

- 2013 Mar 4 [cited 2013 Aug 14]. Available from: http://www.idsa.in/idsacomments/IndiasDefenceBudget2013-14_lkbehera_040313.
6. Evans DB, Tan-Torres Edejer T, Adam T, Lim SS, for the WHO CHOICE MDG Team. Methods to assess the costs and health effects of interventions for improving health in developing countries. *BMJ*. 2005;331:1137-40.
 7. Strebel PM, Cochi SL, Hoekstra E, Rota PA, Featherstone D, Bellini WJ, Katz SL. A world without measles. *J Infect Dis*. 2011 Jul;204 (Suppl 1):S1-3.
 8. Slack MP, Azzopardi HJ, Hargreaves RM, Ramsay ME. Enhanced surveillance of invasive *Haemophilus influenzae* disease in England, 1990 to 1996: Impact of conjugate vaccines. *Pediatr Infect Dis J*. 1998 Sep;17(9 Suppl):S204-7.
 9. Tate JE, Haynes A, Payne DC, Cortese MM, Lopman BA, Patel MM, Parashar UD. Trends in national rotavirus activity before and after introduction of rotavirus vaccine into the national immunization program in the United States, 2000 to 2012. *Pediatr Infect Dis J*. 2013 Jul;32(7):741-4.
 10. Kang G. HPV vaccines: separating real hope from drug company hype. *Indian J Med Ethics*. 2010 Jan-Mar;7(1):56-7.
 11. Mantel C, Wang SA. The privilege and responsibility of having choices: decision-making for new vaccines in developing countries. *Health Policy Plan*. 2012 May;27 (Suppl 2):ii1-4.
 12. World Health Organization. WHO vaccine reaction rates information sheets [Internet]. Geneva:WHO;2013 [cited 2013 Aug 14]. Available from: http://www.who.int/vaccine_safety/initiative/tools/vaccinfosheets/en/index.html.
 13. Miller E, Andrews N, Stellitano L, Stowe J, Winstone AM, Shneerson J, Verity C. Risk of narcolepsy in children and young people receiving AS03 adjuvanted pandemic A/H1N1 2009 influenza vaccine: retrospective analysis. *BMJ*. 2013 Feb 26;346:f794.
 14. Miller E, Goldacre M, Pugh S, Colville A, Farrington P, Flower A, Nash J, MacFarlane L, Tettmar R. Risk of aseptic meningitis after measles, mumps, and rubella vaccine in UK children. *Lancet*. 1993 Apr 17;341(8851):979-82.
 15. World Health Organization. Causality assessment of adverse event following immunization (AEFI): user manual for the revised WHO classification WHO/HIS/EMP/QSS 2013 [Internet]. Geneva: WHO; 2013 Mar [cited 2013 Aug 14]. Available from: http://www.who.int/vaccine_safety/publications/aevi_manual.pdf.
 16. WHO. Statement of the Global Advisory Committee on vaccine safety on AEFI related to pentavalent vaccine (DPT Hib Hep B) use in Asia [Internet]. Geneva:WHO; 2013 JunA [cited 2013 Aug 15]. Available from: http://www.who.int/vaccine_safety/pentavalent3.pdf.
 17. Greaves F, Donaldson L. Measles in the UK: a test of public health competency in a crisis. *BMJ*. 2013 May 1;346:f2793.
 18. Parker SK, Schwartz B, Todd J, Pickering LK. Thimerosal-containing vaccines and autistic spectrum disorder: a critical review of published original data. *Pediatrics*. 2004 Sep;114(3):793-804.
 19. Rowhani-Rahbar A, Klein NP, Dekker CL, Edwards KM, Marchant CD, Vellozzi C, Fireman B, Sejvar JJ, Halsey NA, Baxter R; Risk Interval Working Group of the Clinical Immunization Safety Assessment Network. Biologically plausible and evidence-based risk intervals in immunization safety research. *Vaccine*. 2012 Dec 17;31(1):271-7.
 20. Poland GA, Jacobson RM, Ovsyannikova IG. Trends affecting the future of vaccine development and delivery: the role of demographics, regulatory science, the anti-vaccine movement, and vaccinomics. *Vaccine*. 2009 May 26;27(25-26):3240-4.
 21. Poland GA, Jacobson RM. Understanding those who do not understand: a brief review of the anti-vaccine movement. *Vaccine*. 2001 Mar 21; 19 (17-19):2440-5.

The H1N1 influenza pandemic: need for solutions to ethical problems

PRATEEK BHATIA

Assistant Professor, Department of Paediatrics, Post Graduate Institute of Medical Education and Research, Sector 12, Chandigarh 160012 INDIA e-mail: prateekbhatia@rediffmail.com

Abstract

The rapid spread of the novel influenza virus of H1N1 swine origin led to widespread fear, panic and unrest among the public and healthcare personnel. The pandemic not only tested the world's health preparedness, but also brought up new ethical issues which need to be addressed as soon as possible. This article highlights these issues and suggests ethical answers to the same. The main areas that require attention are the distribution of scarce resources, prioritisation of antiviral drugs and vaccines, obligations of healthcare workers, and adequate dissemination and proper communication of information related to the pandemic. It is of great importance to plan in advance how to confront these issues in an ethical manner. This is possible only if a comprehensive contingency plan is prepared with the involvement of and in consultation with all the stakeholders concerned.

Introduction

A novel influenza virus of swine origin, A H1N1, emerged in Mexico in 2009 and spread rapidly, in a matter of weeks, across multiple countries in the four major continents. The high mortality among young Mexicans, coupled with the rapid spread of the virus worldwide, revived memories of the devastating severe acute respiratory syndrome (SARS)

epidemic of 2003. Sensing the initial panic and in view of the case fatality associated with the virus, many countries rushed to control the epidemic. Some of the most drastic steps were taken by China and Hong Kong. The former quarantined Canadian and Mexican nationals, while the latter sealed off an entire hotel when the first case of H1N1 influenza (a Mexican guest) was detected. All other guests and the staff were placed in quarantine [<http://news.bbc.co.uk/2/hi/asia-pacific/8032157.stm>]. Soon, the World Health Organization (WHO) raised the pandemic alert level to five and declared an orange alert. All healthcare workers were required to wear N95 masks at work and have their temperature monitored twice daily. Each patient could have only one visitor a day, and checkpoints were set up at all hospital entrances. The movement of patients and healthcare workers between hospitals was restricted, and rotations of junior doctors suspended. Medical conferences were cancelled, leave for healthcare workers was curtailed, and elective surgical procedures were postponed. Restrictions were placed on overseas travel by hospital employees, and quarantine or viral screening was made mandatory on their return from countries that had reported local transmission. Additionally, travellers who had returned from Mexico were quarantined for seven days. Schools were required to begin monitoring the temperature of all students. Public health

messages were disseminated on social distancing, hand hygiene, and social responsibility.

The widespread panic among the public and growing healthcare burden raised several ethical problems, which needed to be addressed ethically. Since influenza pandemics occur in several waves lasting a year or two, thus requiring the response efforts to be sustained for a prolonged period of time, it is necessary not only to address the ethical issues which may arise during the planning, preparedness or response phase, but also to understand that these problems need to be addressed within an ethical framework.

Are ethical issues a priority during pandemics?

It is rightly said that a good and fair decision is one which is based not only on sound scientific reasoning, but also on the moral values and principles of society. If we fail to incorporate ethical guidelines into our planning process or respond purely scientifically to every issue, we may land up being unfair and appear untrustworthy to the public. This has already been witnessed during the SARS epidemic in Toronto (1), where the healthcare organisations learned that the costs of failing to address ethical concerns were severe. These costs included lowering of the morale of hospital staff, confusion about roles and responsibilities, stigmatisation of vulnerable communities and misinformation.

Role of ethics in planning for pandemic influenza

The incorporation of ethics into plans to counter pandemics can be described as "the application of value judgments to science" (2). According to Thompson et al (3):

While the ethics might have little to contribute to understanding the mechanism of influenza virus transmission, it can make a significant contribution to debates such as what levels of harm the public are prepared to accept, how the burdens of negative outcomes should be distributed across the population and whether or not more resources should be invested in stockpiling antiviral medications.

Thompson et al (3) and Torda (4) proposed an ethical framework to guide sound decision-making and fair handling of ethical issues. They developed the framework after an extensive review of the literature available on clinical and public health ethics, following which they vetted it together with the stakeholders concerned. The two important components of their framework were (i) ethical decision-making processes, and (ii) ethical values.

According to the authors, the ethical process should encompass the principles of openness and transparency with regard to the decisions taken. Further, it should be scientifically and morally reasonable and rational, include inputs from the stakeholders, be accountable during the time of crisis, and be responsive to critical review and revisions. The important ethical values to be considered are the duty to provide care, the principle of equity, privacy, proportionality, solidarity, and mutual trust.

Table 1 presents the main ethical issues related to influenza pandemics, along with the authors' ethical, rational and scientific prescriptions on how these issues should be addressed. The scientific view of the importance of each of these ethical issues is reviewed in the subsequent paragraphs.

Ethical issues pertaining to pandemic influenza

The following ethical issues pertaining to pandemic influenza need critical analysis and consideration.

- The development of a comprehensive contingency plan/policy, involving the stakeholders and public
- Schemes prioritising vaccination, antiviral therapy and personal protective devices
- Rationing of scarce resources for intensive care and acute care
- The obligation of healthcare workers to serve under stressful and risky conditions
- Adequate dissemination and communication of information

1. The contingency plan

The most important step towards planning or preparing to meet an impending epidemic is the framing of a "contingency plan" by the healthcare organisation. An important component of a contingency plan consists of the objectives to be achieved in the eventuality of a potential pandemic or before a pandemic emerges. This should be followed by a step-wise, escalating response as the pandemic evolves. It has been noted that though most organisations are able to design a contingency plan to face an epidemic, their plans fail to meet the institutional or public needs. This is because most of the ethical issues concerning the population likely to be affected are either not foreseen or defined clearly, or the decision-making process is marked by the absence of healthy public engagement and discussion. In his critical analysis of the contingency plans of three nations (the UK, the USA and Canada) on how to face pandemics, Kotalik (5) found similar shortcomings. The plans lacked proper and clear guidelines on how to address ethical issues pertaining to the pandemic. Most plans fail to work in an emergency situation as they are highly scientific and are not backed by moral values.

The WHO and UK pandemic contingency plans (6,7) stress that the primary objectives of an effective plan must be to save lives, reduce the health impact of a pandemic, and minimise the disruption of health and other essential services. Also essential for an effective contingency plan are a strong leadership, inter- and intra-organisational communication and coordination, as well as clear lines of accountability. Advance planning is also a must, not only to establish but also to rehearse contingency arrangements and to identify and address gaps in preparation.

2. Schemes prioritising vaccination, antiviral therapy and personal protective devices

Pharmaceutical interventions like vaccines and antiviral therapy are required to mitigate the impact of an influenza epidemic.

Until the new virus strain is isolated or characterised, stockpiling of vaccine is not possible. Once the production of the vaccine is under way, batches of the vaccine can become available only in a gradual fashion. A recent WHO report estimated that the global production capacity for current influenza vaccines is 350 million doses per year, which is clearly insufficient for supplying vaccines to all countries. (http://www.who.int/csr/resources/publications/influenza/WHO_CDS_EPR_GIP_2006_1/en/index.html). As only a limited quantity of vaccine may be available to the developing nations, either due to the cost factor or the limited resources available in these countries for mass production, the question arises as to who should get the vaccine during the pandemic. How are the large-scale logistics to be managed and from where are the human resources to be garnered to implement a mass vaccination programme? Also considering the costing of antiviral drugs, the question arises as to how much should be stockpiled or kept as a safety stock. It has been suggested that a stockpile to cater to around 25% of the target population must be maintained and that the contingency plans should clearly spell out details regarding its procurement and storage, in addition to specifying the budgetary constraints.

As per the guidelines issued by the US Centers for Disease Control and Prevention (CDC) on the 2004–05 pandemic (8), the administration of the vaccine should be prioritised in the following order:

1. Pregnant women
2. People who live with or have regular contact with infants below 6 months of age
3. Healthcare and emergency medical services personnel
4. Children and young adults between ages 6 months and 24 years
5. Those with existing health conditions which put them at increased risk of complication

It is important to weigh the disadvantages against advantages while considering a mass vaccination programme. This would include taking into account factors such as the implementation costs of such a programme and the benefits of non-pharmacological interventions, eg isolation, quarantine and personal hygiene. Antiviral drugs are the other mainstay of treatment during pandemics and their use should be prioritised, like that of vaccines, in the case of the development of early symptoms among various high-risk groups.

During an influenza pandemic, additional essential medical supplies, such as gloves, masks, syringes, antipyretics and antimicrobial agents, are required. There is a shortage of these supplies in healthcare facilities in the developing countries, even in non-emergency situations. This shortage can hamper the provision of adequate medical care to patients with pandemic influenza. In addition, it is necessary to have basic personal protective equipment, such as disposable gloves and surgical masks, for healthcare workers. An estimate of the quantity of essential supplies needed, the estimated costs of procurement, a list of local distributors/suppliers, and the

mechanism for early procurement of the supplies should be detailed in the contingency plan. The decisions on the quantity to be purchased should be rationalised on the basis of the gap between the existing resources and the ideal requirement at the time of a pandemic; and consideration should also be given to the costs involved, ie the cost in terms of human suffering or loss of life. A certain quantity of the essential supplies should be purchased and kept as safety stock in the disaster cabinets, for use by healthcare workers during an emergency. The policy-makers should issue appropriate and fair guidelines on the meticulous and judicious use of personal protective equipment and other supplies. The guidelines should give due priority to essential healthcare workers, other workers who provide life-saving services, as well as critical services necessary for society to function as normally as possible. The emphasis must shift from the individual to the general population.

3. Rationing of scarce resources for intensive care and acute care

Healthcare organisations face a disaster alert following the outbreak of a pandemic, if it is severe, as an extremely large number of sick people may require care at the same time. The vital question is: how to provide the best care to all. The principle of equity states that all patients have an equal claim to healthcare, not only under normal circumstances, but under all circumstances. If the chances of survival of one out of two severely sick patients are poor, which of them is to receive care in the ICU? What quantity of the limited but costly resources, such as ventilators, needs to be purchased? To what extent does the capacity of the hospital, in terms of beds, need to be augmented?

Oshitani et al (9) reported that with an incidence rate of 35%, up to 79.1% of hospital beds are required for patients with pandemic influenza in low-income countries. In countries like Bangladesh and Nepal, more than 100% of beds would be required for patients with pandemic influenza, even at an incidence rate of 15%.

To decide upon how to allocate scarce resources and provide equal access to healthcare facilities, the approaches advocated in the several allocation theories may be considered. These are the libertarian, utilitarian, egalitarian and communitarian approaches (10). The libertarian view is that allocation is best left to the marketplace, while according to the egalitarian approach, which is based on the principle of equity, everyone should receive the same treatment, the same amount of treatment and the same opportunity to access the benefits provided. The communitarian approach emphasises consensus among the members of the community on the goals and values they wish to achieve and uphold. The author, however, suggests the adoption of a utilitarian approach, which advocates a proper distribution of resources in order to achieve the best outcomes or greatest benefit for the greatest number of people. Patients coming to hospitals can be medically prioritised into those who will probably live only with treatment, those who will probably live without treatment and those who will probably die with treatment.

Decisions on the provision of rationalised care may also be made on the basis of the quality adjusted life years technique. An ethically reasonable approach would be to reject those patients who might survive, but who would spend a long time in the intensive care unit.

During the planning process, steps must be taken to allocate an amount of the budget that has been fixed in advance for the purchase of vital or life-saving equipment. The amount fixed should be based on the number of patients who are likely to require acute/critical care, the population the hospital caters to and the level of care the hospital is expected to provide. It is also necessary to mobilise the staff and ensure that vital equipment is available for use by rescheduling surgeries / procedures fixed earlier to a later date. Further, the situation must be assessed repeatedly, on a day-to-day basis. These measures should be clearly spelt out in the contingency plan. Most importantly, these decisions or policies should involve and draw upon inputs from the community health officials, healthcare workers and the public, and be put across in a clear, transparent, fair and systematic manner.

4. The obligation of healthcare workers to serve under stressful and risky conditions

Kotalik (5) rightly asserts that a successful response to an influenza pandemic depends greatly on the attitudes, skills and efforts of healthcare workers.

Dr Joanna Tse Yuenman, a 35-year-old physician specialising in respiratory diseases, was the first doctor working in a public hospital to die of SARS during the 2003 Hong Kong epidemic [http://english.peopledaily.com.cn/200305/23/eng20030523_117091.shtml]. Her death generated a great outpouring of public emotion in Hong Kong. Two quotes (11) that express the sentiments regarding her sacrifice are, "As a doctor, her duty was to save lives," and, "...the dedication and professionalism of the front-line medical personnel went far beyond the simple duties of a job."

Healthcare workers are expected to work outside their normal scope of practice, put in extra hours, fill in for workers who are ill and be prepared to move where their services are most needed. What are the healthcare organisation's obligations towards them? Is it professionally right for healthcare workers to go home and leave their colleagues to cope? Should there be legal provisions to force the staff to work during a pandemic?

Healthcare organisations should ensure the safety of their workers and protect them. They should support their staff during a pandemic. The healthcare workers should be kept informed about the situation and what is expected of them. They should be encouraged to formulate their responses, which should then be discussed in an open forum. Priority-based prophylaxis/vaccination should be administered and safety measures, such as the provision of personal protective equipment, should be taken. This helps to reduce staff absenteeism and prevents healthcare workers from becoming vectors of the infection. Though the extent to which healthcare

Table 1
An overview of ethical problems and an ethical approach to these during influenza pandemics

Problem	Suggested ethical approach
Lack of a comprehensive contingency plan/policy document	Frame a policy document in consultation with and with the involvement of all the stakeholders concerned. Incorporate both scientific and moral viewpoints. Keep the document open-ended, subject to a process of review. Make sure the document clearly spells out the roles and responsibilities of all concerned.
Issue of prioritisation of vaccine, antiviral drugs and personal protective devices	Assess your target population and identify the rough percentages of high-risk groups. Consider the limitation of resources and the time gap until the vaccine, drugs and protective devices can become available to the target population. Stockpile the necessary items for at least 25% of the target population at any given time. Formulate strict policy guidelines on the issue of vaccines/drugs and protective devices as per priority.
Extent of augmentation of resources needed to provide best and optimal care to all	Adopt a utilitarian approach of saving the maximum number of lives. Allocate separate assessment and triage areas within healthcare facilities/hospitals. Prioritise patients to be admitted to the ICU or acute care on the basis of their age, symptoms, underlying illness or chances of survival. Never prioritise them on the basis of race, gender, religion or citizenship Lay down guidelines on an increase in the bed strength, availability of laboratory services and number of ventilators on the basis of the hospital's resources, the target population it caters to and the expected number of cases likely to be encountered.
Obligation of healthcare workers to serve under stressful and risky conditions	Provide priority-based protection to healthcare workers. Provide the healthcare workers with an assurance that they will receive incentives in the form of extra remuneration for additional hours of duty and special off days after the pandemic is over. State clearly the organisation's policy that healthcare workers are bound to discharge their moral duty unless there is a compelling reason not to.
Inadequate dissemination and communication of information	Clearly spell out and define the line of command for all communications. Make the public aware of the emergency numbers and the nodal officers they can contact. Conduct health education campaigns on influenza for the general public. The situation should be reassessed through time-bound meetings and periodic reviews of the contingency plans/decisions

workers are obliged to risk their lives to deliver clinical care is difficult to quantify, ethically, it must be made clear to them that they should discharge their duty unless it conflicts with one or more of their other moral duties, i.e. if they do not have a stronger, more compelling reason to absent themselves from duty, then they have an obligation to risk their lives and come to work.

5. Adequate dissemination and communication of information

The plan for dealing with an influenza pandemic should be communicated to the government authorities at various levels and to the related institutions. Attempts should be made to disseminate the provisions of the plan in a systematic manner.

Who defines and controls the protocol for communicating information on the pandemic?

How is the information disseminated? What measures are being taken to inform the population likely to be affected? Are any mechanisms in place for the redressal of complaints or grievances, and how are decisions on such matters taken and communicated?

The plan of the healthcare organisation should clearly specify the line of authority and define a single command which would serve as the channel for the communication of all information. This may entail identifying and appointing designated nodal officers for pandemic control and surveillance.

There should be mechanisms to ensure the proper collection and compilation of the necessary guidelines, as well as the systematic issuance of the guidelines to all the stakeholders concerned. No miscommunication, duplication or delay should be allowed in the percolation of the important information. Efforts should be made to promptly involve and notify the sections of the public likely to be affected by the pandemic. In this context, utilising the services of a dedicated team of the community health officials of the organisation or help from NGOs would be useful, as would be targeted public health education and awareness campaigns. Such campaigns would minimise the spread of panic, while the public's involvement and support would help in addressing many ethical issues in a more fair and transparent manner. A mechanism to ensure accountability must be put in place so that the process of decision-making is ethical throughout the crisis. Further, scope should be given for the elaboration and refinement of the contingency plans on the basis of inputs from the stakeholders, government guidelines, public complaints and suggestions.

Conclusion

Influenza pandemics pose an ever-growing threat and in the near future, the morbidity and mortality associated with them

might greatly increase among all age groups. Our healthcare system needs to gear up for this challenge and plan strategic measures well in advance. Several ethical issues of a complex nature may crop up and hamper healthcare efforts or undermine public trust, but if we adopt an ethical framework for decision-making in our plans, our efforts to control the pandemic may well make a considerable impact. The aim of this article has been to highlight the importance of an ethical process while planning for the eventuality of a pandemic, and to outline and find ways of addressing the various ethical problems which may come up during the preparedness or response phase of an influenza pandemic.

References

1. Singer P, Benatar SR, Bernstein M, Darr AS, Dickens BM, MacRae SK, Upshur REG, Shaul RZ. Ethics and SARS: lessons from Toronto. *BMJ*. 2003;327:1342-4.
2. Perhac RM. Comparative risk assessment: where does the public fit in? *Sci Technol Hum Val*. 1998;23:221-41.
3. Thompson AK, Faith K, Gibson JL, Upshur REG. Pandemic influenza preparedness: an ethical framework to guide decision-making. *BMC Med Ethics*. 2006;7:1-11.
4. Torda A. Ethical issues in pandemic planning. *Med J Aust*. 2006 Nov 20;185(10 Suppl):S73-6.
5. Kotalik J. Preparing for an influenza pandemic: ethical issues. *Bioethics*. 2005 Aug;19(4):422-31.
6. World Health Organization. Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits [Internet]. Geneva:WHO; 2011 May 5 [cited 2013 Aug 20]. Available from: <http://apps.who.int/gb/pip/>.
7. National Health Service. Pandemic flu: UK health departments' UK influenza pandemic contingency plan [Internet]. London:NHS; 2005 Oct [cited 2013 Aug 20]. Available from: <http://www.dh.gov.uk/pandemicflu>.
8. Centers for Disease Control and Prevention. Use of influenza A (H1N1) 2009 Monovalent Vaccine Recommendations of the Advisory Committee on Immunisation Practices (ACIP), 2009. *MMWR* 2009;58(RR10):1-8.
9. Oshitani H, Kamigaki T, Suzuki A. Major issues and challenges of influenza pandemic preparedness in developing countries. *Emerg Infect Dis*. 2008;14(6):875-80.
10. Beauchamp TL, Childress JF. *Principles of biomedical ethics*. 3rd edition. Oxford: Oxford University Press; 1994.
11. Gardiner D. Are you coming to work during pandemic flu? *Anaesthesia*. 2008 Aug;63(8):803-5.

Medical regulation in India: an outsider's perspective

RAJAN MADHOK

Former member, General Medical Council, Chairman, British Association of Physicians of Indian Origin, 43 Hookhams Lane, Renhold, Bedford, UK
e-mail: rajan.madhok@btinternet.com

Abstract

This personal comment briefly describes the working of the General Medical Council, the medical regulator in the United Kingdom (UK), with the aim of informing the discussion on how to regulate medical education and doctors' practice in India. Given that the ministry of health and family welfare is still debating the final constitution of the Medical Council of India, this paper is timely.

Introduction

The issue of the regulation of medical education and doctors'

practice continues to attract attention in India due to the ongoing uncertainty about the future of the Medical Council of India (MCI), the media attention sparked by programmes such as "Satyamev Jayate" and the subsequent reaction of the Indian Medical Association (1). Since 2010, various boards of governors (BOGs) have been established for short terms, and the ministry of health and family welfare established yet another one with effect from May 2013, with a term of six months (<http://mciindia.org/>). The lack of a properly constituted BOG and the continuing uncertainty are not helping to take forward the