<u>COMMENTS</u>

The Epidemic Diseases Act of 1897: public health relevance in the current scenario

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Abstract

Recently, many states in India have invoked various provisions of the Epidemic Diseases Act of 1897 to control communicable diseases. In this context, the Act was reviewed with reference to its relevance in the current context of surveillance and other relevant Acts and legislations at the national and international levels. It is felt that the Act has major limitations in the current scenario as it is outdated, merely regulatory and not rights-based, and lacks a focus on the people. There is a need for an integrated, comprehensive, actionable and relevant legal provision for the control of outbreaks in India.

Introduction

India has witnessed many large outbreaks of emerging and re-emerging infectious diseases in the recent past (1). The outbreak of a cholera epidemic due to the O139 strain in 1992, that of plague in Surat in 1994, the large-scale spread of chikungunya and dengue fever, and that of avian influenza (H5N1) and pandemic H1N1 influenza were some which caused widespread havoc. The resurgence of diphtheria, and the outbreaks caused by the Nipah, Chandipura and Japanese encephalitis viruses and Crimean-Congo haemorrhagic fever also posed a threat to the country's public health in the last decade. The emergence of drug-resistant tuberculosis and malaria and New Delhi Metallo-beta-lactamase (NDM-1) - resistant organisms is also a matter of concern for the country. As in any other country, diseases with the potential for international spread, such as Ebola virus disease and Zika virus, also pose threats to the public health security of India.

Legal frameworks are important during emergency situations as they can delineate the scope of the government's responses to public health emergencies and also, the duties and rights of citizens. In recent years, many states in India have invoked various provisions of the Epidemic Diseases Act of 1897 to force H1N1-affected persons to be segregated and get

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themselves treated at recognised hospitals, to direct private hospitals to set up isolation treatment facilities and to notify cases of dengue and H1N1 (2–4). In this context, it is important to critically evaluate the Epidemic Diseases Act of 1897, its relevance in the current context and whether it has kept up with the recent global developments in disease surveillance, disease control and rights perspective.

This review attempts to describe the Act, its historical aspects and key elements, the current status of the Act. Further, it aims to identify its limitations and lacunae, and describe disease surveillance and response in the country. Finally, it sets out to examine key legislations and the sections of these which are relevant for updating Acts or reforms in this area and for proposing recommendations.

Description of the Epidemic Diseases Act, 1897

The Epidemic Diseases Act was passed in 1897 with the aim of better preventing the spread of "dangerous epidemic diseases" (5). It evolved to tackle the epidemic of bubonic plague that broke out in the then Bombay state at the time. The Governor General of colonial India conferred special powers upon the local authorities to implement the measures necessary for the control of epidemics.

The Epidemic Diseases Act is one of the shortest Acts in India, comprising just four sections. The first section explains the title and the extent, while the second gives powers to the state and Central governments to take special measures and formulate regulations that are to be observed by the people to contain the spread of disease. The third section describes penalties for violating the regulations, in accordance with Section 188 of the Indian Penal Code. The fourth deals with legal protection to the implementing officers acting under the Act (5).

According to the provisions of Section 2 of the Act, which describes the powers of the government, "When the state government is satisfied that the state or any part thereof is visited by or threatened with an outbreak of any dangerous epidemic disease; and if it thinks that the ordinary provisions of the law are insufficient for the purpose, then the state may take, or require or empower any person to take some measures and by public notice prescribe such temporary regulations to be observed by the public. The state government may prescribe regulations for inspection of persons travelling by railway or otherwise, and the segregation, in hospital,

temporary accommodation or otherwise, of persons suspected by the inspecting officer of being infected with any such disease." (5: p 2). Section 2A empowers the Central government to inspect any ship leaving or arriving at any port and for detention thereof, or of any person intending to sail therein, or arriving thereby. Section 3 states, "Six months' imprisonment or 1,000 rupees fine or both could be charged out to the person who disobeys this Act."

The Act was executed vigorously to control the plague epidemic that broke out in the 1890s (6-8). The powers it conferred were invoked to search for suspected plague cases in homes and among passengers. There was forcible segregation of affected persons, disinfections, evacuation, and demolition of infected places. The assembly of crowds was prevented, public meetings and festivals were banned and pilgrimages suspended. Alleged humiliation (including public stripping) of and violence against women gave rise to concerns among the citizens, and riots were reported in some areas. In many places, military powers were used to ensure the proper implementation of the preventive measures (6-8). Historian David Arnold called the Act "one of the most draconian pieces of sanitary legislation ever adopted in colonial India" (7) and Myron Echenberg reported in his book that "the potential for abuse was enormous" (8). The execution of the Act remained more or less dormant after Independence.

Limitations of the Epidemic Diseases Act in the changed context

The Act was formulated about 118 years ago and thus has major limitations in this era of changing priorities in public health emergency management. The factors leading to the emergence and spread of communicable diseases have also changed over the years. Some of the factors that need to be addressed now are the increasing rates of international travel, more extensive use of air travel compared to sea travel, greater migration within states for the sake of earning a livelihood, the transition from agrarian to industrial societies, increased urbanisation, grossly increased density of populations in certain areas, increasing intensity of contact with animals and birds, man-made ecological changes, changing climatic conditions, technologies of mass food production, breakdown of public health measures and biosafety lapses. The Epidemic Diseases Act needs modifications in the changing scenario. For example, it is too oriented towards travel by ship and silent on "air travel", which was uncommon at that time. The epidemiological concepts used in relation to the prevention and control of epidemic diseases have also changed over time. The Epidemic Diseases Act is not in line with the contemporary scientific understanding of outbreak prevention and response, but only reflects the scientific and legal standards that prevailed at the time when it was framed. To cite an example, the Act places too much emphasis on isolation or quarantine measures, but is silent on the other scientific methods of outbreak prevention and control, such as vaccination, surveillance and organised public health response. The political scenario in the country and Centre-state relationships have changed. The Act of 1897, as such, is not sufficient to deal with the prevention and control of communicable disease in the current situation.

Definition of "dangerous epidemic disease"

The definition or description of a "dangerous epidemic disease" is not provided in the Act. There is no clear definition of whether an epidemic is "dangerous" on the basis of the magnitude of the problem, the severity of the problem, the age of the population affected or its potential to spread internationally. It is essential to know who decides on what a "dangerously epidemic disease" is and what criteria the definition is based on, if we are to prevent misuse of the Act and also for transparency.

Disease surveillance and coercive notification

In India, the Epidemic Diseases Act, 1897, requires medical practitioners to notify the public health authority about anybody with a communicable disease and disclose the identity of the person. Notification is essential for good surveillance and to get an idea about the burden of disease in the community, as this helps in planning, implementing and evaluating programmes for the control of the disease. Different states have made many diseases notifiable under various public health acts. Tuberculosis has been made a notifiable disease recently by the Government of India, though the order does not mention that it is supported by an Act (9). The Goa Public Health Act allows for the disclosure to public officials of an individual's HIV status. Ethical issues associated with the forcible notification process have been widely discussed (10).

Since the implementation of the Integrated Disease Surveillance Units (IDSP), each district has a surveillance unit and a rapid response team (RRT) to quickly manage the outbreak of a disease in any part of the country. To augment surveillance activities and response mechanisms, a wide network of epidemiologists, microbiologists and entomologists has been made available in all district and state headquarters under the IDSP. Information technology connectivity has been established with all states, districts and medical colleges for the rapid transfer of data. The IDSP has been trying to involve the private sector in the disease surveillance process, but with limited success (11). The barriers to getting notifications include: the absence of a felt need in the public sector to involve the private sector; the inability of public sector staff to deal with the private sector; and a lack of mutual respect for each other in both sectors. On the other hand, the private sector seems to have fears regarding confidentiality, the complexity of the reporting procedures, apprehensions about losing patients, a lack of recognition from Government and ignorance about why and whom to notify (12). Legal provisions should not be used as shortcuts to get the private sector to notify cases; instead, the real issues should be addressed. There are good examples of surveillance systems getting notifications from the private sector without the use of coercion (13,14). Polio surveillance

is a good example of private sector participation in disease surveillance. The North Arcot District Health Information (NADHI) surveillance system in Vellore and the Kerala model of district-based surveillance are illustrations of effective private sector participation in disease surveillance. Nonfinancial incentives, such as the inclusion of names in the network directory, representation in surveillance committees, good-quality training, reliable feedback mechanisms, constant support, encouragement and hand-holding, have been identified as major factors which have helped to facilitate notifications from the private sector. Using coercion to get notifications and collect information should be the last option, which should be resorted to only after all the above said factors have been addressed and only if its benefit clearly outweighs the risks.

The Epidemic Diseases Act from a rights perspective

The Epidemic Diseases Act is purely regulatory in nature and lacks a specific public health focus. It does not describe the duties of the government in preventing and controlling epidemics. The Act emphasises the power of the government, but is silent on the rights of citizens. It has no provisions that take the people's interest into consideration. Peoplecentredness is about considering people's needs, desires, values, social circumstances and lifestyles, and working together to develop appropriate solutions. The Act is also silent on the ethical aspects or human rights principles that come into play during the response to an epidemic. Individual autonomy, liberty and privacy should be respected to the greatest extent possible, even during the enforcement of laws. It would have been good if the Act stated clearly the situations under which the authorities may curtail the autonomy, privacy, liberty and property rights of the people. Using a fair process in such situations (eg closing down a hotel) would ensure that officials make impartial decisions and would also help to reduce the community's misperceptions.

Rather than containing clear executive instructions, the Epidemic Diseases Act is more or less like a guidance document. It does not mention any scientific steps that the government needs to take to contain or prevent the spread of disease.

The Act says that "the state may empower any person to take some measures" (5: p 1). Today, we have a better structured public health system, with specific people in charge of delivering primary care services. The prevention of outbreaks of epidemic diseases and their control is the responsibility of primary care. The IDSP is in place for the early detection of outbreaks. The District Chief Medical Officer, along with the district-level team and the primary health centre medical officer, field workers and other community health workers, lead the workforce for the control and prevention of outbreaks. When such a system is in place, going by the Act's prescription that "any" person may be empowered does not make sense. The word "any" cannot be accepted in the current context, and "who" can do "what" needs to be specified.

As for the ethical aspects of a national epidemic law, it is necessary to address equitable access to healthcare. The ethics of public health actions taken in response to an outbreak should be considered, as should the obligations of healthcare workers during an outbreak and the obligations of society to them in return. Finally, the obligations of the states and those of intergovernmental organisations must be taken into account.

Public health legislation to combat communicable diseases in India

The country has many legal provisions which can be used to take public health measures to prevent and control an epidemic, including provisions of the Indian Penal Code, the Livestock Importation Act, 1898, Indian Ports Act of 1908, Drugs and Cosmetics Act of 1940, and Aircraft Rules of 1954 (15).Bringing all the legal provisions for preventing outbreaks under a single legislation would be challenging, though it would be beneficial for effective implementation and monitoring.

In 1955 and 1987, the Central government developed a Model Public Health Act, but failed to persuade the states to adopt this. The Public Health Act was revised by the National Institute of Communicable Disease (currently the National Centre for Disease Control) a decade ago, but the revisions have still not been approved by the government.

State initiatives for public health legislations

Many states formulated their own public health laws and many amended the provisions of their epidemic disease Acts. The Madras Public Health Act was passed in 1939. This was the first of its kind in the country. The government of Himachal Pradesh included provisions for compulsory vaccinations in its Epidemic Diseases Act, while Madhya Pradesh, Punjab, Haryana and Chandigarh conferred powers on specific officials to execute various provisions of the Act. Bihar gave the state government the power to make requests for vehicles during epidemics. While it is true that the priorities of the states are different, the platform of a common law for combating infectious disease that the states should work on should be the same. There are instances in which different parts of a state are following two different public health acts. For example, the southern districts of Kerala follow the Travancore-Cochin Public Health Act, 1955, while the northern districts follow the Malabar Public Health Act, 1939. Municipal Acts in different states vary in quality and content, and many are vague about the measures to be taken during the outbreak of a disease (15). Most of the public health Acts in the states are "policing" Acts, intended to control epidemics, and do not deal with coordinated and scientific responses to prevent and tackle outbreaks (15). Recently, many states, such as Gujarat and Karnataka have drafted public health bills which seem promising, as they have put in place a structure for better surveillance while ensuring that citizens are not denied their health rights.

What we require is a legal framework relevant to the current context. A good public health law infrastructure establishes not only the powers of the government, but also shapes the government's role in preventing and controlling diseases. The Epidemic Diseases Act, 1897, is outdated and not relevant, as discussed above. Many others who have reviewed the Act are of the same opinion (16). The lack of uniformity between the various acts followed in different states has also been highlighted above. There is a need for an integrated, comprehensive, actionable and relevant legal provision for the control of disease outbreaks in India. This should be articulated in a rights-based, people-focused and public health-oriented manner. The National Health Bill is one such proposed legislation (17).

The draft National Health Bill 2009 attempts to ensure a legal framework for providing essential public health services and powers for an adequate response to public health emergencies through effective collaboration between the Centre and the states. The Bill adopts a rights-based approach and upholds the right to treatment and care. It clearly states the public health obligations of the government. It also mentions the formation of public health boards at the national and state levels for smooth implementation and effective coordination. There are provisions for community-based monitoring and mention of grievance redressal mechanisms which would ensure transparency. For better accountability, it would have been good if the Bill had clearly mentioned the roles and responsibilities of each department and the nodal agencies for preventing and controlling epidemics. To cite an example, the Disaster Management Act, 2005, describes in detail when to act, who is to act, what measures are to be taken at different levels, how to implement, how to coordinate, and what the roles and responsibilities of each department and the authorities are during emergencies (18).

Given that the private sector accounts for nearly 70% of India's healthcare, this sector has a critical role to play in supporting the traditional public sector-led response to the prevention and tackling of outbreaks. There are many successful publicprivate partnership (PPP) models in healthcare and the lessons learnt from these need to be incorporated for better private sector participation in communicable disease control. Investing in mechanisms to bring private-sector players together is likely to contribute to better coordination, greater resources, more time and expertise during an emergency. During epidemics, there should be provisions in the Act, to maintain standards in quality of care, rationality of treatment, cost of care, treatment protocol and ethical behaviour applicable to both public and private sectors and these need to be regulated through bodies with the involvement of people from both sectors and mutually agreeable professional organisations.

The draft National Health Bill has limited reference to ethical frameworks or the protection of human rights during the response to epidemics. The Public Health Emergency Response

Act in Mexico is an example in which a clear description of the individual civil rights of persons quarantined or isolated is provided (19).

In this context, the possibility of setting up a public health regulatory authority such as the Food Safety and Standards Authority of India or Telecom Regulatory Authority of India (TRAI) may be considered. TRAI was established to regulate telecom services. Its functions included the revision or fixation of tariffs for telecom services, which was earlier done by the Central government. One of TRAI's objectives is to protect the interests of service providers and consumers (20). A public health regulatory authority can propose, review and revise public health legislations on a periodic basis, recommend and lay down public health priorities, collaborate with health systems for strategic planning, provide scientific advice and technical support for the framing of state rules, help to streamline the procedures, see to the uniform implementation of laws, and act as a coordinating body which bears the overall responsibility for the effective working of the regulatory system. An agency that defines standards could ensure uniformity in the measures to be taken for the control of an outbreak and disease surveillance, including legal actions. Provisions for engaging and strengthening the civil society and measures for promoting inter-state communications for the control of infectious diseases should be considered in the legal frameworks.

Conclusion

There is a need to strengthen legal frameworks to prevent and control the entry, spread and existence of communicable diseases in India. The Epidemic Diseases Act 1897, which is more than a century old, has major limitations when it comes to tackling the emergence and re-emergence of communicable diseases in the country, especially in the changing public health context. Over the years, many states have formulated their own public health laws and some have amended the provisions of their epidemic disease Acts. However, these Acts vary in quality and content. Most are just "policing" acts aimed at controlling epidemics and do not deal with coordinated and scientific responses to prevent and tackle outbreaks. There is a need for an integrated, comprehensive, actionable and relevant legal provision for the control of outbreaks in India that should be articulated in a rights-based, people-focused and public health-oriented manner. The draft National Health Bill 2009 is one such proposed legislation, but it is still in its long gestation period and its fate is unpredictable.

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Guidelines for stem cell science and clinical translation

SUNIL K PANDYA

The International Society for Stem Cell Research has released its updated guidelines for stem cell research in order to provide "assurance that stem cell research is conducted with scientific and ethical integrity and that new therapies are evidence-based." The guidelines were updated by a Guidelines Update Task Force consisting of twenty-five scientists, ethicists and experts in healthcare policy from nine countries. The chairpersons of this task force are Jonathan Kimmelman, George Daley and Insoo Hyun. There is no representative from India, the only person of Indian origin on it, Mahendra Rao, represents The New York Stem Cell Foundation.

A study of these guidelines shows us how unscientific and unsupervised the usage of stem cells in clinical practice is in India. We desperately need immediate corrective action with implementation of these or similar guidelines and strict and

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severe punishment of all those flouting them. The full force of government and judiciary must back the application of these guidelines.

The lack of such guidelines is luring innumerable patients and their families to questionable, unscientific and unethical practices, usually at great cost and at times to their financial ruin, without any proven benefit.

The very first section of the guidelines deals with *Fundamental ethical principles*. It defines the primary goals of stem cell research as the advancement of scientific understanding and the generation of evidence for addressing unmet medical and public health needs. "This research should be overseen by qualified investigators and coordinated in a manner that maintains public confidence...Key processes for maintaining the integrity of the research enterprise include those for independent peer review and oversight, replication and accountability at each stage of research." (Emphasis added)(1:p 3).

This section also emphasises the primacy of patient welfare. "Physicians and physician-researchers owe their primary duty to the patient and/or research subject... Application of stem-cell based interventions outside of formal research