

# Telemedicine practice guidelines in India: Global implications in the wake of the COVID-19 pandemic

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## Abstract

Telemedicine is the delivery of healthcare services from a distance, by use of information and communication technology. There have been no statutory regulations or official guidelines in India specific for telemedicine practice and allied matters so far. For the first time, the government of India released telemedicine practice guidelines for Registered Medical Practitioners on March 25, 2020, amid the COVID-19 outbreak. This review would initiate the discussion on the features of the guidelines, their limitations, and their significance in times of the COVID-19 pandemic. The guidelines are with a restricted scope for providing medical consultation to patients, excluding other aspects of telemedicine such as research and evaluation and the continuing education of healthcare workers. The guidelines have elaborated on the eligibility for practicing Telemedicine in India, the modes and types of teleconsultations, delved into the doctor-patient relationship, consent, and management protocols, and touched upon the data security and privacy aspects of Teleconsultation. After releasing the guidelines, the telescreening of the public for COVID-19 symptoms is being advocated by the government of India. COVID-19 National Teleconsultation Centre (CoNTeC) has been initiated, which connects the doctors across India to All India Institute of Medical Sciences (AIIMS) in real-time for accessing expert guidance on the treatment of the COVID-19 patients.

## KEYWORDS

India, practice guidelines, teleconsultation, telemedicine



### Highlights

- The government of India released telemedicine practice guidelines for Registered Medical Practitioners.
- Eligibility to deliver Telemedicine, types and channels through which Telemedicine are to be delivered have been elaborated.
- Restricted scope, lack of training material on telemedicine principles, lack of a dedicated governance mechanism, and the haziness over the jurisdictional authority of state medical councils are the limitations.

## INTRODUCTION

Telemedicine uses electronic communication and information technology (IT) to support the delivery of healthcare services and medical education to people at a distant site, i.e., to those who are not able to reach the healthcare provider in person (Sood et al., 2007). It is a means to improve the health outcome in patients by providing them access to healthcare and healthcare information. The term “Telemedicine” coined in the 1970s means “Healing at a distance” literally (Strehle & Shabde, 2006). Telemedicine, in its current form, has a history from the later parts of the 19th century. A physiologist in the Netherlands, Willem Einthoven, made recordings of electrical cardiac signals of a patient more than a kilometer away with a string galvanometer by using the telephonic transmission (Barold, 2003).

Over the years, telemedicine has been providing a myriad of services during natural calamities: remote monitoring of patients, educating the healthcare professions, establishing collaboration with the experts by linking the physicians and reducing the unnecessary cost incurred on transport and time for in-person consultation for conditions that do not warrant it (Chellaiyan et al., 2019; Ryu, 2012). Telemedicine was introduced to India as a pilot project of Indian Space Research Organization (ISRO) in 2001 by linking a well-developed hospital (Apollo Hospital) in Chennai to a peripheral rural hospital in Andhra Pradesh (Indian Space Research Organisation, 2021). ISRO has been spearheading telemedicine in India and has paved the way for its operationalization from just being a technology demonstration. It brought the specialty healthcare services to the doorsteps of rural and remote areas using technology. Apollo Telemedicine Networking Foundation (ATNF) is one among the pioneers of telemedicine globally. Apollo TeleHealth is one of the largest telemedicine networks in south Asia.

There were no official telemedicine guidelines in India till 2019. Coronavirus disease 2019 (COVID-19) has boosted telemedicine in India in a huge way. The need for risk-free contactless communications between physician and patient has also paved the way for the flourishing of several electronic applications (e-applications) related to healthcare consultations worldwide like Amwell, Doctor on demand, MDlive and Babylon. In India, e-applications like Practo, 1 mg and Lybrate have flourished. The government of India has also launched its telemedicine service, eSanjeevani (National TeleConsultation Service, Ministry of Health and Family Welfare, 2020). eSanjeevani is the government of India's flagship web-based national teleconsultation portal. During the first lockdown, eSanjeevaniOPD was rolled out by the government on April 13, 2020 (Press Information Bureau, Government of India, 2021).

As specified by World Health Organization (WHO), the scope of telemedicine includes patient consultation, diagnosis, prevention and treatment as well as research and continuing education of healthcare workers (HCWs), provided the objective of such activities is advancing the health of individuals as well as the communities (Ryu, 2012). The services



include but are not limited to teleradiology, teleophthalmology, telecardiology, telestroke, telepediatrics, teleconferencing, and teleclassroom. Specialized projects such as National rural telemedicine network, National medical college network, among the medical colleges across the country, and National Cancer Network (ONCONET) are being implemented in India (Chellaiyan et al., 2019). Individual medical institutes and hospitals also conduct telemedicine services for patients, link primary care centers or physicians (Chellaiyan et al., 2019). The principles and procedures for practicing telemedicine in India are taken from the international telemedicine guidelines and the statutes of India, like the Indian Medical Council (IMC) Act 1956, Information Technology (IT) Act 2000, Clinical Establishment Act 2010, Drugs & Cosmetics Act 1940, and so forth (Ateriya et al., 2018). However, there have been no dedicated statutory regulations or guidelines of any sort, specific for telemedicine practice and allied matters, in India. The issue came to the forefront when the Bombay High Court delivered a verdict against a doctor couple in a case of criminal negligence, wherein the physician made a prescription without a diagnosis over the telephone (Deepa Sanjeev Pawaskar And Anr vs. The State of Maharashtra on 25 July 2018, 2018). The telemedicine practice guidelines for Registered Medical Practitioners (RMPs), Ayurveda, Siddha, Unani (ASU) practitioners and Registered Homeopathy Practitioners (RHPs) were issued by the Government of India on March 25, 2020, April 7 and April 10, 2020, respectively (Board of Governors in supersession of the Medical Council of India, 2020b). The elements and principles of ASUs and RHPs guidelines are almost the same as that of RMP guidelines, with the only difference being adherence to homeopathy and ASU regulations while practicing it. The timing is of particular interest, as it was immediately a day after the nationwide lockdown to contain COVID-19 was announced. Through this paper, we describe the guideline creation process as a matter of historical record, the scope of the newly released Indian telemedicine practice guidelines for RMPs and their significance during this pandemic as well as the framework for understanding modes and types of consultations. It will also offer a thorough analyses of medico-legal aspects relevant to telemedicine under the guidelines.

## GUIDELINE CREATION PROCESS

Guidelines have been prepared by the Board of Governors, created in a supersession to the Medical Council of India, in collaboration with NITI Aayog, the government think tank for planning and policymaking (Board of Governors in supersession of the Medical Council of India, 2020b). The Indian Medical Council code (Professional Conduct, Etiquette and Ethics Regulation, 2002) was amended by introducing clause 3.8 in 2020 by permitting telemedicine consultations by RMPs under the telemedicine practice 2020 guidelines in Appendix 5. The “Telemedicine Practice Guidelines” are added as “Appendix 5” to the 2002 regulations, as there are already four appendices. Following these guidelines, the Board of Governors, CCH also amended and adopted the “Telemedicine Practice Guidelines” for homeopathic practitioners on April 10, 2020 (The Board of Governors, Central Council of Homeopathy, 2021).

Though the rationality for the guidelines is explicitly mentioned at the beginning of the document, it does not talk about the process and the experts involved in making it. The crucial aspect of stakeholder consultation with the RMPs, patients, technical platforms, and the medical institutes that already provide telemedicine services remains unanswered. Later a set of Frequently Asked Questions and their answers were released by the council (Board of Governors in supersession of the Medical Council of India, 2020a). The Technical groups worked, and the process involved in developing telemedicine guidelines has been a part of the guidelines in other countries (Intan Sabrina &

Defi, 2021; Ministry of Health Singapore, 2015; National Initiative for Telehealth Guidelines, 2003; Province of BC Health Authorities, 2014) National initiative for telehealth guidelines was established in Canada to have a more comprehensive consultation and participative process to arrive on the recommendations for telehealth (National Initiative for Telehealth Guidelines, 2003).

## SCOPE OF THE GUIDELINES

The areas and the context where it can be used have been spelled out (Ryu, 2012). The guidelines are with a restricted scope for providing medical consultation to patients, excluding other aspects of telemedicine such as research and evaluation, the continuing education of HCWs, and complex teleinterventions like robotic surgeries. Hence, the guidelines' title could have been "Teleconsultation Practice Guidelines" as it aptly reflects the scope of the guideline rather than the "Telemedicine Practice Guideline." It also specifies the jurisdiction of the guidelines as applicable only for services provided in India. It outlays the broad principles and the seven elements essential to have teleconsultation (Board of Governors in supersession of the Medical Council of India, 2020b). The commitment and flexibility to update the guidelines as and when required has been provided, similar to other countries (Ministry of Health Singapore, 2015).

Singapore has comprehensive guidelines encompassing the details of organizational structure and equipment required to provide telemedicine, including instruments like the stethoscope, and technological support required while providing telemedicine services, which has not been included in Indian guidelines (Ministry of Health Singapore, 2015). The guidelines developed by the American Telemedicine Association (ATA) is also of comprehensive nature, and is regularly updated based on critical evaluation and feedback. ATA is a non-profit organization with complete focus only on advancing telehealth and has been in action since 1999. WHO has acknowledged 15 Cross-border legalities involved in the Telemedicine service provisions (Ryu, 2012). On June 11, 2020, the Insurance Regulatory and Development Authority of India (IRDAI) issued guidelines advising insurers to allow telemedicine wherever consultation with a medical practitioner is allowed in the conditions of the policy contract. With these critical inclusions, the practice of telemedicine became legitimized and moved out of the regulatory gray space. Later, in May 2020, telepsychiatry operational guidelines were released jointly by the Indian Psychiatric Society (IPS), Telemedicine Society of India (TSI), and National Institute of Mental Health and Neurosciences (NIMHANS) (Indian Psychiatric Society & Telemedicine Society of India In collaboration with National Institute of Mental Health and Neuro Sciences, 2020). In the telepsychiatry versus Mental healthcare act 2017, areas of concern or conflict such as maintenance of records, informed consent, advance directive, and person's rights with mental illness have been addressed (Duffy & Kelly, 2019). This guideline gives practical advice to psychiatrists for incorporating telepsychiatry services as a part of regular day-to-day clinical practice.

The prescription of psychiatric medicines is also an area of concern. List O and A drugs can be prescribed during the first consultation through video consultation only. However, drugs such as Zolpidem and Lorazepam fall under the Narcotic Drugs and Psychotropic Substances (NDPS) Act ambit and hence not to be prescribed online (Indian Psychiatric Society & Telemedicine Society of India In collaboration with National Institute of Mental Health and Neuro Sciences, 2020). The psychiatrist can convey an online Prescription to an RMP or a HCW via collaborative teleconsultation. List B drugs can be prescribed in telefollow-up consultation only, while a prohibited list of drugs cannot be prescribed online.



## MODES AND TYPES OF CONSULTATION

The modes of communication, such as audio, video, and text, are permitted to be utilized in the teleconsultation process. The consultation can be between the patient and RMP, RMP and RMP, and health worker and RMP, thus providing space for assistance, expert opinions, and real-time linkages for referral during the teleconsultation. It also allows for asynchronous consultation, wherein the availability of patients and RMPs for a real-time teleconsultation may not coincide. The consultation has also been categorized as the first consult and follow up consult. In case the patient is consulting for the first time with an RMP for a current condition or the patient has consulted for the same health condition more than six months ago or the patient has consulted for a different health condition earlier, then the consultation is called as first consultation (Board of Governors in supersession of the Medical Council of India, [2020a](#), [2020b](#); Dinakaran et al., [2020](#))

On the other hand, follow up consultation is defined as the patient's consultation with RMP within six months of the previous in-person consultation for the same health condition. In case of the presence of new symptoms which are not in the same health condition, it is not considered a follow-up. Similarly, in case of failure of RMP to recall the previous consultation context and treatment, it is not considered a follow-up consultation (Board of Governors in supersession of the Medical Council of India, [2020a](#), [2020b](#); Dinakaran et al., [2020](#)).

The guideline also paves the way for the caregiver or HCWs to interact with RMPs or facilitate the patient consultation and consultation between two RMPs when an expert opinion or referral is deliberated. According to the guidelines, every consult, whether first or follow-up, shall be undertaken only after confirming the absence of any condition requiring emergency care (Board of Governors in supersession of the Medical Council of India, [2020b](#)). South Africa's telemedicine guidelines have minimal scope allowing only a video consult and the presence of a consulting health provider in person with the patient for examination, while expert assistance or opinion is provided by service consultant remotely (Health Professions Council of South Africa, [2020](#)). It is similar to that of telecollaboration (Ministry of Health Singapore, [2015](#)). Prescription of list A drugs for the new consultation requires a video consultation. Also, there is a lack of knowledge about current technology platforms among people, including HCWs, which might hinder effective communication.

## MEDICO-LEGAL ASPECTS

The identification details of the patient and the RMP must be established and verified before initiating the medical consultation. The possible mechanism to ensure and verify each other's identity has been spelled out in the guidelines (Board of Governors in supersession of the Medical Council of India, [2021](#)).

### Physician–patient relationship

The decision to manage the specific condition in teleconsultation or otherwise is left to the professional judgment of the RMP. Conversely, if a patient prefers in-person consultation over teleconsultation, the same cannot be forced upon him (Board of Governors in supersession of the Medical Council of India, [2020b](#)). The guidelines take a balanced approach in managing the patient preferences and professional caliber of the RMP. Thus, it provides for shared decision making between the patient and the healthcare provider in terms of utilizing the services. All records of the patient consultation shall be maintained similar to the in-person consultation. This is in line with the practices outlined in the recommendations of



other countries (Ministry of Health Singapore, 2015; Province of BC Health Authorities, 2014). The third party (applications or platforms) could have access to the audio and video recordings of the teleconsultation between the doctor and patient. There needs to be a way to address the issues arising out of private data leaks in public.

## Consent, professional ethics and data security

The concept of informed consent has been included as an essential element in teleconsultation. Implicit or implied consent is taken if the patient initiates the teleconsultation. An explicit consent in words understood by the patient must be obtained if the RMP initiates the consultation, and the same must be mentioned in patient records (Board of Governors in supersession of the Medical Council of India, 2021). Countries around the world have an informed consent obligation to conduct telemedicine services (Ministry of Health Singapore, 2015; National Initiative for Telehealth Guidelines, 2003; Province of BC Health Authorities, 2014; Telemedicine laws and developments: A state-by-state analysis, 2014). The RMP shall adhere to all the professionals' ethics and conduct established under the Indian Medical Council (IMC) Act and regulations (Board of Governors in supersession of the Medical Council of India, 2021; The Board of Governors, Central Council of Homeopathy, 2021). Data security shall be maintained in accordance with the Information Technology (IT) Act of India (Board of Governors in supersession of the Medical Council of India, 2021). According to the IT Act, the patient's consent must be taken before collecting data from him/her (Ateriya et al., 2018). However, the specific clauses, obligations, and penalties pertaining to the informed consent for data and security breaches have not been provided in the guidelines. This, along with the lack of an accredited course to understand the nuances of telemedicine, may alienate a common RMP from exploring the teleconsultation services. Though the right to privacy has been held as a fundamental right and an integral part of the right to life by the apex court of India (Province of BC Health Authorities, 2014), the lack of specific data protection laws or rules as in the United States of America (USA) must also be acknowledged (Ateriya et al., 2018). The Personal Protection Bill, 2018, is yet to be made an Act, thus having gaps in privacy safeguards (Ministry of Health Singapore, 2015). The Consumer Protection Act (CPA) will be applicable for teleconsultation, as long as the consultation is charged by the RMP or the Institute (Board of Governors in supersession of the Medical Council of India, 2021). Explicit mention about CPA is missing in the guidelines.

## Diagnosis, treatment, and payments

The RMPs can provide health promotion and prevention messages to the patient. The RMP must mention a diagnosis before the prescription in the teleconsultation (Ryu, 2012). The RMP enjoys the same discretion and accountability in diagnosing and prescribing medicines in teleconsultation as he does in the conventional in-person consultation. However, there is a restriction or prohibition on the type of drugs prescribed through various modes of teleconsultation (Table 1) (Board of Governors in supersession of the Medical Council of India, 2021). Flexibility to alter the list by the competent authority is provided within the document. The RMP can charge fees for the teleconsultation similar to that of an in-person consultation. Most of the states in the USA, such as Arkansas, Alabama, Arizona, etc., have their insurance system, Medicaid, reimburse the cost paid for all telemedicine by the patients, while states like Idaho pay for certain services like telepsychiatry (Telemedicine laws and developments: A state-by-state analysis, 2014). Even though the guidelines prohibit the advertisement of RMP's about their telemedicine services, the telemedicine platforms



**TABLE 1** Matrix of the permissible drug lists based on the type and mode of consultation

List of medicines and its mode of teleconsultation	Prescription mode (video/ audio/text)	Nature of consultation (first-consultation/ follow-up)	Medicines included
List O: It will comprise those medicines which are safe to be prescribed through any mode of teleconsultation	Any	Any	<p>Over-the counter medications</p> <ul style="list-style-type: none"> <li>• Antipyretics: Paracetamol</li> <li>• Cough Supplements: Lozenges</li> <li>• Cough/Common-cold medications (such as combinations of acetylcysteine, ammonium chloride, guaifensin, ambroxol, bromhexene, dextromethorphan)</li> <li>• ORS Packets</li> <li>• Syrup zinc supplements: Iron and folic acid tablets, vitamin D, calcium supplements</li> </ul> <p>Medication given on emergency basis (notified by government of India) Example Chloroquine for Malaria</p>
List A: These medications are those which can be prescribed during the first consult which is a video consultation and are being re-prescribed for re-fill, in case of follow-up.	Video	First consultation	<p>First consult medications</p> <ul style="list-style-type: none"> <li>• Ointments/lotion for skin ailments: ointments clotrimazole, mupirocin, calamine lotion, benzyl benzoate lotion, etc.</li> <li>• Local ophthalmological drops such as: ciprofloxacin for conjunctivitis, etc.</li> <li>• Local ear drops such as: clotrimazole ear drops, drops for ear wax, etc.</li> <li>• Follow-up consult for above medications</li> </ul> <p>Follow-up medications ("re-fill")</p> <ul style="list-style-type: none"> <li>• Hypertension: enalapril, atenolol, etc.</li> <li>• Diabetes: metformin, glibenclamide, etc.</li> <li>• Asthma: salmeterol inhaler, etc.</li> </ul>
List B: Is a list of medication which RMP can prescribe in a patient who is undergoing follow-up consultation in addition to those which have been prescribed during in-person consult for the same medical condition	Any	Follow up	<p>Follow-up, medications prescribed as "Add-on" Example:</p> <ul style="list-style-type: none"> <li>• hypertension: e.g., add-on of Thiazide diuretic with atenolol</li> <li>• Diabetes: addition of sitagliptin to metformin</li> </ul>
Prohibited list: An RMP providing consultation via telemedicine cannot prescribe medicines in this list.	Not to be prescribed	Not to be prescribed	<p>Drugs listed under Narcotic Drugs and Psychotropic Substances (NDPS), Act, 1985 and schedule X drugs Example: anticancer drugs, morphine, etc.</p>



invariably tend to advertise or promote them indirectly about their consulting hours, fees, mode of payment etc.

## Training and registration of RMPs in telemedicine

The person eligible to do the teleconsultation has been mentioned as RMPs, as defined under the IMC Act (Board of Governors in supersession of the Medical Council of India, 2020b; The National Medical Commission Act 2019, 2019; The Indian Medical Council, 2002). They should have also qualified in an online course on telemedicine within 3 years of the notification of the guidelines for legally practicing telemedicine. However, during the interim period, any RMP can practice teleconsultation by adhering to the principles and norms mentioned in the guidelines (Board of Governors in supersession of the Medical Council of India, 2021). This may be seen as a way to fast-track the adoption of telemedicine by RMPs in India during the COVID-19 emergency situation. However, the non-release of even a short course on telemedicine, along with the guidelines, is a point of contention. While it can be taken as a start, giving such a leeway to practice without an appropriate channel for instilling the principles of telemedicine, especially when issues of data security and personal data protection are there, may raise legal questions in a court of law. The state of Alabama in the USA mandates special licenses for telemedicine from physicians (Telemedicine laws and developments: A state-by-state analysis, 2021). Similar training and qualification are expected in Singapore to practice telemedicine (Ministry of Health Singapore, 2015).

## TELEMEDICINE PLATFORMS

The guideline spells the responsibility of the platforms that facilitate telemedicine to ensure the authenticity and credentials of the RMP enlisted to provide the teleconsultation in their platform. Any violation of the norms by the firms may lead to their blacklisting (entities to be avoided or distrusted as being deemed unacceptable by the Medical Council of India or its successors (Board of Governors in supersession of the Medical Council of India, 2021). The technology platforms are supposed to appoint a grievance officer, as mentioned under the IT Act (Ateriya et al., 2018). But the current telemedicine guidelines leave it vague with a mention of “proper mechanism” to address the grievance or queries (Board of Governors in supersession of the Medical Council of India, 2021).

## LEGAL STATUS OF THE GUIDELINE

Telemedicine has been given legal status in India (The gazette of india: extraordinary, 2020). On May 12, 2020, the government published the guidelines in the gazette (The Gazette of India: Extraordinary, 2020). The “Telemedicine Practice Guidelines” are included as “Appendix 5” to the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002’. However, it is also clearly stated that these guidelines are not applicable for using digital technology to conduct surgical or invasive procedures remotely. Countries have issued telemedicine practice as guidelines (Ministry of Health Singapore, 2015), as well as statutory rules (Ateriya et al., 2018). European Union has taken multiple initiatives and directives to promote telemedicine, yet a common legal framework or a law still evades them (Raposo, 2016). A statute, Telehealth Advancement Act, 2012, is available for telemedicine in the USA (Ateriya et al., 2018).





## NATIONAL PORTABILITY AND THE JURISDICTIONAL ISSUES

The guideline allows an RMP to practice teleconsultation all over India, that is, national portability (Board of Governors in supersession of the Medical Council of India, 2021). This breaks the boundaries by enabling doctors to provide services and patients to avail themselves of services in states other than their residential ones. However, there is no clarity on whether a medical council registration of the patient's state is required for the doctor to do the teleconsultation since all regulations and rules of in-person consultation under IMC apply to teleconsultation. Also, the jurisdiction of state medical council on matters of professional misconduct and disciplinary action against the RMP in cases of inter-state teleconsultation needs detailed clarifications. Health is a state subject in India. Hence the regulations of the state governments might be a potential hindrance in the practice of telemedicine.

## TELEMEDICINE IN RELATION TO COVID-19 SCENARIO

COVID-19 pandemic is the catalyst for the release of guidelines on teleconsultation in India. Telescreening for COVID-19 symptoms, based on which patients can be referred to COVID-19 designated hospitals or other hospitals, is being recommended (Enabling Delivery of Essential Health Services during the COVID 19 Outbreak: Guidance note Background, 2021). The project COVID-19 National Teleconsultation Centre (CoNTeC) has been conceptualized by the Indian Ministry of Health and Family Welfare and has been implemented by the All India Institute of Medical Sciences (AIIMS), New Delhi (COVID-19 National Teleconsultation Center & AIIMS New Delhi, 2021). CoNTeC connects the doctors across the country to AIIMS in real-time for the treatment of the COVID-19 patients, and doctors would be available in the facility 24 × 7 and to keep it functioning 24 h. Worldwide, there is a thrust towards telemedicine in this COVID-19 times. In the USA's response to coronavirus, due importance has been given for telehealth. (Koonin et al., 2020; Kichloo et al., 2020) Most insurance companies across the US are reimbursing teleconsultation for COVID-19 infection (The Henry J. Kaiser Family Foundation, 2021).

## CONCLUSION

Though the present guidelines released in India for telemedicine are not comprehensive, they could be taken as a starting point. They have initiated the attempt to legitimize the existing teleconsultation services provided in India appropriately. However, the limitations in terms of the restricted scope, lack of training material on telemedicine principles for RMPs, lack of a dedicated governance mechanism such as the National telemedicine agency, and the haziness over the jurisdictional authority of state medical councils over professional misconduct remain to be worked out. Further revisions and fine-tuning of the guidelines addressing the above concerns should be taken up as the next step in the telemedicine governance of India.

## CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

## ETHICS STATEMENT

The article is a review paper on the guidelines available in the public domain. Hence, ethical review was not necessary.



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**How to cite this article:** Venkatesh, U., Aravind, G. P., & Velmurugan, A. (2022). Telemedicine practice guidelines in India: Global implications in the wake of the COVID-19 pandemic. *World Med. & Health Policy*, 14, 589–599. <https://doi.org/10.1002/wmh3.497>