**Legality of Mandatory Vaccination**

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***Abstract****-Vaccination in India has been going for the past 60 years and is seen as a major part of the public health policy of independent India. Its ability to provide for an efficient and cheap form of preventive health care makes it the most viable option for a developing state such as India. However, in an effort to achieve total vaccine coverage, the government ends up forcing the vaccine without taking into account the objections raised by the general populace which leads to a reduction in the accountability of the government when faced with issues of vaccine related side effects. The government needs to provide for a better AEFI system which will help it in tracking vaccine coverage as well as provide for a vaccination data bank for safety and efficacy purposes.*

Key Words: forced care, AEFI, transparency, consent

Abbreviations: AEFI- Adverse Events Following Immunization, MMR- Measles, Mumps and Rubella

Introduction

Vaccination1 relies on what is known as ‘herd immunity’ i.e. if the number of vaccinated people is high, the number in itself acts as a barrier and reduces the chance of those people, who are for some reason not vaccinated, of getting infected. The herd immunity threshold depends on the infectiousness of the disease in question such as 72-88% for mumps and between 90-95% for Measles.2 A high rate of vaccination therefore protects the entire community which includes the unvaccinated as well as those on whom the vaccine fails to produce the desired effect.

While the Indian system has done a commendable job, there does exist a dark side to it. The issue has to be contextualized by looking at the history of vaccination in India during the rule of the British, since they were the ones who introduced modern vaccination during the early nineteenth century.

History of vaccination in India

Vaccination began with the discovery of the smallpox vaccine in 1796 by Edward Jenner and was within 4 years available in India. However, prior to the advent of the vaccine itself, inoculation practices were widely practiced in India as a form of defence against the dreaded disease.4 The Colonial government banned the concerned practice and introduced ‘trained vaccinators’ in order to tackle the disease. The vaccinators were to tour the territories and provide the vaccine for a small fee which was to be their primary source of income.5

It was only by the 1850s that the government provided for a fixed salary to the trained vaccinators in order to prevent them from charging exorbitant rates for vaccination.6 The government established centres to produce the vaccine within India in order to reduce the cost and the corresponding logistical problems in importing the vaccine from England.

Legal improvements albeit only on paper followed. The government initially passed the Vaccination Act of 1880 in Bengal which specifically outlawed inoculation and made it increasingly compulsory for children to be vaccinated.7 The British government also passed the Compulsory Vaccination Act in 1892 in order to effectively deal with the Smallpox epidemic making it the first instance of mandatory vaccination in the Indian subcontinent.8 However as previously stated, these acts were never implemented.

British reports from the mid-1800s to 1910 reflect a sharp distrust and conflict between the Western Colonial Science and the indigenous traditions. This can be reflected by the amount of trust the local population had in the Tikadaars (inoculators) despite the practice being banned by the British. The British government failed to take into account the distrust in which the invaders were held in India. Every effort of the British was seen as a way of counteracting the growing nationalistic spirit of India which was not adequately addressed by the rulers. The Little Dreyfus Affair of the 1890s further destroyed the credibility of the vaccine programme.9

Vaccine Production Centres

Vaccination manufacture in India began during the early twentieth century with the colonial government prioritising it on account of an outbreak of Cholera in 1896 and the subsequent establishment of the Haffkine Institute in 1899 concerning the production of the plague vaccine.10 Prior to that, the government had in established a production centre for the manufacture of smallpox vaccine in Shillong. There was establishment of a few more centres of vaccine production in Kasauli and Madras.11 However, the production in these centres was too low and suffered from an extreme dearth of funds which hampered the nascent immunization projects being undertaken by the various local governments.

The First World War coincided with the Influenza pandemic which killed millions of people all over the world including India. The 1919 act which has been seen as a major landmark from the point of view of devolution of powers from the centre to the state, was important in this regard as the task of health services which included vaccination against polio was transferred to the provincial governments. While the legal benefits of such an act cannot be understated, the provinces suffered from a severe dearth of funds and legislative will, leading to a poor immunization record and a continuous high death rate.

As with the First World War, the Second World War’s effects were severely felt in the field of health since the vaccine coverage went down drastically. The number of smallpox cases increased manifold with the number of people afflicted with the disease being more than what had been prevalent during the 1920s and 1930s. The Joseph Bhore Committee report of 1946 provided for a summary of the problems plaguing the public health system of India which included vaccine preventable diseases such as plague and smallpox. It stated that by the 1940s India had the highest number of people afflicted with smallpox.12 The report provided for a detailed list of the vaccine manufacturing centres in India and their functions. As per the report, it can be ascertained that the number of institutions dealing with vaccination research and production was extremely low as compared to the population which was required to be vaccinated.

Post-independence, the noticeable achievements of the Indian immunization programme have been the eradication of smallpox and polio by 1975 and 2012, the start of the Universal Immunization Programme in 1985 along with the creation of a National Vaccine Policy.

Legality of Mandatory Vaccination in India

While Health care in general is dealt with under the Directive Principles13, public health and sanitation come directly under the state list. Several judgements have reiterated the responsibility of the state government in this matter. But this does not mean that the Central government does not have a legislative duty to deal with such matters. Public health has always been a major concern for every government since it directly affects the people and through it the government, which so ever it may be. This can be showcased by a variety of acts passed by the Government since the times of the British to deal with the issue of vaccine preventable diseases:

* The Vaccination Act, 1880: The act specifically deals with prohibition of inoculation with a focus towards compulsory vaccination of children with the smallpox vaccine. It is a small act of 22 sections and allows for the selective application of the act in certain areas. In the areas where the act applies, non-vaccination without a sufficient cause allows for punishment under section 22.14

The act while putting an overarching emphasis on vaccination, does not properly regulate the role of vaccinators primarily the private ones.

* The Epidemic Diseases Act, 1897: This is a British era law which despite being a century old has a lot of relevance in the present times as can be observed by its application by several states even as late as 2009 when there was a possibility of an outbreak of Swine Flu.15 It provides for legal immunity to the person acting under the act. During the time period it was enacted, the act was seen as one of the most draconian acts in the health sector since it virtually allowed the government to do anything in the name of epidemic control. Measures included forcible segregation of affected persons, demolition of effected areas, banning of public gatherings which included festivals and much more.16 A major drawback of the act is the fact it does not proper explain the powers provided for to the authorities. The act is seen as being of a regulatory nature which deals only with situations post outbreak of an epidemic and there is no mention of any preventive measures to deal with the same.
* Government of India Act 1919: This act, regarded one of the most important in the political history of India was important for public health reasons since it devolved on the provincial governments, the responsibility of maintaining public health.17 The act included increased emphasis on smallpox vaccination by the governments.
* Drugs and Cosmetic Act, 1940: This act which has been amended several times deals primarily with quality control over the sale of drugs. The act encompasses vaccines by stating that they come under the category of ‘new drug’ and are thus liable under the provisions of the said act. It provides for a detailed procedure for clinical testing for the drugs which are being considered for public health purposes.

The legislation works in tandem with the guidelines provided for by the WHO regarding vaccines. Its importance is highlighted because of the fact that India is a major exporter of vaccinations and it becomes highly important to establish a proper quality control mechanism for the same.

* State acts
  + The Punjab Vaccination Act: the act is similar to the 1880 act and allows for vaccination to be done in children and states that no remuneration should be charged by public vaccinators while private ones may charge a fee as prescribed by the government.18 There is a provision granting powers to a superintendent to ensure proper coverage.

The act was corroborated by the ordinance of 1958 which repeals not only the 1880 act but also 5 other enactments.19

* + Madras Public Health Act, 1938: The act is important since it has recently come under the limelight due to the MMR (Measles, Mumps and Rubella) campaign of the government in Tamil Nadu, wherein there have been instances of parents refusing to get their children vaccinated. The act was enacted for making vaccination compulsory. Part II of the act deals with the issue of how to control the spread of a disease by preventing the infected person from not using public services such as the library, etc.20 Furthermore, it allows the magistrate, in case of an infected area to prevent the assembly of more than 50 people along with the concerned officers being given special powers to deal with the same.21 Chapter 8 deals with the prevention and treatment of such diseases. This act should be seen as a last resort since it provides wide ranging powers to the government authorities.22 However while the act may in itself be seen as a little harsh, one needs to take into account the fact that the act is applicable with places only where there is a high risk of an epidemic which could jeopardise public health of the concerned area, along with the possibility of it spreading even further.

The problem regarding the proposed applicability of the said act is because of a lack of public trust in the governmental vaccination program. This corroborated by a lot of unfounded rumours and well as a host of wide ranging powers (along with their misuse) tends to confound the problem making it an extremely difficult task for the state.

Present Scenario: Contextualising Trust Deficit within the sphere of Mandatory Vaccination

A high vaccination coverage rate does not necessarily mean that there is acceptance of the same. There has been an increased resistance to vaccination both by the educated as well as the uneducated class in areas where vaccination is easily available. To gauge the scope of the problem, one leads to take into account the health care providers dealing with vaccines since they are the ones who are responsible for improving the scope of programme.

The health care system in India has a vast but institutionally weak public sector and an upcoming private sector which provides for apparently better health care facilities. However, issues in the two sectors compound the public health problem. While the governmental sector suffers from an institutional and infrastructural weakness, the private health sector has in recent times been seen as existing for the sole purpose of profit.23 Their profit motive is seen as being a major source of scepticism for the population (exorbitant rates in health care costs create a trust deficit in the system). Since the health care coverage of the Indian system is weak, a massive push towards immunization which tries to cover remote areas, which have been traditionally ignored by the state, makes people sceptic about the intentions of the state, thereby making people hesitant towards vaccination.

AEFI and a substantial deficit in data collection: India has a relatively poor AEFI surveillance system. To put things into perspective, the AEFI system (Adverse Events following immunization) is highly important in order to monitor the effectiveness of a vaccine within the vaccinated areas. Increased surveillance, regular check-ups are some of the methods through which it should be maintained. The purpose of the AEFI system is to monitor the effectiveness of the vaccine along with keeping a constant check on the issue of whether there are any side effects to the same. Since the AEFI system is very weak, situations arise where all sorts of diseases and adverse effects following immunization are wrongfully blamed on the vaccine. This leads to a massive trust deficit and in the present digital age, information or rather misinformation travels very quickly. A lack of AEFI surveillance system makes the state unable to deal with post vaccination issues since there is no proper ground work to analyse the after effects of a vaccine. The MMR vaccine has remained in controversy ever since its very inception. It was criticised by Andrew Weikfield24 based on false reports and claims, leading to a severe trust deficit in the vaccine. The WHO has several releases asserting the importance and safe nature of the vaccine,25 as a form of damage control to prevent the erosion of public trust which despite its best efforts, did happen.

Furthermore, parents refute the vaccination requirement on two grounds:

* Quality of the vaccine: For which the government has to reiterate the approval of the vaccine from various National and international organisations.
* Quality of the government medical department injecting the same: The Indian health sector is plagued with the problem of a lack of trust in the government run vaccination programmes. This is due to the non-existence of an accountability mechanism against the state for any possible vaccine side effects thereby creating the impression that the state is above reproach in such matters.

However, on the same lines, governmental non transparency towards the vaccination program is a major problem. Vaccines usually come with a good reputation based on their efficiency and approvals from the WHO and other national bodies. The controversy surrounding the unethical conduct of vaccine trials(HPV) by the PATH organisation, without proper consent forms and the resultant deaths along with the government inaction in making the organisation culpable creates a scenario where the government run vaccine programmes lose their credibility26. This incidence highlights the fact that vaccine testing without proper consent is extremely problematic since the only way through which a state can justify mandatory vaccination is by claiming that the dose is beneficial and non-lethal (the claim itself getting nullified by such instances).

Mandatory Vaccination: The Road Ahead

From a legal point of view, the state has the right and duty to focus upon mandatory vaccination in the pursuit of achieving the betterment of its citizens. But such as argument in itself contradicts the stand of the state as vaccination is but a part of preventive health which requires the state to provide for a clean environment, drinking water, proper sanitation and in the nearby future clean air. Various judgements in several parts of the world are testament to the fact that the courts usually follow the utilitarian argument of focussing specifically on the benefits of the vaccine for the population as the most important factor in their being literally forced upon the population. As mentioned above, there have been instances of the Indian state itself using obsolete British era laws in order to get a legal backing for mandatory vaccination. While such a system does exist and to a certain degree work, there is a need to move away from it. Using the trust factor of a reliable vaccine as an argument to justify this policy of forced vaccination is extremely controversial and problematic.

School based immunization programme: Parental scepticism to a vaccine is a major issue reported by vaccinators as creating a lot of hurdle in immunization coverage. While the issue is valid, one needs to look at the reasons for the same. Even though there may be instances of misinformation, it can be said that the non-transparency of the state is the reason for such skepticism. While the Indian government has been constantly raising massive awareness campaigns for several vaccines, a lack of support from the educational sector hampers the same whom the researcher believes can be seen as the primary movers of an immunization programme. Schooling in India usually does not have a proper heath care system in place. Furthermore, there are instances of there not being a certified doctor on the premises who can counsel the parents regarding the better health care of their children. This creates an atmosphere where the students and their families face a serious dearth of knowledge concerning preventive healthcare. This gets compounded by a lack of intervention by the government at such institutions for dealing with such a knowledge and trust deficit along with the non-existence of a mechanism to adequately deal with parental concerns regarding the vaccination program. So when the government does a conduct a mandatory campaign drive, there arise issues due to a lack of parental consent for the same. One can say that a lack of effort by the government to properly publicise the vaccine and answer its various issues at a preliminary stage lead to a larger and much more negative problem during the implementation stage. Therefore, it is pertinent that the government work in tandem with the educational institutions to deal with the knowledge deficit and focus more on educating people about preventive healthcare and the role of vaccines in it. Parental interaction prior to the implementation vaccination programme will help reduce the lack of information and help the parents in making an informed decision.

Health facility based immunization programme: Most of the vaccination programmes in India are usually conducted with the help of dispensaries and primary healthcare centres which are supposed to be present in every town and village. But the process is impeded by a general lack of infrastructure as well as a dearth of personnel, especially in the rural and far off areas (areas which require the maximum amount of social engagement). Furthermore, the general neglect of the existing infrastructure makes people extremely hesitant in going to government run dispensaries, with a preference towards the private sector. However, while the preference towards the private sector is not bad per se, such an option does not exist for the people living in remote places as the sector does not have the outreach capabilities of the government. This system basically highlights the problems plaguing the Indian health care system in general. Thus in order to deal with such issues, it is high time that the governments both the centre and the state, increase their health budgets in order to achieve a better coverage rate. The spending which was 1% of the national budget has recently been increased to approx. 2.5%, which despite being a major achievement, falls short of what is being spent in other welfare states.27 Furthermore the state needs to focus on delivering qualitative healthcare at the existing healthcare centres in order to be viewed as a responsible trustee of public and specifically individual health (which can lead to better vaccination coverage).28

Is the Indian state allowed to act in a paternal manner and enforce such policies on the poor and illiterate population of India: As mentioned earlier, the vaccine testing conducted by the PATH foundation in India was more or less with the tacit partnership with the government. One might argue that such a population may not be able to make an informed decision due to which it is for the state to go through with vaccination, by hook or by crook. But the government itself loses its stand when it is a tacit accomplice in the above mentioned scenario. This compounded by a lack of accountability and transparency creates an atmosphere of no information. It is but a consequence of this no information scenario that the people become downright critical of the vaccination program. Thus one can say that the government has to be made accountable for vaccination. It is important that the AEFI system be made as efficient and deep rooted as possible since the system might be the only way for the government to nullify misinformation and provide the masses with a reliable source of information regarding the reliability of a vaccine.29 Furthermore, it can allow the state to efficiently deal with the Adverse effects following a vaccine.

Lastly, it is high time that the state comes up with a law similar to that of the National Childhood Vaccine Injury Act of the United States. While the act was passed for altogether different reasons in the US30, a law based on such an act may help in legally acknowledging the existence of possible vaccine related side effects (injuries and deaths) and consequently help in the creation of a separate legal field dealing primarily with vaccinations, since the issue of their accountability is still in its infancy.

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1. The WHO defines vaccine as, “a biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism, and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins. The agent stimulates the body's immune system to recognize the agent as foreign, destroy it, and "remember" it, so that the immune system can more easily recognize and destroy any of these microorganisms that it later encounters.”

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*Ibid.*

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This was prevalent during the first half of the nineteenth century. The creation of trained vaccinators for smallpox vaccine had a varied effect. A major problem with the vaccinators was the charging of a fee for the vaccine. Furthermore, the distrust of the British, a belief in traditional medicinal practices and general illiteracy and poverty made it hard for the vaccine to spread throughout, thereby limiting the benefits of the vaccine. The government faced severe logistical problems as the vaccine was imported from England and there was a dearth of adequate storage facilities in the poorer parts of the British territory.

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TheVaccination Act of 1880

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The affair which caused a lot of embarrassment to the British due to the death of several people from the concerned vaccine was later revealed to be a fake since the handling of the vaccine had not been hygienic.

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Article 47, article 45 of the Constitution of India, 1950.

Section 22: Punishment of offences. Whoever commits any of the undermentioned offences (that is to say):-

(a) violates the provisions of section six,

(b) neglects without just excuse to obey an order made under section eighteen,

(c) breaks any of the rules made under section nineteen 2 or twenty, or

(d) neglects without just cause to obey an order made under section eighteen after having been previously convicted of so neglecting to obey a similar order made in respect of the same child, shall be punished as follows (that is to say):- in the case of the offence mentioned in clause (a), with simple imprisonment for a term which may extend to three months, or with fine which may extend to two hundred rupees, or with both; in the case of the offences mentioned in clauses (b) and (c), with fine which may extend to fifty rupees; and in the case of the offence mentioned in clause (d), with simple imprisonment for a term which may extend to six months, or with fine which may extend to one thousand rupees, or with both.

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Punjab Vaccination Act of 1953, Pb. Act No. 49( Nov 9, 1953).

Section 16: Repeal. — The following enactments are hereby repealed: -

(a) the Vaccination Act, 1880;

(b) the Sind Vaccination Act, 1892;

(c) the Bombay District Vaccination Act, 1892, as applicable to the former State of Khairpur;

(d) the Punjab Vaccination Law Amendment Act, 1925;

(e) the Punjab Vaccination Law Amendment Act, 1929; and

(f) the North-West Frontier Province Vaccination Law (Amendment) Act, 1947

Section 73, Madras Public Health Act of 1938, T.N Act 3(Mar 3,1939).

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