.5 weeks. The same report suggests that among the people who were found to be infected, around 80% exhibited mild to moderate symptoms. So, the expected time taken by an infected individual to recover is 2.5 weeks or roughly 18 days. Assuming that 18 days is also the expected time taken by an infected individual to die (the range is 2–6 weeks), the probability of a case closing in one day, $Pr(closed)$, is then 1/18.

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Furthermore, the total number of infected individuals at time t can be written as

$$I_t = I_t^{\text{test}} + I_t^{\text{notest}},$$

where I_t^{test} and I_t^{notest} denote the number of infected individuals who have been tested and not tested, respectively. We can rewrite the above equation as

$$I_t = \frac{1}{1-a} I_t^{\text{test}},$$

where $a = I_t^{\text{notest}}/I_t$ is the ratio of infected individuals who do not get tested. Of course, we do not know the value of a . But we might be able to offer an educated guess. One assumption is that because testing is a choice, infected individuals who are asymptomatic are more likely to not get tested. In that case, one way to approximate a is to use the asymptomatic rate. Preliminary studies suggest that the percentage of people with asymptomatic or mild symptoms is around 80%.¹¹ We choose a (more conservative) value of a equal to 0.9. As of April 12, $I_t^{\text{test}} = 9,100$ and $D = 300$. With $a = 0.9$, $I_t = 91,000$. The mortality rate is then equal to 0.33%. Hence,

$$\pi_d = 0.0033 \times 1/18 = 0.0002,$$

and the probability of recovery is

$$\pi_r = 1/18 - \pi_d = 0.0553.$$

Value for the infection probabilities: Let χ be the transmission rate, i.e., the expected number of individuals who can get infected in time t by someone who is already infected. To get a value for χ , one can use the following relation:

$$R_0 = \chi / (\pi_r + \pi_d),$$

¹¹www.ecdc.europa.eu.

where R_0 , the basic reproduction number, is the expected number of individuals who will be infected by a single infected individual over the course of a disease. We use $R_0 = 2.2$, which is in the mid-range across studies looking at the R_0 for COVID-19 (Wang *et al.*, 2020). This gives us $\chi = 2.2 \times 0.0555 \approx 0.12$.

We assume that the transmission probabilities due to consumption (π_1), work (π_2), and social interactions (π_3) add up to 0.12. At the beginning of a pandemic, we then have

$$\pi_1 \times C^2 + \pi_2 \times N^2 + \pi_3 = 0.12,$$

where C and N are the pre-pandemic equilibrium values for consumption and labor, respectively. Time Use Survey data for India (1999) suggest that an average Indian spends 68 hours per week outside home. Out of these, around 35 hours are spent on work, 2 hours are spent on consumption-related market activities, and the rest on activities that could lead to social interactions. It follows that

$$\frac{\pi_1 \times C^2}{\pi_1 \times C^2 + \pi_2 \times N^2 + \pi_3} = \frac{2}{68}$$

and

$$\frac{\pi_2 \times N^2}{\pi_1 \times C^2 + \pi_2 \times N^2 + \pi_3} = \frac{35}{68}.$$

Solving, we have $\pi_1 = 6.5 \times 10^{-8}$, $\pi_2 = 0.0023$, and $\pi_3 = 0.0557$.

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Chapter 3.2

COVID-19 and Global Education: Evidence from India

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Abstract

Schools closed across the globe in March 2020, affecting 1.6 billion learners, constituting 91% of all enrolled students in the world and 99% in low-income countries. India had one of the longest durations of school closures, more than twice the global average, with schools starting to open fully only in 2022. Even regularly scheduled school closures result in learning loss, which is typically larger for children from weaker socioeconomic backgrounds. In the case of the pandemic, these effects are likely to be magnified, both in terms of the magnitude of the learning loss and its unequal distribution. In this chapter, we focus on the impact of the pandemic on education in India. Using the Annual Status of Education Report (ASER), nationally representative surveys conducted during 2020 and 2021, we present findings on children's access to learning opportunities and educational support available at

home in rural India. In addition, ASER provides new data on learning loss for three states in India. While the state was extremely successful in providing textbooks to children during this period, it was less so in providing other learning materials, such as access to remote classes or other online resources. In states where a field survey to assess learning levels could be done, there was a learning loss of over a year. With a shock like this to the system, going back to “business as usual” when schools reopen is not really an option. The chapter discusses some of the academic strategies that can be implemented successfully to face current teaching–learning challenges.

Keywords: virtual education; COVID-19; pandemic; India

1. Introduction

Schools closed across the globe in March 2020. This school closure happened in 194 countries, affecting 1.6 billion learners, constituting 91% of all enrolled students in the world and 99% in low-income countries (UNESCO, 2021a). Even one year later, over 800 million students were experiencing disruptions to their education, with full school closures in 31 countries and reduced teaching in another 48 countries (UNESCO, 2021b). According to the most recent data available from UNESCO, 18 months into the pandemic, the global average for school closures (full and partial) is just under nine months (35 weeks), with schools being closed for over a year in countries, such as the US (62 weeks) and India (73 weeks) (data as of September 30, 2021 from UNESCO, 2021a).

This is not the first time schools have been closed for an extended period of time; there is some literature on the impact of school closures due to natural disasters or teacher strikes.¹ But such school closures have tended to be localized and not of such a long duration. It is evident that the impact of the current pandemic on education will be global and is likely to be much larger and perhaps more long lasting than anything we have seen before.

When schools are closed, even for a short time, say due to scheduled summer breaks, there is some learning loss and some disengagement with learning, simply due to the lack of in-person instruction.² Even under

¹ See for example, Andrabi *et al.* (2020).

² See for example, Slade *et al.* (2017).

normal circumstances, children from poorer backgrounds suffer relatively more. Richer parents can compensate for the lack of instruction by adding supplemental educational resources and paid tutors. In addition, children from more affluent backgrounds tend to have more educated parents who can help them study at home. In the case of a pandemic, these effects are likely to be magnified, both in terms of the magnitude of the learning loss and its unequal distribution.

Even though most countries pivoted as fast as they could and started sharing learning materials remotely using a variety of online platforms, the concern has been that the shift to online instruction is likely to affect students from low-income families far more adversely. There have been a variety of studies trying to estimate the extent of the learning loss due to the pandemic, but they have focused largely on OECD countries. Azevedo *et al.* (2020) simulate the learning loss due to school closures. In their most pessimistic scenario — school closures of seven months — which we have already crossed, globally, children will lose almost a year of learning-adjusted years of schooling, with long-lasting effects on lifelong earnings. The study suggests that the effects on learning are likely to be exacerbated for children from weaker economic backgrounds, who are unable to access remote learning resources and also do not have adequate learning support at home. Kuhman *et al.* (2020) use estimates of learning loss from studies of absenteeism and summer closures in the US to project learning losses of as much as 63% of the normal annual gain in achievement in math. They also find that the SES achievement gap is likely to widen. Bacher-Hicks *et al.* (2020) use internet search data to study the use of online learning resources in the US when schools were closed. They also find that the pandemic is likely to widen achievement gaps across rural–urban schools as well as high- and low-income areas.

All of these studies use existing estimates to project learning losses during the pandemic. In contrast, in a study using data from an online math platform in the US, Chetty *et al.* find that children from high-income areas experienced only a temporary reduction in learning, while children from low-income areas remained 50% below baseline levels persistently. Similarly, Engzell *et al.* (2020) compare learning data on primary school children in the Netherlands as soon as schools reopened with a baseline conducted prior to the school closures and find that the learning loss is 55% larger for children from less-educated households. Interestingly, they

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find no difference across sex, grade, or subject. The importance of parental education in mitigating the effects of school closures is also underscored by Andrabi *et al.* (2020) in their study conducted after the 2005 earthquake in Pakistan. The study finds that while children living close to the earthquake fault line scored significantly worse on academic tests, even three years after the quake, these effects were completely mitigated for children of better educated parents. Several international agencies (such as the World Bank, UNICEF, and FCDO) quickly put together a variety of studies conducted during the pandemic to provide insights of what needs to be prioritized for learning in the current times.³

In this chapter, we focus on the impact of the pandemic on education in India. As in the rest of the world, schools shut down in India in March 2020. However, the duration of school closures in India has been one of the longest — more than twice the global average (UNESCO, 2021a). While there were instances of sporadic reopening for some grades and a great deal of variation across states as well as urban and rural areas, all schools across the country have only fully reopened by March–April 2022.⁴ As in the rest of world, Indian schools also shared a variety of learning material during the period when schools were closed. However, while there is a fair amount of information about the type of content and material being shared, not much was known about whether children were receiving this material and how they were engaging with it. As schools reopen, it becomes critical to understand what worked and for whom. It is most likely that the shift to remote learning widened the variations in access to education and accentuated equity issues in learning in India as well.

³Global Education Evidence Advisory Panel (2022). Prioritizing learning during COVID-19.

⁴After the first closure in March 2020, schools opened across some states between September and December 2020 but promptly closed as COVID-19 cases began to rise again. The second wave of COVID-19 in India subsided after May 2021, and while schools started reopening across some states (for some grades), there was no full-fledged reopening. The third wave of COVID-19 hit India in December 2021, leading to re-shutting of schools which had opened only recently. It is only after the passing of the third wave, in March 2022, that schools across all states and grades will finally reopen in April 2022, two full academic years after they shut down in March 2020. See Annexures 1 and 2 in ASER 2021 for more details.

In the next section, we present some results from studies undertaken during the pandemic in India. In Section 3, we discuss the findings from two large-scale, nationally representative surveys, which focused on access to learning opportunities and educational support available at home for rural Indian children. Section 4 provides new data on learning loss for three states in India. Section 5 delves into the lessons from some of the learning strategies that have been used during the pandemic in India. Section 6 concludes with a discussion of some short-term and long-term implications.

2. Evidence from Studies on Education During the Pandemic in India

There is not much large-scale evidence available on the impact of COVID-19 on education in India, and by and large, studies have focused on access to learning materials and whether children faced any challenges studying remotely. With movement severely restricted during the pandemic, most studies had to rely on the use of phone surveys to collect information. Since there is no representative frame available for phone numbers across different geographies, researchers had to rely on previous studies or draw respondents from areas they were working in. For instance, in a study focusing on 13 states they operate in, Save the Children (2020) finds that about 80% of children were facing obstacles in learning during the time schools were closed, while 75% reported that they could not use the internet due to limited access and 30% said that they had no support for learning. The study sample consisted of 754 children in the age group of 11–14 years. Similarly, in a rapid assessment of 1,200 parents and 500 teachers across five states, Oxfam India (2020) finds that 82% of the parents faced challenges in supporting their children to access digital education and 84% of the teachers struggled with delivering lessons through digital media.

Magic Bus (2020) surveyed 3,700 of the most vulnerable families within their national network to study the impact of the pandemic on livelihoods and education. In their sample, 41% of the households said that they are unable to afford school fees and 83% of the children did not have

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access to online learning. Ghatak *et al.* (2020) also focused on adolescent children from marginalized households and reported low uptake of educational content broadcast on TV. In a sample of 3,176 households from five Indian states, they find that only 11% of the children had watched any educational content on TV even though 52% of them had a TV at home.

All studies confirmed limited access to learning resources shared remotely and a growing rural–urban digital divide. However, none of the studies focused on the impact this would have on learning outcomes. An exception was a study by Azim Premji University (2021), as part of their field studies in education. Using data from a pre-COVID-19 baseline and a follow-up assessment done in January 2021, the study gives estimates of learning loss for children in primary grades.

At the start of the pandemic in March 2020, an assessment of language and mathematics in 16,067 children in 1,137 public schools across 44 districts in five states was done by teachers who were closely affiliated with the Azim Premji Foundation. The selection of children was based on discussions with the teachers, covering children whom the teachers had taught in the previous year and were familiar with. The same children were assessed in the same competencies about a year later in January 2021. The study found evidence of large learning losses. In language, 92% of the children in grades 2–6 had lost at least one specific ability from the previous year. The language abilities that the children were tested on included reading familiar words, reading with comprehension, and writing simple sentences based on a picture. Similarly, in math, 82% of the children in grades 2–6 had lost at least one specific ability from the previous year. The math abilities that the children were tested on included identifying single- and two-digit numbers, performing arithmetic operations, using basic arithmetic operations for solving problems, describing 2D/3D shapes, and reading and drawing inferences from data.

With limited access to learning materials while schools were closed, these estimates of learning loss are not surprising and are in line with the international evidence. Furthermore, the learning gaps are likely to be exacerbated for already disadvantaged children, further widening equity gaps. While the pandemic has affected most sectors, what is also clear is the disproportionate impact it has had on the already vulnerable groups, with education being no different. None of the studies discussed above

compare the impact of the pandemic on different groups of children, most likely due to limited sample sizes or the focus on only certain kinds of households. Furthermore, none of them provide national estimates, and often, the sample is limited to participants of certain programs.

In the next section, we discuss the evidence from the nationally representative Annual Status of Education Report (ASER) conducted in over 50,000 households across almost all rural districts of the country in September 2020 and 2021.

3. Large-scale Evidence from Rural India: ASER 2020 and 2021 (Phone Surveys)

Soon after schools were closed in India, as in many other countries, school systems began to share different kinds of learning materials using a variety of modes. The materials ranged from traditional materials, such as textbooks and worksheets, to educational content broadcast over radio and TV, and finally sharing remote web-based resources, such as recorded and live online classes. Many states, including Assam, Jammu and Kashmir, Manipur, Madhya Pradesh, and Uttar Pradesh, shared learning materials in all these forms. Others, such as West Bengal, shared textbooks and online resources; Tripura shared textbooks and had educational programs on TV. By and large, though, most states shared textbooks and some sort of web-based content.⁵

However, though there was a fair amount of information on what Indian states were doing to facilitate learning while schools were closed, very little was known about whether these materials were reaching children and what kinds of learning activities they were engaged in. All global predictions, as discussed above, pointed toward large losses that would be unevenly distributed, with already vulnerable groups taking the brunt of the suffering, but there was hardly any systematic information on what was the actual situation on the ground.

⁵For more details, see Annexure 2 in ASER 2020: <http://img.asercentre.org/docs/ASER%202021/ASER%202020%20wave%201%20-%20v2/annex2-learningmaterialssharedbystategovernments.pdf>.

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The Annual Status of Education exercise (facilitated by Pratham) pivoted by departing from the usual practice of actual field surveys focused on generating estimates of basic reading and arithmetic. With schools closed and movement in the field restricted due to the pandemic, no reliable estimates of learning loss were actually available and all information gathering could only be done via phone surveys. In 2020 and 2021, ASER conducted surveys via phone to explore the underlying educational trends and learning opportunities during this time of prolonged school closure. Schools had been closed for more than a year and a half, long enough for two ASER phone surveys to be conducted one year apart (September 2020 and September 2021) so that the changes during this school closure period could be studied.

Both waves of ASER, in 2020 and 2021, probed the following types of questions: What decisions were made within families about their children's education? What opportunities were available to households in different parts of the country? What was the relationship between home and school during this period of crisis? Whether the learning materials were actually reaching children, and were there any differences in access, with certain groups of children being at a disadvantage? Were children engaging with learning materials while they were studying at home? Did they have other resources to help them learn outside the classroom?

Such questions are important at any time but even more critical today. In the current context, it was crucial to understand how much learning loss we could expect to see and for whom, as well as what factors could potentially help to control the damage. Furthermore, these questions were important to answer in order to design educational programs during this period as well as to chart out a plan of action for what should happen in classrooms when schools did reopen. Whether as a family or a school or a school system or a country, planning the next effective steps is crucial. Data that are systematically collected from a nationwide sample in a timely fashion can be invaluable for visualizing the path forward.

The two waves of ASER in 2020 and 2021, both nationwide, phone-based surveys focused on rural areas in India, were designed to grapple with some of these questions. The surveys covered almost all rural districts of India and was designed to be representative at the state and national levels. Table 1 gives the sample description of the two surveys.

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Table 1. ASER 2020 and 2021: Sample description.

ASER Year	Age Group Surveyed	Covered			Surveyed		Contacted		Of Total Schools, Schools that Were Open
		States & UT	Districts	Villages	House- holds	Children	Total Schools		
ASER 2020	5–16	30	584	16,974	52,227	59,251	8,963	0	
ASER 2021	5–16	30	581	17,184	76,706	75,234	7,299	4,872	

Both surveys focused on the following four domains:⁶

- *Enrollment*: Whether the child is currently enrolled in school or preschool, type of school, and grade enrolled in.
- *Learning support at home*: Whether someone at home helps the child to study, and if so who, and whether the child has a private tutor.
- *Access to learning materials*: Whether the child received learning materials, such as textbooks, or other learning materials, such as worksheets, or remote learning resources from the school, and if so how did they receive the material.
- *Engagement with learning materials*: Whether the child engaged in any learning activities and if so what kind of activities.

In addition, the ASER 2020 and 2021 surveys collected data on household resources, such as availability of smartphones, household assets like TVs and vehicles, and parents' education. While the ASER survey does not collect detailed information on the socioeconomic status of the household, the information on parents' education can be used as a proxy for affluence. According to ASER 2020, children with low parental education are less likely to have a smartphone — 45% as compared to 79% of children with high parental education.⁷ They are also more likely

⁶For more details, see ASER Centre (2020 and 2021).

⁷“Low” parental education is defined as both parents having completed Grade 5 or below, and “high” parental education is both parents having completed at least Grade 9; “moderate”

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to send their children to government schools — 84% as compared to 54% of children with more educated parents.

Children from economically weaker backgrounds typically tend to have lower learning outcomes. There are a variety of channels through which this effect operates. For instance, children from poorer households tend to have less educated parents who are unable to provide learning support comparable to those in richer households. Parents support their children's learning in a variety of ways. They help their children with their homework; they understand the importance of education and encourage their children to focus on school work; if they can financially afford it, they send their children to private schools and/or provide supplementary resources, such as private tutors, to help them academically; they, especially mothers, spend more time with the child, providing input into the overall development of the child. Remote learning opens up another channel that widens the learning disadvantage of relatively poorer children. These children may not have access to devices, such as computers, tablets, and smartphones, that are needed for remote instruction and therefore may not be able to access the learning materials provided remotely by the state during the pandemic.

In the next section, we use the ASER 2020 and 2021 data to examine the impact of the pandemic on education in rural India. We also focus on equity issues so as to examine if the brunt of the impact of the pandemic was borne by already vulnerable groups. Using parental education as a proxy for affluence, we try to highlight the differences in enrollment, learning support, and access to and engagement with learning materials across different groups of children.

4. Influence of the Pandemic on Children's Education in India: Highlights of Findings from ASER 2020 and 2021 (Phone Surveys)

In this section, we briefly discuss the patterns and trends of enrollment, learning support at home, access to learning materials and learning opportunities, and engagement with learning materials during the pandemic.

parental education is a residual category containing all other combinations of mother's and father's schooling. In rural India, 22.5% of children have parents with low education, compared to 27.6% with high parental education. The remaining 50% are in the middle.

4.1 Enrollment

One of the major concerns about the impact of the pandemic on education, especially in developing countries, was that it might also result in an increase in dropout rates. With economic activity slowing down and family budgets getting squeezed, it was possible that the older children would drop out of school. In the case of India, this was a distinct possibility, with very few institutional safety nets available to protect unemployed workers and the government not offering any substantial cash-based relief package for workers or businesses to protect employment. The migrant crisis further exacerbated the problem, with migrant workers moving back to villages, leading to a possible influx of migrant children from urban to rural areas.

Overall, there is an increase in the proportion of children enrolled in government schools between 2018 and 2021 (Table 2). From 2006 to 2014, there had been a steady increase in the proportion of children enrolled in private schools at the elementary stage. After plateauing around 30% for a few years between 2014 and 2018, there has been a significant decline during the pandemic years (between 2018 and 2021). The causes of this decline in private school enrollment may have to do with financial distress in rural families as well as difficulties faced by the low-cost or budget school sector in surviving the economic disruptions brought on by the pandemic.

The increase in government school enrollment is evident across all grades and for boys as well as girls. Like with many other indicators of human development in India, there are wide variations across states. The highest increase in government school enrollment over this period is seen in Uttar Pradesh, going from 43.1% in 2018 to 56.3% in 2021. Kerala also saw an increase from 47.9% to 59.8%. It is also possible that households were responding to entitlements offered by government schools that ranged from textbooks and learning materials to food rations in lieu of midday meals. In fact, Uttar Pradesh, India's largest state, implemented a massive direct benefit scheme for all children enrolled in government schools in 2021.

The proportion of children not currently enrolled in schools in the age group of 6–14 years, went up from 2.5% to 4.6% between 2018 and 2020 with no further increase in 2021 (Table 3). However, if we disaggregate by

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Table 2. Enrollment trends (all-India rural).

Age: 6–14	Government Schools	Private Schools	Other Kinds of Schools	Not Enrolled	Total
2018	64.3	32.5	0.7	2.5	100
2020	65.8	28.8	0.8	4.6	100
2021	70.3	24.4	0.7	4.6	100

Source: ASER (2018–2021).

Table 3. Percentage of children currently not enrolled in schools.

Age group	% Children Currently Not Enrolled in School		
	ASER 2018	ASER 2020	ASER 2021
Age 6–14: All	2.5	4.6	4.6
Age 7–10: Boys	1.4	4.7	4.7
Age 7–10: Girls	1.4	4.1	4.1
Age 11–14: Boys	2.9	3.9	4.3
Age 11–14: Girls	3.6	3.9	3.9

Source: ASER (2018–2021).

age groups, the largest drop in enrollment between 2018 and 2020 is for the youngest age group, with the proportion of 7–10-year-olds not currently enrolled in school rising from 1.4% in 2018 for boys and girls to 4.7% in 2020 for boys and 4.1% for girls. This increase may simply be due to the fact that many young children (6–7-year-olds) were waiting to seek enrollment when schools reopen.

Schools shut down in India in March 2020 at the end of the 2019–2020 academic year.⁸ A new cohort of children (6–7-year-olds) would have normally started school in April 2020. To encourage universal enrollment into formal schooling, many state governments have enroll-

⁸The school year in most states in India is from April to March of the following year.

ment drives at the beginning of the school year. However, with schools shut or with the primary grades not yet open and physical movement restricted in the field due to the pandemic, it is quite possible that many young children did not get enrolled but would do so when schools reopen. Therefore, it would be premature to conclude that dropout rates have increased for the youngest age group, and the correct picture would only emerge once schools reopen for primary grades and enrollment settles down.

Given that the pandemic had a much larger adverse impact on the incomes of the poor, it is possible that unenrolled children were much higher among children from poorer families. However, for children with less educated parents, while enrollment rates were slightly lower in the younger age groups, the overall enrollment rates actually increased between 2018 and 2020, driven mainly by the huge rise in the enrollment rate for the 15–16 year age group, most likely due to the push to universalize secondary education.

4.2 Learning support at home

One of the key drivers of academic achievement is the learning support children receive at home. This could be in the form of parents or other family members helping the child to study or more organized supplementary resources like a paid tuition.

The ASER 2020 survey delved into the question of who supports learning at home. Overall, in ASER 2020, 75% of the enrolled children reported receiving help from family members to study at home. Younger children were more likely to get help than older children — 81.5% of the children in grades 1–2 received help from family members as compared to 68.3% of the children in grades 9 and above. This is not surprising since parents may not be able to help with the more difficult curriculum of higher grades. Similarly, mothers were more likely to help children in primary grades and older siblings in higher grades. While we don't have past evidence on how much help children get at home in studying, this finding is noteworthy in that different family members stepped up to the task during a period when schools were closed.

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However, here we see big differences in terms of parental education. Parental help to children rises with education (Table 4). Parents with low education are less likely to help their children with school work — only 55% of the children with low parental education received any learning support at home compared to almost 90% of the children with high parental education.

Beyond school enrollment, there is another important facet of access to education, that we need to consider — paid “tuition” classes. This is a gray area. Data on tuition classes are not easy to find. The ASER survey routinely collects data on tuition, and the trends over time show distinct patterns across India. In the northern and northwestern states, such as Punjab, Haryana, Rajasthan, Himachal Pradesh, and Uttar Pradesh, private school incidence is relatively high and tuition-taking is low. In contrast, in the eastern states, such as West Bengal, Bihar, and Odisha, private schooling is low. But even for young children, going to “tuition” is a major feature of the educational landscape.

According to ASER, at the all-India level, incidence of paid tuition has remained between 25 and 30% for the last many years. However, an increase was observed in 2020 with the proportion of children taking tuition rising from 28.6% in 2018 to 32.5% in 2020. This number further increased to almost 40% in 2021 (Table 5). At the state level, in 2018, well over 50% of children of school going age in Odisha, Bihar, and West

Table 4. Percentage enrolled children who get help at home in terms of parents' education and family member.

	Low Parental Education	Medium Parental Education	High Parental Education
No help	45.2	23.5	10.6
Father	14.0	32.3	30.1
Mother	7.6	20.6	45.1
Elder sibling	23.2	14.1	7.6
Other	10.0	9.5	6.6
Total	100	100	100

Source: ASER (2020).

Table 5. Percentage of enrolled children who take tuition by grade.

Grade	ASER 2018	ASER 2020	ASER 2021
Grade I-II	24.2	33.2	37.0
Grade III-V	27.7	32.9	39.4
Std VI-VIII	28.6	30.7	38.9
Std IX+	35.5	33.6	41.1
All	28.6	32.5	39.2

Source: ASER 2018–2021.

Bengal were taking some form of tuition classes. In 2021, this figure had gone over 60% in Odisha and well over 70% in Bihar and West Bengal. In fact, the incidence of tuition has increased across almost all states — perhaps a natural response to the prolonged school closure. It is curious that while economic disruptions may have moved children out of private schools (in fact, in many cases, the pandemic destroyed the economy of low-cost private schools), parents were still able to access tuition classes, where they had to pay fees. This may be due to the fact that tuition classes are a local phenomenon, where payment may be adjusted flexibly and quickly based on demand and supply negotiated between the tutor and the family. It is clear that the large and growing “tuition” sector needs to be better understood in terms of its role in education provision and learning support in rural India. The decisions to open or shut government schools are taken by authorities at district or state level, with school teachers having no say in when or how school reopening can happen. But for the tuition sector, all decisions are local, flexible, and can be immediate; these classes open or shut easily, responding instantly to local conditions with different waves of the pandemic.

4.3 Access to learning materials and learning opportunities

ASER 2020 and 2021 asked households about smartphones at home. Data indicate that the availability of smartphones in households has almost

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doubled since 2018. This is true for families whose children are enrolled in government schools as well as private schools. From ASER 2020 figures, it was clear that a smartphone had been bought since the lockdown began in one out of ten households to help children with studies. When asked the same question in ASER 2021, we find that the proportion had increased to 27.9%. In 2018, 29.6% of the families with children enrolled in government schools had smartphones. This number increased to 56.4% in 2020 and to 63.7% in 2021. For families with children enrolled in private schools, the equivalent figure climbed from 49.9% in 2018 to 74.2% in 2020 and to 79% in 2021. Overall, approximately 67.6% of the households with school-age children had smartphones in 2021. ASER also shows that access does not automatically mean use. While there are wide variations across states, a little over one-fourth of all children with at least one smartphone are able to access the phone easily and another one-fourth is not able to access the phone at all.

As mentioned earlier, the states shared a variety of learning materials while schools were closed, including textbooks, worksheets, educational content on radio and TV, and online resources, including live online classes. These materials were shared in a variety of ways — phone calls, messaging services, such as WhatsApp and SMS, as well as through personal visits, with teachers visiting homes and/or parents visiting schools.⁹

ASER 2020 reports on whether children received these learning materials and, if so, how. States were extremely successful in sending textbooks to children, with 80.5% of the enrolled children responding that they had textbooks of their current grade. The reach was quite even, with 79% of the children with “low” parental education receiving textbooks as compared to 83% of the children with high parental education.

However, in the case of other learning materials, the success rate was much lower, with only 35% of the enrolled children responding that they had received any other (apart from textbooks) learning material from their schools, in the week prior to the survey. Unlike the case of textbooks, the equity gap is larger here, with only 26.7% of the children with low

⁹About two-thirds of the surveyed children in ASER 2021 were in schools that had reopened at the time the survey was being conducted. Therefore, we focus on the ASER 2020 findings on access to and engagement with learning materials.

parental education receiving any material as compared to 49% of the children with high parental education. There could be a variety of reasons for this large gap in access. First, as noted earlier, a majority of children at the lower end of the income distribution are enrolled in government schools, and these schools were slightly less successful at distributing learning materials as compared to private schools — 33% of the children in government schools reported receiving learning materials as compared to 40% in private schools.

Second, while schools used a variety of ways to share materials and activities, such as WhatsApp and other messenger apps, in-person visits, and phone calls, by and large, they relied on one medium — 87% of the children received learning materials only via one medium. Among these children, the predominant source was WhatsApp (72%), though there was some compensation for the lack of a smartphone, with about 20% of the children getting the materials through personal visits through either teachers visiting homes or parents visiting schools. Again, with a majority (55%) of children in relatively poorer households not having a smartphone, their access to whatever learning material was being distributed would be limited.

Therefore, during the period when schools were closed due to the pandemic, the predominant learning resource available to the children with low parental education was their textbooks, with some limited support from parents and tutors. This has clear implications for the kind of learning activities these children could engage in, if at all, as we will see in the next section.

4.4 Engagement with learning materials

In addition to asking about the availability of learning materials, ASER 2020 also asked whether children had engaged in any learning activities in the week prior to the survey. The survey also differentiated between different kinds of material the child engaged with — textbooks, worksheets, educational content on TV or radio, and web resources, including live online classes. Even though only 35% of the children responded that they had received any learning material (other than textbooks), 70% said that they had engaged in some kind of learning activity in the previous

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week. Not surprisingly, though, majority of the children worked with traditional materials, such as textbooks and worksheets (Table 6). Only a fifth of the children watched educational programs on TV and a negligible proportion on the radio — but this was more due to the availability of such programs in a state since not all states were broadcasting educational content. However, barring three states,¹⁰ all states were allegedly sharing online video lessons, but only a fifth of the children watched educational videos or recorded classes on web-based mediums, and only 10% attended live online classes. Of course, it could just be that households did not have the necessary technology or had other tech-related problems in viewing online resources. ASER 2020 probed parents on some of the reasons for not receiving learning materials from the school, and predominantly (68%), the response was that the school was not sending any materials; 25% said that they didn't have a smartphone; 11% had no Internet access; and 5% blamed connectivity issues.

The equity gap is evident in the engagement with learning activities as well, with 40% of the children with “low” parental education doing no learning activity as compared to 20% of the children with “high” parental educations. With limited access to digital devices, only 4.7% participated in online classes as compared to 20% of the better-off children (Table 6). This is important because among the learning materials/resources shared by the state, the closest thing to “instruction” were online videos/classes. In other words, children whose parents had little or no education suffered both in terms of their access to learning materials as well as the quality of learning material they could access. They also started off with a much larger learning deficit — according to ASER 2018, the proportion of children in Std. V with low parental education, who could read a Std. II-level text was 35% as compared to 70% of the children with high parental education. What this means is that the adverse impact of school closures on learning outcomes will affect economically weaker children

¹⁰These states were Arunachal Pradesh, Meghalaya and Tripura. For more details see Annexure 2 in the ASER 2020 report: <http://img.asercentre.org/docs/ASER%202021/ASER%202020%20wave%201%20-%20v2/annex2-learningmaterialssharedbystategovernments.pdf>.

Table 6. Percentage of the enrolled children who engaged in learning activities by parents' education and type of material.

Parents' Education	Traditional		Broadcast		Online	
	Textbook	Worksheet	TV	Radio	Videos/Recorded Classes	Live Online Classes
Low	50.2	28.4	13.5	1.9	11.1	4.7
Medium	59.2	33.8	19.0	2.8	19.8	8.9
High	69.2	44.0	25.7	2.9	33.3	20.0
All	59.7	35.3	19.6	2.7	21.5	11.0

Source: ASER 2020.

disproportionately, further widening the gap between the more well-off children and poorer children.

5. Estimates of Learning Loss Using ASER Data (State-Level Field Surveys)

It is well known that the basic learning levels of children in elementary schools in India had been chronically low for more than a decade before the pandemic struck India. In fact, the ASER series, which were carried out annually from 2005 to 2014 and then in 2016 and 2018, is a valuable and unique source of learning data over time. For the period 2008–2018, Figure 1 shows that the learning levels have remained persistently low for over a decade. In India, by the end of Grade 2, children are expected to be reading simple text fluently and doing basic arithmetic operations like addition and subtraction with carryover and borrowing with two-digit numbers. Based on these criteria, ASER data from 2018 indicate that in Grade 3, less than 30% of the children are at “grade level” both in reading and in math.

While some studies have simulated the impact of the pandemic on learning outcomes, there are not many estimates available that are based on assessments undertaken during this period. This is especially true for developing countries. As mentioned earlier, ASER 2020 and 2021 were phone-based surveys and did not assess children remotely. However,

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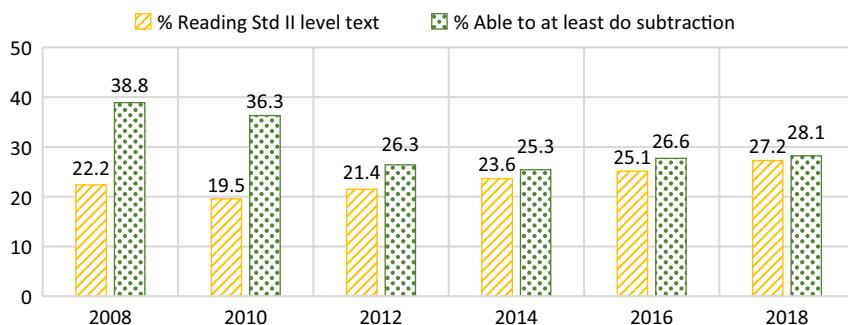


Figure 1. Percentage of Std. III children who are at "grade level."

Source: ASER data for rural India.

ASER found windows of opportunity to return to villages and communities in states where resumption of field activities was possible: It conducted state-wide field surveys in Karnataka in March 2021 (2020–2021 school year), Chhattisgarh in October–November 2021 (2021–2022 school year), and West Bengal in December 2021 (2021–2022 school year). During the period when the surveys were conducted, schools were still closed in Karnataka and West Bengal, and children were studying remotely. In Chhattisgarh, schools had been open for about a month or so at the time of the survey, though they shut down again in December 2021. Data from the surveys can be used to generate estimates of learning loss. Even though these were not national surveys, they are representative at the state level and useful in so far as they give us an idea about the magnitude of the loss.

Figure 2 gives the timeline of the three state surveys, and Table 7 gives the sample sizes.

Figure 3 shows the reading levels in Grade 3 over time for the three states. State-level estimates clearly show sharp drops in reading ability between 2018 and 2020–2021 for all three states. Learning levels that were either improving or steady between 2014 and 2018 dropped significantly during the pandemic. In fact, in all three states, the 2020–2021 levels were below the 2014 levels. For instance, in Chhattisgarh, about a fifth of the children in Grade 3 were reading at grade level in 2014. By 2018, this number had increased to about 30%; however, in 2021 only

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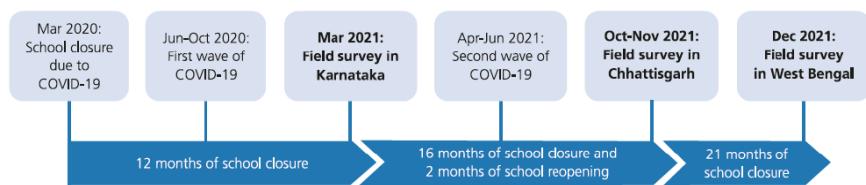


Figure 2. Timeline of ASER field surveys.

Table 7. ASER field surveys: Sample description.

ASER Survey	Districts Reached	Villages Covered	Households Surveyed	Children Surveyed
ASER Karnataka Field survey (Mar 2021)	24	670	13,365	18,385
ASER Chhattisgarh Field survey (Oct–Nov 2021)	28	1,677	33,432	46,021
ASER West Bengal Field survey (Dec 2021)	17	510	10,141	11,189

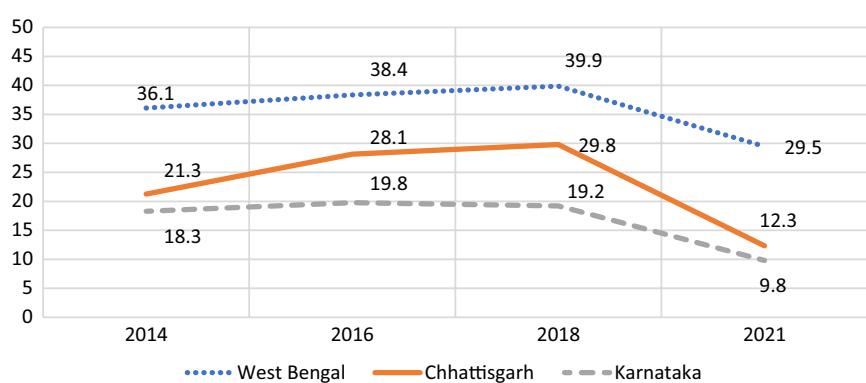


Figure 3. % of children in Grade 3 reading at Grade 2 level.

12% children in Grade 3 were able to read a Grade 2-level text. We see a similar situation for reading in Grade 5 (Table 8). Again, learning levels that had been steady or rising since 2014 plunged during the pandemic.

A similar pattern is seen in arithmetic as well (Figure 4 and Table 9). In all three states, children's ability to do basic arithmetic operations, in

Table 8. % Children in Grade 5 reading at Grade 2 level.

	West Bengal	Chhattisgarh	Karnataka
2014	53.2	52.4	47.2
2016	50.4	56.0	42.1
2018	50.7	59.5	46.0
2021	48.5	44.6	33.6

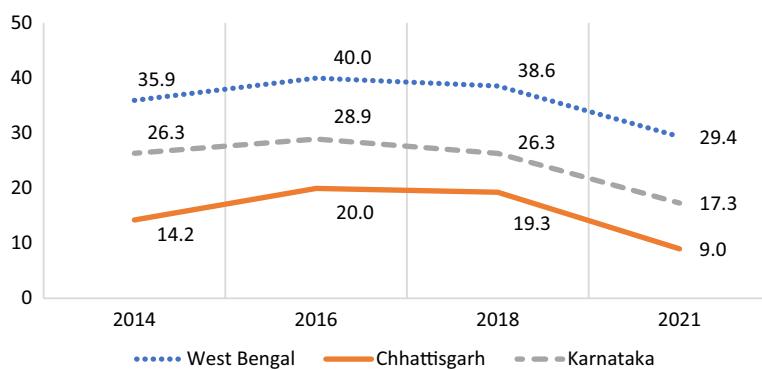


Figure 4. % Children in Grade 3 who can at least do subtraction.

Table 9. % Children in Grade 5 who can do division.

	West Bengal	Chhattisgarh	Karnataka
2014	32.5	18.0	20.1
2016	29.3	23.0	19.7
2018	29.7	26.8	20.5
2021	26.2	13.0	12.1

primary grades, fell sharply in the last two years, wiping out any gains made since 2014. For instance, in Karnataka, about a fourth of the children in Grade 3 were able to do simple subtraction problems. While there was not much improvement in 2016 and 2018, in 2020, there was a significant decline, with only 17% of the children in Grade 3 being able to do subtraction.

Table 10. % Children enrolled in government schools in Karnataka who can at least read a Std II-level text

Grade	2016	2017	2018	2019	2020
2	6.8		7.4		3.0
3	18.9		19.4		9.8
4	29.8		35.2		17.8
5	41.9		47.6		32.8

The pandemic-induced, recent learning loss can also be clearly seen in a cohort table for Karnataka (Table 10). For example, observe the cohorts moving from Grade 2 to Grade 4. Children who were in Grade 2 in 2016 were in Grade 4 in 2018 (red cohort). In this two-year period, the ability of the cohort to read a Grade 2–level text increased from 6.8% to 35.2% (28.4 percentage points over this period, or 14.2 percentage points annually). However, consider another cohort (purple diagonal): two years later, for children who were in Grade 2 in 2018 and in Grade 4 in 2020, the corresponding increase was from 7.4% to 17.8% (only 10.4 percentage points in two years, which implies 5.2 percentage points annually). The growth in learning is less than half of that possible in a “usual” year, implying a learning loss of over a year. A similar pattern is seen for Chhattisgarh as well.

These estimates compare quite well with simulations done by the World Bank and the learning losses that are being seen in other developing countries (The World Bank, UNESCO, and UNICEF, 2021). If we assume that the data trends seen in Karnataka, Chhattisgarh, and West Bengal are likely to also be seen in other states as well, then we can expect at least a one-year learning loss for children in India, especially in the younger grades.

6. Strategies and Interventions that Have Been Employed in India and Learnings

As in other countries, a variety of remote learning strategies was tried in India in the past year and a half. These ranged from local-level efforts by

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schools or communities to large-scale interventions by governments and larger institutions. For remote learning, the efforts can broadly be categorized as follows:

- Online classes or video lessons;
- Phone messages, usually WhatsApp messages;
- Radio or television programs.

Online classes were largely used by private schools where availability of devices to children was high and connectivity was not a problem. In some states, online classes were also used for higher grades. At least for India, there is no publicly available, systematic study on the scale of impact of online classes on children's learning that can be compared to offline learning as is done in normal times. Comparing the results of board exams from pre-COVID-19 years with the past two years is also not helpful, as the examination content and processes have been modified during the pandemic.

One of the strategies that was widely used in the government school system was the use of smartphones and WhatsApp to deliver learning materials, usually worksheets or videos demonstrating learning activities. In some contexts, individual teachers sent materials, and in others, governments at the district or state level delivered learning resources in a coordinated fashion.

Several reports that were published at different times of the crisis have collated or summarized these efforts by governments in India.¹¹ However,

¹¹A group of organizations and consulting companies who work with state governments has collected and collated inputs and experiences from the states in which they operate. These "best practices" can be found at https://centralsquarefoundation.org/Home%20Learning%20Playbook_Final_31st%20August.pdf.

The Ministry of Education at the central government level put together a digital report. See https://www.education.gov.in/sites/upload_files/mhrd/files/India_Report_Digital_Education_0.pdf.

Another compilation can be found at <https://centralsquarefoundation.org/articles/how-to-design-effective-home-learning-programs-takeaways-from-7-indian-states.html>.

Also, see chapters on India in the publication available at <http://www.ibe.unesco.org/en/news/arning-build-back-better-futures-education-lessons-educational-innovation-during-covid-19>.

a systematic assessment of the strategies across all states, aiming to establish effectiveness or success, is not available.

6.1 Learnings from Pratham programs during the pandemic

Pratham's own "direct" programs reach over 10,000 communities on a daily basis. A variety of strategies for remote engagement and learning was tried here as well. Several learnings from observing, tracking, and analyzing these remote efforts are worth highlighting.¹² For the first several months, the goal was engagement rather than learning. Children and families were going through a difficult period and hence needed to be engaged in activities that could help them take their minds off economic uncertainties or fear about health issues. By focusing on engagement, we learned a lot about how to facilitate and sustain continued participation, how to keep motivation high, and how to constantly iterate and improve content to make delivery better. Some of the key learnings are outlined in the following.

Reaching out to as many children and families as possible is crucial from an equity point of view. Here are some key points that emerged during the early days of the lockdown and the prolonged period of school closure:

- **Persistent efforts for reaching out reap results:** Prior to the pandemic, especially in programs where face-to-face daily interactions were happening in communities and schools, there was no need to collect or use phone numbers. When the pandemic suddenly hit and lockdown was imposed, Pratham teams had very few phone numbers of children's families with them. However, as a determined and systematic reach out effort was initiated, many more phone numbers became available. In the early days of the lockdown, at least one

¹²For most of the period of April 2020 – October 2021, Pratham sent messages to children and families in approximately 11,000 rural and urban communities where there had been a direct Pratham connection in pre-COVID times. About 300,000 messages went out every day on average. At the peak of the "reach out" campaigns, the numbers were close to 475,000.

person in each community was contacted, and through them, the teams reached out further to at least one person in each hamlet. With such a cascading approach, the strategy was to persist until we were sure that the reach had been maximized in every hamlet. Internal data indicate that Pratham's education programs were sending out close to 56,800 messages on April 12, 2021, and this figure increased to 207,400 by June 12, 2021.¹³ Having a list of active phone numbers of families and keeping this list updated is a must and an essential part of the preparedness for future disruptions.

- **Unit of operation changed during pandemic from village to hamlet:** Prior to the pandemic, the usual unit of operation for Pratham's education programs was the local government primary school and the catchment area or village (and the same in urban areas) around it. However, as the lockdown proceeded, for reaching out, tracking, and other activities, the sub-village unit — usually the hamlet — was the most useful. Even as schools are reopening, the hamlet-wise tracking of re-enrollment and attendance is proving to be very handy in terms of planning the next course of action.
- **SMS messages were needed in addition to WhatsApp for maximizing reach:** Early in the pandemic, at least for Pratham communities, it was clear that smartphones were available only in some families. Depending on the location and the context, the incidence of families in these communities who had access to smartphones ranged from 30% to over 60%. However, close to 90% had access to some kind of phone — usually a basic phone.¹⁴ These data and experiences from the ground indicated that to communicate with as many families as possible, there was an urgent need to use messages for basic phones. Over time, about 40–45% of all Pratham messages were SMS messages and the rest were WhatsApp messages. Depending on the social structure into which the messages were being sent, a combination of messaging (SMS and WhatsApp) was also done. For example, for hamlet-wise mothers' groups, individual mothers received SMS messages on a daily basis, but once a week, the group leader (often referred to as SmartMom)

¹³See Pratham report 1 (MME 2020–2021).

¹⁴Pratham's internal data (MME 2020–2021).

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would receive digital content for group activities. With a large section of the population not being able to access smartphones, it is critical that both SMS and WhatsApp options are used equally; the delivery and content needs to be continually adapted to these conditions.

- **Dynamic nature of access to digital devices:** In the first few weeks of lockdown, when all family members were at home, children's access to the available smartphones was high. However, as lockdown restrictions loosened up, adults in the family began to go out for work, and we noticed a fall and delay in children's responses. Furthermore, as the economic disruptions continued, some households had difficulty in buying internet time. (ASER 2021 data show that, on average, 26% of the children in households with smartphones do not have access to a digital device and that access varies considerably by age and grade.) The key lesson is that the availability of a smartphone in households does not guarantee ongoing and continuous access. Changing external conditions can influence how and when children get to use the phone for educational purposes. Therefore, ongoing tracking of access is essential if remote learning mechanisms are to be used for a long period of time.

Ongoing interactions and conversations help in keeping children's engagement and family participation high. Two-way communication is crucial for improving content and delivery: In many different ways, during the period of school closure, we learned about the importance of ongoing two-way communication for feedback and follow up:

- **Ongoing interactions with a known person sending messages gets more engagement than bulk messaging:** Early in this period, a decision had to be taken on how messages would go out. While the WhatsApp technology enables easy distribution to groups with two-way channel of communication built in, that is not the case with SMS. Yet, it was felt that given the limitations of content delivery in text form and the weaker economic background of these households, families that received SMS messages would need more hand-holding and interactions. Instead of using bulk messaging, it was decided that a Pratham team member would send out SMS messages to families. It

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would be the same person who would call the family once a week or once a fortnight to understand the current status of the family and to receive feedback on the activities being sent. The ongoing human interaction also encouraged children to send back their responses either in the form of video, audio, photographs, or text. It was not uncommon for children to be sending their responses to the activity prompts via neighbors' or friends' phones. Whether children or parents, a large part of the motivation to share and respond to content that was being sent was due to the personal touch of the sender. This was very important for maintaining high engagement over a long period of time.

- How human interaction leads to better traction for digesting information was clearly visible in a six-week COVID-19 awareness campaign, involving large-scale phone messaging, that was carried out by Pratham in May–June 2021.¹⁵ Uptake of SMS and WhatsApp messages were similar, with nearly two-thirds of the recipients reading these messages. (This also means that a third of all messages received were not being read). In the tracking study that was done during this campaign, a set of contacts were spoken to only once during the week (spot-check contacts), while the rest were spoken to every day of the week. Data show that ongoing communication on a daily basis made a significant difference in reading messages, understanding content, doing related activities, and in sharing of information with other family members and friends.
- **Who in the household helps children with learning activities received through the phone:** If there is one smartphone in the family, it is usually in the hands of the adult male (father or brother). A deep dive into a small number of families was done in May–June 2020 to understand who receives the messages and who does the activities with children in the family.¹⁶ Based on these studies, it seems that more fathers receive the messages but more mothers are engaged in helping the children. These patterns of engagement and participation vary by the child's grade.

¹⁵ See Pratham report 2_KAS (MME 2020–2021).

¹⁶ See Pratham report 3a and 3b (MME 2020–2021).

Social structures can be leveraged for maximizing reach and participation: In much of the discussion in this chapter on the role of educational technology in children's education, the focus is on the nature and type of digital content, access to devices, and connectivity. In Pratham's remote work during COVID-19, we have found that social structures (existing ones, such as friendships within the community, or new ones, such as children's groups and mothers' groups) can play a big part in deepening engagement. Group activities and individual contact are both important in keeping continuous participation at a high level:

- Young children learn more if there is engagement from family members: A Pratham study of an early childhood program showed that children have better learning outcomes if there are ongoing activities at home.¹⁷ Learning gains are higher for those children whose mothers own phones and are educated, but some of these advantages are evened out when mothers without cell phones or without much education are part of mothers' groups.¹⁸

Content needs to be adapted for use depending on how you are sending and who is receiving:

- While WhatsApp messages can have video, audio, or text files, SMS is limited to 160 characters. Maximizing the activities that could be done within this character limit needed creativity. Discussions and feedback from parents also helped in this matter.
- For parents, it was important to follow “reaching at the right level” if we wanted their continued engagement. If the activities that were sent were too “school-like,” the family members passed them on to their children to do on their own. If the activities were connected to real life, then there was greater involvement of those in the household.

¹⁷ See Pratham report 4a (MME 2020-21).

¹⁸ See Pratham report 4b and 4c (MME 2020-21).

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7. Implications for the Future

To think about the implications for the future, it is useful first to look back at existing empirical evidence. Two questions can help to draw out guidance for the future. First, what was the situation with children's education before COVID-19 or in "normal" times? Second, what do past trends in schooling and learning tell us about what to expect in the future?

The last nationwide ASER of all rural districts was conducted in 2018. The enrollment data from 2018 indicate that over 97% of children in the age group 6–14 were enrolled in school. It would be fair to say that in terms of access to school, India had reached close to universal levels. The situation with basic learning was nowhere near satisfactory (Table 11).

As Table 11 shows:

- By Grade 3, less than 30% were at grade level. Even in pre-COVID-19 times, majority of children had fallen behind grade level in the first few years in primary school. A little under 20% were two grade levels behind, i.e., at Grade 1 level, but more than half of all children were not even at Grade 1 level.
- By Grade 5, only half of all enrolled children were reading at Grade 2 level or higher. Close to 30% were not even at Grade 1 level even after five years of schooling.

Table 11. % children at different levels of reading by grade.

Grade	Beginner	Letter	Word	Grade 1 Text	Grade 2 Text	Total
Grade 1	42.7	32.6	13.7	5.2	5.8	100
Grade 2	21.3	30.2	21.3	12.5	14.7	100
Grade 3	12.1	22.6	20.8	17.3	27.2	100
Grade 4	7.6	15.9	16.6	19.3	40.7	100
Grade 5	5.9	11.7	13.0	19.1	50.3	100
Grade 6	3.8	8.8	10.5	17.2	59.8	100
Grade 7	2.5	6.5	8.3	15.0	67.7	100
Grade 8	1.9	5.3	6.7	13.2	72.8	100

Source: ASER 2018, all-India (rural) all children enrolled in school.

- Even after eight years of schooling, one out of four children enrolled in Grade 8 had difficulty reading simple text.

Overall, the all-India (rural) data for basic arithmetic were even more worrying.

Second, ASER data are available annually for the period 2005–2014 and then every two years till 2018. This data can be used to see what children gained in terms of basic learning year on year in the normal years of the pre-COVID period. Using ASER data, cohorts over time can be tracked for every state. Let us use one state, Karnataka, as an example. Remember that for issues related to learning, Karnataka's figures for basic reading and arithmetic have been close to the national average.

ASER 2018 data for Karnataka also show similar patterns to the all-India data (Table 12). A substantial proportion of children in a grade are well below the expectations for that grade.

If we take a look at the cohorts over time, e.g., children who were in a particular grade in 2016, and track them to see their levels in successive grades two years later, we find that depending on the grade and the cohort, in a pre-COVID-19 year, children may have gained approximately 14 percentage points annually in terms of the ability to read basic text fluently. For example, if we follow the red cohort (Table 13), children who were in Grade 2 in 2016 were in Grade 4 in 2018. In this two-year period,

Table 12. % children at different levels of reading by grade.

Grade	Beginner	Letter	Word	Grade 1 Text	Grade 2 Text	Total
Grade 1	45.6	40.5	10.9	1.7	1.4	100
Grade 2	19.1	31.1	29.7	12.8	7.4	100
Grade 3	10.4	18.5	29.3	22.4	19.4	100
Grade 4	5.0	13.4	21.8	24.6	35.2	100
Grade 5	4.9	8.7	15.3	23.5	47.6	100
Grade 6	4.8	6.7	12.5	19.0	57.0	100
Grade 7	2.7	7.0	11.5	17.2	61.6	100
Grade 8	2.2	4.9	6.5	16.3	70.1	100

Source: ASER 2018, Karnataka (rural) children enrolled in government schools.

Table 13. Percentage of government school children who can at least read a Grade II-level text.

Grade	2016	2017	2018
Grade 2	6.8		7.4
Grade 3	18.9		19.4
Grade 4	29.8		35.2
Grade 5	41.9		47.6

Source: Karnataka, ASER 2016 and 2018.

the ability of the cohort to read a Grade 2-level text increased from 6.8% to 35.2% (28.4 percentage points for a two-year period is about 14.2 percentage point change annually). Similarly, we follow the orange cohort (those in Grade 3 in 2016 were in Grade 5 in 2018). In this two-year period, the ability of the cohort to read a Grade 2-level text increased from 18.9% to 47.6% (28.7 percentage points for a two-year period is about 14.3 percentage point change annually).

Interestingly, in Karnataka, in 2019–2020, there was a partnership between the Department of Elementary education and Pratham to implement a “teaching-at-the-right-level” program whose goal was to build basic reading and math skills. The program called “*Odu Karnataka*” was carried out for about 60 days in all government primary schools in 20 out of the 30 districts in the state. In this period, for two hours a day, the grade-level curriculum was put aside and the teacher focused on building basic literacy and numeracy skills of her children. Table 14 shows that in a short period of two months, schools were able to help their children gain 20–30 percentage points in basic reading and arithmetic.

These pieces of empirical evidence can help in joining the dots between past experiences and future directions. Once schools open and instructional activity begins, it will be crucial to focus on basic reading and math skills. On the one hand, we know that the pre-COVID-19 situation was far from satisfactory and needed urgent action. Since then, the pandemic has devastated the country and hit children’s education hard; as the data in previous sections showed, there has been a weakening of

Table 14. Summary of *Odu* Karnataka program results in 2019-2020.

Academic Year	Name of Program	Focus Grades	Districts in Program	Teaching Days During Program	Schools in Program	Total Number of Children Tested at Baseline	Learning Improvement for Grades 4 & 5	
							Change in Basic Reading Level	Arithmetic Level
2019-20	<i>Odu</i> Karnataka	Grade 4 and 5	20/30	60 days	21,635	5,24,000	31 pc pt. increase	21 pc pt. increase

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learning levels in the state. On the other hand, Karnataka has a promising track record of providing learning support (as in *Odu Karnataka*) with good results. Logically, if the curriculum were to be put aside for some time during the day in the next few months and the “teaching-at-the-right-level” approach was to be applied in the remaining 15 weeks till the end of the school year, Karnataka could potentially see a “catch up” that may generate learning gains higher than those in a normal school year.

As we look ahead, it is worth remembering that the pandemic is not yet over. School reopening may not be a one-time event. There is likely to be intermittent school closures as local-level incidence of COVID-19 rises and abates. Hence, school reopening may need to be visualized and planned for in a dynamic way. As schools begin to reopen in India, close tracking of re-enrollment and attendance will be essential until enrollment and attendance patterns stabilize. Following COVID-19 protocols may mean that different children attend classes at different days and times. These variations in how schools are internally organized will need to be monitored closely. The decisions made in this regard have implications for who is supposed to come to school and when, and therefore, who gets how much exposure to instruction.

How the system helps children return to school will be critical. Unlike densely crowded urban areas, where opinions can be divided, majority of rural parents in India want their children to go back to school and children too are eager and willing. This enthusiasm is essential fuel for “building back better.”

With schools having been closed for a long period of time, students of all ages need time and opportunity to settle down and reconnect with each other and with teachers. Children in today’s first and second grades have never been to school. They have to be helped to get ready for schooling and learning. Another example: Today’s Grade 5 children attended school almost two years ago while in Grade 3. They are now returning to school older and, perhaps, more worldly-wise. But they too will need help to settle in. Will schools demonstrate new ways to welcome children? Will the interaction between parents and teachers help to build trust and faith? These are key mechanisms to keep in mind in the current context.

As the country navigates through this stage of the pandemic, there are academic strategies to be developed and modified to face current

teaching–learning challenges. The use of grade-level curriculum may not be useful immediately. Instead, meeting children at the level where they are and using “teaching-at-the-right-level” approach is the need of the hour. Even the National Education Policy 2020 recommends that acquiring strong foundational skills needs to be a top priority. Available research from other countries shows that while school closures can lead to learning losses, what school systems do once schools reopen is even more critical. Making children deal with grade-level curriculum after almost a two-year gap or hurrying them through the syllabus is not an appropriate response in the current context. In fact, investing time and effort now in rebuilding and strengthening children’s ability to read with understanding, their capacity to apply problem-solving skills, and learning to help each other in the classroom may provide the big boost needed to bring the education system back to where it was in pre-covid times and move further ahead.

The digital divide has been talked about widely. But after the experiences of the last two years, it is evident that a digital component of teaching–learning is here to stay. Assuming connectivity will continue to increase, in order to level the playing field, setting up device libraries at school level or village level may be one possible solution. Individuals and families can borrow devices on a priority basis. How will schools organize to even out the inequities? Will government schools take the lead in this regard?

Data and experiences of the past year and a half give us a glimpse into a period of transition in education. Will schools go right back to their old ways? Will new methods of engaging with children and parents emerge? Will appropriate teaching–learning goals and activities be adopted for the rest of the school year? Ground-level action will indicate which way our education system will go in the near future.

In India’s case, the schooling situation before COVID-19 was close to universal. But in terms of guaranteeing basic learning, available data (ASER and others) clearly show that major instructional changes were needed even before COVID-19 struck. The learning crisis, which predates COVID-19, has worsened with almost two years of school closure. To ensure learning for all, children have to acquire basic skills in time during the early years of primary school. Launched in 2020, India’s New Education Policy strongly prioritizes foundational skills as well.

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As schools reopen, there is an opportunity for the entire education system to make a serious move toward guaranteeing learning for all. School systems will need to design flexible and fast assessments that enable teachers to quickly assess where children are. Instruction will need to be planned to start from where children are and then work together to take them to where they need to be. Depending on the context, the instructional design will have to integrate outreach to children who are, as yet, not attending school. If the next year is used for foundation building and for “catch up,” then it is possible for schools and communities to “build back better.”

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Chapter 3.3

Severity of the COVID-19 Pandemic, Regional Heterogeneity, and Food Insecurity: The Case of India

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Abstract

In India, no state or union territory has been spared by the pandemic, especially in the second wave, but the spread of infections has been disproportionate, and the policy response and outcomes have been varied. This chapter examines the inequalities in the incidence (using number of infections and deaths as a measure) and severity (using

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relative severity ratio as a measure) of the pandemic across states and union territories of India over time. There are observed differences in the infections, deaths, and severity indicators — higher for the richer states compared to the relatively poor regions — and are explained using socioeconomic, meteorological, and geographical factors. The interplay between affluence and the concomitant urbanization, environmental risks, and comorbidities, which have been found to be associated with higher fatality rates, cannot be ruled out. The COVID-19 pandemic has had a devastating impact on the global economy and the food systems, posing a significant threat to the food security of people across the world. India's food markets have been significantly impacted by the spread of COVID-19, facing both demand and supply shocks, thus impacting the quantity of food available at wholesale and retail markets and the price at which it sells. There is also evidence of rising food expenditure shares across income deciles and social groups in rural and urban India. Considering the plight of small and marginal farmers when introducing agricultural market reforms and boosting aggregate demand, especially among the deprived, could possibly reduce the pandemic-driven food insecurity in the country. As there is continuing uncertainty about how the COVID-19 epidemic will pan out in the near future, the need for enforcement of safety protocols emphasizing prevention, dissemination of accurate information regarding treatment, promotion of vaccination through community engagement and collaboration between the government and civil society organizations is vital.

Keywords: food insecurity; pandemic; COVID-19; India

1. Introduction

The COVID-19 pandemic, which is said to have originated in China in the later part of 2019 in Wuhan city of Hubei province, spread across the world like wildfire. On March 11, 2020, the World Health Organization (WHO) declared the COVID-19 outbreak as a pandemic after assessing the alarming rate of spread and severity of the virus accompanied by brazen inaction around the world. As a result, several countries sealed their international borders and instituted various measures, such as lockdowns,

quarantines, and social distancing, to flatten the curve of the infection. In addition to travel restrictions, there have been international trade restrictions, which combined with widespread labor shortages have resulted in massive economic turmoil and supply chain disruptions, threatening livelihoods and food supply across the world. Thus, the COVID-19 pandemic, which began as a global public health crisis, gradually unfolded into a global economic and humanitarian crisis and turned into a food security emergency.

The first positive COVID-19 case was registered in India on January 30, 2020; it was a student in Kerala who had returned from China. While there were only three cases in India till the end of February 2020, the number started increasing rapidly in early March. India reported its first death due to COVID-19 on March 13, 2020, soon after which the Indian government sealed its international borders, suspended all visas to India, banned domestic travel by rail as well as air, and eventually announced a complete lockdown of the country (on March 24, 2020) to prevent community spread of the virus. Since March 2020, there has been first a gradual, followed by a steep increase in both confirmed cases and deaths linked to the deadly virus. As a fresh outbreak of the deadly COVID-19 struck the country in mid-April 2021, the number of confirmed cases and deaths associated with the virus soon started rising again at an exponential rate, this time surpassing the peak of the first wave. As on June 30, 2021, India ranked third globally in terms of total deaths due to COVID-19, after the United States (US) and Brazil, and second in terms of total number of cases, after the US.

India comprises 28 states and 9 union territories, including the National Capital Region. No state or union territory has been spared by the pandemic, especially in the second wave, but the spread of infections has been disproportionate, and the policy response and outcomes have been varied. This asymmetric impact of COVID-19 across states, both in terms of spread and mortality, has its explanation in not just medical factors, such as availability and accessibility of healthcare resources, but several socio-demographic, economic, geographical, and meteorological factors (Bhadra *et al.*, 2021; Gupta *et al.*, 2021; Middya and Roy, 2021; Giri *et al.*, 2021; Sharma *et al.*, 2020). Furthermore, the restrictions on movement due to policies to contain the spread of COVID-19 have had an

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impact in the form of disrupted value chains across all regions of the country (Seth *et al.*, 2020; Varshney *et al.*, 2020).

This chapter attempts to examine the spatial heterogeneity of COVID-19 infections and fatalities through the lens of several non-medical factors. Furthermore, due to the inherent problems in using the number of infections or deaths as a measure of the pandemic, the study uses a new indicator — relative severity ratio — as a better measure for regional comparison. Since the COVID-19 pandemic has had a devastating impact on the global economy and the food systems, posing a significant threat to the food security of people across the world, this study also examines the impact of the pandemic in India on the various dimensions of food security.

The chapter is structured as follow. Section 2 traces the trends in the COVID-19 cases and deaths in India and at the state level since the onset of the pandemic until June 30, 2021, capturing both the first and second waves. Section 3 describes the new indicators used to measure the severity of the pandemic and examines the regional heterogeneity in this measure, with underlying explanations in socioeconomic, geographical, and meteorological factors. Section 4 studies the impact of the COVID-19 pandemic on food prices (an important determinant of economic access to food as well as food composition) and *mandi* arrivals (an important determinant of food availability). Section 5 concludes from a policy perspective.

2. COVID-19 Cases and Deaths in India

2.1 Trends in COVID-19 cases and deaths in India

The total number of recorded COVID-19 infections in India crossed the 100 mark on April 15, 2020, and within a fortnight, it touched 1,000, and then, within another fortnight, it crossed 10,000. As the pandemic progressed, a nationwide lockdown with very stringent restrictions was announced on March 24, 2020, and went through four phases (with some relaxations in each subsequent phase) until May 31, 2020. At that time, the cases were approximately 1,75,000. This number increased by 20 times within three months of the “Unlock,” reaching 3.7 million. The

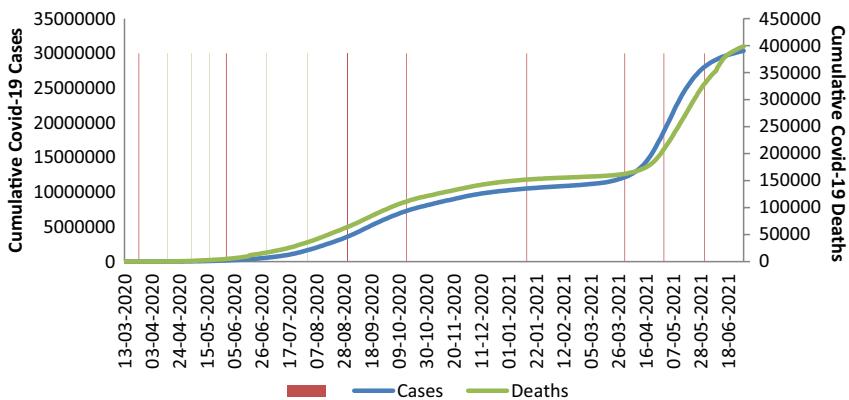
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Figure 1. Cumulative COVID-19 cases and deaths in India.

period October–November is usually the onset of the winter season in India, along with the festive and wedding seasons, and also the time when pollution levels are higher than at other times of the year, particularly in northern India. Given that nine of the 15 most polluted cities globally are in India, it could be surmised that the ability of the Indian population to fight against COVID-19 is impaired because people's lungs are severely affected by air pollution. By October 15, 2020, the number of infections in the country was 7.3 million.

Figure 1 shows the cumulative number of COVID-19 cases and deaths in India for the period March 2020 – June 2021.¹

The vaccination program to safeguard citizens from the raging COVID-19 pandemic started on January 16, 2021. The first and second phases of the immunization program aimed at vaccinating health workers and frontline personnel and then senior citizens and people with underlying health conditions or comorbidities, respectively. In the midst of the third phase of the vaccination drive that began on April 1, 2021, with the aim of vaccinating all citizens above 45 years of age, a more severe and

¹The data on the daily COVID-19 cases and deaths are collated from Ministry of Health and Family Welfare, India, at the state level (for the 28 states and 9 union territories) and at the all-India level for the period March 13, 2020 to June 30, 2021, with familiar caveats of underestimation (Anand *et al.*, 2021).

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lethal second wave of COVID-19 hit the country. Statewide lockdowns were announced in this period. This was followed by the government announcing the fourth phase of the vaccination drive, with the aim of inoculating those aged 18 years and above starting from May 1, 2021. As of June 30, 2021, the cumulative number of COVID-19 cases was more than 30 million, and the COVID-19-linked deaths were just short of the 400,000 mark. Half of these were added over a period of less than 10 weeks starting in mid-April 2021.

India's second wave was driven by virus mutations and a failure to follow COVID-19 safety protocols, especially amidst events such as election rallies, farmers' agitations, and religious gatherings. The deadly second wave has had severe consequences in the form of spiraling cases, reduced supply of essential treatments, and increased deaths, particularly in the young population.

The number of cases added per day increased gradually and peaked at around 98,000 in mid-September 2020 and gradually tapered off until February 2021. This was followed by a rapid rise between March 2021 and mid-May 2021, when it peaked at 400,000 cases per day, followed by a rapid decline. A similar pattern was observed in the COVID-19 deaths per day, though the peak was observed with a lag of two weeks from the peak in the number of cases. Thus, the peak of daily new cases in the second wave was approximately four times the peak of the same in the first wave, but the time taken to reach the peak was much shorter. Figure 2 shows the daily COVID-19 cases and deaths in India during March 2020 – June 2021.

2.2 State-wise trends in COVID-19 cases

At the time of completion of the four phases of the nationwide lockdown, i.e., on May 31, 2020, the four states of Maharashtra, Tamil Nadu, Delhi, and Gujarat accounted for more than 65% of the total caseload. Together, these four states comprise 20% of India's population. Delhi had recorded 0.93 infections per 1,000 population, followed by Maharashtra at 0.51 infections per 1,000 population by the time Lockdown 4.0 had completed and the government announced a phased "Unlocking" of the country. By

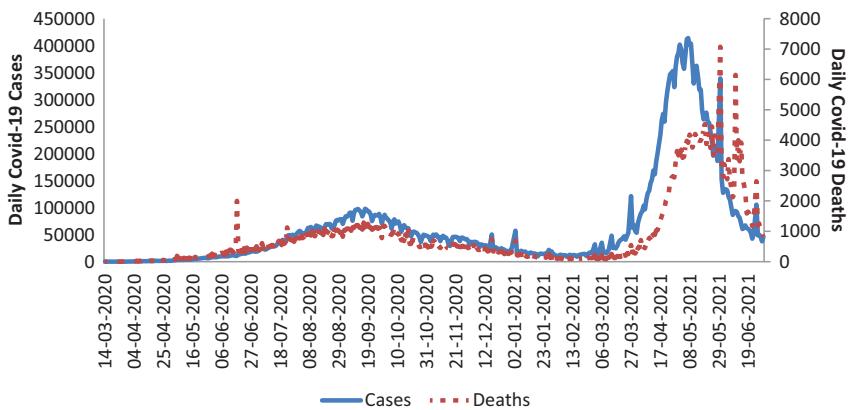
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Figure 2. Daily COVID-19 cases and deaths in India.

October 15, 2020, the incidence of COVID-19 per 1,000 population was the highest in Goa at 25 (one of the smallest states of the country but an attractive tourist destination, particularly in winter seasons). It was also high in the union territory of National Capital Territory of Delhi (at 17). At the peak of the second wave, the National Capital Territory of Delhi, by this time, had an incidence of 61 infections per 1,000 people. With Goa at 57, Kerala at 44, and Maharashtra at 37, there was a countrywide crisis as pressure on the health infrastructure mounted.

These examples suggest that while the entire country was hit badly by the virus, some states had to bear a greater burden than the rest. Several non-medical factors, particularly the socioeconomic, meteorological, and geographical factors, can help explain the heterogeneity that existed among states in terms of the severity of the pandemic.

In Table 1, we show the clusters of states created based on the size, affluence and urbanization, and observe the distribution of total cases in the country across the clusters. At the beginning of the pandemic, the 10 most populated states, along with the National Capital Territory of Delhi were the hubs, where the number of cases was high. However, by the beginning of the last quarter of the year 2020, the burden was borne by all states and union territories. It is interesting to note that the 10 medium-populated states and the 9 least populated states, home to almost a quarter

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Table 1. Share of different states in the country's overall COVID-19 cases.

	Share of Cumulative COVID-19 Cases in Total (All India)							
	Share in total population	May 30, 2020	September 1, 2020	October 15, 2020	January 15, 2021	March 31, 2021	May 1, 2021	June 30, 2021
10 Most Populated States ⁽¹⁾	74.1%	78.3%	75.0%	70.5%	65.2%	65.4%	66.1%	65.0%
10 Medium-Populated States ⁽¹⁾	22.4%	8.1%	18.0%	22.5%	26.0%	26.5%	25.5%	27.4%
9 Least Populated States ⁽¹⁾	1.9%	0.4%	1.5%	1.8%	2.1%	2.0%	1.7%	2.2%
National Capital Territory of Delhi ⁽¹⁾	1.4%	10.0%	4.7%	4.3%	6.0%	5.4%	6.0%	4.7%
6 Union Territories ⁽¹⁾	0.3%	0.3%	0.7%	0.8%	0.7%	0.7%	0.7%	0.7%
5 Rich Highly Populated States ⁽²⁾	28.2%	60.2%	56.7%	53.1%	46.4%	48.2%	46.8%	46.4%
5 Poor Highly Populated States ⁽²⁾	45.9%	18.1%	18.3%	17.4%	18.8%	17.2%	19.4%	18.7%
Rank in Urbanization ⁽³⁾ :								
1 (37.5–50%)	27%	59%	47%	47%	46%	46%	49%	50%
2 (30–37.5%)	18%	8%	23%	21%	21%	19%	17%	18%
3 (24–30%)	17%	11%	7%	8%	9%	8%	9%	9%
4 (10–24%)	35%	8%	17%	17%	16%	15%	16%	16%

Notes: (1) The 10 most populated states are Uttar Pradesh, Bihar, Maharashtra, West Bengal, Madhya Pradesh, Rajasthan, Tamil Nadu, Karnataka, Gujarat, and Andhra Pradesh. The 10 medium-populated states are Odisha, Jharkhand, Telangana, Kerala, Assam, Punjab, Chhattisgarh, Haryana, Jammu and Kashmir, and Uttarakhand. The nine least populated states are Himachal Pradesh, Tripura, Meghalaya, Manipur, Nagaland, Goa, Arunachal Pradesh, Mizoram, and Sikkim. The six union territories are Puducherry, Chandigarh, Dadra and Nagar Haveli and Daman and Diu, Ladakh, Andaman and Nicobar Islands, and Lakshadweep.

(2) The distinction between rich and poor states is based on the per capita net state domestic product at current prices (2011–2012 series) for the year 2018–2019.

Source: Economic Survey 2020–2021. Of the 10 most populated states, the five states ranked higher on per capita income are Karnataka, Gujarat, Tamil Nadu, Maharashtra, and Andhra Pradesh, and the five states ranked lower on per capita incomes are Rajasthan, West Bengal, Madhya Pradesh, Uttar Pradesh, and Bihar.

(3) The figures in the brackets in this column correspond to the range of urbanization for the states considered in the category. Urbanization is measured as the percentage of total population residing in urban areas based on the 2011 Census of the Government of India.

of the population of the country, shared less than 10% of the burden of the cumulative COVID-19 cases in the country just after the nationwide lockdown period. But within three months, the spread was immense, and these states shared 20% of the burden. As of the last day of June 2021, 30% of the total infections in the country were found in these 19 states.

Within the first category of the 10 most populated states, a comparison between the relatively rich states and the poor states is interesting. The rich states have borne a disproportionately higher burden of the cases throughout our period of analysis. The five rich, highly populated states have contributed almost half of the caseload of the country. If we cluster the top 20 populated states by the degree of urbanization, the following findings emerge. The top five urbanized states comprising 27% of the country's population were responsible for almost 60% of the cases in the initial months of the pandemic. Though this share came down in the subsequent months, it continued to be responsible for almost half of the cases in the country. At the other extreme, the five least urbanized states, comprising more than a third of the country's population, were responsible for approximately 15% of the cases in the first and second waves.

2.3 State-wise trends in COVID-19 deaths

In the following table (Table 2), we create clusters of states basis of size, affluence and urbanization, and examine the distribution of COVID-19 deaths in the country across the clusters. At the beginning of the pandemic, the 10 most populated states, along with the National Capital Territory of Delhi, contributed more than 95% of the deaths. However, by the beginning of the last quarter of the year 2020, the burden was borne by all states and union territories, particularly increasing in the medium-populated states. Within the first two categories of the 10 most populated states, a comparison between the relatively rich states and the poor states is striking. The rich states have borne a disproportionately higher burden of the deaths throughout our period of analysis. The five rich, highly populated states have contributed almost half of the COVID-19 deaths in the country. A classification of states by urbanization levels reveals the same story as in the previous section. The top five urbanized states are responsible for almost 50–60 percent of the deaths throughout the

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Table 2. Share of different states in the country's overall COVID-19 deaths.

	Share in Total Population	Share of Cumulative COVID-19 Deaths in Total (All India)					
		30 May 2020	1 September 2020	15 October 2020	15 January 2021	31 March 2021	1 May 2021
10 Most Populated States ⁽¹⁾	74.1%	88.0%	83.2%	80.0%	74.2%	73.2%	70.8%
10 Medium-Populated States ⁽¹⁾	22.4%	3.8%	8.8%	12.6%	16.1%	17.4%	19.0%
9 Least Populated States ⁽¹⁾	1.9%	0.1%	0.6%	1.2%	1.9%	1.9%	2.6%
National Capital Territory of Delhi ⁽¹⁾	1.4%	8.0%	6.8%	5.3%	7.1%	6.8%	7.6%
6 Union Territories ⁽¹⁾	0.3%	0.1%	0.6%	0.8%	0.8%	0.8%	0.7%
5 Rich Highly Populated States ⁽²⁾	28.2%	66%	62%	59%	52%	52%	50%
5 Poor Highly Populated States ⁽²⁾	45.9%	21%	15%	16%	17%	17%	17%
Populated States ⁽²⁾							

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Rank in Urbanization: ⁽³⁾						
1 (37.5–50%)	27%	66%	63%	59%	54%	55%
2 (30–37.5%)	18%	10%	16%	17%	18%	16%
3 (24–30%)	17%	11%	6%	7%	7%	9%
4 (10–24%)	35%	5%	8%	10%	11%	13%

Notes: (1) The 10 most populated states are Uttar Pradesh, Bihar, Maharashtra, West Bengal, Madhya Pradesh, Rajasthan, Tamil Nadu, Karnataka, Gujarat, and Andhra Pradesh. The 10 medium-populated states are Odisha, Jharkhand, Telangana, Kerala, Assam, Punjab, Chhattisgarh, Haryana, Jammu and Kashmir, and Uttarakhand. The nine least populated states are Himachal Pradesh, Tripura, Meghalaya, Manipur, Nagaland, Goa, Arunachal Pradesh, Mizoram, and Sikkim. The six union territories are Puducherry, Chandigarh, Dadra and Nagar Haveli and Daman and Diu, Ladakh, Andaman and Nicobar Islands, and Lakshadweep.

(2) The distinction between rich and poor states is based on the per capita net state domestic product at current prices (2011–2012 series) for the year 2018–2019.

Source: Economic Survey 2020–2021. Of the 10 most populated states, the five states ranked higher on per capita incomes are Karnataka, Gujarat, Tamil Nadu, Maharashtra, and Andhra Pradesh, and the five states ranked lower on per capita incomes are Rajasthan, West Bengal, Madhya Pradesh, Uttar Pradesh, and Bihar.

(3) The figures in the brackets in this column correspond to the range of urbanization for the states considered in the category. Urbanization is measured as the percentage of total population residing in urban areas based on the 2011 Census of the Government of India.

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pandemic. The five least urbanized states are responsible for only less than 15% of the deaths in the first and second waves.

2.4 First wave versus second wave: A state-wise comparison

The second wave of COVID-19 in India was much deadlier than the first wave and saw the daily case count touch 400,000. It affected younger people, the elderly, as well as people with low comorbidity conditions. Despite the availability of drugs in hospitals and pharmacies, presence of trained, mostly vaccinated health workers, enhanced bed capacity, three approved vaccines, markedly reduced test prices, and easier treatment affordability, the second wave saw a much faster disease spread. There were greater oxygen and mechanical ventilation requirements for patients in the second wave, leading to acute shortage of hospital beds, oxygen supply, medicines, and ventilators across the country for COVID-19 patients. Even though the death rate was lower in the second wave, due to the alarmingly high number of infections, the total death numbers were unfortunately high. In this section, an attempt is made to see whether the spread and concentration of COVID-19 cases are markedly different between the first and the second wave.

As seen in Figure 2, the peak of the first wave, in terms of the number of cases in the country, was witnessed around mid-September 2020 and the peak of the second wave in the first week of May 2021. The following figure (Figure 3) shows the state-wise distribution of pandemic indicators, comparing the peaks of the two waves.

Our findings are summarized as follows.

At the all-India level, the peak of the second wave in terms of number of cases was more than four times the peak of the first wave. This multiple varies across states (Figure 3(A1)). The northeastern states are at the lower end, with their daily case count in the second wave being less double than that in the first and with Mizoram being an exception, where the second wave peak was a little lower than five times the first. Tamil Nadu, West Bengal, and Gujarat seemed to have controlled the spikes in the first wave, but their second wave peaks were close to 10 times the first wave peak. Karnataka and

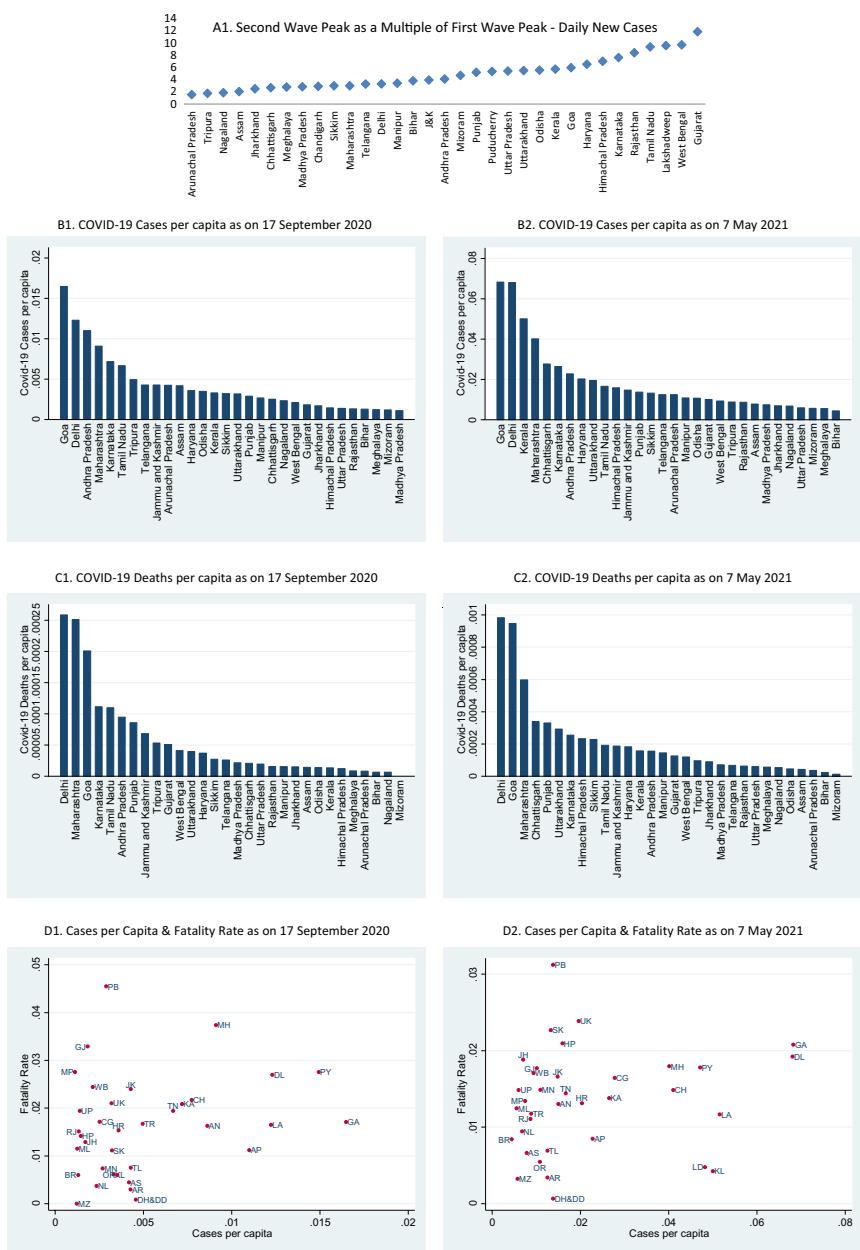
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Figure 3. State-wise pandemic indicators at the peaks of the first and second waves.

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Rajasthan shared a similar story, with their multiples in the range of 7.5–8.5. Four states went to the polls in April, and election rallies in these states have been held responsible for the second wave in India at several forums. These are Tamil Nadu, West Bengal, Kerala, and Assam. This is evident in the recorded multiples, particularly in the first three states. The Kumbh Mela in Uttarakhand, a religious gathering, was scheduled from April 12, 2021 to April 27, 2021. This state, along with the neighboring Uttar Pradesh, had a peak in the second wave that was more than five times the first one.

Figure 3(B1) and (B2) show the per capita cases for 29 states and the NCT of Delhi on the two days when the all-India cases peaked in the first and second waves, respectively. Notable findings are as follows. The five poorest states of the country, namely Bihar, Uttar Pradesh, Rajasthan, Madhya Pradesh, and Jharkhand, had the lowest per capita caseload at the peak of both the first and second waves. These also happen to be landlocked states. The states with high per capita caseloads in both the waves were the relatively prosperous coastal states — Andhra Pradesh, Tamil Nadu, Kerala, Karnataka, Maharashtra, and Goa. Overall, the more urbanized states seem to rank higher in per capita cases in both the waves, and the less urbanized states seem to rank lower. There are exceptions, however. Assam and Odisha, with low degrees of urbanization, display high per capita cases in the first wave. Kerala, Punjab, West Bengal, and particularly Gujarat, with high degrees of urbanization, had lower per capita cases in the first wave. During the second wave, there are fewer exceptions to this hypothesized relationship, with Gujarat and West Bengal standing out. Noticeable changes in rankings are seen in the case of Kerala: from 14/30 in the first wave to 3/30 in the second. Kerala fares relatively well in the first wave. Its first wave took off late, and the recorded COVID-19 deaths were surprisingly low through 2020. However, during the second wave, infection rates soared, and it had one of the highest per capita case loads. Andhra Pradesh and Tamil Nadu, which were on top of the per capita cases chart in the first wave, moved lower in the ranking in the second wave. A noticeable upward blip is seen in the case of Telangana (from 8/30 to 15/30), Tripura (from 7/30 to 21/30), and Assam (from 11/30 to 23/30).

Figure 3(C1) and (C2) show the per capita COVID-19 deaths for 29 states and the NCT of Delhi on the two days when the all-India cases peaked in the first and second waves, respectively. Notable findings are as

follows. In both the waves, the per capita deaths are the highest in Delhi, Maharashtra, and Goa. These states also witnessed the highest caseloads, with significant pressure mounting on the existing healthcare system. A noticeable change in the ranking can be seen in the case of Chhattisgarh. It ranked 17/30 in terms of per capita deaths in the first wave and moved to the fourth position during the second wave. Similarly, Kerala, which ranked lower in the first wave, moved up significantly during the second wave.

Figure 3(D1) and (D2) show the cases per capita and fatality rate (calculated as a ratio of cumulative COVID-19 deaths and the cumulative COVID-19 cases lagged by two weeks) for the states and union territories of India at the peaks of the first and second waves, respectively. Punjab stands out in both the waves, with a lower case rate but a high fatality rate. Delhi and Goa record both high case rate and fatality rate in the two waves. The fatality rate mostly declined in all states, primarily because of the significantly higher or high number of cases in the second wave. However, Bihar and Jharkhand stand out, with a higher fatality rate in the second wave compared to the first. This is also seen in the northeastern states and the smaller states of Goa and Himachal Pradesh, mainly because of the very low fatality rates in the first wave in each region. Uttarakhand is an exception to the above; it witnessed high fatality rates in the first wave but an even higher rate in the second wave.

3. Severity of COVID-19 Pandemic in India

COVID-19 has been more fatal than many recent epidemics. Thus, the daily death toll has been unusually important in understanding the COVID-19 pandemic. The lack of testing in many countries and the virus' ability to spread from people who are asymptomatic make counting the number of infections very difficult (Subbaraman, 2020). The low recorded COVID-19 mortality during the first wave “fed government narratives on the successful handling of the pandemic,” possibly explaining the complacency in following safety protocols (Banaji, 2021). Thus, despite the official numbers being suspect and the huge variations in death surveillance between states and between urban and rural areas, the COVID-19 death toll is a better tracker of the progression of the pandemic and the effectiveness of containment than other measures. In this section, we examine the severity of the pandemic in India for a 15-month period (March 2020 – June 2021)

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using alternative measures — the cumulative severity ratio (CSR) and the daily severity ratio (DSR) — which use the official estimate of deaths from COVID-19 as a ratio of all-cause mortality. The study of CSR and DSR across the regions of India is useful, as the comparison with previous mortality patterns gives a region-specific flavor to the severity of the pandemic, which can be used to corroborate the realities on the ground.

Furthermore, we examine some non-medical factors that may help explain the variation in these ratios across states. The choice of the factors is based on the extant literature on the socioeconomic, geographical, and meteorological correlates of the COVID-19 pandemic, including our own research (Imai *et al.*, 2021).

3.1 Defining severity ratio

A new indicator, “relative severity” (Schellekens and Sourrouille, 2020), is used to examine the unequal distribution and progression of COVID-19 deaths across regions. The relative severity ratio is defined as the ratio of the total deaths attributable to COVID-19 over a given period to the expected total deaths from all causes, under the counterfactual assumption that the pandemic had not taken place, over a base period of the same length. In addition to this ratio (which will be denoted as CSR), a World Bank study has defined a daily severity ratio (DSR) that tracks the progression of the severity of the pandemic in each region. For the purpose of this study, these indicators are calculated at the all-India level and for individual states and union territories for the 15-month period starting from mid-March 2020 until the end of June 2021, covering both the first wave and the more lethal second wave.^{2,3}

$$^2 \text{Algebraically, Cumulative Severity Ratio}_t = \frac{\text{Cumulative Covid Deaths}_t}{\left(\frac{\text{No. of Deaths in a pre pandemic year}}{365} \times \text{Length of Pandemic}_t \right)},$$

where Length of Pandemic_t = No. of days between t and Date of First Covid Linked Death in the Region

$$\text{Daily Severity Ratio}_t = \frac{\text{New(daily) Covid Deaths}_t}{\left(\frac{\text{No. of Deaths in a pre pandemic year}}{365} \right)}.$$

³The COVID-19 data are collated from the Ministry of Health and Family Welfare, Government of India. The data on the past mortality patterns are based on the state-wise number of registered deaths in 2018 from the Ministry of Health and Family Welfare, Government of India.

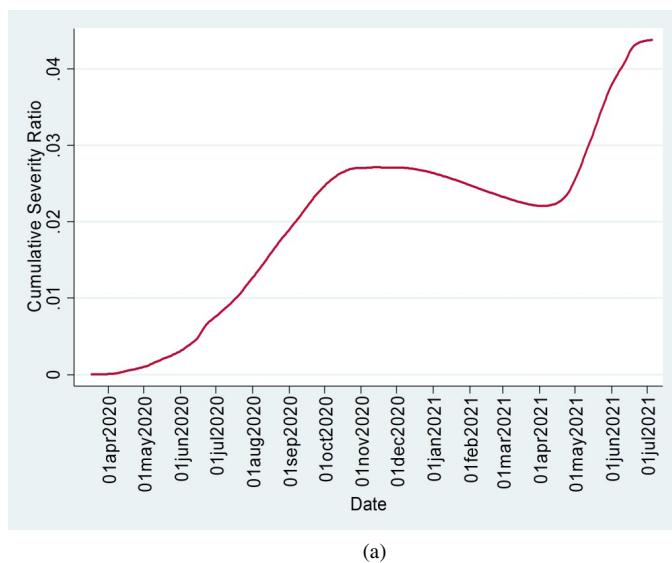
The advantages of using CSR and DSR to measure the severity of the pandemic are manifold. First, using COVID-19-linked deaths rather than cases is better because of the lack of testing in many countries and the virus' ability to spread from people who are asymptomatic, which makes counting the number of infections very difficult. Second, CSR and DSR express the COVID-19-linked deaths to the pre-pandemic mortality patterns. These are better measures compared to the case fatality rate, which uses the ratio of deaths to number of infections. Third, the progression of the severity ratios is a good indicator of the pressure on the health system to effectively deal with the rising number of cases. Thus, despite the limitation that the number of COVID-19 deaths is underreported, the study of the severity ratios is likely to yield useful insights.

3.2 Trends in severity ratios

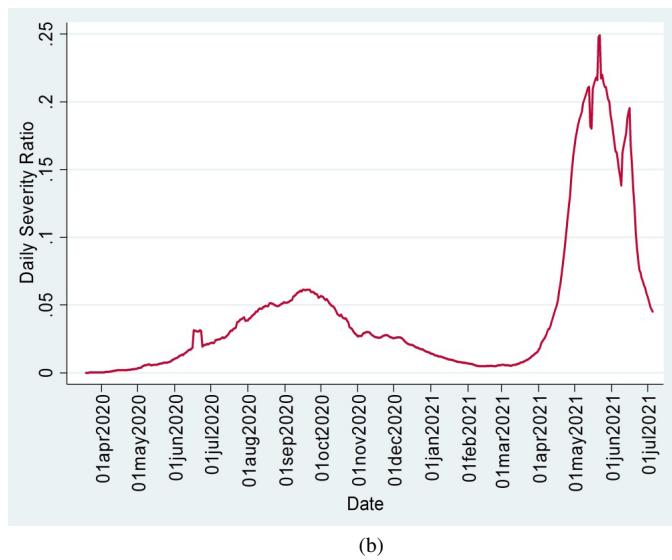
Figures 4(a) and 4(b) show the CSR and DSR for India since the onset of the pandemic, i.e., from March 13, 2020, when the first COVID-19-linked death was reported, till June 30, 2021. As of May 30, 2020, when the nationwide lockdown ended, the CSR for the country was 0.29%. By the end of August 2020, the ratio had reached 1.8% and stayed around that level for the next six months. In fact, a minor decline in the ratio was seen just before the onset of the second wave, since the rate of growth of number of deaths was declining. However, as the death numbers jumped up significantly during the second wave, the CSR crossed the 4% mark in June 2021. To understand the significance of this number, the Global Disease Burden Report (2019) suggests that all respiratory infections and tuberculosis accounted for 8% of all deaths in India in 2019. All types of cancer accounted for 6%, chronic respiratory diseases accounted for 6%, and mental disorders accounted for 5% of all deaths. This suggests that COVID-19 is among the top causes of deaths in India.

An increase in the DSR overtime is not only due to the interplay between the causative virus, the host, and the environment but also a reflection of the increased pressure on the healthcare system due to the sudden increase in cases. The DSR allows examination of the speed and strength with which the pandemic progresses in a region. The daily severity ratio peaked in the first wave around mid-September 2020 at a level greater than 5%, which then came down to 1% by March 2021. During the

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(a)



(b)

Figure 4. (a) Cumulative severity ratio and (b) daily severity ratio in India: March 2020 to June 2021.

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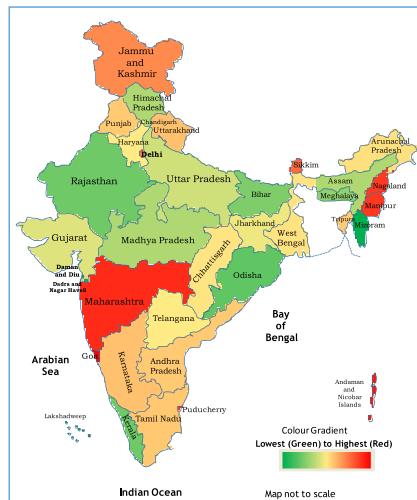
second wave, a sharp and swift increase in the DSR was witnessed as COVID-19-linked deaths skyrocketed, crossing the 20% mark at the peak of the second wave.

There is significant heterogeneity across the states in the progression of CSR and DSR. Just after the completion of the nationwide lockdown at the end of May 2020, Gujarat and Maharashtra were two states with CSR greater than 1% (in comparison to the all-India CSR of less than 0.3%), with Delhi's level just touching 1%. While Gujarat did not witness an increase in the subsequent months, the CSRs for Maharashtra, Delhi, and Goa crossed the 5% mark by the end of August 2020. Some of the other large states, such as Andhra Pradesh, Jammu & Kashmir, Karnataka, and Tamil Nadu, also witnessed sharp increases in their CSR. Goa and the Union territory of Puducherry saw their CSRs double from 6% and 5%, respectively, on September 1, 2020, to 12% and 10% on October 15, 2020. At around the peak of the second wave, all states (big and small) had CSRs greater than 1%, barring Rajasthan, Odisha, and Bihar, partly because these states had recorded higher (all causes) pre-pandemic deaths. Among the northeastern states, Mizoram seemed to have had the best control over the pandemic. Figure 5 shows the distribution of CSR and DSR across the states during the peaks of the first and second waves. As can be seen from the graphs, the concentration in the severity of the pandemic in few states during the first wave reduced by the time the second wave hit the country.

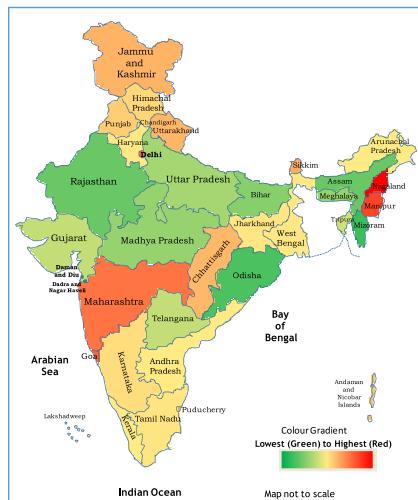
Comparison of DSR across the states over time helps us to understand the progression of the pandemic in terms of the path and the peak. The states of Gujarat, Haryana, Telangana, and Kerala had a gradually rising daily severity ratio all the way up to the second wave peak, but no peak was observed during the first wave. The second wave peak for these states lies in the ratio range of 15–35%. A similar trend is observed in the five relatively poor states of Assam, Bihar, Madhya Pradesh, Uttar Pradesh, Rajasthan, and West Bengal, where there is no noticeable first wave peak but the second wave peak is lower than 15%. Odisha had the lowest second wave peak at 5%. In Karnataka, Punjab, and Tamil Nadu, two peaks are observed, with

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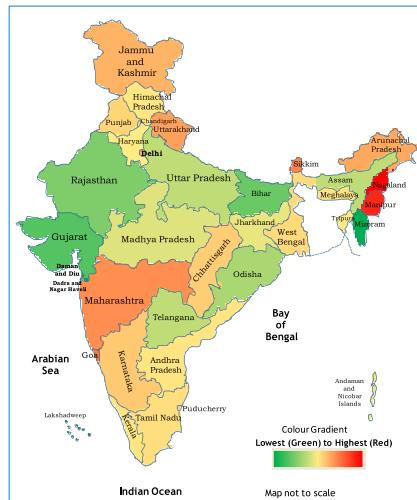
Cumulative Severity Ratios for as on 15th Oct 2020



Cumulative Severity Ratios as on 1st May 2021



Daily Severity Ratios as on 15th Oct 2020



Daily Severity Ratios as on 1st May 2021

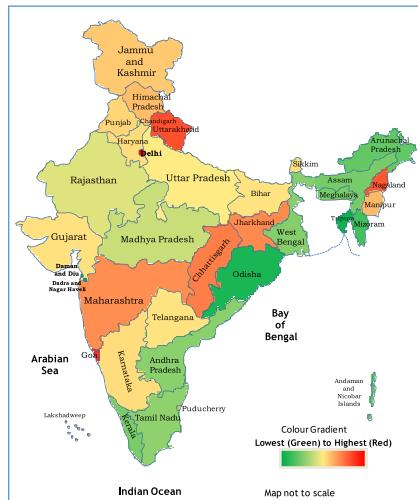


Figure 5. (Color online) State-wise distribution of relative severity ratios in India around the peaks of the first and second waves.

the second peak higher than 30% and the first peak lower than 10%. Maharashtra and Uttarakhand follow a similar path, but the second wave peak crosses 100% in both these states. Chhattisgarh, Jammu and Kashmir,

and Jharkhand also follow a similar path, with the second wave peak around 50%. Among the smaller states and union territories, Delhi's second wave DSR peaked at 100% and Goa's crossed 175%. Delhi also observed the highest first wave peak at 34%. The peak severity observed during the full course of the pandemic helps to understand the dynamic path and to classify regions by the role played by COVID-19 in all other causes of deaths.

3.3 Regional heterogeneity in severity ratios: Analysis of socioeconomic and environmental factors

We examine the interstate heterogeneity in the severity of the pandemic by looking at socioeconomic, meteorological, and geographical factors. Individual factors, such as age, sex, socioeconomic condition, underlying comorbidities, and lifestyle, have been identified as significant influencing factors in the spread of and mortality due to COVID-19, but these factors are likely to be influenced by country- or state-specific factors, such as lockdown policies, state of health infrastructure, and economic and social conditions (Pardhan and Drydakis, 2020). Gupta *et al.* (2020) analyze the epidemiological data of COVID-19 from 17 countries with more than 20,000 cases as of mid-April 2020 and find that the number of cases per capita and the fatality rate are correlated to some extent with urbanization but to a greater extent with the proportion of elderly in the total population. Based on a cross-country analysis, Virmani (2021) shows that urban areas are more susceptible to the spread of COVID-19, primarily because work and social interactions in rural areas are likely to take place in more open and ventilated spaces, while urban areas may have a higher density of population and lower physical distance between people during meetings and indoor activities, especially those in closed, air-conditioned rooms. At the same time, unplanned urbanization and the associated environmental changes, food and water scarcity, natural disasters, and displacement of population have led to a varied epidemiology of infectious diseases (Myers and Patz, 2009). Meteorological parameters are also among the crucial factors affecting the spread of infectious diseases. The average temperature, humidity, and precipitation have been found to be positively correlated with the number of COVID-19 cases in

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Singapore (Pani *et al.*, 2020), whereas a negative correlation of air temperature with daily new COVID-19 incidence and deaths was found in Spain (Zoran *et al.*, 2021). Temperature and humidity have a nonlinear relationship with the spread of COVID-19, based on a study in Ghana (Aidoo *et al.*, 2021). In addition to average temperature, minimum temperature and air quality have also been found to have a significant relationship with the COVID-19 epidemic in the initial months in the US, with no scientific evidence that warm weather could suppress the pandemic (Bashir *et al.*, 2020).

While the existing studies have focused on the socioeconomic, demographic, and environmental factors to explain the spread of infections and fatality rate, we extend this argument to assess if there is a rich–poor divide in the severity of the pandemic in India and what could be the possible explanations for this divide.

Our first variable of interest is per capita income at the state level, which not only captures the overall economic development at state level but also the health infrastructure or funding at the state level. Second, it is widely debated whether the weather influences COVID-19 infection cases and/or is linked to deaths. So, we also examine if variations in temperature, humidity, and rainfall explain the statewide heterogeneity in the severity of the pandemic. Finally, the degree of urbanization captured by the share of people living in urban areas is studied to check for any difference in the progression of the pandemic in the various states and union territories.⁴

Table 3 shows the average CSR and DSR for the 10 richest and 10 poorest states of the country as measured by per capita incomes⁵ on different dates during the pandemic. Throughout the pandemic, the average CSR and DSR for the richer states were higher than those for the poorer

⁴The per capita net state domestic product at current prices (2011–2012 series) for the year 2018–2019 is taken from the Economic Survey 2020–2021. The weather indicators (temperature, rainfall, and relative humidity) have been taken from Modern-Era Retrospective Analysis for Research and Applications (MERRA). The degree of urbanization captured by the proportion of population living in urban areas is taken from Census, 2011.

⁵We restrict our analysis to the 20 large states. The severity ratios for the nine excluded states (Himachal Pradesh, Goa, Sikkim, and the six small states of Northeast India) are shown separately. The table also shows the severity ratios for the National Capital Territory of Delhi and the six other union territories.

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Table 3. Average severity ratios for states based on income.

		Share in total Population	30 May 2020	1 September 2020	15 October 2020	15 January 2021	31 March 2021	1 May 2021	30 June 2021	CSR & DSR
10 Richest States ⁽¹⁾	38.7%	CSR DSR	0.3% 0.9%	2.2% 6.3%	3.2% 5.3%	3.1% 1.5%	2.7% 2.3%	3.1% 20.3%	5.7% 7.4%	
10 Poorest States ⁽¹⁾	57.8%	CSR DSR	0.2% 0.3%	1.0% 3.1%	1.7% 3.2%	1.9% 0.8%	1.6% 0.8%	1.9% 17.0%	3.5% 2.8%	
9 Least Populated States ⁽¹⁾	1.9%	CSR DSR	0.1% 0.0%	3.4% 3.9%	5.8% 12.3%	7.4% 3.9%	5.6% 1.5%	5.6% 24.7%	15.8% 28.7%	
National Capital Territory of Delhi ⁽¹⁾	1.4%	CSR DSR	1.0% 6.8%	6.4% 4.7%	6.7% 10.1%	8.7% 2.8%	7.2% 1.8%	9.1% 93.4%	13.2% 1.4%	
6 Union Territories ⁽¹⁾	0.3%	CSR DSR	0.2% 0.0%	6.3% 11.2%	5.9% 2.6%	3.8% 0.5%	3.1% 1.1%	3.1% 19.3%	13.1% 5.6%	
10 Most Urbanized States ⁽²⁾	45%	CSR DSR	0.3% 0.9%	2.2% 6.0%	3.1% 4.6%	2.9% 1.1%	2.5% 2.2%	2.8% 14.3%	4.7% 7.2%	

(Continued)

Table 3. (*Continued*)

	Share in total population	30 May 2020	1 September 2020	15 October 2020	15 January 2021	31 March 2021	1 May 2021	30 June 2021
10 Least Urbanized States ⁽²⁾								
Least Urbanized States ⁽²⁾	51%	CSR DSR	0.1% 0.3%	1.1% 3.4%	1.8% 3.9%	2.1% 1.1%	1.7% 0.8%	2.2% 23.0%

Notes: (1) The 10 richest states are Haryana, Karnataka, Telangana, Kerala, Uttarakhand, Gujarat, Tamil Nadu, Maharashtra, Punjab, and Andhra Pradesh. The 10 poorest states are Bihar, Uttar Pradesh, Jharkhand, Assam, Madhya Pradesh, Jammu Kashmir, Chhattisgarh, Odisha, West Bengal, and Rajasthan. The nine least populated states are Himachal Pradesh, Tripura, Meghalaya, Manipur, Nagaland, Goa, Arunachal Pradesh, Mizoram, and Sikkim. The six union territories are Puducherry, Chandigarh, Dadra and Nagar Haveli and Daman and Diu, Ladakh, Andaman and Nicobar Islands, and Lakshadweep. (2) The 10 most urbanized states are Tamil Nadu, Kerala, Maharashtra, Gujarat, Karnataka, Punjab, Haryana, Telangana, Andhra Pradesh, and West Bengal. The 10 least urbanized states are Bihar, Assam, Odisha, Uttar Pradesh, Chhattisgarh, Jharkhand, Rajasthan, Jammu and Kashmir, Madhya Pradesh, and Uttarakhand.

states, with a narrowing of the gap in the second wave in comparison to the first wave. This can partly be due to the lower pre-pandemic deaths (the denominator of our ratio) and better reporting of deaths in richer states. But the interplay between affluence and the concomitant urbanization, environmental risks, and comorbidities, which have been found to be associated with higher fatality rates, cannot be ruled out. This is corroborated by our findings of the average CSR and DSR of the nine least populated states of the country, which have a significantly higher magnitude, mainly driven by the fatality rates in Sikkim and Goa, two states with the highest per capita income in the country. There is a significant positive correlation between per capita incomes and COVID-19 severity ratios, but there is a reduction in the magnitude of the coefficient during the peak of the second wave as compared to the peak of the first wave in September–October 2020 (see Table A1 in the technical appendix for the correlation coefficients between the severity ratios and per capita incomes, weather indicators, and urbanization). The second wave saw a brutal impact of the pandemic on practically all the regions of the country.

Despite the mixed results and the ongoing debate, the studies examining the relationship between weather and the incidence of the pandemic could be used as a basis for policy formulation in general. The findings would be helpful in assisting public health professionals to develop control measures, as India experiences diverse weather characteristics across regions in all seasons. We find a negative correlation between the temperature and the severity ratios throughout the pandemic (except in the initial months when the concentration of the pandemic was in a few states only). The magnitude of this correlation coefficient increased in the second wave, which is also the peak summer time in the entire country, so the warm regions experienced a greater severity of the pandemic compared to the warmer regions. If we restrict our analysis to the 20 largest states only (which comprise more than 90% of the country's population), similar results are found, and the magnitude of the correlation coefficients is larger compared to the results of the all-India analysis. The relationship between the severity of the pandemic and humidity is unclear for 2020. A positive relationship is seen throughout the first six months of 2021, but these are also the moderately humid months of the entire year. The period June–October witnesses maximum

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rainfall in the country. It is in this period that the correlation coefficient between the severity of the pandemic and precipitation is found to be positive, implying that wetter areas bore the brunt compared to the dry ones. In the remaining months, the interregional variation in rainfall is very small and the correlation coefficients are mostly insignificant. The positive correlation may be attributed to the fact that the coastal states, which receive a significant proportion of the rain, are also among the more prosperous ones compared to the landlocked states. Similar results are found when the analysis is restricted to the 20 largest states only, and a significant coefficient is also found in the non-monsoon months.

The virus first originated in Wuhan and then spread to other urban cities in Italy, the US, and Spain. But the spread of the virus from these and other highly industrialized urban centers to the peripheries and subsequently to the rural areas was inevitable. Whether there are observable differences in the severity ratios across the regions of India with different levels of urbanization is examined in this section. Throughout the pandemic, the average CSR and DSR for the more urbanized states were higher than those for not so urbanized states, with a narrowing of the gap in the second wave in comparison to the first wave. The higher density of population in urban areas, making social distancing difficult, and the consequent pressure on the medical infrastructure because of alarmingly high cases are possible explanations for the high severity ratios. The correlation coefficients between urbanization and COVID-19 severity ratios are positive throughout the pandemic, with the magnitude reducing in the later months. Even when the analysis is restricted to the 20 largest states only, thus excluding the union territories and smaller states, some of which are highly urbanized, the correlation between the severity ratios and the degree of urbanization is positive.

4. Food Insecurity

Food security can be seen as the economic access to food (which is a function of income generation and food prices), availability (which is a function of robust food supply systems), utilization (which is a function of food composition and nutrient content), and stability of these three

dimensions over time. The impact of the COVID-19 pandemic on all four dimensions of food security is attracting greater attention from researchers.

Disruptions in the food systems due to the pandemic relate to both the production side (food production, processing, and distribution) and the demand side (economic and physical access to food). Restrictions on movement due to policies to contain the spread of COVID-19 have had an impact in the form of disrupted value chains, particularly in informal markets, but the impact on prices depends on the resilience of the value chains (Devereux *et al.*, 2020; Reardon *et al.*, 2020). Loss of income has also affected the economic access to food due to reduced purchasing power. Using a data set from a large online grocery retailer in India, Mahajan and Tomar (2021) study the impact of the unanticipated COVID-19-induced lockdowns on product stockouts and prices in India to find that product availability fell by 10% for vegetables, fruits, and edible oils, with minimal impact on the prices of these food commodities. They also find a 20% fall in the quantity of arrivals of vegetables and fruits to support the fall in product availability at retail centers. Kaicker *et al.* (2021) offer a robust pre- and post-pandemic comparison of means and variances of food commodities' prices and the price wedge between them in four major cities (Mumbai, Pune, Nashik, and Nagpur) of Maharashtra, which is one of the worst COVID-19-affected states of India. While no significant difference in average wholesale and retail prices are found, the price wedges display significantly higher variances during the lockdown period with a few exceptions. Time-varying volatility is observed in both wholesale and retail prices, suggesting an important role of random supply and demand shocks, such as unseasonal rains and panic buying.

Examination of the third dimension, i.e., utilization (Laborde *et al.*, 2020; Headey and Ruel, 2020) suggests a shift from a more nutritious diet to cheaper and less nutritious food as a result of the pandemic. Analysis of the Consumer Pyramids Household Survey in India suggests a relatively small decline in per capita expenditure for cereals but a significantly large decline in nutritious food items, such as fruits, eggs, fish, and meat, as a result of the pandemic (Dreze and Somanchi, 2021). In addition to the structural deficiencies in the food systems in low- and middle-income countries, such as inadequate infrastructure, lack of access to services, and

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high dependence on weather conditions, the inability of the food systems to cope with shocks (such as droughts or mobility restrictions as posed by the current pandemic) is an important factor explaining disruptions in food supply operations, leading to food shortage, food losses, or price volatility (Bene, 2020).

Since India's food markets have been significantly impacted by the spread of COVID-19, with both demand and supply shocks, this impacts the quantity of food available at wholesale and retail markets as well as the price at which it sells. This section offers an analysis of the impact of the pandemic on market arrivals and prices at a pan-India level, covering a period of 15 months through the pandemic and nine months prior to that. We see not just the short-run impact of the lockdown but also a longer-term one, as well as a wider spread/geography. We compare the impact on prices of nonperishable commodities (wheat and rice) and perishable commodities (tomatoes, onions, and potatoes).

An aspect that has not received much attention is the rise in the share of food consumption expenditure in the total household consumption expenditure. If Engel's law holds, the higher the food share, the greater the impoverishment. As stated, "the greater the proportion of the total outgo which must be used for food. The proportion of the outgo used for food, other things being equal, is the best measure of the material standard of living of a population."

Based on data on monthly household expenditures on food, from CMIE-CPHS over the period January 2019 – August 2021, Kaicker *et al.* (2022a, 2022b) find that the pandemic-induced lockdowns resulted in a sharp increase in the share of food in total expenditure across rural and urban India. The movement restrictions at the onset of the pandemic acted more like a temporary shock than a permanent one, which resulted in a declining share of food in total expenditure, but stabilized at a level higher than that observed pre-pandemic. A slight increase was also observed during the more deadly second wave, where some states used closures and containments as measures to control the spread of the disease, but no nationwide restrictions were imposed. This phenomenon is observed among households across income levels and among all social and religious groups, but the intensity of shifts varied. In urban areas, the shift in food budget share due to the nationwide lockdown in April 2020 was

narrower for lower income deciles and wider for higher income deciles — partly attributable to higher expenditure on food sourced from outside and on ready-to-eat meals and to consumption of more expensive foods as people worked from home. In rural areas, the shift was highest for the lowest decile and for the lower castes (SCs and STs), suggesting that the poorest in rural areas were the worst affected by the lockdown, which is not surprising.

Spurts of higher food share are alarming for three reasons: inferior cereals are substituted for expensive cereals; lower amounts are spent on more nourishing foods, such as fruits and vegetables; and other essential nonfood items, such as education and healthcare are neglected. Thus, spells of impoverishment during the pandemic were not infrequent, and the lower income deciles in both rural and urban areas bore the brunt of it.

4.1 Food prices and market arrivals during the COVID-19 pandemic

Figure 6 shows the trends in the prices of major food commodities during the period July 2019 – June 2021.⁶ Tomato prices spiked shortly during the first phase of the nationwide COVID-19 lockdowns. This sudden jump in prices at both the retail and wholesale levels can be attributed to demand shocks, such as panic buying by consumers fearing nonavailability due to the lockdowns and supply shocks in the form of disruption in food supply chains across the country, along with *mandis* remaining shut intermittently. The price wedge has increased in both the lockdown phases coinciding with the first wave (April–June 2020) and the second wave (April–June 2021) of the pandemic in India. This surge in prices continued and a gradual decline was witnessed only in early 2021. The price

⁶We collected the retail and wholesale prices of five commodities (tomato, potato, onion, wheat, and rice) from the Price Monitoring Division. The market arrival data were collected from the Agricultural Marketing Information Network (AGMARKNET). The *mandi* arrivals refer to the total quantity (in tonne) of food commodities arrivals from agricultural produce markets. The weekly *mandi* arrival quantities have been collated for 22 states of India for the five food commodities.

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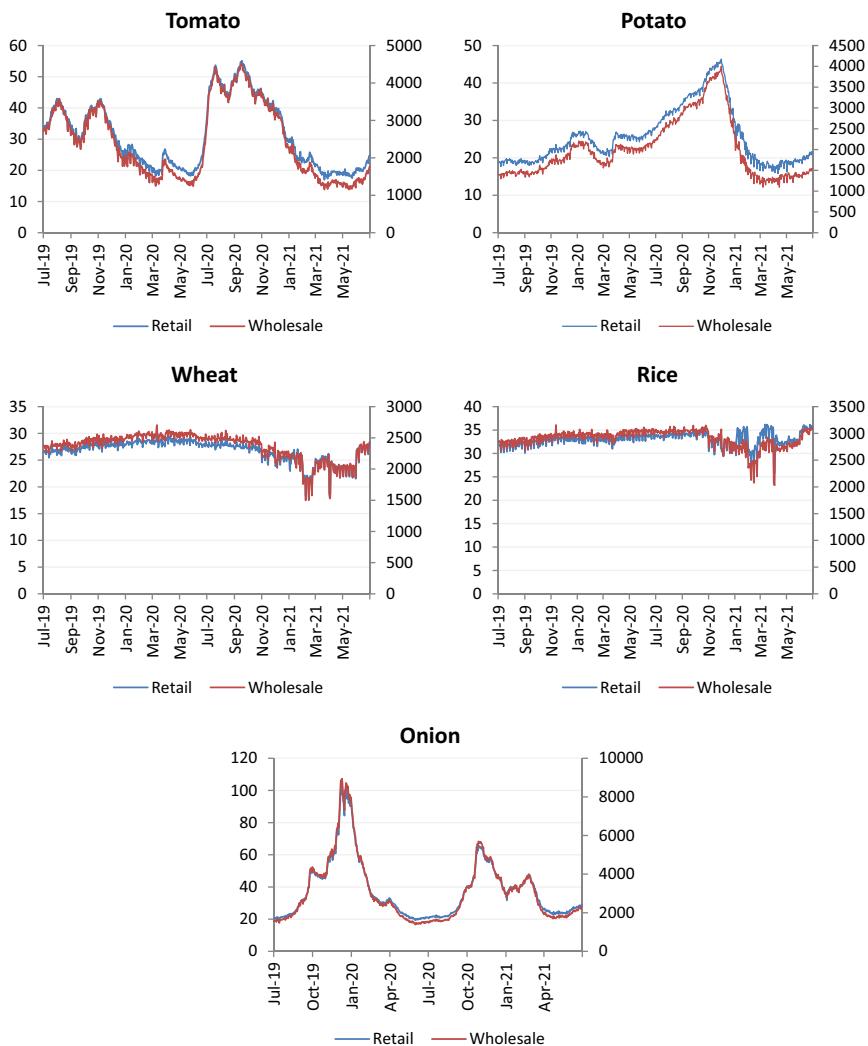


Figure 6. Trends in food prices before and after the pandemic.

wedge for potatoes gradually narrowed until the two prices converged in December 2020. The price wedge is, however, seen to be increasing rapidly during the second COVID-19 wave in India. Both the retail and wholesale prices of onions spiked in the final quarters of 2019 and 2020 compared to the rest of the year. While onions are consumed every day

and hence their demand remains consistent all year, the seasonal nature and concentration of supply coming from mainly three states in the country — Maharashtra, Karnataka, and Madhya Pradesh (contributing approximately two-thirds of India's onion production) — could be associated with the rise in prices during the final quarter of every year. Onions follow a *rabi*, or winter crop, cycle, and the harvests arrive in the markets by April, when the prices are usually lower; the prices increase steeply as October approaches, with stocks getting depleted. Thus, the prices peak after the monsoon season almost every year. It was particularly bad in 2019 because domestic production was adversely affected by unseasonal flooding, which not only destroyed the produce but also made transportation rather difficult. The price of onions does not display much variation on account of the COVID-19-induced nationwide lockdowns in both 2020 and 2021.

It is also interesting to note that wheat and rice had very similar price trends during the period under study. Not much variation in the prices is seen, and this can be attributed to the nonperishable nature of these two commodities. The stability in these prices could also be on account of the fact that the government continues to be a major buyer of wheat and rice in India. It is only in the year 2021 that we note some fluctuations in the prices. The slight downward trend in the prices of wheat and rice can be related to the effort of the government to keep inflation low, as reflected in the Open Market Sale Scheme (OMSS) policy for the year 2021–2022. Under this scheme, the government sells rice and wheat at the reserve price to bulk buyers and consumers. However, as the second and more lethal wave of the pandemic hit the country, the prices of both these important food commodities can be seen to follow a rising trend.

Figure 7 shows the trends in *mandi* arrivals at the national level aggregated using state-level weekly *mandi* arrival quantity data for 19 states for the 104 weeks from July 1, 2019, to June 30, 2021.

Despite the fact that movement of essential commodities was permitted during the COVID-19-induced nationwide lockdowns, market arrivals of major agricultural commodities dropped sharply. This can be seen in the case of all commodities (except wheat), irrespective of their perishable characteristic. The *mandis*, where farmers sell their produce,

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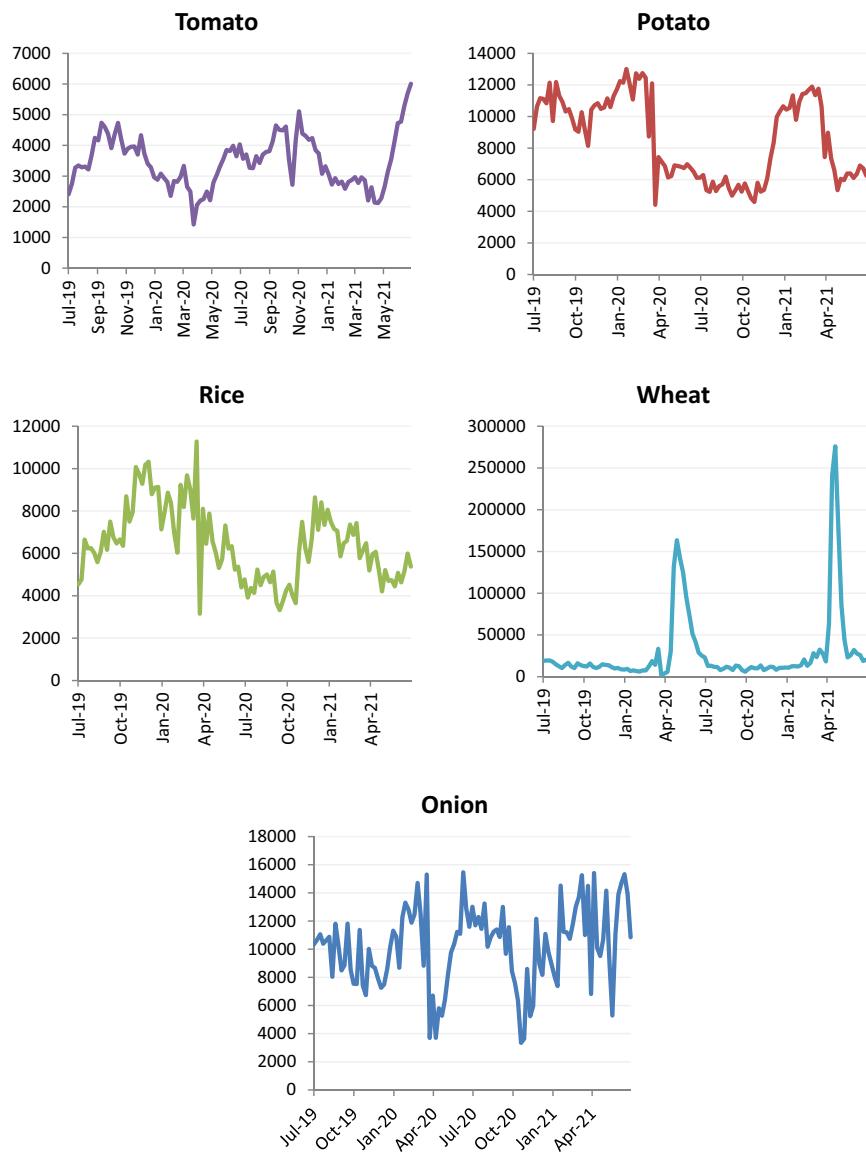


Figure 7. Trends in *mandi* arrivals before and after the pandemic.

were sporadically closed. It was only the *mandi* arrivals of wheat that bounced back sharply in the first half of the lockdown phase II (April 15 – May 3, 2020), and all other commodities experienced a rather slow

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and gradual revival in market arrivals as the unlocking phases progressed.

Just after the nationwide lockdowns, on June 5, 2020, the Government of India announced three agricultural ordinances, which brought major reforms to the functioning of the country's agricultural markets. Under a new central law on interstate trade, farmers have the freedom to sell their produce in any market within and outside the state of their residence, without being hamstrung by Agricultural Produce Marketing Committees (APMCs). Through another ordinance on contract farming, farmers would get a share of the post-contract price surge after they sign agreements of contract farming with private players. Also, they will have the cover of minimum guaranteed price if open-market/*mandi* rates fall drastically. These ordinances, along with another one through which the Essential Commodities Act has been amended easing stock holding restrictions on commodities, are associated with substantial reductions in *mandi* arrivals. The APMCs network across India witnessed substantial fall in market arrivals. These were particularly noticeable in many market centers of Maharashtra and Uttar Pradesh, where the farmer community organized themselves and boycotted the APMCs altogether, thereby directly selling to aggregators and food processing firms. Apart from the reforms, closure of restaurants and hotels also contributed to lower *mandi* arrivals of fruits and vegetables. We also observe a decreasing trend in the market arrivals around the period September–October 2020. This time period coincides with the following two major events: (i) the month of September 2020 saw the peak of the first wave of COVID-19 cases in India; and (ii) during this period, there were months-long farmer protests against the new ordinances announced by the government in June 2020.

India experienced a more severe wave of COVID-19 in April–May 2021. This period yet again saw lockdowns enforced by the states; however, these were less stringent as compared to the ones in the same period a year ago. While agricultural activity, as well as inter- and intra-state movement of essential food commodities, was permitted across the country, a significant decline in the arrival quantities was observed in the *mandis*. As can be seen from the arrival figures above, wheat arrivals contracted sharply, there were significant fluctuations in the market arrivals

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of onions, and *mandi* arrivals of tomatoes, potatoes, and rice also followed a downward trend. It can also be seen that, except wheat, the market arrivals of all other four commodities revived immediately after the passing of the peak of the second wave of COVID-19 infections in the country. Even though there were contractions in the market arrivals of all major food commodities, the situation still appeared better compared to that of April–May 2020.

4.2 Comparison of levels of and variation in prices and arrivals before and after the lockdowns

We make a comparison of the levels of and the variation in prices (whole-sale and retail), price wedges, and *mandi* arrivals of the five commodities at the all-India level.⁷ Whether the mean differences are statistically significant is tested using the independent sample *t*-test, and the statistical significance of the difference in the variances of the variables across the time periods is tested using the variance ratio *F*-test.⁸

We first compare the pre-pandemic period (July 2019 – March 2020) with the same nine-month duration the following year (July 2020 – March 2021). This latter period was characterized by the gradual opening up of the country after the strict nationwide lockdown and just before the second wave set in, inducing the next set of statewide restrictions on mobility. The whole-sale prices of onions, rice, and wheat are lower in the second period compared to those in the first, while the wholesale prices of potatoes and tomatoes are higher. This price behavior can be attributed to the perishable nature of tomatoes and potatoes, semi-perishable nature of onions, and non-perishable nature of rice and wheat commodities. The retail prices also exhibit similar results for all commodities except rice, which showed a slight increase in the second period. The price wedge of all commodities except onions increased in the second period. In the case of *mandi* arrivals, potatoes and rice saw a decline in their arrival quantities in the second period. The wholesale and retail prices as well as the price wedge of onions exhibit lower

⁷The prices and the arrivals data have been aggregated for the 20 largest states of the country representing 92 centers.

⁸ See Tables A2 and A3 in the technical appendix for the results of these tests.

variability in the second period. However, the prices of perishable commodities (potatoes and tomatoes) show higher variability in the second period.

We also compare the period of second quarter of 2020 (characterized by the strict nationwide lockdown) with the second quarter of 2021 (characterized by the restrictions imposed during the second wave). The wholesale price of all commodities, except onions, was lower in the second period. The higher wholesale price of onions can be associated with the unseasonal flooding during the year 2019, which resulted in a significant loss of winter harvest of onions in major states, such as Maharashtra, and subsequently lower stocks being available during the summer months. The retail prices also reflect similar results for all the five commodities. The price wedge increased in the case of onions (semi-perishable), rice and wheat (nonperishable), while it decreased for potatoes and tomatoes (perishable). The *mandi* arrivals of all commodities, except rice, were higher during the second period as compared to the first. This can be a result of less stringent lockdowns during the second wave of COVID-19 in India (April–June 2021) and could also reflect some degree of adaptability to the new normal. The lockdowns during the first wave also saw some major agricultural reforms, which resulted in large-scale protests by farmers across the country, and consequently, the *mandi* arrivals were affected considerably. However, the results are not statistically significant. The retail and wholesale prices of all five commodities exhibit significantly lower variation during the second period. A possible reason for this behavior of prices can be associated with the unanticipated and stringent nature of the first set of nationwide COVID-19 lockdowns imposed in April–June 2020 to curb the spread of the virus. The price wedges of perishable commodities (tomatoes, potatoes, and onions) show lower variation in the second period, while the price wedge of nonperishable commodities (rice and wheat) exhibit significantly higher variation. The *mandi* arrivals show mixed results, with the variation being higher for onions, tomatoes, and wheat and lower for potatoes and rice during the second period.

In sum, the pandemic-induced lockdowns impacted both the prices of agricultural food commodities and their variation, thus affecting the economic access dimension of food security. Because of the adverse impact on *mandi* arrivals, especially during the lockdowns, there was a disruption in food supply chains.

5. Conclusions and Policy Recommendations

In this chapter, the inequalities in the incidence and severity of the pandemic across the states and union territories of India over time are examined. Our study supports the finding that the pandemic has had greater intensity in regions with higher per capita income and urbanization. That the richer regions show a higher number of cases compared to the poorer regions could partly be attributed to better rate of testing. Additionally, because the richer regions are more likely to attract more frequent business trips and are therefore initially expected to be the hubs of the COVID-19 infection, which is likely to spread to other regions with the passage of time. Urban areas are more susceptible to the spread of COVID-19, primarily because of greater density, congestion, and being home to urban slums with inadequate hygiene and sanitation.

The study of severity ratios across the regions of India is useful as the comparison with previous mortality patterns helps explain the interstate heterogeneity of the severity of the pandemic and its related policies. These ratios, as a measure of the severity of the pandemic, are useful as they reflect the efficiency of treatment and healthcare response. There are observed differences in the severity indicators also — higher for the richer states compared to the relatively poor regions — and are explained using three factors: socioeconomic, meteorological, and geographical.

There is significant heterogeneity across states in the progression of CSR and DSR. Throughout the pandemic, the average CSR and DSR for the richer states and the more urbanized were higher than those for the poorer states. This gap between the richer/more urbanized states and the poorer states is found to have narrowed in the second wave compared to the first wave. This can partly be explained by the lower pre-pandemic deaths in the richer states (the denominator of our ratio), in addition to better reporting of deaths in richer states. But the interplay between affluence and the concomitant urbanization, environmental risks, and comorbidities, which have been found to be associated with higher fatality rates, cannot be ruled out. The wide gap in the ratios between the richer and poorer states in the initial phases is also because the pandemic had not “run its full course,” and the narrowing of the gap during the second wave

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raises questions about the effectiveness of individuals' and state's efforts in mitigating and slowing the pace of infection.

A negative correlation between temperature and the severity ratios and a positive correlation between rainfall and the severity ratios are found. That the less warm regions and those experiencing more rainfall bore the greater brunt of the pandemic does not imply that warm weather can suppress the pandemic. These findings are particularly helpful in assisting public health professionals while developing control measures, as India experiences diverse weather conditions across regions in all seasons.

Several studies have examined the clinical risk factors for the mortality of patients with COVID-19, including old age, pre-existing comorbidities, and macroeconomic and environmental risk factors, such as socioeconomic deprivation and air pollution. But the alarmingly high fatality rate during the second wave, as compared to the first, can be attributed to the lack of accessibility to oxygen and other critical medical resources for the infected. The differences across regions in the relative level of underestimation of COVID-19 deaths are also an important factor in generating the observed variation in CSR and DSR across states and union territories. A coordinated response by the center and state to make publicly available important epidemiological and health capacity data at the district level is imperative (to say the least). The relationships examined here can be valuable for governments planning an alternative strategy toward formulating environmental and health policies to respond to new COVID-19 outbreaks and prevent future crises.

The COVID-19 outbreak has affected populations across the world, posing new medical, economic, and social challenges. The shutting down of international as well as state borders and the consequent bottlenecks in farm labor, processing, transport, and logistics, as well as a sharp drop in demand, have had a huge disruptive impact on supply chains, including that of food. The agriculture value chain in India also witnessed several unforeseen challenges, including shortage of labor — mainly due to mass reverse migration and a sharp increase in transportation costs arising due to rise in excise duty on petrol and diesel. Even though the movement of essential commodities was permitted during the COVID-19-induced nationwide lockdowns in March–May 2020, market arrivals of major agricultural commodities

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dropped sharply. Most agricultural reforms in India were aimed at improving access to markets and the participation of primary producers. However, while this has been beneficial in improving the situation for large farmers, the bargaining power of smallholder farmers remains critically low. It is important to consider the plight of small and marginal farmers, as they account for 86.08% of the total operational agricultural holdings in the country and contribute roughly 40% of the total marketable surplus.

There is continuing uncertainty about how the COVID-19 epidemic will pan out in the near future. The year 2021 began with several new vaccines showing efficacy in randomized trials, but despite 26 authorized COVID-19 vaccines globally and at least another 200 in development, the first few weeks of the year 2022 brought a sense of uncertainty. Nearly two years after the first COVID-19 case was registered in India, the country ranked third globally in terms of total deaths due to COVID-19 and second in terms of total number of cases. More than 6.5 million cases and 15,000 deaths were added to India's tally in January 2022 alone. The increased detection of the Omicron variant in the initial weeks of the year raised concerns about whether we would see another deadly wave that is worse than the second. There are reasons why we should be wary. First, vaccination does not eliminate the risk of infection. Besides, the chances of vaccination reducing transmission to others are undermined by the finding that the new variants spread even in the absence of symptoms. Moreover, vaccine-induced immunity wanes with time and new variants. For instance, a growing body of ongoing research suggests that the vaccines used in most of the world offer almost no defense against the Omicron variant. The necessity of booster doses, except for the immunocompromised, is not fully understood, but it is likely that they will prolong protection. Another concern with vaccinations is the hesitancy around getting inoculated. In short, the current regime of vaccination offers neither "herd immunity" nor long-term protection.

The failure to follow COVID-19 safety protocols amidst events such as election rallies, farmers' agitations, and religious gatherings, has had severe consequences in the form of spiraling cases, reduced supplies of essential treatments, and higher deaths — particularly among the youth during the second wave. There is a need to enforce these safety protocols, emphasizing prevention, dissemination of accurate information regarding treatment, and promotion of vaccination. Community engagement and collaboration

between the government and civil society organizations can help achieve these objectives. A comparison of the state-wise incidence of the pandemic during the first and second waves reveals the importance of decentralization of essential health services, as a one-size-fits-all approach is flawed. States and districts should have the autonomy to respond to the changing local situations, and there is an important role for technology in streamlining the management of resources (including funds) within and across regions. There is a need for an active management information system, with accurate data on demographic distribution of cases, deaths, hospitalizations, and vaccinations, along with statistical modeling, to predict the spatial spread of infection can enable regions to proactively prepare for likely caseloads in the future.

Above all, behavioral changes among large segments of the population to maintain social distancing and to avoid overcrowding in markets, weddings, and religious festivals are imperative to contain the virus. Transmission of information by credible agencies — not necessarily official agencies — is likely to influence behavior. That the political leaders have shown scant respect for guidelines to prevent overcrowding in election rallies and are often seen without masks act as impediments to the desired behavioral changes in the masses. With elections due in seven states in 2022 and the intensification of new mutations of the virus in recent months, a reversal of the declining incidence and virulence of COVID-19 is not unlikely.

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Technical Appendix

Table A1. Correlations between severity ratios and socioeconomic and meteorological indicators.

	Lockdown Phases	Partial Opening Up Phases	Complete Opening Up	Festival and Winter Season	Initial Vaccination Phases	Onset of Second Wave	Peak of Second Wave
Correlation Between	Mar 12 – May 31, 2020	Jun 1 – Aug 31, 2020	Sep 1 – Oct 15, 2020	Oct 16 – Jan 15, 2021	Jan 16 – Mar 31, 2021	Apr 1 – Apr 30, 2021	May 1 – June 30, 2021
CSR & Per Capita Incomes	0.22***	0.16***	0.29***	0.27***	0.22***	0.26***	0.17***
DSR and Per Capita Incomes	0.11***	0.21***	0.39***	0.09***	0.16***	0.25***	0.06**
ALL INDIA							
CSR and Temperature	0.22***	-0.05***	-0.01	-0.06***	-0.20***	-0.29***	-0.22***
DSR and Temperature	0.27***	-0.09***	-0.16***	-0.15***	-0.05**	-0.15***	-0.21***
CSR and Humidity	-0.14***	0.09***	0.02	0.13**	0.25***	0.23***	0.12***
DSR and Humidity	-0.22***	-0.03	-0.04	0.03	0.13***	-0.14***	0.06***
CSR and Rainfall	-0.05*	0.03	0.08***	0.04**	0.03	0.03	0.03
DSR and Rainfall	-0.07**	-0.04**	0.08***	0.08***	0.02	-0.03	-0.00

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20 LARGEST STATES ONLY					
CSR and Temperature	0.19***	-0.20***	-0.29***	-0.10***	-0.21***
DSR and Temperature	0.23***	-0.26***	-0.34***	-0.10***	-0.01
CSR and Humidity	-0.11*	0.21***	-0.08***	0.02	0.21***
DSR and Humidity	-0.06**	0.23***	-0.12***	-0.09***	0.15***
CSR and Rainfall	-0.03	0.09***	0.06	0.02	0.07***
DSR and Rainfall	-0.03	0.09***	0.03	0.05***	0.05***
CSR & Urbanization	All India	0.30***	0.21***	0.30***	0.18***
States Only	Large	0.24***	0.40***	0.44***	0.40***
DSR and Urbanization	All India	0.17***	0.24***	0.19***	0.01
States Only	Large	0.29***	0.39***	0.35***	0.21***
					0.12***
					0.37***
					0.19***
					0.09**
					0.15***
					0.07***
					0.15***

Note: ***, **, and * denote significance at 1%, 5%, and 10%, respectively.

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Table A2. Independent sample *t*-test results of differences in means.

	July 2019 – March 2020 Compared with July 2020 – March 2021	April–Jun 2020 Compared with April–June 2021
<i>Wholesale Price</i>		
Onion	8.15 (8.71)***	-1.67 (-3.67)***
Potato	-8.82 (-22)***	6.59 (16.24)***
Rice	0.28 (0.93)	2.67 (5.33)***
Tomato	-5.45 (-8.67)***	2.85 (5.56)***
Wheat	1.76 (6.91)***	3.76 (9.13)***
<i>Retail Price</i>		
Onion	9.12 (8.90)***	-1.97 (-3.76)***
Potato	-10.08 (-23.88)***	7.21 (16.26)***
Rice	-0.98 (-2.96)***	0.69 (1.25)
Tomato	-6.84 (-9.88)***	3.45 (5.70)***
Wheat	1.66 (5.52)***	3.25 (6.88)***
<i>Price Wedge</i>		
Onion	0.97 (3.54)***	-0.29 (-0.71)
Potato	-1.26 (-8.42)***	0.62 (2.32)**
Rice	-1.26 (-10.22)***	-1.98 (-9.16)***
Tomato	-1.39 (-4.94)***	0.60 (1.61)
Wheat	-0.11 (-1.56)	-0.51 (-4.12)***
<i>Mandi Arrivals</i>		
Onion	-146.34 (-0.12)	-2846.07 (-1.22)
Potato	2988.68 (2.66)***	-738.95 (-0.54)
Rice	2721.95 (6.49)***	758.02 (1.53)
Tomato	-27.96 (-0.11)	-626.24 (-1.25)
Wheat	1374.42 (1.05)	-8050.86 (-0.38)

Note: The figure denotes the difference in the mean value of the commodity prices and arrivals. A positive and significant value implies that the prices — retail and wholesale, price wedge, and *mandi* arrivals in the second period are significantly lower than in the first period. The figure in the parentheses denotes the *t*-value. ***, **, and * denote significance of the difference at 1%, 5%, and 10%, respectively.

*Severity of the COVID-19 Pandemic, Regional Heterogeneity, and Food Insecurity 465*Table A3. Variance ratio *F*-test results of differences in variances.

	July 2019 – March 2020 Compared with July 2020 – March 2021	April–Jun 2020 Compared with April–June 2021
<i>Wholesale Price</i>		
Onion	1.65 (2.72)***	1.45 (2.10)***
Potato	0.52 (0.27)***	1.14 (1.29)**
Rice	0.91 (0.83)**	1.25 (1.57)***
Tomato	0.74 (0.54)***	1.50 (2.24)***
Wheat	1.08 (1.18)**	1.08 (1.18)
<i>Retail Price</i>		
Onion	1.73 (2.99)***	1.22 (1.49)***
Potato	0.55 (0.30)***	1.12 (1.25)*
Rice	0.88 (0.77)***	1.09 (1.20)
Tomato	0.69 (0.47)***	1.34 (1.79)***
Wheat	1.05 (1.09)	1.19 (1.42)***
<i>Price Wedge</i>		
Onion	1.34 (1.79)***	1.04 (1.07)
Potato	0.79 (0.63)***	1.63 (2.66)***
Rice	0.43 (0.18)***	0.37 (0.14)***
Tomato	0.85 (0.73)***	1.49 (2.21)***
Wheat	0.73 (0.53)***	0.72 (0.52)***
<i>Mandi Arrivals</i>		
Onion	0.96 (0.92)	0.64 (0.41)***
Potato	1.26 (1.59)***	1.02 (1.04)
Rice	1.53 (2.35)***	1.29 (1.67)***
Tomato	0.81 (0.66)***	0.68 (0.46)***
Wheat	1.21 (1.47)***	0.55 (0.30)***

Note: The figure denotes the ratio of the standard deviation of the commodity prices and arrivals. A value greater than 1 and significant implies that the variation in prices and *mandi* arrivals in the second period is significantly lower than the variation in the first period. A value less than 1 and significant implies that the price and *mandi* arrivals variability in the second period are higher. The figure in the parentheses denotes the *F*-value. ***, **, and * denote significance of the difference at 1%, 5%, and 10%, respectively.

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Chapter 3.4

Disproportionate Effect of COVID-19 on Women¹

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Abstract

Similar to past pandemics, the effect of COVID-19 too is not gender-neutral. The disproportionate physiological and psychological impacts of the COVID-19 pandemic on females have affected their personal and professional spheres. This chapter calls attention to the physical and mental health risks that women faced and the consequences that they suffered. The global economic downturn caused by COVID-19 — a “Shecession” — led to inordinate job losses for females. The rationale behind this has been explained in terms of “care economy” and

¹This chapter benefited from the suggestions received from Anil Deolalikar, Anindya Chakrabarti, and Manisha Rathi.

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“motherhood penalty.” We perceive that among the long-standing gender inequities, it is important to have an encouraging outlook and thus put forward positive impacts of this pandemic on women at micro and macro levels. Finally, the chapter discusses policy implications to better handle future pandemics, along with research opportunities therein.

Keywords: gender effects; COVID-19; pandemic

1. Introduction

A disease is categorized as a “pandemic” when it can affect all (*pan*) people (*demos*); however, the effects of the disease may not be the same. In the past, pandemics have had disproportional impacts on men and women; likewise, the effects of the COVID-19 pandemic are not gender-neutral. Academic literature suggests that during COVID-19, while men faced higher mortality and morbidity (Connor *et al.*, 2020; Richardson *et al.*, 2020), women faced increased domestic violence (Aguero, 2021), increased informal care responsibilities (Zamarro and Prados, 2021), higher job losses (Albanesi and Kim, 2021), teenage pregnancy (UNFPA, 2020), and increased mental health issues (Paudel, 2021). The disparity in the effects calls for different remedies, and thus, policymakers need to comprehend gendered impacts of the pandemic. This will help them to handle the current recurring crisis more efficiently and be better prepared for future challenges that may arise.

As much as it is important to consider gendered impacts, it is also salient not to generalize the problems that women worldwide are facing during the ongoing pandemic. Macro-level observations suggest that women in developing countries are experiencing increased domestic violence due to closer proximity, while the women in developed nations are reporting exacerbated mental health issues. Drilling down further, on the one hand, a segment of working mothers in urban areas is observing increased workload due to the closure of education and childcare centers; on the other hand, rural women are suffering from reduced access to basic health and hygiene. To add to the variation, there is a new gap of psychological distress reported by mothers of school-age and younger children

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compared to women who don't have kids (Zamarro and Prados, 2021). Evidently, the pandemic's impact on women encompasses various dimensions of psychological, economical, and sociological problems. Considering that these problems are not independent of each other, it is important to apply a demography-based lens to comprehend a holistic picture.

Beyond the pandemic, and also in general, women face greater professional challenges due to their biological structure, which makes them physically weaker than men, as well as due to societal norms that discriminate against women. Adding to the woes, there exists a "motherhood penalty" that restricts the occupation choices of females (Kleven *et al.*, 2019). Moreover, in developing countries, women also face a "marriage penalty," as cultural restrictions are severe for married women as compared to their unmarried counterparts (Afridi *et al.*, 2020; Chatterjee *et al.*, 2015; Chaudhary and Verick, 2014; Sudarshan and Bhattacharya, 2009). Both these penalties interrupt women's labor market participation.

Furthermore, in the light of health impacts, it has been found that despite the use of more preventive care, women, on average, report more mentally and physically unhealthy days per year as compared to men (Connor *et al.*, 2020; Frieden *et al.*, 2013). Women also have worse outcomes for existing health conditions, including diabetes (Roche and Wang, 2013), asthma (Frieden *et al.*, 2013), and myocardial infarctions (Mehta *et al.*, 2016). Women experience more distress from stressful life events, especially when it is affecting others (Kessler and McLeod, 1984; Kniffin *et al.*, 2021; Paudel, 2021). These studies signal that, based on intrinsic and extraneous reasons, females may be bearing intensified mental and physical health issues during the COVID-19 pandemic. The effect of these issues can be witnessed in their professional spheres.

The disproportionate impact of this pandemic has brought forth the classic debate of "grotesque" gender inequalities (Gross, 2020). The employment losses of women and men during COVID-19 differed from earlier recessions (Albanesi and Kim, 2021). Unlike the countercyclical nature of women's labor supply in past recessions, COVID-19 has caused women more job losses. Moreover, an increase in the existing sources of conflict related to male partners' insufficient parenting support during the pandemic has been observed (Calarco *et al.*, 2020), which may cause

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mothers to be more likely than fathers to exit their jobs and become unemployed (Landivar *et al.*, 2020). Other studies also hint at inequality in the impact of the pandemic among working women; for example, Barkowski *et al.*, (2021) find that women with children worked for longer hours as compared to those without children.

Finally, in contrast to many studies showing an adverse impact of the pandemic on women, we also manifest that all is not lost and there seems to be still some light at the end of a gender-distorted global tunnel (Kniffin *et al.*, 2021; Rathi *et al.*, 2021). There are positives too that have come out of this pandemic, especially for women. For instance, it is now being recognized that a set of feminine traits and values can be effective in crisis management and moral decision-making (Tinghog *et al.*, 2016), particularly about health issues (Flynn *et al.*, 1994). Research on politics and gender shows that unusual environments can activate stereotypes of women as trustworthy, honest, and competent lawmakers in public health and, while doing so, can harness increased public support for female political candidature (Piazza and Diaz, 2020). Positive media reports of response to the pandemic from female leaders worldwide provide further reason to assure an increase in the political support for female candidates.

In this chapter, we bring together literary research that highlights the differential impact of COVID-19 on women from different perspectives. The rest of the chapter proceeds as follows. In Section 2, we obtain a macroeconomic perspective to explain how the COVID-19 induced recession is different from previous recessions. In Section 3, we explain the impacts of COVID-19 on women in households. In Section 4, we describe the health issues faced by women due to the pandemic. Section 5 describes the effect of the pandemic on women in terms of limited academic research. Finally, we describe the positive impacts of COVID-19 on women in Section 6 and conclude with ideas for future pandemic research in Section 7.

2. The COVID-19 Pandemic: A “Shecession”

2.1 Global perspective

The global downturn caused by COVID-19 is termed “shecession” (and not recession) because of its severe impact on women compared to men

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(Fabrizio *et al.*, 2021). Typical recessions affect manufacturing and construction sectors, where men's employment is concentrated. The COVID-19 pandemic, because of the nature of the virus, affected jobs which were concentrated in social sectors.² As of 2019, in the US, 66% of the total female workers were employed in social sectors (Alonso *et al.*, 2019). Therefore, a major reason for this pandemic to be termed as shecession is to do with industries focused on female-centered jobs and how badly these industries got affected.

A study covering the period 1962–2014, by Doepeke and Tertilt (2016), shows that men's jobs are focused on sectors that have cyclical exposure. Women's employment, on the contrary, is countercyclical, as they increase their labor supply to compensate for men's job losses in a recession (Albanesi, 2019; Coskun *et al.*, 2020). This pandemic is labeled "shecession" because, unlike previous recessions that typically affected men more than women, many studies provide evidence that this pandemic has large negative effects on women's labor market outcomes (Adams-Prassl *et al.*, 2020; Couch *et al.*, 2020; Forsythe *et al.*, 2020; Yasenov, 2020).

To pin down the reasons for the falling female wages and jobs, one needs to assort occupations. We generate a framework inspired by Albanesi and Kim (2021) that classifies jobs as inflexible or flexible based on the option to work remotely and high-contact or low- contact depending on the physical proximity to other people. For example, a nurse's job in a hospital is high-contact due to closeness with people and is inflexible as it cannot be done from home on a phone or computer. Table 1 shows females' share in these four different categories of occupation using Current Population Survey (CPS)³ in February 2020. Due to the nature of the pandemic, the jobs most affected are the ones that are inflexible and

²Social sectors, as defined by Shibata (2021), are those industries where output requires interpersonal interaction to consume, e.g., hospitality and tourism, air transportation, and veterinary services.

³The Current Population Survey (CPS), sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics (BLS), is the primary source of labor force statistics for the population of the United States.

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Table 1. Females' share in different types of occupation.

	High-contact	Low-contact
Flexible	76%	50%
Inflexible	73%	19%

Source: CPS (February 2020).

require high contact, and it can be seen in Table 1 that women overrepresented this category.

The inflexibility or non-telecommutable nature of female jobs became a major reason for the decline in women's jobs during COVID-19. Using American Time Use Survey (ATUS) data in 2017 and 2018, Alon *et al.*, (2020a) find that 28% of male workers as compared to 22% of female workers are employed in these highly telecommutable occupations. These numbers suggest that during the crisis, in terms of their occupations, more men than women could easily adapt to the changing work environment.

The question now bothering the world's economists is whether jobs lost will be restored and employment will return to pre-pandemic levels. Albanesi and Kim (2021) conjecture that if the recovery from the pandemic is associated with a rebound of female participation to pre-pandemic levels, the rebound in aggregate employment may be faster compared to recent cycles. Our understanding after studying recessions in the recent past has shown that pandemics are generally followed by jobless recoveries, and employment in labor markets has struggled to regain pre-recession levels. While those are the concerns at the global level, as we will study in the next section, the issues in developing countries, such as India, are a little different.

2.2 India-specific perspective

India imposed one of the strictest lockdowns in the world to prevent the spread of COVID-19.⁴ Restricted movement during lockdown meant that many could not go out for work, and employees in many sectors were

⁴<https://covidtracker.bsg.ox.ac.uk/stringency-scatter>.

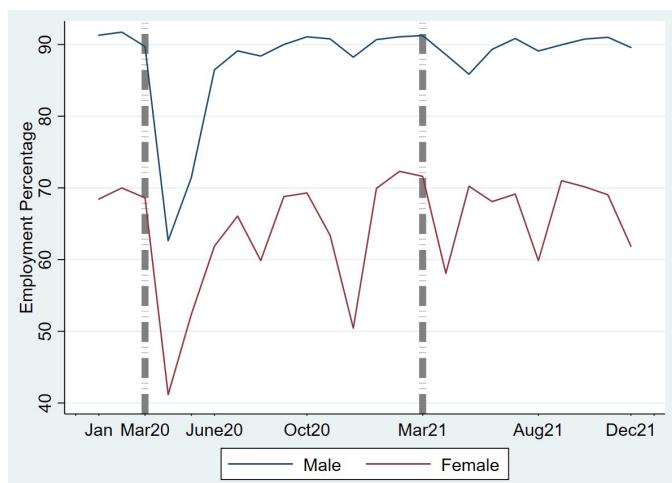


Figure 1. Percentage of male/female (age 15 years or more) in the labor force employed from January 2020 to December 2021. Vertical lines indicate the starting of the first and second waves of COVID-19 in India on March 2020 and March 2021, respectively.

Source: CMIE CPdx.

either laid off or were sent on leave without pay. To study the inordinate impact of the pandemic on employment in India, we use monthly household panel data available in the Consumer Pyramids database (CPdx) provided by the Centre for Monitoring the Indian Economy (CMIE).⁵ We study the change in employment percentage of all eligible men and women in the labor force from January 2020 to December 2021. As shown in Figure 1, both first and second waves of COVID-19 that started in March 2020 and March 2021, respectively, was followed by a dip in employment percentage. We find that while the percentage of employed men mostly recovered after the culmination of both COVID-19 waves, the female employment percentage on average is yet to get back consistently to pre-pandemic levels.

⁵Consumer Pyramids dx comes from Consumer Pyramids Household Survey. It provides anonymized record-level data at the level of individual households and members of households. The service delivers data collected from an all-India representative sample of over 170,000 households. This is a panel sample that is surveyed repeatedly over time.

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Unsurprisingly, like the rest of the world, the impact of COVID-19 in India, too, is gendered. Our analysis is supported by recent literature. For example, Kesar *et al.* (2021) use phone-based survey data from 12 Indian states to find that women, especially in rural areas, were more likely to lose jobs compared to men. Chiplunkar *et al.*, (2020), using job postings on an employment portal (Shine.com), find a big contraction in hiring in the early months of the pandemic in India. They find that advertisers posted fewer jobs in female-dominated occupations, and this contraction in hiring was mostly for young, less-educated female job seekers.

Ironically, on the one hand, women suffered disproportionately more job losses; on the other hand, hazardous, risky, and stigmatized jobs were exclusively handled by females (Deshpande *et al.*, 2020). All frontline health workers that form the backbone of the primary healthcare system in India — Accredited Social Health Activists (ASHA), auxiliary nurses and midwives (ANMs), and *anganwadi* workers (Integrated Child Development Scheme or ICDS workers) — are women.

In the last two decades in India, we see that though the gaps between men and women in educational attainment have narrowed, those in labor force participation have widened (Deshpande *et al.*, 2020). Did the pandemic act as a catalyst in worsening this situation? To inquire this, we study how labor force participation rate (LFPR) and working population ratio (WPR) were affected by COVID-19. Using the Periodic Labour Force Survey (PLFS) 2019–2020,⁶ conducted by the National Statistical Office in India, we aggregate data at the quarterly level to study the impact of COVID-19⁷ from the first quarter (Q1) of 2020 (January 2020 to March 2020) to the second quarter (Q2) of 2020 (April 2020 to June 2020).⁸ As shown in Figure 2, compared to males, the percentage decrease in LFPR

⁶The Periodic Labour Force Survey (PLFS) was designed with two objectives in the measurement of employment/unemployment. The first objective was to measure the dynamics of labor force participation and employment status for only the urban areas. The second objective was to measure the labor force estimates on key parameters in both usual status (ps +ss) and current weekly status for both rural and urban areas.

⁷On 22nd March 2020, the Government of India announced a strict lockdown. The 68-day, four-phased lockdown started from March 24 to May 31, 2020 to deal with COVID-19.

⁸Since the last PLFS survey report is available only till June 2020, we can study the impact of only the first wave of COVID-19.

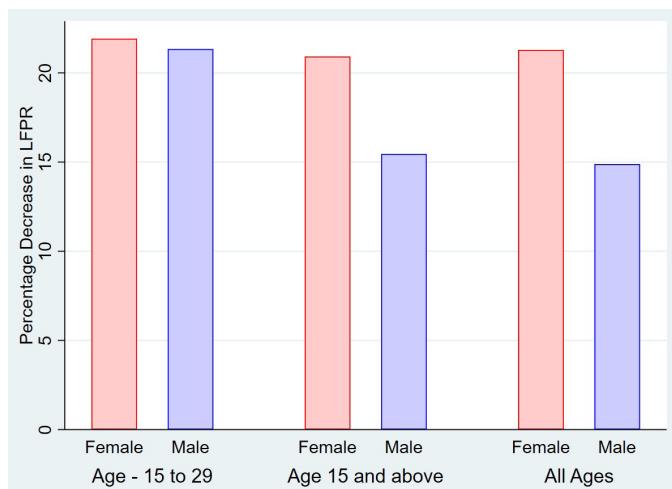
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Figure 2. Percentage decrease in labor force participation rate from Q1 (January 2020 to March 2020) to Q2 (April 2020 to June 2020) for males and females across ages in urban India.

Source: PLFS (2019–2020).

is higher for females from age 15 to 29. This difference becomes even more prominent when we consider all ages. Similarly, when we look at the change in WPR from Q1 to Q2 of 2020, we find a stark difference between males and females for ages 15 and above (see Figure 3). This change in women's employment indicates that the pandemic indeed acted as a catalyst in an already frail situation.

3. Impact of COVID-19 on Society

Women own the greater responsibility of caregiving to housemates in a household. They fulfill this responsibility either by themselves or with the support of domestic help. However, the involvement of other housemates — typically males and young kids remains limited. Since curbing COVID-19 required social distancing, the offices and schools were closed for physical activities. It caused a double blow for women — housemates were confined at home, whereas house helpers were not allowed in the home. Moreover, other external help, such as childcare

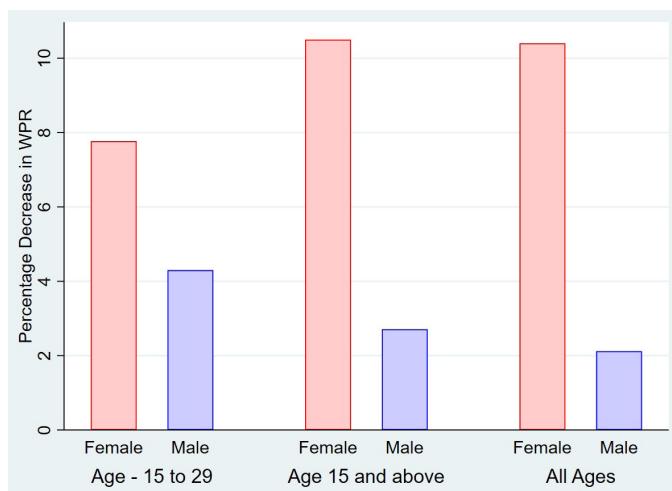


Figure 3. Percentage decrease in working population ratio from Q1 (January 2020 to March 2020) to Q2 (April 2020 to June 2020) for males/females across ages in urban India.

Source: PLFS (2019–2020).

facilities, were closed, which further increased females' responsibility toward kids at home (Alon *et al.*, 2020a). Though there was increased participation from men in household work and childcare duties during lockdowns, most of the burden fell disproportionately on women (Farre *et al.*, 2020).

3.1 Care economy

Globally, women are responsible for 75% of the unpaid care and domestic work in communities and homes every day (Moreira da Silva, 2019). According to the International Labor Organization (ILO), women around the world, on average, perform 4.5 hours of unpaid care work every day, whereas men perform 1.5 hours (Pozzan and Cattaneo, 2020). This unpaid care work is referred to as the care economy, the reproductive economy, or the core economy by different researchers (Power, 2020). The onset of

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COVID-19 has increased the burden of unpaid care work that was already shouldered by women across the world.

In the face of a shock to the demand for home childcare, the literature suggests the persistence of an unbalanced division of childcare within couples, characterized by women specializing in caring activities regardless of changes in their employment status. For example, Sevilla and Smith (2020) find that when both partners work from home, the share of the additional childcare done by women is 65.5% as compared to 59.2% of childcare done before COVID-19.

Collins *et al.* (2021) assess how heterosexual, dual-earner married couples with children have adjusted to COVID-19. They find that mothers with school-going or young children have reduced their work hours up to five times more than fathers. Consequently, the gender gap in work hours has increased by 20–50%. In fact, the gender gap exists even if we control for heterogeneity in job characteristics, indicating that other social factors play a role (Adams-Prassl *et al.*, 2020).

By now, we know that both men and women lost jobs during COVID-19's first wave. We have also shown that, proportionally, women lose more jobs than men. Ideally, if people lose their job, they should be more available for additional work. Astonishingly though, as per the PLFS survey, in India, when respondents in different statuses of employment were asked if they would be available for additional work, women responded as being less available than men. As we show in Figure 4, the available number of hours for additional work by men increases by 48.48% (13.2 to 19.6) from Q1 to Q2 of 2020 in the "all" category. Compared to that, the available number of hours for females increases only by 13.6% (14.7 to 16.7).

A natural explanation for the lower number of available hours can be the increased additional unpaid care and domestic work by females. Thus, it is the increased household responsibility that forbids women to take up extra work in the job market. An important point to note is that unpaid "reproductive labor," which includes cooking, caring, and cleaning, is far more time-consuming and effort-demanding in India, as compared to what is described in the literature from the Global North (Deshpande and Kabeer, 2021).

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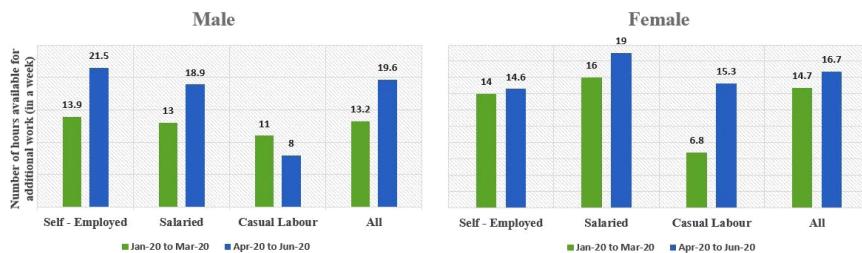


Figure 4. Average number of hours available for additional work by workers in different statuses of employment in urban India.

Source: PLFS (2019–2020).

3.2 Motherhood penalty

In both emerging and advanced economies of the world, there is a substantial “motherhood penalty” that affects women before, during, and after pregnancy (Albanesi and Kim, 2021). The penalty comprises occupational choices and labor supply on intensive and extensive margins (Kleven *et al.*, 2019), and all these begins well before women think about bearing children (Adda *et al.*, 2017). Heggeness (2020) uses the COVID-19 shock as a natural experiment to explore the life of working mothers when external support didn’t exist. She finds a unique juggling act by working parents, wherein those mothers who continued working increased their working hours⁹ while many others lost jobs.

Couch *et al.* (2021) observe a widening of the male–female gap in the employment-to-population ratio. The gap has widened for women with school-age children but not as much for women with younger children. Waldfogel (1998) calls this as “family gap” based on the wage differential between women with and without children. Over the past few decades, as the gender gap has been narrowing, the family gap has been widening. Brodeur *et al.* (2021) observe dwindled employment opportunities for women with school-age children during the pandemic. Researchers have attributed most of these reductions in women’s employment to additional childcare responsibilities, also termed the “COVID motherhood penalty.”

⁹Driven by fathers losing their jobs or reduction in their work hours.

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To identify the impact of this increased unpaid work on the paid work hours, we check out the change in percentage distribution of work hours from Q1 to Q2 of 2020 in India. Figure 5 shows that women who worked for less than 12 hours in a week have increased from 1.3% in Q1 to 3.4% in Q2 of 2020, while women who worked for 48–60 hours in a week reduced from 38.9% to 19.9% as COVID-19 hit India. Thus, the figures glaringly highlight the reduction in the labor force participation rate by women.

Owing to the substantial cost of bearing children for women's careers, an important question for investigation could be to quantify the magnitude of these costs, and also, how they decompose into lost earning opportunities, loss of skills during interruptions, and lower accumulation of experience. Thus, there are lots more that can be done in this space.

3.3 Domestic violence

International organizations and scholars have argued that lockdowns increase violence against women (Bradbury-Jones and Isham, 2020; Peterman *et al.*, 2020; UNFPA, 2020; Van Gelder *et al.*, 2020). This argument is based on recent scholarship suggesting that intimate partner violence (IPV) increased during past epidemics (Durevall and Lindskog, 2015; Roesch *et al.*, 2020). Domestic violence is also associated with economic downturns in both low- and middle-income countries (Buller

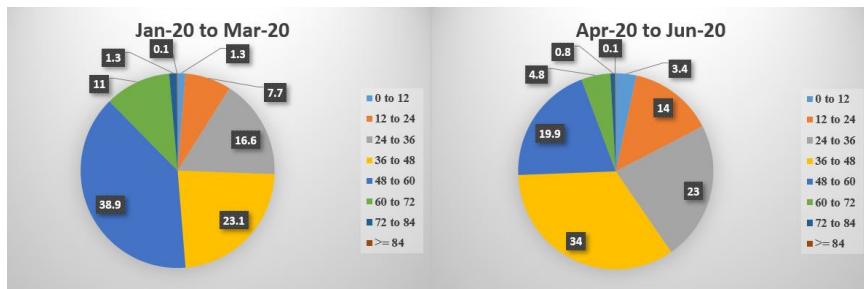


Figure 5. (Color online) Percentage distribution of the number of hours worked by urban females in a week before and after COVID-19.

Source: PLFS (2019–2020).

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et al., 2018; Cools and Kotsadam, 2017) and advanced economies (Van der Berg and Tertilt, 2012).

Incidents of gender-based violence (GBV) and IPV increased globally during the Zika (2016) and Ebola (2014) outbreaks (Davies and Bennett, 2016) and are escalating during COVID-19 (Connor *et al.*, 2020). Leslie and Wilson (2020) document the pandemic's impact on police calls for service for domestic violence and find that the pandemic increased domestic violence calls by 7.5% during March–May of 2020, with effects concentrated during the first five weeks after the lockdown began. According to UNFPA (2020), 15 million additional instances of GBV will occur globally every three months while stay at home restrictions are in place. These numbers are especially concentrated in developing countries, where people live in close proximity, and because of the lack of space in homes, pandemics can exacerbate domestic violence (Aguero, 2021; Alon *et al.*, 2020a; Brown *et al.*, 2020).

4. Health Risks for Women

4.1 Physical health

It has been well established that men suffer from greater morbidity and mortality once infected with SARS-CoV-2 (Connor *et al.*, 2020). But health risks, both physical and mental, faced by women during COVID-19 are equally brutal, if not less. As per the U.S. Census Bureau,¹⁰ in 2020, women are concentrated in roles that have high proximity and prolonged contact with the patients. According to Ellington (2020), pregnant women infected with the virus are at greater risk for severe illness, including intensive care unit admission and increased risk of hospitalization and mechanical ventilation. Additionally, there have been increased cesarean section among COVID-19-positive patients, which are often performed before term, increasing the risk and complications for both the neonate and the mother (Della Gatta *et al.*, 2020; Matar *et al.*, 2021). Furthermore, it was found that lactating and pregnant women are at increased risk of

¹⁰<https://www.census.gov/data/tables/time-series/demo/industry-occupation/median-earnings.html>.

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exclusion from clinical trials and thus may not be receiving precise COVID-19 medications (Connor *et al.*, 2020).

4.2 Mental health

Apart from the physical issues, there are many mental health issues faced by women during the pandemic. Sociological research on women's roles hypothesizes several sources of stress: lack of social support, empathic vicarious stress, workforce participation, caregiving responsibilities, and parenthood (Thomas, 1997; Williams and Kurina, 2002). Follow-up studies demonstrate that greater dissatisfaction with social roles correlates with increased levels of stress in women (Sumra and Schillaci, 2015; Thomas, 1997). The female gender and the younger age have both been associated with worse psychopathology during COVID-19 (Maffly-Kipp *et al.*, 2021). Women's mental health was worse than men's, as women were more concerned about getting and spreading the virus and women recognized the virus to be more lethal and widespread than men (Etheridge and Spantig, 2020; Oreffice and Quintana-Domeque, 2021; Paudel, 2021).

Women turned out to be more pessimistic about the present and future state of the UK economy, as calculated in terms of their forecasted future and contemporaneous unemployment rates (Oreffice and Quintana-Domeque, 2021). One-third of US women encountered cancelations or delays in sexual and reproductive healthcare.¹¹ Women refrained from visiting medical stores and health facilities due to movement restrictions or fear of COVID-19 exposure. According to UNFPA (2020), if COVID-19-related disruption and an average lockdown continue for six months, around 47 million women in 114 low- and middle-income countries will be unable to use modern contraceptives.

The association between the pandemic and mental health is more pronounced among individuals staying at home, which includes a large section of women who are more anxious and emotionally unstable (Paudel, 2021). The effects of poor mental health of parents have also been seen to trickle down to their next generation. Farahati *et al.* (2003) find that parents' mental

¹¹ <https://www.census.gov/data/tables/time-series/demo/industry-occupation/median-earnings.html>.

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illnesses increase the probability of high school children dropping out and have more consistent negative effects. These indicate dire repercussions of the pandemic on women's health and their dear ones on multiple fronts.

5. Women in Academia

The underrepresentation of women in academia is well established (Deryugina *et al.*, 2021). Specifically, in the fields of mathematics, physics, and computer science, there exists considerable heterogeneity, with women representing only 15% of authors (Huang *et al.*, 2020). Before the pandemic, women represented about one-third of all full professors in the US and an even smaller proportion in Canada and Europe.¹² Moreover, women received fewer grants, published fewer articles, and were less likely to be promoted or granted tenure than men (Hechtman *et al.*, 2018; Holman *et al.*, 2018; Huang *et al.*, 2020).

The spread of COVID-19 and subsequent measures, such as school closures, have, in all likelihood, exacerbated these gaps (Deryugina *et al.*, 2021). An interesting study by Amano-Patino *et al.* (2020) finds that out of 647 authors who have contributed to COVID-19-related research so far, only 12 mid-career female authors have contributed to the data set of papers (NBER, CEPR, and CEPR COVID Economics). The irony of the matter is jarring, as females, ideally, are best placed to present COVID-19-related research because of their emotional connection and understanding of the fellow feelings of the other affected females. But the reason for their inability to do so can be elucidated by the terms already explained above, namely care economy, gender norms, and motherhood penalty (Ceci *et al.*, 2014; Cheng, 2020).

6. Positive Impacts of COVID-19 for Women

A positive outlook may prove essential not only for improving long-standing gender inequities and enhancing development but also for assuaging the disproportionately allocated hardships of COVID-19

¹²<https://www.catalyst.org/research/women-in-academia>.

(Piazza and Diaz, 2020). We find evidence of the positive impacts of the pandemic on women in the world both at the macro and micro levels.

6.1 Macro perspective

Globally, several female leaders (e.g., Angela Merkel, Jacinda Arden, Tsai Ing-wen) are known to have tackled COVID-19 effectively. Their leadership positions enabled them to combine their power and feminist characteristics in addressing pandemic situations credibly. This, in turn, might have positively impacted several other women worldwide with a distant assurance of being important. Though few researchers have indicated their preference for a masculine leader in times of crisis (Van Vugt *et al.*, 2008), the literature on gender stereotypes asserts that female politicians are perceived to be more empathetic, compassionate, honest, trustworthy, and liberal than their male counterparts (Alexander and Andersen, 1993; Dollar *et al.*, 2001; Funk *et al.*, 2021; Huddy and Terkildsen, 1993; McDermott, 1997; Morgan, 2015; Piazza and Diaz, 2020).

According to researchers of political economics, male politicians are perceived to be proficient policymakers in the “high politics” areas of the economy, agriculture, crime, employment, fiscal affairs, and security (Herrnson *et al.*, 2003; Lawless, 2004), while female politicians are considered to be efficient policymakers in the “low politics” areas of family, education, and health (Alexander and Andersen, 1993; Herrnson *et al.*, 2003; Huddy and Terkildsen, 1993; Leeper, 1991). However, a keen look at research in psychology indicates that females have more attentive communication styles (Campbell, 2013), better conscience (Schmitt *et al.*, 2008), and higher responsiveness to risk (Eckel and Grossman, 2008). Taking all these feminine qualities together, along with the performances of leading female policymakers during the COVID-19 pandemic, there is a possibility of the feminine style getting recognized in the future for dealing with crises (Kniffin *et al.*, 2021).

6.2 Micro perspective

At the household level, the pandemic has ushered in a new positive in terms of fathers’ increasing initiative to help their counterparts in child-care. In some cases, COVID-19 has caused men to either lose their jobs

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or opt for the telecommuting option; on the contrary, the females of the family have to go out for work. In such families, there is an inescapable choice for men to learn and provide childcare (Alon *et al.*, 2020b). On the same lines, many businesses are becoming aware of childcare needs and rapidly adapting to flexible work schedules and work-from-home options (Alon *et al.*, 2020b).

As a result of this change, many couples are better able to manage their daily routines via division of tasks (Sevilla and Smith, 2020). An important part of this change is that it is not momentary but sustained. In developing countries like India, we find a sharp increase in the time spent on the household by men during lockdown (see Figure 6) in April–May 2020. As the economy opened, we can see a fall in this time spent on the household, but it never goes back to the pre-pandemic level.

Even after two years of the pandemic, the time spent on homely affairs by men is consistently higher than what it used to be before COVID-19. Thus, there seems to be a behavioral shift. With such a shift, women can be more confident about the help from their housemates,

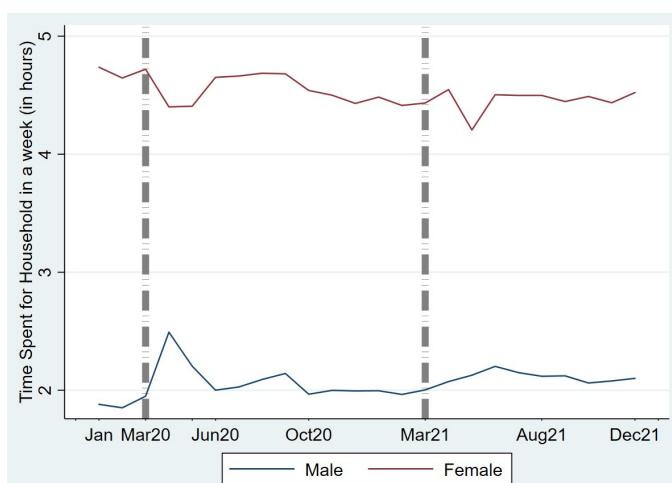


Figure 6. (Color online) Average time spent on work done for the household and its members in a week by males and females (with age greater than or equal to 12 years) from January 2020 to December 2021. Vertical lines indicate the starting of the first and second waves of COVID-19 in India on March 2020 and March 2021, respectively.

Source: CMIE CPdx.

particularly husbands. Furthermore, as the growing children witness this behavioral shift and learn from it, there will be an overarching impact on gender socialization in the long run, which for women is something to cheer about!

6.3 Case study

We share a small case study to show how, though indirectly, the pandemic positively impacted pregnant females in India.

Policymakers in the developing world wish to use the widespread availability of mobile phones to reduce the information asymmetry between the rich and the poor. While a plethora of information is being shared on the supply side, it is becoming imperative to understand whether the recipients are benefiting from the information. A prominent example is the Indian government's introduction of pre-recorded messages at the beginning of every phone call made by anyone within India after the COVID-19 pandemic began. Sadish *et al.* (2021) show that these messages lead to less engagement and less reduction in misinformation.

This indicates that there are frictions involved in engaging with technology. To examine the potential frictions, Rathi *et al.* (2021) leverage the exogenous shock caused by COVID-19's first-wave-induced lockdown in India. The study uses a unique database comprising two million call records of mobile-phone-based healthcare interventions for underprivileged pregnant women in India. Women enrolled in the program receive free mobile voice calls that provide critical and timely healthcare information at different stages of pregnancy.

Underprivileged females who otherwise used to work as daily wagers or as housemaids had either lost their jobs or had to work at reduced wages during the pandemic. Lower wages and the lockdown induced by pandemic appeared as a boon for technology engagement. Lower wages meant a lower opportunity cost of time to engage with technology, and lockdown meant that females who didn't own a mobile phone could use their husband's phone to engage with technology. As a result, it was found that the percentage duration of the informative calls heard by females significantly increased during COVID-19 (first wave). Females who listened to the calls for a longer duration would have benefited more from

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the program in managing their pregnancy. Thus, COVID-19 turned out to be a cause of increased technology engagement that helped the poor.

7. Discussion

It has become imperative for policymakers across the world to understand that the effects of pandemics, from Black Death in 1346 to COVID-19 in 2019, have never been gender-neutral. Governments need to understand the demographics and social fabric of their country while handling future pandemics. For example, a unique feature in India related to female labor force participation is the U-shaped relationship between women's LFPR and their education (Bardhan, 1985), as shown in Figure 7. This means participation rates are highest among illiterate women; it declines as women get primary and secondary levels of education to rise again as women gain tertiary education (Mammen and Paxson, 2000; Olsen and Mehta, 2006).

Two things can explain the downward-sloping part of the U-shaped relationship between female education and participation. First is the “Sanskritization” effect,¹³ wherein poorer, lower-caste households seek to signal improvements in their status by imitating the behavior of higher-status households (Kingdon and Unni, 2001). Second, as women get primary education, the household per capita income rises, and this income effect leads females to move out of the labor force to focus on their domestic responsibilities. Thus, the participation rates decline with rising income (Das *et al.*, 2015; Kapsos *et al.*, 2014; Srivastava and Srivastava, 2010). The upward-sloping part of the U-shaped relationship can be ascribed to the effects of “modernization” that brings on rising aspirations with rising education (Deshpande and Kabeer, 2021).

The presence of distinctive features like these makes it important for policymakers to pre-understand the country’s demography before counteracting future pandemics. Generic reactions to pandemics can badly affect

¹³The concept “Sanskritization” was first introduced by the famous Indian sociologist Prof. M. N. Srinivas. He explained the concept of Sanskritization to describe the cultural mobility in the traditional caste structure of Indian society in his book, *Religion and society among the Coorgs of South India*.

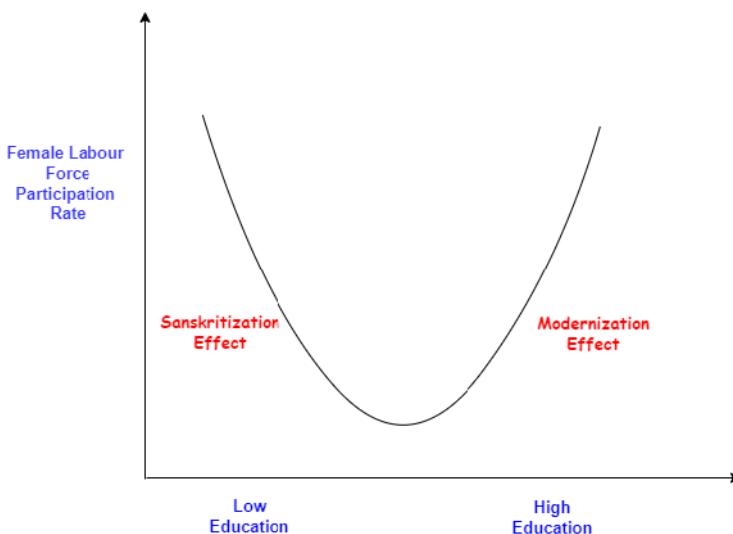
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Figure 7. U-Shaped curve between female labor force participation and education.

some sectors of society and put them on the back burner for a very long time, which we suspect will happen to many women across the world after COVID-19.

The purpose of this chapter is to highlight the inordinate issues faced by women during COVID-19. We bring together different pieces of academic literature from sociological, psychological, economic, and health backgrounds to indicate the differential impacts on women. Though social and psychological aspects have been well covered in literature, we feel that the facets of political, economic, and technological nature can be explored further. For example, it has been established that COVID-19 had gendered impacts and that females lost more jobs, but how much is the loss to society? Quantification of the loss to humankind when females are suddenly out of the workforce at the micro or macro level can be helpful to policymakers in the long run.

Additionally, we know that due to the nature of the COVID-19 pandemic, there has been a sudden increase in technology usage. The pandemic pushed females to become more involved in nourishing the care economy, which also meant that staying at home might have given them more access

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and time to use the technology. It needs to be studied what changes, positive or negative, this upsurge in technology usage has brought to women. On the political side, there is a huge opportunity to determine the magnitude of benefits that a country or region with female leaders as decision-makers brought to that place. Such research would pave the way for both voters and future legislators to decide who their leader should be in the future. In the end, though we tried to be comprehensive at best, we cannot promise that we have captured every aspect of the consequences for women; we rather wish that future researchers delve deeper into the nuances and explore more as the virus evolves with its variants across the world.

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