

The Ethics of Responding to a Novel Pandemic

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Abstract

Recent epidemics and pandemics have highlighted a number of ethical concerns about the response to the increasing threat of emerging infectious diseases. Some of these ethical concerns are very fundamental. They include why a pandemic was declared, how much clinical information can be collected for public health without threatening patient confidentiality and how to ensure fairness in the distribution of resources. We discuss these issues and suggest approaches to resolve these dilemmas as we anticipate the next pandemic.

Ann Acad Med Singapore 2011;40:30-5

Key words: Bioethics, Emerging infectious diseases, Ethics, Influenza, Pandemic, Quarantine, SARS, Surveillance

Introduction

“A man without ethics is a wild beast loosed upon this world.”

Albert Camus (1957 Nobel Prize for Literature)

As the microscopic ‘wild beasts’ of infectious diseases are loosed upon this world with an ever increasing frequency in recent years, there is a corresponding need for us to come up with strong guiding principles by which to tame both them and us. Camus himself in his classic novel of the plague of Oran described some of the existential issues confronting a community during an epidemic of a highly contagious pathogen.¹ Highly infective viral (and occasionally bacterial) epidemics traverse a landscape that is fraught with ethically loaded decisions. This is due to their invisible but yet widespread nature and potentially catastrophic consequences, and also due to their widely differing effects on different levels of society.

This article describes the ethical issues that have faced previous pandemics — during the SARS as well as H1N1. We then proceed to examine these issues from the Singaporean context and make recommendations on ways

to resolve ethical dilemmas in future pandemics.

What is A Pandemic?

Although most people would understand a pandemic as a disease which affects all of humanity, wreaking death and destruction in its wake, there are also well argued scientific criteria for what constitutes a pandemic.² In 2009, the World Health Organisation (WHO) changed their definition of a pandemic to “when an animal influenza virus to which most humans have no immunity acquires the ability to cause sustained chains of human-to-human transmission leading to community-wide outbreaks. Such a virus has the potential to spread worldwide, causing a pandemic.”³ Interestingly, the original definition contained 2 other conditions – high morbidity and high mortality rate. This has become a major issue of contention amidst allegations of undeclared conflicts of interest and the changed landscape of international health after the passage of the new International Health Regulations.

At the time that the influenza pandemic was declared, nearly 30,000 people in 74 countries had been confirmed to be infected, but only 144 had died, which works out to

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a case fatality rate of less than 0.5%⁴, even without taking into account the universally accepted under-reporting of the denominator data due to the limitations of testing for the novel pandemic virus. In fact, in more recent data with the benefits of enhanced surveillance and molecular diagnostics, Singapore researchers reported a fatality rate of 7 per 100,000 for the 2009 Influenza A (H1N1) 2009 pandemic.⁵ This is actually lower than the case fatality rate for seasonal influenza. As seasonal influenza disappeared during the peak of the H1N1 2009 influenza pandemic,⁶ it is possible that this was the first pandemic in history which actually lowered global mortality! In contrast, Severe Acute Respiratory Syndrome (SARS) had an average case fatality rate of 15%⁷ but was not declared a pandemic by the WHO as the revised international regulations were not in place and the definition of a pandemic by the WHO had not been changed.

The declaration of a pandemic has much more than just semantic implications. Due to concerns about an influenza pandemic with high mortality and morbidity, and with the encouragement of the WHO, several countries had pandemic plans in place. Most of these plans referenced the WHO pandemic plan and included variations on the WHO pandemic stages. At the different stages of the pandemic, various actions were called for including in most cases, stockpiling of influenza vaccines and antivirals once a pandemic or imminent pandemic was declared. After 2005, most countries did not adjust their pandemic plans to take into account the impact of severity of the pandemic and thus, were locked into contracts or plans which committed them to purchasing these stockpiles regardless of the degree of severity of the pandemic.⁸⁻¹⁰ There has been intense speculation in some circles about why these two conditions were removed.¹¹ By altering this definition, the WHO lowered the threshold for classifying a disease as a pandemic. Was this in response to an anxious public, keen to have early activation of resources and quick governmental action regardless of the initial apparent severity of the novel disease? Cynics have argued that the revised definition only benefits the pharmaceutical industry that stands to profit the most from a pandemic — including producers and suppliers of vaccination, antiviral and personal protective equipment — as the general public is not likely to benefit much from the amelioration of a mild pandemic and in fact might lose on essential healthcare through the diversion of resources from endemic problems. Bulk purchases of “pre-pandemic” vaccines and antivirals represent a tremendously efficient means of guaranteed sales with few of the attendant costs of detailing and direct marketing that are required for the regular, proven seasonal influenza vaccines.¹² The WHO, however, has countered, that we were dealing with an unknown virus from the start and it was necessary to build

a large stockpile from the start. Furthermore, countries have the right to choose whether or not to commit to buying these vaccinations. Hindsight has limited ethical force. As data become available, plans should be adapted accordingly. However, such changes were to a large degree resisted by most countries.

It is reassuring that the issue of conflicts of interest and the decision making process that went into the revision of the WHO pandemic declaration are now coming under scrutiny from a high level body led by a highly respected scientist and hopefully the findings from that review will greatly improve our understanding of these decisions. The ethical implications are tremendous and the debate will be informed for years to come. Although there has not been a change in the formal pandemic plans to date, there are likely to be changes in the future once the lessons of the pandemic have been analysed more completely.

Surveillance

In order to declare a pandemic — either a mild one or a severe one, it is obviously essential to know that there is indeed a new disease circulating and to obtain accurate information about its aetiology, epidemiology and of course, severity. This can only be done through an effective system of surveillance.

Surveillance refers to the systematic ongoing collection, collation and analysis of data and the timely dissemination of information to those who need to know so that the necessary action can be taken.¹³ This can occur on several different levels.

At the very basic, having effective surveillance means that the public health authorities or academic institutions need to have access to clinical data. Traditionally, the sanctity of patient-physician confidentiality has been elevated to almost the level of that between a confessor and priest or a lawyer and client.¹⁴ Most individuals, however, recognise the limitations to such confidentiality. Even in terms of lawyers and priests, there are extreme situations such as when someone confesses credibly to planning a murder that confidentiality can be ethically breached. Most emerging infectious diseases have been detected initially by an alert clinician who informs either the academics or the public health system.¹⁵ For many diseases, such “breaches of confidentiality” will be accepted by the majority of patients as they will be perceived as being in the interest of the safety and health of the wider population as a whole (including the family and friends of the “index case”). Unfortunately, for a number of other diseases, the “exposure” associated with the revelation of clinical information carries a great deal of real or perceived stigma. For example, the index case in the SARS epidemic in Singapore was publicly identified in

the Singapore media as the epidemiology was outlined in the press on a regular basis. This, together with the trauma associated with losing many of her close family and friends, led to significant psychological morbidity.¹⁶ Similarly, the first few cases of pneumocystis carinii pneumonia which heralded what has become the world's most deadly pandemic were identified among young homosexual men in Los Angeles,¹⁷ at that time, a greatly stigmatised group. It took years before the epidemic was recognised and many countries were in denial about HIV/AIDS for more than a decade.

The International Health Regulations (IHR) (2005) require Member States to keep data “confidential and processed anonymously as required by national law.”¹⁸ Many countries have data protection statutes, but these laws make exceptions for surveillance in the context of a public health threat.¹⁹ In situations where for example, employment or livelihood of the infected or recovered individual could be affected, there is a significant ethical tension between protecting the privacy and well-being of the individual versus protecting the public against real or apparent threats to their health. Nowhere is this more acute than in the healthcare setting. Again, the experience of SARS can be instructive. In the early days of the SARS epidemic, healthcare workers were becoming infected but still going to work as the high levels of absenteeism due to illness placed stresses on an already challenged healthcare system. While appearing to be ‘hardworking’ and ‘dedicated’, by going to work while ill or incubating the illness, they inadvertently ended up infecting many of their colleagues and patients, some of whom even died as a result.²⁰ In a culture in which taking sick leave is viewed negatively, there is often a perverse incentive which encourages healthcare workers to go to work while incubating potentially serious infections.

In Singapore, surveillance is carried out within the community, with weekly reports of acute respiratory infections compiled from public sector hospitals and polyclinics. In addition, virological surveillance of influenza viruses is routinely carried out by the National Influenza centre. These reports are all anonymised and individual patient data are not accessible to the public health authorities. In addition, hospital surveillance mandates that patients fulfilling criteria of atypical pneumonia, prolonged unexplained fever and sudden acute respiratory death be reported to the Ministry of Health (MOH).²¹ The Infectious Diseases Act in Singapore was recently strengthened²² despite some concerns from the medical and bioethics community. The changes increase the mandates for clinicians to report either confirmed or suspected cases of diseases of public health importance to the MOH with punitive measures being threatened for those who fail to comply.

Once an index case for a novel emerging infectious disease has been identified and confirmed, it is then critical to know the extent and spread of the disease in order to plan a response, to contain the infection and prevent or mitigate the effects of a pandemic. In order to do this, some kind of screening will have to be done. Mass screening always carries ethical implications especially if it is mandatory. Laws governing premarital screening for HIV, for example, have been hotly debated.²³ Current diagnostic technology, however, does not allow for example for the mass screening of the entire population (for existing or potentially pandemic infectious diseases) to be done easily.

During SARS, another form of surveillance emerged – the measurement of core body temperature in public locations such as libraries, schools and offices. Many countries introduced the use of thermal scanners at points of entry and some even continue to employ them although evidence of their efficacy is lacking.^{24,25} This generates another ethical issue in that the liberty of individuals is subjected to an imperfect test. Most tests are not 100% sensitive or specific but generally, the impact of a false positive or false negative test is limited to the individual patient. For a novel pandemic virus, especially one that is highly feared because of its lethality, false negative and false positive tests can have devastating consequences not only on the individual but also on the family and community who might be subjected to either unnecessary quarantine in the event of a false positive or unprotected risk in the event of a false negative. At the same time, by their very nature, tests for novel emerging infectious diseases are likely to be less than perfect at the time they are first introduced. This introduces a huge challenge for decision makers and for those who are trying to communicate the implications of screening test results to the public at large.

Once widespread screening is in place, it is highly likely that more cases will be identified together with those identified by conventional epidemiology. The International Health Regulations (IHR) (2005) require member states to notify WHO of all events that may constitute a ‘public health emergency of international concern’.¹⁸ Consequently, countries are expected to have at least the capacity to detect and monitor events that might fall into this category. Developing nations may be pressured to improve their surveillance infrastructure for novel potential pandemic agents, but in doing so may divert resources from areas of greater need, such as endemic conditions like Acquired Immunodeficiency Syndrome (AIDS), tuberculosis and malaria. The current H1N1 2009 pandemic (for which WHO has finally declared the post-pandemic phase) claimed 18,000 lives in the year and two months since its appearance,²⁶ approximately the number of individuals who die in one week from malaria.

Resource Management in Pandemics

Distribution of scarce medical resources is a sensitive issue during a pandemic. Should these resources be diverted away from endemic and common diseases both communicable and non-communicable? Who should resources be diverted to? How should resources be split between different interventions? Two main principles have traditionally aided decision-making.

The first principle is that of utility/efficiency — to maximise the aggregate benefit of public health interventions with available means. This involves a focus on interventions with a high chance of success or favourable cost-benefit ratios. We have done a cost-effectiveness analysis of the infection control response to an emerging viral pandemic and have come to the conclusion that the critical factor is the severity of the pandemic.²⁷ Again, this points out how one of the principal lessons of this pandemic has been the critical importance of accurate data on disease severity.

The second principle is that of equity — how benefits and burdens are distributed within the population. Fairness implies that equal weight is given to equal claims of persons regardless of their age, position or state. Good stewardship refers to the ability to maximise benefits when allocating resources, and avoid and/or reduce collateral damage that may result from resource allocation decisions.²⁸

Antiviral drugs for influenza are an example in point. Timely treatment of symptomatic patients reduces duration of disease by one day and potentially reduces the chance that the person will suffer from severe complications of influenza. They can also be used for post-exposure prophylaxis, which has been shown to be effective in limiting transmission of influenza.²⁷

Given the current pharmaceutical industry approach to just-in-time manufacture, stockpiling in advance is the main option for assuring an adequate supply for your own country, but pre-exposure prophylaxis requires very large quantities and costs up to 30 times as much as treatment stockpiles.²⁹ Moreover, if some countries build extremely large stockpiles, this may reduce the opportunity for lower income countries to purchase antiviral drugs required for a reasonable minimum stockpile. On the other hand, prioritising antivirals for treatment of symptomatic treatment would be more reasonable from an egalitarian perspective. Pharmaceutical companies and governments have a shared responsibility to improve availability and affordability of antiviral drugs, including allowing the production of generic formulations and technology transfers. It is striking that while the US government took action against the manufacturers of generic HIV drugs in Brazil,³⁰ they did not hesitate to consider compulsory licensing of the

antibiotic ciprofloxacin during the anthrax scares of 2001.³¹

The economic burden of a pandemic is felt especially exquisitely in developing nations. In order to dam the spread of highly pathogenic Avian Influenza H5N1, at least 140 million birds were culled in 10 Asian countries, with direct economic costs of the outbreak estimated at more than US\$10 billion. In the most seriously affected parts of Indonesia, more than 20% of permanent industrial and commercial farm workers lost their jobs.³² Early detection of disease in poultry followed by rapid and effective culling has been advocated as the key in containing the spread of disease and elimination of the virus from poultry in a defined area. However, if these drastic measures lead to economic losses for many financially needy individuals in the absence of compensation, the incentives in fact might be in the direction of concealment rather than accurate surveillance of infection. This would be extremely counterproductive to pandemic containment measures.

Access to vaccination is another critical issue. It has been shown that access to seasonal influenza vaccination correlates roughly with GDP per capita with a few notable exceptions.³³ The strains used to produce a vaccine for a pandemic virus are likely to come from developing countries, particular in East and Southeast Asia where these viruses emerge due to the close nexus between humans and animals. Many of these viruses are collected and identified by scientists and clinicians at great personal risk. They are then often rapidly transported to research centres in developed countries and then given to pharmaceutical companies based in the North. The ensuing vaccines are then sold commercially to the developing countries at prices that they cannot afford. Attempts have been made to try to address this issue through the use of standard materials transfer agreements which have been in place within developed countries for years.³⁴ Unfortunately, the experience with the H1N1 2009 vaccine distribution does not give one confidence that the equity issues related to vaccine distribution are close to being solved.

Isolation and Quarantine

The Siracusa Principles are widely recognised as international guidelines for measuring valid limitations on human rights. The principles make clear that even when the state acts for good reasons, it must respect human dignity and freedom. It requires that state limitations must use “the least restrictive and intrusive means available, and not arbitrary, unreasonable or discriminatory”.³⁵ Striking a balance between individual and collective can be a difficult task, especially when it involves the restriction of movement to prevent transmission.

Under what circumstances can utilitarian ideas

legitimately trump other interests? The Siracusa guidelines are a legal document, but they do not help to resolve the ethical dilemma. Singapore is not signatory to the International Covenant on Civil and Political Rights, and thus is not bound by these legal guidelines which are based on ethical principles. Indeed, Singapore has taken a different approach to pandemic planning, as laid out by the Siracusa guidelines. It is probably too early to determine whether Singapore's approach is the right one — history will eventually be the judge.

Three telephone calls were made per day to the home of each individual in quarantine. Surveillance cameras were placed in homes where people were quarantined and inhabitants were required to take their temperature on camera. In addition, an electronic wrist or ankle band was used as enforcement measures, with a fine of over US \$5000 for breaching quarantine. In Hong Kong, barricades and tape were used to confine infected residents in a large housing complex. This is despite Siracusa guidelines stating that quarantine and isolation should be voluntary whenever possible, and should be enforced by the least intrusive means possible, and if possible minimising economic burdens on those quarantined. Evidently, different countries have different norms at different times, and enforcement measures must be viewed in context of what society considers reasonable to ensure compliance. Even in the US, with its culture that celebrates liberty and freedom, the widespread acceptance of the surveillance state under the Patriot Act has been recognised a higher priority for communal well-being, compared to individual freedoms. In the setting of the threat of terrorism (in the United States) or infectious diseases and accompanying societal disorder (in Asia), these intrusive measures may well be acceptable in these contexts.

Quarantine refers to the restriction of the activities of asymptomatic persons who have been exposed to a communicable disease to prevent disease transmission in the event that they have become infected. In contrast, isolation is the separation, for the period of communicability of persons known to be infected to prevent or limit the transmission of the infectious agent. Both may be accomplished by stay in own home, stay at designated facility or travel out of affected area. Although the form may differ, they always represent a significant deprivation of an individual's liberty in the interests of public health.

An ethical dilemma arises in isolating a case of infection at home, since this can increase the infection risk for contact persons. Isolation and quarantine were used widely and effectively in Asia and Canada during the SARS outbreaks in 2003. These interventions played a major role in containment, since SARS patients were infectious only after they became symptomatic. Unlike SARS, the transmission characteristics of influenza allow little time for isolation

because individuals can be infectious before the onset of symptoms and diagnosis often takes some time. There have been analyses of the impact of quarantine and isolation and these suggest somewhat limited efficacy.³⁶ These might call into question the balance between deprivation of liberty for an intervention with limited benefits. Quarantine is even more controversial than isolation as potentially individuals with no risk at all to the community might be segregated and in fact exposed to people who are harbouring the illness. This has been a concern through the centuries and questions have been raised about inadequate hygiene and protection for those under quarantine to prevent the quarantine centers themselves from becoming areas of widespread disease spread.

Conclusion

In this article, we have reviewed a number of the key ethical issues that confront practitioners both clinicians and public health professionals when a novel pandemic virus strikes. The Singapore approach to these matters may differ from that prescribed by international bodies. However, the implementation of ethics is influenced by the prevailing political situation and the culture of the society. It is important for a conversation to begin to discuss these issues in the local context. We hope that by raising these concerns, a cohesive approach to the ethics of the pandemic response can be incorporated into the national and international pandemic plans of the future.

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