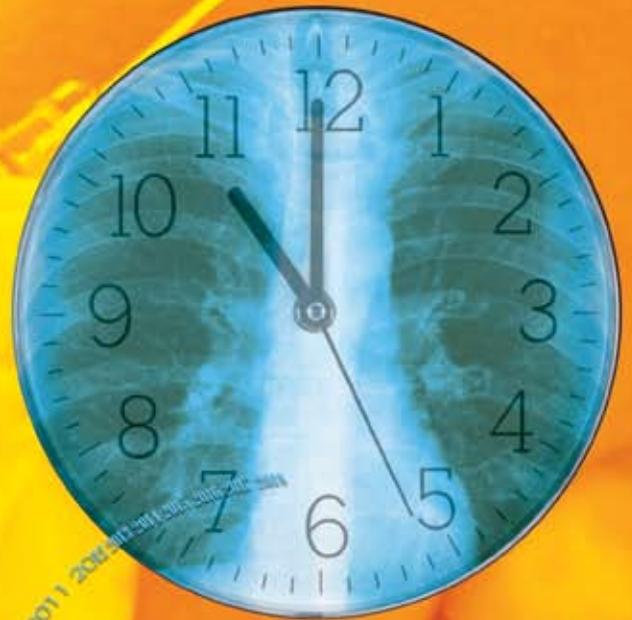




# ELEVENTH FUTURES FORUM

on the ethical governance  
of pandemic influenza preparedness



Copenhagen, Denmark

## KEYWORDS

DISEASE OUTBREAKS - ethics - prevention and control  
INFLUENZA, HUMAN - prevention and control  
DISASTER PLANNING - organization and administration  
PUBLIC HEALTH - ethics  
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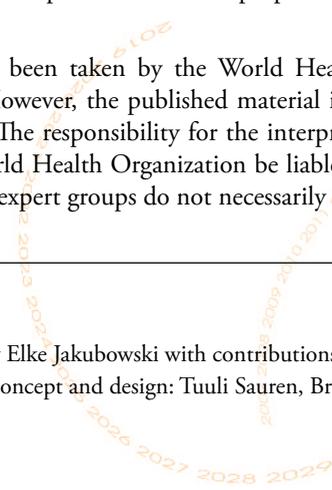
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## WHO Futures Fora series

WHO Futures Fora aim to stimulate free debate among high-level policy-makers over emerging public health issues and to address these issues proactively. They are designed to offer policy options for public health decision-making. Their objective is approached through a series of meetings in an impartial environment, offered by WHO.

The Futures Fora are a platform for sharing know-how and developing strategies to address new public health challenges. Practical policy-making experience is mainly presented through case studies from countries. The meetings are held regularly with some degree of informality and under the Chatham House Rule to ensure confidentiality. When all or part of a meeting is held under the Chatham House Rule, participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed. The WHO Regional Office for Europe publishes the main findings and conclusions of the Fora in policy briefings on its web site (<http://www.euro.who.int/futuresfora>). Rather than reflecting consensus and providing recommendations, these briefings delineate the range of policy options available in countries in addressing specific challenges and opportunities for health.

Previous Fora have focused on: rapid response decision-making, cooperation in the face of terrorism, ethics of health systems, evidence-based recommendations, crisis communication, unpopular public health decisions, patient safety, governance and public participation, and equity in health.

# Introduction

## Forum topic: ethical governance of pandemic influenza preparedness

By adopting the Health for All update in 2005 (1), the Member States in the WHO European Region promoted ethical governance as a value-based principle for health policy-makers in the Region. Ethical governance is a policy concept underpinning fair, equitable, transparent and accountable approaches to policy-making, and thereby contributing to improving the performance of health systems. But how is this concept applied in practice? The Eleventh Futures Forum reviewed some countries' experience in applying ethical governance approaches to a major contemporary policy concern: preparedness for an influenza pandemic.

This topic was chosen to enable participants in the Forum to review and discuss generic principles and instruments of ethical governance. Thus, the findings deriving from the Forum may apply also to other contemporary concerns with health policy and systems. Pandemic influenza preparedness is a future-oriented health policy concern of high priority to WHO for several reasons.

First, the 20<sup>th</sup> century showed that, although rare, influenza pandemics are recurrent events. Three occurred in the 20<sup>th</sup> century and, in view of the periodicity of events, the 21<sup>st</sup> century may likewise experience influenza pandemics.

Second, influenza pandemics occur with the emergence of new influenza viruses that have not previously circulated among human beings, so that people have not developed immunity to them. Such a new virus has been detected and monitored for about 10 years: the virus that causes avian influenza. Although this virus primarily infects birds, it has caused a number of laboratory-confirmed cases of influenza among human beings in the past few years. In the WHO European Region, outbreaks caused by influenza A/H5N1 in animal populations were first observed in Kazakhstan and the Russian Federation in 2005. Since then, 28 countries have experienced animal outbreaks. In the first quarter of 2006 there were 20 laboratory-confirmed human cases with 9 fatalities: 8 cases and 5 deaths in Azerbaijan, and 12 cases and 4 deaths in Turkey. No human H5N1 outbreaks have been reported since January 2007, but outbreaks were observed in poultry in the Czech Republic, Germany, Hungary, the Russian Federation, Turkey and the United Kingdom. The occurrence of bird-to-human and human-to-human transmission, as well as the high mortality of previously healthy people who became infected with the virus, has alerted the international health community to prepare better for an influenza pandemic that may soon emerge.

Third, it is feared that, owing to the magnitude and speed of international travel, an influenza pandemic will spread much quicker across country borders than in the past, possibly becoming even a global problem. All countries therefore need to be as well prepared as possible, and can learn much from each other about how to optimize preparedness.

Fourth, influenza pandemic preparedness seemed to be a particular appropriate topic for the Eleventh Futures Forum because ethical considerations are especially relevant in planning for a pandemic. For example, it is assumed that, particularly at the outset of a pandemic, countries may experience a substantial shortage of

pandemic-specific vaccines and possibly also trained and prepared human resources. In such a case, decisions will have to be made on how to allocate the available resources, including vaccines and other supplies. Thus, decision-makers and clinicians will need to have principles and criteria beforehand, which they can then use to make rapid, justifiable decisions at the very outset of a pandemic. Again, such tools for decision-making in countries in the case of an influenza pandemic may be tested on other policy concerns.

Fifth, WHO's emphasis on pandemic influenza preparedness has to be regarded in light of its broader work on health security in 2007 (2,3) and is closely related to the coming into effect of the International Health Regulations (IHR) on 15 June 2007 (4). The IHR aim to prevent, protect against and control public health threats of international concern. They provide WHO with the mandate to ensure that countries assess and notify the international community of any event (a manifestation of disease or an occurrence that creates the potential for disease) that may constitute such a threat, as well as any health measure implemented in response. Explicitly for the case of influenza, all cases of human influenza caused by a new virus subtype must be notified. The IHR were adopted by all WHO Member States and are legally binding for all but three.

In summary, the topic of the Eleventh Futures Forum was regarded as a concrete policy-making example that participants could use to discuss broader and more generic ethical governance approaches in European health systems.

## Scope and purpose of the Forum

The Eleventh Futures Forum aimed to review and discuss ethical governance principles and instruments to improve the performance of health systems. Pandemic influenza planning was chosen as the topic for discussion, as most of the Region's 53 Member States had adopted action plans. In addition, the countries were developing ethical considerations for these plans, since few of them discussed such issues, or offered systematic ethical justification and criteria for decisions (5).

There are a number of key ethical questions for decision-making in an influenza pandemic. For example, decision-makers could ask: how to ensure equitable, fair and cost-effective access to curative drugs, vaccines and medical treatment; how to set priorities for medical treatment; and how to allocate resources to prevent and treat influenza.

The Futures Forum aimed to provide an opportunity for European countries jointly to review their experience and discuss such unsolved questions regarding the ethical governance of influenza preparedness. Its purpose was to enable the participants to identify good practices, exchange and learn from experience in ethically governing pandemic influenza preparedness and identify some of the knowledge gaps. It was hoped that the Forum would thereby contribute to global work on the ethics of pandemic influenza planning, and, through the exchange of experience with the tools countries are using for ethical policy-making, further promote and concretize the policy principles of ethical governance of health systems in the WHO European Region. The Forum thereby also aimed to feed into the work of the WHO Regional Office for Europe in preparing its European Ministerial Conference on Health Systems in June 2008, of which governance will be a major topic.

This Forum was held in continuation of the series' cycle relating to the theme of health systems governance, drawing on previous Fora on the ethics of health systems, health systems governance and public participation,

steering towards equity in health and other topics. The Forum and this report also took account of findings of the WHO global project on addressing ethical issues in pandemic influenza planning (5).

### Structure of this report

Following this introduction, **Chapter 1** reports on the state of pandemic influenza planning with respect to the underlying principles of ethical considerations. **Chapter 2** reports on WHO's work on ethical considerations in developing a public health response to pandemic influenza. **Chapter 3** presents some possible guiding principles for ethical decision-making on the example of setting priorities for the distribution of medical goods. **Chapter 4** presents case studies from Norway, Switzerland and the United Kingdom on their ethical frameworks for pandemic influenza planning. **Chapter 5** discusses national decision-making structures for pandemic influenza planning and response, presenting a case study from Belgium. **Chapter 6** deals with public participation in ethical questions of pandemic influenza preparedness, and presents views on whether to incorporate the public's view in planning for a pandemic. **Chapter 7** provides the Forum's conclusions.



## 1. Pandemic influenza planning in countries



The Forum was attended by representatives from 12 European countries; all had adopted preparedness plans for pandemic influenza and regularly provided reviews and updates according to international guidance from WHO and the European Centre for Disease Prevention and Control (ECDC). The formal incorporation of ethical considerations – as integral parts of the action plans or through distinct ethical frameworks – varied between countries, but there was consensus that most plans required more work in making ethical principles and criteria for decision-making more explicit. ECDC's review of the plans in this context was thought to be an important step towards further improving their ethical aspects.

**Belgium** has a national plan that focused on addressing the implications for local government and the private sector. Two bodies provide advice on ethical considerations: the national bioethics committee, an independent organ reporting to Parliament, and the high-level council of health, which makes recommendations on pandemic influenza planning to the Government. Some current ethical issues concern migration: for example, how to include Belgian citizens living abroad and how to plan for multinational communities such as that in Brussels.

In **Cyprus** a plan was finalized and launched in 2005; ethical aspects were discussed during a recent ECDC review mission. Cyprus is in a very particular situation when it comes to ethics, for example, related to equitable access to vaccines and care. One reason is that the population of Cyprus triples during the summer. In addition, Cyprus has opened its borders to refugees during crises in the Middle East. Further, the Government is concerned about protecting Cypriots residing in other countries. The country had ordered stockpiles of vaccines to be able to vaccinate 10% of the population by the end of 2007. Nevertheless, while a bioethics community is effectively addressing these questions on the national level, more attention needs to be paid to regional-level implementation.

Municipalities in **Denmark** are responsible for developing strategies to prevent and treat diseases. National guidance addresses all sectors other than health. The country has a contingency preparedness plan, and is following it. For example, stockpiling of influenza vaccines is restricted to that required by the regulations set out in the plan, and would not cover the whole population in a pandemic. Thus, criteria are needed to decide on the population groups to be prioritized for vaccination in such a case, and ethical principles and criteria for decision-making in a pandemic need to be made much more explicit in the plan.

**France** developed an influenza pandemic preparedness plan in 2004, published it in 2005 and has revised it twice since then. The plan sets out the overall strategy, the organizational structure and the mechanisms for working during a pandemic, and includes scenarios for decision-making. A parliamentary hearing assessed the plan. Its second chapter sets out some ethical considerations, based on the recommendations of a national symposium intended to provide ethical guidance for the plan. The symposium underlined the importance of social mobilization in ethical pandemic influenza preparedness. Discussions on the ethical aspects of technical collaboration with less developed countries during a pandemic, including providing tools, are also taking place. The next step in planning will be at the level of the seven regions of France.

In **Germany** the national pandemic influenza preparedness plan (published in 2005, updated in 2007) already has regional equivalents in all 16 federal states. Oseltamivir (Tamiflu) stockpiles enable treatment for 20% of

the population. The country's national plan was discussed and agreed by high-level federal and state politicians in working groups. Three aspects need to be considered in prioritizing vaccines or antiviral medication:

1. ethical values;
2. the best theoretical way to act on them; and
3. the logistical capacity and feasibility of the approach.

In Germany the first are identified as the goal of maximizing the reduction of morbidity and mortality in a pandemic. For the second, modelling work could contribute greatly to determining an approach; here, Germany is building capacity. At any rate, it appears that, even when groups most at risk were identified, which might only be possible when a pandemic had started, choosing the way to go may not be straightforward. For example, if elderly people were identified as being at the highest risk of death, it may still be better to vaccinate children first because this approach could prevent transmission and reduce the momentum of the pandemic, thereby lowering the chance of infection more efficiently. Assuming one had found the answers and identified the risk groups and the groups to prioritize, more questions may arise. For example, if people with chronic illnesses should be prioritized, who comprised this group? For example, would an immune-suppressed patient take priority over a person suffering from diabetes or the other way around?

Here the third aspect, the feasibility of any strategy, comes into play, which may be the main strength of Germany's approach. The discussion with many stakeholders at the level where decisions have to be implemented led to a very pragmatic decision laid down in the pandemic plan. The goal is to reduce morbidity and mortality, and, after the vaccination of health care workers and essential service personnel, the population would be vaccinated by year of birth, starting with the young.

**Israel** has had a national influenza preparedness plan for more than three years. To maintain official awareness of the plan, the country carried out two simulation drills of pandemic influenza scenarios involving all ministries and the army. The drills focused on the distribution of oseltamivir (Tamiflu) in the case of a pandemic; stockpiles are established for 25% of the population. In spite of progress in pandemic preparedness, some questions remain open, many of which have ethical dimensions. One field of concern, as in other countries, is the problem of ensuring consistency between neighbouring countries' quarantine plans to enable effective protection of populations. In addition, there are many potential tensions between groups within countries. For example, can governments ensure that different cultural and ethnic groups accept the principles underlying priority setting? And how can one explain to a mother who is a health care worker that she is entitled to vaccination while her husband and children are not?

ECDC has reviewed **Luxembourg's** pandemic preparedness plan and other preparedness activities. Ethical considerations are not a specific focus of the plan and require more work during future updates. As do other countries, Luxembourg focuses on better addressing cross-border cooperation issues. For example, about 60% of Luxembourg's workforce comes from abroad. Would these people be protected by national law or through their home countries? In this context, more intensive work would be useful to make peer reviews of national plans to limit the inconsistencies regarding these cross-border issues.

**The Netherlands** has worked on pandemic influenza preparedness for many years, undertaking many exercises. The stockpiling of sufficient doses of oseltamivir (Tamiflu) has created a feeling of effective preparedness, but

concern remains that, in a real influenza pandemic, the situation might still be chaotic, as people's lives would be at stake. Certainly, more work on ethical norms and standards in consensus with other ministries would be helpful.

**Norway** published its first preparedness plan in 2001, and has updated it in line with WHO recommendations several times. A national committee was established to put different aspects of the plan in operation, such as ensuring the supply of vaccines to at least 5% of the population. The committee had secured a commitment from industry to provide a sufficient vaccine supply. In this phase of Norwegian preparedness planning, ethical considerations are considered extremely important. Although remedies supply is assessed as sufficient according to WHO and ECDC standards, there is no guarantee that it would meet actual needs during a pandemic.

**Portugal** launched its national influenza pandemic preparedness plan in 2006. An ECDC review mission was felt to be useful in raising awareness of ethical considerations. The focus at the national level is on assisting the regions to develop their own pandemic preparedness plans.

**San Marino** has drafted a pandemic preparedness plan but not yet launched it, while some questions remain about collaboration with Italy on issues affecting both countries. For example, which country would close the borders in case of a pandemic, or how could health care or other workers working across the borders be protected?

In **Sweden** public health policies and legislation are developed and adopted at the national level, but implemented at the regional and municipal levels. The country adopted its national contingency plan for influenza preparedness in 2005 and has further developed it since then. The plan provided guidance for regional-level planning for pandemic influenza preparedness. In a review of the plan, an expert advisory committee found that it required further work to incorporate ethical considerations. For example, the committee advised that the plan should more explicitly address ethical criteria and arguments for prioritizing prevention and treatment of certain population groups in case of a pandemic. This was in concordance with findings of a review mission of ECDC and WHO in spring 2007.

**Switzerland** started pandemic preparedness planning 10 years ago, revisiting the plans periodically. The last update of the national plan took place in 2006. The current revision of the updated plan focuses on personal hygiene and pre-pandemic vaccines. The 26 cantons are expected to finalize their own plans during 2008. A big political challenge is to get other sectors involved with pandemic planning, as this is still understood as the task of the health sector in Switzerland. Communication and transparency of information were seen as major ethical tasks, as people must understand the criteria upon which certain decisions are based.

The **United Kingdom** has had a pandemic influenza preparedness plan for many years. Recent revisions focused on making it cross governmental and introducing an ethical framework for decision-making in case of an influenza pandemic. Principles for ethical decision-making were tested in a public consultation prior to finalizing the framework for pandemic influenza preparedness. The consultation strongly rejected the fair innings argument, on the basis that age should not be a criterion for prioritization. The fair innings argument promotes the egalitarian concept of equal opportunities, which implies that a child or young adult has a stronger claim to protection than an elderly person who has been able to live a full life-span, so that vaccination should prioritize younger people.

## 2. Ethical considerations in developing a public health response to pandemic influenza: the work of WHO



### About the WHO project

WHO ran a project on ethical issues in pandemic influenza planning from 2005 to 2007 (5). Its objective was to identify Member States' considerations in developing a public health response to pandemic influenza. Four working groups addressed different aspects of pandemic influenza planning, identified in a consultation with Member States in May 2006:

1. equitable access to therapeutic and prophylactic measures;
2. the ethics of public health measures in response to pandemic influenza;
3. the role and obligations of health care workers during an outbreak of pandemic influenza; and
4. issues arising between governments when developing a multilateral response to a potential outbreak of pandemic influenza.

The groups' reports were discussed at a global consultation in October 2006, and WHO issued a summary publication on ethical considerations for developing a public health response to pandemic influenza (6). A series of regional and country support activities was organized to contextualize the global report. The following summarizes the project.

### Definition of ethics and sources of ethical judgement

Ethics is a puzzling term with numerous connotations. The WHO project used ethics as a way to describe how people should ideally act. Thus, the focus of ethics is on human behaviour and a normative standard is attached to it: namely, that from an ethical perspective, one can assess what is right and wrong in human behaviour. Substantive ethics provide for human behaviour in terms of what to do, and procedural ethics relate to the way to do it.

Ethical judgments may have a number of possible sources or points of reference: personal values, religious beliefs, social norms and laws. Laws may promote ethical values but they also may have non-ethical justifications. Any laws should ideally be subject to ethical analysis, but ethical considerations go beyond legal considerations.

Ethical considerations have cultural underpinnings.

### General ethical considerations related to pandemic preparedness

A number of general considerations come into play in addressing the ethics of pandemic influenza preparedness. First, this involves striking a balance between people's rights, interests and values. Second, ethical judgments need to be brought into conjunction with the scientific evidence base. At the outset of an influenza pandemic, evidence is likely to be rare, so that ethical judgments will need to close a time gap. When scientific evidence becomes available, however, reviewing ethical judgments in light of this new evidence is equally important.

A balance must also be struck in relation to resource constraints, which will determine the extent of possible ethical judgment related to, for instance, the level of possible vaccination coverage. No matter what choices are to be made, ethical policy-making will always require a certain degree of transparency, public engagement and social mobilization.

## Priority setting and equitable access to prophylactic and therapeutic measures

The issue of priority setting and equitable access to prophylactic and therapeutic measures was addressed by the first working group in the WHO project and is further elaborated in Chapter 3 of this report. The working group acknowledged the importance of the decision-making process. It stated that policy questions need to be distinguished from clinical judgments, and focused much discussion on how to separate the two. For instance, if a policy rules that the medically worst-off patients should be prioritized, then clinicians must still identify them. This eventually opens the possibility of leaving priority-setting decisions to the clinical level. This possibility needs to be addressed at the policy level; ideally the clinical decision would naturally take account of an existing policy.

The working group also had two principal considerations as to the criteria for priority setting: utility to society and equity. Decisions based on utility, for instance, could give essential health service workers priority in prophylactic and therapeutic measures, so that they would continue to ensure the functioning of the health system, or be based on the likelihood that medical intervention would reduce transmissibility or diminish the societal burden of disease in another way. In contrast, decisions based on equity could give priority to the medically worst-off patients, those at greatest risk of dying or particularly vulnerable population groups. Chapter 3 further elaborates on these notions using the concrete examples of vaccination, antivirals and mechanical ventilation.

## Obligations of and to health care workers

Working group three dealt with obligations of and to health care workers, and faced considerable difficulties in reaching consensus, including detailing the concept of obligation. Obligations might be based on morals, contracts or professional orders, or on other legal provisions that are enacted regardless of morals, contracts or orders. For instance, a government might pass a law requiring health professionals to come to work in a pandemic influenza. There was consensus that obligations to work during a pandemic must be balanced against others, such as professionals' duty to their children; on continuous duty during a pandemic, such professionals would require time or alternative means to provide such care. Obligations also need to be balanced against individual rights and interests.

The group recommended that countries devote some attention to developing policies defining health professionals' obligations in an influenza pandemic. This process should, for instance, involve not only government players but also professional societies, unions and others.

In addition, the group addressed the difficulty of clearly defining health professionals. For instance, would they comprise only the physicians and nurses working around influenza patients or include any other medical support staff? Even within the medical and nursing professions, how will countries define essential health care

workers in case of an influenza pandemic? The working group also discussed whether obligations should be defined for work within a professional's usual terms of reference or extend beyond them.

Further, there was some level of agreement that the enforcement of obligations should take account of the principles of necessity and proportionality: that is, they should be restricted to cases when clear benefits are to be expected.

Governments' obligations to health care workers were also discussed. Evidently, health care workers' increased obligations would need to bring them some gains. For instance, if health professionals take additional risks and larger workloads during a pandemic, they will expect governments and employers to contribute equally to minimizing their risks of infection and potentially to grant them compensatory benefits. For instance, a policy of prioritizing health professionals in vaccination or other preventive measures may come into play here. Governments may also introduce additional benefits for health professionals, in the form of financial incentives or benefits in kind, such as granting life insurance benefits.

Finally the group discussed promoting compliance with professional obligations. Formal sanctions may not be necessary or desirable, although a distinction needs to be made between the normal consequences of not showing up to work and the imposition of additional penalties. The consensus view was that any sanctions should be established in advance, with the participation of the people to be affected. An open question remains as to whether the imposition of sanctions should be conditional on the government/employers' fulfilment of reciprocal obligations.

## Discussion

The Forum participants' discussion of the working group's conclusions revealed mixed views on managing health professionals in pandemic influenza planning and response. It also showed that most countries are still working on their positions on professional management during a pandemic. Some countries clearly seem to assume that health professionals would volunteer during a pandemic, rather than be forced to work. There are limitations on this notion, however, as the numbers of professionals who would voluntarily make themselves available is not known. For instance, there are assumptions in North America that only about a fourth of health professionals would be prepared to work full-time or more than full-time in a pandemic.

Another option is to include lay people in medical service provision, although this, too, has major limitations; policy-makers will have no guarantee whether the need and demand for medical work will be met.

More solidarity may be expected from the older generation of professionals, who grew up with the spirit of solidarity in the 1960s, but the younger generation may be more difficult to attract to voluntary work.

Some arguments favour governments' explicitly asking health professionals to come to work; for example, making this compulsory might increase the status of work during a critical stage of a pandemic. If a government makes such a request, this may make it easier for health professionals to justify the work to their relatives.

Evidently policy-makers will have to ensure that health professionals working during a pandemic obtain extra benefits, and support for their families, as they will not be available to fulfil their usual obligations. Additional resources will need to be mobilized for this purpose. As this may become difficult when resources are needed

to combat the pandemic, alternative mechanisms will need to be sought. For instance, policy-makers may ask pensioners to care for the children of health workers who are continuously on duty.

Another concern is related to the challenge of encouraging health professionals who were trained in medical areas not related to pandemic influenza, to take on new functions. Notably, professional orders do not necessarily cover professional obligations and what happens in cases of non-compliance. There was broad consensus that imposing sanctions on those who do not meet their obligations set by governments would be extremely unpopular and might have negative effects.

Whatever the policy is, it is unlikely to result in an ideal solution to how best to manage health professionals in pandemic influenza planning and response.

## Developing a multilateral response

The fourth working group was devoted to developing a multilateral response to pandemic influenza. This can be seen from eth viewpoint of not only global justice and solidarity but also countries' evident interest in containing the epidemic, which will be a very strong argument in favour of international collaboration. Such collaboration would be beneficial in many areas, including surveillance and information exchange, virus sharing and vaccine development, rapid response and containment efforts, avoidance of disparities in care across borders and international peer review of preparedness and response measures. Ethical considerations in providing assistance to the countries in most need include ensuring that assistance is: granted in the acute phase, as well as after the pandemic, sensitive to local preferences and circumstances, and provided in agreement with the recipient country.



### 3. Principles for ethical decision-making in pandemic influenza planning

*“Ethics is about arguments that others can reasonably accept.”*



One of the major concerns in planning is the allocation of scarce medical resources – for example, antiviral drugs, mechanical ventilation and vaccination – in a pandemic. This implies a concern about ethical principles’ taking account of the one substantive principle targeting general human rights, and two more procedural principles of equity and fairness, and following fair procedures that enhance accountability.

#### Principles

##### **Objective: maximization**

A substantive principle would be to do the most good (that is, to maximize health protection) with the limited resources available. Maximizing health protection needs to be further defined, however, as it might relate to, for example, people’s lives, health or economic welfare. Decisions based on this principle might aim to save the most lives with the available resources or maximize health benefits, measured in quality- or disability-adjusted life-years (QALYs or DALYs) or life-years gained. Decisions aiming at general economic utility would require priorities to be set on particularly productive economic institutions or people, for instance.

Among the three decision-making principles, the principle of saving people’s lives is favoured by pandemic influenza policy-makers in countries and has been used as a simple and reasonable target in disaster situations. It is easier to communicate and justify to the public than, for example, the principle aiming at economic utility, which can be more easily abused. It is also easier to predict, and brings together utilitarian objectives and human rights. The disadvantage of the principle of maximizing health benefits is that it may imply that priority is given to securing possibly small benefits for many people over saving lives.

##### **Objective: ensuring equity and fairness**

A second principle is related to the objective of ensuring equitable and fair decisions in an influenza pandemic. Equity and fairness considerations have two implications: giving equal weight to the equal claims of individuals, which will prevent discrimination against and favouritism towards different population groups, such as rural and urban populations. A second implication is that unequal weight is given to unequal claims. For example, the medically worse off may have stronger claims to life-saving care than healthy people; high-risk groups will have stronger claims than low-risk groups, and young people will have stronger claims than elderly ones, who have had much more opportunities for a full life (the fair innings argument).

## **Objective: ensuring fair procedures and accountability**

This procedural principle is easier to implement than the others, as it can be related to more concrete steps, such as:

- ensuring publicization and raising awareness of the ethical principles for decision-making and their justifications;
- ensuring through consultation that the justifications are reasonably acceptable to all;
- ensuring concrete procedures for evaluations and revisions of pandemic influenza policies, plans and activities; and
- instituting clear policies and appointing authorities to enforce compliance.

## **Scenarios for the application of ethical principles**

This section provides examples of the application of the principles elaborated above to the distribution of medical goods in influenza planning.

### **Distribution of antiviral drugs**

Antiviral drugs can be used to treat infected patients, or prevent infections before and after exposure. Ethical considerations regarding antiviral influenza drugs apply not only to distributive decisions in countries but also the distributive aspects of stockpiling between countries, particularly since the drugs' availability is limited. Thus, a country that stockpiles for coverage of its whole population might undermine others' opportunities to acquire minimum protection.

What would then be a good-practice example of the ethical use of national stockpiles in the case of a pandemic? A health ministry could use national stockpiles to treat symptomatic patients, according to predetermined and published criteria, such as: to save the most lives possible, to focus first on the worst-off population groups or to sustain the functioning of the health care system, which implies giving priority to professionals caring for infected people. If not all patients can be treated, owing to the limited quantity of drugs available, then priority could be given to life-saving pandemic responders who are ill, patients at high risk of severe disease and death and relatively young patients. The health ministry would undertake targeted post-exposure prophylaxis to slow down the beginning of the outbreak and allow further drugs to be produced. Decision-makers would devote attention to low-income countries at risk of an influenza pandemic that cannot afford to purchase drugs.

### **Mechanical ventilation**

Applying criteria for the distribution of mechanical ventilation is more a medical/clinical than a policy question. Thus, medical criteria have been published to propose guidance for the triage of mechanical ventilation in case of a pandemic (7). Most of these have proposed that priority be given to those with a clear perspective of swift recovery, thus excluding patients with low chances. It has even been suggested that, in case of a pandemic influenza crisis, these criteria might be used to determine inclusion in intensive care units.

When more patients satisfy all medical criteria, selection will need to be made through non-medical criteria (for example, random selection or selection by age). Medical criteria for ethical decision-making have the advantage that they can be related to scientific evidence.

## **Vaccination coverage**

Vaccination is a medical procedure with a public health dimension and has features implying specific ethical policy considerations. For example, vaccination is only sensible for people not yet infected; it offers people the highest possible level of health protection against infection besides non-exposure, and, following a shortage of vaccine supply, one can expect supply to recover and increase over time.

Possible vaccination priorities for care providers therefore need to be supported by suggested ethical policy criteria. These could be, for instance, prioritizing children, with the possible justifications that by nature children spread disease and thus need to be immune to contain the disease within a population, and the fair innings argument. Policy-makers may also decide to prioritize groups at high risk of infection at certain times, but this would only be fair if all people had the prospect of being vaccinated over time. In general, giving high priority in vaccination to people caring for others in a pandemic has not been difficult to justify, although (as mentioned) differentiating these people from others may not be simple in a real case.

## **Concerns in defining and applying ethical decision-making principles**

### **Gaps between theory and practice**

Although policy-makers agree that principles for decision-making in case of a pandemic will be needed, numerous concerns arise in actually defining them. A major one is that principles are developed in theory, while unforeseen questions may hamper practical application in a real case.

To give a concrete example, a national plan for pandemic influenza preparedness may rule that personnel in charge of saving lives will be prioritized in vaccination and prophylactic antiviral therapy. How can one decide on entitlements of people involved in saving lives? This might be easy to determine for health care personnel, but what about the entitlements of fire-fighters, police officers, ambulance drivers or even those in charge of catering or cleaning in health institutions?

### **Communicating ethical principles across cultures**

Another area of difficulty is related to defining ethical principles across cultures. There is currently insufficient confidence in applying ethical principles in multicultural societies, as priority considerations within populations may differ widely.

### **Weighting different criteria**

Another problem is the question of weighting the different decision-making criteria against each other. In general, criteria for decision-making that leave less scope for interpretation will probably be preferred.

For example, the criterion of saving the highest possible number of lives might be preferred over the fair innings argument, since saving lives offers little scope for interpretation. In contrast, a weakness in the fair innings argument is that it can only be based on probabilities for the length of lives. Thus, it might be considered that, whenever possible, medical criteria should replace the criterion of age, as in the example of mechanical ventilation above.



## 4. National provisions for ethical decisions in influenza pandemic planning and response

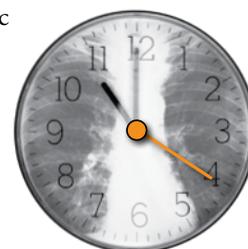
### The United Kingdom

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*“Pandemic influenza planning and response raises complex ethical problems on many issues and on many levels – from national policy to individual decision-making.”*

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The United Kingdom has a special committee to work on ethical aspects of pandemic influenza: the Committee on Ethical Aspects of Pandemic Influenza (CEAPI) (8). CEAPI was set up following recommendations of the Chief Medical Officer in his report of July 2005. It is set up on the level of the United Kingdom so that all four entities – England, Wales, Scotland and Northern Ireland – are represented. The 23 members vary in background; they include clinicians and representatives of professional bodies in the health sector, and representatives of the social sector, trade unions, private sector and media, as well as ethicists and lawyers. CEAPI’s main task is to develop an ethical framework for decision-making in case of an influenza pandemic.



The framework, which is part of the national influenza pandemic preparedness plan, applies to responses across the Government and is mainly designed for planners and policy-makers. CEAPI agreed to an overarching principle of equal concern and respect, which draws together a number of different ethical principles (see Table 1). These mean that:

- everyone matters;
- everyone matters equally but may not be treated identically;
- each person’s interest concerns everyone and society; and
- harm to anyone matters, so minimizing harm is a central concern.

The draft framework is composed of seven substantive principles and a composite principle of good decision-making. This framework is to be used as a checklist to ensure that all ethical dimensions are considered. Principles, however, are often in tension and have to be balanced. Thus a judgement is always necessary, and the framework cannot act as a calculator. The framework was subjected to public, policy and expert consultation between March and May 2007, with more than 150 comments received from individuals, institutions and professional bodies. These will be taken into account in revising the framework. The implications will still have to be worked through in specific situations, such as priority setting in the distribution of medical goods, for which concrete criteria would have to be formulated.

Principles	Content
1. Treating people with concern and respect	This means that: <ul style="list-style-type: none"> <li>everyone matters;</li> <li>people should be kept informed;</li> <li>people’s choices should be respected as much as possible.</li> </ul>
2. Minimizing harm	This includes physical, psychological, social and economic harm.
3. Fairness	This means that: <ul style="list-style-type: none"> <li>everyone matters equally;</li> <li>people with an equal chance of benefiting from an intervention should have an equal chance of receipt;</li> <li>good reasons are needed to treat some people differently from others: non-discrimination.</li> </ul>
4. Working together	This means: mutual aid, personal responsibility and sharing information.
5. Reciprocity	This means supporting those who are asked to face increased risks or burdens during a pandemic.
6. Keeping things in proportion	This means providing: accurate information and action that is proportionate to the potential risks and benefits.
7. Flexibility	This means adapting to new information and changing circumstances.
8. Good decision-making	This includes: openness and transparency, inclusiveness, accountability and reasonableness, which includes a basis in appropriate evidence and ensuring that the decision is practicable.

*Table 1. Principles included in the United Kingdom draft ethical framework for pandemic influenza planning*

## Switzerland

***“One of our key questions was: what is the least unfair solution?”***

Switzerland is a country in which people – experts as well as other citizens – have high expectations for public health policies. Thus, when the Federal Office of Public Health worked to update the national pandemic influenza preparedness plan in 2005, the national ethics committee wanted to know whether the planning team had taken account of ethical considerations. The committee proposed to provide a chapter of the plan addressing ethical considerations. When the drafting group started work on this chapter, it confronted numerous challenges, such as how to make sure that the ethical principles and objectives that had been designed in theory would remain valid in the very complex situation of a real influenza pandemic.

Much of the discussion concerned decision-making in view of scarce resources, so that a major issue in drafting the chapter was to agree on criteria for priority setting. While age did not play a major role in the discussions, people were afraid of an imbalance in the availability of appropriate medical goods in a pandemic: for instance,

that sufficient stocks of antivirals would be obtained, but a substantial shortage of ventilators, for example, would occur, so that the lack of ventilators would counteract the benefits from comprehensive coverage with antivirals. The initial discussions resulted in more concrete questions to be addressed:

- to clarify the ethical problems arising from issues relating to the distribution of scarce resources to prevent and treat pandemic influenza; and
- to define the principles for allocation procedures.

These considerations resulted in an agreement on goals to be achieved in, for example, defining resource allocation criteria.

The whole group finally agreed to the following goals:

- to preserve life;
- to minimize the number of victims;
- to sustain/create a climate of trust and solidarity;
- to ensure an orderly distribution of scarce resources and goods;
- to maintain essential public services; and
- to maintain public order.

The implications of some of these were extensively discussed, such as the goal of maintaining public order; the drafting group was concerned that an influenza pandemic would result in excessive government control. The group also discussed a set of values – such as solidarity, individual freedom, proportionality, privacy, fairness and trust – and formulated a number of assumptions, including that members of society:

- would want to act in as a united manner as possible;
- would want to stand with and support those in need of help and make joint efforts;
- would have an instinct for self-preservation, and fear and trauma could have unexpected effects; and
- would not all voluntarily comply with restrictions in a life-threatening crisis.

The group debated priority setting in particular, leading to consideration of possible options, such as making more resources available, transferring resources from other areas less important to life or limiting resources. Distribution of medical goods such as vaccines would have to be managed under the view of fairness, which means that every individual is considered equal, although all could not be treated according to their individual claims. Thus, realizing ideal fairness in distribution would not be feasible, but policy-makers should aim to identify the least unfair decision as a solution. In addition, some broader societal principles justify distribution decisions, such as the needs to contain infection, to save the maximum number of patients and to maximize the effectiveness and efficiency of prevention and treatment. These would need to be met through a number of process-oriented principles, such as transparency, timely provision of information and triggering of debate, practical feasibility, adaptability and accountability.

Translating these into practice would entail a number of mechanisms for international and national intra- and intersectoral cooperation. In particular, these would include cooperation with neighbouring countries, the groups and individuals concerned, and policy-makers at all levels (federal, cantonal and local), and regular review of measures implemented and planned.

## Norway

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*“We seem to have good plans in place, but we don’t know whether they are sufficient – this has yet to be proven in a real case.”*

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In Norway, regulations on pandemic influenza planning are linked to legislation on the prevention and control of communicable diseases with special provisions for crises. This legislation delegates formal authority for decision-making to the Norwegian Institute of Public Health and the Directorate for Health and Social Affairs, although in practice the health ministry and other government institutions would be likely to resume some duties, such as those linked to crisis communication. An advisory committee is working on priority-setting questions in pandemic influenza planning. Criteria for resource allocation in case of a pandemic are based on scenarios that were developed on projected probabilities. For instance, different criteria are set for the most likely case and the worst-case scenario. The latter is based on the example of the 1918 influenza pandemic, in which 50% of the population was infected.

The priorities set give different groups particular weight. The first is health care professionals in close contact with patients, and patients with particular (chronic) diseases. The next category of people comprises those with the highest potential for further prevention of influenza among the population. This category is still being consolidated, but it may mean that priority will be given to younger people. Special attention is also given to fairness in geographical distribution of medical goods, such as vaccines.

While the pandemic influenza preparedness plan is thought to provide a good advance agreement on the lines of decision-making and consecutive accountability, it is not expected to provide a blueprint in case of an influenza pandemic. Even with the plan in place, the Government must still make and/or approve many decisions and communicate them to the public.

## Discussion

The cases of Norway, Switzerland and the United Kingdom illustrate that countries are already devoting considerable effort to addressing the ethical aspects of pandemic influenza planning. In Switzerland and the United Kingdom, principles for ethical decision-making and criteria – for instance, for setting priorities in making medical goods available to certain groups – have been worked out for integration into the national preparedness plans. In Norway, lines of decision-making and thus responsibility and accountability in case of a pandemic are regulated and an advisory committee is working on ethical guidance for different scenarios and probabilities.

Nevertheless, considerable uncertainties may still need to be taken into account when planning for an influenza pandemic. For instance, what level of solidarity can one expect in a crisis? Governments’ decisions on priority groups for access to certain medical goods in case of a pandemic will require a certain level of compliance by the population with these decisions. This will require solidarity. Past crises, however, such as the heat-wave in 2003, which caused 5000 deaths in excess of the regular mortality rate in France, illustrated that these basic social values can be put at risk. Policy-makers planning for an influenza pandemic may therefore need to take account of a potential decline of solidarity, or tailor policies to the individual from the outset.

This was done in Switzerland, for instance, where the Government explicitly promoted the purchase of ventilation masks by Swiss citizens to prevent infections through direct contact in case of an influenza pandemic. The Government launched information campaigns illustrating the benefits of masks and recommending stockpiling of masks in individual households. The purchase of masks was entirely voluntary, however, and the government did not regulate their prices. In effect, a highly competitive market for masks emerged, and numerous outlets started to sell them, including petrol stations and department stores. This competition brought down the price to €2 for 50 masks. As a side effect, health institutions realized that they had purchased masks – for instance, for surgery – at far higher prices. The mass media were divided on the Government’s recommendation to purchase masks.

France has launched information campaigns recommending frequent hand hygiene in general, and mask use for people suffering from influenza in the case of seasonal influenza. Other countries, such as the United Kingdom, have instead focused on recommending hand hygiene alone.

## 5. National decision-making structures on pandemic influenza planning and response

### Belgium

In Belgium, decision-making for public health is divided among policy-makers at different levels: federal, regional and community. The regions and communities are responsible for preventive measures in public health. This also applies to influenza prevention; for instance, seasonal influenza vaccination is provided at the regional level. A regional health minister handles the public health affairs of the 10 regions. Although a national plan provides some guidance for regions (see below), the 10 regional health ministries develop their own contingency plans. The Federal Public Service (FPS) – in essence a national health ministry – acts as a focal and reference point for public health, but by no means as the solely responsible institution. Nevertheless, it provides some specific authoritative expertise in pandemic influenza planning through, for instance, the supervision of associated scientific institutions: the Scientific Institute of Public Health, the Veterinary and Agrichemical Research Centre and the Superior Health Council. In addition, the FPS runs the federal agencies for drug and food safety.

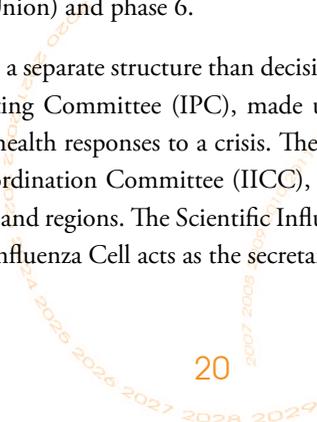


A special commission for pandemic influenza planning, the Interministerial Influenza Commission, was appointed in October 2005, as a result of a joint decision by the FPS, the regional governments and the communities. It was headed by a commissioner who was accountable to several federal ministries and managed 12 staff. The Commission was advised by a scientific advisory board, and accountable to a board with representatives from all the administrations and departments concerned. The Commission had two major tasks: to draft a national pandemic plan by summer 2006 and to coordinate all the activities to be undertaken in ensuring national influenza preparedness.

In 2006 the first national pandemic influenza preparedness plan was approved; a first national influenza pandemic exercise followed. The Commission then became part of the incident and crisis management department of the FPS, and was renamed the Influenza Cell. The Influenza Cell is now responsible for revising the national preparedness plan in the light of conclusions from the national exercise.

For response to an influenza pandemic, national coordination has become a core activity, drawing on the lessons learned from earlier health crises in Belgium, such as the dioxin crisis in 1999. National coordination comes into effect when a pandemic is declared by WHO and international spread is observed: at phase 4, with confirmed human cases in Belgium or in bordering territories, and in general at phase 5 (except for all cases confirmed outside the European Union) and phase 6.

Decision-making in a crisis follows a separate structure than decision-making in normal circumstances. In these circumstances, the Influenza Piloting Committee (IPC), made up of representatives of the political parties, makes decisions related to public health responses to a crisis. These are then coordinated and managed within the Interministerial Influenza Coordination Committee (IICC), which includes representatives of the federal departments and the communities and regions. The Scientific Influenza Committee provides scientific advice to both the IPC and the IICC. The Influenza Cell acts as the secretariat of these three bodies.



In a crisis, the Prime Minister must approve all major decisions. The Governmental Crisis and Coordination Centre (GCCC) coordinates crisis response, and is headed by a person appointed by the Prime Minister. The GCCC has a management unit, chaired by the minister of the interior with the support of the minister of public health; an assessment unit responsible for operations, monitoring and analysis; and a communication unit responsible for outbreak communication and press relations. Thus, in a crisis the internal affairs minister takes charge, not that for public health. Decision-making authority does not change at subnational levels.

### Discussion

The experience in Belgium illustrates that many problems related to an effective and ethical response to the threat of an influenza pandemic rest in the need to coordinate action at the national level, while public health legislation provides for a fairly decentralized management of public health responses.

Some other countries address the problem of coordination in a crisis. For instance, public health service delivery in **Norway** is delegated to the 430 municipalities; in case of a pandemic, they would formulate individual responses. There is no central coordination mechanism, partly due to the tradition of entrusting medical professionals with effectively managing public health responses to crises at the service delivery level. The question whether there should be a centralized coordination system has not yet been answered at the policy level.

Similarly, **Sweden** has 21 county councils, and some coordination is done at the level of the standing committee of county councils. Nevertheless, the municipalities are in charge of public health responses to an influenza pandemic: for instance, closing schools when infections accumulate. In Sweden, too, the question of central-level coordination mechanisms is still to be tackled.

**Israel** handles this issue somewhat differently; the Ministry of Health is the central authority responsible and accountable for public health responses to an influenza pandemic. In contrast to arrangements in Belgium, in Israel the Minister of Health is responsible for managing large public health emergencies. Similarly, the Director-General for Health in the Ministry has a fair amount of authority to decide on concrete measures to protect population health, such as closing schools or other institutions that may carry some potential for the further spread of an infectious disease. The Director-General for Health can also call a committee of directors-general from different ministries to make decisions with effects beyond the health care sector.

In the **United Kingdom**, decision-making is dispersed, especially since very few decisions clearly lie within one sector only. The country therefore also uses an interministerial national committee to make these decisions. For instance, oseltamivir (Tamiflu) stockpiling was decided at the national level, but many private companies have started stockpiles to protect their staff, and the Government has little information on how these companies will distribute the drug during a pandemic. This poses a real problem in terms of ethical allocation criteria and illustrates the need for an intersectoral approach.

In **Denmark**, responsibility for public health is delegated to subnational levels and in general the central level prefers not to intervene unless necessary. In some matters related to the delivery of clinical care, the National Board of Health is responsible for overseeing the implementation of national policies. For example, the Ministry of Health tried to limit waiting time for all cancer patients requiring radiotherapy treatment to a maximum of four weeks; when it became evident that the target could not be reached, the National Board of Health engaged in a priority-setting exercise to select patients for treatment abroad.

## 6. Endorsing ethical principles through public involvement



### Means of public participation

The Forum discussion generated a range of possible direct means of promoting public participation in endorsing ethical principles through, for instance, surveys (providing quantitative information on views and preferences), focal groups, public fora or conferences (providing quantitative information), web site publications of policies (including the encouragement of feedback and suggestions) and hotlines to policy-makers and/or experts. Media communications are indirect means of ensuring better public information.

### Survey on public participation

The participants were asked three questions. The following summarizes the results.

#### **Are you aware of any provisions in your general public health legislation for incorporating people's views into public health policy choices?**

Overall, general public health legislation in most countries does not yet provide for the incorporation of the public's views, partly since decision-making by democratically elected representatives is already thought to represent the population's preferences. Nevertheless, some countries have defined principles and methods of incorporating people's views in their national health policies or plans.

In some countries, regulations on incorporating the public's views into public health policy choices are defined for particular public health fields, such as legislation on genetically modified organisms in Belgium.

Some countries delegate the responsibility for ensuring public involvement to other institutions. For pandemic influenza planning, Israel has delegated this responsibility to the Israeli council for medical bioethics.

While the Netherlands and the United Kingdom have no explicit legal provisions, their new legislation is more and more subject to organized public hearings and consultations with patient organizations and other bodies that have a representative function.

#### **Does your work on influenza pandemic preparedness provide for the incorporation of people's views and preferences for policy choices in case of an influenza pandemic?**

Some countries concentrate on discussing their preparedness plans with professional bodies.

Denmark, Israel and Luxembourg have published their plans on the Internet for public scrutiny and encourage feedback and suggestions in general, not necessarily on the ethical dimensions of the plan that need further elaboration. In Belgium, public consultation is planned.

Sweden has organized focus groups to discuss people's views and fears on pandemic influenza planning. In addition, all the municipalities have been consulted to define the list of essential services in a pandemic.

## **What do you think in general about giving people the opportunity to express their views on such choices (advantages, disadvantages)?**

Public participation is associated with obvious advantages, such as; increased public information, awareness and preparedness, greater potential compliance with critical policy decisions as the public feels part of the decision-making process, and greater transparency of policies. Policy-makers may benefit from public participation by better understanding the public's hidden preferences and concerns on critical public health choices.

Nevertheless, arguments can be made against public participation on such difficult choices as priority setting for access to medical goods in a pandemic. These include the possibility that the discussion could become very emotional, and create confusion and anxiety among the population, particularly as pandemic influenza is a complex public health emergency that requires objective and evidence-based responses. Thus, policy-makers might prefer to focus on engaging experts and specialists who advise the government on policy choices, rather than the general public.

In addition, it will not be possible to demonstrate how people's views are incorporated into decision-making, and this may create additional frustration. Policy-makers will therefore have to give clear definitions of the objectives and limitations of consultation. Methodological problems can also arise, as different focus groups may generate conflicting results. Further, policy-makers will need to take care that public discussion is not abused to communicate other issues, such as people's dissatisfaction with the government. Finally, public participation may significantly slow down the policy-making process.





## 7. Conclusions and recommendations

### Incorporating ethical considerations in pandemic preparedness planning

There was broad agreement in the Forum that the time is right to address the ethical aspects of pandemic influenza planning and that ethical considerations are of national and international concern and major public health relevance. The participants also agreed that national pandemic preparedness plans are suitable tools to address ethical principles and criteria for decision-making. All countries represented at the Forum reported on progress in their pandemic influenza planning, but planned to do more to incorporate ethical considerations into their plans and to make ethical principles and criteria for decision-making more explicit.

France, Switzerland and the United Kingdom have started to design explicit ethical frameworks for pandemic influenza planning. Although they present their values, principles and criteria in different ways, they are moving in the same direction: the conclusion that responses in a case of a pandemic will rest on a number of principal values related to trust and solidarity, respect for people and their individual choices, and a commitment to minimize harm and to ensure the fairness, transparency and accountability of public policy. Yet policy-makers also need to recognize that some of these principles might still need to be balanced in a real pandemic, as they may present conflicting foundations for decision-making (for example, solidarity and respect for individual choices).

### Deciding on principles for normative ethical decision-making and their objectives

A number of measures during an influenza pandemic require decisions to be made; these might be based on different criteria, such as lives saved, age or focus on those most at risk. Ideally ethical standards and principles should be set and communicated to the public before a pandemic occurs. They might be driven by the objective of the decision, or procedural. For example, setting priorities for the distribution of medical goods might best be based on the objective of saving the greatest number of lives. This is simple and intuitively reasonable to communicate and justify in a disaster. Maximizing general utility (such as economic productivity) is often an objective more open to abuse and more difficult to communicate and justify. Maximizing health benefits, on the other hand, may involve giving priority to securing small health benefits for many people, at the expense of saving lives.

Principles must also be agreed on procedural aspects, such as equity, the fairness of procedures and accountability. Regarding equity, the fair innings argument is not acceptable to most countries. Decisions will have to be made so that equal weight is given to individuals' equal claims and that unequal weight is given to unequal claims. This means that, in general, the worse off have stronger claims to life-saving care.

Ensuring fair procedures and accountability is probably the easiest principle to implement, as more concrete steps can be recommended, such as:

- ensuring publicization and raising awareness of the ethical principles for decision-making and their justifications;
- ensuring through consultation that the justifications are reasonably acceptable to all;
- ensuring concrete procedures for evaluations and revisions of pandemic influenza policies, plans and activities; and
- instituting clear policies and appointing authorities to enforce compliance.

Defining normative principles and their objectives is by no means easy, however, as different principles may conflict and allow different interpretations in a real case.

### **Striking the balance between effective centralized authority and decentralized decision-making**

In responding to an influenza pandemic, countries will face the challenge of ensuring effective implementation at the regional and local levels and meeting a high demand for public accountability for measures such as priority setting in access to medical goods, which might be critically regarded by the public. There are good arguments for a single and central authority that has sufficient power to implement public health responses at all levels of the country. On the other hand, many decisions related to the public health response to an influenza pandemic will not affect only health but also many other sectors; this is an argument for a strong intersectoral coordination mechanism. In responding to a pandemic, many countries will need to deal with considerable autonomy on subnational levels – such as regions, counties or municipalities – in tailoring public health service delivery to their local needs. Countries such as Belgium have therefore created special command structures for an influenza pandemic or other public health crises, which will supersede existing authorities in a non-critical phase such as planning. Thus, decision-making in crisis follows different lines of responsibility in Belgium, which emphasizes central control and gives executive power to a national coordination structure commanded by the interior ministry.

Many countries deploy a decentralized model for public health decision-making, and therefore still face the challenge of translating ethical frameworks for pandemic influenza planning to the regional level. In many cases, preparedness plans are first developed at the national level and then the regions are assisted to develop their plans accordingly. Special attention has to be given to the private sector, which does not always adhere to public policies.

### **Ensuring that preparedness involves all sectors and remains dynamic**

Several countries have revised their national pandemic influenza preparedness plans to make them intergovernmental: for instance, forming interministerial commissions in Belgium, Israel and the United Kingdom. In fact, many aspects of a response to a pandemic are intersectoral and do not affect only the health sector. Israel has also undertaken drills involving all ministries and industry.

## Ensuring ethical standards in cross-border care

The Forum participants discussed three questions in the context of ethical dimensions of cross-border care: how to deal with tourists and citizens living abroad, the influx of refugees and the people who work across borders. For example, how does one set priorities for periods in which increased numbers of people temporarily reside in countries, such as the tourist season? Who is responsible for protecting expatriates: their host country or countries of origin?

To address these issues, it was suggested that international groups of peers working on pandemic influenza preparedness plans be formed to limit inconsistencies in addressing cross-border issues.

## Managing health professionals in pandemic influenza planning and response

Health professionals' management to prepare for a pandemic was perhaps the issue of most interest to participants at the Forum. Different possibilities were identified to make sure that health professionals would make themselves available to provide medical services during a pandemic. Government orders may help to raise the profile of this work, and enable health professionals to free themselves from other obligations. Still, many policy-makers prefer to count on either voluntarism or professional orders. Policy-makers will have to ensure that health professionals obtain extra benefits for making themselves available during a pandemic, and receive support for their families. This will require additional resources that need to be set aside at the outset of a pandemic. Sanctions for those who do not comply with their obligations to come to work should be avoided.

One of the key challenges is better to define the group of health professionals obligated to come to work and care for patients during a pandemic.

## Ethics and public participation

Overall, general public health legislation does not yet provide for the incorporation of the public's views into most countries' health policies or plans, but some countries have addressed principles and methods for public participation. While some countries have defined concrete structures for public participation in health policy-making, many organize more and more public hearings and consultations on new legislation.

As mentioned, public participation might be promoted through surveys, focal groups, public fora or conferences, web publications of policies that encourage feedback and suggestions, and hotlines to policy-makers and/or experts.

Some countries concentrate on discussing their preparedness plans with professional bodies; others publish their plan on the Internet for public scrutiny and encourage feedback and suggestions in general, but not necessarily on the ethical dimensions of the plan that need further elaboration.

The question of whether ethical considerations in pandemic influenza planning should be subject to public participation does not have only one answer. Public participation has advantages from the perspective of both the public (such as increased awareness and preparedness, and greater transparency of policies) and policy-makers (such as achieving greater compliance with policies and understanding the public's hidden preferences

and concerns on critical public health choices). There are also disadvantages; for example, public participation may trigger confusion and anxiety in the population and retard the decision-making process. Thus, policy-makers might prefer to focus solely on evidence-based decision-making, matched with engaging experts and specialists to advise on policy choices, rather than the general public. This view is supported by the assumption that the public has already participated in democratically electing their representatives as decision-makers for health.

Overall, there is no correct answer to the question of whether the public should be involved in ethical choices in pandemic influenza planning; policy-makers will need to weigh the advantages against the disadvantages. Further work is needed, for example, to decide more specifically what policy areas are to be subject to public consultation.

### Managing uncertainty in pandemic influenza planning

The discussion of cases in countries showed that policy-makers face considerable uncertainty in projecting how best to manage a pandemic influenza crisis. Although planning can enhance preparedness and minimize uncertainty, countries still need to make momentous choices. Unfortunately, there are no blueprints for the best and most ethical choices.

### Last word

Although it was aimed to generate generic insights into ethical governance approaches in countries, the Forum showed that the principles of ethical governance are very topic specific. Influenza is a very particular disease, from which patients either recover (in most cases) or die. The infection itself cannot become a chronic disease. As it has in the past, influenza may also wipe out large parts of populations. This makes ethical considerations very particular; thus generic approaches to ethical governance must still be reviewed in the technical context of particular public health challenges.

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