

Addressing ethical issues
in pandemic influenza planning
DISCUSSION PAPERS

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Introduction

In March 2006, the World Health Organization (WHO) convened four working groups to review the literature and develop preliminary conclusions on key ethical issues in pandemic preparedness and response. The working groups included experts in ethics, law, and public health, WHO staff, and country representatives. This volume includes the background papers prepared by the chairpersons in consultation with their working group members.

In chapter I, Marcel Verweij of Utrecht University (Netherlands), chairperson of the working group on “**Equitable access to therapeutic and prophylactic measures**”, explores the challenge of allocating vaccines, antiviral medications, ventilators, and other scarce resources during a pandemic. He identifies three key ethical principles to guide such allocation decisions: efficiency, equity, and procedural fairness. While the principle of efficiency can be interpreted in multiple ways, Dr Verweij argues that the most defensible approach to efficiency in the context of a pandemic is to focus on saving the greatest number of lives. The principle of equity requires efforts to avoid discrimination, minimize unfairness, and prioritize individuals who are most likely to die without intervention. In addition, the “fair innings” approach to equity suggests that it might be appropriate to give priority to younger persons over older persons, although such an approach is likely to be controversial in many countries. Finally, procedural fairness requires policy-makers to ensure that prioritization decisions are made pursuant to impartial procedural mechanisms, that decision-makers are publicly accountable, and that the decision-making process is designed to promote public trust.

Chapter II is written by Larry Gostin, chairperson of the working group on “**Isolation, quarantine, border control, and social distancing**” and Ben Berkman, both of Georgetown University

(United States of America). This chapter explores a broad range of non-pharmaceutical public health interventions, including surveillance, personal and community hygiene, health facility infection control, isolation and quarantine, social distancing, and international travel and border controls. The authors emphasize that these interventions must be implemented within the context of internationally-recognized human rights principles, including those protecting freedom from arbitrary arrest, the right to movement, right to nondiscrimination, and the right to health. According to the Siracusa Principles, interventions that interfere with human rights must be in accordance with the law; based on a legitimate objective; strictly necessary in a democratic society; the least restrictive and intrusive means available; and not arbitrary, unreasonable, or discriminatory. In addition, principles of public health ethics emphasize the importance of distributive justice, transparency, and promoting public trust. The authors highlight the importance of mitigating the privacy and autonomy risks of public health interventions, providing due process protections to individuals whose liberty is restricted, and favouring voluntary compliance over coercion as much as possible.

In chapter III, Ross Upshur of the University of Toronto (Canada), who served as chairperson of the working group on “**Role and obligations of health-care workers during an influenza pandemic**”, discusses the importance of ensuring adequate numbers of health-care workers during a pandemic. He notes that, while most health-care workers provided exemplary service during the severe acute respiratory syndrome (SARS) crisis of 2003, some failed to report for duty. In addition, surveys of health-care workers’ attitudes reflect a substantial reluctance among many workers to provide care for patients during infectious disease

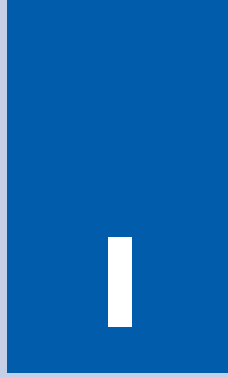
outbreaks. Dr Upshur argues that a duty to work during infectious disease outbreaks should be considered an ethical obligation for professional health-care workers. He also emphasizes that governments and health-care institutions have reciprocal obligations to make the workplace as safe as possible and to provide care and support for workers who become ill. He urges societies to adopt measures to encourage health-care workers to work voluntarily during a pandemic, and cautions against the imposition of sanctions on health-care workers who are unwilling to work.

Finally, in chapter IV, Robert Archer, chairperson of the working group on “**Pandemic influenza planning and response – transnational issues for governments**”, explores the role of international cooperation in pandemic preparedness and response efforts. He notes that international law and human rights principles require countries to help one another during public health emergencies. Governments also may be motivated to cooperate

in pandemic preparedness and response efforts to further their national interests or based on an ethical sense of solidarity. Governments must balance their commitments to the international community with their primary obligation to protect the health and safety of their own populations. Mr Archer explains the importance of international cooperation before, during, and after a pandemic.

Together, these four background papers provided the framework for the discussion at the WHO global consultation entitled “**Addressing ethical issues in pandemic influenza planning and response**” held in October 2006, as well as for the publication that grew out of that consultation, “*Ethical considerations in developing a public health response to pandemic influenza*”.¹ This volume is intended to complement that publication by providing a more comprehensive analysis of the ethical and policy issues which WHO considered in its deliberations. WHO is grateful for the working groups’ scholarship and insights.

¹ “*Ethical considerations in developing a public health response to pandemic influenza*”. Geneva, World Health Organization, 2007, available at: http://www.who.int/csr/resources/publications/WHO_CDS_EPR_GIP_2007_2c.pdf



Equitable access to therapeutic and prophylactic measures

Marcel Verweij, Utrecht University

ON BEHALF OF WORKING GROUP ONE

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1

Aim and context

It is generally expected that sooner or later a novel influenza A virus subtype, easily transmissible from person to person, will emerge and cause pandemic disease. Humans will have little or no immunity to this virus, which could spread at least as easily as common seasonal influenza and infect many people worldwide potentially resulting in very high mortality and morbidity rates. Some scenarios assume attack rates of up to 35% and lethal disease in 1–2% of persons who develop symptoms, yet such assumptions may be a gross overestimation or underestimation of the crisis (1). Mass production of a specific pandemic vaccine will not start for several months, and in the mean time the possibilities for prevention and treatment are limited. Depending on supplies, antiviral drugs could play an important specific therapeutic and prophylactic role. The global demand for antiviral drugs and medical care would be likely to exceed global (and affordable) supplies. Many patients may develop respiratory failure and require mechanical ventilation and the need for such intensive care will go far beyond available resources. Moreover, the disease will hit health-care professionals and related personnel: working in the front-line they run greater risks of infection than other citizens. This will increase pressure on the health-care system, where much more must be done with fewer staff. Triage decisions for allocating scarce treatment possibilities will be inevitable. Such decisions need to be made for supportive medical care (e.g. ventilators), antibiotics, antiviral drugs, and vaccines, as well as for access to health-care facilities in general.

One essential way to avoid chaos and to promote an adequate response to a pandemic is to develop action plans for pandemic preparedness. Allocation of scarce medical resources such as anti-

viral drugs, and development of vaccination strategies are important issues in such plans. Triage and priority-setting clearly raise ethical questions: is it morally justified to give certain persons access to life-saving treatment and to refuse others – and if so, which choices should be made and by whom? In 2006 many countries published action plans for an influenza pandemic but few provide discussion of such ethical issues and even fewer offer systematic ethical justification for priority setting (2, 3).

This paper formulates ethical principles and arguments for setting priorities in the distribution of scarce medical resources during a pandemic, especially antiviral drugs, vaccines, access to medical care, and bed and equipment allocation. Priority setting in a pandemic will be a deeply controversial issue. This is not only because there will be extreme shortages in supply of potentially life-saving treatment, but also because routine health-care procedures for illnesses other than influenza may not be applicable or appropriate where drastic interventions are required to mitigate the effects of the pandemic. However, ethical theories do provide clarification and reasonable justification for the principles that should guide decision-making.

This paper argues for specific priorities on the basis of maximizing health benefits (notably saving most lives) and equity, but also acknowledges that basic moral principles allow consideration of certain other priorities. The conclusions can only be provisional and incomplete given the lack of important data and inevitable conflicts between and within the basic moral principles. Moreover, some situations involve emergencies and tragedies of such magnitude that ethical theory has little practical guidance to offer.

2

Ethics and scarcity in a pandemic – general considerations and principles

2.1 Circumstances

Throughout the last decades it has been very difficult to establish consensus-based or well-justified principles for priority setting in health care (4). In an influenza pandemic the same controversies regarding priority setting arise, but now in extraordinary circumstances. The demand and need for health care will be much higher than in normal times and simultaneously the health-care system (like many other social institutions) will be weakened as a result of ill and absent staff. If only a few people get the care they need, this may raise public distrust in health-care professionals, institutions and governments. Moreover, fear of the disease might paralyse the life of the society or lead to panic and further distrust in governments and institutions. In such circumstances, the objective of developing principles for priority setting seems even more controversial than in normal health-care settings. Finally, important data, more or less available in normal circumstances (how effective are the various medical options; which groups are most at risk; which patients most urgently need treatment; and how many are they), are not available in advance of an influenza pandemic.

However, these extraordinary features do not necessarily render attempts at priority setting impossible, and to some extent they might even facilitate the development of some principles. First, a pandemic is to be considered as a worldwide emergency where all or almost all individuals are susceptible and therefore threatened. Thus policies should focus on protection of all members of the population at large. This is an objective that few will reject. Second, the uncertainties about who will be most at risk of severe illness and death in a pandemic might necessitate focusing on general principles and arguments, instead of giving priority to specific groups or persons. If everyone is uncer-

tain about who would, and would not, benefit from certain proposals, this might help generate some agreement on principles.

Two further complexities need to be mentioned at this stage. The first relates to the different types of health-care delivery, and the second to the differences in high-, middle- and low-income countries. The types of health-care delivery considered are vaccination, patient care, and antiviral drugs and they differ in many relevant respects. Vaccination is intended for preventive purposes aimed at those who have not yet been infected; (hospital) medical care involves therapy aimed at the (very) ill, and antiviral treatment can be used as early treatment of patients and as post-exposure or pre-exposure prophylaxis. Whereas resources such as antivirals, antibiotics and access to intensive care and hospital beds are expected to diminish through utilization during the course of the pandemic (if they are available in the first instance), pandemic vaccine availability may increase after the first months of scarcity. This difference in resource availability over time justifies having distinct approaches for priority setting.

The second complexity is that the differences between high-income countries and middle- and low-income countries will be immense. Some high-income countries expect to have sufficient stockpiles of antiviral drugs for treating all persons who develop symptoms of influenza. Low-income countries will probably have no stockpiles at all. A similar situation applies to vaccination. Many high-income countries are signing contracts with pharmaceutical companies in order to reserve production capacity and get vaccines as soon as these are produced. Low-income countries will not have such contracts, and hence might have no vaccine to distribute. This obviously raises questions concerning international aid and justice, which are discussed more extensively in chapter IV.

Many options discussed in this paper may not be available to low-income countries. It is also clear that low-income countries must balance their efforts in pandemic preparedness with regular health-care needs, given that such needs often remain unmet even in normal circumstances. Any adequate response to a pandemic requires infrastructures for primary care and prevention. Hence for many low-income countries the first priority for pandemic preparedness may involve strengthening their basic health-care facilities and infrastructure.

2.2 General principles for priority setting: efficiency, equity, and procedural fairness

When a major disaster is overwhelming a population, and many lives are at stake, there are strong moral reasons to protect the population and save as many as possible with available resources. On the other hand, distribution of scarce medical resources should also be equitable and fair.

The first general principle – to save the greatest number of lives – can be considered as a principle of **efficiency** or **utility**, to maximize the aggregate benefit of public health interventions with available means. This involves, among other things, a focus on interventions (and patient groups) that have a high chance of success. The importance of efficient action is obvious, but it is not obvious that success should be measured in terms of saving most lives. An alternative utility approach would be to aim at broader health benefits, in terms of life-years or quality-adjusted life-years (QALYs) gained. Broader still, public health interventions could aim at maximizing expected utility, which also includes non-health benefits such as the protection of essential economic functions. This is a discussion on the level of ethical theory, but the implications are very practical (see section 2.3).

The second general principle, **equity**, is not concerned with the best aggregate outcome of policies, but with how benefits and burdens are distributed within the population. Fairness implies that equal weight is given to equal claims of persons. Policies in which access to health care depends on nationality, ethnic group, gender, or social security registration are clearly unjust. But also policies that succeed in saving as many lives as possible can be unfair, for example if priority is given to vaccination of people in urban areas (where vaccination might be most

efficient and prevent most infections) and persons in rural areas have little or no prospect of getting vaccine. Equity may also support giving priority to saving young persons above elderly. Various implications of fairness are discussed in section 2.4.

The two basic principles, efficiency and equity, can conflict if priorities are to be set. Where decisions are based upon weighing competing values, it is important that there are **fair procedures for accountability** in place (see section 2.5).

Before discussing the principles and their conflicting interpretations in more detail, it must be emphasized that many general practical policy objectives, as outlined by WHO (5), can be supported from any reasonable account of efficiency and equity. In the case of a first outbreak, rapid response is essential, aiming at containment at the source. Subsequently, interventions should aim at preventing, for as long as possible, the introduction of the virus into non-affected populations. If an outbreak of influenza infection cannot be contained, policies should aim at reducing possibilities of transmission within the population using pharmaceutical and non-pharmaceutical interventions to the limits of their availability. Ultimately maintaining essential services, including the public health-care systems, will be crucial. Such steps are essential in any account of equitable and efficient response to pandemic influenza.

2.3 Efficiency

This section discusses in more detail the principle of efficiency, i.e. maximizing protection of the population with the available means. The key message is that **saving most lives** is the preferred outcome measure. There are strong reasons to avoid focusing on non-health benefits (e.g. general utility), but it is reasonable to include indirect health benefits as a measure of outcome. This implies that in some cases it is justified to give priority access to prevention and treatment to people who save lives.

A departure from principles that are considered most relevant and decisive in normal health care priority setting

A common assumption in health care is that those patients who are most ill and urgently require treatment should be treated first. In an influenza pandemic a different approach might be justified and necessary. Pandemic influenza will spread rapidly,

potentially affecting or killing many people, and it will put the health-care system under very heavy pressure. All persons run the risk of acquiring infection, many (if not all) are at some risk of fatal illness, and clearly not all can be saved. Vaccination and antiviral prophylaxis are not only beneficial for the persons who receive the vaccine or drug but also help to prevent further spread of the virus and hence offer benefits to others. In these circumstances it makes sense to depart from the principle of prioritizing the most needy and urgent, and to allocate health-care resources in such a way that as many persons as possible are protected – within certain constraints of fairness.

Consequentialist and non-consequentialist arguments for saving the greater number of lives

The idea that scarce resources should be allocated in such a way that maximum beneficial effect can be expected is consequentialist. Consequentialism is the ethical theory which requires us to compare the options we have and then to choose the option with the best expected aggregate outcome. This theory holds that our primary moral duty is to promote the general good. Non-consequentialist theories, on the other hand, will first emphasize that the rights of individual persons need to be respected, or their basic capabilities need to be secured. If we consider human life to be of central value, consequentialism supports allocation of resources so as to save as many lives as possible. The restriction to ‘saving lives’ however can be criticized. Some consequentialist approaches, for example utilitarianism, endorse a broader account of value, e.g. welfare, or utility, in which diverse goods are combined such as life, health, happiness, a healthy economy, etc. As a result, utilitarianism can sometimes prioritize protecting the economy above protecting lives. Other consequentialist approaches favour maximizing health benefits in terms of life years gained (QALYs, DALYs,¹ etc).

However, for various reasons, the aim of saving most lives may be preferable from a moral point of view. First of all, to save most lives with given resources can also be justified by appeal to non-consequentialist theories. For example, Scanlon’s contractualist theory (6) rejects interpersonal aggregation of harms and benefits because this allows policies that sacrifice someone’s life or

basic health in order to secure small benefits for the greater number. Such a trade-off however can be avoided if the ultimate focus is only on saving lives and not on smaller health benefits. Moreover, the principle of saving most lives can be considered consistent with a rights-based theory that assumes that all persons have an equal right to life and hence have an equal claim to protection of their lives. Such non-consequentialist theories accept that, if not all lives can be protected it is justified to protect as many lives as possible (7).²

Secondly, there are also consequentialist reasons for preferring policies that save most lives over policies that maximize general utility. Arguably, the latter policies aim to protect societal and economic functions, which in turn support giving priority access to prevention and treatment to governments and other leaders. However, if governments and persons in power receive a level of protection that is inaccessible to large sections of the public, this will quickly raise suspicion and distrust among the public. In contrast, a principle to **save as many lives as possible** is very simple and clear, and cannot be easily tailored to secure only the interests of groups who are in power. This further helps to avoid unfairness and to promote public acceptance.

Separate spheres and indirect benefits

The previous arguments support a focus on *saving most lives*. They do not rule out alternative approaches aiming to maximize broader health benefits e.g. in terms of life years saved, or DALYs or QALYs gained. Yet, the scope is restricted to concerns about health and disease, and non-health benefits should not determine rationing policies in health care. Of course, protecting the economy and other sources of welfare are highly important, but these concerns and their weight vis-à-vis con-

¹ The Disability Adjusted Life Year or DALY is a health gap measure that extends the concept of potential years of life lost due to premature death (PYLL) to include equivalent years of ‘healthy’ life lost by virtue of being in states of poor health or disability. One DALY can be thought of as one lost year of ‘healthy’ life and the burden of disease as a measurement of the gap between current health status and an ideal situation where everyone lives into old age free of disease and disability (source <http://www.who.int/healthinfo/boddaly/en/print.html>).

² Hirose (8) shows that in a contractualist framework it is even possible to accept the principle to save the greater number without relying on aggregation. Assuming that all persons whose life is in danger have an equal claim to be saved, the Pareto principle and the requirement of universalization are sufficient to argue for saving most lives.

cerns about public health should play a role in decisions about the size of the budget for public health. For example, building a stockpile will require large amounts of extra funds and deliberation about how many resources should be made available will depend on weighing the importance of non-health goods, such as welfare or education. Rationing decisions within the health budget should however focus on maximizing health benefits, preferably in terms of lives saved. This implies accepting different spheres for decision-making (8). Note however that there is no reason to separate care for pandemic influenza patients from care for patients with other diseases; if health-care resources are allocated to maximize health benefits, all patient groups must be taken into account.

If the focus is on health benefits and saving lives, a second issue is whether indirect benefits should also be taken into account (8). For example, treating health-care workers is not only beneficial because it might save their lives, but if they recover, they will contribute to saving the lives of further persons. Therefore, it makes sense to give health-care workers priority access to treatment. In normal health-care circumstances, such considerations are often considered inappropriate and unfair. However, in an influenza pandemic many people will die, and the number will grow rapidly if essential health services cannot be sustained. A policy that gives some priority to protecting and treating people who save lives will reduce overall mortality and hence significantly increase each person's chance of survival. For that reason, the policy can be justified. This approach also mitigates an ethical dilemma for health-care workers who are asked to assume an increased risk of disease while caring for influenza patients, and it provides a practical incentive for them to come to work.

In conclusion, in response to a pandemic it is essential for governments to protect the population at large. Even though a pandemic will be a threat to all values in societal life, there are strong consequentialist and non-consequentialist reasons for focusing on policies that maximize health benefits. The principle to save as many lives as possible is a reasonable specification of maximizing health benefits, although other specifications can also be acceptable. Even though a focus on saving lives will be less unfair than a focus on broader health

benefits, conflicts with equity (see below) are still inevitable.

2.4 Equity

The second principle, equity, or fairness, involves giving equal weight to equal claims. This general idea has already played a role in shaping the principle of saving lives. There are however further implications of equity (notably egalitarian concerns) which need to be clarified. Equity supports (1) a rejection of various forms of discrimination; (2) attempts to minimize unfairness; (3) giving priority to groups who have a relatively strong claim to life-saving treatment, such as persons at high risk of severe disease and death; and, (4) if the fair innings argument is accepted, giving priority to persons who are relatively young.

Discrimination and group favouritism

Some practices are inconsistent with any account of fairness. In the face of a pandemic there is a danger that authorities who have the power to set priorities and allocate resources will favour their own friends, families, or ethnic group, or otherwise discriminate according to religion, gender, etc. For example, authorities might decide to use limited stockpiles of antivirals for prophylaxis to protect themselves and their groups, and leave others in a situation where no antivirals will be available for treating persons who become ill. Such discrimination is grossly unfair and violates basic human rights. If decisions about who should or should not be saved from a lethal disease are just based on personal characteristics of members in the population (kinship, friends, ethnicity, nationality, gender, etc), then obviously such decisions violate the equal worth of persons. Priority setting should be based upon criteria that are relevant and justifiable to all – not just to one's own group. If priorities are set on the basis of personal preferences of those in power, this will normally lead to a situation where groups who are suppressed or otherwise worse off will be neglected. Moreover such policies will probably not protect the health of the public in any efficient way.

Minimizing unfairness

Issues of fairness do not arise only in cases of explicit discrimination. A policy that aims to save the greatest number of lives (or to maximize health benefits more generally) can be unfair as well. For

example, focusing vaccination on urban areas might save more lives more efficiently than focusing on rural areas, because in urban areas there are more person-to-person interactions, hence more transmission of the virus, than in rural areas. However this policy could leave the rural areas unprotected. If the sole principle is to save most lives with given resources, such forms of unfairness may be inevitable. However, priorities should be devised in such a way that unfairness is minimized where possible. In the example above, this would support a more proportionate distribution of vaccines over urban and rural areas. This does not necessarily imply that the vaccine must be given to equal portions of both populations. Some modelling studies suggest that directing limited vaccine supplies to children would reduce virus transmission in communities (9). If this is true, using such a strategy in urban and rural areas would give both children and adults a reasonable prospect of protection and thus strike a reasonable balance between saving most lives and equity. However, such modelling studies are based on multiple assumptions and their outputs need to be interpreted with caution.

Priority to worst-off: risks

The above considerations do not exhaust the implications of equity. Equity also supports giving priority to persons who are worst off (10). This idea is one of the basic principles in Rawls's egalitarian theory of justice (11).

As mentioned earlier, normal health-care practices are often based upon egalitarian considerations, giving priority to treating the patients who are sickest. This principle is less obvious in the emergency context of a pandemic where the population at large needs to be protected. At the same time, it would be problematic to focus all resources on preventing illness, and leave untreated all persons who become ill. Yet which persons could rightly claim they are the worst off and should therefore be given priority in rationing policies?

If priorities are set with the aim of saving lives (and not more broadly maximizing welfare) then it makes sense to restrict evaluation of people's situations to issues that are relevant for the value that is at stake, that is, their life. Persons who are worst off from an economic point of view do not have a stronger claim to be saved than any other. On the

other hand, someone who is very ill has a stronger claim to care than someone who is now, and may remain, healthy. This supports prioritizing therapy over prophylaxis in many cases; an argument which is especially relevant in making decisions about antiviral treatment. For the same reasons, one might argue that high-risk groups (e.g. the elderly; immunocompromised patients) have a stronger claim to protection than other persons. However, the groups who will be at increased risk and the extent of that risk will depend on the specific features of the pandemic; these groups may differ from the well-known risk groups for seasonal influenza.

The fair innings argument

There is a second way in which some people have a stronger claim than others to have their lives protected, and this has to do with age and the opportunities they have already had in life. In this respect, a child or young adult has a stronger claim to protection than an elderly person who has been able to live a long life (12, 13). Put another way, death at 80 years of age is not as bad as death at 40, and death at 5 years of age is worse than at 40. This leads to a specific account of fairness, known as the fair innings argument. The basic egalitarian principle is that institutions should promote equality of opportunity. Older persons will have had many more opportunities in their life than persons who die at young age and therefore, when we can save some but not all, it is fair to save younger people first. While the fair innings argument supports giving priority to saving the lives of the young above the elderly, it does not specify age groups or cut-off points for prioritization. Decisions about where to draw the line will be based on availability of resources. There are also completely different (non-egalitarian) arguments for prioritizing children and especially young adults. If society at large is at risk, then from a utilitarian point of view it could make sense to protect those groups that will be most important for the sustainability and rebuilding of society now and in the future (14). Moreover, prioritizing young people might also be consistent with the consequentialist approach to maximize life years gained. Hence, there are reasonable justifications for giving priority to saving relatively young people, but arguably such approaches will be controversial in many societies.

It is clear that egalitarian approaches can point in completely different directions: some will give priority to saving the elderly, assuming they run a higher risk to severe disease and death than others; other approaches will prioritize young persons, given that they have not had the same opportunities of life as the elderly.

Reciprocity towards persons who accept risk for the common good of saving lives

Special consideration should be given to the circumstances of health-care workers and others who play an essential role in fighting the pandemic and may do so in a situation in which they themselves run a greater risk of being infected than those in the general population (15). If health-care workers who treat influenza patients, and also people who clean contaminated spaces, run significant risks in their work, they may have a very strong claim to be protected against disease or to be treated in the best manner possible when they get ill. Society needs them to accept risks and therefore it would be fair if society offered them protection which might compensate for this increased risk. This argument raises questions about scope; not only which groups should be given special treatment for reasons of fairness, but also what level of protection they can reasonably claim. Is the provision of personal protective equipment (PPE) sufficient? Or should they also have priority access to vaccination or even pre-exposure prophylaxis? Priority treatment if they get ill is justifiable and also provides a practical incentive for individuals to accept increased risk of exposure.

This argument of reciprocity depends on whether, in the case of pandemic influenza, health-care workers and other pandemic responders do indeed run a significantly greater risk of infection than other citizens. If there is an increased risk to health-care workers, then reciprocity supports giving priority access to protection (vaccine, PPE, and antiviral prophylaxis) in such a way that their risk will be similar to that of other citizens. Based on a similar rationale it may be appropriate to give priority treatment to health-care workers. However, if influenza is spreading very easily within society, there may be little or no increased risk of exposure in hospitals. Moreover, if there is an increased risk of exposure in hospitals, consistent use of PPE may

reduce that risk to health-care workers to a level that is similar to that of other citizens. In such cases, the argument of reciprocity will not support further priority health care for health-care workers.

However, there is also an independent (consequentialist) argument for prioritizing health-care workers and other pandemic responders as a group to be protected; such a policy will contribute to sustaining the health-care system, preventing nosocomial spread of the infection, and otherwise save the lives of people. This argument supports giving health-care workers priority access to PPE, post-exposure prophylaxis, and vaccination. It may also support giving access to antiviral treatment if they get ill as this would increase the chance that they will recover and be able to continue their (life-saving) work.¹ This argument however is not a matter of fairness or equity.

2.5 Accountability: fair procedures, public consultation, and trust

Even if there is consensus about efficiency and equity as central moral principles for priority setting, this will not take away moral conflict. Efficiency and equity will clash in a number of cases, and moreover, the principles themselves can be understood in different ways. Given these controversies and the grave impact on the lives of all, it is important that decisions about priorities are legitimate and trustworthy. Daniels and Sabin (4) emphasize that setting limits to health care can only be legitimate if rationing decisions are made on the basis of fair and reasonable procedures. During a pandemic, panic and anger may undermine trust in government and health care, which would lead to further problems in society. Clear and fair procedures that also promote public justification of policies may help to sustain trust and prevent public resistance to some extent, even though the possibilities for accountability during the pandemic may be limited. These procedures should at least consider the following:

¹ Note that the reciprocity argument only applies to pandemic responders who are at increased risk. The consequentialist argument may apply to a much broader group of persons who are important for saving the lives of others (including vaccine producers and firefighters).

1. Publicity

Decisions about the rationing of antiviral drugs, vaccination, and medical care should be made public. If decisions and justification are not public, people have no reason to believe that priority setting is done in a legitimate way. In most countries, pandemic preparedness plans are in the public domain, yet much more needs to be done to inform the public about policies and procedures, and the inevitability of controversial priorities.

2. Reasonableness

The rationale for the decisions should appeal to reason and principles that are accepted as relevant by people who are disposed to find terms of cooperation that are mutually justifiable. Obviously such reasons should be as clear as possible. Public consultations may help to develop arguments and hence to strengthen justification and support for the policy.

3. Revision procedures

Decisions about priority should be revisable in the light of new evidence or new arguments and the public must be aware of this possibility. There should be clear procedures for such revisions. A distinction should be made between (a) revisions on the basis of new clinical and epidemiological evidence and other factual issues, and (b) revisions on the basis of ethics or politics. The principles for priority setting should be decided during pandemic planning; despite the many uncertainties, it is possible to outline general moral arguments for priority-setting in pandemic preparedness plans. More importantly, the emergency situation of a pandemic does not offer a fruitful context for moral discussion and public consultation. On the other hand, before a pandemic many relevant clinical and epidemiological data will not be available, and new evidence collected during the pandemic will have implications for policies. For example, if the primary strategy for using antiviral drugs is to contain a local outbreak, new evidence about the virus might clarify whether, and how, such an objective can be attained.

4. Compliance regulations

From the point of view of fairness it is not only important that fair policies, criteria and procedures are developed, but also that these are complied with. Hence, there should be clear regulations

and authorities to promote, control and enforce compliance.

One procedural strategy to avoid inequity and to sustain trust in the professional ethics of health-care workers is to separate clinical and allocation roles; allocation is done by politicians and managers, and physicians can focus on treating their patients. Veatch (16) argues that, although this makes sense in normal medical care, it does not in mass disaster situations where it is inevitable that health-care workers will triage and select patients on site. Whether such distinction of roles is possible in a pandemic is not completely clear. Determining who should get priority access to antiviral treatment, prophylaxis, or vaccine should not be done by individual health-care workers, but preferably at a national level; or at least within institutions that are accountable in a democratic process. Eligibility criteria should be made very clear (explained and justified) to the public and to health-care workers. However, for triage in hospital medical care this model may be less applicable. For example intensive care specialists will have to select patients on the basis of several factors; even if general criteria are set on a national level, application of such criteria will require professional assessment and judgement in individual cases.

Given the importance of trust in allocation procedures, and in government and health-care institutions in general, there is a further issue that requires careful consideration. Above it is argued that priority should be given to sustain the (public) health-care system and to prioritize prophylactic or therapeutic antiviral treatment of health-care workers. However, there are many more persons in roles essential for sustaining public health and societal life at large: members of government, police, key persons in public health policies, military forces, captains of industry, etc. Such persons might even require 'for the common good' prophylactic treatment with antivirals or first access to a new vaccine. However, extreme caution should be exercised in non-medical and non-public health criteria for priority setting. The more persons in essential roles are given antiviral drugs for prophylaxis, the more this creates possibilities for favouritism, abuse and other inequities, which will further undermine public trust in health services and policies.

3

Antiviral drugs

3.1 Background, circumstances and main questions

If there is no effective vaccine against pandemic influenza, the main pharmaceutical option is the use of antiviral prophylaxis and treatment. Antiviral drugs affect the ability of an influenza virus to replicate in an infected individual. In this way they help to reduce both the spread of the virus within an individual (and hence symptomatic disease) and transmission of the virus to other individuals. Antivirals can be used to treat symptomatic patients; timely treatment reduces the duration of disease by one or two days on average. More importantly, it appears to significantly reduce the chance that a person will suffer the severe (including fatal) complications during seasonal influenza (17, 18).

Antivirals can also be used for prophylaxis, either pre-exposure or after exposure to an infected patient. Pre-exposure prophylaxis should last as long as the infection risk is present, plus 7–10 days after the last exposure. Current recommendations based on indirect evidence from seasonal influenza stipulate that prophylaxis with oseltamivir for periods of up to 8 weeks is considered safe (19).¹ Post-exposure prophylaxis should start as soon as possible after exposure (a course of 7–10 days with oseltamivir). Individuals receiving prophylaxis may experience a mild or sub-clinical infection that actively immunizes the person against the influenza subtype (20).

Because supplies of antiviral drugs will be limited and it will not be easy to increase production capacity when a pandemic arises, stockpiling in advance is the only option for assuring an adequate supply when the need comes (21). Decisions about the size and use of antiviral stockpiles during the pan-

demie should take into account the fact that pre-exposure prophylaxis requires very large quantities of antivirals and thus costs up to 30 times as much as treatment stockpiles (22). Consideration should also be given to the fact that a substantial number of people who receive pre-exposure prophylaxis might not have become infected even if they had not received prophylaxis.

Given this background, several interrelated ethical questions arise for priority setting in preparation and response to an influenza pandemic.

- Should antivirals be used for therapy or for prophylaxis? (see 3.2).
- Should governments build stockpiles of antivirals? How should such investments be related to other health-care resources? Should private purchase of antiviral drugs be prohibited if this would undermine public health policies? (see 3.3).
- Which groups should be given priority access to antiviral prophylaxis and treatment? (see 3.4).

3.2 The use of antivirals in a pandemic: general objectives

If the key objective of pandemic preparedness planning is to mitigate the effects of a new influenza virus on human health and welfare (preventing morbidity, mortality and minimizing social disruption), an important strategy is to slow down the spread of the virus in order to gain time for development and mass production of pandemic vaccine. Theoretically, providing all persons within a population with access to antiviral drugs as pre-exposure prophylaxis could effectively contribute to this goal. Prophylactic strategies for all persons would obviously save most lives; prophylaxis for high-risk groups only would still save a very large group. However, this approach is not feasible in any

¹ http://www.who.int/csr/disease/avian_influenza/guidelines/pharmamanagement/en/index.html

country given the amount of drugs required. Furthermore, unless a specific vaccine is available, such populations would become vulnerable again once prophylaxis is stopped. Moreover, if some countries could afford building extremely large stockpiles, this may reduce possibilities for other countries (especially low- and middle-income countries with less bargaining power) to purchase antiviral drugs required for a reasonable minimum stockpile. Hence, if some countries aim at maximum protection against pandemic influenza this will reduce the possibilities for other countries to develop a very basic stock of antivirals which might have been otherwise used to treat needy patients, which is unfair.

On the other hand, prioritizing antiviral drugs for treatment of symptomatic patients can be well supported on the basis of the moral framework discussed in section 2. Early symptomatic treatment may prevent further transmission and hence create individual benefits as well as public health benefits. Moreover, assuming fixed expenditures on antiviral drugs, symptomatic treatment will save more lives (hence is more cost effective in this sense) than prophylactic treatment of high-risk groups (22). By preferring therapy to prophylaxis, priority is given to treating persons who are in immediate need, which can be well-defended from an egalitarian perspective.

Giving priority to therapy does not imply that preventive use of antiviral drugs is to be avoided completely. Targeted mass prophylaxis at the source of a new outbreak can have enormous effects on global public health. It might at least delay further spread of an early pandemic, and even contain the outbreak of a new influenza virus at source (23, 24). Such efforts are essential for the protection of public health throughout the world, and targeted antiviral policies at the source of a pandemic should be supported by all nations, and be coordinated by WHO in collaboration with the nation involved.

If containment at the source fails to halt global spread of the virus, national governments might still further delay the spread by means of post-exposure prophylaxis of persons (health-care workers, household contacts, and others) who have had close contact with the first persons introducing virus into an area. This strategy also helps to support and sustain health-care facilities during the

very first period of a pandemic. Prophylactic use of antiviral drugs should however be limited and should not reduce the supplies which are needed (and reserved) for treating patients. In this way, antiviral policies can create optimal protection of public health and human life, while minimizing unfairness.

3.3 Stockpiles and availability of antiviral drugs

Several studies have indicated that in high-income countries, stockpiling antiviral drugs for therapeutic purposes can be cost effective or even cost saving (22, 25). This supports current policies in many countries to create stockpiles. Many other countries however will not be able to purchase antiviral drugs at all, either because of the price or because of limited supplies and production capacities.

For an adequate global response to the threat of a pandemic, sufficient production capacity and access to antiviral drugs (affordable cost and distribution of resources) are essential. This applies to governments in high- and low-income countries alike, as well as to the pharmaceutical industry. Meanwhile, it would be fair that wealthy countries reserved parts of their antiviral resources for health aid for the developing world. The expectation of having access to antivirals might further motivate less wealthy countries to develop or maintain adequate surveillance capacities essential for global public health. Pharmaceutical companies and governments have a shared responsibility to improve availability and affordability of antiviral drugs. Mechanisms for increasing accessibility to antivirals include allowing the production of generic formulations of these drugs and technology transfers from commercial parties to states.

Governments of low-income and middle-income countries should also set clear priorities in order to balance the use of scarce financial resources on antiviral stockpiles with the use of resources for improving basic health care to meet current priority needs of the population. The opportunity costs of maintaining a stockpile are very high, and drugs may expire before a pandemic occurs. Moreover, prescription of drugs and monitoring patient compliance requires a basic health-care infrastructure that will be useful and important at all times. Many countries should therefore give priority to creating

and maintaining such health-care infrastructure and not focus health-care resources to antiviral stockpiling.

Finally, the availability of antivirals may further decrease if persons and companies start creating private stockpiles. If this undermines necessary public health policies, governments have strong reasons to interfere and prohibit private sale of antiviral drugs. On the other hand, liberty-limiting interventions can only be legitimate if public health policies in such a country, including procedures and policies for distribution of antiviral drugs, are well-justified and fair.

3.4 Priority targets and groups

It is essential to maintain international (WHO) stockpiles of antivirals for mass application as part of a strategy for pandemic containment at the initial source. At a national level, countries will ideally have their own stockpiles of antiviral drugs which:

- are sufficient to treat all citizens who develop influenza symptoms; since the attack rate of pandemic influenza is unpredictable, it is difficult to provide clear guidance on the optimal size of an antiviral stockpile;
- allow for post-exposure prophylaxis (health-care workers, household contacts) when pandemic influenza is introduced in a population, aiming to delay further spread of the disease;
- can support public health interventions or medical aid in countries that have no or insufficient antiviral stockpiles.

Within a country, which groups should be given priority for prophylaxis and treatment? On the basis of the objectives and principles discussed in this and the previous section, these priority groups can be distinguished:

1. *Post-exposure prophylaxis for health-care workers*

This may delay further spread and nosocomial infection and therefore prevent breakdown of the health-care system when used during the first stage of local spread of pandemic influenza in a newly affected country/area.

2. *Treatment of symptomatic patients*

If it is not possible to treat all symptomatic patients with antiviral drugs, it will be necessary

to assign priority groups among patients. The principles of efficiency and equity support considering the following as priority groups:

- *Patients in high-risk groups for severe disease and death*

Both the principle to save most lives and considerations of fairness support priority antiviral treatment for influenza patients at highest risk of death, as this is likely to increase their survival. This group will be identifiable only after the pandemic has started.

- *Patients that are also workers who have an essential role in saving lives*

Persons whose professional role is necessary to save lives and those who are indispensable for sustaining the health-care system can be given priority because this can be expected to maximize health benefits. This priority group includes vaccine developers and health-care professionals, and possibly decontamination workers. Some subgroups may also be given priority for reasons of fairness and reciprocity if they run a disproportionate risk in their efforts to fight the virus and save lives.

- *Patients who are relatively young, i.e. children and younger adults*

The egalitarian argument of fair innings supports giving priority to saving the lives of younger persons.

In times of drug scarcity it is tempting to treat more patients with a decreased dose or shortened course of antiviral drugs. There are insufficient data at present, but such practice might prove less effective than standard therapy and facilitate the development of drug-resistant virus strains, which are harmful to treated patients and the public health. Therefore the distribution of reduced doses among a larger group should not be considered as a fair and just response to scarcity, unless new scientific evidence emerges to show that reducing the dose will not reduce clinical benefit and not prompt spreading of resistant viruses.

4

Priority setting in therapeutic care

4.1 Background, circumstances and main questions

For numerous patients antiviral treatment will not be available, and even patients who have been treated with antivirals might need other supportive therapies to respond to possible super-infection and/or respiratory distress. In a pandemic, large groups of patients will require intensive care, including mechanical ventilation, and far more will at least need basic relief of symptoms. The number of hospital beds, both in general wards and in intensive care units will be insufficient, and it is unlikely that patients who are admitted will recover rapidly and be discharged. It is difficult to predict the average duration of hospitalization of patients suffering from pandemic influenza infection, as it will depend on disease features that are as yet unknown. For SARS patients, the average length of hospital admission was 18 days in Singapore (26) and 10.5 days in intensive care in Toronto (27). It is clear that this will put immense pressure on the health-care system, as the number of persons who will develop serious respiratory problems, or otherwise suffer from severe symptoms, will grow steadily until the peak of the outbreak.

For several weeks or months, hospitals and medical services of an affected area will be unable to accommodate all health-care needs. In these circumstances it is inevitable that seriously ill patients (potentially large numbers) will not get necessary life-sustaining treatment or even basic relief of symptoms. As in the case of scarcity of antiviral drugs and vaccines, decisions about priorities must be taken. Triage of hospital care – notably mechanical ventilation – will however be much more dramatic, given that patients have acute and severe needs. Patients who are excluded from mechanical ventilation may die rapidly. Physicians and nurses will face deep and tragic dilemmas. Which patients

should be given priority? Can or should special beds or departments for influenza be allocated, and how should such allocations be weighed against the availability of medical care for persons who suffer from ‘regular’ diseases or accidents? Should triage criteria apply only to withholding or also to withdrawing medical care?

4.2 Objectives and principles

Triage involves ‘sorting’ patients into groups: some are excluded from treatment, others are considered eligible for treatment. Treatment and non-treatment decisions are paramount in health care, and often patients are excluded from (even life-sustaining) treatment because the intervention is deemed medically futile (28). However, in extreme scarcity, exclusion criteria will be much more restrictive than standards of medical futility and will also exclude patients for whom treatment is still considered necessary and useful.

Similar to judgments about medical futility, triage decisions should be based upon professional standards that are publicly justifiable. In this way, controversial and deeply troubling decisions are not left to the discretion or subjective assessment of individual caregivers. Priorities should be based upon general triage criteria that are reasonably acceptable to everyone. On the one hand this involves appeal to the basic normative principles discussed previously; maximization of health benefits (notably saving lives) and equity. On the other hand, criteria should be defined and specified on the basis of medical evidence about health needs and factors which determine the chance of recovery.

4.3 Triage of mechanical ventilation

In critical care, the primary focus is on saving lives by responding to acute health crises. Triage decisions aimed at saving the most lives with limited

resources will give less priority to patients who are expected to recover less easily. Although the implications of such decisions will be harsh and controversial, the basic principle to save the greatest number of lives possible can be reasonably justified to anyone.

A first step in a fair and efficient triage system is to exclude from treatment patients for whom mechanical ventilation is not considered absolutely necessary. Arguably such patients would not be admitted to intensive care in normal times either. From a medical point of view, all remaining candidates will be equally badly off; that is, all require mechanical ventilation to survive.

A second step would be to formulate triage criteria aimed at saving the greatest number. Such criteria should be evidence-based where possible. To date little work has been done in formulating operational rules for triage in intensive care units in times of pandemic emergency. Hick and O’Laughlin (29) have presented several tiers of criteria (mostly medical), which impose increasingly severe restrictions to access. The idea is that when application of tier 1 criteria does not accommodate supply and demand, triage need to be more restrictive, and hence the stricter tier 2 criteria are applied in addition to tier 1 criteria. Tier 3 criteria are even more restrictive. A different triage protocol, based on the same underlying principle to use resources as efficiently as possible, has recently been proposed by Christian et al. (30). The latter protocol specifies criteria that aim to exclude persons who have a very bad prognosis even if treated, as well as persons who may benefit from treatment but only after intense use of resources and prolonged critical care that cannot be justified in a pandemic.

What if tiered criteria are not sufficient to accommodate demand and supply?

Tiered criteria will not prevent situations where several patients satisfy all criteria. One approach in such a situation is to give responsible physicians discretion to make such decisions on the basis of their medical assessment of the situations of all candidates. This raises some problems. In the first place, it will be difficult to avoid bias, subjective judgments, or even prejudice. Even when choices are solely based on relevant medical conditions (e.g. B’s oxygenation status is lower than A’s, and therefore

A’s prospects are considered slightly better) this will be rather arbitrary, especially if the choice has to be made between two patients who could in theory both be granted treatment based on the criteria for eligibility. The differences between patients will be too small to justify saving A and not B, and therefore such a choice can be neither clearly justified on grounds of saving the largest number, nor on fairness.

Two other approaches however can be justified from a fairness point of view. The first is to save the younger of two persons with comparable medical conditions, on the grounds of the fair innings argument. Again however, this argument loses force when age differences between candidates are very small; although a 25-year-old has had more time of life than a 24-year-old, the difference is too small to justify saving the latter and not the former. A second approach opts for procedural fairness; if there are no relevant differences between two patients, both should have an equal chance to receive life-saving treatment. Such last-resort decisions could be based upon a lottery or possibly a ‘first-in-line’ procedure.

Special treatment for patients with influenza-related disease

There are two remaining issues concerning the scope of triage procedures. The first is whether the criteria and procedures apply to influenza patients only, or to all patients who require mechanical ventilation. Although there will be pragmatic reasons for cohort care and special wards, and intensive care departments might be designated for influenza patients, scarcity will apply to all critical care departments. It would be unfair to treat influenza patients differently from ‘regular’ critically ill patients. The same criteria and procedures therefore apply to all patients. At the same time, some regions and hospitals may face different levels of scarcity, and, assuming that possibilities to transport patients between hospitals and regions will be limited, different hospitals and regions may have different ‘tiers’ of criteria in place for choosing who is eligible for admission versus who should be treated at home.

Withholding or also withdrawing treatment

A second issue is whether triage criteria must be applied for decisions to withhold and to withdraw mechanical ventilation. This is a controversial issue because applying the criteria to withdrawing treatment implies that patients for whom ventilation could still be beneficial are extubated (although they would be expected to have a small chance of recovery within limited time) (30).¹ However, if the criteria are not used for withdrawing patients, ICUs may soon be full of patients whose conditions are much worse than those of patients who need ventilation and who fulfil the triage criteria. As a result, the gap between supply and demand will grow larger, forcing the hospital to apply further tiers of criteria that are even stricter.

Is there a moral basis for not applying the triage criteria to decisions about withdrawal of treatment? Many physicians and other health-care workers may feel they have a duty not to abandon their patients, which means they can and should give priority to patients for whom they have already accepted responsibility.² Although there are good pragmatic reasons for such special obligations in normal circumstances (for example they support relationships of trust), in the context of a pandemic such considerations are less appropriate. If very large numbers of persons get infected and require care, health-care workers can no longer prioritize patients who are already commended to their care. They should give equal attention to all who need it, and aim to save as many patients as possible – which applies to patients who are treated as well as to those who wait to be treated. This supports applying triage criteria to decisions to withhold and to withdraw treatment. In the context of a pandemic, this means that it could be justifiable to extubate a patient who might still benefit from mechanically-assisted ventilation. This conclusion will be controversial in many if not all societies. It might be that health-care professionals and the public simply do not accept such

decisions, even if these are rationally justified. An efficient triage policy may then not be sustainable, which could be a pragmatic reason for not applying the triage criteria to withdrawal of life support.

4.4 Allocating hospital beds

Triage for eligibility of access to mechanically-assisted ventilation raises clear and important dilemmas. However, in large parts of the world there is no intensive care available at all, neither in times of a pandemic, nor in normal circumstances. There will however be a shortage of supply of regular medical care in the hospital as well. How should priorities be set in allocating hospital beds? This topic is in a way much more complex than allocating mechanical ventilation. Withholding ventilation from someone who needs it will normally lead to fatal complications within a short time. If a sick patient is not given a regular hospital bed, the consequences are not as clear and depend on the treatment and care that can be offered when the patient is admitted.

What sort of care can be given to influenza patients in a non-ICU setting? Apart from treatment of bacterial super-infections, most forms of treatment will consist of symptom relief: paracetamol and other drugs to relieve pain and fever; intravenous rehydration; management of hypoxemia and bronchospasm with medication, supplementary oxygen, and respiratory drainage. Patients may feel so ill that they require help with feeding, etc.

There will however not only be pandemic influenza patients; other diseases and accidents will be as common as always. Many patients will still need surgery, radiotherapy, heart treatment, orthopaedic treatment, psychiatric care, etc. Hence, there will be a very broad range of different patients requiring hospitalization, and, depending on available resources there will also be a broad range of treatments that can be offered, although there may be important shortages of supplies. All hospital departments may face shortage of syringes, intravenous equipment, antibiotics, and even clean sheets and beds.

The maximizing principle for priority setting cannot be applied easily in such circumstances. Determining which priorities will produce most effect will be impossible, because the data that are needed to compare the effects of completely different forms of treatment in the special circumstances of a pan-

¹ Christian et al. (30) offer specific criteria for reassessment of patients and withdrawal of critical care.

² Note that the well-established thesis that there is no moral difference between withholding and withdrawing treatment is not the central issue here. That thesis normally applies to decisions about futile or non-beneficial treatment. In the current context however, treatment is not withheld because it is considered futile for this patient, but because more patients may be saved if this patient is not treated.

demographic are not available. Moreover, many interventions do not compete directly; hence it makes little sense to compare the cost-effectiveness of radiotherapy for certain cancer patients with primary care for influenza patients. Specialized wards, equipment, and staff cannot easily be given a different task, and cancer patients may not be helped by providing them with just a hospital bed and basic supportive care.

However, some recommendations are sensible and may find support on the basis of the maximization principle and the principle of equity:

1. To save lives and sustain the health-care system it will be important to prevent nosocomial infections where possible. This supports assigning special wards or hospitals to influenza patients. Arguably, an influenza pandemic will also require the creation of a facility for the provision of basic (non-specialized) supportive care and symptom relief to influenza patients.
2. Patients should be treated and cared for at home, by their family members, whenever possible. Patients who do not have family members who can give them the care they need should be given priority to non-specialized hospital care and primary care beds.
3. In some cases regular treatment for example for a cancer patient, will be unsafe or insufficiently effective if the patient acquires influenza. In some specialized departments or treatment facilities (oncology, surgery, etc.) it may therefore be justified to give priority to non-influenza patients, and to postpone interventions for patients who do develop influenza. However, such a decision may be equally appropriate in a non-pandemic context.
4. In a pandemic all hospital departments will face scarcity and therefore need to set priorities more strictly. Specifying criteria that aim at maximizing health benefits may be impossible (as noted above). Setting priorities on the basis of medical need, giving priority to patients who are worst off from a medical point of view, may be more feasible. Hence, as in 'normal' health care circumstances, there are good reasons for distributing hospital beds and medical care primarily on egalitarian grounds, that is, to those who need medical treatment most urgently.

5

Vaccination

5.1 Background, circumstances and main questions

In contrast to antiviral prophylaxis which provides a protection limited in efficacy and duration, an effective and safe vaccine would offer sustained protection against infection as long as the vaccine continues to match the circulating strains. Vaccination not only protects the vaccinated individuals from becoming ill; if sufficient people are vaccinated this also reduces further transmission of the virus within the population and hence prevents infection and illness. Even if the vaccine is poorly matched to circulating virus strains, it may have large effects at a population level (24, 31).

It is however not expected that an appropriate vaccine will be available to the public at least for the first six months after the start of the pandemic, and for large numbers of people this will be far too late. Even when a vaccine has finally been developed and approved, deployment will be incremental and there will be insufficient production capacity to accommodate the enormous demand worldwide. Coordinated action is necessary to optimize availability of vaccines (32).

An effective vaccine against pandemic influenza will be quite different from current vaccines against seasonal influenza. Such newly-developed vaccines raise concerns about safety and therefore will be subject to strict regulations. The possibility to streamline legal regulations for vaccine approval if such a new vaccine may mitigate a devastating pandemic is discussed briefly in section 5.3.

In contrast to antivirals and medical care interventions, influenza vaccination can only be applied as a preventive measure. Therefore, the target group consists solely of persons who have not yet been infected. Persons who have been infected with the pandemic virus strain and have recovered from illness or only had mild disease will already

have developed immunity and do not need vaccination. Timely antiviral treatment of symptomatic influenza patients does not obstruct such natural immunization. However, even when the virus has spread across the world for six months or more, many persons will not yet be immune, and for them vaccination (if available) will offer the best form of protection.

A second important difference is that vaccine supply, in contrast to antiviral drugs and medical care, will increase over time. Some high-income countries will aim to produce or purchase sufficient vaccines for all target groups, but not all groups can be vaccinated at once. Two doses may be needed to gain immunity in a totally naive population,¹ although the use of adjuvant may allow the use of a single dose. The ethical question is then which groups should receive vaccine first and which groups (several weeks or months) later. In low-income countries supplies will be severely limited and the ethical problems of prioritizing which groups should receive vaccine will be more analogous to those in the previous chapters.

5.2 Ethical considerations for vaccination priorities

In the previous sections it has been argued that giving priority to persons who are at high risk of death if infected can be justified from the point of view of saving most lives and from considerations of equity. In the case of vaccination however, other priorities may also be efficient and fair, or even preferable on grounds of equity.

First, vaccination programmes may have an impact on virus transmission, yielding health benefits that go beyond the benefits for vaccinated persons. Some modelling studies suggest that vac-

¹ If no cross immunity with influenza viruses previously and recently circulating in human populations

cination of specific groups who play an important role in transmission, for example children, could have an impact on virus spread (9) (see also section 2.4). However, the results of these studies must be considered with caution as they are based on a range of assumptions which may not apply in reality. Moreover, a strategy of vaccinating groups important in transmission might save fewer lives than vaccination of groups who are at highest risk of death from influenza. However, vaccination that effectively prevents virus transmission offers protection that is beneficial to all persons (high or low risk alike) in a population.

Second, as argued above (see section 2.4), an egalitarian approach would favour persons who are the worst off. It is not obvious that persons who are healthy now, but would be at high risk of death if they got ill, are to be considered to be worse off now and therefore have a stronger claim to vaccination. In a pandemic everyone (also persons in low-risk groups) faces the risk of developing influenza and may experience severe, even lethal complications. It would be unfair if persons at some risk are not given access to vaccination at all only because others run an even higher risk of lethal disease if they become infected. Moreover, vaccination of persons at high risk may result in them being even better off than persons in low-risk groups and hence it is not obvious that prioritizing them would be fair.

From the point of view of fairness, some argue that the most equitable approach could be a weighted lottery, in which all persons participate, but where higher risk increases one's chance of being vaccinated. In such a way, the chances of surviving the pandemic could be spread more equitably (33, 34). Many pragmatic reasons may count against applying lottery procedures for life-protective interventions, and certainly it would be difficult to assign weights fairly.

A different approach would be to take into account that – at least in some countries – the supplies of vaccine will increase over time. Although persons at highest risk may not have a stronger claim than others on vaccination *per se*, their need for protection is more urgent. Hence they have a stronger claim to be vaccinated first, assuming that others can be vaccinated later. Setting priorities over time may be a reasonable alternative to a

weighted lottery. In short, if the increasing supplies of vaccine will be sufficient to vaccinate all persons in a population within a limited time, then it is reasonable to vaccinate high-risk groups first. If it is clear that not all can be vaccinated, fairness may require different vaccination priorities.

Third, there are also egalitarian (fair innings) arguments for giving priority to children and younger adults (see also section 2.4). If young persons get ill and die, then vaccination protects their chances to live a reasonable life-span and have their fair share of opportunities in life. This supports decisions to consider children as a priority group, but it might also give reasons to prioritize younger adults above the elderly. Assuming that the elderly will be at high risk, this direction might well conflict with considerations in the previous paragraph.

Finally, health-care workers and other life-savers who are still not immune when a vaccine becomes available may be given priority access because that will produce indirect health benefits. Vaccination prevents both severe and mild disease and will therefore protect health-care workers so that they can continue their important work in a health-care system that is already under severe pressure.¹

5.3 Research and safety considerations

Developing a vaccine against pandemic influenza is of crucial importance. An effective and usable vaccine will however be quite different from current vaccines against seasonal influenza. It will be necessary to induce sufficient immune response with a vaccine dose as small as possible. Research and development will be needed to design more potent and effective vaccines, inducing protective responses after one dose only (so that more people can be vaccinated than if more injections per person are needed) and/or inducing broad spectrum and long-lasting immunity against both seasonal and pandemic influenza strains (32).

The use of a new vaccine type raises moral and

¹ It is less clear that such vaccine priority can also be based on reasons of reciprocity (cf. 2.4). If health-care workers, while working for the common good, face disproportionate risk of infection, reciprocity supports giving them priority access to protection, in order to compensate for the increased risk. It would be unfair if their risk is higher than that of other, comparable citizens. However, fairness will not support reducing their risk far below that of other citizens – which is what effective vaccination might do. [Murphy R. Ethics in the coming plague: the distribution of pandemic influenza vaccine. Master's Thesis. Utrecht: Ethics Institute, 2006].

regulatory issues about safety. What side-effects would be acceptable? Given the potential effects of vaccination on the spread of pandemic influenza and on mortality, even a relatively high frequency of side-effects, or the occurrence of some harmful effects, may still be acceptable. Evaluation of risks will however not be a simple calculation of aggregation of harms and benefits. For example, if there are concerns about the safety of a new vaccine, it will be problematic to vaccinate children for the common good (as argued in the previous section). If there is significant risk associated with the vaccine, it is unfair to vaccinate children to protect the population at large, especially given that most children will not be able to consent to vaccination. Arguably, although vaccine side-effects may be justified more easily in a pandemic, the safety requirements for a vaccine will be very strict, if only because, like in normal times, vaccination programmes will not be successful if people do not trust the safety of the vaccine (35).

There will also be many legal and regulatory issues before a new vaccine can be used to protect populations. If harmful effects are accepted more easily during a pandemic, it might be unfair to hold vaccine producers liable for all such effects. Hence, clear arrangements are necessary, if only to encourage producers to develop vaccines. A second issue concerns the approval of a new vaccine. All persons have a shared interest in regulatory policies that enable vaccine producers to bring effective and safe vaccines to the market as soon as possible. This should not preclude thorough assessment of vaccine safety. On the other hand, vaccine approval regulations throughout the world could be further harmonized and streamlined. Ideally formal approval of a vaccine in the United States of America for example, would be sufficient for approval in Europe as well, and vice versa.

6

Conclusions

General

In preparing for a pandemic, governments and public health institutions should develop criteria and policies for allocation of medical resources. These should take the following principles into account:

- **Efficiency** or **utility**: maximizing health benefits with given resources, preferably (although not necessarily) in terms of saving most lives.
- **Equity**: giving equal weight to equal claims of persons. This implies that group favouritism and other forms of discrimination must be avoided. It also supports giving priority to groups who are worst-off, notably those at highest risk for influenza-related death, and it may also support giving priority to persons who are relatively young. Equity and efficiency will often conflict. The controversies in applying these principles underline the need for accountability.
- **Accountability**: having fair and reasonable procedures for justification, public consultation, and enforcement of compliance. One important mechanism to ensure accountability is to specify general rules for priority setting that are publicly justifiable, and avoid case-by-case decisions during the pandemic to the extent possible.

If priority access to health protection or therapy is envisioned for some groups, this should be stated clearly and should be subject to discussion. For example, a government may wish to prioritize access to the following groups:

- Preventive measures (PPE, antiviral chemoprophylaxis, vaccination) for professionals such as health-care workers who are involved in saving the lives of many others. This helps to sustain health-care functions and prevent nosocomial infections. The group of life-savers could also include vaccine developers and other profes-

sionals who are necessary in response to the pandemic. However, this argument to prioritize life-savers can inflate rapidly and may also be easily abused at the cost of vulnerable groups. Governments should be very reluctant to broaden such criteria.

- Persons who are at high-risk of developing severe complications and dying from influenza, who therefore would have a stronger claim (if they get ill) to antiviral treatment, access to hospital beds and to vaccination with the pandemic vaccine (once available), compared to persons who are at lower risk and for whom these interventions are less crucial for survival.
- Therapeutic and prophylactic measures for those who have enjoyed fewer life years, on the ground of the fair innings argument. However, since this argument will be controversial it should only be adopted after extensive public consultation, and only if other prioritization criteria are insufficient.

Antiviral drugs

If a new pandemic influenza virus subtype is detected early, i.e. while its spread is still very localized, there may be a role for deployment of international (WHO) stockpiles of antivirals as part of a strategy for rapid containment by interrupting transmission or delaying further spread. These stockpiles are intended for use in treatment and mass prophylaxis in populations in close proximity to the source, in addition to implementation of social distancing and quarantine measures (36).

Once a pandemic virus is spreading globally, countries should use antiviral stockpiles primarily for treatment of patients and avoid massive pre-emptive prophylactic use at a national level. In their decisions about the magnitude of antiviral stockpiles and

their application, governments should also support low-income countries that may not be able to afford antiviral drugs.

Within a country, a number of priorities for the use of antiviral drugs can be considered:

1. **Post-exposure prophylaxis for health-care workers** at the beginning of the pandemic, after exposure to the very first cases in the country. This may both reduce the risk of nosocomial infection and prevent the health-care system from breaking down during the first stage of the pandemic.

2. **Antiviral treatment of all symptomatic patients**

If it is not possible to treat all symptomatic patients with antiviral drugs, it will be necessary to assign priority groups among patients, such as:

- *Patients who are also workers with an essential role in saving lives*, because this increases the chance that they will recover and continue their work.
- *Patients belonging to groups at high-risk of severe disease and death*, because for them treatment is more urgent, and this may save most lives.
- *Patients who are relatively young, i.e. children and younger adults*. The egalitarian argument of fair innings supports giving priority to saving the lives of younger persons. Such a policy may be more controversial than others, yet it may be one approach among others, especially where antiviral drugs are extremely scarce.

Medical care for patients

Most influenza patients will require (at least) basic medical and nursing care and relief of symptoms, some of them in hospital and intensive care units. Providing this care will require adequate primary care facilities and infrastructure, which may not be available in low-income countries, especially in rural areas. Developing and maintaining health-care infrastructures for primary care is therefore a major priority for pandemic preparedness in those contexts. Moreover, such investments will be beneficial for the population irrespective of a pandemic.

In critical care, the primary focus is on saving

lives by responding to acute health crises. Triage decisions aimed at saving the most lives with limited resources may give lower priority to patients who are expected to recover less easily. Triage can be done by developing several tiers of successively stricter medical criteria for determining eligibility for treatment. Yet, even when the most restrictive criteria are applied, there will be situations where there are two or more patients eligible for one intensive care bed or for specific equipment (e.g. ventilator). It is therefore essential to develop fair and explicit standards for choosing between patients in such situations. The fair innings argument will be one of the few justified grounds for making decisions in such a context, hence it might be appropriate to choose between patients with comparable medical conditions by giving priority to the patient who is significantly younger. Eligibility criteria should apply to all diseases for which resources might be limited, not just to influenza-related illness. Criteria should include standards for withholding or withdrawing life-sustaining treatments. Other possible mechanisms include giving all eligible patients an equal chance of treatment (i.e. a lottery).

It is difficult to specify clear guidelines for allocating non-ICU hospital beds and medical care on the basis of the general principles of efficiency and equity. Equity supports prioritization according to medical need. Some practical recommendations include avoiding nosocomial infections by creating special departments for influenza patients and giving persons without support of family or neighbours priority access to basic care facilities.

Vaccination

There are several reasonable, though sometimes competing directions for priority setting in vaccination:

- Prioritizing health-care workers and other life-savers helps to sustain the health-care system and produces indirect (health) benefits.
- Vaccinating groups of people known to be central to spreading infection (e.g. children of school age if pandemic influenza spreads with the same pattern as human seasonal influenza) may be most effective in reducing transmission and hence in reducing the attack rate. This approach may not save most lives, but it does offer all per-

sons (who are not yet immune) within a population a prospect of benefit.

- Vaccination is most urgent for persons who are at highest risk of death from influenza once infected. Epidemiological studies during the pandemic will indicate such highest-risk groups. The risk of death once infected may differ by country and depend on socioeconomic status, age, underlying conditions, and availability of health care. For persons at increased risk of death if infected, vaccination is more urgent than for others, but

it is unfair to vaccinate only these people if not all others can be vaccinated. If increasing supplies of vaccine will be sufficient to vaccinate all eligible persons in a population within a limited time, then it is reasonable to vaccinate high-risk groups first.

- If it is impossible to vaccinate all eligible persons within limited time, fairness may require different priorities. One approach could then be to follow the fair innings argument and prioritize children and young adults.

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ANNEX

Members of Working Group One

Clement Adebamowo

Division of Oncology and Department of Surgery, University College Hospital, Ibadan, Oyo State, Nigeria.

Dan Brock

Department of Social Medicine and Division of Medical Ethics, Harvard Medical School, USA.

Nouzha Guessous-Idrissi

Chair of the International Bioethics Committee of UNESCO, Casablanca, Morocco.

Iwao Hirose

The Oxford Centre for Ethics and Philosophy of Law, University College, Oxford, and the Faculty of Philosophy of the University of Oxford, Oxford, United Kingdom.

Marcel Verweij (Chair)

Ethics Institute, University of Utrecht, The Netherlands.

Dan Wikler

Department of Population and International Health, Harvard School of Public Health, USA.

John Williams

World Medical Association, Geneva, Switzerland.

WHO

Guitelle Baghdadi

Health Technology and Pharmaceuticals/Medicines Policy and Standards/ Policy, Access and Rational Use, World Health Organization, Geneva, Switzerland.

Alice Croisier

Global Influenza Programme, Department of Epidemic and Pandemic Alert and Response, World Health Organization, Geneva, Switzerland.

Delanyo Dovlo

Evidence and Information for Policy/Health systems delivery, World Health Organization, Geneva, Switzerland.

Gregory Anton Hartl

Communications Adviser, World Health Organization, Geneva, Switzerland.

Frederick Hayden

Global Influenza Programme, Department of Epidemic and Pandemic Alert and Response, World Health Organization, Geneva, Switzerland.

Claudia Garcia Moreno

Family and Community Health/ Gender, Women and Health, World Health Organization, Geneva, Switzerland.

Kidong Park

Global Influenza Programme, Department of Epidemic and Pandemic Alert and Response, World Health Organization, Geneva, Switzerland.

Ana Maria Henao Restrepo

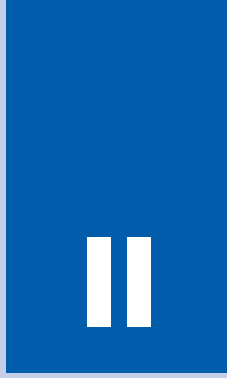
Family and Community Health/Immunization, Vaccines and Biologicals/Initiative for Vaccine Research/Product R&D, World Health Organization, Geneva, Switzerland.

Christoph Steffen

Global Influenza Programme, Department of Epidemic and Pandemic Alert and Response, World Health Organization, Geneva, Switzerland.

Dick Thompson

Communications Officer, Communicable Diseases Cluster, World Health Organization, Geneva, Switzerland.



Isolation, quarantine, border control and social-distancing measures

Larry Gostin and Ben Berkman, Georgetown University

ON BEHALF OF WORKING GROUP TWO

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List of abbreviations

FAO	Food and Agriculture Organization of the United Nations
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social, and Cultural Rights
IHR	International Health Regulations
OIE	International Office of Epizootics
PPE	Personal protective equipment
SARS	Severe acute respiratory syndrome
UDHR	Universal Declaration of Human Rights
UN	United Nations
WHO	World Health Organization
WTO	World Trade Organization

Introduction

Public health measures, both pharmaceutical and non-pharmaceutical, can be important mechanisms for protecting a population's health during a pandemic. However, these measures can impose significant burdens on individual rights (e.g. autonomy, privacy, and liberty) and economic and social welfare (e.g. trade, tourism, and business).

This paper presents a framework based on ethics and human rights for evaluating the use of public health measures in response to a pandemic. After presenting general ethical principles and human rights obligations, the paper focuses on describing the types of public health interventions that might be used during a pandemic and the ethical issues these interventions raise. It then outlines ethical principles that countries should consider in using

these interventions, mitigating factors that might make such principles difficult to apply and practical solutions that take these factors into account.

Ethical considerations are also presented in relation to veterinary measures that might be implemented during the pandemic alert period when influenza viruses usually affecting only animals are thought to create a risk of disease in humans.

Given the globe's diversity of economic resources, governance structures, and cultural norms, it is unreasonable to assert that there is one set of ethical ideals that must guide the implementation of all public health measures. Moreover, even with the best ethical aspirations, the crisis situation created by a pandemic will put enormous strains on the best laid plans.

1

An ethics and human rights framework

National and global strategic plans take a variety of forms, but share a common set of tools for preventing the spread and mitigating the impact of a new influenza pandemic. Many of the barriers to effective interventions are technical and have been thoroughly discussed elsewhere (1). This paper focuses on the formidable ethical challenges that have not previously received sufficient attention (2, 3). Many countries have developed plans for combating pandemic influenza, but the vast majority do not mention ethical issues; those that do fail to take a comprehensive approach.

Pandemics can be deeply socially divisive, and the political response to these issues not only impacts public health preparedness, but is also important to a good and decent society. In addition, there are circumstances in which public health measures implemented in response to a pandemic threat or actual event (e.g. non-voluntary isolation, quarantine, movement restrictions, rationing) may impose significant restrictions on individual liberty. Therefore, it is particularly important to show respect for ethical principles and international law, especially human rights law, when developing national policies for pandemic influenza. This section sets out the relevant ethical and human rights principles that should be considered when planning to combat a highly pathogenic influenza outbreak.

1.1 International human rights

The basic characteristics of human rights are that they are inherent in all human-beings; they are universal, so that people everywhere in the world are “rights-holders;” and they impose significant duties on the state (4). State duties encompass the obligation to *respect* so that states do not interfere directly or indirectly with the enjoyment of human rights; *protect* so that states take measures to prevent private actors from interfering with the rights;

and *fulfil* or facilitate so that states take positive measures (e.g. legislative, budgetary, and promotional) to enable and assist individuals and communities to enjoy rights. Basic human rights are protected under international law so that a state can no longer assert that systematic maltreatment of its own nationals is exclusively a domestic concern (5).

The main sources of human rights law are the Universal Declaration of Human Rights (UDHR) (6), two international covenants on human rights (the International Covenant on Civil and Political Rights (ICCPR) (7) and the International Covenant on Economic, Social, and Cultural Rights (ICESCR) (8)). The United Nations (UN) has promulgated numerous treaties dealing with specific human rights violations including racial and gender discrimination, the rights of the child, genocide, and torture (9, 10, 11, 12). Human rights are also protected under regional systems, including those in Europe (13), Africa (14), and the Americas (15).

The Universal Declaration of Human Rights (UDHR)

The UDHR, adopted in 1948, identified specific rights and freedoms that deserve promotion and protection. The UDHR was the organized international community’s first attempt to establish “a common standard of achievement for all peoples and all nations” to promote human rights (6, Preamble). The UDHR represents a milestone in the struggle of humanity for freedom and human dignity, stating that human rights are self-evident, the “highest aspiration of the common people (6, Preamble).” Article 1 proclaims: “All human beings are born free and equal in dignity and rights.”

The Universal Declaration is not a treaty, but a resolution with no explicit force of law. Nevertheless, its key provisions have so often been applied

and accepted that they are now widely considered to have attained the status of customary international law (16). The UN General Assembly has declared that the principles embodied in the Universal Declaration “constitute basic principles of international law.”(17) Moreover, it has “acquired a moral and political authority equal to that of the (United Nations) Charter.”(18) In any event, the Declaration has inspired and influenced many international conventions and is reflected in national constitutions, legislation, and in the decisions of national and international tribunals.

Most relevant to the ethics of public health interventions, the UDHR provides that all people have: the right to freedom from arbitrary arrest, detention, or exile (6, article 9); the right of movement and residence within and between the borders of each state (6, article 13), and the right to freedom from discrimination. While the UDHR served as the preliminary description of rights, two binding covenants followed.

International Covenant on Civil and Political Rights (ICCPR) & International Covenant on Economic, Social and Cultural Rights (ICESCR)

Both the ICCPR and the ICESCR were adopted in 1966 and entered into force in 1976. The ICCPR imposed an immediate obligation “to respect and to ensure” civil and political rights. A sister covenant, the ICESCR, requires state parties:

to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized ... by all appropriate means, including particularly the adoption of legislative measures.

The language of “progressive realization” and “maximum resources” may have been inserted because economic and social rights typically require greater funding and more complex solutions than civil and political rights. Still, the Committee on Economic, Social and Cultural Rights, established by the ICESCR, made it clear that states parties do have immediate obligations; “steps” towards the goal of full realization “must be taken within a reasonably short time.” States parties have “a minimum core obligation to ensure the satisfaction of ... each of the rights.” The Committee also said

that states parties should immediately implement legislation and judicial remedies to ensure non-discrimination in the exercise of economic and social rights (Art. 2(1)) (19).

These covenants provide a number of rights that are relevant to the implementation of public health interventions: the right to freedom from cruel, inhuman, or degrading treatment or punishment; the right to freedom of movement and residence; the right to freedom from arbitrary detention; and most notably the right to health.

The right to health encompasses the international obligation for all nations to promote and protect the health of its civilians, especially by facilitating access to basic health-care services. The right to health is, however, not equivalent to a right to health care nor is it an absolute right. It must be evaluated against both the means available to the state and the biological and socioeconomic characteristics of the individual concerned (20). Furthermore, the right to health cannot be seen in a vacuum; it depends on the realization of other human rights such as the right to life, the right to privacy and the right to non-discrimination. The right to health thus encompasses a broad spectrum of socioeconomic factors and has to be extrapolated to the underlying determinants of health such as hygiene, housing, environment, and clean drinking water (20).

Regional Conventions: European Convention on Human Rights and Fundamental Freedoms and its Protocols (ECHR), American Convention on Human Rights and the Banjul Charter on Human Rights and People’s Rights

The European Convention on Human Rights and Fundamental Freedoms and its protocols (“European Convention”) (13), the American Convention on Human Rights (“American Convention”) (15), and the Banjul Charter on Human Rights and People’s Rights (“Banjul Charter”) (14) identify many of the same rights and liberties as the Universal Declaration. Public health measures could violate the right to privacy (13, 15), the right to be free from inhumane or degrading treatment (13), the right to freedom of movement (13), and the right to be free from discrimination (13).

1.2 Valid limitations on human rights

Human rights have transcending value, but international law does allow restrictions when necessary for the public good. Under the UDHR, the sole purpose for the limitation of rights is to secure “due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and general welfare in a democratic society” (6, Art. 29(2)). States may not “perform any act aimed at the destruction of any of the rights and freedoms” proclaimed in the Declaration (6, Art. 30).

The two covenants diverge in their treatment of permissible derogations and limitations. ICCPR’s most fundamental guarantees are so essential as to be absolute and no state, even in a time of emergency, may derogate from them. ICCPR, however, allows states parties “in time of public emergency that threatens the life of the nation” to suspend most other civil and political rights (7, Art. 4). The state must officially proclaim the public emergency and cannot engage in discrimination. The principal conditions for restraints on civil and political rights are that they must be prescribed by law; enacted within a democratic society; and necessary to achieve public order, public health, public morals, national security, public safety, or the rights and freedoms of others (7). However, states parties may not impose restrictions aimed at the destruction of rights or their limitation to a greater extent than provided in the Covenant (Art. 5(1)) (21).

The Siracusa Principles

Conceptualized in 1985 at a meeting in Siracusa, Italy, the Siracusa Principles are widely recognized as a legal standard for measuring valid limitations on human rights (22). The Principles make clear that even when the state acts for good reasons it must respect human dignity and freedom. Echoing the language of ICCPR, the Siracusa Principles require that state limitations must be: in accordance with the law; based on a legitimate objective; strictly necessary in a democratic society; the least restrictive and intrusive means available; and not arbitrary, unreasonable or discriminatory. International tribunals have relied on the Siracusa Principles to require states to use the least restrictive measure necessary to achieve the public health purpose (23, 24).

It is far more difficult to think about legitimate

limitations on economic, social, and cultural rights. ICESCR permits

such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society (Art. 4) (25).

Since the ICESCR includes a “right to health,” one can conceptualize any measures necessary to attain health protection for the population as valid limitations on other rights. For example, the Covenant requires states parties to take steps to prevent, treat and control epidemic, endemic, and occupational diseases (8, Art. 12(2) (c)). Thus, compulsory measures such as vaccination, treatment, or isolation would be permitted only if necessary to protect the public’s health.

1.3 Public health ethics

International human rights principles stress the importance of individual rights and freedoms, but make it clear that these freedoms can be restricted when the public’s health is threatened. Striking this balance between the individual and the collective can be a difficult task, especially under conditions of scientific uncertainty and crisis. Therefore, it is important to articulate the values of public health ethics that should influence pre-pandemic planning.

Public health necessity

Public health powers are exercised under the theory that they are necessary to prevent an avoidable harm. Early meanings of the term “necessity” are consistent with the exercise of police powers: to necessitate was to “force” or “compel” a person to do that which they would prefer not to do, and the “necessaries” were those things without which life could not be maintained. In order to justify the use of compulsion, government must therefore act only in the face of a demonstrable health threat. The public health officials must be able to prove that they had “a good faith belief, for which they can give supportable reasons, that a coercive approach is necessary” (26).

The standard of public health necessity requires, at a minimum, that there must be a reasonable basis for believing that the subject of the compulsory intervention actually poses a threat to the community. In the context of infectious diseases,

for example, public health authorities could not impose personal control measures (e.g. mandatory physical examination, treatment, or isolation) unless the person was actually contagious or at least there was reasonable suspicion of contagion. While this standard is obviously resistant to precise definition, it is important that countries clearly delineate what criteria for suspicion will be used and provide procedural safeguards.

WHO and other international organizations play the role of international arbiter providing advice on determinations of public health necessity, reasonableness of measures, proportionality, and other relevant criteria.

Reasonable and effective means

Under the public health necessity standard, governments may act only in response to a demonstrable threat to the community. The methods used, moreover, must be designed to prevent or ameliorate that threat. In other words, there must be a reasonable relationship between the public health intervention and the achievement of a legitimate public health objective. Even though the objective of the legislature may be valid and beneficent, a public health intervention must be an effective means of combating the public health threat. A policy that entails personal burdens and economic costs is only justified if the government can demonstrate that there is a reasonable chance of protecting the public's health (27). Because it is extremely difficult to exactly define "reasonable chance" for all potential situations, the government has an obligation to engage in ongoing evaluation of the public health intervention and its effectiveness.

Proportionality

The public health objective may be valid in the sense that a risk to the public exists, and the means may be reasonably likely to achieve that goal – yet a public health regulation is unethical if the human burden imposed is disproportionate to the expected benefit. Public health authorities have a responsibility not to overreach in ways that unnecessarily invade personal spheres of autonomy. This suggests a requirement for a reasonable balance between the public good to be achieved and the degree of personal invasion. If the intervention is gratuitously onerous or unfair it will overstep ethical boundaries.

Distributive justice

This ethical principle requires that the risks, benefits, and burdens of public health action be fairly distributed, thus precluding the unjustified targeting of already socially-vulnerable populations. Beauchamp and Childress view distributive justice as the "fair, equitable, and appropriate distribution in society determined by justified norms that structure the terms of social cooperation" (28).

In the context of public health, the principle requires that officials act to limit the extent to which the burden of disease falls unfairly upon the least advantaged, and to ensure that the burden of interventions themselves is distributed equitably (29, 30). Thus, in the exercise of compulsory powers, distributive justice requires a fair allocation so as not to unduly burden particularly vulnerable populations. Distributive justice has been viewed as being so central to the mission of public health that it has been described as its core value; as Beauchamp has said "The historic dream of public health... is a dream of social justice" (31).

Distributive justice does not merely require a fair allocation of risks and burdens. It also recognizes that public health often distributes benefits such as vaccines, treatment, or other services. Problems of the fair allocation of benefits arise under conditions of scarcity, where there is competition for resources. This might occur, for example, with a scarcity of medical treatment in the midst of an influenza pandemic.

Trust and transparency

Public health officials have the responsibility to involve the public in the process of formulating public health policies as well as to explain and justify any infringement on general moral considerations. Public health officials should honestly disclose relevant information to the public. Accordingly, citizens should have the right to request and receive information, and their input should be solicited (26, 27, 32).

The need for transparency stems in part from the government's ethical imperative to treat citizens with respect, by offering reasons for policies that infringe moral considerations (32, 33). Transparency is also essential to create and maintain public trust and accountability (32). Openness and accountability are important to public health gov-

ernance because of their intrinsic value and capacity to improve decision-making. Citizens gain a sense of satisfaction by participating in policy-making and having their voices heard. Even if the government decides that personal interests must yield to common needs, the individual feels acknowledged if he/she is listened to and his/her values are taken into account.

Transparency also has instrumental value because it provides a feedback mechanism – a way

of informing public policy and arriving at more considered judgments. Open forms of governance engender and sustain public trust, which benefits the public health enterprise more generally. Without public support and the voluntary cooperation of those at risk, coercive public health interventions would be difficult to achieve. The public must be able to trust that their government is acting in their best interests.

2

General ethical themes

2.1 Community participation

WHO's constitution of 1948 states that "Informed opinion and active cooperation on the part of the public are of the utmost importance in improving health" (34). Community participation in pandemic preparedness and response is critically important. The ethical principles of trust and transparency require that the public be involved in decisions that will affect it. During a pandemic many actions taken will impose losses on members of society, in terms of both money and autonomy. Similarly, actions not taken will leave society at risk of disease. Balancing the risks of action and the risks of inaction will require education of, and input from, the public in whose name public health policy-makers act. This will help to ensure that the policies ultimately adopted are well-suited to local circumstances and values.

At the national level, community participation includes advocacy, delivery of services, cost-sharing and support to patients. Each person should have the opportunity to contribute to public discourse and thus must be adequately informed so that they are able to participate and are not treated simply as members of the population to be "managed" by the authorities. Priorities need to be identified based on fundamental requirements in a community, its expectations and financial capacity. Thus, an ethically-appropriate policy in one country, or even one city, may be ethically inappropriate in another, due to varying norms and benefits from, or losses imposed by, an intervention.

Community participation has a positive impact on the success of project development and implementation, on the promotion of a sense of responsibility, and can even reduce alienation among socially excluded groups (33). Time and resource constraints may considerably complicate community outreach programmes during a pandemic. Con-

sequently, government must gain the public's trust by providing adequate and accurate information well in advance. Of course, some issues will develop very quickly or unexpectedly during a pandemic, precluding advance information. In this case, government should provide the necessary information as quickly as possible, and community involvement in decision-making should be as great as the circumstances of a situation allow. When expediency does not allow full involvement by the community before policies are enacted, a post-enactment review process is particularly important to ensure transparency and accountability and should incorporate community involvement.

2.2 Evaluation of effectiveness of interventions

In the event of a pandemic, the use of all possible intervention strategies must be considered because the effectiveness of a specific intervention is difficult to predict and evaluate. Which measure or combination of measures works best at each stage of the pandemic is a key question. For a number of reasons this is difficult to answer. First, evidence of effectiveness is often historical or anecdotal, with few controlled or systematic studies (35). Second, an intervention's effectiveness depends on the transmission pattern of the pandemic, which cannot be fully understood in advance and may change over time (1). Third, an intervention's usefulness depends on the pandemic phase. In the pandemic alert period, surveillance, medical prophylaxis and isolation are important tools. During a pandemic the focus shifts to delaying spread through non-pharmaceutical interventions and mitigating impact through medical treatment (1).

Evaluation of effectiveness of interventions is important not only from a public health perspective, but also from an ethical perspective. To the extent that interventions impose costs and burdens

on individuals or the population, they are ethically warranted only to the extent that they are effective and proportionate in terms of benefits and burdens. Multiple, targeted approaches are likely to be most effective, but they can have deep adverse consequences for the economy and civil liberties. As such, government should employ the least restrictive option possible. Given this principle, and the uncertain utility associated with public health interventions, prospective monitoring of outcomes and further evaluation of the impact of interventions and strategies will need to be carried out. Measures that entail serious liberty or economic costs are not ethically acceptable unless there is adequate evidence that they are effective. Thus it is important to encourage research whenever possible. Adequate resources for population-based research are urgently needed (36).

2.3 Resource allocation

Perhaps the greatest ethical issues of pandemic preparedness and response concern the allocation of scarce resources. Some of these issues are discussed more in depth in chapters I and IV of this volume. A pandemic may overtax the immediately available resources of even the richest countries on the planet; less wealthy countries are likely to be overwhelmed. In 1918, influenza-related mortality was highest in the least developed parts of the world and lowest in the wealthiest countries (37). Given the higher baseline levels of mortality, the greater prevalence of HIV/AIDS (and many other diseases such as malaria and tuberculosis), and reduced access to health care in many developing countries, these countries are likely to experience greater morbidity and mortality in any future influenza pandemic. These countries are also those that have the least resources available to protect their citizens and to slow transmission of the disease.

The demands of distributive justice require that resources be expended equitably, with attention paid to meeting the needs of those who are most vulnerable. In the context of pandemic influenza, this means that resources must be used so as to alleviate the greatest amount of human suffering and death, with particular attention to people who systematically suffer disadvantage. If developing countries are at greatest peril from the disease, then wealthy countries have a duty to assist them

to provide the greatest degree of protection feasible given the worldwide scarcity of resources. Developed countries have an obligation to do what is possible to prevent the burdens of an influenza pandemic from falling most heavily on those people who are already the least advantaged.

Early in a pandemic at least, both wealthy and developing countries will benefit from resource sharing. Some modelling studies, based on as yet untested assumptions, suggest that there could be a brief window of opportunity to extinguish transmission of an emerging pandemic virus if adequate pharmaceutical (mass chemoprophylaxis) and non-pharmaceutical measures were implemented in a timely manner and on a certain minimum scale (38). But all available measures are expected only to slow transmission once a full-fledged pandemic is underway (38). To the extent that a pandemic is likely to begin in a less developed country, effectiveness of the intervention demands that wealthy countries assist poorer countries combat a nascent pandemic.

In addition, in all countries, a fair system for allocating health-promoting resources must be developed. The demand for medical care, hygienic measures, and other resources is likely to exceed the supply, so it is important that these resources be allocated in an equitable manner and with attention paid to obtaining the greatest degree of health promotion possible. Resources should also be distributed in a non-discriminatory fashion. To the extent possible, there should be transparency and broad participation in the rationing scheme.

2.4 International cooperation and coordination

The protection of public health and national risk management is primarily the responsibility of national authorities. Thus all countries should develop a national influenza preparedness plan. In designing a justifiable containment strategy, each country needs to consider its specific factors such as national political structures and principles, educational and cultural environment, the prevalence of the virus, and the strengths and weaknesses of the national health-care system. While different national approaches are ordinarily not a problem, considerable variation between national plans could prevent or delay an efficient response in a

multi-country public health emergency (39). Cooperation among national authorities and coordination by international bodies is thus necessary (39). The *WHO global influenza preparedness plan* (40) and the *WHO interim protocol: rapid operations to contain the initial emergence of pandemic influenza* (41) are intended to “assist Member States and those responsible for public health, medical and emergency preparedness to respond to threats and occurrences of pandemic influenza.”

Particular emphasis on cooperation and coordination can be seen in the International Health Regulations (IHR) (2005) (42), a revision of the 1969 Regulations. The purpose and scope of the Regulations are “to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.” IHR(2005) introduces the term “public health emergency of international concern,” defined as an extraordinary public health event which is determined to constitute a public health risk to other states through the international spread of disease; and to potentially require a coordinated international response. The Regulations require countries to develop, strengthen and maintain core public health capacities to detect, assess, and notify WHO of events that may constitute a public health emergency of international concern via National IHR Focal Points in each State Party (43).

On 15 June 2007, IHR(2005) became legally binding on all WHO Member States except those

that submitted reservations. However, in light of the concern surrounding avian influenza, in May 2006 the Fifty-ninth World Health Assembly adopted Resolution WHA59.2, calling upon WHO Member States to comply immediately and voluntarily with those IHR(2005) provisions relevant to the pandemic influenza risk.

There is also a need for cooperation between international agencies. The burden of responding to a pandemic, especially in its early stages, will be borne by many partners, including international agencies (e.g. WHO, FAO, and OIE), national, regional and international laboratories, nongovernmental organizations, civil society bodies, and government. It will be important for knowledge gained by one entity to be disseminated quickly to other entities. WHO has a key role to play in coordinating global data analysis and disseminating information, and in providing leadership for identification of critical questions for urgent operational research.

Further, given the scarcity of resources available to stem a pandemic, it will be important that work done by one agency is not unnecessarily duplicated by others. This also has implications for distributive justice, particularly in the most resource-constrained parts of the world where much of the technical response will be conducted by international agencies, and where efforts unnecessarily spent will trade off with other, potentially life-saving efforts. The issues of international cooperation and coordination are discussed in more detail in chapter IV .

3

Non-pharmaceutical public health interventions

Non-pharmaceutical public health interventions, independent of pharmaceutical measures, will be vital to slow the spread of an emerging or established pandemic (44, 45). This section briefly identifies and describes the various interventions (see Box 1). These are discussed in more detail in subsequent

sections, focusing on the ethical issues raised by each of the traditional public health interventions, and drawing on lessons learnt from past influenza pandemics (46) and the outbreaks of severe acute respiratory syndrome (SARS) (47).

BOX 1

Non-pharmaceutical public health interventions

Surveillance: 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.*

Personal Hygiene: The use of basic hygienic measures by individuals to reduce the risk of transmission of infections. Main personal hygienic measures against influenza and other respiratory diseases include hand washing and respiratory hygiene (covering one's mouth when coughing, or coughing etiquette i.e. using disposable paper tissues, etc).

Community hygiene: A set of measures for the prevention of spread of infection through implementation of community actions aimed at maintaining hygiene in public places and at household level, and at ensuring food safety.

Health-care facility infection control: A set of measures intended to help prevent the spread of pathogens in health-care settings by means of safer practices for patients, health-care workers, visitors, and the environment within health-care facilities. It incorporates all aspects of infection control, e.g. education, surveillance, environmental management, waste management, outbreak investigation, standard and additional precautions, cleaning, disinfection and sterilization, employee health, and quality management in infection control.

Isolation: The separation, for the period of communicability, of infected persons (confirmed or suspected) in such places and under such conditions as to prevent or limit the transmission of the infectious agent from those infected to those who are susceptible or who may spread the agent to others.*

Social distancing: A range of community-based measures to reduce contact between people (e.g. closing schools or prohibiting large gatherings). Community-based measures may also be complemented by adoption of individual behaviours to increase the distance between people in daily life at the work site or in other locations (e.g. substituting phone calls for face-to-face meetings, avoiding shaking hands).

Quarantine: The restriction of the movement of healthy persons who have been exposed to a suspected or confirmed case of a highly communicable disease during the likely infectious period.* It is a precaution aimed at preventing further spread of infection to other people.

International travel and border controls: Measures that are designed to limit/control spread of infection across entry points to the country (road, air, sea). They can include travel restrictions, entry or exit screening, reporting, health alert notices, collection and dissemination of passenger information, travel advisories or restrictions, etc.

When an avian influenza virus of pandemic potential is circulating in avian and human populations during a pandemic alert period, the implementation of additional strategies is recommended to

- prevent and control infection/disease in animal populations
- limit interaction between human and potentially infected poultry/poultry products to reduce risk of exposure and infection of humans.

* adapted from Last, JM. *A dictionary of epidemiology*. 4th ed. Oxford, Oxford University Press, 2001.

4

Surveillance

Surveillance and outbreak investigations are the backbone of public health. These activities provide public health authorities with essential data to understand the epidemic threat, identify and design appropriate interventions, and inform the public accordingly. Surveillance and investigation strategies include early warning systems, rapid diagnosis, screening, reporting, contact investigations, and monitoring trends.

It is clear that surveillance is necessary to quickly identify and respond to a pandemic influenza outbreak. IHR(2005) requires Member States to notify WHO of all events which may constitute a “public health emergency of international concern.” Consequently, once a country identifies an acute threat for public health, it is expected to immediately begin investigations and simultaneously notify WHO of the event and related information (outcome of risk assessment, needs for assistance). The “triggering criteria” of early pandemic activity cannot be fully set out ahead of time. Public health officials should thus be vigilant and report all plausible signals that a pandemic virus may be emerging (e.g. an increased transmissibility of an influenza A(H5N1) virus from person to person, or isolation of an influenza virus sub-type not previously circulating in humans).

4.1 Global responsibility to develop core surveillance capacities

Ideally, all countries should have the capacity to perform core surveillance functions. However, such a recommendation is vacant for poor countries which lack the resources for animal or human surveillance and containment of outbreaks (45). In large parts of Africa and Asia, the capacity for veterinary and human surveillance is limited or nonexistent (48). Many developing countries are being pressured to improve their existing surveillance infrastructure, but in doing so may divert resources from areas of

greater need. It is, for example, very hard to convince the government of a poor country with much of its population infected with HIV or malaria to invest scarce resources towards the monitoring of a potential influenza threat (46). Developed countries should be aware of this trade-off which confronts developing countries and should be encouraged to increase investment and capacity building in developing countries to ensure that enhanced surveillance does not occur at the expense of managing the multitude of their ongoing public health threats. Opportunities for synergistic use of existing resources in neighbouring countries or at international level should be examined (e.g. regional or international laboratory testing capacities). Protecting global health requires governments around the world to cooperate and collaborate.

Many countries have recently recognized this ethical imperative, pledging US\$ 1.9 billion to meet the costs estimated by the World Bank to contain avian influenza (49, 50). However, this money will only temporarily address the need for surveillance. The avian influenza threat might not manifest itself for years, and future pandemics are almost certain to occur. Thus, it would be ethically desirable to pursue the larger goal of creating sustainable public health systems across the globe. To this end, the WHO Commission on Macroeconomics and Health estimated that industrialized countries would have to spend US\$ 27 billion in 2007 to meet global needs for essential public health services (51).

4.2 Mitigating privacy and autonomy risks

Surveillance poses privacy risks as governments collect sensitive health information from patients, travellers, migrants, and other vulnerable populations (52). IHR(2005) require Member States to keep data “confidential and processed anony-

mously as required by national law.” Many countries have data protection statutes, but these laws make exceptions for surveillance in the context of a public health threat (53, 54). Countries should enact public health information privacy laws to require justifiable criteria for data disclosure and to prohibit wrongful disclosures, for example, to employers, insurers, and immigration or criminal justice authorities (55). Whenever a government authorizes or mandates the disclosure of identifiable health data, the proposed use, the reason for disclosure, and the extent to which third parties can have access to the data should be made public.

In a crisis situation, however, it may be necessary to disclose information without undue delay. When the immediate use of the information is necessary for an important public health purpose and is restricted to the confines of the public health system, disclosure can be warranted. In order for disclosure to be justifiable, the identity of the affected person should be protected as much as possible. The inclusion of any uniquely identifiable characteristics, such as a name, government identification number, fingerprint, or telephone number should be avoided especially when the information is released outside the public health system. Cases should remain anonymous or their details should be encrypted when reasonably feasible. In any event, the right to privacy and personal autonomy require

that only the minimum amount of information necessary to achieve the goal will be released and to as few people as possible. Dignity and respect for the person should be protected. A breach of the right to privacy can result not only in economic harms such as unemployment, loss of insurance, or of housing, but also in social and psychological harm.

Screening and testing can pose serious threats to a person’s privacy and to lesser extent bodily integrity. Ideally, public health officials need to receive the individual’s informed consent prior to performing any medical tests. Although education programmes will often lead to voluntary testing, mandatory testing might be necessary to advance the public good. Interference with the right to bodily integrity and the right to refuse testing may be permissible only when the mandatory testing policy is clearly necessary and effective in protecting the public health, when it is performed by competent public health officials, and when the least intrusive means are used. If such a policy is required, compulsory testing should be limited to individuals known or at least suspected to be infected and should be done in a fair and non-discriminatory way. The people whose rights are being infringed should be informed of the reasons for the infringement and about possible means of appeal. As in all cases, the use of coercion should be the last resort.

5

Hospital infection control and personal and community hygiene

Hygienic measures to prevent the spread of respiratory infections are broadly accepted and have been widely used in previous influenza pandemics (56) and the SARS outbreaks, although with uncertain benefits (57, 58). Infection control measures include hand-washing, disinfection, respiratory hygiene (etiquette for coughs, sneezes, spitting), and personal protective equipment (PPE; masks, gloves, gowns, eye protection) (57, 58). Evidence supports hospital infection control measures, but the effectiveness of hand hygiene, disinfection, respiratory hygiene, or PPE in preventing transmission of influenza in the community is unclear (56, 59, 60). Research is needed to understand the appropriate role of community hygiene in a future pandemic. For example, mask use was common, even legally required, in the 1918 influenza pandemic and SARS outbreaks, but no controlled studies have evaluated its effectiveness during an influenza pandemic.

5.1 Ensuring the appropriate use of hospital infection control

The SARS-associated coronavirus was spread efficiently in hospitals which did not adopt strict infection control procedures (57). Disinfection, hand hygiene, and use of PPE for aerosol-generating procedures should be standard hospital practices (57). If an influenza virus of a new sub-type has the same transmission pattern as seasonal influenza, high attack rates of influenza among health-care workers (61) and efficient transmission in crowded areas (1) would be expected. Health-care workers who do not practice strict infection control would be at increased risk of infection and of amplifying transmission to patients and staff within the health-care setting. It is therefore vital to train health-care workers and monitor the use of infection control measures before and during the pandemic. This is possible through the appropriate use of supervi-

sory procedures and/or legal oversight or licensing requirements.

There are ethical concerns regarding use of hospital infection control procedures. The first of these is an issue of distributive justice. The level of resources that can be dedicated to infection control will vary substantially between and within countries, and a fair system for allocating scarce infection control resources should be developed. It is also important to involve hospital staff in planning for the implementation of heightened infection control and to devise a fair system for determining who carries out tasks that involve increased risk. Such a process enhances the transparency of the plan. Control methods should be culturally sensitive and those that require restricting valued personal and cultural behaviours (such as the shaving of beards to properly fit masks) should be carried out through consultation with affected people. In addition, policies that are implemented should reflect the findings of the best available scientific research.

Ideally, countries should create training and monitoring programmes to ensure that hospitals use standard infection control procedures effectively. Training programmes should be based on available science to maximize effectiveness and should strive to provide health-care workers with the information needed to minimize risks both to their own and their patients' health. Health-care workers should be involved in the creation of such programmes and implementation at health-care facilities should be adapted to the specific features of the institution.

There are limitations that may impede countries' abilities to implement an ideal infection control programme. Some countries will lack the resources to purchase adequate PPE for a long-lasting epidemic, and some may lack sufficient health infrastructure to implement new programmes on a speedy basis.

Civil unrest may impede monitoring of programmes and legal infrastructure may have to be developed to enforce compliance with training and monitoring efforts.

For countries facing substantial limitations, alternatives to the ideal exist. The strictness of infection control may have to be relaxed (e.g. surgical masks may have to be substituted for N95 masks; open windows and exhaust fans may have to be used to foster air exchanges in the absence of central air conditioning). If areas do not have access to isolation rooms, segregating infectious patients into separate wards or hospitals or recommending home stay for mildly-ill patients may be appropriate. In addition, training without full monitoring of compliance may be necessary if monitoring is not feasible.

Countries will also have to develop a method to ration scarce PPE and to determine how to distribute masks and other PPE in a fair manner. Such plans should give serious consideration to questions of justice and seek a rationing scheme that protects health to the greatest degree possible. Plans should be devised openly, with an opportunity for both experts and the lay public to be heard. It is important that a fair process is used and that scarce resources are not distributed in a discriminatory fashion or as a benefit for political support.

Policy-makers will also have to address the problem of critical shortages in infection control and patient care equipment (e.g. particulate respirators, surgical facemasks, hand sanitizers, disinfectants, ventilators, intensive care beds) (62). Given the potential duration and scope of a pandemic, which may comprise several waves of outbreaks, even stepped-up production of PPE will be overwhelmed by the demand, especially if use in hospitals and the community is widespread. International collaboration will be needed to address this problem. Further research is needed to develop reusable respirators (63) and to determine the effectiveness of alternatives to N95 respirators (63). It is critical that research is conducted in a collaborative manner in the various countries where it occurs, and that information is broadly distributed in a manner that fosters trust and transparency. Cooperation between industry, governments, and researchers will facilitate improved production of equipment and greater efficiency at meeting shortages.

5.2 Encouraging personal and community hygiene

Even if hygienic measures are effective they are challenging; professionals and the public must use them properly and consistently until the risk subsides. Studies demonstrate the inconsistent use of infection control procedures in hospitals, and that the general public has not uniformly adopted even basic hygiene practices such as hand washing (64). During the SARS epidemic, people in affected areas were shown to use protective measures inconsistently (65).

Improving use of infection control procedures

To improve the consistent use of infection control procedures, it is important that the public is informed of the need for such measures, and that accurate information, including the uncertainty of the effectiveness of the recommended interventions, is provided. In past epidemics, misinformation has been rampant, and this has led to substantial public anxiety, reliance on word-of-mouth for information, and purchase of ineffective and expensive products (66). Issues of distributive justice arise because ineffective or inaccurate communications impact the most marginalized members of society most heavily; those without access to alternative, credible sources of information and those for whom wasting resources would have the greatest adverse effects. Furthermore, the members of the public have a dignitary interest in being provided with adequate information to make informed decisions about their own health.

Community level preparedness and public education

Public education campaigns grounded in the science of risk communication are important as the acceptability of health measures is vital to community adherence. The information disseminated through public education campaigns should be clear, uncomplicated, not sensational or alarmist, and as reassuring as possible. Research indicates that panic is generally rare during civil emergencies. However, providing clear, consistent, credible information which instructs people how to protect themselves will assist them in coping with the fear of emergencies and their own protection (67). It is important to avoid information that fails to treat members of the public as rational agents; instead

the public should be treated as a partner, enhancing the principle of transparency.

Ideally, it is important to account for variations in settlement patterns as part of planning for community level preparedness. Different types of settlements (i.e. cities, towns, rural communities) present unique risks and challenges in the event of a pandemic. Similarly, communities may have unique cultural characteristics (e.g. religion, race, ethnicity) that can interact with emergency preparedness endeavours. In many places, public education campaigns may be made more difficult by multiple languages being spoken in a community and by varying levels of literacy and access to the media. Preparedness plans must take account of these geographical and cultural differences. They must also take steps to include diverse media sources. This can be accomplished by encouraging community involvement in the planning and implementation process and by utilizing leaders from many subpopulations in communities.

A lack of mass media infrastructure will impede

broad dissemination of information in some areas. Resource constraints also prevent some populations from receiving messages that are distributed via media that are costly to acquire, and a lack of governmental infrastructure may make dissemination of messages much more difficult. Furthermore, in some areas, media that caters for particular subpopulations may not be available, and portions of the population may have insufficient education for messages to be easily disseminated. Countries should strive to reduce these problems by using the communication networks that are available. Health-care workers and trusted sources in communities should be consulted and informed about community hygiene measures so that they can assist communication efforts. They can also help to tailor messages and make them accessible to target audiences. Messages should be posted in places where all members of the community are likely to see them, such as markets, public places, and in written media, and they also should be announced on radio and television.

6

Decreased social mixing/ increased social distance

Social distancing (separation) and limitation of community movement have been used during past pandemics (68, 69). There is little evidence to show that school closure reduces seasonal influenza transmission (70), and it is assumed, but not proven, that decreased social mixing slows the spread of respiratory disease (1). Thus, in the face of pandemics, policy-makers have closed public places (schools, childcare, workplaces, mass transit) and curtailed large gatherings by cancellation of public events (sports, arts, conferences). As the level of fear rises, the public may choose to avoid public gatherings. Predicting the effect of policies to increase social distance is difficult as infected persons and their contacts may be displaced into other settings, and individuals may voluntarily separate in response to perceived risk (35). Thus additional research needs to be conducted on behaviour during influenza epidemics and pandemics and the effects of social distancing on transmission of influenza viruses.

Social separation, particularly for long duration, can cause loneliness and emotional detachment, disrupt social and economic life (education, trade, business), and infringe individual rights. Community restrictions raise profound questions of faith (religious worship), family (funeral attendance), and protection of the vulnerable (food, water, clothing, medical care). Public health authorities should utilize whatever means possible to mitigate the adverse effects of social separation.

6.1 Government authority and accountability

Undoubtedly, most judicial systems would uphold reasonable community restrictions, but legal and logistical questions loom; who has the power and under what criteria to order closure and for what period of time? What threshold of disease should trigger closure and should thresholds be different

for different entities (schools, events, etc)? Under what circumstances should compensation for closures be paid? Should there be penalties for non-compliance? If so, which ones? How to enforce restrictions and assure population safety remain critically important but unanswered questions in most countries.

One fear is that governments might implement strict restrictions on personal liberties unnecessarily, by implementing restrictions before they are needed, extending them beyond a disease crisis, or enacting restrictions that do not decrease influenza transmission. In these situations, restrictions could encroach on the important values of necessity and proportionality. Furthermore, it is important to remember that the effects of restrictive policies will be borne most heavily by those with the fewest resources, thus inappropriate social distancing actions have distributive justice implications. Lastly, there is the concern that governments might use social distancing in a discriminatory fashion, targeting ethnic or religious minorities, or as a pretext to crack down on dissidents who assemble to protest.

Ideally, questions of government authority and accountability will be answered by policy decisions made before a pandemic emerges and taken as part of an open and transparent process that encourages input from all sectors of society. Governments should define explicitly who has the power to order social distancing strategies, and for what period of time. Governments should also state clearly the criteria under which such power is to be exercised and delineate the legitimate bases for any differential treatment. Penalties should be proportional to offences and not based on irrational fears or discriminatory beliefs.

However, detailed preparations for pandemic influenza are not necessarily of high priority in many countries that are dealing with important

and immediate public health concerns. Furthermore, some countries lack the legal and governmental infrastructures to implement the ideal procedures outlined above. In such countries, a full determination of issues of government authority and accountability prior to a pandemic may be extremely difficult. In addition, pandemics are difficult to predict, and information acquired as a pandemic evolves may render obsolete some present beliefs on various social distancing strategies.

Governments should elaborate their preparedness plans in a transparent manner involving as broad a cross-section of society as possible before an influenza pandemic occurs, and in the event of a pandemic should implement social distancing policies in a fair and non-discriminatory manner. This will not only take into account important ethical considerations, but also improve the likelihood that the public will accept social distancing as a means to slow disease transmission. Given that compliance with social distancing instructions will be difficult to enforce, public acceptance is critical to the success of the measures.

6.2 School and workplace closure

Closure of school and workplaces presents difficult ethical issues. The effectiveness of this move is uncertain, and it raises important questions of distributive justice. Workplaces represent the livelihoods of both employees and employers, so closure can cause severe financial hardships. In addition, lost profits due to closures may cause companies to go out of business, leading to job losses and other economic hardships. These problems may have a significant effect even on those people who possess a "safety net", but for people living at a subsistence level, the effect of lost income is far worse. If closures remain in place for a significant duration, such people may be unable to pay for shelter, food, or medicine. Thus, because of the adverse consequences of implementation, criteria should be defined for reducing closures as soon as feasible to a level that allows their sustainability over long time periods if needed.

Ideally, public health authorities should work in cooperation with industry and trade unions, prior to an emergency, to establish mutually-agreeable work closure procedures. However, a situation may arise where workplace closures are recommend-

ed or required, but a business chooses to remain open. In this instance, employment protections are needed for workers who wish to comply with a social distancing order against the wishes of their employer. Conversely, businesses may close in compliance with instructions, but workers' needs for income cause them to seek other work. Governments need mechanisms to encourage compliance with a social distancing order and although they should retain the legal power to enforce closures if absolutely necessary, it is preferable that they subsidize lost profits and incomes as necessary.

Practical constraints, such as more pressing priorities, may prevent some countries from enacting this solution. Furthermore, some countries may be unable to provide compensation for workplace closure. In 1918, each wave of the influenza pandemic lasted for several months in a given country, and most locations were hit by several waves. In some of the twentieth century epidemics, mortality was higher in subsequent waves (37). The resources needed to compensate for lost income or profits for this amount of time may well be out of the reach of many of the world's governments.

In light of these constraints, governments should attempt to weigh carefully the risks to health and welfare from workplace closures and other social distancing measures against those risks that might be prevented by the effects of closure on disease transmission. For each country, the balance of risks may be resolved differently, depending on resources and the number of people living at or below subsistence level. Countries should consider tactical closures if necessary; perhaps only those entities that most facilitate transmission should be closed.

Schools have been identified as a primary driver of seasonal influenza transmission (35, 71) and are also believed to be a substantial factor during pandemics. Studies of the effect of school closures during the 1918 pandemic are in progress; initial observations indicate that very early closure (when few children are infected) is necessary to substantially mitigate transmission within the community. However, school closure may encourage students to congregate in other places where transmission might occur; thus protective sequestration of such students would be necessary. This would present additional burdens for children, parents and governments. In addition, the adverse consequences

of prolonged school closures on students, teachers, and families have led to substantial debate regarding the sustainability of this intervention.

Closures of workplaces and public places could eventually be lifted after the level of disease in a community has exceeded a predetermined level (threshold, peak) if reopening would not be expected to lead to another outbreak in the community.

6.3 Provision of necessities

If people are instructed to avoid crowded public places or if those places are required to close, there will be a need for people to procure food, medicine, and other necessities. Similarly, controls placed on the movement of people and goods may limit access to facilities that remain open, including access to medical care. There is a distributive justice concern relevant to all of these issues: those with the least resources should at least be provided with additional resources before closures occur and have access to (public or private) means of transportation to allow access to medical care in case of emergency. Assuring access to emergency care will encourage patients to comply with procedures for home treatment of mildly-ill individuals.

Ideally, governments should set up networks for the distribution of necessary provisions to citizens' homes. Distribution should be conducted in a manner that takes into account the ease of access to provisions in particular communities. It should be consistent and reliable, and should provide necessities such as food and medicine for the duration of social-distancing measures. It should also be conducted in such a manner as to minimize interactions between healthy and potentially infectious people. Those people responsible for distributing provisions should use infection control precautions to decrease the likelihood that they will spread dis-

ease. Transportation for medical care should be provided as needed by personnel who understand the risks involved in transporting potentially infectious people and who are provided with appropriate PPE to protect themselves and to prevent them acting as disease vectors. Similarly, a programme should be put in place for the removal of the deceased from homes in a safe and efficient manner.

Resource constraints and logistic difficulties are likely to impede such a programme in many areas. Many governments may lack the resources to provide food, medicine, and other necessities to their citizens during a pandemic, and even if the resources are available, the workforce needed to conduct distribution may be absent, especially at the height of a pandemic when a substantial number of people are ill. Furthermore, there may be an insufficient number of people who are prepared to interact closely with potentially infectious people to allow such a system to function. This may be especially true for medical transport and mortuary services.

As a minimum, governments should try to facilitate the provision of resources to areas before they are affected by disease. To the extent possible, governments should give advance warning of disease and make recommendations about what food, medicine, and other supplies should be stockpiled and in what quantities. If they are able, governments should provide these for people unable to afford the necessities. Governments should provide access to medical care to the greatest extent possible, perhaps by giving qualified personnel direct care-giving responsibilities even if those professionals do not normally provide direct patient care. Governments should also provide a means by which people who have recovered from influenza, and thus are presumably immune, could volunteer to assist others in the provision of necessities.

7

International travel and border controls

Transnational public health law is increasingly important in global health, as evidenced by the IHR and communicable disease regulations proposed by national agencies (72). These legal initiatives reflect WHO's recommendations for border controls (73, 74). Transnational containment measures can be far-reaching: entry or exit screening; reporting; health alert notices; collection and dissemination of passenger information; travel advisories or restrictions; and physical examination or management of sick or exposed individuals. These kinds of powers were exercised in Asia and North America during the SARS outbreaks, although their effectiveness is not established (75, 76). The IHR (42, 72) also authorize sanitary measures at frontiers or on conveyances, i.e. inspection, fumigation, disinfection, pest extermination, and destruction of infected or contaminated animals or goods.

7.1 Economic impact of international travel and border controls

Nations seek to safeguard their citizens' health from external threats, even in a global world where people, animals, and goods rapidly diffuse across national boundaries. Although border protection is legitimate, it can severely disrupt travel, trade, and tourism. The World Trade Organization (WTO) defends free commerce, but permits science-based trade restrictions to protect the public health (77). This protection needs to be balanced against the global economic impact of any trade or travel restrictions or border control policies. Closure of borders, as has been discussed in Australia, New Zealand, and the United States of America, will have an enormous global economic impact. World travel and tourism account for about 10% of global gross domestic product and 8% of global jobs, generating more than US\$ 4 trillion in economic activity and over 200 million jobs in 2005 (78). During the

SARS outbreaks, tourist arrivals in Asia dropped by 30–80% for various countries in the region. After travel bans were put in place, almost half the planned international flights to south-east Asia were cancelled. Even Australia, which was largely unaffected by the disease, saw a 20% decline in international arrivals due to fears of becoming infected during travel. Thus even if countries do not officially close their borders during an influenza pandemic (such as planned by Canada), voluntary social distancing will certainly disrupt trade, transport and travel (78).

Given the sensitivity of economic disruptions of trade and travel during a pandemic, international coordination of border control policies to avoid misunderstanding and promote cooperation will be essential. Although the economic impact will be considerable for both developed and developing countries, the long-term consequences will be harder for the latter to overcome. Industrialized countries should be aware of this when making decisions with transnational impact. Governments should only take those measures that are necessary to address the actual risk to the community. Travel and border control measures should be implemented in a non-discriminatory fashion, and only when the harms caused by the intervention are proportionate to the benefits.

7.2 Governmental transparency and coordination

Before and during a pandemic, WHO will issue transparent and clearly justified travel recommendations in accordance with IHR (2005), which countries will be expected to follow. For their part, individual countries should communicate all relevant information on the emergence of a public health threat to the international community. This responsibility is related to the surveillance duties and the issues that

accompany them. Ultimately, it is the responsibility of the national governments to use whatever policy instruments they have available to ensure that they can comply with the requirements of IHR (2005). Reporting and surveillance responsibilities may be beyond the capacity of developing countries (see section 4). The industrialized countries should show solidarity and be transparent in the way they carry out health protection responsibilities.

Fear of infection and uncertainty about the risk and virulence of the virus can have a negative impact on the global economy. Reactive and uncoordinated national actions to close borders or embargo trade could give the wrong message in the early days of a pandemic and inadvertently fuel fears at the point of the pandemic's emergence. Public fears and economic reactions in the early stages of the SARS epidemic were amplified by concerns that some governments were withholding information about the disease. To avoid unwarranted travel disruptions and economic burdens, governments have the responsibility to honestly

disclose credible scientific information as early as possible.

7.3 Civil liberties

The freedom of movement is a basic right protected by national laws and international treaties but it is subject to limits when necessary for public health (79, 80). International travel restrictions and border controls can infringe upon civil liberties and, in particular, these strategies can present serious risks to privacy. For example, containment measures may require the travel industry to collect and disclose passenger data (81). Privacy burdens are justified only if necessary to obtain high-quality surveillance data and in accordance with fair information practices as set out in the surveillance section (see section 4). To avoid discrimination and to ensure proportionality, public health officials should inform the affected individuals about the reasons for the infringement of privacy, the intended use of the information and the extent to which third parties will have access to the data.

8

Isolation and quarantine

The terms “quarantine,” “isolation,” and “compulsory hospitalization” are often used interchangeably, but they are in fact distinct. The modern definition of quarantine is the restriction of the activities of asymptomatic persons who have been exposed to a communicable disease, during or immediately prior to the period of communicability, to prevent disease transmission in the event that they have become infected (81, 82). In contrast, isolation is the separation, for the period of communicability, of persons known to be infected in such places and under such conditions as to prevent or limit the transmission of the infectious agent (82–85). Quarantine and isolation can be accomplished by various means, for example the individual may stay in their own home, the individual or group stay at a designated facility, or travel out of an affected area may be restricted (85). Whatever techniques are used, it is important to treat symptomatic, potentially exposed, and non-exposed populations differently. For example, it would be inappropriate to place infected individuals in the same room within a facility as those who are only potentially exposed. There is also an ethical dilemma associated with isolating a case of infection at home, since this intervention can increase the infection risk for contact persons, especially when protective modalities (e.g. masks, antiviral prophylaxis) for those residing in the same household cannot be provided.

Isolation and quarantine were used widely and effectively in Asia and Canada during the SARS outbreaks in 2003 (39). 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 and quarantine. Nonetheless, if implemented early these interventions are projected to provide real benefits in slowing down the spread of influenza.

However, if isolation of infected persons, quarantine of exposed persons, and quarantine of a geographic area (cordon sanitaire) are effective interventions, they are the most complex and legally/ethically controversial public health powers. Although the form may differ, they always represent a significant deprivation of an individual’s liberty in the name of public health. Quarantine and isolation represent the tension between the interests of society in protecting and promoting the health of its citizens and the interests of individuals in civil liberties such as privacy, non-discrimination, freedom of movement, and freedom from arbitrary detention (39). While these civil liberties are protected by both universal and regional human rights declarations and conventions, large-scale public health threats can require extraordinary measures by governments. Coercive public health powers such as quarantine and isolation can be legitimate when justified by carefully balancing the public health interests of society against the freedom of the individual (39). To pass the balancing test, the benefits to the public should outweigh the burdens or harms quarantine may place on individuals. In addition each country should comply with the Siracusa Principles (22, discussed in section 1.2).

8.1 Legal authority

Authority for isolation and quarantine should be clear and lawful, with fair procedures and criteria based on risk. A government’s jurisdiction and power should be contained within clear boundaries proscribed by law, which create accountability to the public generally and to affected communities in particular. These public health powers restrict individual autonomy and liberty. Therefore, any law authorizing their use should clarify the criteria under which a person may be quarantined. Statutory criteria should incorporate rigorous scientific meas-

ures of risk, and be structured to allow quarantine only when necessary for public health. Measures as coercive as quarantine and isolation should be used only when there is a reasonable basis for believing that they will be effective in controlling the spread of the disease (82).

Resource and time restraints in circumstances of scientific uncertainty can, however, necessitate immediate government action without prior medical testing of each individual. In addition, the availability of accurate tests and competent medical staff can be limited. At a minimum, the state's power should, however, be exercised fairly, and never as a subterfuge for discrimination. In a crisis situation, reasonable suspicion based on known contact with the H5N1 influenza virus can suffice to issue a quarantine or isolation order. However, to ensure the legitimacy of the measures taken, the decision to use restrictive measures needs to be made in an open, fair and legitimate manner. The public has a right to know the legitimate public health reasons for restricting liberty. Public health authorities should fully and honestly disclose their reasons for action and allow community participation. Transparency will enhance public trust and acceptance of the proposed containment measures (86, 87). For example, in the current pandemic alert linked to circulation of an highly pathogenic avian influenza A(H5N1) virus, reasonable suspicion based on known contact with the H5N1 virus can suffice to issue a quarantine or isolation order.

8.2 Due process (natural justice)

Due process, or natural justice, is central to the ethical application of isolation or quarantine. In addition to substantive protections, judicial procedures are necessary to ensure the legitimate use of isolation and quarantine. Fairness here is specified in terms of the process, rather than the outcome. Although it is desirable that only those that are really infected are being confined, infallibility cannot be guaranteed. The feasible goal is to try to protect public health while minimizing human rights violations and ethical concerns.

Of particular concern is the protection of groups of people (especially minority populations) from the inappropriate use of state power. Regardless of a country's judicial system and infrastructure, exercise of the power to restrict individual movement

should comply with the Siracusa Principles and the ICCPR, both of which require that such actions are not arbitrary, unreasonable or discriminatory. As such, countries should have procedural mechanisms for groups to challenge the unjustified use of the quarantine or isolation power. Furthermore, quarantine or isolation orders should only be valid for a scientifically justifiable period of time. Public health officials should publicly justify their decision and re-evaluate their order on a regular basis, thus ensuring the legitimacy of the decision-making process and the accountability of the decision-makers.

Beyond collective challenges, many judicial systems uphold the ideal that individuals have a right to their own due process. While this value is legitimate, it should be noted that individual hearings may not be feasible during a pandemic. Many countries do not possess the judicial infrastructure to cope with the sheer number of hearings that would be required by a mass quarantine. Furthermore, existing infrastructure will be strained by the morbidity and mortality associated with a highly pathogenic influenza pandemic. However, in developed countries with strong judicial infrastructures, individualized due process should be maintained to the extent feasible given the conditions imposed by the pandemic (86, 87).

8.3 Monitoring and enforcement: voluntary or least intrusive means

Quarantine and isolation should be voluntary whenever possible, and when that is impossible, should be enforced by the least intrusive means available. However, if governments expect full voluntary compliance, the decisions need to be made in an open and fair manner and society should ensure that those who are quarantined or isolated receive adequate care and do not suffer unfair economic burdens (88).

Research in the aftermath of SARS showed that people understood and accepted the need for restrictive measures. Many perceived it as their civic duty and were willing to sacrifice their right to freedom of movement (88). While Canadians generally complied voluntarily with quarantine requests, public health officials in other countries studied such as China, China Hong Kong Special Administrative Region, and Singapore had to use more coercive measures. If necessary, justified, and

within legally prescribed boundaries, public health officials should be allowed to enforce containment measures (89). The least restrictive measures should be applied first, followed by a graded application of more restrictive measures when evidence indicates their necessity (89). In Hong Kong SAR, for example, barricades and tape were used to confine infected residents in a large housing complex (90). In Singapore, three telephone calls were made per day to the home of each individual in quarantine to confirm that the individual was there (91). Surveillance cameras were placed in homes where people were quarantined and, to avoid fraud, inhabitants were required to take their temperature on camera (90, 91). Also electronic wrist- or ankle-bands were used as enforcement measures (91). Singaporeans, moreover, faced a fine of over US\$ 5000 for breaching home quarantine orders.

Acknowledging that different countries have different norms and needs, different enforcement measures must be viewed in the context of what a given society considers to be a reasonable means of ensuring compliance. At a minimum, the monitoring and enforcement measures adopted should have a reasonable and proportionate relation to the achievement of the public health objective and should be implemented in a fair, non-discriminatory, and culturally acceptable manner to ensure privacy and bodily integrity (91). In addition, enforcement mechanisms should be utilized in conjunction with appropriate civic engagement and public education.

8.4 Ensuring safe, humane implementation of isolation or quarantine

When the protection of a community's health requires that individual liberty and autonomy are restricted, the principle of reciprocity obliges society to provide those affected with support mechanisms which are capable of supplying all the necessities of life. During quarantine, this includes being housed in safe and humane conditions, receiving food and water, receiving adequate medical care and psychosocial support where needed. Recent studies have confirmed that quarantine imposes serious financial and psychological hardships on the affected individuals. About 30% of quarantined individuals have been found to suffer from posttraumatic stress disorder and depression (92). Quarantine needs to be implemented in a humane, sensitive manner. The IHR (2005) provisions on care and treatment of persons detained for health reasons include references to the need for sensitivity on gender, religious, and ethnic issues.

Distributive justice requires that officials limit the extent to which the personal and economic burdens of a public health threat fall unfairly upon individual citizens. A lack of resources and amenities should be addressed in the most fair and equitable possible way. Governments as well as national and international organizations should stockpile medical supplies and food. An influenza pandemic will require a vision of solidarity among nations and asks for collaborative approaches that set aside traditional values of self-interest and territoriality (see chapter IV).

9

Complementary veterinary measures for reducing human exposure to the H5N1 influenza virus

Close proximity between animals and humans poses serious risks of human infection with an avian influenza virus able to cross species barriers from birds to humans. Repeated human infections with such a virus could foster emergence of a novel influenza virus subtype of pandemic potential (93). Consequently, a critical early preventive strategy is to limit animal/human interchange of any influenza virus able to cross this species barrier to infect humans. Domestic birds, fighting cocks and migratory birds, and poultry workers and equipment are vectors for spreading avian influenza viruses among birds/flocks (94). Some avian influenza viruses are also able to infect mammals other than humans (e.g. H5N1 in tigers (95), leopards (96), pigs (96), domestic cats (97) and stone martens (98)). Strategies to diminish the risk of exposure include separation of animal and human populations; health and safety in animal farming; management of diseased or exposed animals; veterinarian surveillance; and sometimes vaccination of flocks.

9.1 Avoiding proximity

Safe farming practices and the separation of animals and humans are critically important from a public health and economic perspective. The separation is hard to accomplish however given a culture of close contact between animals and humans in most countries. The domestication of poultry is often necessary for family survival (99). In many African and Asian countries, backyard chickens are kept not only for food but also as pets (99). In Hong Kong SAR, thousands of residents are avid birdwatchers and Kowloon's famed Bird Garden is one of the world's largest marketplaces for exotic birds of all kinds (100). In Paris (France), Venice (Italy) and London (United Kingdom), thousands of pigeons attract many tourists to the market squares. With regard to mammals, the recent dis-

covery of the H5N1 virus in domestic cats caused many families to lock their pets inside.

Thus given cultural norms, an animal/human separation policy in which animal species are segregated within the same farm and raising of domestic poultry in biosecure settings can cause both economic hardship and social unrest. In Thailand and the Philippines, for example, cockfighting is both a source of income and a national pastime. While fighting cocks are both victims and culprits in the bird influenza epidemic, citizens are reluctant to sacrifice their cultural traditions for a potential public health threat. Governments and health-care officials should publicize clear rationales for such separation orders and should initiate and facilitate constructive public discussion about measures that can be taken to suppress the transmission of the virus.

9.2 Due process and compensation for culling decisions

Given that disease containment strategies can have a profound impact on the lives of individuals, it is ethically imperative that governments carefully construct their animal control policies. While mass slaughter of diseased and exposed animals seems to be the most logical way to achieve eradication of H5N1, it raises significant ethical concerns. A massive culling of birds can have a devastating economic toll on the poultry industries of affected nations and the livelihoods of all classes of poultry owners, producers and their employees. There are approximately 6 billion chickens and 850 million ducks in the south-east Asia region, which accounts for about one-quarter of the world's poultry trade. Two countries currently affected by avian influenza outbreaks, China and Thailand, account for 15% of the global poultry trade. Economic studies further indicate that those hardest hit by culling of flocks

are individual farmers for whom poultry production is their sole source of income generation (96).

Culling has already played an important role in combating the current avian influenza threat. In order for culling decisions to be justified, the public benefit should outweigh the personal burdens placed on individuals and families and appropriate compensation should be provided to affected persons. Judicial procedures are necessary to ensure that a fair balance is struck between the interests of society and of the affected individuals. Governments should incorporate due process into their culling procedures by creating an a-priori procedure for fair reviews of a decision to cull. Affected individuals should receive some notice of the proposed containment measure and be permitted to consult a legal counsel. Furthermore, there is a need to consider implementing proper compensation to farmers, assistance with re-establishment of flocks, and help in transition to biosecure farming practices.

The extent to which procedures can be implemented depends, however, on the urgency of the emergency and the availability of resources. Public health officials might have to mitigate the ideal procedural standards given the circumstances. Therefore, at the very least, to ensure non-discrimination and proportionality, public health officials need to publicly justify their decision and the criteria applicable to the proposed measures. Moreover, the process by which decisions are made should be open to scrutiny and the basis upon which decisions are made should be publicly accessible. Transparency and community participation in the decision-making process will enhance trust and acceptance. *Post hoc* review measures should be put in place to ensure that decision-makers are accountable for their actions.

The economic impact of culling decisions, especially on small farmers, is significant. So far, the virus has already led to the deaths of about 200 million birds (around US\$ 20 billion worth of consequences for the countries affected), and to the impoverishment of millions of small farmers whose livelihoods depend on poultry. Consequently, the principles of distributive justice and reciprocity require adequate compensation as an ethical imperative (93). This could include provision of alternate sources of food if culling involves depleting a family's source

of nourishment. A recommendation of this nature will be vacant, however, without financial aid from developed countries.

In light of the economic consequences, when poultry export industries and the livelihood of farmers are at stake, it is uncertain that affected countries and individuals will be sincere about reporting the extent to which their flocks are infected (101). Adequate compensation and open communication will, however, increase the incentive to report outbreaks. In addition, education programmes could be directed to decreasing the stigma and social hostility towards the infected people and countries, as well as to promote changes that diminish risky behaviours and practices that foster bird-to-bird and bird-to-human transmission of virus. International cooperation and coordination will be essential.

9.3 Mitigating the economic impact of trade restrictions

Avian influenza causes severe financial and trade impacts; industry profitability, employment, household livelihoods, and, potentially, food security, are being adversely affected by recent H5N1 outbreaks in many countries around the globe. Hundreds of millions of domesticated fowl have been culled or have died of infection, devastating domestic poultry production (102). The overall impact of the current strain of avian influenza hurts all livestock sectors by increasing price volatility and generating uncertainties in markets. The short-term costs to economies are considerable; the long-term implications for trading patterns, policy formulation, investments and overall industry developments will be substantial (103).

The detection of the avian influenza virus threatens not only to transform the eating habits of the population, but also to sharply curtail the export market. Countries and regions have introduced large-scale import controls and bans. When considering a trade restriction, ethical considerations should balance the risk to public health against the harm that will be done by the restriction.

Both international and national agencies, including WHO and WTO, have supported and adopted the position that trade bans should be based on science and established rules. Nuisance bans on poultry imports because of small, localized outbreaks

of the H5N1 virus in exporting countries should be avoided. In May 2005, the OIE advised to “allow trade to occur from certain zones (geographical areas) or from compartments (a group of farms, an enterprise, or another managed unit) within a country even though avian influenza may be present in a completely separate zone or compartment in that

country”(103). To that end, the regionalization of bans should be promoted. Timely dissemination of all relevant information about influenza outbreaks, interactions among animal and human health authorities, and rapid containment and eradication of the virus where it has emerged are necessary conditions for regional bans to be effective.

10

Conclusion

Preparing for an influenza pandemic forces society to face a number of difficult issues, many of which transcend mere scientific effectiveness; public health emergencies raise serious ethical issues that are central to society's commitment to freedom and social justice. Even when effective, public health interventions can have deep adverse consequences for economic and civil liberties. It is vital that individual rights are only sacrificed when necessary to protect public health. As such, laws must clearly establish the criteria under which government can

exercise emergency powers. These laws must also provide adequate due process and ensure that any infringements of individual rights are minimized.

The threat of an influenza pandemic is real. If the threat manifests, millions of lives will be lost. This is a catastrophe in itself, but the tragedy will be even worse if society ignores the ethical concerns. An immediate political and social response to these ethical concerns is crucial, so that in the event of a pandemic, we are equipped – scientifically and ethically – to deal with its impact.

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ANNEX

Members of Working Group Two

Julienne SN Anoko

Université Rene Descartes Paris V, La Sorbonne, Paris, France/Luanda, Angola.

Benjamin Berkman

Center for Law and the Public's Health, Georgetown University Law Center, Washington, DC, USA.

Lawrence Gostin (Chair)

Georgetown University Law Center, Washington, DC, USA.

Manoj Kurian

Health and Healing Mission Team, World Council of Churches, 1211 Geneva 2, Switzerland.

Michael Selgelid

Centre for Applied Philosophy and Public Ethics and Menzies Centre for Health Policy, The Australian National University, Canberra, Australia.

WHO

Alice Croisier

Global Influenza Programme, Department of Epidemic and Pandemic Alert and Response, World Health Organization, Geneva, Switzerland.

Jane Natalie Drew

NMH/MSD/MHP. World Health Organization, Geneva, Switzerland.

Kathleen Sarah Galbraith

Department of Epidemic and Pandemic Alert and Response, World Health Organization, Geneva, Switzerland.

Gregory Anton Hartl

Communications Adviser, World Health Organization, Geneva, Switzerland.

Asako Hattori

Department of Ethics, Trade, Human Rights and Health Law, World Health Organization, Geneva, Switzerland.

Frederick Hayden

Global Influenza Programme, Department of Epidemic and Pandemic Alert and Response, World Health Organization, Geneva, Switzerland.

Asiya IA Odugleh-Kolev

Communicable Diseases Cluster, World Health Organization, Geneva, Switzerland.

Kidong Park

Global Influenza Programme, Department of Epidemic and Pandemic Alert and Response, World Health Organization, Geneva, Switzerland.

Geneviève Pinet

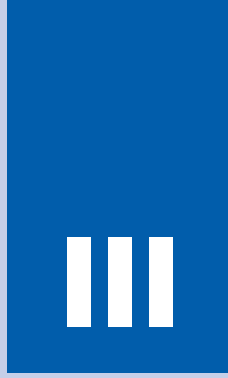
Department of Ethics, Trade, Human Rights and Health Law, World Health Organization, Geneva, Switzerland.

Christoph Steffen

Global Influenza Programme, Department of Epidemic and Pandemic Alert and Response, World Health Organization, Geneva, Switzerland.

Dick Thompson

Communications Officer, Communicable Diseases Cluster, World Health Organization, Geneva, Switzerland.



The role and obligations of health-care workers during an outbreak of pandemic influenza

Ross Upshur, University of Toronto Joint Centre for Bioethics

ON BEHALF OF WORKING GROUP THREE

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Introduction

Neither were the physicians at first of any service, ignorant as they were of the proper way to treat it, but they died themselves the most thickly, as they visited the sick most often; nor did any human art succeed any better. Supplications in the temples, divinations, and so forth were found equally futile, till the overwhelming nature of the disaster at last put a stop to them altogether.

Thucydides, History of the Peloponnesian War

So the plague defied all medicines; the very physicians were seized with it...men went about prescribing to others and telling them what to do...and they dropped down dead, destroyed by that very enemy they directed others to oppose. This was the case of several of the most skilful surgeons.

Defoe, Plague Diaries

Since ancient times, communicable diseases have posed threats to those providing care for the afflicted. In modern times, such as in recent severe acute respiratory syndrome (SARS) and Ebola outbreaks, front-line health-care workers (HCWs) in both the developed world and developing world were at increased risk of serious morbidity and mortality from infection acquired while providing care. This risk holds for both professional and non-professional HCWs.

An influenza pandemic, even a “mild” one like the 1968 pandemic, will place increased demands on communities and health systems globally. As the precise nature of a future pandemic cannot be predicted, it is prudent for planners to prepare a response that entails mobilization of the entire health-care system with significant involvement of the community sector. The voluntary participation of groups in the community sector is essential to any rational response to a pandemic. Thus it is important that pandemic planners identify and

engage with these groups as part of the planning process so that roles and expectations are made explicit and decisions about the employment of human resources are transparent.

In addition, response to a pandemic will call upon a wide range of caregivers from both the formal and informal health-care system, and involve clinical and non-clinical HCWs, professional and non-professional staff. Thus a challenge facing all pandemic planners is to identify and engage those sectors of the community that will be first responders to a pandemic and ensure their participation in a pandemic plan. The ethical basis and values sustaining this engagement have been outlined in a report (1).

Governments have an obligation to ensure the safety and health of populations living within their territory, regardless of ethnicity, nationality, religion, income, or registration in a social service system (see chapter II). This means that governments are obliged to provide a response to a pandemic threat. They also have an obligation to ensure the ability of HCWs to provide care in a manner that protects their health as much as possible. The recognition of mutual vulnerability and of reciprocal obligations is integral to understanding the ethical challenges posed by pandemic influenza.

Human resources are the foundation to an effective pandemic response. Yet, pandemic planning is evolving in the midst of a global crisis in human resources in health care. As a recent editorial in the *Lancet* (2) noted:

Years of underinvestment in health, coupled with enforced economic reforms that restricted investment in public health services and education, have left many countries with critical shortages of health workers. The attractions of international migration, and concentration of the remaining professionals in urban areas, means, according to the *World Health*

Report, that many national health systems are weak, inequitable, unresponsive, and unsafe. This situation is made worse by changing epidemiological threats and the fact that the skills of available professionals are often not well matched to the local population's health needs.

In the modern context, health care is delivered by a set of diversely constituted and funded heterogeneous systems with huge disparities in terms of both human and technological resources. Given the immense diversity and complexity of health services in the many WHO Member States, it is difficult to give specific guidance on human resource planning for a pandemic situation which is relevant in all necessary details and in all contexts. The call for engagement by the World Medical Association (WMA) in their Resolution on Avian Influenza adopted by the WMA General Assembly, held in Santiago, Chile, in 2005,¹ is necessary and commendable. However, it is essential that engagement is framed around issues of importance.

This document was prepared by a Working Group (see Annex) as background information for

a WHO consultation (3) on "Ethical issues in pandemic influenza planning" held in Geneva, Switzerland, on 24–25 October 2006. The purpose of the document is to outline the salient ethical issues regarding the role and obligations of HCWs to provide care during an influenza pandemic. It comprises five sections. The first section outlines the ethical issues related to HCWs' obligations to provide care during a pandemic. The second section examines professional codes of ethics and summarizes recent key papers in the ethics literature relevant to pandemic planning. The third section examines the obligations of society to HCWs. The fourth section briefly highlights some recent empirical studies relevant to pandemic planning. The fifth section is a summary including suggestions which were proposed for discussion during the WHO global consultation.

In the document hereafter health-care professionals (HCPs) are distinguished from health-care workers (HCWs) who may include professional and non-professional care deliverers involved in a pandemic response.

¹ The World Medical Association has recognized the potential global morbidity and mortality as a result of the H5N1 strain of avian influenza (WMA General Assembly, Santiago 2005). The WMA has committed to work with member National Medical Associations (NMAs), the WHO and other stakeholders to track the progress of the disease and propose the necessary measures to minimize its impact on the global human population. The WMA has also urged governments to engage with NMAs to prepare for the possibility of a pandemic.

1

Ethical issues involved in HCWs' obligation to provide care in a pandemic

HCWs and others will be an integral part of any pandemic response. SARS was primarily an outbreak in health-care institutions and actually quite limited in scope; patients became infectious after onset of symptoms resulting in much more limited transmission at community level than in health-care settings where infection control procedures were inadequate. In contrast, influenza infection, with its efficient person-to-person spread, short incubation period, and undefined period of contagiousness before disease onset, results in high rates of illness during a pandemic. Subsequently, depending on the characteristics of the illness, there are high demands for health care and possibly high mortality rates. The exposure of HCWs to the pandemic influenza virus will occur in both occupational and community settings and HCWs are likely to face additional risks to their own health in responding to an influenza pandemic. The level of acceptable risk that HCWs should countenance in the conduct of their duties, especially in care delivery to infectious patients or in disaster situations, is perceived differently depending on the society and the circumstances.

The historical record of HCWs in response to communicable diseases has been uneven. Emmanuel (4), writing in the aftermath of SARS, made the following observations:

The history of physicians' responses to ... contagions is mixed. Galen is reported to have fled from Rome during a plague in 166. Although in the 14th century some physicians stayed and cared for the sick, most responded to the Black Death by fleeing. Defoe indicates in *A Journal of the Plague Years* – a novelistic chronicle about London's great plague of 1665 – that most physicians were called "deserters". In the mid-19th century, nascent professional organizations began to articulate the physician's ethical obligation to care for the sick during epidemics. The SARS epi-

demical tested the dedication of a medical profession that might have been weakened by increasing commercialization, poor morale, an emerging preference for easier professional lifestyles, and the pervasive self-centred individualism of the larger society.

HCWs have responded with admirable courage and self sacrifice in response to communicable diseases such as SARS and Ebola. One might ask, therefore, whether an ethical problem truly exists. There is little doubt that the vast majority of HCWs performed their jobs effectively under considerable stress and sometimes at significant personal risk. Many HCWs provided exemplary care, and still others behaved in truly heroic fashion, scores of nurses, doctors, respiratory technicians, other professional and non-professional health workers laboured extremely long hours at personal risk. This demonstration of HCWs going above and beyond the call of duty, which proved necessary to control the disease, was morally commendable. It can be expected, although not guaranteed, that a similar response would be evident globally in the case of an influenza pandemic.

At the same time, however, serious concerns did surface during SARS outbreaks about the extent to which HCWs would tolerate risks of infection to themselves (5). Some balked at providing care to those infected with an unknown virus. In some circumstances, staffing became an issue in SARS wards and assessment centres; indeed, failure to report for duty during the outbreak resulted in the permanent dismissal of some hospital staff. As a consequence, the risk that was faced during the SARS epidemic was not distributed equitably, and those HCWs who volunteered to provide care faced the greatest exposure (6). Similarly, in Ebola outbreaks, there are reports of doctors and nurses fleeing their posts for fear of contracting the disease or because of pressure from family members (7).

Following such outbreaks, many HCWs who cared for patients with serious communicable diseases raised concerns about the protections that were provided to safeguard their own health and that of their family members. Conflicting obligations were another significant concern. HCWs are bound by an ethic of care and therefore obligations to the patient's well-being should be primary. At the same time, however, HCWs have competing obligations to their families and friends, whom they fear infecting, in addition to obligations to themselves and to their own health (particularly those with special vulnerabilities, such as a co-morbid condition). HCWs have faced stigmatization and serious threats to their families as a consequence of providing care (7, 8). During outbreaks some HCWs questioned their choice of career and subsequently some decided to leave their profession and pursue new ventures, indicating an unwilling-

ness or inability to care for patients in the face of risk. Recent survey data from the United States of America indicate that mixed views exist concerning the duty to care for patients during infectious disease outbreaks (9).

Concerns about the duty to care for persons with infectious diseases were salient in the early response to HIV/AIDS. At that time professional opinions in both nursing and medicine were firm in reiterating the obligation of HCWs to provide care to those with HIV/AIDS (10, 11). This may be the standard that should be set for an influenza pandemic.

It is clear that the issue of duty to care has emerged as a matter of paramount concern among HCWs, hospital administrators, policy-makers, and bioethicists (5, 12, 13). Hence it is essential for planners to have clear recommendations for the HCWs responding to a pandemic.

2

Guidance provided by professional codes of ethics and ethical theory regarding obligations to care

Traditional sources of guidance to HCWs come from codes of professional ethics. Additional guidance comes from the literature in ethics.

2.1 Codes of ethics

In the past, some codes of ethics, such as those of the American Medical Association (AMA) had quite explicit guidance for physicians, in particular regarding their duties and obligations during an infectious disease outbreak. For example, for over 100 years the following provision was found in the AMA code of ethics (as cited by 14):

...when pestilence prevails, it is their (physicians') duty to face the danger, and to continue their labours for the alleviation of suffering, even at the jeopardy of their own lives.

This provision was deleted from the AMA code of ethics in the 1950s and it is questionable whether such stringent requirements would be endorsed as an expectation by current professional associations. It is of interest, that a revision of the Canadian Medical Association Code of Ethics in 2004, subsequent to the SARS outbreak, was silent on the issue. Most codes of ethics provide general proscriptions forbidding discrimination, but do not address the level of risk that HCWs should take in the delivery of care.

A review of published codes of ethics found that professional codes employed variable wording regarding duty to care. Few codes contained direct language addressing an infectious disease emergency. At the time of writing, 61 professional codes have been reviewed. Of these 29 codes had no mention of duty to care, 23 had broad statements (such as the WMA International Code of Medical Ethics: "A physician shall give emergency care as a humanitarian duty unless he is assured that others are willing and able to give such care." (15)), eight had what could be construed as specific directions

to members.¹ A good example of this would be the AMA policy document "*Physician obligation in disaster preparedness and response*" (16) adopted in June 2004:

National, regional, and local responses to epidemics, terrorist attacks, and other disasters require extensive involvement of physicians. Because of their commitment to care for the sick and injured, individual physicians have an obligation to provide urgent medical care during disasters. This ethical obligation holds even in the face of greater than usual risks to their own safety, health or life. The physician workforce, however, is not an unlimited resource; therefore, when participating in disaster responses, physicians should balance immediate benefits to individual patients with ability to care for patients in the future.

It is important to note that the AMA's provisions leave it to the discretion of the HCP to assess the level of risk to be taken.

2.2 Recent ethics literature

Clark (12) has recently argued that the duty to care for those with infectious diseases is a primary ethical obligation for HCWs for a number of reasons, including:

1. The ability of physicians and HCWs to provide care is greater than that of the public, thus increasing their obligation.
2. By freely choosing a profession devoted to care for the ill, they assume risks.
3. The profession has a social contract that calls on members to be available in times of emergency.

The first criterion is likely to be universal. In most contexts HCWs do have special training that puts

¹ Limitations of this analysis are that it was restricted to the English language and those codes found via the search strategy described. The search is ongoing with the assistance of the Bioethics Library Services at the Kennedy Centre for Bioethics.

them in a better position to provide care and aid the sick and suffering and this increases their obligation to provide care. However, it might not hold true for HCWs without specialized training, informal care providers, volunteers and other members of the community, but this does not mean that they are under no obligation.

The second criterion may be true in principle, but in fact most HCWs, particularly in the developed world, have little awareness of their increased risk of contracting a communicable disease. Reviews of the literature indicate that in non-pandemic times HCWs are at significant risk of occupationally-acquired infectious diseases. Sepkowitz (17, 18), in a two-part review of occupationally-acquired infections in HCWs concluded that this risk is an unavoidable part of daily patient care and is associated with substantial illness and occasional death.

A review (19) from the perspective of the developing world found that rates of communicable disease transmission were high in health-care contexts; appropriate infection control measures, particularly personal protective devices, were generally unavailable; and education levels were low. The authors concluded:

Along with international agencies, national budgets should provide resources to ensure the safety of medical personnel. The expenditures should not be viewed as an increase in the cost of health care in developing nations, but rather as insurance to protect each nation's investment in its health care work force. The inevitable consequence of continued inattention will be a mounting toll of disease and death among productive health care workers in places where their loss can least be afforded.

As for the first criterion, the second imposes no additional obligations on non-professional and voluntary responders to a pandemic.

The third criterion is of value in those settings where a social contract between professions and governments can be argued to exist, which is not the case globally, particularly in systems with large privately-funded components.

Reid (13), in the aftermath of SARS, argued that:

Duty to care is not based upon particular virtues of the health professions, but arises from social reflection on what response to an epidemic would be consistent with our values and our needs, recognizing our shared vulnerability to disease and death. Such reflection underwrites a strong duty of care, but one not to be borne solely by the altruism and heroism of individual healthcare workers.

Reid's reflection captures the fact that a pandemic response will entail both professional and non-professional HCWs. While non-professional HCWs do not have obligations rooted, however opaquely, in codes of ethics and historical practices, they may have relevant contractual obligations. The important role that they play in the response to a pandemic must be emphasized (20). Furthermore, it is essential that HCWs acknowledge and accept the possible risks of occupationally-acquired disease. Reid's emphasis on social reflection on the response that would be consistent with the values and needs of communities is an important reminder of the communicative nature of pandemic planning.

2.3 Scope of work obligations

A pandemic will result in a surge in demand for HCW services. It can be expected that there will be absence due to illness among HCWs and probably also their family members. Concerns have been raised that HCWs will be assigned to tasks for which they lack adequate training. In times of emergency, governments and health-care organizations may invoke the need for such reassignments. It is recommended that such possibilities be raised and discussed during pandemic planning so that all participants are aware of the possible range of duties that may be expected of HCWs and that all liability issues are discussed.¹

¹ See for example the human resource strategy in the Toronto Academic Health Sciences Network <http://portal.sw.ca/tahsn/default.aspx>

3

Societal responsibility and reciprocity

The moral duty to behave responsibly and not knowingly put other people at risk is not a duty that is confined to HIV infection or to other life-threatening diseases; it is a duty of all people with communicable diseases. It is, however, also a duty which we can expect people to discharge only if they live in a community that does not leave them with all the burdens involved in discharging this duty (21).

While much of the discussion post-SARS has been about the duties of HCWs, there are other important ethical issues that need to be addressed, including *reciprocity* and *solidarity*. If workers are to take high risks, there is a duty upon society, in particular on their institutions, to support them. This is an important aspect of the principle of reciprocity. Pandemic planners must help workers cope with the high stress of a pandemic, and acknowledge that their work is dangerous. For example, they need to provide for the health and safety of workers, and for the care of those who fall ill on duty. There is also a need for fair and workable human resource plans for emergency situations. These will entail clear workplans and specific detailed instructions on roles and obligations. Limitations imposed during SARS outbreaks resulted in a loss of work for some HCWs. The imposition of employment restrictions should not result in financial hardship or job loss and should not unduly affect part-time staff.

In addition to moral obligations, in many countries there is a legal obligation to ensure a safe workplace, including in the health-care system. While absolute safety of health-care institutions cannot be assured in a pandemic, the rights of workers must be respected.

Health systems vary around the world in the amount of support that they can give to HCWs charged with the responsibility of providing care in

a pandemic. It is an unfortunate fact that immense disparities exist in health-care systems globally; many are unable to provide protective equipment required in the management of infected patients; sometimes they do not provide soap and essential disinfectant. In the event of an influenza pandemic, it is highly unlikely that sufficient vaccines (if available and effective) or antiviral medication will be available in all health-care systems.

As Sepkowitz (17, 18) and Sagoe-Moses et al. (19) note, many infections can be prevented by appropriate use of hygienic techniques. Pandemic planners have an obligation to ensure that all pandemic responders are provided with education and training on appropriate hygiene. To the greatest extent possible, personal protective equipment and other infection control modalities should be provided to HCWs. Although high technology responses such as vaccines and antivirals may not be available, hand hygiene agents and education should be provided globally. Although there is no direct evidence of their value in an influenza pandemic, the evidence does suggest that, if used correctly, there is likely to be a protective effect in other viral respiratory outbreaks. The risk to caregivers is not only physical, but also psychological and psychosocial support is an important consideration in pandemic planning.

3.1 The role of community and voluntary organizations

A wide range of community-based organizations such as civil society organizations,¹ nongovernmental organizations (NGOs), faith-based organizations etc. are likely to be involved in pandemic planning. In many contexts, medically-oriented organizations

¹ Voluntary civic and social organizations and institutions as opposed to governmental and commercial institutions.

are already either integrated in primary health-care delivery or providing parallel input in coordination with the governmental public health system. Although not necessarily designated as HCWs, members of such organizations can play important roles in a pandemic response, and may be exposed to increased risk in the course of providing care. Pandemic planners are advised to ensure the participation of community-based organizations in planning efforts as this will enhance the legitimacy of such efforts in communities.

3.2 The role of sanctions

Governments and public health agencies are charged with the obligation to protect populations from infectious disease threats. As such, through a variety of means, they are also empowered to consider the use of sanctions in order to ensure a response from HCWs.¹ This is considered highly undesirable. Instead, it is recommended that voluntary measures are employed to ensure the participation of HCWs in the pandemic response.

¹ For example, two provinces in Canada have tabled legislation that has been interpreted as supporting conscription for HCWs in the event of an infectious disease emergency.

4

The attitude of HCWs and the public towards care in a pandemic – a summary of recent literature

Empirical research is of value to planners to understand some of the issues of concern that may be expressed in their jurisdiction. There is a limited but informative literature on attitudes towards care in a pandemic and this may aid in the development of strategies to increase voluntary participation.

A qualitative study (22) of general practitioners in Tasmania, Australia, found that they expressed a willingness to provide professional services in a pandemic. Their motivation for this was largely altruistic and they recognized the high personal risk of becoming infected. Participants did not have stockpiles of antivirals or personal protective equipment within their practices and felt that government had a duty of care to stockpile on behalf of the general practice workforce. Failure to provide personal protective equipment was seen to reduce the duty to care. Participants were interested about receiving further information and training in pandemic preparedness.

A survey of workers in public health agencies in Maryland, USA (20), found that nearly half of the local health workers indicated that they would not report for duty during a pandemic. Clinical staff were more likely to state they would report for duty than technical and support staff. The perception of the importance of one's role in the agency's overall response was the single most influential factor associated with willingness to report to work.

A survey of hospital employees in Germany (23) reported that 28% of respondents stated it was "professionally acceptable" to fail to report to work in order to protect themselves and their families from infection and 77% did not agree that HCWs failing to report to work should be dismissed from employment.

The College of Family Physicians of Canada survey of the public (24) indicated that an overwhelming majority of respondents (86%) said it was important at a time of serious medical emergency – such as a widespread influenza outbreak

or natural disaster – to be able to turn to their family doctor for information and advice. Almost every Canadian polled (96%) indicated the importance of family doctors having access to the information, equipment, supplies, and other support needed in the event of a public health emergency. Respondents also strongly agreed (93%) that primary-care professionals must be involved in the development of emergency plans for Canada because they are sure to be on the front-line in the event of a public health emergency.

Experience with Ebola outbreaks has indicated that knowledge of local healing practices and cultural patterns of care in the community are important for disease control. Summarizing the experience of three Ebola outbreaks, Hewlett and Hewlett (7) write:

...knowledge of local and biomedical models contributed to the eventual control of the outbreak. Local nurses and other health care workers were aware of these models and were in a position to negotiate the cultural models more readily than international teams sent to control the outbreaks.

These studies, although limited, contain important messages for pandemic planners. They illustrate the stated willingness of HCWs to serve during infectious disease emergencies. They also contain cautionary evidence that unwillingness to serve is a reality and that the perceived importance of the role that will be played by HCWs is an important predictive factor. They highlight the importance of culture in the control of communicable diseases. Pandemic planners, therefore, have an important task in ensuring that all relevant responders are aware of the essential role they must play. A crucial goal of pandemic planning is to communicate that need and engage in a transparent and inclusive planning process. Education for HCWs on best infection control practices should be included as part of the planning process.

5

Conclusions

An influenza pandemic will test health systems and communities globally. The goal of pandemic planning is to mitigate the harm such a pandemic can cause to societies. HCWs will play an essential role in the response, and one task of pandemic planning is to ensure a well-prepared cadre of pandemic responders.

An influenza pandemic will highlight the universal vulnerability of the human species to infectious disease. The response should be truly global in scope, and global planning should strive for a response based on solidarity.

HCWs have unique skills that confer a moral obligation to respond to a pandemic influenza, and their participation will be essential to an effective response. The level of risk a HCP can legitimately be asked to assume depends on both the benefits expected to result from the professional's efforts and the level of support he/she can expect to help minimize the risks. Many individuals are likely to assume their professional obligations voluntarily, but some may be unwilling to accept substantial risks to their own health, particularly if they have other obligations, such as family caregiving responsibilities. Since balancing these competing considerations is ultimately a matter of personal conscience, it is generally inappropriate to conscript professionals into service. However, some individuals may have pre-existing legal or contractual obligations to work during a pandemic, and violation of these obligations may entail reprimands or loss of employment.

Pandemic planners should therefore plan for measures guaranteeing an efficient and safe working environment by:

1. ensuring that the discharge of duties is given sufficient support throughout a period of extraordinary demands;

2. providing education and training of all HCWs on hygienic measures (such as hand hygiene) that reduce risk to HCWs and recipients of care;
3. taking steps to enhance and enable the voluntary participation of HCWs in a pandemic response;
4. assessing local circumstances;
5. ensuring the participation of formal and informal care networks in pandemic response planning including clinical and non-clinical professional and non-professional HCWs;
6. developing human resource strategies that cover the diverse occupational roles, that are transparent in how individuals are assigned to roles during a pandemic response, and that are equitable with respect to the distribution of risk among individuals and occupational categories;
7. ensuring that processes are in place to accommodate legitimate exceptions to the provision of clinical care (e.g. pregnancy, immunodeficiency, family member affected);
8. recognizing the role of gender and culture (including religion) in the provision of health care and its relevance to an effective pandemic response.

Professional associations should, by way of their codes of ethics, provide clear guidance to members in advance of an influenza pandemic and identify mechanisms, or develop means to inform members as to expectations and obligations regarding the duty to provide care during a communicable disease outbreak and during an influenza pandemic.

Governments should commit to provide all HCWs at risk (professional or non-professional), including those working in a hospital setting or at community level with:

1. technical advice and epidemiological evidence as available;
2. means for patient isolation, personal protective equipment, soap and disinfectant;
3. antivirals for early treatment of illness and pre- or post-exposure prophylaxis, if sufficient stocks are available;
4. the possibility to be vaccinated with the appropriate vaccine as soon as it is available in the country.

It is also advisable to avoid sanctions intended to increase the compliance of HCWs in delivering care during a pandemic; governments wishing to take steps to ensure a response from the health-care sector should be urged to employ voluntary measures. If a government chooses to sanction HCWs who fail to respond, sanctions should be applied within the context of the existing rules of professional associations and contract law (e.g. reprimand or loss of license, dismissal from employment) and should not contravene the human rights of the HCW or their family in any way.

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ANNEX

Members of Working Group Three

Tarif Bakdash

Damascus University School of Medicine, AMIDEAST Centre, Damascus, Syrian Arab Republic, and Case Western Reserve University, Cleveland, Ohio, USA.

Tesfamicael Ghebrehiwet

International Council of Nurses, Geneva, Switzerland.

Amy Haddad

(for the International Pharmaceutical Federation)
Creighton University Medical Center, Center for Health Policy and Ethics, Omaha, Nebraska, USA.

James Johnson

(for the World Medical Association)
British Medical Association, London, United Kingdom.

Susan Maybud

International Labour Organization, Geneva, Switzerland.

Ross Upshur (Chair)

Joint Centre for Bioethics, and Department of Family and Community Medicine, University of Toronto, Canada.

WHO

Gerry Eijkemans

WHO/Sustainable Development and Healthy Environments/Occupational and Environmental Health, World Health Organization, Geneva, Switzerland.

Annette Nkowane

Department of Evidence and Information for Policy/Human Resources for Health, World Health Organization, Geneva, Switzerland.

Alice Croisier

Global Influenza Programme, Department of Epidemic and Pandemic Alert and Response, World Health Organization, Geneva, Switzerland.

Frederick Hayden

Global Influenza Programme, Department of Epidemic and Pandemic Alert and Response, World Health Organization, Geneva, Switzerland.

Kidong Park

Global Influenza Programme, Department of Epidemic and Pandemic Alert and Response, World Health Organization, Geneva, Switzerland.

Christoph Steffen

Global Influenza Programme, Department of Epidemic and Pandemic Alert and Response, World Health Organization, Geneva, Switzerland.



IV

Pandemic influenza planning and response – transnational issues for governments

Robert Archer, International Council on Human Rights Policy

ON BEHALF OF WORKING GROUP FOUR

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Preface

This paper discusses the international and multilateral responsibilities that states have to assist and support other states, and the peoples of other states, during an influenza pandemic. It provides practical points of reference for consideration by states that may wish to request or provide international assistance or cooperation. It should be noted that agreement on international law or understanding in this area is not well-developed; the paper therefore provides preliminary guidance with regard to policy rather than formal advice.

The paper is divided into five sections. The Introduction (1) describes the paper's terms of reference and the assumptions that underlie the argument it makes. Section (2) identifies broad legal principles that are relevant, including relevant policy commitments by states, and goes on to consider

reasons why states find it difficult to apply these principles operationally. Section (3) considers specific issues that will arise at different phases of a pandemic, and offers advice on how these might be managed, taking account of the principles (and obstacles to their implementation) identified in section (2). Section (4) considers issues of fairness and equity. Section (5) draws conclusions and makes some recommendations.

This paper is one of four papers commissioned by WHO to consider the ethical dilemmas that will arise in the course of an influenza pandemic. The papers were discussed at an international meeting convened by WHO on 24–25 October 2006 in Geneva, Switzerland. As for the other papers, this paper has been prepared by an expert panel supported by consultation.

1

Introduction

This paper considers moral dilemmas or challenges that states may face in their international or transnational relations when they request action, assistance or cooperation from other states in the event of an influenza pandemic, or are requested by other states or multilateral organizations to assist or cooperate. Chapters I, II and III address issues of national responsibility. In some instances, national issues have an international dimension and, where another paper has addressed these, this one does not. The scope of the paper has also been limited for other reasons. Firstly for practical grounds, because the paper cannot cover all of the many issues that might be raised. Secondly, many aspects of transnational and multilateral obligation remain unresolved both in international law and by states. The paper does not attempt to analyse these questions substantively; it merely alludes to aspects of this important emerging area of policy in the argument it develops.

In order to keep the paper to a reasonable length, the Working Group made several assumptions:

1. When a new pandemic influenza virus emerges and starts to spread, no containment/quarantine measures will prevent most countries from being affected. This means that (perhaps with rare exceptions) all countries must prepare to manage a domestic epidemic. We will not face a position where, for any length of time, “untouched” countries can assist ones that are affected.
2. Under the foreseeable circumstances, vaccines or prophylactics will not be readily available in time or in sufficient quantities to protect the

majority of people effectively in most regions of the world. In particular, if the virus becomes transmissible, there will probably not be time to develop and produce a vaccine fast enough for use on the majority of unaffected populations during the first pandemic wave. For this reason too, all countries (possibly with rare exceptions) must prepare to manage a domestic outbreak of pandemic influenza infection.

3. It is very hard in advance to make reliable predictions of rates of morbidity and mortality. We do not know how grave or widespread the crisis created by a pandemic will be in different regions and countries. This has important implications for international preparedness. If the pandemic turns out to be relatively mild in some regions, it will be possible to scale up international assistance. On the other hand, if rates of morbidity and mortality are high across the globe, few countries will be in a position to help others. This problem will arise only during the phases of a full-blown epidemic; but during these phases the policy implications are significant and efforts should be made to prepare for them.

This paper aims to provide states with realistic and practical advice concerning their international responsibilities during different phases of a pandemic. Before examining these in more detail, we look first at relevant general principles regarding states’ responsibilities abroad; and at some of the commitments states have made that may be considered relevant in the event of a pandemic.

2

General considerations

When considering the degree to which states may have responsibilities abroad, it is helpful to begin by noting that states may choose or be obliged to take action abroad for a number of reasons. Governments may do so to protect or promote national interests or to fulfil their obligations under international law or human rights law. A government may also act from ethical motives or a sense of solidarity with other societies – increasingly often because its own people require it to act ethically on their behalf.

In this context, it is relevant that the pandemic itself (although not necessarily the way in which it is managed) is a “no fault” event. It can be likened to a natural disaster, rather than a catastrophe caused by human interventions or irresponsibility. No actor or state is accused of being the cause of the problem.

This is significant in terms of obligation, and also international action. Theoretically the obligation on a state to assist other states is much stronger where the state has some causal responsibility. Indeed, if its responsibility is demonstrable, the state will have a direct duty to repair or compensate for the problem in question. In practice, however, direct responsibility for international problems is notoriously difficult to demonstrate. The “no fault” character of this crisis means that governments are much more likely to be willing to assist one another cooperatively. It is much easier for them to do so if the disaster concerned is considered a natural event and no issues of fault stand in the way of acting ethically.

This is helpful because, in comparison to many other areas of policy, states have a good record of responding collectively when natural threats to health have been identified. Their management of the epidemic of severe acute respiratory syndrome

(SARS) is a good example. Considerable coordination and cooperation as well as determination were involved, and the effort was successful. In a similar way, states have cooperated effectively in global vaccination programmes where national and global health interests coincide and where international coordination was fundamental to success. In other areas of policy, effective cooperation on this large scale is not widespread.

As noted above, questions of fault may well arise in the management of a pandemic. Governments may be accused of putting lives at risk by hoarding medicines without justification, implementing commercial or travel restrictions that delay shipments of vital supplies, mistreating foreign nationals who enter their country, putting the populations of other countries at risk by acting incompetently, or applying discriminatory policies with respect to their own citizens or citizens of other countries. Such issues are raised briefly below and discussed in the previous chapters.

The first main point, therefore, is that a state does not have to deal with the difficult problem of fault when it considers its *general* responsibility to assist other states in the event of a pandemic. But if states are free to act to help other states or peoples abroad, do they have a well-defined and understood legal or moral responsibility to do so? Again, in *general* terms they do. Most states have accepted certain legal obligations (if they have signed human rights treaties, for example) and all have made political commitments to assist other states if need arises. Thus the essential issue is – does the state in question have the capacity to assist while continuing to fulfil its essential responsibilities, particularly to its citizens and other people under its jurisdiction?

2.1 Obligations

The UN Charter (1) includes international cooperation among its purposes: “To achieve international cooperation in solving international problems of an economic, social, cultural or humanitarian character, and in promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language or religion” (Article 13).

The Universal Declaration on Human Rights (UDHR) (2) guarantees respect for economic, social and cultural rights (including matters of health), considering them “indispensable for human dignity”, and proclaims that they should be realized “through national effort and international cooperation” (Article 22). Though the UDHR is a Declaration rather than a legal treaty, its status is such that it is widely considered to be part of customary international law.

States that are signatories to the International Covenant on Economic, Social and Cultural (ESC) Rights (3) have made a formal legal commitment to help one another:

“Each State party to the present covenant undertakes to take steps individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present covenant by all available means, including particularly the adoption of legislative measures” (Article 2.1).

The Covenant includes commitments to promote health and take steps to prevent, treat and control epidemics (Article 12).

The Convention on the Rights of the Child (4) includes a similar clause:

“States Parties shall undertake such measures to the maximum of their available resources and, where needed, within the framework of international cooperation” (Article 4).

Specific guarantees in the treaty concerning health mention the needs of developing countries.

This paper does not encompass an argument of the legal standing of these and other references to international obligations abroad but briefly it can be said that states recognize an obligation to cooperate although the extent of the obligation remains a subject of continued discussion (see below). It

can also be affirmed that states that have ratified the international covenant on ESC rights, or the Convention on the Rights of the Child, or signed the UDHR, have made legal commitments to assist other states to achieve human rights objectives. It can equally be shown that the right to protection from illness and disease, and protection of the right to life, are rights that fall within the above undertakings – but again, the extent of the obligation they generate is still a matter for discussion.

2.2 Commitments

In addition, the great majority of states have made public commitments (that fall short of legal undertakings) to provide assistance and cooperate to achieve humanitarian and human rights objectives.

In the Millennium Declaration (5), for example, Heads of State recognized that

“in addition to our separate responsibilities to our individual societies, we have a collective responsibility to uphold the principles of human dignity, equality and equity at the global level. As leaders, we have a duty to all the world’s people, especially the most vulnerable...”

The Declaration goes on to state that “Global challenges must be managed in a way that distributes costs and burdens fairly in accordance with basic principles of equity and social justice...”. Heads of State reaffirmed their commitment both to UDHR and to the full protection and promotion of human rights. It should also be noted that the Millennium Development Goals (MDGs), attached to the Declaration and adopted as targets by the great majority of states, include specific obligations in relation to health that cannot be met if the impact of a global influenza pandemic is not addressed collectively. Goal 8, moreover, affirms the general commitment of states to assist one another internationally to promote development (5).

The International Health Regulations (IHR) (6) include similar language, whose meaning is illuminated by the texts above. The World Health Assembly Resolution adopting the revised IHR (WHA 58.3) urges Member States to collaborate in implementing the Regulations (paragraph 5.2), and to assist developing countries in particular (paragraph 5.3); it also requests the Director-General to collaborate with States Parties in providing technical cooperation and logistical support (paragraph 6.5), and

in mobilizing financial resources to provide support to developing countries (paragraph 6.6). The Regulations themselves state that, when a public health emergency of international concern occurs, WHO may offer to mobilize international assistance (Article 13.4) and that “When requested by WHO, States parties should provide, to the extent possible, support to WHO-coordinated response activities” (Article 13.5).

In brief it can be said that:

- the great majority of states have made legal undertakings and political commitments in general terms to help protect the health of people in all countries (not just their own);
- the states’ first and primary obligation is to the people for whom they are directly responsible;
- a state’s obligation to help other countries and populations abroad is increased
 - if it has resources to spare, and
 - a government abroad lacks the means to protect the health of its people.

It is fair to say that these positions are generally not contested; their implications for action may be (see next section).

2.3 Obstacles to implementation

Two issues in particular have made it difficult for governments to implement these acknowledged responsibilities in a transparent and effective way.

The generality of the obligation

First, the obligations are set out in general terms. They provide no criteria for judging how a state should assess the extent of its obligations abroad in particular cases. With respect to a pandemic, no criteria indicate how much country *A* should give country *Z*, either relative to another country *B*, or relative to its own budget, national income, and needs. Because there are no agreed criteria for assessment, efforts to cooperate internationally are frequently incoherent. When a crisis occurs, it is usual that some wealthy states offer little or nothing, while the majority pledge far more than they finally give. It is a pattern of behaviour that positively damages the reputation of governments. However, bad faith is not an adequate explanation; while no rules exist to guide contributions, the pattern will persist.

Efforts have been made to assess the obligations of states more fairly. States make contributions to the UN that reflect their wealth. In practice, nevertheless, a major part of the UN’s income is voluntary, reflecting states’ unwillingness to make fixed assessed contributions to its programmes. Rich governments pledged to provide 0.7% of their gross national income in aid. However, few donor states have ever achieved this target, and the pledge did not indicate how aid is to be allocated – how much will go to whom for what. However, establishing useful rules of assessment is acknowledged to be extraordinarily challenging, but without such rules, inclusive and effective international collaboration will remain extremely difficult to achieve in particular cases, and to sustain in general. The non-specific wording of MDG 8 merely confirms that, while states acknowledge their general commitment to a just international order, they wish to retain their freedom to choose how much and what they assist. While this is so, international assistance will remain uneven and inadequate.

Should a pandemic occur, states’ reluctance to accept degrees of obligation will be a significant obstacle to achieving an adequate international response. If WHO Member States, and WHO itself, could establish some benchmarks or working rules for assessing the financial contributions of states *during* the pandemic, it would greatly assist decision-making and effective response. The adoption of a transparent and predictable assessment system for financing the international response to the pandemic would also help significantly to forestall criticisms of discrimination and unfairness that will otherwise be almost inevitable.

The issue of sovereignty

A second issue has prevented states from putting into operation their obligation to assist abroad. In international law and state practice, national governments claim sovereignty over the territories they govern and have the primary responsibility to provide for and protect people within their territory. Where a population is not protected, however, it has been unclear how the duty of countries abroad to act to protect that population is conditioned by the behaviour of the national government in question. Are national governments entitled, on grounds of sovereignty, to refuse assistance from

abroad – or do third-party governments have a greater duty to assist when a national government fails to protect the people in its territory?

There has been some progress in clarifying this issue recently, although it remains an extremely sensitive matter for states. A report entitled *“The Responsibility to Protect”* published by the International Commission on Intervention and State Sovereignty (ICISS) in 2001 (7) argued that states have a duty to intervene abroad, in strictly defined circumstances, when a national government fails to protect its people or puts them at risk. A UN High Level Panel on Threats, Challenges and Change, appointed by the UN Secretary-General, took up the ICISS arguments in a report entitled *“A more secure world: our shared responsibility”* (8), as did the UN Secretary-General himself in his report *“In Larger Freedom”* (9). The ICISS report was recognized in the Outcome Document (10) of the UN World Summit in September 2005. These documents considered interventions that use force to protect human rights. The fundamental argument is relevant, nevertheless, to cases of humanitarian crisis, including pandemics. Indeed it is easier to apply them in such cases, because (unlike military interventions) international interventions on humanitarian grounds usually assume the consent and cooperation of the host state and are likely to be more effective for this reason.

Essentially, the argument is that where a state is not able to protect people in its territory, and their lives and safety are at risk as a result, the international community has a duty to intervene to protect those people. At least in extreme cases, sovereignty should give ground to human need. The significance of this argument is that it makes clear that in such instances, the underlying obligation of states is to assist the people of another state. State–state relations are the currency of normal international relations; but at least in crises, including pandemics, a more primary obligation to protect people and fundamental rights may trump the normal terms of state–state relations. This is a new paradigm, still settling down, that in time may become highly relevant to the management of global problems, including catastrophes.

It is still difficult to foresee how the principle of the responsibility to protect would affect international behaviour in practice. It may be argued,

for example, that countries which cannot raise domestically the resources they need to combat a pandemic, but which have clearly made efforts to address the challenge and respect international recommendations, have a stronger claim to international support than states which behave irresponsibly, for example by running down their health services or misusing aid they have received. Yet the principle that governments have a duty to act to protect people who are made vulnerable by the action or inaction of their governments would lead states to devote more attention and resources to countries where governance is worst.

With respect to a pandemic, it may be feared that in a few cases misgovernment would be such that it would create unacceptable risks not only for the local population but also for international peace and security. Forceful intervention might be considered under such circumstances, as justified by Chapter 7 of the UN Charter (1) or the ICISS document (7), but it must be hoped that such an extreme step will be avoided. Forceful intervention, resisted by an incumbent government on grounds of national sovereignty, creates possibly the most favourable environment for the rapid spread of infectious disease.

However, more limited forms of intervention might be required where a national government is not able to implement certain health measures because it has lost the confidence of (or is in conflict with) some of the communities under its jurisdiction. Where feasible, WHO may administer such services, but given the demands a pandemic will make on WHO and other institutions, the involvement of a broader range of actors could become necessary.

2.4 Additional considerations

In practice, several additional considerations influence the degree of responsibility of governments to act abroad. These include the degree to which:

- they are aware of a problem and the threats it poses;
- they possess knowledge (expertise and technology) that enables them to control or manage the problem and the threat it presents; and
- they have the necessary financial, logistical (human resources, material) and administrative capacity to act effectively.

Some brief remarks on these issues illustrate their relevance to the case of a pandemic.

Awareness

When natural disasters or catastrophes occur, the international community often takes time to become aware of the event or of the threats it poses, but in the case of a pandemic there is very high awareness. This undoubtedly increases the responsibility of states to take action.

However, while states are unquestionably aware that a pandemic will create major risks, it is not so clear exactly what those risks are – or how great they are – because the character of the pandemic cannot be predicted in advance. This fact will tend to inhibit effective action, and may also lead to ineffective or inappropriate action (for example, the stockpiling of a drug that eventually proves to be ineffective against the pandemic virus that emerges). The fact that states cannot predict the level of risk they face reduces their capacity (and, in practical terms, their duty) to act.

Expertise and technology

Although the international community is intellectually equipped and well-resourced, it does not possess in advance the expertise and technology that will be required to deal with a future pandemic, and in crucial respects cannot acquire that expertise or technology before the pandemic takes form. This also inhibits the capacity of governments (and international institutions that represent them) from acting effectively to protect people whose health will be threatened, and in practical terms limits their duty to act. It should be noted that the effects of this lack of knowledge, on the duty to act and the ability to act, vary at different phases of the pandemic (see below).

Resources and administrative capacity

The international community has considerable logistical and administrative capacity that can be deployed through WHO and other international institutions, or through bilateral technical cooperation and assistance. However, because it is not possible to predict the duration and impact of a pandemic before it occurs, neither is it possible to predict the extent to which national resources will need to be deployed in rich as well as poor countries. Since it must be assumed that governments

will meet national needs first (and within reason should do so to be in accordance with international human rights law), states are not in a position to promise in advance that they will have spare resources (medical supplies, equipment, personnel, or funds) for use abroad. This too is a practical constraint on their duty to assist other countries.

2.5 Decision-making procedures

The above considerations reinforce the need for states (and WHO) to put procedures and decision-making arrangements in place, in advance of a pandemic, that will enable them to assess the impact of the pandemic as it occurs. This in turn will enable them to take more transparent and responsible decisions about allocation of resources nationally and internationally and will help to forestall subsequent criticisms that states were discriminatory or unfair in allocating resources.

In the absence of such arrangements and procedures, a state will find it hard to distinguish between a decision to take responsible precautions to protect its own people, and a decision that will later be perceived as inequitable or unjustified, unnecessarily causing harm to people abroad who might have been assisted. For example, a government may have to judge whether it should stockpile medicines for later waves of infection that may or may not occur, or make part of its stockpile immediately available to medical staff in another country, thereby potentially saving many lives but perhaps increasing the risk faced by its own people. States will similarly have to judge when it is appropriate to divert medical (or military) personnel from national duties to assist populations abroad where medical and logistical skills and resources are lacking.

At present, the international community is not addressing these issues and this lack undoubtedly presents a major challenge to planning and preparation, and restricts the ability of states to fulfil fully and effectively their international responsibilities towards other countries. At the same time, they already understand the seriousness of the threat and already know that rapid and effective responses will need to be developed during a pandemic. This increases their duty to prepare and put in place decision-making procedures that will operate rapidly and robustly both during and after the crisis.

The demands that a pandemic will make on

public resources, and the level of public anxiety that it will generate, will put decision-makers and decision-making systems under exceptional strain. While governments will certainly wish to retain final authority over expenditure of international as well as national resources, it is likely to be appropriate to establish high-level expert bodies to set certain objectives, agree ethical and scientific criteria for international programmes and the allocation of international funds, and provide guidance on their application. Such professional bodies could bolster public confidence in the objectivity and fairness of decisions made, which could be of considerable help to political leaders operating under extreme pressure. It is therefore suggested that exceptional

decision-making mechanisms should be introduced to manage the crisis, and that these should probably include both a political and an expert dimension.

It may be that different procedures and mechanisms will be required to manage the pre-crisis phase, the crisis phase, and the phase after the pandemic ends. An internationally-approved mechanism could be proposed to examine the strengths and weaknesses of preparedness planning during these different phases, reviewing for example the adequacy of preparedness plans, the issues that have not been properly considered, and the institutional obstacles that stand in the way of proper planning.

3

Specific issues during different phases of a pandemic

This section considers specific issues that may arise during different phases of a pandemic, and evaluates governments' responsibility to assist in relation to the principles and commitments identified in the previous section.

In reviewing these issues, it is important to reinforce the assumptions made earlier (see introduction):

- It is not possible to predict in advance what form the epidemic will take, how dangerous or infectious it will be, or whether it will spread evenly or unevenly across the planet.
- Policies to contain the pandemic within a country or region are unlikely to be successful for long, although vigorous containment efforts should nevertheless be made in the early phases.
- Vaccines or medicines to control the pandemic will not be available in adequate quantities in any country and across the globe there will be a severe shortage.
- A policy of quarantine and border control will not allow a country to remain unaffected; except in very few cases (some islands), countries that seek to "isolate" themselves from the pandemic are likely to succeed in delaying spread of infection for a short time only.
- It is not possible to predict how long a pandemic will last, though several waves of infection may be expected, with possible variations in morbidity and mortality rates over time in the same country.

The analysis below is based on these assumptions although it does not take account of all eventualities. A simple model of the pandemic's phases has been adopted. It does not necessarily reflect what will occur, but it has been chosen to help to iden-

tify differences in state responsibilities, and opportunities for action, in the four situations outlined below.

1. Pandemic alert phase, before emergence of the pandemic virus (prevention and preparation phase).
2. Pandemic alert phase with an identified pandemic virus (containment can still be attempted).
3. Pandemic phase (maximum impact).
4. Post pandemic period.

3.1 Pandemic alert phase, before emergence of the pandemic virus

In this phase (i.e. now) governments and international agencies including WHO, have opportunities to put in place plans for containment for phase 2, and procedures and decision-making processes for managing the crisis in phases 3 and 4.

As noted above, the practical capacity of states to prepare adequately is limited by the fact that the form and severity of the pandemic cannot be predicted in advance. It is nevertheless possible to strengthen the general capacity of states to cope with a pandemic by:

- enhancing vaccine and antiviral production capacities
- training medical and veterinary staff
- enhancing surveillance and monitoring capacity in countries
- disseminating accurate information that keeps the public well-informed
- preparing national plans
- controlling or eradicating the disease among poultry and other animals
- allocating funds, including aid funds, to achieve these objectives.

As far as practicable, the allocation of resources for these purposes should not be at the expense of efforts to prevent and treat other diseases, and the donor community should monitor its financial support to the poorer countries with this in mind.

All countries have a duty to take steps to protect people under their jurisdiction from the threat to health that a pandemic will cause. However, richer countries well-endowed with medical resources are clearly in a position to help strengthen the capacity of other countries by providing financial assistance, equipment or personnel. It is in their interest to do so, because this will also reduce the threat posed to their own people and interests. Issues of equity will arise in this situation. Given that medical resources and capacity are limited, it will be important to provide help fairly, if possible according to transparent criteria. If the threat of mutation of the virus is highest in countries where avian influenza has become established, for example, it may make sense to concentrate available resources in those countries. Such decisions should be based on scientific judgements which the authors of this draft are not in a position to make.

States and the international institutions that represent them, including WHO, should take steps during this time to strengthen existing procedures, or put in place new ones, to enable them to take decisions more rapidly and soundly during the peak phase of the pandemic, as well as planning for the aftermath. They have a responsibility to do this, not only because it is in their interest, but because they are already aware that a pandemic could severely threaten the infrastructure of states and their capacity to cope. In abnormal conditions such as a pandemic, governments tend to default towards narrow perceptions of national interest (not least because of the pressure of public opinion), even though rational and cost-effective policies may require states to allocate significant resources abroad as well as at home. It might cause much additional loss of life and precipitate disaster, if under domestic pressure richer countries were to hoard their resources nationally. This might make it impossible to provide forms of international assistance or take actions that would more effectively protect their own citizens, as well as citizens of other countries.

Consequently in this phase states need to:

- agree and install procedures for assessing :
 - the nature of the burden that states face during the peak stage of a pandemic;
 - the contributions that states should make to international assistance during the pandemic period;¹
 - the needs and criteria for international allocations.²
- make contingency plans for the aftermath.

It is important to establish procedures designed to operate robustly and effectively *during* the pandemic period, recognizing that decisions regarding the gravity and spread of the pandemic cannot be made in advance, and that, for the same reason, the full extent of the availability of funds for international work cannot be assessed in advance either. In the absence of agreed decision-making procedures for assessment, governments will find it very difficult to take swift and sound decisions to support international assistance and cooperation.

In the same spirit, governments and international organizations should establish a sound information policy. This should obviously address the requirements of the current phase – providing explanations to the public of the threat posed by avian influenza, etc. – but should specifically foresee the challenges that will arise during the peak phase. If the public is not made aware that it will be necessary to work internationally as well as nationally to protect public health during a pandemic, governments may find it much more difficult to propose and implement sound policies. If the need for international coordination is made clear to the public, they are more likely to support such policies, even if international policies divert resources from national programmes. Therefore governments should develop information policies to explain why some expenditure during the pandemic should be devoted to international purposes, on health grounds and on grounds of national interest as well as for ethical reasons.

Finally, states should take action during this phase, in cooperation with expert organizations such as Office International des Epizooties (OIE) and the Food and Agriculture Organization of the United Nations (FAO), to help countries strengthen

¹ taking account of the burden assessment above

² taking account of the burden assessment above

the capacity of their veterinary services and compensate farmers and households that keep poultry for the loss of their birds as a result of avian influenza control programmes. If small producers and households are not compensated, they are unlikely to declare that they have birds or report cases of avian influenza, thereby significantly increasing the risk of mutation of the virus and an eventual pandemic. In addition, the income and nutrition of poor households is likely to be particularly affected by culling. Compensation can therefore be justified on human rights, ethical and development grounds. The development agencies of countries in the Organisation for Economic Co-operation and Development (OECD) should be encouraged to develop compensation programmes for small-scale poultry producers in poor countries, in support of WHO, OIE, FAO and other organizations that monitor the incidence of avian influenza and prevent its spread.

3.2 Pandemic alert phase with an identified pandemic virus

In the initial period of a pandemic, it will be important to mount a strong international effort to contain its spread – even if such an effort is unlikely to be successful. Governments have a duty to support such efforts, either by contributing resources, equipment and personnel, or by submitting to the constraints that any containment policy will impose on countries that are within the containment area(s). Such efforts can be justified on grounds of national interest, as well as ethical and human rights grounds, because, if a policy of containment did succeed in stopping the pandemic, many lives would be saved across the globe, including in the countries that provided support and assistance.

In this situation major restrictions on movement and cross-border travel may be introduced globally or in certain regions. The introduction of such measures, while potentially necessary, obviously creates the risk of discrimination and abuse. Foreigners, travellers, displaced people, asylum seekers, and individuals belonging to minorities that live on both sides of a frontier are particularly at risk. Their rights may be violated; they may be stigmatized, or accused of “importing” the virus. Travellers from certain countries and regions are more likely to suffer discrimination than travellers from

others and particular attention should be given to the treatment of migrants and displaced people. Certain categories of people, including migrants, might face deportation to countries where the risks of infection (or other threats to their person) will be much higher.

In general, measures controlling movement and cross-border travel should be monitored to ensure that they are applied in a manner that is non-discriminatory and do not facilitate or provide cover for violations of rights (see chapter II).

3.3 Pandemic phase (maximum impact)

It is particularly hard to predict the character of this stage (and its possible substages) and therefore difficult to generalize about the issues of ethical policy and international obligation that are likely to occur. In order to provide a useful assessment, two scenarios are distinguished; in one the pandemic is global in spread and is characterized by high rates of infection and mortality; in the other, the pandemic is relatively mild in both respects. In reality of course, the situation may not be so tidy. Rates of infection and morbidity may vary across the globe. The pandemic may also have high levels of infection but low morbidity and vice versa. Moreover, there is no reason to suppose that a pandemic will take the form of a single wave of infection; there could be several waves that vary in gravity and infectiousness and spread differently across the globe. It is therefore important to stress that the distinctions below are made to facilitate analysis; they do not purport to reflect the likely characteristics of a real pandemic.

Scenario 1: high morbidity and mortality rates

Countries are likely to be overwhelmed, forced to devote most of their resources to managing the domestic effects of the pandemic and providing domestic health care. Medicines and vaccines will not be available in sufficient quantities (or at all). Health and government services will be overstretched or will break down, adding new health risks. The willingness of states (and their populations) to invest resources in international programmes of protection and health care will decline sharply and it will certainly be difficult and may become politically impossible to deliver such programmes, even if they are valuable and there is

exceptional need. Most states will be thrown back on their own resources. In some societies chaotic conditions will emerge.

In these circumstances, it is likely that various kinds of violation of rights will occur as fear of the pandemic spreads and rates of illness rise. Foreign communities may be subject to discrimination or attack; they might also be expelled from the country, without regard for their safety or residence claims. Other minorities may be excluded from access to health care. More generally, certain groups of people may secure privileged access to health care, vaccines etc.

If the pandemic has an acute and disruptive impact on countries that are important economically, it is also possible that it will trigger a worldwide economic crisis. This is more likely now than in the past, given the greater integration of global markets. In this respect, planners should not only address the impact of such a crisis on global distribution of key pandemic response supplies. They should also consider whether, in some situations, the countries that would suffer most from a pandemic would not necessarily be the poorest. In certain conditions populations that rely more on small-scale agriculture could fare better than people living closely-packed in cities. The urban populations are not only more exposed to infection; they also depend more directly than farmers on health and other services, and rely for their income on employment that (in many export industries) is acutely vulnerable to fluctuations in demand.

In this scenario, it must be assumed that fewer resources will be available for international programmes to assist the countries hit hardest by the pandemic. Therefore, the prior creation of procedures to assess the gravity of the impact of the pandemic, and assess the responsibilities of richer countries to respond to need abroad, is vital. If the impact on the world economy were to be dramatic, such procedures might also assist rich states to respond to demands to put together a "Marshall Plan" to refloat global trade in the aftermath period.

Scenario 2: high morbidity but low mortality rates

In an alternative scenario the pandemic takes a milder form. It may cause fewer deaths or cause

mild disease with fewer complications, or may affect different regions of the world unevenly, so that some countries and regions are only lightly touched. In these circumstances, the prospect of maintaining a higher level of international assistance improves, and states and international organizations may be able to provide effective assistance to some of the countries that are hardest hit, even during the peak phase.

Under these conditions, the availability of procedures for assessing the seriousness of the pandemic, and the degree to which richer and better-endowed states can assist others remains essential, because it will still be difficult, in the midst of the crisis, for governments to make sound decisions that are not driven uniquely by narrow views of national interest.

Difficult decisions that may need to be taken include:

- Whether to release for use abroad vaccines or medicines that had been stockpiled for domestic use.
- Whether to divert medical staff (e.g. public service, private practitioners, military...) who have been working on the domestic crisis to assist other countries.
- Whether to allocate funds set aside for the pandemic to international rather than domestic programmes.
- Whether to increase production of medicines or vaccines, even though domestic demand has stabilized or begun to wind down.

Decisions on all the above may need to be taken even when it cannot be guaranteed that a new wave of infection will not occur.

Information policies will again be crucial during this phase. It will be a challenge to explain why scarce resources should be expended abroad rather than at home, particularly in countries where the pandemic is *relatively* mild, but nevertheless poses exceptional demands on the health system and creates severe anxiety in the general public. A communications strategy designed to make such explanations plausible to the general public will need to be put in place earlier rather than later.

3.4 Post-pandemic period

If the pandemic is severe, some countries will be severely undermined by loss of qualified personnel and will have many other problems (e.g. crop failure, collapse of services, financing difficulties, caring for orphaned children, crime, etc). The international community will be under a strong moral and political obligation to help and, to do so adequately, states should make contingency plans to manage such an eventuality.

If the pandemic has a marked impact on the global economy, as may be the case, states may need to develop a reconstruction plan for refloating the economy. This possibility should be considered in contingency planning. Programmes to restore glo-

bal employment could be required if the pandemic triggers a major economic depression or a global or regional economic crisis.

If the impact is less global, some countries will nevertheless suffer severely. Plans to provide medical personnel and resources to countries that have lost a critical number of nurses or doctors should be considered. Plans to strengthen the capacity of countries to train additional hospital staff during the recovery period and restart training programmes may be required. Particular attention should also be given to the provision of health care in rural and poor urban areas, where health care services may be particularly lacking following a pandemic.

4

General issues of fairness and equity

Issues of fairness and equity are easier to state than to manage. In practice, government policies will be determined by states' perceptions of national interest, combined with an assessment of what programmes abroad will be effective. WHO and international agencies will obviously need to help states make sound judgements about (a) what level of threat they face; and (b) what programmes are worth supporting financially during different phases of a pandemic.

Both questions pose issues of equity and fairness. States may choose to avoid the issue of equity, for example if they consider immediate national protection to be the only priority. Failure to give serious consideration to equity may also lead states to make poor decisions about what is in their interest. Some, for example, may stockpile a vaccine or drug for national use that turns out to be unnecessary, whereas strategic deployment of the same resources abroad would have far more value. States should also take into account the long-term costs of leaving other countries or regions in great difficulty following the pandemic. It may be morally right as well as economically sensible to resist public pressure to invest resources at home, and instead invest abroad to enable hard-hit societies to recover.

An information policy is important here. Information to the public should make reference to the larger ethical issues, and explain global as well as national dimensions of the pandemic, with a view to enabling governments to adopt the most rational and effective policies. It will also be important to develop a long-term strategy that is not driven by crisis. Government and international planners may wish to draw on the experience of development agencies, who are regularly confronted with the challenge of moving coherently from policies designed to address humanitarian crises to ones that promote long-term development. If health

ministries, governments and international agencies think of the pandemic only in terms of crisis, and do not plan for long-term recovery, not only will policies be inadequate, but they will generate forms of inequity and discrimination that are likely to generate social and economic problems in the future.

Political leaders and officials responsible for managing a pandemic should therefore put in place planning processes that will identify their objectives in the five years following a pandemic, and identify policies that need to be in place if these objectives are to be achieved. They should not remain in crisis mode – and should not be only in crisis mode even during a pandemic's peak phase. Special emphasis should be put on the importance of regional coordination during all stages of managing the pandemic.

When considering issues of equity and discrimination, it will evidently be important to consider groups that are especially exposed to risk. Among these are poor communities with fragile access to health and other services, and groups who are often exposed to particular risks (including women, children and minorities). As part of national and international response plans, reporting systems should be put in place to ensure that the impact of a pandemic on such groups can be monitored. Human rights techniques of reporting may provide useful tools for this work.

This said, simple assumptions should not be made in advance about which groups are likely to prove vulnerable during a pandemic. Although all age groups were affected, the 1918 influenza pandemic killed a very large number of young adults. If this proved to be true again it would be important (as with HIV/AIDS) to make sure that grandparents and other elderly carers receive adequate levels of protection and support, as they might be crucial for child-care provision in the aftermath of the pandemic.

5

Conclusions

Principles of equity, non-discrimination, solidarity and reciprocity have been recognized in numerous legally-binding international and human rights standards. Governments should take steps to ensure that adequate international assistance is made available so that all countries can contribute to the international and national efforts that will be necessary to prevent a pandemic from occurring and to minimize its effects in all societies if it does occur. In framing documents that set out how states and societies should respond to and manage an influenza pandemic, human rights principles and international legal obligations should inform the approach of WHO and other international organizations.

During each phase of a pandemic, governments will respond best to policy recommendations that draw together arguments based on national interest, human rights principles (and other bodies of international law), and ethical values. The power of ethical values and notions of human solidarity should not be underestimated, even in a severe crisis, especially if these values can be focused through the media. This underlines the importance of developing a sound communications policy (see below).

Arguments based on human rights obligations and ethical principles will be more effective before the onset of a pandemic and after it ends. Appeals to international law during the height of a pandemic (except where egregious violations of rights are in question) will have little purchase if the mortality rate is high and states find themselves under acute pressure at home. Where the pandemic is less aggressive, it will be possible to appeal more effectively to principles, agreed rules and international legal obligations.

Advance planning

Planning should give full consideration to issues of equity and fairness. This is difficult because it is already clear that no government will be in a position to provide full or adequate protection to everyone. Vaccines will not be available and in many circumstances a shortage of health-care workers and resources will make it impossible to provide proper care. The commitment to equity and fairness does not imply giving everyone the same treatment, however. It implies taking decisions about the allocation of scarce resources transparently according to criteria that are rational, and applying these criteria consistently. National and global public opinion will expect this.

It is vital to prepare as well as possible before a pandemic occurs. Much can be done in the pre-pandemic phase to reduce risk, strengthen the readiness and capacity of veterinary and medical services nationally and internationally, and increase public awareness and understanding. Preparation of regional and national plans can make an essential contribution to preparedness.

However, some essential policy decisions cannot be taken before the pandemic occurs, and when it does decision-makers will come under intense pressure. Critical mistakes may be made during the peak pandemic phase because governments will be under tremendous pressure to think only of their own needs and their own people, even though it may not be rational or in the country's best interest to do so. It is therefore vital to establish in advance decision-making procedures that will permit governments and international institutions to make rapid assessments about the level of risk and priorities of need during the peak phase, and sound decisions during each phase of the pandemic.

These decision-making procedures should aim to provide governments with sound foundations for

making decisions in relation to national and international action that will help to mitigate the effects of the pandemic, diminish its long-term economic and social consequences, and save life in an equitable manner. They should take account of the need to balance the political and technical dimensions of decision-making; the need for sound and objective scientific and ethical criteria; and the need to sustain public confidence in the fairness and effectiveness of public policies. In the absence of robust and effective procedures, governments will find it very difficult to take soundly-based decisions and will be seen to have acted unjustly and incompetently, probably at great human cost, and possibly at great economic cost over the longer term.

Pandemic alert phase

Calls for international cooperation to contain a pandemic are likely to be supported during the initial alert phase. If a pandemic takes hold, however, sharing of resources internationally will become difficult unless it can be clearly demonstrated that such sharing will protect the populations of nations that share, as much as (or more than) policies that focus exclusively on national protection.

Post-pandemic phase

Governments, and international organizations including WHO, have a particular responsibility to consider the aftermath of a pandemic. Ethical, national interest and human rights arguments will again coincide. It is important to plan ahead for this phase, and not to wait until the crisis is over and resources are stretched and organizations exhausted. Although it is understandable for indi-

viduals to focus on self interest at the onset of a pandemic, governments can already foresee that it will be essential to act globally afterwards to repair the damage. In the post-pandemic phase it will be vital to share resources and substantial budgets will need to be set aside for international support to enable economies and societies that are hardest hit to recover. Recovery programmes will probably need to give particular support to medical and health-care professionals and health systems, which may suffer especially high rates of loss.

At all stages, international monitoring should give particular attention to the protection of groups of people whose claims to equitable treatment may be vulnerable during a pandemic. Those at risk include travellers, minorities, migrants, and stateless people. Their access to health care should also be monitored.

Communications

The issue of fairness underlines the importance of communication. Governments should put in place a well-considered communications strategy that will explain the nature of the pandemic, the choices that states face, and the human rights, ethical and self-interest arguments in favour of specific policy choices. A communications strategy that perceives national interest in very narrow terms is unlikely to assist governments to take sound decisions. Communications strategies should therefore give adequate attention to the fact that the pandemic is global, with global implications, and that policies designed to protect national interest and national health should have an international dimension.

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ANNEX

Members of Working Group Four

Robert Archer (Chair)

International Council on Human Rights Policy,
Versoix, Switzerland.

Gideon K Bruckner

World Organisation for Animal Health (OIE), Paris,
France.

Ruth Faden

Phoebe R. Berman Bioethics Institute, Johns
Hopkins University, Baltimore, Maryland, USA.

Nouzha Guessous-Idrissi

Chair of the International Bioethics Committee of
UNESCO, Casablanca, Morocco.

David Legge

School of Public Health, La Trobe University,
Melbourne, Australia.

Stephen Marks

School of Law, City University of Hong Kong,
Kowloon, Hong Kong, China.

Susan Maybud

International Labour Office (ILO), Geneva,
Switzerland.

Christoph Rehmann-Sutter

University of Basel, Unit of Ethics in Biosciences,
Basel, Switzerland.

Henk Ten Have

United Nations Educational, Scientific and Cultural
Organization, Paris, France.

WHO

Alice Croisier

Global Influenza Programme, Department of
Epidemic and Pandemic Alert and Response,
World Health Organization, Geneva, Switzerland.

Kathleen Sarah Galbraith

Department of Epidemic and Pandemic Alert and
Response, World Health Organization, Geneva,
Switzerland.

Gregory Anton Hartl

Communications Adviser, World Health
Organization, Geneva, Switzerland.

Frederick Hayden

Global Influenza Programme, Department of
Epidemic and Pandemic Alert and Response,
World Health Organization, Geneva, Switzerland.

Kidong Park

Global Influenza Programme, Department of
Epidemic and Pandemic Alert and Response,
World Health Organization, Geneva, Switzerland.

Christoph Steffen

Global Influenza Programme, Department of
Epidemic and Pandemic Alert and Response,
World Health Organization, Geneva, Switzerland.

Dick Thompson

Communications Officer, Communicable Diseases
Cluster, World Health Organization, Geneva,
Switzerland.