**Effective and ethical communication of COVID-19 health policies and strategies require transparent open data sharing between scientists, governments and policy makers**

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**Abstract**

A fundamental basis for the effectiveness of policy-making of any nation should be the open and transparent communication between a government and its citizens. In the case of the COVID-19 pandemic, to avoid deaths due to poor policies and decision-making, governments should welcome the input of ideas from the public, but most importantly, be able to screen carefully, and effectively, research that their national scientists conduct while carefully monitoring international research, given that pandemic is global. Yet, not all data that is generated is trustworthy. Much of it may be preliminary. Another sector of published “work” may be opinion. Thus, absent a vaccine, claims of success and breakthroughs must be thoroughly scrutinized pre- and post-publication since the lives of members of the public are at stake. An open data (with appropriate blinding) policy should apply to research that is nationally and privately funded, for institutional and government researchers.

**Keywords:** ICU; ISS; open data; public health policies; SARS-CoV-2; transparent communication

The letter by Tripathy (1) points out an important and fundamental weakness underlying effective science-supported government-based policies and strategies related to COVID-19, namely political interference, which may have a detrimental effect on publication ethics. The frequent notable lack of transparency in the relationship between policymakers and scientists may undermine the ethics of the public health decision-making process in this pandemic. For this reason, the US Food and Drug Administration decided to protect its integrity from politics claiming that the agency will make decisions only on the basis of “good science and sound data” before approving or authorizing a vaccine for COVID-19 (2). Healthcare policymakers increasingly look at scientific evidence to justify their policies and actions, or lack thereof, to avoid criticism via the media and public opinion. Ethical challenges may arise for policymakers who have to decide between a “suppression” strategy by implementing a strict lockdown, and a “mitigation” strategy, such as “flattening the curve” or mask wearing. Many socio-economic implications derived from this choice (3) are compounded by not-as-yet fully understood scientific characteristics of COVID-19, making decisions pertaining to policy more complex, more so absent a vaccine. Effective and transparent communication, coupled with real-time decisions based on open access (OA) epidemiological data that is critically assessed by scientists, the media, policy-makers and/or the public, may result in a more successful and robust strategy to combat COVID-19. The open disclosure of scientific evidence is essential in order to protect public trust and to address any confusion regarding policies, and hesitation by the public in following government-based recommendations (4).

Evidence-based policy-making is the gold standard in public health, but an upgrade to the platinum model of open data policies can mitigate scientific uncertainty by eliminating unreliable sources of scientific knowledge, as Tripathy (1) alluded to in the *Lancet* and *New England Journal of Medicine* cases that involved unreliable data sourced from Surgisphere, and unverified by the editors of those journals. In the era of electronic health records, inferences drawn from open research (5) and shared data (6) provide a useful and robust infrastructure that may inform epidemiological inquiries and guide treatment protocols when clinical trial data does not exist. Thus, pooled publicly available datasets are invaluable and necessary, even if there are privacy-related issues with patient-level COVID-19 data (6). This can be dealt with easily by blinding data. The World Health Organization has encouraged open sharing of data and results to deal with public health emergencies such as the current COVID-19 pandemic (7). While some scientists are increasingly sharing their data for research purposes through public platforms, preprint servers and OA journals, some governments and policymakers do not appear to be adopting the same philosophy.

In Italy, in the face of the second COVID-19 wave, the President of the Council of Ministers issued a new decree on November 3, 2020 that extended minimum**precautionary measures to counteract and contain the spread of COVID-19 to December 3, 2020, most likely because of, and in response to, the relaxation of policies during the** “flattening the curve” stage (8)**.** The Italian Ministry of Health (IMH) instituted three risk scenarios (yellow, orange and red flags) with increasingly restrictive measures that assigned risk level on the basis of a pool of 21 indicators, adopted as a ministerial decree on April 30, 2020, including: process indicators on data quality and diagnostic assessment, investigation and contact management capacity, outcome indicators for transmission rates, and the healthcare service’s resilience. In particular, the focus was on data of new cases, *Rt* (effective reproduction number), number of outbreaks, and saturation of Intensive Care Unit (ICU) and overall bed capacity for COVID-19 patients (9).

The risk scenarios are essentially based on three major risk determinants, namely the probability of local transmissibility of the infection, the preparedness of regional healthcare services, and a composite metric that considers the resilience of the local territory. Even though the 21 indicators were made public and the rationale of the document was explained, data used to estimate the risk level was not disclosed (9). In Italy, the decentralization and fragmentation of healthcare services restricted timely interventions and effectiveness during the first COVID-19 wave (10, 11). However, the decision-making process is entrusted to a Permanent Council (“Conferenza Permanente Stato-Regioni”) composed of central and regional governments. The new decree was criticized by Italian regions that proposed to simplify the 21 indicators to only five parameters: positive/swab ratio only taking into account new positive cases; *Rt* calculated by the COVID-19 integrated surveillance system established by the Istituto Superiore di Sanità (ISS); ICU bed capacity saturation for COVID-19 patients; overall bed capacity saturation for COVID-19 patients; local resources for testing, tracing and isolating strategy (12). However, the ISS claimed that in epidemiology, such an important decision-making process requires considerable caution and that, as a general rule of thumb, more indicators need to be analyzed in combination to give more information (13).

A concern raised by these regions, however, was the timeliness of publishing data, since delays inevitably impact predictive models used for decision making. For this reason, Nino Cartabellotta, President of the Gimbe Foundation, an Italian non-profit organization that works on healthcare issues, proposed at a Senate hearing on November 10, 2020 to make predictions using worst-case scenarios, e.g., by lowering *Rt* threshold or using upper bounds of confidence intervals (9, 14).

Furthermore, Cartabellotta called for more transparency in data availability and interpretation by the government by disaggregating data, making it freely available, real time, in a machine-readable format, to allow their rapid processing by different databases, and to be checked by independent researchers (14). According to Cartabellotta, data should not only be shown by region, but also by province and city. Finally, not only the overall daily ICU and hospital beds occupied, but also the new daily patients hospitalized with symptoms and admitted to intensive care should be displayed (15). The ISS is the leading technical scientific body of the Italian National Health Service and is supervised by the IMH (16). ISS regularly publishes infographics and extended reports related to COVID-19 on a dedicated platform (EpiCentro) to provide integrated surveillance. Data are processed by the ISS, which integrates microbiological and epidemiological data provided by all regions and autonomous provinces (APs) and by the ISS SARS-CoV-2 national reference laboratory. Data on laboratory-confirmed SARS-CoV-2 infections are provided on a daily basis to the ISS by all regions/APs. Individual data are updated daily by each region/AP and include information on pre-existing diseases and patients’ clinical conditions. Very importantly, this procedure protects sensitive personal data and, therefore, according to the IMH, data disclosure by the Italian Government has to be partial (17).

Even though the Italian Government announces any decision on the basis of data collected and elaborated by the ISS, there is much debate in Italy among scientists on open public data. The lack of transparency can indeed undermine trust in science and public health institutions by the public, and increase conflicts between governments and their regions. Maintaining the public’s confidence in public health leaders and authorities is essential for an effective response to COVID-19 (18). Decisions should be made openly and transparently, data should be accessible, for scrutiny and auditing, and the public should be able to avail this information through appropriate communication (19). Open data that is freely and efficiently provided by policymakers, similar to strategies suggested for journals and their editors (20), is an essential value to guide ethics-based decision-making in this and future pandemic crises.

**References**

1. Tripathy JP. Is publication ethics becoming a casualty of Covid-19? *Ind J Med Ethics*. Published on 2 September 2020. (in press) doi: 10.20529/IJME.2020.092
2. Sharfstein J. How the FDA should protect its integrity from politics. *Nature.* 2020;585:161. doi: 10.1038/d41586-020-02542-8
3. Nicola M, Alsafi Z, Sohrabi C, Kerwan A, Al-Jabir A, Iosifidis C, Agha M, Agha R. The socio-economic implications of the coronavirus pandemic (COVID-19): A review. *Int J Surg.* 2020;78:185-193. doi: 10.1016/j.ijsu.2020.04.018
4. Adam D. Even the ‘best science’ doesn’t have the final word on covid-19. *New Scientist*. 19 March 2020. [Cited 2020 November 24]. Available from: <https://www.newscientist.com/article/2238019-even-the-best-science-doesnt-have-the-final-word-on-covid-19/>
5. Chirico F, Teixeira da Silva JA, Magnavita N. “Questionable” peer review in the publishing pandemic during the time of COVID-19: implications for policy makers and stakeholders. *Croatian Med J*. 2020;61(3):300-301. doi: 10.3325/cmj.2020.61.300
6. Cosgriff CV, Ebner DK, Celi LA. Data sharing in the era of COVID-19. *Lancet Digit Health*. 2020 May;2(5):e224. doi: 10.1016/S2589-7500(20)30082-0
7. Moorthy V, Henao Restrepo AM, Preziosi MP, Swaminathan S. Data sharing for novel coronavirus (COVID-19). *Bull World Health Organ*. 2020 Mar 1;98(3):150. doi: 10.2471/BLT.20.251561
8. Teixeira da Silva JA, Tsigaris P. The role of lockdowns and health policies for Covid-19 in Italy. *Italian J Med.* (in press) doi: 10.4081/itjm.2020.1366
9. de Belvis AG, Fattore G, Morsella A, Pastorino G, Poscia A, Ricciardi W, Silenzi A. Monitoring and surveillance. Easing of measures (transition measures): Monitoring and surveillance. [Cited 2020 November 24]. Available from: <https://www.covid19healthsystem.org/countries/italy/livinghit.aspx?Section=2.1%20Physical%20infrastructure&Type=Section>
10. Armocida B, Formenti B, Ussai S, Palestra F, Missoni E. The Italian health system and the COVID-19 challenge. *Lancet Public Health.* 2020;5(5):e253. doi: 10.1016/S2468-2667(20)30074-8
11. Magnavita N, Sacco A,Chirico F.Covid-19 pandemic in Italy: Pros and cons. *Zdrowie Publiczne i Zarządzanie.* 2020;16(4):32–35.
12. Gagliardi A. Coronavirus, le Regioni: considerare solo 5 indicatori per le fasce di rischio. No di Speranza: restano 21. *Il Sole 24 Ore.* [2020 November 17; Cited 2020 November 24]. Available from: <https://www.ilsole24ore.com/art/coronavirus-regioni-governo-rivedere-21-parametri-fasce-rischio-ADERJs2?refresh_ce=1> (in Italian)
13. Istituto Superiore della Sanità. Il sistema di valutazione del rischio, ecco come e perché funziona. [Cited 2020 November 24]. Available from: <https://www.iss.it/primo-piano/-/asset_publisher/o4oGR9qmvUz9/content/iss-il-sistema-di-valutazione-del-rischio-ecco-come-e-perch%25C3%25A9-funziona>.
14. Matarrese L. Nino Cartabellotta: “Sui dati della pandemia un clamoroso autogol”. *The HuffPost*. [2020 November 18; Cited 2020 November 24]. Available from: <https://www.huffingtonpost.it/entry/nino-cartabellotta-non-rendere-pubblici-i-dati-della-pandemia-e-un-clamoroso-autogol_it_5fb50a10c5b664958c7c6737> (in Italian)
15. Da Rold C. I dati della discordia sulla pandemia in Italia. 19 November 2020. *Le Scienze*. [Cited 2020 November 24]. Available from: <https://www.lescienze.it/news/2020/11/19/news/covid-19_dati_open_pandemia_casi_morti_terapia_intensiva_criteri_chiusure_rt_calcolo_rischio_previsione-4838180/> (in Italian)
16. Istituto Superiore della Sanità- Epicentro. COVID-19 integrated surveillance: key national data. [Cited 2020 November 24. Last updated 15 November 2020]. Available from: <https://www.epicentro.iss.it/en/coronavirus/sars-cov-2-integrated-surveillance-data>
17. COVID-19 integrated health surveillance privacy information. [Cited 2020 November 24. Last updated 15 November 2020]. Available from: <https://www.epicentro.iss.it/coronavirus/pdf/informazioni-privacy-iss-sorveglianza-integrata-covid-19.pdf>
18. Rasmussen SA, Jamieson DJ. Public health decision making during Covid-19-fulfilling the CDC pledge to the American people. *New Eng J Med*. 2020 Sep 3;383(10):901-903. doi: 10.1056/NEJMp2026045
19. Government of Ireland. Department of Health. Ethical framework for decision-making in a pandemic. Published on 27 March 2020. [Cited 2020 November 24. Last updated 24 September 2020]. Available from:<https://www.gov.ie/en/publication/dbf3fb-ethical-framework-for-decision-making-in-a-pandemic/>
20. Teixeira da Silva JA, Bornemann-Cimenti H, Tsigaris P. Optimizing peer review to minimize the risk of retracting COVID-19-related literature. *Med Health Care Philos.* (in press) doi: 10.1007/s11019-020-09990-z

**Conflicts of interest:** None (financial or other).

**Funding:** This research received no funding.

**Author contributions:** Both authors, who are co-corresponding authors, contributed equally to all aspects of the paper, including, but not limited to, conceptualization, investigation, writing (original draft preparation, subsequent drafts), reviewing, and editing. Both authors have read and agreed to the published version of the manuscript.