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Ethical considerations in developing a public health response to pandemic influenza

World Health Organization

ETHICS, EQUITY, TRADE AND HUMAN RIGHTS

EPIDEMIC AND PANDEMIC ALERT AND RESPONSE

Ethical considerations in developing a public health response to pandemic influenza

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[1] Renamed Department of Ethics, Equity, Trade and Human Rights as of 1 November 2007.
[2] Renamed Cluster of Health Security and Environment (HSE) as of 1 November 2007.

Glossary

Confidentiality: The obligation to keep information secret unless its disclosure has been appropriately authorized by the person concerned or, in extraordinary circumstances, by the appropriate authorities.

Epidemic/pandemic (*1*)**:** An epidemic is the occurrence in a community or a region of cases of an illness, specific health-related behaviour or other health-related events clearly in excess of normal expectancy. A pandemic is an epidemic occurring worldwide or over a wide area crossing international boundaries, and affecting a large number of people. The *WHO global influenza preparedness plan* (*2*) includes six phases in a pandemic scale, divided into three periods: the inter-pandemic period, the pandemic alert period, and the pandemic period. (These phases are defined in order to propose a framework for pandemic preparedness planning activities; the proposed phases may not all be detectable in sequence).

Equity: The fair distribution of benefits and burdens. In some circumstances, an equal distribution of benefits and burdens will be considered fair. In others, the distribution of benefits and burdens according to individual or group need will be considered fair. For example, in some circumstances, it may be equitable to give preference to those who are worst off, such as the poorest, the sickest, or the most vulnerable (*3*). Inequities are differences in health that are unnecessary, avoidable, and are considered unfair and unjust (*4*).

Fair innings argument: This argument reflects the idea that everyone is entitled to some "normal" span of life years. According to this argument, younger persons have stronger claims to life-saving interventions than older persons because they have had fewer opportunities to experience life (*5*). The implication is that saving one year of life for a young person is valued more than saving one year of life for an older person.

Fair process: Daniels and Sabin (*6*) propose the following key elements in a fair process for setting priorities:

- **Publicity:** The process, including the rationale for setting priorities, must be made public and transparent; consultations and public hearings should be held. Publicity and involvement of key stakeholders are particularly important in contexts where policy and programmatic decisions occur in a multi-actor environment and affect large parts of the population.
- **Relevance:** The affected stakeholders must view as relevant the reasons, principles and evidence that form the basis of the rationale for fair decision-making on priorities.
- **Revisability and appeals mechanisms:** In the case of new evidence and arguments, the process must allow for reconsidering and revising decisions. It must allow for an appeals process that protects those who have legitimate reasons for being an exception to the adopted policies.
- **Enforcement or regulation:** There must be a mechanism in place that ensures that the previous three conditions are met.

Human rights: Human rights are universal legal guarantees protecting individuals and groups against actions that interfere with fundamental freedoms and human dignity. Some of the most important characteristics of human rights are that they are guaranteed by international standards; legally protected; focus on the dignity of the human being; oblige states and state actors; cannot be waived or taken away (although the enjoyment of particular human rights may be limited in exceptional circumstances); are interdependent and interrelated; and universal (*7*).

International travel and border controls: Measures that are designed to limit and/or con-

trol the spread of infection across entry points to a country (by road, air, sea, etc). They can include travel advisories or restrictions, entry or exit screening, reporting, health alert notices, collection and dissemination of passenger information, etc.

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 (*1*).

Necessity: Public health powers are exercised under the theory that they are necessary to prevent an avoidable harm. Government, in order to justify the use of compulsion, 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" (*1*).

Palliative care: Palliative care is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and assessment and treatment of pain and other problems, physical, psychosocial and spiritual (*8*).

Prophylactic measures: Measures to defend against or prevent disease.

Proportionality: 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.

Quarantine: The restriction of the movement of healthy persons who have been exposed to a suspected or confirmed case of infection with a highly communicable disease during the likely infectious period (*1*). It is a precaution aimed at preventing further spread of infection to other people.

Reciprocity: A relationship between parties characterized by corresponding mutual action. Reciprocity calls for providing something in return for contributions that people have made (*3*). For example, reciprocity implies that society should support those who face disproportionate burdens in protecting the public good, as well as taking steps to minimize those burdens as much as possible (*9*).

Social-distancing measures: 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 worksite or in other locations (e.g. substituting phone calls for face-to-face meetings, avoiding hand-shaking).

Distributive justice/global justice: This ethical principle requires that the risks, benefits, and burdens of public health action be fairly distributed. Beauchamp and Childress (*10*) view distributive justice as the "fair, equitable, and appropriate distribution in society determined by justified norms that structure the terms of social cooperation". *Global justice* is social justice on a global scale and it requires countries, particularly developed countries, to ensure not only that their own citizens are protected, but also that other countries, particularly developing countries, have the means to protect their citizens.

Solidarity: Union or fellowship between members of a group or between peoples of the world. Individuals in solidarity with one another are firmly united by common responsibilities and interests, and undivided in opinion, purpose and action (*11*).

Therapeutic measures: Measures taken to combat infection or disease.

Triage (*1*)**:** The process of selecting for care or for treatment those of highest priority or, when resources are limited, those who are more likely to benefit (from the French "*trier*": to sort, choose).

Transparency: An ethical principle that requires policy-makers to ensure that their decision-making process is open and accessible to the public, through clear and frequent communication of information.

Utility/efficiency: The principle of *utility* requires that one acts so as to maximize aggregate welfare. This implies an additional principle of *efficiency*, i.e. the idea that benefits should be obtained using the fewest resources necessary.

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1
Introduction

Although we cannot predict when the next influenza pandemic will occur, since the 16th century, the world has experienced an average of three pandemics per century, occurring at intervals of 10 to 50 years (*1*). Morbidity and mortality have varied across pandemics, making accurate predictions of the impact of the next pandemic impossible. However, a new influenza pandemic may result in a significant burden on human health and lead to major social and economic disruption. In addition, the implementation of public health measures aimed at limiting social interaction (such as restrictions on gatherings and population movements) are likely to have a major impact on trade and tourism. In view of these possible consequences, countries and the international community must prepare to cope with a pandemic and mitigate its impact.

Many critical ethical questions arise in pandemic influenza planning, preparedness and response. These include: Who will get priority access to medications, vaccines and intensive care unit beds, given the potential shortage of these essential resources? In the face of a pandemic, what obligations do health-care workers have to work notwithstanding risks to their own health and the health of their families? How can surveillance, isolation, quarantine and social-distancing measures be undertaken in a way that respects ethical norms? What obligations do countries have to one another with respect to pandemic influenza planning and response efforts?

If these questions are not properly addressed in planning, the response efforts in the event of a pandemic could be seriously hampered. A publicly-discussed ethical framework is essential to maintain public trust, promote compliance, and minimize social disruption and economic loss. As these questions are particularly difficult, and there will be insufficient time to address them effectively once a pandemic occurs, countries must discuss them now while there is still time for careful deliberations.

Responding to the request by Member States, WHO's Departments of Epidemic and Pandemic Alert and Response and of Ethics, Trade, Human Rights, and Health Law[1] launched a joint project on "Addressing ethical issues in pandemic influenza planning". In March 2006, WHO established four working groups (corresponding to Chapters 3–6 of this document) to deliberate on key ethical questions related to a potential influenza pandemic. On 18–19 May 2006 technical meetings of the working groups took place in Geneva, Switzerland. Based on the discussions at those meetings and the comments received, four background papers were written. These papers then formed the basis for deliberations at a global consultation that took place on 24–25 October 2006 in Geneva. The consultation was attended by some 100 experts and representatives from international organizations, WHO staff from regional offices and headquarters, and observers from Permanent Missions in Geneva. The main objective was to discuss, on the basis of the draft background papers, the ethical issues to be addressed in developing and implementing a public health response to pandemic influenza, and to lay the groundwork for the formulation of WHO guidance in this field. This document has been produced from the insights gained from the consultation, further international meetings, and other inputs including the report entitled *Stand on guard for thee* (*2*) by the University of Toronto Joint Centre for Bioethics (WHO Collaborating Centre), Canada, the discussion forums organized by the Espace Ethique (Paris, France), and WHO regional

[1] Renamed Department of Ethics, Equity, Trade and Human Rights as of 1 November 2007

workshops on rapid containment held in Cambodia, Indonesia, Kazakhstan and Saudi Arabia.

The purpose of this document is to assist social and political leaders at all levels who influence policy decisions about the incorporation of ethical considerations into national influenza pandemic preparedness plans (for link to national plans see Annex). The document focuses on priority setting and equitable access to resources, restriction of individuals' movements as a result of non-pharmaceutical interventions (including isolation of cases, quarantine of contacts, and limitation of social gatherings), the respective obligations of health-care workers and their employers and governments, and the obligations of countries vis-à-vis each other. Key ethical principles emphasized include equity, utility/efficiency, liberty, reciprocity, and solidarity. The document also addresses the need for transparent and timely sharing of information to improve evidence-based policy design and facilitate public engagement in the decision-making process.

This document addresses issues related to public health, primarily those likely to arise during the pandemic alert period and the pandemic period (see Glossary). Since specific decisions will depend on local circumstances and cultural values, it will be necessary to adapt this global guidance to the regional and country-level context, with full respect to the principles and laws of international human rights.

2
General ethical considerations

Balancing rights, interests and values

Preparedness planning for an influenza pandemic involves balancing potentially conflicting individual and community interests. In emergency situations, the enjoyment of individual human rights and civil liberties may have to be limited in the public interest. However, efforts to protect individual rights should be part of any policy. Measures that limit individual rights and civil liberties must be necessary, reasonable, proportional, equitable, non-discriminatory, and in full compliance with national and international laws.

In balancing competing interests and values, policy-makers can draw on ethical principles as tools for weighing conflicting claims and for reaching appropriate decisions. Ethics does not provide a prescribed set of policies; rather, ethical considerations will be shaped by the local context and cultural values. The principles of equity, utility/efficiency, liberty, reciprocity, and solidarity (see Glossary) are especially helpful in the context of influenza pandemic preparedness planning. Although these principles often give rise to competing claims, they provide a framework for policy-makers to assess and balance the range of interests that follow from them. All ethical deliberations must take place within the context of the principles of human rights, and all policies must be consistent with applicable human rights laws.

The evidence base for public health measures

Public health measures that involve significant costs and/or burdens should be reserved for situations where they can be reasonably expected to make a difference to the consequences of a pandemic. Because little may be known about the virulence and transmissibility of the next influenza pandemic virus until it has started spreading widely, judgments about the likely effectiveness and benefits of public health measures will often be difficult and may change over time. Policy-makers should base their decisions on the best available evidence at any given time. To facilitate these efforts, in the event of a pandemic, WHO will attempt to disseminate evidence-based guidance as rapidly as possible, as the pandemic threat evolves. Preparedness plans should be flexible enough to allow timely adaptation as new evidence about the nature of the disease arises.

Transparency, public engagement and social mobilization

Public engagement and involvement of relevant stakeholders should be part of all aspects of planning (*3*). Policy decisions and their justifications should be publicized and open to public scrutiny. This will help to:

- increase public awareness about the disease-related risks and enable people to take steps at individual, family, workplace and community level to prepare for and respond to an influenza pandemic;
- contribute to the development of adequate and effective plans and increase public confidence that policies are reasonable, responsive, non-discriminatory, and in line with local circumstances and values;
- secure the agreement of the public and civil society on the use of therapeutic and prophylactic measures and their distribution;
- provide useful feedback to planners regarding both information that they may lack (such as on local conditions) and the acceptability of their plans to the general public;
- maintain public trust, add to the legitimacy of plans, and ensure the accountability of decision-makers both in the planning stage and during a plan's implementation;

- promote public compliance and mitigate fears of the unknown and the possibility of social disruption or panic that can result, particularly in circumstances where the public is expected to make sacrifices and possibly incur financial loss or infringements of their personal autonomy.

Information, education, and communication

In order for public engagement in preparedness planning to be meaningful, effective modes of communicating with and educating the public about the issues involved are essential. The principles of outbreak communication are: trust; transparency; communicating to the public early, dialogue with the public; and planning (*4*). Advance planning will allow the development of strategies that will reach the entire population and that are linguistically and culturally appropriate. The following types of information should be communicated during all periods, including the inter-pandemic period:

- the initiatives being undertaken to allow citizens or communities to participate in the development of pandemic response policies;
- the nature and scope of the threat and related risks, and the spread of the pandemic;
- the steps that are being taken to respond to the pandemic, including new policy developments and their justifications;
- scientifically sound, feasible and understandable measures people can take to protect themselves and/or others from infection.

The decision-making criteria and procedures that will be used during an influenza pandemic should be communicated to the public as far in advance as possible. Some of this information will inevitably be uncertain and this uncertainty should also be communicated in clear, non-alarmist language. Information available will change continuously throughout the pandemic, requiring adjustments of response strategies based on ongoing assessments of the risks and potential benefits of interventions. These adjustments, and the justification for them, should be communicated to the public.

Resource constraints

While all countries must make reasonable efforts to prepare for an influenza pandemic, differences in access to resources mean that what is reasonable for one country may not be reasonable for another. In developing countries, limited resources and immediate health-care needs may make it difficult to develop and implement comprehensive plans (*5*, *6*). In some cases, it may be possible to generate resources by using available funds more efficiently. In addition, some measures, such as developing culturally-sensitive communication strategies, may be achievable with a relatively modest commitment of resources. However, at some point countries will have to make difficult decisions about the relative weight to be given to pandemic preparedness compared to other important public health priorities, such as HIV and malaria. These decisions about resource allocation should be informed by a process of public engagement, and their rationale should be clearly communicated to the public.

The resource constraints facing developing countries, as well as the global nature of the threat, underscore the importance of international cooperation in developing a global response to an influenza pandemic (see Chapter 6).

3

Priority setting and equitable access to therapeutic and prophylactic measures

An influenza pandemic will require countries to make difficult decisions regarding the allocation of limited therapeutic and prophylactic measures (see Box 1). Many different ethical principles can be applied to rationing and priority-setting in health care. The principle of utility, for example, suggests that resources should be used to provide the maximum possible health benefits, often understood as "saving most lives". The principle of equity requires that the distribution of benefits and burdens be fair (see Glossary). When these principles conflict, the appropriate balance to be struck should be determined in an open and transparent process that takes into account local circumstances and cultural values.

General considerations

As part of pandemic influenza planning, policymakers should establish a **process for setting priorities and promoting equitable access** that:

- involves civil society and other major stakeholders in the decision-making process (see Box 2) so that decisions about the criteria to be used in allocating scarce resources are made in an open, transparent, and inclusive manner;
- incorporates clear, pre-established mechanisms for revising decisions based on new evidence when appropriate.

Even when access to treatment or prophylaxis is limited, the public is entitled to **timely and accurate information**. Communication strategies should ensure that the public has access to information about:

- the availability of drugs for treatment and prophylaxis;
- the availability of other preventive and therapeutic measures;
- the standards and procedures that will be used to guide the allocation of drugs and other preventive and therapeutic measures;
- how individuals can access whatever therapeutic and prophylactic resources are available for themselves, their families, and their communities.

Regardless of the criteria selected to govern the allocation of therapeutic and preventive measures, certain **basic elements** will be important in all plans. These include:

- facilitating access to the highest level of treatment possible given available resources, with careful attention to the needs of all populations (see also Chapter 6);
- providing clinicians with clear and transparent screening and treatment protocols in line with the latest guidance from WHO or relevant national health authorities;
- incorporating mechanisms that
  - ensure that the guidelines and protocols are followed;
  - enable clinicians to inform health authorities when clinical experience suggests the need for revisions of the protocols;
  - enable clinicians to take part in the process of updating guidelines and protocols as the pandemic progresses;
- proposing prioritization criteria related to the maintenance of a functioning health-care system as needed in a crisis situation, ensuring
  - a fair balance between treatment of influenza patients and the treatment of patients with other serious conditions;
  - among non-influenza patients, the prioritization of access to the general health-care infrastructure;
  - among influenza patients, the identification of those who will receive hospital-based versus home-based care, and criteria for early discharge (potentially even if still infectious).

BOX 1

Allocation of scarce resources – Swiss Influenza Pandemic Plan 2006 (*7*)

The Swiss National Advisory Commission on Biomedical Ethics drafted a document on ethical questions in pandemic preparedness, which was integrated into the Swiss Influenza Pandemic Plan. The following tiered model for the allocation of scarce resources is adapted from the Swiss Influenza Pandemic Plan:

1. During the first phase, everyone who needs treatment will receive it. This phase will continue until the number of those requiring treatment exceeds the capacity of the enhanced treatment facilities. In this phase treatment will be administered to individuals on a "first come, first served" basis or to those who are already being treated for another illness.
2. The second phase begins when it is no longer possible to treat everyone because therapeutic capacity is exhausted and some have to be turned away. In this phase, scarce therapeutic resources will be reserved for those whose conditions are most threatening.
3. Finally, the third phase corresponds to the triage used in war or disaster situations. From the outset of this phase scarce resources should be reserved for patients with life-threatening conditions. When all those with life-threatening conditions can no longer be treated, priority will be given to those who are expected to have the best chance of survival as a result of treatment. Conversely, treatment in this phase will, if possible, be withheld only from those who are unlikely to benefit from it. Individuals with a poor prognosis will be given palliative treatment only in this phase.

Criteria for use in prioritization

Although the principle of utility is not the only relevant ethical consideration, it is an important factor to take into account when establishing prioritization policies. **Utility considerations** include:

- for individual benefit
  - — the likelihood that an individual with pandemic influenza disease will experience a medical benefit if provided antiviral and adjuvant treatment;
  - — the likelihood that an individual at risk of infection will become infected/ill if influenza-specific antiviral prophylaxis is not provided;
- for community benefit
  - — the likelihood that an infected individual will infect other persons if not given access to antivirals (for treatment or prophylaxis) and infection control measures;
  - — the overall reduction in disease burden expected to result from the intervention;
  - — the potential value of giving priority to:
    - essential health-care workers
    - other workers who provide life-saving services
    - workers who provide critical services necessary for society to function as normally as possible; such policies should be developed with great care, given the danger that those which favour certain categories of workers may be perceived as unfair and undermine public trust.

Another principle, which may sometimes conflict with utility considerations, is equity. **Considerations of equity** may lead to giving priority to:

- the worst-off (in terms of severity of illness)
- vulnerable and disabled populations
- uninfected persons who are at high-risk of developing severe complications and dying from influenza if they become infected.

Different views exist on whether it is appropriate to consider **age** in making prioritization decisions.

- The "fair innings" argument (see Glossary) supports giving priority to relatively young persons.
- The goal of reducing overall disease burden might also provide a rationale for favouring younger persons, even if the fair innings argument is not accepted.

Age-based prioritization criteria should be adopted only after wide public consultation. Such criteria

BOX 2

Inclusion of Maori in pandemic planning – New Zealand (*8*)

The influenza pandemic in 1918 hit the indigenous Maori population of New Zealand especially hard. Even today, they have a poorer health status than the general population and often have a lower socioeconomic status. They are therefore considered a vulnerable population from a health perspective. The Ministry of Health included Maori representatives in its pandemic planning process to protect the needs of this vulnerable group in a future pandemic.

In December 2005, the Ministry of Health convened a meeting with a Maori focus group of seven members, including health and disability sector experts as well as District Health Board Maori managers, to identify key issues for the Maori. It was decided in this meeting to create a Pandemic Maori Reference Group. During a second meeting in June 2006, issues discussed included the development of fact sheets for Maori communities and access to other resources, Maori engagement with District Health Boards and the role of Maori providers, workforce preparedness, and community infrastructure and needs. The Pandemic Maori Reference Group is now part of the health sector branch of New Zealand's pandemic planning process.

should rely on broad life stages, rather than ranking individuals based on differences of only a few years.

Policy-makers should ensure that criteria for priority setting **do not discriminate** against individuals based on inappropriate characteristics, including but not limited to

- gender
- race and ethnicity
- religion
- political affiliation
- national origin
- social or economic status.

Additional considerations related to priority in access to vaccines

The current state of influenza vaccine production technology used in many countries suggests that the first doses of a vaccine against a new pandemic influenza virus will not be available until 5–6 months after the pandemic has been declared. Production of sufficient doses to meet global demand could take additional months. Therefore, it is critical that policy-makers at all levels, in consultation with political and civil society leaders, agree on how the vaccine will be used as it becomes available (see Box 3). Many consider that vaccination is most urgent for persons who are at highest risk of dying from influenza if infected. Epidemiological studies during the pandemic should help to identify such high-risk groups, but this information may not exist when the vaccine first becomes available. The risk of death once infected may differ by country and will depend on age, socioeconomic status, underlying health conditions, and availability of health care including access to antivirals for treatment or prophylaxis. In addition, a policy of vaccinating those at highest risk of dying will not necessarily be consistent with other possible goals, e.g. reducing spread of infection in the population.

There are thus several reasonable although sometimes competing approaches to prioritizing who should be vaccinated (*9*). These include:

- prioritizing health-care workers and other essential service providers to help sustain the health-care system;
- vaccinating groups of people known to be central to spreading infection or "super-spreaders" (if this strategy is expected to be effective);
- vaccinating persons at increased risk of death if infected.

Additional priority setting criteria may be required; one approach could be to prioritize children and young adults based on the fair innings argument (see above).

Medical and nursing care

Many influenza patients will require basic medical and nursing care, including treatment directed at relief of symptoms. Developing and maintaining health-care infrastructures for primary care is a major priority for pandemic preparedness, especially because such investments will be beneficial at all times and not only during a pandemic.

In addition, plans should address:

- the rules for terminating treatment of patients suffering from pandemic influenza and other diseases and conditions, so that other patients can have access to scarce resources (such as mechanically-assisted ventilation);
- the importance of providing palliative/supportive care to all persons who need it.

BOX 3

Community participation in vaccine priority setting – Public Engagement Pilot Project on Pandemic Influenza 2005 (*10*)

The Public Engagement Pilot Project on Pandemic Influenza (PEPPPI) was launched in 2005 by a consortium of organizations in the United States of America to pilot test a method of engaging the public in vaccine-related policy decisions. Consultations were conducted with citizens-at-large and a stakeholder group that included representatives from organizations with an interest in pandemic influenza and expert consultants. The goal of PEPPPI was to develop an improved plan for pandemic influenza that would be likely to receive public support, and to demonstrate that public engagement can be productive in the policy process for pandemic influenza preparedness.

A first consultation was convened with the stakeholder group to frame the issues, secure background information and to raise awareness of the ethical dilemmas related to vaccine prioritization. A second consultation invited citizens-at-large to select highest priority goals for an influenza vaccination programme. A follow-up meeting with the stakeholder group was held, as was a broader citizen-at-large consultation where citizens were asked for their feedback on the priority goals established during the initial citizen-at-large consultation. In total the consultations involved approximately 300 participants with diverse backgrounds and points of view.

The groups reached a high level of agreement that the first immunization goal should be assuring the functioning of society, followed by the goal of reducing individual deaths and hospitalizations due to influenza. This project showed that stakeholder groups and citizens-at-large can be engaged in the policy-making process around pandemic influenza preparedness; they can learn about a technical issue, interact respectfully, and reach a productive outcome on complicated technical policy issues.

4

Isolation, quarantine, border control and social-distancing measures

Countries have an obligation to minimize the burden of disease on individuals and communities, but they must do so in a way that is respectful of individual rights and liberties. The need to balance the interests of the community and the rights of the individual is of particular importance in the implementation of public health measures such as isolation, quarantine, social distancing and border control. While all of these measures can legitimately be attempted in order to delay the spread or mitigate the impact of an influenza pandemic, the burden they place on individual liberties requires that their use be carefully circumscribed and limited to circumstances where they are reasonably expected to provide an important public health benefit.

Internationally-accepted human rights principles provide the framework for evaluating the ethical acceptability of public health measures that limit individual freedom, just as human rights provide the foundation for other pandemic-related policies. Many of the considerations discussed in this chapter are in fact explicitly incorporated into human rights documents. The Siracusa Principles (*11*), one such relevant document, state that any limitations on 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 distributive justice require that public health measures do not place unfair burdens on particular segments of the population. Policy-makers should pay specific attention to groups that are the most vulnerable to discrimination, stigmatization or isolation, including racial and ethnic minorities, elderly people, prisoners, disabled persons, migrants and the homeless.

Core governmental responsibilities

With appropriate international financial and technical assistance, countries should **develop core capacities for public health surveillance and response** that comply with the international legal obligations in the framework of the International Health Regulations (IHR) 2005 (*12*). They should also **review existing public health laws** to ensure that they

- provide authority for appropriate actions that might be necessary in the event of a public health emergency;
- clearly delineate the procedures that must be followed to institute particular public health measures;
- recognize the importance of grounding public health actions in scientific evidence;
- pay attention to ethical principles of necessity, proportionality, social justice, liberty, confidentiality, reciprocity, fair process, efficiency, transparency and accountability;
- protect the confidentiality and security of personal information and limit the disclosure of personal health information to the minimum necessary to achieve legitimate public health objectives; information should be shared only for legitimate public health purposes, and to the maximum extent possible individuals should be informed about third parties' access to their personal information, the intended use of the information and the reasons the information is being shared.

Countries should develop **community-specific communication and social mobilization strategies** that

- are linguistically and culturally appropriate;
- are developed with community input;
- provide comprehensive, timely, and balanced information based on the best available scientific evidence and expert opinion;
- keep communities informed on the nature and evolution of the threat and on developments in governmental policy, including changes in public health laws;
- provide scientifically sound, feasible, and understandable measures that people can take to protect themselves and others from infection, such as personal and community hygiene practices.

Considerations related to specific public health strategies

The appropriateness of specific public health strategies cannot be determined in advance of an influenza pandemic. The effectiveness of selected measures will depend on factors that are currently unknown, especially the pathogenicity and the transmission pattern of a new influenza virus subtype. In considering whether to adopt particular public health strategies, countries should rely on the best available scientific evidence. Restrictions on individual liberties should not be adopted unless there is a reasonable expectation that they will have a significant impact on containing the spread or mitigating the impact of the disease, and they should be terminated when they no longer appear to offer significant benefits. All public health measures must accord with international human rights laws and national legal requirements, and governments should pay special attention to protecting the interests of vulnerable populations.

In planning for the use of particular public health measures, countries should take into account the following factors.

Plans related to **social-distancing measures** should

- to the extent possible, provide means of mitigating adverse cultural, economic, social, emotional, and health effects for individuals and communities;
- provide employment protection for workers who comply with social-distancing measures against the wishes of their employers;
- incorporate the input of employers, unions, and other relevant stakeholders, particularly with respect to plans for work closure procedures and the use of alternative work schedules;
- be made available in advance to the key actors who will be charged with implementing these measures so that they can adapt them to the local culture and context and prepare for their implementation.

Plans related to **travel restrictions and border controls** should

- accord with the WHO recommendations (*5, annex 1*) for each stage of a pandemic and be adaptable to evolving international recommendations;
- respect, to the extent possible, the individual right to freedom of movement;
- ensure informed consent of affected travellers for examinations, prophylaxis, and treatment in accordance with the IHR (2005) (*12*).

Plans related to the **isolation of symptomatic individuals and quarantine of their contacts** should

- be voluntary to the greatest extent possible (see Box 4); mandatory measures should only be instituted as a last resort, when voluntary measures cannot reasonably be expected to succeed, and the failure to institute mandatory measures is likely to have a substantial impact on public health;
- provide for infection control measures appropriate to each confinement context (such as hospitals, temporary shelters, or homes) in order to protect others from infection;
- ensure safe, habitable, and humane conditions of confinement, including the provision of basic necessities (food, water, clothing, medical care, etc) and, if feasible, psychosocial support for people who are confined;
- consider the development of mechanisms to address the potential financial and employment consequences of confinement;

- protect the interests of household members of individuals who are isolated and treated at the household level, including recommending or providing alternative housing if living with the isolated patient is likely to put them at significant risk of illness (for example, immunocompromised family members);
- provide fair procedures for making decisions about affected individuals; in extraordinary circumstances, exceptions to normal procedural protections may be appropriate where immediate action is essential to protect the health of others, but in all cases legal recourse should be available to individuals to challenge their isolation or quarantine.

BOX 4

Attitudes towards the use of quarantine – a multisite research survey (*13*)

A telephone survey designed in the USA by the Harvard School of Public Health and the US Centers for Disease Control and Prevention was conducted in four locations: China, Hong Kong SAR; China, Province of Taiwan; Singapore; and the USA. Respondents were given information on the use of quarantine in the event of an outbreak of a communicable disease and questioned on their attitudes towards this public health measure. These four locations were chosen based on their past exposure to quarantine measures; the USA being the location where quarantine has not been used in recent experience.

In all locations, a majority of respondents supported quarantine measures for persons suspected of having been exposed to a communicable disease (China, Hong Kong SAR, 81%; China, Province of Taiwan, 95%; Singapore, 89%; USA, 76%). Support was lower in all locations if refusal to comply with a quarantine order could lead to arrest (China, Hong Kong SAR, 54%, China, Province of Taiwan, 70%; Singapore 68%; USA, 42%).

The study showed variations with respect to the approval of measures for monitoring compliance with quarantine policies. In general, respondents in the USA were less supportive of restrictive monitoring measures than respondents in the other locations. In all four locations, a majority supported monitoring through periodic telephone calls and daily visits, but periodic video screening received less support. The majority of respondents in the USA rejected electronic bracelets and guards positioned in front of quarantined buildings, whereas these measures were supported by a majority of respondents in China, Hong Kong SAR, China, Province of Taiwan, and in Singapore.

A large majority of USA respondents preferred home quarantine, whereas a smaller number of respondents in the other locations preferred quarantine at home to institutional quarantine. The main worries about being quarantined in a health-care facility were being exposed to someone with the contagious disease, overcrowding, and difficulty communicating with family members.

The authors concluded that policy-makers need specific plans to deal with the public's concerns about compulsory quarantine policies.

5

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

The availability of health-care workers will be essential in order to provide an effective response to an influenza pandemic. Therefore countries should develop policies that clearly delineate health-care workers' obligations, in order to give them notice of what will be expected of them (for an example, see Box 5). In developing such policies, countries should consider that obligations can be recognized in one or more of the following ways, which are not mutually exclusive:

- **Moral obligations** – Moral obligations are based on a society's understanding of "right" and "wrong" behaviour and/or appeal to universal sets of values. They tell people what they "should" do, but they are not in themselves legally binding. Policies that address individuals' moral obligations can play an important role in creating social norms in favour of particular behaviour.
- **Professional obligations** – Professional obligations are based on a particular profession's own understanding of how members of that profession should behave. Professional obligations are often set by professional associations through a formal deliberative process and may be set out in guidelines or codes of ethics. Violations of professional obligations can sometimes result in sanctions within the profession, such as reprimands or loss of certain professional privileges.
- **Contractual obligations** – Contractual obligations are obligations that individuals have voluntarily assumed as part of an agreement with someone else (e.g. employment agreements). When people do not uphold their contractual obligations, they may be required to pay money to the other party to the contract, or they may suffer other penalties, such as loss of employment.
- **Non-contractual legal obligations** – Many laws create binding obligations, the violation of which can result in civil and/or criminal penalties. Some legal obligations are also moral or professional obligations. However, not all moral or professional obligations are backed by legal requirements.

A strong case can be made for recognizing a moral obligation to provide care during an outbreak of communicable disease, especially a disease of pandemic proportions. The arguments for recognizing such an obligation are strongest for workers, such as physicians, respiratory therapists and nurses, whose specialized training gives them critical skills that cannot be provided by other persons. However, even for workers with specialized skills, the moral obligation to work during an influenza pandemic is not unlimited. Judgments about the scope of any particular worker's moral obligations must take into account factors such as the urgency of the need for that individual's services and the difficulty of replacing him or her, the risks to the worker and indirectly to his or her family, the existence of competing moral obligations, such as family caregiving responsibilities, and his or her duties to care for other (present and future) patients.

The difficulty of establishing clear rules about the scope of health-care workers' moral obligations suggests the need for caution in translating such obligations into legally enforceable duties. From an ethical perspective, the least problematic enforcement mechanisms are those that have been voluntarily adopted by those who will be affected by them. Thus, governments should encourage professional organizations to develop policies regarding professionals' obligations to work during epidemics of communicable diseases. Similarly, employers and workers should review existing contractual obligations (such as employment agreements) to ensure that they contain appropriate requirements for epidemics. Countries should enact laws requiring

health-care workers to work during a public health emergency only if they conclude that moral, professional, and contractual obligations are unlikely to be sufficient.

Health-care workers' assumption of increased risks to their health during an influenza pandemic gives rise to reciprocal obligations on the part of governments and employers. Preparedness plans should ensure that mechanisms to satisfy these reciprocal obligations are in place (see below).

Establishing the nature and scope of health-care workers' obligations

Policies outlining health-care workers' obligations should

- be developed by or in consultation with those who will be directly affected by these policies, including professional organizations, unions, and other relevant groups;
- cover the diverse occupational roles of health-care workers who may be exposed to increased risk during an influenza pandemic, including non-conventional health-care practitioners (e.g. traditional healers) involved in the response plan;
- consider the appropriateness of assigning health-care workers to functions not normally within their scope of responsibilities, including assigning non-professionals to perform tasks that are normally performed by professionals, or assigning professionals to work in areas for which they are not licensed or trained;
- recognize that the duty to work notwithstanding risks to one's own health is not unlimited;
- ensure that health-care workers are asked to assume risks only when their participation can reasonably be expected to make a difference to the consequences of the pandemic (e.g. reducing morbidity and mortality, alleviating pain and suffering, preventing nosocomial infection, limiting the spread of the pandemic at the community level);
- seek to distribute risks among individuals and occupational categories in an equitable manner, taking into account the fact that some categories of workers may have to be exposed to greater risks given the nature of their activities;
- accommodate legitimate exceptions regarding assignment of individuals with fragile health status to risky situations (e.g. individuals who are immunodeficient or pregnant);
- be discussed in an open and transparent manner before they are implemented.

Reciprocal obligations of governments and employers

In exchange for health-care workers assuming increased risks to their health during an influenza pandemic, governments and employers have certain reciprocal obligations. Governments and employers should seek to **minimize risks to health-care workers** to the extent reasonably possible by

- ensuring that adequate infection control systems are in place in hospitals and other health-care facilities;
- providing preventive measures (e.g. prophylaxis, personal protective equipment, infection control protocols) to health-care workers, in line with technical advice and updated as new epidemiological evidence becomes available;
- considering the appropriateness of giving health-care workers priority access to antiviral drugs and medical care if they develop influenza;
- providing health-care workers with access to psychosocial treatment and support.

These risk reduction methods are important for the protection both of health-care workers and of the public. To avoid the further spread of infection, workers have an ethical obligation not only to use the protective measures that are offered to them, but also to report if they become infected and to accept temporary exclusion from work until they are no longer infectious.

Governments, professional organizations, and health-care employers should ensure that health-care workers receive **adequate education and information** about

- the risks associated with taking care of patients affected with all communicable diseases, including pandemic influenza;
- measures they can take to help protect themselves and others, and the risks associated with not using those measures;
- expectations regarding their duty to provide care during an influenza pandemic or other communicable disease outbreak;

- information about any social benefits available to them or their families;
- information about the legal or other consequences of failing to work.

Governments should use their best efforts to **develop or strengthen benefits systems** that will provide

- medical and social benefits in the case of illness or disability of health-care workers during an epidemic;
- death benefits to the family members of health-care workers who die after being exposed to the pandemic influenza virus in the course of their work.

Promoting compliance with health-care workers' obligations

Policies setting forth health-care workers' obligations during an epidemic of a communicable disease can be influential even if they do not create any enforceable legal obligations. When such policies are developed through a transparent, equitable, and accountable process, they are likely to be accepted as legitimate by those who are affected by them. As such, they can contribute to a climate in which workers feel a personal moral responsibility to continue working despite an increased risk to their health.

Any policies that go beyond moral guidance to include **sanctions for non-compliance** – whether adopted by governments, professional organizations, or individual employers – should be tailored as narrowly as possible. Because excessive sanctions could infringe the human rights of health-care workers, countries should ensure that policies on sanctions comply with the Siracusa principles (*10*) and other applicable human rights standards. In addition, such policies should

- be established in advance by government authorities and/or professional organizations, and broadly disseminated to those who will be governed by the policies;
- reflect judgments about the level of risk that health-care workers can reasonably be expected to assume in fulfilling their obligations;
- take into account the appropriateness of imposing sanctions if the reciprocal obligations of governments and employers have not been met;
- take into account the relevance of mitigating factors, such as individuals' competing obligations to care for sick family members or others, when deciding about the imposition of sanctions;
- ensure that fair procedures are followed before sanctions are imposed;
- provide for an appeals process for health-care workers who have been sanctioned, either during or after the pandemic period.

The considerations in this chapter relate specifically to health-care workers. In order to minimize the societal disruption of an influenza pandemic, countries may also want to consider their relevance to workers outside the health-care sector who provide essential services. Such workers include those in public utilities, workers in factories that provide indispensable (medical) supplies, and key administrative decision-makers.

BOX 5

Health-care workers – the Canadian Pandemic Influenza Plan for the Health Sector (*14*)

Rather than focussing exclusively on the obligations of health-care workers, the Canadian Pandemic Influenza Plan for the Health Sector (CPIP) provides guidance on mitigating the expected health-care worker shortage during an influenza pandemic. The CPIP recommends the establishment of a human resource management team to plan and implement the management of workers during a pandemic. Relevant considerations for such planning and implementation include the expanded, new or different responsibilities that health-care workers may be required to take on, the recruitment of additional staff for the pandemic response (e.g. retired physicians, trainees, therapists, technicians, etc), and the provision of advanced and refresher training for health-care workers and potential recruits regarding pandemic plans, changing roles and responsibilities, supervising volunteers, crisis management, and emergency planning.

The CPIP also outlines reciprocal obligations to health-care workers. Liability insurance should be provided for workers and volunteers who may be required to act outside the scope of licensing or other authorization. Additionally, health-care workers should be considered a high priority for immunization during a pandemic because they are critical to the pandemic response. Health-care workers should also be provided with personal and emotional support, family care and job protection.

The CPIP acknowledges that under emergency legislation, provincial and federal governments may have the authority to designate "Essential Services" workers where an emergency has been declared and to compel such workers' time with due compensation. However, the CPIP also urges that compelling workers should be a last resort and should only be used after all other methods of obtaining a sufficient number of health-care workers to respond to a pandemic have been reviewed. Moreover, the CPIP points out that a state of emergency may not be declared and so system-wide (as opposed to institution-based) planning should be undertaken to mitigate a health-care worker shortage.

6

Developing a multilateral response to an outbreak of pandemic influenza

There are several reasons for policy-makers to incorporate international considerations into influenza pandemic preparedness planning. First, the ethical principle of solidarity (see Glossary) suggests that countries should respond collectively when natural threats to health are identified. Second, countries have obligations to help one another under international laws, including human rights laws; many of these obligations are affirmed and elaborated upon in IHR (2005) (*12*). Finally, an influenza pandemic is inherently a global crisis; lack of response to a pandemic threat in one country puts all other countries at increased risk. It is therefore in each country's national interest to contribute to international efforts to prevent and respond to an influenza pandemic.

Yet, it is one thing to agree in principle that countries should assist one another before and during an influenza pandemic and another to work out the details of what such cooperation actually entails. Because resources will be limited, countries are likely to face difficult choices between the need to protect their own populations and to support international efforts. Advance planning at the international level can help countries clarify what they expect of one another during each period (pre-pandemic, pandemic alert, pandemic and post-pandemic). In addition, international cooperation is likely to increase the effectiveness of national preparedness plans.

The importance of international cooperation

Because of the global impact of an influenza pandemic, international and regional cooperation and coordination in the development and implementation of influenza pandemic preparedness plans will be essential to an effective response, particularly in countries with common borders (see example in Box 6). In addition, cooperation will help to make plans technically and ethically sound, ensure that national plans are transparent, and contribute to their legitimacy. International efforts should include mechanisms to:

- promote cross-border cooperation in surveillance and exchange of information at all periods including pre-pandemic, pandemic alert, pandemic and post-pandemic periods;
- facilitate countries' participation with WHO in joint rapid containment efforts (*15*) in order to stop, or at least slow, the spread of the initial emergence of pandemic influenza;
- avoid disparities in care across borders;
- promote the timely and accurate sharing of scientific information;
- promote international evaluation or peer review of national influenza pandemic preparedness plans through a public and transparent process, taking into account the availability of resources;
- promote principles of fair process, equity, and global justice.

Sharing specimens and promoting equitable access to pharmaceutical interventions

Broad international cooperation in the **development and dissemination of vaccines and treatments** is in the interests of all countries as such cooperation offers the best chance of minimizing the global impact of an influenza pandemic (*16*). According to the principle of reciprocity, each country should do what it can to contribute to this effort, with the understanding that it can expect the same from the rest of the international community. Therefore, countries should:

BOX 6

International issues – the Belgian preparedness plan for pandemic influenza (*17*)

The Belgian preparedness plan for pandemic influenza advocates for a coordinated European response to pandemic influenza. Such a coordinated response could prevent the risk of medical "shopping" where persons cross borders to access treatments or vaccinations not available in their home country.

The national plan identifies potential discrepancies in country responses in the provision of protective equipment and therapeutic and prophylactic measures, as well as hospital care, communication and trade, and proposes solutions for a coordinated response. A coordinated response could also prevent the requisitioning of health-care workers practising outside their native countries, a prospect that could leave some countries facing an even worse shortage of health-care workers.

The plan states that Belgium will provide equal treatment to foreigners who are in Belgium, regardless of their legal status in the country. Likewise, foreign nationals will be subjected to the same public health measures as those applicable to Belgians. The authors base this policy on equity considerations and also on the need to protect Belgian citizens from infection by untreated individuals living within national borders. Belgium encourages other countries in Europe to take a similar position with respect to foreign nationals living within their borders.

- continue to support, strengthen and improve the WHO Global Influenza Surveillance Network and its procedures through the timely sharing of viruses or specimens with WHO Collaborating Centres;
- participate in the development and implementation of frameworks and mechanisms that aim to ensure fair and equitable sharing of benefits, in support of public health, among all countries, taking into particular consideration the specific needs of developing countries.

Assistance to countries in need

National and international policy-makers should establish and test mechanisms to **provide coordinated assistance to countries in need**. These mechanisms should:

- address needs for both financial and technical assistance (e.g. collaboration for laboratory diagnosis);
- incorporate fair and objective criteria for providing assistance;
- apply to countries in need both during and after an influenza pandemic;
- facilitate rapid assessments and timely decision-making;
- consider the potential contributions of both governmental and nongovernmental actors;
- ensure that support is provided in a manner that is technically sound, sensitive to local social and cultural circumstances, and in line with the national influenza pandemic preparedness plans;
- ensure that, to the extent possible, international support is provided following discussion and agreement with the host country or, when that is not possible, with international organizations such as WHO.

Issues for countries receiving assistance

Countries that receive financial and/or technical assistance have a duty to use this assistance appropriately by:

- ensuring that resources are directed according to need rather than for political reasons;
- providing donated medications and influenza pandemic vaccines at no cost to the recipient, in order to promote equitable access;
- passing on any unneeded donations to other countries that can use them.

Attention to the needs of all populations, regardless of their legal status in a country

International and national monitoring should pay particular attention to the **needs of all populations**, regardless of their legal status, especially with respect to access to health care. Such populations include but are not restricted to

- displaced persons
- refugees
- asylum seekers
- migrants
- travellers.

Communication policies

The International Health Regulations (2005) are legally binding regulations adopted by most countries to contain the threat from diseases that may spread rapidly from one country to another. Under the IHR (2005), States Parties to the Regulations are required to notify WHO of all events "that may constitute a public health emergency of international concern" (PHEIC). This notification obligation, expanded since IHR (1969) (*18*), includes novel or evolving public health risks, taking into account the context in which the event occurs, and includes human influenza caused by a new virus subtype. Notifications must occur within 24 hours of assessment by the country using the decision instrument provided in Annex 2 of IHR (2005). Notifications must be followed by ongoing communication of detailed public health information on the event, including, where possible, case definition, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed.

In addition to international notification, in order to promote public understanding and support for international collaboration in pandemic response efforts, governments should establish **coherent and transparent communication policies** (*4*) that:

- promote collaboration between countries, particularly at the regional level;
- explain the importance of international cooperation in minimizing the adverse health, social, industrial, and economic effects of an influenza pandemic and its aftermath;
- articulate how such international efforts are grounded in ethics and human rights.

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ANNEX
Additional bibliography and links

WHO resources

Addressing Ethical Issues in Pandemic Influenza Planning. Four discussion papers. Geneva, World Health Organization, forthcoming. Will be available at: (http://www.who.int/ethics/influenza_project/en/index.html, accessed 1 October 2007)

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Avian influenza: WHO Guidelines, recommendations, descriptions, full list in chronological order at: http://www.who.int/csr/disease/avian_influenza/ guidelines/en/index.html (accessed 1 October 2007)

WHO web page on influenza http://www.who.int/csr/disease/influenza/en/index.html (accessed 1 October 2007)

WHO web page on the International Health Regulations (2005) http://www.who.int/csr/ihr/en/ (accessed 1 October 2007)

A link to some of the published National Influenza Pandemic Plans can be found at: http://www.who.int/csr/disease/influenza/nationalpandemic/en/index.html (accessed 1 October 2007)

Other key resources

New Zealand National Ethics Advisory Committee

Getting through together: ethical values for a pandemic. The National Ethics Advisory Committee – Kahui Matatika o te Motu (NEAC) has completed its work on ethical values for a pandemic. *Getting through together* emphasizes using shared values to help people to care for themselves, their whanau and their neighbours, and using shared values to make decisions in situations of overwhelming demand. *Getting through together* also gives guidance on some key issues in pandemic ethics. (http://www.neac.health.govt.nz, accessed 1 October 2007)

UK Department of Health

The ethical framework for the response to pandemic influenza. The ethical framework is designed to assist planners and strategic policy-makers with ethical aspects of decisions they face before, during, and after an influenza pandemic. It may also help clinicians and other health and social-care professionals with decisions

they need to make in the same context. (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/Publications PolicyAndGuidance/DH_073179, accessed 1 October 2007)

CDC USA

Ethical guidelines in pandemic influenza. As part of its planning for a possible outbreak of pandemic influenza, the Centers for Disease Control and Prevention (CDC) worked with the Ethics Subcommittee of the Advisory Committee to the Director, CDC to identify ethical considerations relevant to public health decision-making during the planning for and responding to pandemic influenza. (http://www.cdc.gov/od/science/phec/guidelinesPanFlu.htm, accessed 1 October 2007)

Documents from the Bellagio meeting

With support from the Rockefeller Foundation, an international group of experts met in Bellagio, Italy, from 24–28 July 2006 to consider questions of social justice and the threat of avian and human pandemic influenza, with particular focus on the needs and interests of the world's disadvantaged. (http://www.hopkinsmedicine.org/bioethics/bellagio, accessed 1 October 2007)

Plate-forme veille et réflexion "Pandémie grippale, éthique, société"

This site is an initiative by the "Espace éthique" and the "Université Paris-Sud 11" dedicated to the ethical aspects of a potential flu pandemic (in French). (http://www.espace-ethique.org/fr/grippe.php, accessed 1 October 2007)

Provincial Health Ethics Network

The Provincial Health Ethics Network (PHEN) is a non-profit, non-partisan organization which provides resources to people in Alberta, Canada, to support systematic and thoughtful analysis of ethical issues in the health system.(http://www.phen.ab.ca/pandemicplanning/ accessed 1 October 2007)

Quebec Public Health Ethics Committee (Comité d'éthique de santé publique, CESP)

Opinion about the public health dimension of the Quebec plan for fighting against pandemic influenza (in French). (http://msssa4.msss.gouv.qc.ca/fr/sujets/ethiqSP.nsf/22f2ea9b71e5846d85256d0a00761591/35570c61afcd975685256ead00636ccc/$FILE/AVIS_PQLPI-MS_vf.pdf, accessed 1 October 2007)