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Ethics of planning for and responding to pandemic influenza Literature Review

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Literature Review

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1. Introduction

1.1 Purpose of this review

The review was prepared on request of the Swiss National Advisory Commission on Biomedical Ethics. It is intended to serve as background information for the deliberations and development of recommendations of this Commission on the preparatory measures for influenza pandemic. In order to support this public activity of the multidisciplinary Commission, the review is avoiding specialist language and narrow topics that likely would be of interest only to experts.

1.2 Scope of the review

Given that the Commission's role is essentially normative, that is, expected to provide advice on morally preferable, acceptable, and unacceptable goals, and to suggest ways and means to respond to the pandemic, this review will be carried out with a normative preference. However, since the literature of normative bioethics dealing specifically with ethical issues in planning and responding to influenza pandemic is extremely limited, it is necessary to also include references from the broader writings of public health, control of infectious diseases and some adjacent areas that can possibly inform the normative work pertaining to influenza pandemic. However, as even this systematic survey of normative literature proved to be insufficient as a basis for original, reality grounded, forward looking normative work on influenza pandemic, the reviewer deemed it necessary to review, at least selected empirical (i.e. descriptive and experimental) literature of medical and social sciences and seek their conclusions, comments and observations that are relevant to the development of bioethical norms for influenza pandemic response. The empirical literature that has been generated in the last few decades by the medical, biological and social sciences on such topics as public health, control of infectious diseases, influenza and resource allocation is vast. Given the constraints of time and space available for this literature review, no claims can be made about the completeness of the survey of this empirical literature.

The adequate resolution of ethical issues is important, but of itself, it is not sufficient criteria for a complete review of a public health policy. To this end, it would be desirable to examine a broader set of concerns—scientific, political, social, and economic—that pandemic influenza planning engenders. These may be referred to at times, but a thorough discussion of this set of concerns is outside the purview of this review. Further, a pandemic influenza will be an opportunity for numerous research projects, many of them involving human subjects. The ethical issues concerning such research are not examined in this document. Also, outside the scope of this literature review will be the international and global dimensions of influenza pandemic planning and response.

Final limitation: This review will not provide a systematic analysis of the ethical framework or ethical content of the national pandemic influenza plans of various countries, nor of the numerous documents developed by WHO or other super-national bodies. It will, however, review references in the scholarly literature that critique these plans from an ethical perspective.

The review will focus on references published in English, but a few essential references in other languages are included.

1.3 Method of review

1.3.1 Literature Search Strategy: The references that were considered for incorporation in this review were identified by searching bioethics databases (ETHX in the Web, Philosophers Index), medical and scientific databases (Medline/Ovid, EMBASE, PubCrawl, HealthSTAR). Selected key words also were used in Google and Librarians' Index to expand the searches.

1.3.2 Organization of References: All located references considered for inclusion in the survey were placed into a dedicated file in *RefWorks* software which is Internet based, and this software was used to cite references in the text of the review and to generate the attached list of references.

2. Public health ethics

The threat of influenza pandemic has greatly increased over the past several years due to the emergence of avian viruses that have infected humans and caused deaths in several countries. Experts believe that predicting and preventing the natural events that lead to the emergence and transmission of a pandemic influenza virus is most difficult. But, it is possible to be prepared and to react quickly and decisively when such an event occurs. Surveillance, that is tracking of novel viruses in both human and animal populations, development of effective countermeasures, such as vaccines and antiviral drugs, and the creation of capacity to limit spread of the pandemic virus and care for influenza patients are all possible and equally important measures (Fauci, 2006). Planning the response against this threat requires the creation of a major public health program, and the actual response, as the pandemic arrives, will be a public health intervention on a grand scale. Therefore, in order to develop appropriate positions on ethical issues in pandemic planning and response, we need to understand the ethics of public health as a health discipline and as a practical activity. This section of the review will have two parts. Firstly, I will report on publications of public health specialists; secondly, I will review the bioethics literature.

2.1 Public Health Perspective

The history of public health is marked by frequent controversies about the degree of restriction on personal liberties of citizens that public health authorities and state may impose in the interest of the common good. However, these controversies usually have been presented as issues for politicians and courts, not ethical issues. Legal resolution of disputes almost always favored public health authorities, following the maxim *salus populi supreme lex* (Bayer & Colgrove 2003).

Looking at public health (also called community health) through an ethical lens is a relatively recent undertaking. Major English language textbooks of public health published 30 years ago (Hobson, 1975), (Anderson *et al.* 1978) did not contain sections on ethics of the discipline. The venerable Maxcy-Rossenau textbook of public health underwent 11 editions before inclusion of a full fledged chapter on ethical issues (Lappe, 1986). The most recent 13th edition features a lengthy chapter entitled "Ethics and Public Health Policy" which I will review in detail as a prime example of public health ethics presented by a public health specialist (Last, 1992). The author of the chapter grounded his discussion firmly in the four principles of biomedical ethics: beneficence, non-maleficence, respect for autonomy and justice. I will now review the writer's application of these principles to public health.

The author states flatly that "(B)eneficence is the dominant ethical principle of public health" and argues that "there is clear justification on grounds of beneficence for public health workers to strive for economic, environmental, social, and political conditions that will maximize the prospect for good health" (p.1195). Commenting on the application of the principles of beneficence and non-maleficence, the author described an outbreak of smallpox in New York in 1947 concluding that vaccination provided a major benefit, even if some deaths occurred from its side-effects, and noted: "Similar risk-to benefit ratios have to be calculated for every immunizing agent, indeed for all forms of health care" (Last p. 1189). He admitted that the determination of "acceptable risk" of an intervention that is expected to be beneficial is often difficult, but argued that it is a necessary part of decision making in public health. He commented approvingly on legislation in several states, including Great Britain, France and Switzerland, that provide "compensation for accidents and mishaps associated with use of immunizing agents" (p.1189).

As concerns the principle of respect for autonomy, the author noted that the custom of drastic restriction of personal freedom by quarantine and isolation arose already in the 14th century when the concept of contagion was recognized, and it was not strongly challenged until the emergence of AIDS and HIV infections. He suggested that in the case of AIDS and HIV, human rights concerns as well as the public's compassion toward the infected, such as hemophiliac children and the already stigmatized male homosexuals, lead to a different approach of management from that of other infectious diseases. The strict, mandatory rules were abandoned, instead, efforts were made to control the infection by voluntary testing, unlinked anonymous testing, counseling and education, that is, by measures that did not pose serious intrusion on personal liberties. The author did not address the issue of emerging diseases or influenza in this chapter, but noted that growing concerns about environmental health led to calls for more legal constraints on a variety of activities, including smoking, and concluded, "The rights of individuals have to be balanced against the needs of communities in other respects besides control of communicable diseases" (p.1189). In respect to the use of health records and statistics for epidemiological analysis, the author accepted the argument that "the rights of the individual are congruent with, not in conflict with, the needs of the community because, as a member of the community, every individual benefits from the analyses that are based on individual health records" (p.1190).

Referring to surveillance and research, the writer states, "Individual integrity, if not autonomy, is respected by obtaining informed consent whenever possible to these invasions of privacy" (p.1191), but he does not indicate what is to be done if such consent is refused. The author does not directly respond to the usual accusation that public health interventions are paternalistic, but he does suggest a way to overcome the beneficence versus autonomy dilemma: "We have an obligation to work with people, empowering them, doing whatever may be necessary to promote better health – in short, doing things with, not to, people" (p. 1194).

The principle of justice is also mentioned several times in this book chapter. The writer declares: "Public health is inherently concerned with social justice, with fair and equitable distribution of scarce resources to protect, preserve and restore health." He provides examples of actions motivated by desire for justice, such as, advocacy for access to services without economic and other barriers, and provision of services that would not be available from fee-for-service practitioners to underprivileged population groups. He suggests that the principle of distributive justice may support vaccination of all infants, even if some parents are opposed to it.

In concluding remarks, the author notes the unsettled philosophical bases for public health and “dissonance in our value system”. He presents as an example the fact that our societies spare no effort to save or prolong individual lives, sometimes with heroic interventions, but relatively little effort and resources are devoted to public health problems that affect the lives of a greater number of people. The same author provided a similar discussion of ethical issues in his book *Public Health and Human Ecology* (Last, 1987b).

The American Public Health Association adopted the Public Health Code of Ethics that was intended to state “key principles of the ethical practice of public health”. The Code lists 12 principles and provides brief notes on each of them. They will be listed here in a much abbreviated fashion:

- Prevent adverse outcome
- Respect the rights of individuals
- Ensure opportunity for input
- Advocate for empowerment of disenfranchised
- Protect and promote health
- Obtain community’s consent
- Act in a timely manner...within the resources and mandate given
- Respect diverse values, beliefs and cultures
- Enhance the physical and social environment
- Protect the confidentiality of information
- Ensure professional competence
- Build the public trust and an institution’s effectiveness (American Public Health Association).

2.2 Bioethics perspective

2.2.1 During the first thirty years of this discipline’s existence, almost all of the effort of bioethicists went into the examination of ethics of personal medical care, mirroring the individualistic perspective of Hippocratic medical ethics. The health of the public and its communities and the interventions designed to safeguard them were not, for a long time, subjected to ethical analysis. For example, the *Encyclopedia of Bioethics* does not have a chapter on public health ethics; it has a chapter on philosophy of public health that concludes with the observation that public health is not yet appreciated among philosophers and social scientists as a discipline with a distinctive philosophical perspective (Beauchamp, 1995).

It was noted that this omission of infectious diseases and public health issues from bioethics during the development of the discipline had at least two unfortunate consequences. Firstly, some crucial concepts of modern bioethics, such as informed consent and applications of distributive justice, might have been formulated differently if infectious diseases had been considered (Francis *et al.* 2005). Secondly, ethical concerns and questions arising from the existence of infectious diseases and our attempt to control them were not recognized and addressed (Selgelid, 2005). This omission was unwarranted because historically, infectious diseases have been a unique threat to mankind and a major source of mortality and morbidity and the characteristics of infectious diseases are so distinct that they raise special medical, social and ethical issues (Smith *et al.* 2004).

2.2.2 Is bioethics capable of shaping the ethics of public health? Some scholars are very skeptical. Bayer and Fairchild (Bayer & Fairchild November 2004) concluded that paternalism and subordination of individual rights for the common good are foundational to public health ethics but individualism remains central to bioethics. For these authors, "bioethics is the wrong place to start when thinking about the balances required in defense of the public's health." Lachmann concluded that prevailing doctrines of bioethics would have to be significantly reassessed in order for bioethics to meet the needs of public health (Lachmann, 1998). Leeder was struck by the differences that these fields present in values and obligations (Leeder, 2004). Upshur also observed that clinical ethics is not an appropriate model for public health ethics (Upshur, R. E. G., 2002). In contrast, many other bioethicists, who turned their attention to public health, felt that contemporary bioethics can incorporate public health ethics. Thus, the recent presidential address at the congress of International Association of Bioethics drew the attention of delegates to the need to extend the bioethics debate to include ethical considerations regarding public health (Benatar, October 2003). Some authors set out to survey the scope of public health ethics and addressed some contemporary challenges to public health such as illegal drugs, violence and newly emergent diseases (Beauchamp & Steinbock 1999). A detailed description of issues and approaches that need to be addressed to fully develop public health ethics was provided by O' Neill. For her paper, she chose the subtitle "Thinking beyond borders" and stressed the need to focus on trust, justice and limits of legitimate compulsion, rather than on autonomy and informed consent (O'Neill, 2002). Similarly, Callahan suggests that a number of moral problems raised by public health extend beyond the earlier boundaries of bioethics and require their own ethical analysis (Callahan, D.: Jennings, B., February 2002). The relationship between public health and human rights has attracted the attention of both health lawyers and bioethicists and is being actively discussed (Gostin, 2001).

2.2.3 The prevailing practical approach to resolving ethical questions in clinical medicine, at least in North America, is the application of a set of four (or sometimes more) ethical principles (Beauchamp & Childress 2001). The question that offers itself is this: can principlism, that is, reliance on these elementary principles (sometimes called "Georgetown mantra"), be a suitable basis for at least a basic level of ethical analysis of public health activities in general and influenza pandemic issues in particular? The literature suggests that the answer will be no, if one believes that the principle of respect for autonomy is "first among equals", or that it will prevail most of the time over other principles when a conflict arises (Gillon, 2003). But the answer to this question could also be yes, if one favours giving no special standing to the principle of autonomy and relies on specification and balancing to assist with resolution of conflicts (Beauchamp & Childress 2001). Medical practitioners sometimes pointed out that the conflict between individual autonomy and societal interest is often only theoretical, or a "false antithesis" because the individual, as a member of society, benefits, directly or indirectly, from interventions in the public interest (Black, 1984). Be that as it may, the ideal would be to have a more comprehensive and discipline-specific approach to public health than these ethical principles can provide.

Only in the last few years have some senior scholars in this field embarked on an attempt to develop such a comprehensive bioethics perspective in public health. Three of such papers will be reviewed in detail.

Nancy Kass was perhaps the first scholar who proposed a broad ethics framework for public health, a framework that does not claim to be grounded in any particular ethical theory and intends to be practically oriented. Her "analytical tool, designed to help public health professionals consider the ethical implications of proposed interventions, policy proposal, research initiatives, and programs" consist of six steps, formulated in the form of questions to be answered:

1. What are the public health goals of the proposed program?
This step invites clear identification of goals and benefits of a proposed program and determination of whether it is indeed a public health program and not, say, a social program.
2. How effective is the program in achieving its stated goals?
This is the time to question both efficacy and effectiveness of a proposed program, looking at real evidence and deciding what quantity of data is sufficient to justify the program. These first two steps appear to be related to the principle of beneficence.
3. What are the known or potential burdens of the program?
Here we are invited to consider a variety of burdens and harms, both risks to individual's physical health and social risks such as risks to privacy and confidentiality, risk to liberty and self-determination and risks to justice. The principle of non-maleficence is not specifically mentioned, but appears relevant to this step.
4. Can burdens be minimized? Are there alternative approaches?
This step requires us to minimize burdens, while not greatly reducing the program's efficacy. Again the principles of non-maleficence, while not cited by the author, come to mind here.
5. Is the program implemented fairly?
Concern here is distributive justice that requires fair distribution of benefits and burdens. But the author also reminds us that justice may require unequal distribution of benefits, if it would correct existing inequities.
6. How can the benefits and burdens of a program be fairly balanced?
This last step is the final balancing and it will remind the reader of the principle of utility. The author here stresses the importance of fair process in dealing with inevitable disagreement over details of benefits and burdens and points out that "the greater the burden imposed by a program, the greater must be the expected public health benefit, and the more uneven the benefits and burdens (that is, burdens are imposed on one group to protect the health of another), the greater must be the expected benefits." (Kass, 2001).

A subsequent paper of the same author stresses the importance of justice: ethics will require that public health improvements come through just and respectful means. She believes that bioethics in the future will have to apply its extensive scholarship in distributive justice to questions of global public health (Kass, 2004).

Upshur expressed the view that "the straightforward application of the principles of autonomy, beneficence, non-maleficence and justice in public health is problematic" (Upshur, R. E. G., 2002). He offered a heuristic set of different principles:

- a) harm principle, as stated by Mill: the only purpose for which power can be rightfully exercised over any member of a civilized community against his will is to prevent harm to others.
- b) Least restrictive or coercive means: more coercive methods should be employed only when less coercive methods have failed.
- c) Reciprocity principle: there is an obligation on a social entity such as public health department to assist individuals and communities in the discharge of their ethical duties.
- d) Transparency principle: stakeholders should have input into decision-making which should be clear and accountable.

The author provides examples of application of these principles in certain scenarios but also acknowledges that these principles will not cover other situations such as screening and prevention programs. He is concerned that ethical reasoning in public health needs to consider that public health may use a different standard of evidence for action than clinical medicine and has to accept a higher degree of uncertainty.

2.2.4 A group of prominent US bioethicists and health lawyers wrote a longer and more theoretical paper intended to “map the terrain” of public health ethics (Childress *et al.* 2002). These writers wished to steer away from controversies about the most appropriate theories of bioethics. Nevertheless, they do make two remarks that refer to ethical theories and methods. Firstly, they acknowledge that public health activities are generally understood to be end-oriented (teleological) and consequentialist - the end or consequences desired being the health of the public. This would put public health on a collision course with duty-oriented (deontological) reasoning about the right action. Secondly, the authors recognize the importance of so called casuistical reasoning, that is, comparing any new situation in public health with precedent cases for which morally acceptable solutions were already found.

The main contribution of the authors of this paper was not a critique or acceptance of various approaches to thinking about ethics, but, the proposal to identify “general moral considerations” in public health. The selection of their particular set of considerations was made by looking at the kinds of moral appeals and debates about moral issues in public health in the United States, keeping in mind that these considerations should have universal validity. The list of these considerations starts the four most accepted principles of biomedical ethics:

- A. producing benefits;
- B. avoiding, preventing and removing harms (and producing the maximal balance of benefits over harms and other costs);
- C. distributing benefits and burdens fairly (distributive justice);
- D. respecting autonomy;

To this list, the authors add four other considerations:

- E. protecting privacy and confidentiality;
- F. keeping promises and commitments;
- G. disclosing information honestly (transparency);
- H. building and maintaining trust;

The authors acknowledge that if these general moral considerations should provide concrete guidance in public health ethics, the user has to engage in the processes of specification (that is, determining the meaning and range of these general considerations) and in the process of weighting (determining their weight or strength). Childress and his co-authors argue for necessity to carry out this “difficult moral work” (p.172) that allows to take into account the particular circumstances of public health action that is being analyzed, rather than adoption of a simple but rigid lexical or serial ordering of these considerations.

These scholars recognize that even if such moral work is done, conflicts among general moral considerations will arise. They focus on the common conflict between the general moral considerations that underpin the goals of public health actions – generation of benefits, prevention of harm and maximization of utility – and the remaining moral commitment. They propose five “justificatory conditions” that must be present in order to override such values as justice or autonomy in any particular case. These conditions are:

- A. effectiveness
- B. proportionality
- C. necessity
- D. least infringement of general moral considerations
- E. public justification.

The authors devote special attention to their last justificatory condition, public justification. They understand the public justification of actions that were, or, are being undertaken as one element of a broader commitment, the commitment to public accountability. The accountability is not only retrospective but also prospective and includes soliciting input from the relevant population in the process of formulating public health policies or practices. In relationship to pandemic planning, it is notable that the authors state: "This is especially, but not only, important when one of the other prima facie general moral considerations is infringed, as with coercive protective measures to prevent epidemics" (p.174).

Childress and his co-authors, after explaining how they propose to use their "general moral considerations", make some comments on ethical acceptability of interventions designed to benefit individuals against their expressed wishes, interventions that would be usually labeled as strongly paternalistic. An example would be a public health order of mandatory vaccination. They point out that such discourse involves many complex empirical and normative questions and conclude that strong paternalistic interventions that do not threaten individuals' core values and will likely protect them against serious risks are more easily justifiable than paternalistic interventions under different conditions (p.176). The authors end their discussion by endorsing the concept of respect for and consideration of human rights when making public health decisions, and express their belief that several core values of human rights are captured in their set of "general moral considerations."

2.2.5 The question arises, at this point of discussion, whether even this broad ethical framework is fully comprehensive. Literature suggests that perhaps not, and that there could be some other considerations or principles that ought to be considered when examining public health programs or issues. One such ethical principle that of late is receiving considerable attention is the precautionary principle. It has emerged during international discussions of serious threats to environments and can be found in the 1992 Rio Declaration on Environment and Development. Because a different version of the principle found its way in various international agreements, a conference was held in 1998 which resulted in a consensus, often quoted as Wingspread consensus (Conference Participants, 1998). In essence, the precautionary principle suggests that people have a duty to take anticipatory action to prevent harm, and if harm could be serious, action ought to be taken even in absence of scientific certainty about the threat. The consensus suggested that the principle should be applied to all human activities. At least one scholar thoroughly examined how this principle may be applicable in public health ethics (Wendler, June 2004). The principle is usually understood as creating a constraint on the use of new and not fully proven technology. However, using Wendler's suggestions to an influenza pandemic situation may possibly justify using interventions such as mass vaccination or antiviral prophylaxis, even if evidence could be deemed insufficient by standards of evidence based medicine. The author recommends a research program in which public health specialists, bioethicists and philosophers would elaborate on the theoretical foundation and applications of this principle. Other authors also concluded that the precautionary principle is reasonable, has plausible even if challenging applications, and is compatible with legal and risk assessment approaches to problems of uncertainty (Cranor, June 2004; Wynia, 2005). Jonas could be considered an early promoter of the precautionary principle even if he did not use the term. In developing his theory of responsibility, he argued that if something very important is at stake and our predictive knowledge is insufficient, we have to "give the prophecy of doom priority over the prophecy of bliss" (Jonas, 1984 p. x).

Engelhardt (Engelhardt Jr., H. T. & Jotterand June 2004) pointed out that the precautionary principle could justify technological innovations that would be normally considered problematic (e.g. germ line genetic engineering) if there would be a threat of obliteration of the current human population by pandemics of highly lethal diseases. However, there is also a warning in the literature that injudicious use of the precautionary principle could lead to inaction, refusal of innovation, waste of funds and promote feelings of anxiety within the population (Tubiana, Apr 2001).

Another principle that may deserve consideration in our context is the principle of subsidiarity. It is an old constitutional principle that is imbedded in the history of many federal states and in the political economy; it became more prominent when it was explicitly adopted in the Maastricht Treaty (Backhaus, 1999). It incites us to assure that decisions be made as closely as possible to the citizens who will be affected by them. It proposes that a higher organizational unit take action or make decisions only if a lower organizational unit could not achieve the sought objectives of the proposed action (Schilling, 1995). I was unable to find any evidence in literature that the principle was ever discussed or explicitly applied in public health.

2.2.6 In summary, the work done during the past few years on extending bioethics discussions into the public health domain produced a useful, practically applicable collection of principles, guides and rules. Bioethicists are likely going to alter and expand this material during the next few years, but the work done, even to this point in time, already appears to make an examination of ethical aspects of pandemic plans a manageable task, which would likely improve the quality and acceptability of these plans.

3. Ethics lessons from history of epidemic and pandemics

Outbreaks of influenza can be traced back to the 12th century (Potter, 1998). I will focus here only on a few milestone events that are relatively recent and well documented.

3.1 "Spanish flu" - 1918-1919

During the influenza pandemic of 1918-19, about one third of the population of the world was infected (about 500 million), and it is estimated that at least 50, perhaps up to 100 million people died. Case fatality rate was exceptionally severe, about 2.5%, compared to less than 0.1% in other influenza pandemics (Osterholm, May 5, 2005; Taubenberger & Morens 2006). Movements of troops and war conditions of civilians may have contributed to the impact. Given the cataclysmic proportion of this event, the literature documenting it is not extensive. My search did not identify any scholarly writing that would analyze the ethical aspects of this pandemic, but there are a number of historical and sociological studies, mostly referring to local and national situations. Also there are memoirs and non-fiction books for general readership. A good general description of the pandemic is available in several books (Collier, 1996; Crosby, Jr., A. W., 1977). A volume of studies focusing on the social and medical ramification of this pandemic was published (Phillips & Killingray 2001). One book focused on the heroic efforts of health care professionals and selfless dedication of volunteers (Pettigrew, 1983). Possibly, the most comprehensive book for general readership is "*The Great Influenza*" (Barry, 2004), which is concerned with the relationship between the medical science establishment and the pandemic as it mostly occurred in the US. I will list some of the points made in this book that are relevant to our topic:

- A. Federal and local governments were largely ineffectual. In an attempt to preserve morale, they fostered fear. "No public official ever acknowledged the danger of influenza" (p.334).
- B. Instead of honest and helpful information, a "propaganda machine", guided in US by the federal Committee on Public Information served the public a distorted picture of the situation and gave impractical advice.
- C. The US press operated under informal war censorship. It failed to report the influenza casualties and lost the confidence of its readers (p.335).

- D. There was a critical shortage of nurses, both in the army and in civilian life. Proposals to start rapid training of 'practical nurses' was successfully blocked by women who controlled nursing education; those in the nursing establishment feared that nurses trained outside of formal graduate programs would become handmaids of physicians and diminish the growing prestige of the nursing profession (p.141). The propaganda machine prevented the public from learning the actual severity of the need for nurses (p 143).
- E. The US Army Medical Service was aware of the threat of epidemics among soldiers and proposed effective control measures, but military leaders almost totally and repeatedly ignored the advice of their own service, even when the flu pandemic was already in progress (p.148, 304).
- F. The US Public Health Service and the Surgeon General, who was heading it, avoided public comments and actions until very late into the course of the pandemic (p.312).
- G. In spite of the efforts of many scientists and institutions, the agent causing the pandemic was not discovered. The medical establishment subscribed to an erroneous notion that the influenza was caused by a bacillus (*Bacillus influenzae*) (p. 409). Even though contemporary medical science was in possession of vaccines and antiserums for a dozen diseases of humans and animals (anthrax, cholera, yellow fever, typhoid, plague, and gangrene), no effective vaccine or other treatment methods were discovered that could be applied widely to influenza victims (p. 146). (Influenza virus was finally isolated in 1933).
- H. The US Red Cross did not get government funds or directions, but nevertheless it took massive scale measures to find and pay nurses, furnish supplies for hospitals, and provide home visits (p. 315).
- I. Most influenza patients who were not hospitalized were never seen by a physician or nurse, and most deaths occurred at home (p.329).
- J. As the infection spread, the illness and the fear of infection gradually reduced the flow of available volunteers to a trickle (p. 331).
- K. Even if nurses and physicians were dying in large numbers, the professionals in the US continued to do their duty and were considered by others to be heroes.

The author concluded with a statement, highly relevant to the ethics of pandemic planning and response: "So the final lesson of 1918, a simple one, yet the one most difficult to execute, is that those who occupy positions of authority must lessen the panic that can alienate the members of a society. A society that takes as its motto, "every man for himself" is no longer a civilized society. Those in authority must retain the public's trust. The way to do that is to distort nothing, put the best face on nothing, to try to manipulate no one A leader must make whatever horror exists concrete. Only then will people be able to break it apart" (p. 462).

A brief report on the effects of influenza pandemic on the population of Geneva, Switzerland put forward many similar points. The city was severely affected, 58% of citizens became ill during the two pandemic years. As elsewhere, the mortality was highest among males aged 20-49 years. During the peak of pandemic, hospitals refused to admit flu patients and temporary sites became too quickly overcrowded. Taxi drivers had to refuse to transport flu patients, with the exception of one designated company, which had to disinfect its vehicles after each ride. There was also a major socioeconomic impact on public and private sectors. Telephone, telegraph, post office and public transportation worked only intermittently. Hygiene recommendations were multiple but mutually conflicting; misinformation was frequent, and fear prevailed (Ammon, 2002).

A number of other relevant points were made in other publications that reported on the "Spanish flu" pandemic:

- A. The “scientific triumphalism” of the early 20th century collapsed when it became obvious that bacteriology and immunology utterly failed to curtail or even modify the impact of the pandemic (Tognotti, 2003) and when medical-scientific discourse became, at times, irrational and arcane (Bertucci-Martins, 2005)
- B. Public health measures were instituted in many communities, but they were controversial among the population and difficult to enforce. Their impact was mostly uncertain. However, some normally isolated towns in US and in Canada managed to avoid influenza infections by closing themselves up to any outside contacts and by complete quarantine of their population (Herring, 2000).
- C. The pandemic hit especially hard the small, remote and northern communities and native settlements, where lack of heat, food and human assistance complicated the situation of inhabitants; in some instances whole communities died (Herring, 1994).
- D. Access of good nursing to the sick was the best predictor of outcome of influenza illness. Visiting nurse services for sick at home were perceived as the most valuable of community services (Robinson, 1990).
- E. Sections of cities populated by poor people and with poor sanitation were most severely affected, and influenza made many inequalities in the society more glaring (Souza, 2005). A study of social economic factors found that the mortality among those identified as middle class and bourgeois class was 19-25% lower than working class mortality which was not a statistically significant difference. However, when family accommodation was considered, a large statistically significant difference emerged. Those living in apartments with 4-6 rooms had an average 50% lower mortality than those living in one-room apartments (Mamelund, 2005).
- F. The impact of influenza on Australia was much mitigated by strict quarantine and isolation measures. Political and social aspects of the pandemic in Australia were studied in detail (McQueen, 1975).
- G.

3.2 “Swine flu” -1976

An outbreak of respiratory disease occurred in a military training camp in New Jersey in the spring of 1976. One recruit died; the analysis demonstrated the presence of a new subtype of influenza virus A that was never before isolated from humans but had some similarity with a swine virus. A limited human-to-human transmission within the camp was documented, and experts concluded that the virus had pandemic potential. Prevailing expert opinion was in favor of mass vaccination. The US government did arrange for vaccine production and commenced a national vaccination campaign in the fall of 1976. Within a few months, 48 million Americans were vaccinated, but the program was halted in December of that year because of mounting concerns about a serious side-effect, chiefly 532 cases of Guillan-Barrè syndrome, with 32 deaths. A pandemic did not materialize and in fact, no case of this new virus infection was ever detected outside of the military camp. The public was confused and many health professionals were upset. These events eroded faith in vaccination and in public medicine in general, led to a decline in vaccination for childhood diseases, and led to mistrust in the government (Bernstein, Sept-Oct, 1981).

Because the consent form did not warn recipients of the risk of Guillen-Barrè syndrome, the US government accepted responsibility for the safety of the vaccine and liability for damages. Several million dollars were eventually paid in compensation. The whole management of this event by government and experts was generally regarded as a fiasco even if it was recognized that the organization and the speed of vaccination were a remarkable achievements. A number of books and papers were written to analyze the decision-making process, and proposals were made of how to avoid a similar situation in the future (Dowdle, 1993; Kolata, 1999; Neustadt & Fineberg 1983; Osborn, 1977). There is still some controversy about the interpretation of these events, but these commentators have suggested that the problems were the excessive reliance on unproven scientific theories; the desire of public health experts to show their usefulness; political pressures during the years of presidential election; weak press relations (Rubin & Hendy 1977); and lack of public hearings and consultations.

Following the US example, Canadian authorities also took steps toward a mass vaccination program. Delivery was left to the provinces and a variety of vaccines and vaccination protocols were used across the country. There were also some reports of serious side effects and vaccination was halted prematurely when no excessive influenza outbreaks materialized. There is some limited analysis of these events by Canadian commentators (Morrison *et al.* 1976; Northcott, 1978; Rhodes, 1976).

3.3 SARS epidemics – 2002-2003

3.3.1 Epidemiological background of SARS epidemics

Between November 2002 and July 2003 there was an outbreak of a disease that later became known as severe acute respiratory syndrome (SARS). Over 8,000 cases were reported from China, Hong Kong, Taiwan, Singapore, Vietnam, Canada, USA and 19 other countries. 774 people died of the diseases, many in some of the most advanced hospitals in the world (Maki, 2003). The disease spread rapidly, mainly to people who were in close contact with the infected person, like family members and professional health care providers caring for patients with SARS. However, there was also evidence of indirect transmission within hotels and apartment buildings suggesting entry of the virus into the body through gastro-intestinal tract. The cause of SARS was initially unknown, the fatality rate high, and all therapy was only supportive, focused on symptoms, or experimental.

Under those circumstances, public health authorities in all affected countries, with coordination by WHO, rapidly adopted the same, traditional public health measures: large scale surveillance and screening of febrile illnesses, contact tracing, isolation of patients with SARS, quarantine of thousands of contacts, closure of schools and affected hospitals, restrictions on traveling. The combined effect of these measures was that the infection, which was later determined to be due to a coronavirus that jumped species from animal to man, was brought under control, and at least temporarily driven out of the human population (Maki, 2004; Sampathkumar *et al.* 2003).

3.3.2 Ethical and social issues in SARS outbreaks

Direct US experience was limited to 73 confirmed cases, but the public health measures in use across the nation gave rise to a tension between safeguarding the public's health and maintaining individual rights to privacy, liberty and freedom of movement. A number of US commentators addressed this issue. One paper stated: "That a common set of public health measures worked in contexts as different as China, Vietnam, Singapore, Taiwan, Hong Kong, and Canada should not mask the fact that public health measures are embedded in a broader sociopolitical context. Coercive strategies reflect conceptions of individual rights, the legitimacy of state intrusions, and the appropriate balance between security and liberty" (Gostin *et al.* 2003 p. 3231). The authors identified the following principles as guidance for this situation:

- precautionary principle, as a chief principle because of scientific uncertainty
- using least restrictive/intrusive alternative
- fairness and justice, both procedural and substantive
- transparency
- using voluntary rather than coercive measures whenever possible

They made recommendations on several issues:

- A. Surveillance and contact tracing: name reporting is justified; public needs to be educated about surveillance and how reports will be used; stigmatization of communities may not be preventable but needs to be mitigated, and consultations with affected communities will express solidarity; law enforcement may be appropriate.
- B. Isolation and Quarantine: it is warranted if based on a scientific assessment of risk; restrictive measures need not be applied widely, but targeted; a safe and hospitable environment ought to be provided; enforcement of home quarantine may be necessary; financial burden ought to be borne by community as a whole (for example, by providing sick pay benefits, welfare, disaster relief compensation); procedural due-process ought to be in place (for example, a hearing of people with complaints and disputes).
- C. Travel advisories and restrictions: right to travel, although fundamental, is not unlimited; restrictions to be narrowly drawn and targeted; screening of passengers may be morally appropriate; all persons are to be allowed to return to their home country as soon as it is safe.

These authors conclude that "(a)dooption of ethical recommendations will be a necessary concomitant of epidemic control in democratic societies."

Toronto, capital of Canadian province of Ontario, took the brunt of Canadian SARS epidemics. In their analysis of the ethical dimensions of the SARS outbreak of more than the 200 cases, a multidisciplinary working group (Singer *et al.* 2003) identified ten key ethical values:

- Individual liberty
- Reciprocity
- Transparency
- Privacy
- Protection of communities from stigmatization
- Duty to provide care
- Equity
- Solidarity

These authors also identified what they believed were five most important SARS issues, and discussed how the ethical values should be expressed in dealing with these issues:

- A. Ethics of quarantine: individual liberty to be balanced against protection of public; proportionality demands decisions to be made fairly; reciprocity requires to provide adequate care and avoid undue economic penalties.
- B. Privacy of personal information and the public's need to know: proportionality demands that privacy be respected unless naming of a person is essential to public safety.
- C. Duty of care: the duty determined by professional ethics; reciprocity requires appropriate support and protection, including insurance; the authors reported that they were unable to resolve the issue of limits of professional duty in situations where the lives of the caregivers and their families were at risk.

- D. Collateral damage: restriction on entry to hospitals designated for SARS patients lead to denial of care to other patients that resulted in harm, even deaths, but the harm was not yet fully quantified; ethical concerns that in-patients could not receive visitors (also see Rogers, 2004); risks and benefits need to be weighted; procedural fairness is essential.
- E. SARS in globalized world: rapid spread by air travel recognized; solidarity among nations needs to be adopted both for altruistic reasons and for self-interest; transparency, honesty and good communication are essential.

Another paper "Stand on guard for thee" (University of Toronto Joint Centre for Bioethics and Pandemic Influenza Working Group, November 2005), which incorporates the lessons learned from the SARS experience in Toronto, and was drafted as a proposal for an ethical framework for influenza pandemic planning, will be reviewed in detail in Section 5 of this report.

A report commissioned by the Province of Ontario, "Expert Panel on SARS and Infectious Disease Control" describes concerns and makes recommendations regarding public health functions and models, infection control, emergency preparedness, communications, surveillance and human health resources (Walker *et al.* 2003). In addition, the federal government of Canada set up a National Advisory Committee on SARS and Public Health that examined similar issues from the national perspective (Naylor *et al.* 2003). One of the committee's recommendations, that has since been implemented, was the creation of a Public Health Agency of Canada. The implications of SARS experiences for public health law in Canada were also examined (Ries, 2004).

Many publications have addressed the position of health care workers in Asia and North America during the SARS outbreaks. It was noted that the initial lack of strict infection control measures and lack of isolation facilities in hospitals put health professionals at a very high risk of getting infected (Hsueh & Yang 2005). As a result, about half of all SARS patients in countries outside China were health care workers, who became infected when caring for recognized or unrecognized patients with SARS (Wenzel *et al.* 2005). Professional decision-making was most difficult, with many ethical dilemmas and conflicts, and with the need to appear calm and professional amid chaos, anxiety and hysteria (Ovadia *et al.* 2005). Workers and leaders of a SARS designated hospital acknowledged that, although they made an effort to meet the conditions of accountability of reasonableness, the decision-making was not ideal (Bell *et al.* 2004). The work was also technically and physically demanding with the necessity to be scrupulous in infection control measures, knowing that even a slight lapse could be fatal; the workers also experienced the hardship of using cumbersome personal protection devices (Chen *et al.* 2005; Chow, 2004). A study from Taiwan demonstrated that it is possible to predict the willingness of hospital nurses to serve under SARS conditions. Significant predictors were:

- The nurses' level of agreement with general SARS infection control measures
- Lack of necessity for quarantining health care workers who provided care for SARS patients
- Nurses' physical health status
- Holding a bachelors' degree (Tzeng, 2003; Tzeng, 2004)

A study from Hong Kong showed that SARS crisis enhanced a reconstruction of worldview and affirmed the professional integrity, sense of moral duty and feeling of self-growth of a group of nursing students (Heung *et al.* 2005). On the other hand, a Canadian study of employees in a hospital caring for SARS patients indicated that 29% of staff who completed the General Health Questionnaire (GHQ-12) scored above the threshold point for emotional distress. The rate of emotional distress among nurses (45%) was particularly high. The increased level of concern for personal or family health was correlated with the following factors:

- Perception of a greater risk of death from SARS
- Living with children
- Personal or family lifestyle affected by SARS
- Being treated differently by people because of working in a SARS hospital (Nickel *et al.* 2004)

A paper examining the behavior and public perception of health care workers in Taiwan and China notes that in both countries, these caregivers were called 'heroes'. Authors noted that this label may not be appropriate for average health care workers; however, a number of very selfless acts were documented. The label was also thought to be politically convenient because authorities wished to erase the memories of their policy mistakes in the early stages of outbreaks. The authors concluded, "(a) middle ground for reasonable expectations from health care workers should be expected. While all should act according to the ethics of beneficence, not all persons should be expected to be martyrs for society" (Hsin & Macer 2004). In a similar vein, a US bioethicist observed "despite trends toward commercialization, easier lives, and self-centered individualism, the response of health care professionals to SARS reaffirmed dedication to caring for the sick even at great personal risks as the core ethical principle of medicine" (Emanuel, 2003).

SARS stories also highlighted defects in national health systems, in international data sharing and in influenza pandemic preparedness; and showed that our societies are vulnerable to infections in spite of the sophistication of our defenses (Abraham, 2004).

4. Justice in resource allocation and rationing

4.1 Procurement of resources for pandemic preparedness and response

Reading of any of national pandemic influenza plans like those listed on WHO web site (World Health Organization) shows that pandemic and scarcity seem almost inseparable. If one quarter to one half of the entire population becomes ill, there will be extraordinary demands on everyone and everything that is needed to care for the sick in general, such as health care workers (or trained volunteers), diagnostic facilities, hospital beds, drugs, and supplies. In addition, there will be a large need for specific influenza related resources, especially vaccines and antivirals, but also for intensive care units, ventilators and oxygen. The process of contingency planning for influenza pandemic, if done thoroughly, will lead to the identification of these needs. Once these needs are estimated, the pandemic planners have a choice to either plan for the best possible use of existing, normal resources, and accept that even with the most imaginative and effective use, the resources will be rapidly overwhelmed and exhausted, or, they could propose that these resources be augmented to meet the needs during a pandemic. At this point, a number of questions will emerge: Who should decide how much resources should be committed to fighting influenza?, On what basis should such a decision be made?, Should these additional resources come from existing health care budget or outside of it?, What proportion of resources is to be committed to prevention of the pandemic, versus care for the sick? (Kinlaw, May, 2002). Answers to these questions are outside of the usual range of bioethics expertise and bioethics literature. One of the founding fathers of bioethics observed that the question of how to choose between medical and other societal priorities is "almost, if not altogether, incorrigible to moral reasoning" (Ramsey, 1970) and this view was not seriously challenged. Yet bioethics has a stake here because of its concern for human life and health. What is the relationship between bioethics and politics? "Since human health can be achieved only in human community, an ethics of healthcare is also a politics. In a modern pluralistic society, a politics of ethics demands an effort to increase moral consensus in regard to values and priorities..." (Ashely, Benedict O'Rourke, Kevin, 1989 p. 19). Of course, values and priorities are something that bioethics is accustomed to deal with. Therefore, while bioethics cannot offer final solutions, it can call attention to the importance of making these decisions deliberately and explicitly, and involving those who will be affected by these decisions.

This reviewer suggested elsewhere that pandemic preparedness planners and experts do have an obligation to determine which additional resources will be required to meet the needs of the population, but they cannot command them. They ought to submit those estimates of resource needs, together with estimates of all consequences of meeting those needs to various degrees, to an appropriate political body representing the population involved. This would allow an opportunity for debates and consultations with citizens, and a final decision about resource allocation could be made which will balance the attention of the pandemic threat with attention to other societal priorities (Kotalik, 2005). It will have to be made clear that accepting a shortage of resources for the prevention of a pandemic and for patient care means accepting the risk of a certain number of illnesses and deaths. Rather than presuming a consent of the population with whatever decisions experts and bureaucrats will make, it appears much more morally appropriate to seek actual consent of the population's representatives to accept or eliminate certain risks because in pandemic planning there is an opportunity to do so in advance (Menzel, 1990 p. 33). This way, the policy of preparing for and responding to a pandemic can be both ethically sound and in a fundamental way it will be an evidence-based policy, which will make possible an evidence-based governing (Davies, 2004).

4.2 Distribution and rationing of procured resources

By rationing, I will mean an explicit or implicit policy to withhold specific measures that deal with prevention, investigation, treatment or care for individuals or groups because of its scarcity or cost, even if such an intervention would be or could be beneficial to them (Bradley, 2000). On this account, rationing is a special case of resource allocation, the allocation decisions being necessary whether or not there is scarcity of the resource. Some bioethicists criticized the contemporary notion and practice of rationing, holding that it often is unnecessary, does not increase efficiency and is morally flawed. The identified moral problems were: unjustified discrimination, harm to the patient-physician relationship, and assault on patients autonomy (Wiote & Waithe 1995). Others noted that ordinary people on both sides of the Atlantic reject any form of rationing (Baker, 1995). Many other bioethicists believe that rationing is inevitable in any publicly funded system, because of ever increasing expectations of the population and the constantly expanding range of interventions made possible by new technology and drugs. In a pandemic, rationing of certain measures such as a pandemic vaccine seems “natural” and inevitable, even if the best possible process to augment available resources as referred to in section 4.1 will be used. On other the hand, scarcity of some resources could be largely avoided because they could be gathered in advance and stockpiled for pandemic time, such as personal protection equipment or antiviral drugs or antibiotics.

There is a vast bioethical literature on rationing of health care but no bioethical discourse of rationing under condition of influenza pandemic. Therefore, the best we can do is to look for some methods and proposals for rationing of health care in general or under other special situations which could provide some guidance of how to approach rationing in a pandemic. We can distinguish two approaches to developing a moral perspective on rationing - substantive and procedural.

4.2.1 The substantive approach to rationing means, to adopt some concept or principle of distributive justice. The often quoted principle of justice, “equals must be treated equally, and unequals must be treated unequally” (Beauchamp & Childress 2001 p. 226), is a correct formal principle, also sometimes stated as “similar treatment for similar cases”. However, this principle is really not very helpful in a practical setting, both because it does not specify what is similar or equal, and secondly, because in genuine unavoidable scarcity, which is likely to exist during a pandemic, resources may run out before all ‘similar’ cases can be served. So, we need to turn to some material principles of justice that identify relevant properties that a person must possess to qualify for a particular distribution. The following material principles of justice have been all defended by some theorists (Beauchamp & Childress 2001; Cookson & Dolan 2000), and each plays some practical role in allocation of health care services in our societies:

- a) To each person according to effort (including ‘first come first serve’)
- b) To each person according to merit (merit earned by past contribution)
- c) To each person according to free market exchange (libertarian principles)
- d) To each person according to a lottery allocation (possibly an egalitarian principle)
- e) To each person in order to maximize aggregate population health (a maximizing principle)
- f) To each person according to current and anticipated contribution (possibly a maximizing principle)
- g) To each person according to need (a need principle)
- h) To each person an equal share (an egalitarian principle)

The first four of these principles, often expressed in the provisions of personal care, have a limited applicability to public health in general and pandemic response specifically, and they will not be discussed here. The last four principles will be examined in relationship to pandemic planning.

4.2.1.1. Maximizing principle. The principle that requires to distribute resources in such a way as to maximize the overall health benefits of a population (Cookson & Dolan 2000) is clearly the one which most directly advances the goal of public health. Because the goal of national pandemic plans is most often to minimize overall morbidity and mortality from influenza (Public Health Agency of Canada, February 2004; Steffen *et al.* 2005), this principle appears also very compatible with influenza planning and response. Being broadly utilitarian and striving for efficiency, this principle's application is tied with ability to estimate likely consequences of different courses of public health interventions.

"Utilitarians argue that the standard of justice depends on the principle of utility (which demands that we seek to maximize overall good)" (Beauchamp & Childress 2001 p. 231). Under this system, individual rights are strictly contingent upon social arrangements that maximize net social utility. Utilitarian calculus invites us to assess all possible consequences or outcomes for various ways of distributing resources and adopt such a distribution which will lead most rapidly and with least cost to reaching the ultimate goal of a program. It allows to incorporate cost-effectiveness calculations and express the benefit of reducing mortality and morbidity in Quality adjusted life years (QUALY) (Bradley, 2000). Menzel proposed that when health resources are scarce, they should be distributed to maximized QUALY (Menzel, 1990). But, we know that the people of Oregon (US), who embarked on the development of a publicly funded system of health care, found QUALY counterintuitive; it weighted too much against simple life extension, and they rejected it.

In contrast, Kosten-Nutzen ratio, as used by Swiss pandemic plan (Steffen *et al.* 2005), is simpler and less value charged and not an ethically problematic instrument. It allows to examine different strategies for infection control, and is not offered as a final arbiter of resource allocation, but as a step in a more complex decision-making process.

However, from an overall ethical perspective, problems with the utility principle are many. "At a time when mainstream theoretical ethics utilitarianism has been stringently criticized and is now in considerable disarray as an ethical theory, it has become the darling of the health-care resource allocation experts" (Charlesworth, 1993 p. 112). Many critics pointed out that the promises of utility theory to provide an impartial, almost mathematical way to arrive at the best outcome couldn't be fulfilled. Human acts and policies have consequences or outcomes, but, most of them do not have quantifiable and measurable outcomes, and even those that could be calculated are most difficult to compare with each other. For example, is the prevention of death worth the same or more or less, than prevention of a long-term serious disability? (Charlesworth, 1993). In addition, estimation of consequences of possible action in pandemic situations may easily be mistaken, given that the next pandemic may present us with novel situations and perils.

The other major objection to applying solely the principle of utility to all actions is that it permits or even demands that the burdens and benefits be distributed regardless of its impact on individuals. A study of pandemic scenarios could show, for example, that an overall good could be maximized by denying access to prevention or care to the sickest or most vulnerable people because they would consume resources that could be used for the benefit of others, resulting in a greater overall impact on mortality and morbidity (Veatch, 1981). A public health specialist stated that "(t)he well being of society as a whole is more important than that of any individual" (Last, 1987a p. 351). This would mean, for example, that if a certain amount of vaccine is available, and it is estimated that the elderly who are at the highest risk of influenza deaths are less likely to develop immunity by vaccination than younger people, then, the life-saving claim of an elderly can be ignored in order to maximize the benefits that can be derived from the scarce vaccine.

Most citizens would feel that such an approach is counter-intuitive and that it would impinge on human rights, particularly the right to health care, which in some form or other is operational in many countries.

Besides the complex notion of medical utility (Dickenson, 1999) that was briefly addressed, there is a problem with social utility (Beauchamp & Childress 2001 p. 270). To illustrate: keeping healthy a person who has an important social function (e.g. nuclear power plant operator) has favorable social consequences that would not be obtained by keeping healthy a person who has no discernible social function (elderly person in a nursing home). Clearly, these two forms of utility are interrelated - giving priority to vaccination of the power plant operator rather than to the elderly may possibly be the best way to safeguard the life and health of the elderly whose basic survival is dependent on availability of electrical power.

In section 2, I mentioned that the evaluation of consequences by balancing the risk and benefit of a possible intervention was identified as a primary task of a public health specialist. If the balancing is carried out to assure that there will be, in a broad sense, more benefit than risks, then there is an opportunity to incorporate a variety of other considerations. But if such balancing is aiming to produce the maximal balance of positive value over disvalue, or minimize an impact of an event, the public health official will engage in a strictly utilitarian calculus, which raises all those concerns discussed above.

Finally, in this section, we need to mention rationing based on contributions that a person currently is providing or is expected to provide in the future. This criterion for substantive justice did not receive much attention from theorists and when mentioned, it is not clearly separated from rationing based on merit of past contributions. But as opposed to merit criteria, this rationing principle has an utilitarian purpose. In discussions of pandemic influenza scenarios, there has been a clear understanding among planners that absenteeism due to illness or death among the workers that are responsible for some critical services and infrastructure will lead to societal disruption and more morbidity and mortality. The inclusion of these essential services workers in high priority groups for measures such as vaccination and access to antiviral drugs has been based on perceived needs of their continuous services.

4.2.1.2 Need principles. The British philosopher Bernard Williams stated that "the proper ground for distribution of medical care is ill health: this is a necessary truth" (Williams, 1973 p. 240). Such distribution of resources that is dependent also on ability to pay, (that is market based rationing), Williams consider irrational. Even if we accept health care need as a highest or a major criterion for deciding on prioritization of scarce resources during pandemic, we have a long way to go to provide a guide to practical decision making for such intervention as vaccination or use of antivirals. A variety of health related needs can be most difficult to compare and put in any priority order (Campbell *et al.* 2001 p. 254). Daniels discussed thoroughly the relationship between distributive justice and health care needs and suggested that the needs that ought to concern us are those that are essential in order to achieve or maintain 'species-typical normal functioning'. To Daniels, the term means those functions that are typically required by humans of a particular age in order to have a range of opportunity to construct personal life plans and achieve them (Daniels, 2001). This concept is theoretically interesting but not easy to apply in practical setting.

Parfit pointed out that putting equality as our highest or only value when distributing scarce resources is problematic. Equality could be achieved by 'leveling down', that is, by making those who are better off, less well off, yet not making the situation better for anyone (Parfit, 2001). If, for example, some people acquired a personal supply of antiviral drugs for a three-week preventive course in anticipation of a pandemic in their community, and most people don't have it, then this is certainly an inequality. We could achieve equality by confiscating their 'stockpiles' or convincing them to turn it in to the community stockpile in order to give everyone a one day supply. This would achieve equality, however, a one day supply of the drug would have only minimal preventive value, so it would seem to be an improper moral action.

In pandemic influenza, the needs will be both in the domain of prevention and the domain of care for the sick. To deal with this fact and the reality of a very large discrepancy between demand and supply, the health needs could possibly be subdivided and considered in priority order: critical, essential, basic, felt need, want (Outka, 1989 p. 638). The usual objective, clinical way to evaluate a perceived need is to consider what is likely to happen if the need would not be met. Would the person die, be permanently disabled, suffer from pain or just experience an inconvenience? If evaluation of possible consequences of not being supplied with the intervention that is being rationed is required in order to determine the person's need then again the need principle is consequentialist and utilitarian as is the maximizing principle discussed above. The closeness of maximizing principles and needs principles will be even more obvious if we postulate that rationings decisions could consider not just individuals but can be made for groups or communities on the basis of aggregate needs of those groups or communities. As a result, the needs principles may be subject to the same criticism as maximizing principles described in the previous paragraph.

4.2.1.3 Egalitarian principles. In personal care domain, it does not make sense to provide everyone with equal share of health care because healthy people have no use for it, only the sick need it. Hence, most scholars committed to equality will construct principles or rules that consider firstly the needs of individuals and only then seek equality in distribution of resources meeting these needs. Into this category belongs the 'fair equality of opportunity' rule developed by Daniels and based on writing of Rawls, asking that each person be allowed a fair share of normal range of opportunities present in that society. This egalitarian approach would give priority to people who need to maintain or restore a normal, "species typical" level of functioning (Daniels, 2001). A communitarian approach proposed by Callahan maintains that only basic minimum care is due to those in their late seventies or eighties, rather than actions on extension of life (Callahan, 1987). If Daniels' or Callahan's proposals, which incorporate some form of age based rationing, would be applied to pandemic contingency planning, then the plans could state that both preventive and therapeutic interventions during pandemic could be restricted to people in the first three quadrants of life. But these age-based rationing themes, while they were widely discussed, were not reported to be put in practice in North America or on the continent, and they were criticized on many grounds by other bioethicists (Brock, 1993).

In domain of public health, where not only the sick but potentially all people can benefit from such efforts as preventing the emergence of an infectious disease outbreak, the prospect of constructing a widely acceptable, true egalitarian principle and system of resource allocation would seem to be more promising than in the domain of personal care, but this review did not uncover any publications which would attempt to do that.

4.2.2 Combination of several substantive principles of justice. It is debatable whether a single principle of justice could be selected by a society as being paramount for all purposes in the health sector. It is more likely that any reasonable approach would accept a variety of principles (Baker, 1995 p. 81). This would be especially true in influenza pandemic planning and response measures when multiple decisions would have to be made about the use of resources in a variety of situations.

Three levels of resource allocation can be distinguished (Williams, 2005 p. 69):

- a) At the highest ('macro') level, governments decide how resources are to be divided between the health sector and other sectors and assign resources to various health programs, such as pandemic preparedness measures, and institutions.
- b) At the institutional ('meso') level, the health agencies decide how to distribute resources among various services they provide and various institutional needs.
- c) At the individual patient ('micro') level, health care providers decide on resource allocation in each case as when they are ordering tests and treatments, assigning patients to various level of care and so on.

It is possible and perhaps even desirable to use, for example, a maximizing principle for macro and meso-allocation, and use an individual needs principle for micro-allocation. In this way, a physician or a nurse deciding on micro-allocation may be able to balance justice with compassion and “find ways to minimize any harm that an individual patient may suffer as a result of adhering to public health requirements” (Williams, 2005 p. 72-75).

A bioethicist, who examined actual, already enacted public health policies, concluded that rather than searching for a single authoritative principle of justice for allocation of resources, we have to accept that a variety of principles together will make policies just. She argued that the following principles have a legitimate place in just allocation: the anti-free ride principle, the vital and constant importance to well-being, the difference principle, efficacy, equality, “maximin”, avoid undue burdens, avoid the worst outcome (Rhodes, Winter 2005).

Priority setting criteria that have been developed for organ transplantation (Michaelis, 2002) or for retroviral therapy of AIDS patients (McGough *et al.* 2005) all take into consideration several principles and they are used in complimentary fashion; they could be good models to examine when searching for an ethical rationing system suitable for pandemic influenza planning.

4.3 Rationing of resources and existing inequalities

Recent events surrounding some large human catastrophes, such as tsunamis and hurricanes, brought to our attention the fact that these natural events have a tendency to cause more harm to those people who are already worse off because these people have less options, resilience and resources than others. Influenza pandemic infection may not threaten every citizen to the same degree either. Living in overcrowded conditions, for example, may put a person at a greater risk for infection than one who may be able to maintain a comfortable distance from other potentially infected people. There is a concern, expressed in literature, that public health interventions may further exacerbate the existing inequalities in our societies. Thus, an article in the Encyclopedia of Bioethics reminds us “The history of epidemics suggest that society’s responses have usually included scapegoating marginal and already stigmatized groups and restrictions of their civil rights” (Evans, 1995). In modern times, public health practitioners have been more successful in improving the overall health of the population, rather than improving the health of the most disadvantaged. A recent, extensive examination of these issues (Anand *et al.* 2004) led to the following three points:

- Health care inequalities are of greater importance than other inequalities
- Rawls’ concept of distributed justice, ‘justice as fairness’, makes a compelling case for obligatory and direct effort to reduce existing health inequalities while promoting “most extensive liberty compatible with liberty for all” (Rawls, 1971).
- Personal responsibility for the state of health is not to be denied but a society has as much responsibility as its individuals members for population health improvement

In the context of national pandemic plans, this situation the issue whether the plan anticipates committing resources for people with pre-existing health conditions, which makes them specially vulnerable, and accommodates special populations such as welfare recipients, unemployed, recent immigrants, illegal immigrants and homeless people. Possibly the minimal acceptable condition would be that pandemic response measures should not exacerbate existing inequalities. “Economic inequalities may be part of a fair and reasonable society, as both libertarians and liberal egalitarians seem to agree. But unless we are willing to adopt the libertarian view of what a modern, liberal society should be, introducing additional inequalities into our health system does not appear to be reasonable or fair” (Stingl, 1996 p. 17).

The highest demand that awareness of inequalities in our society could make on a public health program, like a pandemic response plan, would be that the program should be used as an opportunity to diminish as much as possible existing inequalities, at least inequalities in health care and in health. Such conditions would move our actions out of the domain of distributive justice, which the above discussion addresses, into the domain of restorative justice. No support for such an approach in the time of pandemic or similar public health emergency was found in the surveyed publications.

4.2.2 Procedural approach to justice in resource allocation and rationing starts with a premise that an outcome will be just if it is the result of appropriate deliberations. The Toronto report "Stand on Guard for Thee" (University of Toronto Joint Centre for Bioethics and Pandemic Influenza Working Group, November 2005) when seeking to make recommendations on priority setting, including allocation of scarce resources such as vaccines and antivirals, takes this approach. The report also announces substantive values of equity, trust, solidarity and stewardship, but, when it comes to making concrete recommendation, it does not explicate the substantive values. Instead, it proposes that the process must be fair in order to be legitimate - meaning that it has to be reasonable, open, transparent, inclusive, responsive and accountable. The report arrives at three concrete procedural recommendations for governments and the health sector that are described in the section 6.0 of this review.

While the above document is the first that explicitly introduces fair process into pandemic planning, this approach is, of course, not new. A lack of generally acceptable moral theory and a lack of consensus on the importance of a variety of substantive moral values in multicultural liberal societies necessitate that a great deal of our discourse in bioethics, for example, when an ethics committee debates what to recommend in case of a clinical moral dilemma, is based on consensus about a fair process. This situation was illustrated by a qualitative study in a hospital setting (Singer *et al.* 2000). Procedural approach to justice in resource allocation was articulated by Daniels, who when addressing the difficulties of deciding whether to fund new technologies stated: "More generally, we probably lack consensus on principles capable of resolving disputes about rationing. A second wave of efforts to address propriety setting has thus focused on developing fair, publicly acceptable process for making these decisions" (Daniels, 25 November 2000). He proposed that decision makers demonstrate "accountability for reasonableness" with these key elements:

- transparency;
- appeals to rationales that all can accept as relevant to meeting health need;
- procedures for revising decisions in light of challenges to them;
- empirical feasibility;
- sustainability;
- relevance to goals of various stakeholders.

The author stresses that the accountability for reasonableness is an approach that educates all stakeholders about the substance of deliberations involving resource constraints, and thus facilitate social learning. Daniels intended to position his account in the middle ground in the debate between those who are calling for 'implicit' and those who insist on 'explicit' rationing.

The account for reasonableness framework has been used to examine priority setting in Ontario hospitals during the SARS outbreak and was reported to be useful (Bell *et al.* 2004; Reeleder *et al.* 2005). Further evaluation of institutional conditions within which priority setting is being made resulted in a recommendation to add another element to the 'accountability for reasonableness' framework, namely 'the empowerment condition' (Gibson *et al.* 2005).

Commitment to pure procedural justice is often encountered in the work of those who promote a libertarian concept of justice. Thus, Nozick believes that a just society only needs to protect the right to property and the right to individual liberty, and allow persons to take care of their health on their own initiatives, free of any interventions of state, in the free market (Nozick, 1974). Nozick did not address any public health issues, but those who do often admit that individual initiatives are not able to deliver to people the benefits of a public health medicine. The very existence of pandemic plans that are supported by public funds in USA, where personal care is largely based on market model, can be seen as an admission that commitment to liberty and basic procedural justice is not sufficient to deal with the challenge of an influenza pandemic. Yet procedural justice still may play a significant role in our deliberations of rationing in this setting.

In this discussion of procedural justice principles, I will also refer to several proposals for an ethical framework for health care in general which do not start with *ex cathedra* principles, but rely instead on extensive collaboration and participation of citizens and communities to generate these principles in a fair political process. One such communitarian proposal invited an examination of practices, traditions, and commitments by a community that could lead to construction of multiple principles and rules covering various "spheres of justice" (Walzer, 1983). Building on this notion, we can possibly designate influenza pandemic situation a special sphere of justice, and adopt for the pandemic time a different set of principles and rules than we use in when there is no public health emergency.

Another proposal was the use public deliberations to create a 'new golden rule' (Etzioni, 1996). Some such proposals on involvement of public in rationing rely on the designation of certain individuals from a community as citizens' jury (Needham, 2000).

Emanuel submitted a complex, tightly argued vision of ideal of 'liberal communitarianism', which starts with a conviction that a political community that develops a robust mechanism for public deliberation will be capable to construct a conception of the good life. After this conception is articulated, shared and adopted, the community will be able to formulate laws and policies for health care and other aspects of communal life that will make the good life a reality for community members (Emanuel, 1991). This proposal, incorporating the partial truth of both liberalism and utilitarianism could possibly serve as a model for the development of an ethical framework for public health and influenza pandemic planning, but such a project would require a major intellectual, social and political commitment.

4.4 Conclusion

Given the complexity of the pandemic situation, no single account of justice can provide a foundation for rationing during a pandemic influenza situation. It could be argued that the maximizing principle of utility is most compatible with the discipline of public health and most effective in achieving the goals of pandemic planning, that is, maximal reduction of mortality and morbidity. However, if the principle of utility would be the only one used, the outcomes often could be counterintuitive and harsh. This principle would not provide an ethical basis for protection of vulnerable or minorities, for actions of reciprocity, for encouragement of solidarity and for a common sense fairness. We will need to consider incorporating into the ethical framework of public policy for pandemic times other notions, principles and rules that can balance the attention to efficacy with attention to individual and collective needs, to manifest fairness, and assistance for the disadvantaged. Further restrictions on the rule of maximized utility could be imposed by incorporating principles of procedural justice, as expressed in very simple way in 'the accountability for reasonableness' and in a very complex way in the liberal communitarian vision. The outcome would be less than maximized utility, but, more overall justice. Practical application of this blending of ethical principles will be referred to again in the discussion of vaccination and use of antiviral drugs in later chapters.

Note: This review deals with resources and their prioritization as concerns health care interventions and services. The pandemic scenarios, however, raise other issues of scarcity, which are likely to result from societal disruption. There will likely be scarcity of food, drinkable water, heat, electricity, fuel, and transportation. Pandemic plans and bioethics discussions, as yet, have not touched on these issues.

5. Ethics of national pandemic flu planning

An editorial in a recent issue of the journal *Nature* summarized the current situation with pandemic planning and preparedness around the world in this way: "National governments' performance is half-hearted, incomplete and far too slow. International organizations are working with their hands tied behind their backs, for bureaucratic and diplomatic reasons. In short, the level of current efforts is not commensurate with the threat we face (Editorial, 2005). In this chapter, I will address firstly the issue of who, if anyone, has the ethical responsibility for pandemic planning. Then, I will examine proposals for an ethical framework of pandemic plans, and finally, I will report how ethical issues of pandemic plans are reflected in scholarly literature.

5.1 Roles and responsibilities

A philosopher argued that, in contemporary societies, to maintain public health is a moral imperative (Boylan, 2004). If this is so, then, once such a serious danger to public health as influenza pandemic is identified, there is a moral responsibility of public health authorities to mount an appropriate defense. Historical data shows that control of infectious diseases has been the mainstay of activity of public health as this discipline together with public service have been gradually emerging over the past few centuries (Last, 1992). Admittedly, the range of responsibilities of public health authorities in the present time is not entirely settled. Whether or not public health should involve itself in all areas that affect human health, such as housing or diet or prevention of chronic diseases, remains a subject of debate. However, even political conservatives agree that market and consumer oriented medicine is not capable of controlling infectious diseases and that public authorities must intervene in this sphere (Gostin & Bloche 2003). An opinion was advanced that public health services' failure to prepare for possible incidents of bioterrorism would "constitute a massive 'malpractice' error of omission on the part of public health and medical authorities" (Henretig, 2001 p. 719), and this opinion could be extended to occurrences such as a pandemic, which is virtually certain to take place.

It is wise to involve many professionals, organizations and members of the community in public health decision making, however, scholars agree that it is the government that must assume the central role. Only governments equipped with police powers and with the power of taxation can undertake those massive interventions that appear to be necessary in the interest of public welfare (Childress *et al.* 2002). Along the same line, the Institute of Medicine's report, *The Future of Public Health*, gives primacy to government's role when it states: "The mission of public health is addressed by private organizations and individuals as well as by public agencies. But the governmental public health agency has an unique function: to see to it that vital elements are in place and that the mission is adequately addressed" (1988, p.19). Most recently some writers even suggested that the very legitimacy of governments and sovereignty of states ought to be considered conditional to their willingness and ability to prevent spread of dangerous infectious diseases (Daaler & Steiberg 2005).

But, public health professionals are not to be entirely subjected to governmental control. The British Medical Association defined duties of public health physicians as being advisors to the health authority, other statutory bodies and the community at large. These agencies may limit the public health physician's role or oppose his or her recommendations, but, they ought not to silence public health professionals. "To maintain an ethical stance, public health physicians must retain a right to make a direct appeal to the community and not just to its leaders. They must be able to speak on public health issues and ensure that health advice is not suppressed but remains a matter for public debate" (British Medical Association, 1993 p. 242).

Some infectious diseases were eliminated by intense international collaboration. However, the influenza viruses are impossible to eradicate, as there is a large reservoir of all subtypes of Influenza A viruses in wild aquatic birds (Cox *et al.* 2003). Occurrences of pandemic, which has been documented several times per century for the past six hundred years of human history, will almost certainly continue (Kobasa & Kawaoka December 2005). In this situation, and given that the last pandemic took place 37 years ago, public health authorities would appear to have an urgent ethical responsibility to put in place contingency plans that would at least lessen the harm to the population.

A question presents itself, whether the planning should anticipate a severe pandemic like the one of 1918, or a less severe pandemic like the one the world experienced in 1957. This is also an ethical issue because planning for a 1918 type, or a worse case scenario may waste resources, yet, planning for a mild pandemic may eventually cost lives. Many commentators mention this troublesome issue, but the papers by Dowdle (Dowdle, 2001; Dowdle, 2006) provide a very good discussion on this topic. The pandemic plan for Germany is explicitly based on a 1918 magnitude of pandemic, assumed to be a worst case scenario (Fock *et al.* 2002). Others recommend that action plans must be designed to avoid over-reaction to harmless influenza viruses and at the same time be adequate in dealing with a pandemic of a major magnitude. These two situations may need different controls and prevention plans (Snacken, 1996). Recent advances in epidemiological modeling for emerging infectious diseases offer new opportunities to model a variety of pandemic scenarios and can made the planning more accurate and appropriate (Bauch *et al.* 2005; Chretien *et al.* January 2006; Han & Leong 2004).

5.2 Ethical analysis and ethical frameworks of pandemic plans

The realization that another pandemic is unavoidable, and that it has the potential to cause an enormous number of deaths and major social disruption has been for some time a concern of health care professionals and public health services, at least in major industrialized countries. During the past 30 years, there has been a gradual increase of attention paid to developing national pandemic plans; for example, the first drafts in US were prepared in 1970; the first document of this type in Canada was drafted in 1983, and revised in 1988 and 1996 (Tam, T. W. S., Sep/Oct 1999). A pandemic plan for Switzerland was announced in 1997 (Bernasconi & Steffen 1997). The WHO pandemic plan was completed in 1999, and at that time Australia and United Kingdom also released similar documents. A progress report on the plan for Germany was published in 2002 (Fock *et al.* 2002). The Commission of European Communities issued a working paper on Community Influenza Pandemic Preparedness and Response Planning in 2004. At the time of writing this report (February 2006) WHO Website lists 25 national or super-national plans (World Health Organization). None of these national or super-national plans annunciated ethical values that underpin these documents or provided ethical frameworks of the plans. The Canadian plan is the only one that has a brief section which refers to ethical issues in the planning process.

The development in Canada can be usefully described. In 2002, when the Canadian National Pandemic Influenza Plan (CPIP) was in an ultimate draft stage, the federal ministry of health (Health Canada) decided to commission an external advice on ethics and legal issues of the document. The writer of this review was the person who was given the task to provide that advice and his report was delivered to Health Canada in the spring 2003. The report was circulated among members of the national pandemic influenza committee and among other Canadian decision-makers but not released into public domain.

Ethical principles recommended for pandemic planning were outlined and some ethical dilemmas were presented at an international forum in 2003 (Tamblyn & Kotalik Okinawa, Japan October 7-11, 2003). The ethical principles proposed for pandemic planning and for similar public health programs were:

- Principles of beneficence & nonmaleficence
- Respect for autonomy
- Principle of justice
- Principle of subsidiarity
- Precautionary principle
- Principle of proportionate response
- Principle of transparency
- Principle of minimal necessary interferences

Ethical issues which were identified as requiring most urgently further research and discussion were: scarcity of resources; use of vaccine and antiviral; engagement of health care workers; communications with all sectors of society.

Canadian Pandemic Influenza Plan was released in February 2004 with a brief section entitled "Ethical Consideration," indicating that an external review of ethical and legal aspects of the plan was carried out and stated that the ethics report "*attempts to identify relevant ethical principles, rules and values, to develop a reasoned position on some previously articulated and morally problematic measures, and identifies some other moral concerns and questions raised by the planning activities. The report takes the position that the proper initial objective of planning for influenza response is to identify all measures that can diminish as much as possible the impact of the pandemic on our whole population and to assess the benefits and burdens, (including the costs) of these measures*". This section of CPIP concludes by indicating that ethical issues will be further considered in the next draft of the Plan which is now due in 2006 (Public Health Agency of Canada, February 2004 p. 23).

Based on the national plan, Canadian provinces started to develop their own pandemic plans. The Ontario Health Plan for Influenza Pandemic was released in June 2005, and this plan has a section entitled "*Ethics Framework for Decision Making*" (Ministry of Health and Long-Term Care, June 2005). This section is based on the University of Toronto Joint Centre for Bioethics report entitled "*Ethics in Pandemic Influenza Crisis. Framework for Decision Making*", authored by Gibson. Because this is the only pandemic plan articulating explicitly ethical values and rules, this section will be reviewed in detail. The Ontario plan first announces process based criteria and suggests that stakeholders are more likely to accept difficult decisions if decision-making processes are:

- open and transparent (explained, open to scrutiny)
- reasonable (based on evidence, principles, values; made by people who are credible and accountable)
- inclusive (stakeholders could engage in the process),
- responsive (revised and updated as required, with mechanism to deal with complaints and disputes)
- accountable (decision-making sustained throughout the pandemic)

Secondly, the Ontario plan announces core ethical values (not listed in priority), on which the response to influenza pandemic will be based:

- Individual liberty:
Restrictions will be proportional to the risk of public harm, be necessary and relevant to protecting the public good, employ the least restrictive means necessary to achieve public health goals, and be applied without discrimination.
- Protection of the Public from Harm:
Authorities will weigh the benefit of protecting the public against the loss of liberty of some individuals, make stakeholders aware of reasons, benefits & consequences of not complying, and establish process for reviews of decision and complaints.
- Proportionality:
Authorities will use more coercive measures only in circumstances where less restrictive means have failed to achieve appropriate ends.
- Privacy:
Ontario will limit any disclosure to only that which is required to achieve legitimate public health goals, and will take steps to prevent stigmatization.
- Equity:
Decision makers will strive to preserve as much equity as possible between the needs of influenza patients and patients with other urgent needs, establish fair decision making process/criteria for providing individuals with vaccination, antivirals, emergency and essential services.
- Duty to Provide Care:
Health care workers have duty to provide care, which is to be balanced against other obligations, and Ontario will support them by establishing collaboratively practice guidelines, establishing processes for resolution of disputes, complaints and claims for work exemptions, and by striving to provide appropriate equipment and supplies.
- Reciprocity:
Decision makers will take steps to ease social, economic, and emotional burdens of health care workers, patients and families.
- Trust:
Decision makers will take steps to build trust with stakeholders before the pandemic occurs and ensure that decision making processes are ethical and transparent.
- Solidarity:
Solidarity between communities, institutions and government will be promoted by straightforward communication, and by open collaboration championing the health of the general public and service providers.
- Stewardship:
Those entrusted with governance over scarce resources will protect and develop resources and be accountable for public well-being and equity, i.e., fair distribution of both benefits and burdens (Ministry of Health and Long-Term Care, June 2005 p. 9-12).

This ethical framework of Ontario pandemic plan is now being adopted by health care planners in the province and incorporated into regional, local and institutional plans. (See for example, Thunder Bay & Area Pandemic Influenza plan, 2005).

A final document that originated in Canada and deserves attention in this context is the report "*Stand on Guard for Thee*" issued by the University of Toronto Joint Centre for Bioethics in November 2005 (University of Toronto Joint Centre for Bioethics and Pandemic Influenza Working Group, November 2005). The report lists the same 10 substantive values and 5 procedural values that are found also in the Ontario pandemic plan and were outlined above. In addition, the report identified and discussed in detail "Four Key Ethical Issues". Each issue is described, ethical values and processes identified, and 3-4 detailed recommendations are made. The key issues are:

- Health workers' duty to provide care during a communicable disease outbreak
- Restricting liberty in the interest of public health by measures such as quarantine

- Priority setting, including the allocation of scarce resources, such as viral and antiviral medicines
- Global governance implications, such as travel advisories.

The report makes two cardinal recommendations:

- a) National, provincial/state/territorial, and municipal governments, as well as the health care sector, should ensure that their pandemic plans include an ethical component.
- b) National, provincial/state/territorial, and municipal governments, as well as the health care sector should consider incorporating both substantive and procedural values in the ethical component of their pandemic plans.

5.3 Ethical issues in pandemic plans reflected in other literature

A recent article proposing research agenda concerning the avian influenza and the influenza pandemic attracted a letter that points out that in addition to clinical and epidemiological questions, many ethical issues raised by influenza pandemic call for research approach (Tracy *et al.* May 5 2005). However, research and scholarship related to ethics of influenza pandemic is at the moment very limited.

This reviewer published a paper that was the first to identify several pressing ethical concerns in Canadian, US and British national pandemic plans and in their implementation process (Kotalik, 2005). These concerns are listed below, and the corresponding section of this review where the concern is elaborated is indicated in brackets:

- a) Severe scarcity of human and material resource during pandemic was usually accepted without systematic examination of the human cost, without the possibilities of how to alleviate them, and without providing opportunities for the population involved to provide input to these decision; (see Section 4)
- b) Mass vaccination was adopted as the principal instrument for reduction of impact of pandemic on population, but, pandemic plans do not provide concrete estimates of benefits and burdens of these interventions to show that the balance is favorable enough for the implementation of the intervention; (see Section 6)
- c) Pandemic plans make extraordinary demands on health care workers, yet, their professional organizations were not involved in developing these plans, and a reciprocal support that health care workers could expect was not formulated by these plans; (see Section 7)
- d) All sectors of society will be affected by the pandemic and response measure, but the population was not adequately engaged or informed about these matters; (see Section 10) (Kotalik, 2005).

Because these concerns are examined in this review in the corresponding chapters, they will not be further discussed here.

6. Ethics of use of vaccination and antivirals

6.1 Vaccination programs

6.1.1. Decision-making about vaccination in pandemic.

As was noted earlier, bioethicists and public health specialists agree that any decision to use a public health measure, (same as a decision for a medical intervention in personal health care), needs to be based on principles of beneficence and nonmaleficence (Beauchamp & Childress 2001; Childress *et al.* 2002; Kass, 2001; Last, 1992). That is, it must provide the population with significant net benefits, and the burden and risks, which are unavoidable in any intervention, must be minimized and acceptable in relationship to the obtained benefits. "... risk to benefit ratios have to be calculated for every immunizing agent, indeed for all forms of health care" (Last, 1992).

What should count as a significant net benefit? That question is to be answered by referring to the goal of the intervention. Chief goals of pandemic influenza plans are usually formulated in terms of saving lives and diminishing illnesses; additional goals are social in nature. For example, the goal of the Canadian plan is first to minimize serious illness and overall deaths, and second to minimize societal disruption (Public Health Agency of Canada, February 2004 p. 5). The UK plan defines 14 objectives, among which are the following, "limit morbidity and mortality", "treatment and care for large numbers of ill people" and "ensure that essential services are maintained" (UK Health Department, March, 2005).

The goals of the Swiss plan are:

- Lessening premature death
- Reduction of morbidity
- Preservation of adequate health care
- Preservation of essential service
- Insurance of inner and outer security (Steffen *et al.* 2005 p. 8)

6.1.2 Benefits of vaccination.

If these are the goals, and if vaccination is incorporated into plans as one of the chief instruments, then there is an obligation on the part of health planners to show that vaccination is indeed capable of providing benefits which will significantly and likely assist in reaching these goals. Given that this vaccine when available is to be rapidly administered to millions of people, the balancing of risks and benefits has to be careful, explicit and publicly transparent. The evidence of satisfactory balance needs to be supported not only by a majority of expert opinion, but also needs to be understood and supported by politicians, civil servants, health care professionals and citizens at large (Kotalik, 2005).

This is particularly important for this intervention because, while it is implicitly assumed that effective and safe vaccine can be produced, the level of evidence for vaccination benefits and safety in pandemic situation is less than optimal. The efficacy of annual vaccination to ameliorate the seasonal outbreaks of influenza was well investigated. The efficacy of vaccination to prevent laboratory confirmed influenza in healthy adults is estimated to be 68%, and to prevent an influenza-like illness, 24%. Relative risk reduction associated with influenza vaccination of healthy children ranged in 15 randomized clinical trials from 0% to 93%. It was not always possible to demonstrate a decrease of time off work or decrease of the rate of complications in some populations (Demicheli, January 9, 2001; Jefferson & Demicheli 2003). Still, a study of healthy working adults found that the vaccinated group had 43% fewer days off work than the non-vaccinated group (Nichol *et al.* 1995). A very large US study found that influenza vaccination was associated with a reduction in hospitalization and death that amounted to 48% and 31% in two subsequent seasons (Hak E. *et al.* 2002).

The US Advisory Committee on Immunization Practices reviewed all available studies in adults over 65 years and concluded that the current inactivated influenza vaccine's efficacy to prevent influenza respiratory illness is 58% for those living at home and 30% for those living in institutions. The vaccine is 30-70% effective in preventing hospitalization for pneumonia or influenza and 80% effective in preventing influenza related death, although all of these indicators may be lower for those over age 70 (Centers for Disease Control and Prevention, 2005).

However, there has not yet been a published study of vaccination effectiveness during a pandemic, likely because in the past pandemics of 1957 and 1968 there was not enough vaccine available. It is therefore unclear if the magnitude of benefits of vaccination during a pandemic would be similar, smaller, or larger than the benefits accrued during the usual influenza season.

6.1.3 The risks of vaccination.

Historically, vaccines have not been always safe. A notable example is the yellow fever vaccine developed by the Rockefeller Institute in 1940'. More than a million Brazilians received the vaccine before it was determined that many recipients subsequently developed "yellow jaundice". With America's entry into the war, the perceived urgency of vaccinating their troops was so great that the decision makers ignored some of the scientists' warnings about the vaccine being contaminated by a hepatitis virus. Possibly up to 50,000 servicemen were infected and at least 100 of them died before the program was halted in 1942 (Lombardo, 2003). The suspected contamination in the 1950's of the polio vaccine by simian virus 40 and its consequences is only now being investigated (Evenson, Friday, May 3, 2002).

The risk of serious adverse events of vaccination for influenza is generally agreed to be low, but not zero. A vaccine from the same manufacturer could be safer one year and less safe the next year. The higher the urgency to produce a new vaccine rapidly, the more pressure to release a vaccine with less quality control and less clinical testing, as was shown in US in 1976. "Evidence exists favoring the causal association between the 1976 swine influenza vaccine and a serious neurological illness, Guillain-Barrè syndrome in adults, but not in vaccines used subsequent to that season. The reported rate of GBS temporarily associated with [currently used vaccine] is not higher than the expected background incidence of this illness in the Canadian population" (National Advisory Committee on Immunization (NACI), 15 June 2005). The existence of a surveillance system for vaccine-associated adverse events, even if based only on voluntary notification by clinicians and manufacturers, as it is in place in US, Canada and elsewhere, is reassuring, and will be essential for the time of pandemic.

6.1.4 Timing of vaccination.

Another condition for the ethically appropriate use of vaccination is that mass vaccination ought to be initiated at the correct time, not too late and not too early. It is the opinion of most authorities, who have retrospectively assessed the timing of the "swine flu" vaccination (see Section 3 for the events surrounding the emergence of this virus), that mass vaccination had started prematurely, and as a result, money was wasted, people were harmed, and public trust in vaccination and respect for public health authorities had diminished. When critical events and public expectations demand quick and correct action, it would be helpful, beforehand, to create a clear decision making framework that incorporates criteria for the commencement of production and the administration of a pandemic vaccine. (Dowdle, 1993).

6.1.5 Public perception of vaccination.

Pandemic plans need to deal with not only the scientific evidence of possible harm or risk of vaccination but also with public perceptions. Vaccination against contagious diseases has been one of the major success stories of modern medicine. The elimination of smallpox, near elimination of poliomyelitis and a marked decrease in the mortality of childhood diseases are prime examples of the success. At the same time, vaccination, since the time when Jenner published his work on smallpox in 1798, has been a source of considerable controversy. Among a fraction of the population there has been unease and fear related to the presumed side effects of this intervention and there are vocal individuals and groups opposing all or most mass vaccination programs. This played out remarkably in the time of the "swine flu" outbreak in 1976 which was reviewed in Chapter 3. "Anti-vaccination sentiment is growing fast in the United States, in large measure due to the controversial and hotly disputed link between immunization and autism" (Calandrillo, 2004). All US states require proof of immunization for school entry, but parents increasingly seek and are granted exemptions on religious or "philosophical" grounds, even if states have no legal obligation to allow exemptions (Salmon *et al.* 1999; Salmon & Siegel 2001). "Negative media coverage of vaccine issues is adversely affecting acceptance of vaccination" (Andre, 2001). Even if most of the controversy concerns vaccination of children, it affects vaccination in general. Because this lack of complete acceptance of vaccination by the population may interfere with mass vaccination as a cardinal measure to ameliorate the next influenza pandemic, the conditions for ethical justification of vaccination need to be reviewed and taken seriously.

The relationship between safety and efficacy is complicated. Mathematical modeling for mumps vaccination showed that it may not be always in the interest of the community to use a vaccine with the lowest complication rate, if that vaccine is also less effective; however, this finding is difficult to communicate to the public. (Nokes & Anderson 1991).

Public perceptions and application of the precautionary principle could justify changes in a vaccination program, even if science may not require it. An example is the use of thimerosal as a vaccine preservative. Some media reports about the possibility of this chemical causing mental or neurological disorders, like autism, have generated much concern among the public. Large studies did not demonstrate any such association, but in response to public concern influenza manufacturers developed a thimerosal free vaccine, which was recently approved for use in Canada (National Advisory Committee on Immunization (NACI), 15 June 2005).

6.1.6 Burden of vaccination.

Burden to individuals is expressed as common, local and systemic side effects of vaccination, as well as the time that it takes to have the procedure done. Almost all recipients rate these consequences only as "mild inconvenience" (National Advisory Committee on Immunization (NACI), 15 June 2005). The burden of vaccination to society needs to include the implementation cost and the opportunity costs. The former can be well established; the latter, that is the loss of opportunity to fund other pandemic programs or health programs, is more difficult to evaluate. However, mass vaccination also can provide economic benefits, and these benefits also could be incorporated into the balancing exercise. The mathematical modeling in the US provided an indication that a small net saving or small net loss could be anticipated, depending on such factors as the price of the vaccine, the attack rate and selection of population groups for vaccination (Meltzer *et al.* 2000). This approach has been used for other vaccines and also by other jurisdictions (Szucs, March 18 2005). The Swiss national plan incorporates cost-effectiveness analysis of vaccination and antiviral administration strategies (Steffen *et al.* 2005) allowing for a better assessment of burden and benefit than plans which lack such analysis.

6.1.7 Prioritization and rationing of vaccine.

Because the production of a vaccine against a pandemic virus cannot commence until the novel virus is isolated and cultured, even with best effort, the vaccine, at least initially, will be in short supply and will be made available in batches as they leave the production line. Rationing will be unavoidable, even in countries like Canada and US which are committed to produce and supply enough vaccine for every person in their population. In this section, I will review the prioritization guidelines in four countries and discuss some prioritization concerns.

The US National Vaccine Advisory Committee (NVAC) and the Advisory Committee on Immunization Practices (ACIP) approved a prioritization plan in July 2005, which is shown in Table 1. The document lists various critical assumptions, provides definitions of groups, estimates the number of people who may fall into each category and offers a rationale for the priority position. The introduction to the priority document states that "(b)ased on this guidance, state, local, and tribal implementation plans should be developed to 1) include more specific definitions of priority groups and their size; 2) define how persons in these groups will be identified; and 3) establish strategies for effectively and equitably delivering vaccines and antiviral drugs to these persons" (United States Department of Health and Human Services, 2005 p.1).

The US federal plan as announced by the Department of Health and Human Services also indicates the intention to "distribute vaccine to state and local public health departments for pre-determined priority groups based on pre-approved state plans" (United States Department of Health & Human Services & Leavitt November 2005). This statement appears to give state authorities the opportunity to create their own priority groups. Such a process would be in keeping with the principle of subsidiarity (see Section 2.2.5 of this review), provide a better opportunity for input from people who will be affected by the decision and allow to take into account geographic and social differences between states. On other hand, if there are two persons with exactly the same moral claim to vaccination, each living in a different state of the union, one may receive the vaccination and the other not, and this could be criticized as unjust.

Public consultations, initiated in 2005, gave a strong indication that US citizens give the highest priority to assuring the basic functions and services of society be maintained but expected that this would be achieved by the minimum vaccine doses required for that purpose. The goal of reducing individual deaths and hospitalizations due to influenza was placed as a second in importance. There was little support for the use of lottery, or giving priority to young people (Bernier & Marcuse 2005). The process of consultations is described in Section 10 of this review.

Table 1: U.S. Vaccine priority group recommendations

Priority	Group Description	Rationale
Tier 1A	Health care workers <ul style="list-style-type: none"> • With direct patient contact and critical support staff • Vaccine and antiviral manufacturing personnel 	Assure production of drugs and provision of care
Tier 1B	Highest risk groups <ul style="list-style-type: none"> • Patients 65 and older with at least one high-risk condition • Patients 6 month to 65 years with at least 2 high-risk conditions • Patients hospitalized in the past year because of pneumonia, influenza or another high risk condition 	Reduce hospitalization and deaths
Tier 1C	Household contacts and pregnancy <ul style="list-style-type: none"> • Household contacts of children under six months • Household contacts of severely immunocompromised individuals • Pregnant women 	Protect pregnant women, infants, those who cannot be protected directly by vaccination
Tier 1D	Pandemic responders <ul style="list-style-type: none"> • Key government leaders and critical public health responders 	To implement response
Tier 2A	Other high-risk groups <ul style="list-style-type: none"> • Patient 65 and older with no high-risk condition • Patients 6 month to 64 years with one high-risk condition • Children 6 months to 23 months 	Reduce risk
Tier 2B	Critical infrastructure groups <ul style="list-style-type: none"> • Other public health emergency responders, public safety workers, utility workers, critical transportation and telecommunication workers 	Maintain services, assure pandemic response
Tier 3	<ul style="list-style-type: none"> • Other key government health care decision-makers • Individuals providing mortuary services 	Assure pandemic response
Tier 4	Healthy patients 2 to 64 years without any high-risk conditions	Vaccinate all those who want protection

Early in its development, the Canadian Pandemic Influenza Committee recognized the need for ethically defensible rationing, so, considerable attention was devoted to the task of producing a national recommendation on priority groups with the collaboration of all provinces and territories of the country (Public Health Agency of Canada, February 2004 Annex D p. 99). These priority groups for Canada are described below in Table 2. A detailed rationale is provided for each of the priority groups in the national plan and is also indicated briefly in Table 2.

Table 2: Canada – Recommended priority groups for vaccination

Priority	Description of group	Rationale
1	Health care workers, paramedics, ambulance attendants, public health workers, pharmacists	Maintain health services, reduce morbidity & mortality
2	Essential services providers: police, fire-fighters, the armed forces, key decision-makers, utility workers, workers in funeral services, jails, some public transportation	Mount effective pandemic response & community services
3	Persons at high risks of severe outcome of influenza infection, persons in nursing homes, living with high-risk medical conditions, all others age over 65, children 6-23 months, pregnant women	Reduce morbidity and mortality
4	Healthy adults	Reduce morbidity, mortality, and societal disruption
5	Children 24 months – 18 years	

The United Kingdom plan states that “vaccine will have to be distributed equitably and administered to predetermined priority groups first, according to nationally agreed recommendation” (UK Health Department, March, 2005 p. 40). Priority groups for vaccination were established and they are listed in Table 3. It is stated that these groups were formed in this way in order to:

- Maintain the elements of community infrastructure in order to carry out the pandemic plan
- Limit mortality among high-risk groups
- Minimize societal disruption and economy losses
- To reduce morbidity in the general population

In addition, a statement was provided for each group that defines the “advantage” of vaccination for the people in the group (UK Health Department, March, 2005 p. 117).

Table 3: United Kingdom – Recommended priority groups for vaccination

Priority	Description of group	Advantage
1	Healthcare staff	Minimize disruption of health care
2	Providers of essential services: fire, police, communications, utilities, undertakers, army	Minimize effect on vital community functions
3	Those with high medical risk	Consistent with normal influenza policy. Demand for health care will be minimized
4	All over 65 years of age	As above
5	Selected industries	Maintain essential supplies
6	Selected age groups, on advise of WHO	Minimize spread & impact
7	Offer to all	Prevent illness

Also the Australian Management Plan for Pandemic Influenza contains priority groups for vaccination and a rationale for each group as listed in Table 4.

Table 4: Australia – Recommended priority groups for vaccination

Priority	Group description	Rationale
1	Health care workers	They are at increased risk of infection and passing it on to vulnerable patients; perform essential services; caring for sick will reduce morbidity & mortality
2	Other essential workers such as emergency personnel	To maintain essential services
3	Groups most likely to transmit the virus, such as children	Consistent with the goal of containment
4	Those at risk of severe outcome	Reduction in demand for health care services. Reduction in morbidity and mortality

Finally, it should be noted that WHO, besides updating its global pandemic influenza plan in March 2005, that year also issued a WHO checklist for influenza pandemic preparedness planning. The letter document refers to vaccination and provides the following checklist item: "Establish a priority list of groups that should receive pandemic influenza vaccine. For example: animal or bird cullers, veterinarians and farmers in the case of animal or avian influenza; health care workers and workers in essential services when a pandemic is imminent or established " (p.21).

We have seen that all four nations created vaccination priority groups for their populations, reaching very similar results, with some interesting differences. Canadian and UK priority groups are formulated firmly for uniform national application, United States plan appears to be devolving more responsibility for prioritizing vaccination to the lower jurisdictions in their federal structure. All these authorities would proclaim that priority groups may need to be altered, based on epidemiological data from actual pandemic when it becomes obvious, for example, what age groups are most at risk and what are the modes of transmission of infection.

On the margin of this discussion, it could be noted that a desire to protect a group from infection may be accomplished by means other than vaccinating that group. It was shown that mortality of high-risk patients may be reduced by vaccinating their caregivers and household contacts or by vaccinating those within the group who become patients themselves (Glezen, March 10, 1999). Similarly, vaccination of children may not only reduce morbidity and mortality in this group but also "... interrupt transmission of influenza in the population, thereby potentially reducing the number of hospital admissions and deaths in the adult and elderly in an indirect way" (Zambon, 2004).

We do not have any indications that the described prioritization process and priority groups were created on the basis of some explicit ethical principles articulated in advance. Still, if we can attempt to interpret the picture, it appears as if the planners wished to use primarily the maximizing principle, but also were influenced by notions of substantive justice and principle of reciprocity. A blending of principles is also the approach that would likely be recommended by theorists (see Section 2.2.2).

A different approach was offered by the Toronto report *Stand on Guard for Thee*. It identified the issue of scarcity of vaccine and antivirals as one of the "key issues" of preparedness planning. In contrast to the above, it did not propose priority groups or offered a rationale for developing them. The report singled out certain "substantive values" as most applicable to priority setting, namely equity, trust, solidarity, stewardship, but did not explicate these values. Instead, the report focused on the priority setting process. The report indicates that the decision-making process should be reasonable, open and transparent, inclusive, responsive and accountable. Finally, the report makes three recommendations for the priority setting process:

1. "Governments and health care sector should publicize a clear rationale for giving priority access ...to particular groups...The decision makers should initiate and facilitate constructive public discussion about those choices.
2. Governments and health care sector should engage stakeholders (including staff, the public and other partners) in determining what criteria should be used to make resource allocation decisions...and provide a justification for any deviation from the predetermined criteria.
3. Governments and health care sector should ensure that there are formal mechanisms in place for stakeholders to bring forward new information, to appeal or raise concerns...or to resolve disputes" (University of Toronto Joint Centre for Bioethics and Pandemic Influenza Working Group, November 2005 p. 17).

In closing this subsection, we may conclude that the substantive and largely successful effort of creating priority groups based on goals of the pandemic plan as demonstrated in several national pandemic plans, would likely benefit from articulating ethical principles or values that guided the prioritization. The effort could be usefully supplemented by attention to the processes of decision-making. The opportunity for this will come after new epidemiological data is discovered and indicates a necessity to modify the priority groups. In this way, both the distributive justice and procedural justice will be served, and trust in the decision-making authority will be enhanced.

6.1.8 Mandatory vaccination of health care professionals.

Because, in the early stages of a pandemic, the influenza vaccine will be in short supply, a regular feature of all pandemic plans is a prioritization scheme. We have seen that pandemic plans of Canada, U.K, U.S and Australia have all identified health care workers as the highest priority group. There is a strong probability that, if the pandemic virus is proven to be highly lethal, everyone who will be given an opportunity to receive the new vaccine will gladly accept it. However, if the new virus is not likely to cause deaths to healthy people of middle age, or if the efficacy or safety of the vaccine is suspicious, then health care workers may not embrace the idea of a preventive vaccination. Yet, in such situations, there may be strong epidemiological and operational reasons to make immunization desirable for all staff members that are in patient contact.

The health care planners need to be concerned about this type of situation because as it stands, the acceptance of yearly vaccination against influenza among health care professionals and other health care workers has been chronically low, even if vaccination is highly recommended by authorities. Historically, rate of influenza vaccination has been reported as disappointingly low from Australia (Brothertho & Bartlett, Mark J., *et al.* 2003), Belgium (Beguine *et al.* 1998), Scotland (Carman *et al.* 2000), Israel (Habib *et al.* 2000), and USA (Eisenfeld *et al.* 1994). Several of these authors reported their attempt to increase the vaccination rate, usually with only mild and temporary success. Recently, it was estimated, that only 36% of hospital workers in USA are vaccinated yearly against influenza (Fox, 26 February 2004). The vaccination rate of Canadian health care workers during the 2000-2001 influenza season was reported to be 55% (Health Canada, 2001). Will health care staff respond differently during a pandemic and will they all be voluntarily vaccinated? We don't know. In addition to the issue of refusing to treat patients during a pandemic, an unwillingness to accept vaccination could become worrisome "ethical barriers to preparedness" (Wynia, Sept-Oct 2003). To address this unpredictable factor, pandemic planners in the United States and Canada are cautiously looking into the possibility of using a law to make such a vaccination compulsory. For example, the United States' National Vaccine Program Office guide for local and state-wide pandemic planning poses this question: "Does State law allow for "mandatory" vaccination of certain groups if vaccination of such groups is viewed by State public health officials as being "essential" for public safety?" (National Vaccine Program Office, 2004 p. 26).

This issue is to be seen against the background of a larger ongoing debate that is taking place in most countries between those who promote legally mandatory vaccinations for various infectious diseases and those who insist that vaccination programs remain voluntary.

An argument was presented that the current low acceptance of annual influenza vaccination among practicing physicians in Canada is ethically indefensible because an unvaccinated physician can infect patients and the sick time of physicians is likely to compromise provision of services (Rea & Upshur 2001). A commentator to this article basing his opinion on human rights opposed the notion of making such vaccination mandatory, pointed out the absence of mandatory adverse event reporting and lack of compensation for vaccine injured individuals. The author stated that "potential adverse events associated with influenza vaccine are significant considerations when weightings the actual benefits versus risks of vaccination versus those associated with potentially contacting influenza naturally" (Diodati, February 5, 2002).

A paper that examined some principal arguments for and against the notion of a moral obligation of health care professionals to accept vaccination concluded that that such obligation exists (Kotalik, 2006). Further, it was asserted that public health authorities have an ethical obligation to assure that health care professionals are indeed vaccinated. The question, whether these obligations would justify an imposition of mandatory vaccination on health care professionals is the more difficult one. The writer suggested that on balance, arguments presented in favor of mandatory vaccination are more convincing than those against the mandatory approach, providing the vaccine is effective and safe, the pandemic is severe and impossibility of achieving full compliance with a voluntary vaccination program was established (Kotalik, 2006). Consequently, compulsory vaccination would increase the burden on governments to ensure the safety of the vaccine (Salmon *et al.* 2006). Given the difficulties to ethically defend and to sensibly implement mandatory vaccination, it would be best if mandatory vaccination could be avoided and its goals achieved by voluntary participation. An important step in this direction is to initiate, among health care professionals, thorough discussions about an influenza pandemic in general and about the ethical aspects of vaccination as well as other personal measures that could minimize the impact of the pandemic. Hopefully, if we have enough time before the pandemic arrives, this effort can lead to the development of such a high level of moral commitment of health professionals to the response measures that mandatory vaccination will be found unnecessary (Kotalik, 2006).

6.2 Antivirals in a pandemic

6.2.1 Decision-making about use of antiviral drugs.

This discussion will mirror in some ways the discussion of use of vaccination in the previous section of this review. There are two important differences between the use of antivirals and the use of vaccination. Firstly, a vaccine for the pandemic virus cannot be manufactured and stockpiled in advance of the pandemic, whereas, it is possible for antiviral drugs. Secondly, a vaccine is useful only for prophylaxis, whereas, antivirals can be used both for prophylaxis and for therapy of people sick with the influenza virus.

As in the case of vaccines, the ethical decision for the use of antivirals as a public health measure is dependent on deciding whether in a given situation the balance between benefits and burdens & risks is favourable (Last, 1992 p. 1189). The benefits should be linked to the goals of the pandemic influenza preparedness plan. If the goals of the plan are chiefly to decrease morbidity and mortality, then, there needs to be unequivocal evidence that an antiviral drug is able to do that. While vaccines, in general, have been available for a sufficient period of time to undergo many studies in the inter-pandemic periods, antiviral drugs are relatively more recent and studies of their use are more limited.

There are two categories of antivirals, amantadines and neuraminidase inhibitors. The amantadines are older and much less expensive, but at present, they are no longer being considered for use in influenza pandemic because of the high rate of side effect and the fact that current circulating strains of virus became mostly resistant to them. This leaves us with two neuraminidase inhibitors, oseltamivir taken orally and zanamivir which must be used as a nasal spray. Because zanamivir is in short supply and nasal spray is not tolerated by some people, the world's attention has focused on oseltamivir (Tamiflu). Most pandemic plans feature the drug, over 50 countries are stock-piling it, and a public profile of Tamiflu, costing \$2.50 - \$10 per capsule, is now comparable to that of Viagra (Day, 26 November 2005). The most recent US government strategy includes spending more than \$1.4 billion on antiviral drugs research and acquisition (United States Department of Health & Human Services & Leavitt November 2005).

6.2.2. Benefits of antivirals.

Let us look at the evidence of oseltamivir efficacy for prophylaxis. (Prophylactic use requires one capsule a day for the duration of the pandemic flu wave, perhaps about 6 weeks, that makes it 42 capsules per person). The Canadian Coordinating Office for Health Technology Assessment (CCOHTA) reported in 2001 that oseltamivir is well tolerated and reduces the likelihood of contracting influenza in both healthy individuals and those who are at risk for developing complications. The risk of contracting influenza while taking oseltamivir was found to be $\frac{1}{4}$ to $\frac{1}{2}$ of the risk which was present with taking placebo, but it was not reduced to zero. This Centre also reported that there is insufficient evidence to conclude that these drugs reduce complications, hospitalizations and death from laboratory confirmed influenza (Husereau, November 2001). Later reports suggested that the use of Tamiflu produces relative risk reduction ranging from 32 to 84% (Langley & Faughnan November 9, 2004).

Tamiflu can also be used for treatment of persons who are sick with influenza. (Therapeutic use requires minimal 2 capsules per day for 5 days, that is, 10 capsules per person). The evidence for the role of Tamiflu in treatment of suspected influenza was also reviewed by CCOHTA. Their 2002 report indicates that there is insufficient evidence in clinical trials that this drug reduces complications, hospitalizations and/or death in individuals suspected of having influenza and who are at risk of developing complications (Husereau *et al.* 2002a). However, the drug appears to be able to decrease the severity of symptoms from influenza and to decrease the duration of illness by 1.5 to 2.5 days. It also reduces the need for antibiotics (Beardsley-Elliot & Noble Nov 1999; Stiver, 2003). In humans infected with experimental influenza, Tamiflu was able to reduce viral shedding intensity and duration, which means that people on this therapy would possibly be less likely to infect others (Beardsley-Elliot & Noble Nov 1999). Tamiflu should be taken within 48 hours of the onset of symptoms, giving patients little time to obtain a prescription and the drug (Moscona, September 2005 p. 1363). The UK Department of Health, on February 9, 2006, sent a letter to general practitioners advising them to start prescribing Tamiflu for 'at-risk' patients, who were not vaccinated and, who had had a contact with someone with a flu-like disease. This advice was triggered by a high level of flu activity in UK and follows existing national guidelines (Salisbury, February 9, 2006).

From a bioethics perspective there is a concern that available literature on antiviral drugs is not able to answer a number of troublesome questions: Given that almost all clinical trials were sponsored by drug companies (Husereau *et al.* 2002b), would publicly funded trials confirm the reported results? Are we to be concerned that physician-promoters of these drugs have benefited from their links to companies that make these drugs? (Day, 26 November 2005) Will the effectiveness of massive Tamiflu therapy be similar to the efficacy which has been reported under the ideal conditions of clinical trials? Will the pandemic strain exhibit at least the same sensitivity to this drug as the currently circulating strains? Will mass use of the drug quickly lead to drug resistance of the virus and loss of any efficiency of Tamiflu? (Moscona, September 2005 p. 2633). Could mathematical simulation of various uses of Tamiflu provide better indications, and under what situations?

It was reported that Sir Liam Donaldson, England's chief medical officer agreed that doctors have little idea how effective oseltamivir would actually be during a pandemic (Day, 26 November 2005). Experts agree that Tamiflu is the best antiviral drug we have, and it has a place in the overall strategy of pandemic response, but it is hardly a "magic bullet". Some commentators now question whether it is wise to rely on this drug as the preeminent element of pandemic response strategy. "Consequently, reliance on stockpiling antivirals, although probably helpful in reducing hospitalization, will not significantly impede a pandemic" (Gostin, 2006).

The ongoing uncertainty about the effective use of antiviral drugs is expressed in a number of scientific reports. It was suggested that amantadine, even if it is less effective than oseltamivir, could still play some role in combating a pandemic, and apparently, UK Department of Health was holding a stockpile of amantadine capsules (Tooley, August 21 2001). Most disturbingly, recent reports suggested that if the expected pandemic would be caused by some mutation of the current H5N1 virus, oseltamivir may be of limited value.

Two of eight patients in Vietnam who were treated with oseltamivir for H5N1 virus infection developed resistance to the drug and died of the disease (de Jong, Menno D. *et al.* 2005). Emergence of resistant strains was predicted by mathematical modeling and it was proposed that the problem could be alleviated by using the drug only for prophylaxis and not use it at all for symptomatic patients' therapy (Stilianakis *et al.* 1998). In contrast, another epidemiological modeling study suggested that a stockpile covering 25% of the population would be sufficient to treat most clinical cases and it would lead to 50-77% reduction of hospitalization, without using the drug in prophylactic mode (Gani, R. *et al.* 2005).

The above discussion was concerned with the use of oseltamivir as a public health intervention, but this drug needs to be considered also as personal protection device. With the media's reports of increasing concerns about a pandemic, North American sales of Tamiflu has more than tripled in the first part of 2005 comparing with 2004 (The Canadian Press., Monday, August 22, 2005). Family physicians report that they are besieged by requests for prescriptions, and it appears that many individuals are stocking up the drug as a hedge against a possible pandemic. Public health officials usually discourage this trend, however, there has not been any explicit directives from governmental bodies. Some professional societies and private medical groups have strongly advised against private stockpiling. Some physicians have recommended to their colleagues stockpiling for personal use and use of their families, others oppose it (Bartlett & Hayden 2005; Rolfsen, 21 February 2006). Brett and Zuger (Brett & Zuger December 2005) argued that physicians are not obligated to provide prescriptions to their patients who ask for it because it would not likely provide benefit and could confer harm. Authors also suggested that from a public health perspective, physicians have an obligation not to prescribe it. The rationale for their position is as follows:

1. The drug would likely be wasted on viral illnesses other than influenza
2. Patients would likely use the drug in a chaotic fashion

3. It is not yet determined who would be the persons at risk, and who would likely benefit from the drug
4. The pandemic virus may be resistant to the drug
5. Personal stockpiles deplete the supply for patients who could most benefit from it
6. Chaotic use could increase the risk that a resistant strain of influenza virus will develop.

As a reaction to this trend, the maker of Tamiflu, Hoffman-Roche Company suspended sales in some countries. This type of move, to a certain extent, avoids a direct confrontation of access to antivirals as a moral issue.

6.2.3 Burdens and risks of antivirals.

The cost of oseltamivir is a significant issue that is linked to the existence of a patent and the fact that there is only a single producer; so far, governments have been unwilling to use their legal powers to give permission for production of a generic version (Gostin, 2006). However, economical analysis of antiviral treatment for healthy adults in normal influenza season seems to suggest that even with the current cost, the treatment could be cost-beneficial (Lee *et al.* 2002).

Common side effects of oseltamivir were reported to be very mild and infrequent, and drop-out rates were similar to placebo (Cooper *et al.* 2003) . No serious side effects were reported in clinical trials that involved several thousand patients. This is encouraging but cannot remove all concerns. The lessons that have been learned from large scale use of another class of drugs, COX-2 specific inhibitors, is possibly applicable here. These new drugs were promoted for the treatment of arthritis as a safer alternative to older drugs which caused troublesome gastrointestinal adverse events. It was not until these drugs had been used by millions of people, and the incidence of myocardial infarctions and other such events became suspiciously high, that the safety of these drugs was re-assessed. It was shown by systematic review and meta-analysis of clinical trials that the use of these drugs did carry a significant risk of cardiovascular events. As a result, many of these drugs have been removed from the market or restricted for limited indications. It is still not entirely clear if this risk had been known to exist and was never disclosed because makers of these drugs intentionally suppressed their reports of the observed side effects during clinical trials, or, if the original clinical trials (that led to approval of these drugs) were designed to determine the risk of gastrointestinal events only, and not those of cardiovascular events (Caldwell *et al.* March 2006).

Antiviral drugs, particularly oseltamivir that is being stockpiled for pandemic use, have been, until recently, infrequently prescribed. Several meta-analysis of clinical trials that have been reported are concerned mainly with effectiveness (Cooper *et al.* 2003; Jefferson *et al.* 2006) and not safety. It would be prudent to employ the precautionary principle and conduct further evaluations to determine the safety of the mass administration of antivirals. Furthermore, in order to detect any serious problems as early as possible, it is necessary to have, in each country, a single office to which all serious adverse events should be reported, such as MedWatch in US (U. S. Food and Drug Administration Center for Drug Evaluation and Research, 2006).

6.2.4. Prioritization of antiviral drugs

In spite of the considerable attention that antivirals have received in the last few years, there is no bioethics analysis, in the available literature, which focuses on the use of this class of drugs in a pandemic setting. There are two papers in English that address the use of antivirals together with the use of vaccine. One paper examining scarcity issues during a pandemic suggested that the amount of drugs that should be stockpiled cannot be decided by experts only, but should be decided in an expert-informed political process with public input, so that the likely consequences of the decisions are known and accepted by the population involved (Kotalik, 2005 p. 428). Another report pointed out the need for a reasonable, open, inclusive, responsive and accountable process, and made recommendations in that regard to governments and health care sector (University of Toronto Joint Centre for Bioethics and Pandemic Influenza Working Group, November 2005 p. 15). These recommendations are listed in the Section 6.1.

In absence of more scholarly literature on this subject, we need to examine a few pandemic plans and see if we can learn something useful from a comparison of the ways in which they have approached the rationing of antiviral drugs. All national pandemic plans anticipate the scarcity of antivirals and recognize that there needs to be some process for rational distribution, and some plans do contain priority lists.

6.2.4.1 UK plan (UK Health Department, March, 2005) states that “the drugs will need to be given in the most effective way on operational, clinical and cost effectiveness grounds taking into account the stock available. Information on effectiveness may not be available at the start of a pandemic ... Until more information becomes available, general principles are established in this section.” The plan, then proposes the following “provisional strategies”:

- A. Potential prevention of pandemic: for occupational groups at risk of infection with avian influenza
- B. At the onset of pandemic:
 1. Treatment of cases in order of priority:
 - health care workers
 - essential services workers
 - un-immunized people in high risk groups
 - other un-immunized people
 - immunized people
 2. Post exposure prophylaxis: e.g. during an institutional outbreak

Annex G of the UK plan lists a variety of options that encompass both prophylaxis and therapy and are organized according to the WHO phases of pandemic. No attempt is made to prioritize these options. The second issue of the UK plan (October 2005) modified these provisional strategies somewhat and linked them with the WHO pandemic phases. Notably, this version proposed to use antivirals also for possible ‘abortion’ of a potential pandemic, or to delay its establishment and spread, which would be accomplished by short term prophylaxis for close contacts of infected people (United Kingdom Department of Health, 2005). A committee of the House of Lords recently reviewed the state of influenza planning in UK and made many recommendations to the Government. Two of those recommendations are:

“We are extremely concerned in the lack of clarity in the government’s policy on prophylactic use of anti-viral drugs and at the possibility that the government’s order of only 14.6 million courses of oseltamivir may have tied the government into a treatment only policy of using the stockpile. We recommend that the government work together with HPA and the research community to establish the optimal strategy for the use of anti-viral drugs and that further orders, if required, should as a matter of urgency be placed to allow this strategy to be implemented. We further recommend that this strategy should incorporate a rigorous cost-benefit analysis” (UK Secretary of State for Health, 16 February 2006).

6.2.4.2 The United States Department of Health and Human Services constructed the previously quoted 'umbrella' document, HHS Pandemic Influenza Plan (United States Department of Health & Human Services & Leavitt November 2005), which contains sub-headings that correspond to various levels of planning:

- The HHS Pandemic Influenza Plan Fact Sheet states, "At the onset of a pandemic, antiviral drugs from public stockpiles will be distributed to predetermined groups" (p. 2)
- Part 1 - HHS Strategic Plan states, "In advance of an influenza pandemic, HHS, in concert with federal partners and in collaboration with States, will procure sufficient quantities of antiviral drugs to treat 25% of the U.S. population and, in doing so, stimulate development of expanded domestic production capacity sufficient to accommodate subsequent needs through normal commercial transactions. HHS will stockpile antiviral medications in the Strategic National Stockpile, and states will create and maintain local stockpiles."
- Part 2 – Public Health Guidance for State and Local Partners, has a Supplement #7 Antiviral Drug Distribution and Use. This section describes the use of these drugs before an actual pandemic in the management of cases for novel influenza as treatment and prophylaxis of contacts and for containment of disease clusters. Subsequently, it explains the use of antivirals during the pandemic and refers to Part 1, Appendix D, for a list of priority groups and the rationale for prioritization. These recommendations are summarized in table 5.

Table 5: US – Antiviral drugs priority group recommendations

Priority group		Strategy
1	Patients admitted to the hospital	Therapy
2	Health care workers with direct patient contact and emergency medical service providers	Therapy
3	Highest risk outpatients –immunocompromised persons, pregnant women	Therapy
4	Public health responders, public safety, government decision-makers	Therapy
5	Increased risk outpatients - children 12–23 months, persons over 65 years, persons with underlying medical conditions	Therapy
6	Outbreak response in nursing home and other residential settings	Post-Exposure Prophylaxis
7	Health care workers in emergency departments, intensive care units, dialysis centres, emergency medical services providers	Prophylaxis
8	Pandemic social responders and health care workers without direct patient contact	Therapy
9	Other outpatients	Therapy
10	Highest risk outpatients	Prophylaxis
11	Other health care workers with direct patient contact	Prophylaxis

The document also contains a rationale and detailed definitions for each priority group. The rationale has to do with the risk of death, or illness prevention in groups 1, 3, 5, 6, 9, 10, and with maintenance of effective public health or medical care or pandemic response in groups 2, 4, 7, 8, 11.

In addition, a set of “critical assumptions” is provided; the size of every group is estimated; and the number of courses for each priority group is calculated. The cumulative number of courses that would be offered following this program is 133 million. It was recommended that the minimum stockpile size be 40 million courses to allow coverage of the top 7 priority groups. It was noted that the Department of Defense has a separate drug stockpile. Non-citizens living in US were not explicitly considered in deliberations on prioritization.

6.2.4.3 The Canadian pandemic Influenza Plan suggests that antivirals “may have a role as an adjunctive strategy to vaccination...The plan recognizes that further evidence is needed on the effectiveness of neuraminidase inhibitors in reducing complications of influenza” (Public Health Agency of Canada, February 2004 p. 34). Annex E provides more detailed recommendations on the use of drugs. The following priority groups were proposed for planning purposes during the inter-pandemic period:

Table 6: Canada – Priority groups for the use of antivirals

Priority Group		Strategy
1	Persons hospitalized with influenza	Treatment
2	Ill health care and emergency workers	Treatment
3	Ill high risk persons in the community	Treatment
4	Health care workers	Prophylaxis
5	High risk residents in institutions with outbreaks	Prophylaxis, treatment
6	Essential service workers	Prophylaxis
7	High risk persons hospitalized for illnesses other than influenza	Prophylaxis
8	High risk persons in the community	Prophylaxis

It is noted, in the annex, that recommendations and options should be regularly reviewed because of rapidly changing scientific evidence. The goal of reducing mortality and morbidity is reflected in the rationale for priority groups 1,3,5,7 and 8. The goal of maintaining essential services is reflected in the rationale for priority groups 2, 4 and 6.

6.2.5 Some impressions about prioritization of antivirals.

The dominant impression of this reviewer is, firstly, that the prioritization effort is hampered by lack of reliable science. Concerning influenza in the inter-pandemic period, it is stated, “the optimal influenza prevention and treatment strategy is unknown” (Lee *et al.* 2002). This is even truer for pandemic influenza. Secondly, the existing plans neither incorporate nor reject some alternatives and novel methods of using antivirals. For example, stochastic epidemic simulations suggest that to provide close contacts of suspected index cases with an antiviral drug (prophylaxis) can be just as effective as vaccinating 80% of the population and could reduce deaths by about 90% (Longini Jr., I. M. *et al.* April 1 2004). Ethical implications of these new approaches need to be evaluated.

In the absence of firm evidence about these drugs, many assumptions must be made about their usefulness in a variety of situations during a pandemic. This uncertainty, and differences in interpretation of existing data may account for the more variations in prioritization groups that are evident in the plans of different countries than differences in pragmatic goals, moral values or principles. UK planners decided not speculate and kept their prioritization strategy vague, but flexible; the House of Lord committee criticized this. US planners created the most detailed scenarios and recommendations. The Canadian approach is somewhere inbetween these two options. There is an obvious attempt to respect both main goals of Canadian national plan, that is decreasing morbidity and mortality and minimizing social disruption, by creating separate priority groups that support each goal and interspacing them in the descending order of priorities. The approach strives to maximize beneficence, without considering burden and risk. In that sense it is not utility oriented, because utility requires considering both benefits and burdens/risks (Veatch, 2000 p. 128).

There is no bioethical framework explicitly offered in the prioritization sections of these national pandemic plans. When a rationale for a priority group is given, there are no references to justice or fairness or like values. These rationing schemes create many questions about enforcement, as well as people's options and obligations. For example, would the acceptance of drugs for prophylaxis create an obligation to work, regardless of the level of risk? Is there an opportunity to refuse an antiviral drug offered for prophylaxis if a person is, for example, an essential services worker? There is an obvious need for unmasking various ethical dilemmas, locating underlying values, and articulating in moral terms the nature of actions that are under consideration. An ethical analysis can also facilitate the formation of new options and assist in formulation of future research and development projects (Monto, 2006).

7. Ethical issues concerning human resources in pandemic

7.1 Health Care Workers' Duty to Care

Even a brief examination of some of the more detailed pandemic plans (Public Health Agency of Canada, February 2004) will reveal that the expected response to this protracted emergency will make huge demands on health care workers. There will be a shortage of staff because the number of people requiring medical attention will skyrocket and because health care workers themselves also will get sick or they may have to care for sick family members.

Those able to work will find it necessary to provide care and treatment that is more complex than usual. They may be involved in doing new procedures for which they may not be fully qualified. They will be in more danger than the rest of the population of contracting the influenza virus. Even if vaccination (if available) and prophylactic use of antiviral drugs could greatly reduce the risk of infection, it would not entirely eliminate it. Given that influenza may spread across large areas, whole provinces or the whole country within a short time, there may be little or no opportunity to obtain relief and assistance from outside of the community (Kotalik, 2005).

Under such conditions, there is a concern among health planners that workers, even if not physically ill, may not wish to make themselves available for work. A large-scale absenteeism would further threaten the care of the sick and limit the options of pandemic control. This has been identified as one of the key issues in reference to the SARS outbreak as discussed in Section 3.0. It is not known how many staff members refused to work because of the risks, but at least one non-medical employee, who was ordered to screen visitors for possible SARS, refused the assignment; after being fired, the person sued the hospital (Timson, July 16, 2003). Another report noted, "The fear engendered by the high incidence of infection in health care workers during the recent outbreak...made many anesthetists reluctant to treat affected patients...For a number of anesthesiologists, their moral values dictated them that they should treat the SARS patient without regard to the consequences for their own safety...These circumstances made anesthesiologists vulnerable to extreme moral distress" (Bevan & Upshur 2003).

In investigating the duty to care, as it was discharged by professionals in Toronto hospitals during the SARS outbreak, researchers identified three issues: a) numerous references to heroism, b) high level of emotional distress, and c) desire and commitment to care for sick colleagues. These authors developed a sample policy for duty to care in a public health emergency (Godkin & Markwell 2003).

The issue of risk acceptance was extensively discussed about 20 years ago when care for patients with HIV/AIDS became an issue (Macklin, 1993). The responsibility to care for these patients was absorbed by medical professionals, but of course AIDS is a much less infectious condition than SARS or influenza. At present, some commentators suggested, many doctors have forgotten that there are serious risks in caring for patients and they do not consider these risks when deciding on a career in the profession (Gordon, Oct 11, 2005). A recent survey, undertaken in the United States, indicated that 85% of physicians, who responded to a mailed questionnaire, would be willing to continue to care for patients in the hypothetical event of an unknown but potentially deadly illness. But when the same physicians were asked about their willingness to serve patients in a potential outbreak of smallpox without they themselves being vaccinated, only 33% were prepared to do so (Wynia, Sept-Oct 2003).

There is a consensus in the literature that health care professionals, especially physicians, have an ethical obligation to care for patients with contagious diseases like influenza, even if it puts them at risk of contracting the illness. There are, of course, various views on how this duty is grounded or derived. A number of commentators traced a long history of physicians' commitment (and occasional failures of commitment) to treat patients with contagious diseases and considered this history fundamentally and morally important (Emanuel, March 2004). An 18th century American physician wrote, in a letter to his wife, during a yellow fever outbreak: '[If I should become sick] it would be as much your duty not to desert me in that situation, as it is mine not to desert my patients' (Emanuel, March 2004). For some, the commitment to patients' care and effacement of self-interest is a foundational value of a professional and something which generates patients' trust and society's esteem (Pellegrino & Thomasma 1988).

Other writers prefer to justify the existence of duty to care for sick even in risky situations by an implicit social contract between the profession and society at large (Clark, 2002), pointing out the strength of this duty especially for physicians, who were granted by society an exclusive scope of practice (Reid, 2005). However, one author suggests that "A basis for duty to care founded only on doctors' or other licensed health professionals' narrow professional self-interest would be inadequate to underwrite the provision of health care more broadly. It would also give doctor's motivation for purportedly moral actions that is in effect very thin." (Reid, 2005 p. 354). Instead, the author suggests the importance of reflection, on what response to an epidemic would be most consistent with our values and human needs, recognizing our shared vulnerability to disease and death. "The advantage of recognizing a broader social contract underlying the duty to care is that it brings all involved in supporting, maintaining, and running a health care facility under its umbrella, so we can recognize that all health care workers – from medical to administrative to maintenance staff - face a common risk and burden of psychological distress, and face relevant moral dilemmas." (Reid, 2005 p. 354) It may be desirable that all health care workers act, at all times, in keeping with the principle of beneficence; however, this is a principle that, if not carefully specified and linked to certain roles and relationships, was found by others to be overly demanding (Beauchamp & Childress 1994 p. 260-271).

Various dimensions of physicians' duties were discussed in relationship to possible occurrence of bioterrorism, and these very much parallel those relevant to influenza pandemic and other public emergencies (Huber & Wynia 2004; Wynia & Gostin July, 2004). A careful examination of current and historical Codes of Ethics of the American Medical Association led Clark to the conclusion that, in public emergencies, the duty to treat trumps the autonomy rights of US physicians, and that the current Code in our social situation creates a "special obligation to assist in face of critical human need, even if personal risk is involved." This writer also suggested that there could be a standard of "minimal decency" in providing these services as articulated by the profession, under which no physician should fall. He also proposed that willingness to respond to such social needs also promotes a professional interest to maintain self-regulation (Clark, 2005). The American Medical Association members adopted, in 2001, a Declaration of Professional Responsibilities which states that members must "treat the sick and injured with competence and compassion and without prejudice" and "apply our knowledge and skills when needed, though doing so may put us at risk."

Canadian physicians are directed by their Code of Ethics not to deny aid when there is "urgent need" but they can refuse to accept a patient for several "legitimate reasons," some of them listed in the code (Canadian Medical Association, 2004). But the notion of risk acceptance is not mentioned in this code. Nevertheless, selective refusal of service on the grounds of "medical condition" is specifically prohibited and this appears to prohibit refusal of care for people with contagious diseases (Kotalik, March, 2002).

The contentious issue is to what extent a physician can balance the duty of care with possible other obligations, including obligations to oneself. The Canadian code, by listing other physicians' obligations apart from direct patient care, seems to suggest that such balancing is necessary (Kotalik, March, 2002 p. 101). The US code, at least on one interpretation, rules out "juggling" of priorities (Clark, 2005 p. 76). The Canadian Medical Association recently announced the intention to study ethical issues surrounding pandemics, especially as concerns physicians' obligations (Sullivan, 2006). Regardless of how grounded or how strong, the physicians' obligation to treat patients during a pandemic is considered, there is a consensus about the need to reinforce this ethical duty of the profession (Wynia & Gostin July, 2004; Wynia, Sept-Oct 2003) and to "reflect how the line is drawn between self-protection and dereliction of duty" (Bevan & Upshur 2003).

In the midst of the SARS outbreak where some medical workers were placed in quarantine, some got infected and some died, workers were forced to weigh the serious risk to themselves and their families against their duty to provide care for the sick. So, what is the professional's duty to provide care for the sick during a communicable disease outbreak? The Toronto report makes two recommendations:

- "Professional colleges and associations should provide, by way of their codes of ethics, clear guidance to members in advance of a major communicable disease outbreak, such as pandemic flu....as to expectations and obligations regarding the duty to provide care during a communicable disease outbreak."
- "Governments and health care sector should develop human resource strategies...that are transparent...and that are equitable with respect to the distribution of risk among individuals and occupational categories." (University of Toronto Joint Centre for Bioethics and Pandemic Influenza Working Group, November 2005 p. 12)

One reason why physicians and other professionals may be reluctant to serve in various capacities during a pandemic could be a conviction that they are not appropriately qualified. During the last few years, the regulations concerning professional organizations have placed great stress on the need for every professional to determine his or her "scope of practice" in the interest of patient and public safety, efficiency and competency (Canadian Medical Association, Oct 1 2001). The ongoing tendency of professionals to sub-specialize has created a situation where a professional's routine practice may be limited to a narrow class of patients and a few procedures. No doubt, the SARS experience, of large patient volumes and sickness and death of professionals, teaches that a pandemic will make tremendous demands on professionals to take on a larger scope of professional responsibilities and tasks. Yet, the professional's existent training, plus a concern of possible legal liabilities (if a patient gets harmed by a professional working outside the usual scope of practice) may make that professional stand back, when even less qualified assistance could be much increasing comfort or saving lives. Under current regulations, in order to overcome this barrier, a physician would have to undergo additional training, obtain proof of new qualifications, and perhaps request an assessment from the medical college. (College of Physicians and Surgeons of Ontario, September/October 2002). Ideally then, such training programs would have to be incorporated into pandemic plans, or, have the standard regulations about scope of practice declared invalid during the time of a pandemic.

There is another manifestation of duty to care that has emerged as a result of the SARS outbreaks. Several physicians in China, after observing that authorities were hiding the emergence of a new infections disease and later were providing inaccurate statistics, decided that their duty, in spite of the obvious risk they would face in their country, was to inform their medical colleagues abroad. One of them later stated: "As a doctor who cares about people's lives and health, I have the responsibility to aid international and local efforts to prevent the spread of SARS" (Benitez, 2003).

7.2 Reciprocal ethical responsibilities of health care institutions

Having established that bioethics literature and professional codes of ethics support the existence of a strong obligation of health care professionals (and perhaps other health care workers) to care even for patients who can infect them, we need to recognize an equally strong reciprocal obligation of health care organizations, based on reciprocal justice, to make working conditions as safe as possible. This may include the obligation to provide appropriate training, stockpiling of protective gear and supplies, organizing the workplace in such a way that minimizes risk of infection, providing antiviral drugs for prophylaxis, supporting workers' personal and family needs (Singer *et al.* 2003; Tamblyn & Kotalik Okinawa, Japan October 7-11, 2003). This health care sector's duty to support their workers also includes an obligation to try to recruit a sufficient number of contingency workers and volunteers and to train them in the skills that will be required during pandemic, in order to make the service demands on their regular workers during pandemic more manageable (.429Kotalik, 2005).

This obligation of the health care sector is a logical application of the principle of reciprocity and appeared as a practical necessity during the SARS outbreak. *It was recommended that* "Governments and the health care sector should ensure that

- a. care provider's safety is protected at all times, and providers are able to discharge duties and receive financial support throughout a period of extraordinary demands; and
- b. disability insurance and death benefits are available to staff and their families adversely affected while performing their duties (University of Toronto Joint Centre for Bioethics and Pandemic Influenza Working Group, November 2005 p. 12).

However, it is necessary to comment, that apart from publications reviewed above, there has been very little discussion in the peer-reviewed literature about support and benefits that health care workers could reasonably expect. Examination of 400 references located by using key words of "health care professional" and "support" or "benefit" were found to be all dealing with support of patients or clients or groups by health care professionals, none of them concern support for professional caregivers.

7.3 Conscription of health care workers

Health care planners are understandably concerned about the severe relative and absolute shortage of health care professionals and all health care workers that will be required during a pandemic to provide care for sick and carry out preventive measures. Not having a sufficient grasp of the health care workers' commitment to service, they periodically debate the possibility of conscription. This type of compulsory service has never been subjected to any political, ethical or social analysis, except for military duty. A search of literature uncovered some relatively recent discussions of compulsory medical service, but only in Ecuador (Cavender & Alban 1998) and Malaysia (Mahmud Mohd, 2005). There are references to compulsory service for nurses in Norway (Anonymous 1951) and medical personnel in Sweden (Ludin, 1953), but these are more than 50 years old.

It must be noted that the laws of some jurisdictions do provide for conscription of persons to carry our emergency measures, and this may include health care workers. The Canadian Pandemic Influenza Plan noted that some Canadian provinces have such emergency laws, but warned of the "extreme difficulty of enacting or enforcing such legislation," and recommended that "jurisdictions (to) review all other methods of obtaining health care workers in advance of pandemic" (Public Health Agency of Canada, February 2004 , Annex J, section 2.2.3).

There have been a few instances when an attempt to use laws to compel physicians to provide medical services have met with severe resistance on the part of the potential conscripts; and the laws were doomed to failure. For example, bill 114 of the Canadian province of Quebec, adopted in July 2002, was designed to compel the province's physicians to staff emergency departments of hospitals. The bill was strongly opposed by the provincial and national medical associations and eventually the government agreed not to enforce the bill and agreed to find alternative solutions to physicians' shortages (Pengelley, Healther: Wharry, Steve, 2002). Most recently, the Ontario government tabled bill 56, legislation to amend the Emergency Management Act, which would expand the definition of emergency to include dangers caused by disease or health risks. Presently, professional associations and trade unions are expressing their strong disapproval of the bill because of its conscription provision; the bill's fate at the moment is uncertain. The Ontario Government indicated that the legislation is not intended to enable government to force health professionals to work against their will (Ontario Medical Association, 2006). The conclusion of this reviewer is that, reliance on compulsory service of health care workers is problematic, both from a bioethics perspective, as a serious restriction on personal liberty, and for practical reasons, because of difficulties to implement, monitor and enforce such a provision.

8. Patients' care in a pandemic

Earlier sections of this review already addressed some aspects of patients' care, such as deployment of scarce resources in section 4, utilization of antivirals in section 6 and responsibilities of health care workers for patients' care in section 7. In this section, I will review the literature concerning the changing role of physicians at the time when the management of infections is increasingly more important; I will examine the triage of patients during conditions of extreme demand on resources and the public justification for altered standards of care in these situations. Finally, I will comment on institutional responsibility for critical and respiratory care in a pandemic.

8.1 Changing role of physicians

Because of the success in the early part of the 20th century in preventing and controlling infectious diseases, and even eradicating some, such as smallpox, by the 1970's it was thought that human infections were a problem of the past. However, since 1973, more than 30 previously unknown diseases associated with bacteria and viruses have been identified (Lashley, 2006). (For those interested, the *Journal of Emerging Infections* is useful to keep to keep them abreast in this area.) To add to the problem of infection control, during the last few years, there have been incidents of inadequate sterilization or disinfection of medical equipment, and the increasing awareness of hospital transmitted infections are seen as a "silent epidemic" (College of Physicians and Surgeons of Ontario, 2005).

Physicians caring for infected patients will experience some challenges to the dynamics of the traditional patient-physician relationship. In the presence of an infectious disease, a physician must deal with a patient, not only as a victim of a disease, but also, as the vector of a disease that could endanger others. This dual concern, both individual and public, challenges the old assumed loyalty. For example, in an emergency situation, a patient may present with an illness that is suspected to be SARS. According to guidelines communicated to the attending physician, isolation of this patient and quarantine of his healthy appearing wife is indicated. If these persons question isolation and quarantine, the physician needs to carefully explain the recommendation and seek a common ground with these patients; he can try to mitigate the consequences of public health restrictions, can even advocate on the patients' behalf if he believes that an exception to the rule is justified; but at the end, if the patient and his wife do not want to cooperate and do not want to accept isolation or quarantine voluntarily, then, in order to safeguard other patients and the public in general, the physician may have to report the situation to a public health officer who has the power to enforce the emergency public health measures (Lo & Katz 2005).

Another example where a public health interest can impinge on the patient-physician relationship is when a patient asks for an intervention that would be beneficial, but is not recommended by current public health guidelines. For example, a male patient with a chronic illness asks for a pandemic vaccine. An influenza vaccine would normally be indicated for him, but because the pandemic vaccine is in limited supply, it is reserved for patients with a higher risk of influenza complications, and this patient is currently not eligible to receive it. An opinion was advanced that in such a situation, the physician needs to address the patient's concerns and act in the patient's best interest to the extent possible, but should not provide the vaccination contrary to guidelines or misrepresent the patient's condition in order to make the patient eligible for vaccination. "As noted, physicians' primary ethical responsibility in a public health emergency is the well-being of the public, not the interest of an individual patient. Physicians need to be clear in their own minds about their altered responsibilities, the heightened public scrutiny of their decisions, and the importance of a perception of fairness" (Lo & Katz 2005). Another author, examining the ethical concerns of emergency physicians, also agrees that during large-scale disasters, "priorities are likely to be shifted from the needs of individual patients to that of the community and society as a whole" (Mare *et al.* 2004). A point was made that the physicians' role will have to be somewhat different in each phase of an influenza pandemic and that this role will be shaped by recommendations of public health authorities (Campos-Outcalt, 2005; Strikas *et al.* 2001).

There is also a concern as to what extent it is ethically appropriate for health care professionals, at the time of pandemic, to abandon the customary impartiality, that is, to accept and care for all patients according to their medical condition and in keeping with their wishes. There will be much pressure to forgo impartiality and instead to assist in the enforcement of 'law and order' or to comply with other objectives of government and institutions. The following quote captures some of these concerns: "A source of significant moral distress for many health professionals is the danger that, under the threat of emergency and moreover, in the thick of one, they might become agents of law enforcement. As well, many find serious tensions in links forged between public health systems and national security" (Eckenwiler, 2003).

When a physician is caring for an infected patient or is trying to control infection in a community or hospital, he may also experience a conflict with political, legal or administrative authorities. When trying to act according to public health guidelines, a physician may encounter excessive privacy concerns, legal liability fears, economic disincentives, and failures to confront issues that are embarrassing for the institution. "What is likely to be an effective infection control policy may not be a popular institutional policy. Economic implications of an outbreak investigation or infection control strategy may dominate a debate that should be informed by the greatest good for the public" (Vermund & Fawal 1999).

What insight or advice can be gleaned from bioethics in situations where infection control issues create difficulties in the patient-physician relationship? At the level of ethical theory, it was noted that it is the traditional liberal individualism philosophy, as broadly formulated by John Rawl and Ronald Dworkin, which poses more difficulties in encompassing the dual responsibility of physicians: as agents of their patients; and as defenders of public interest. On the other hand, the communitarian philosophy, as promoted by Alasdair MacIntyre, Charles Taylor and Michael Walzer, is intrinsically more capable to accommodate dual allegiances (Tauber, 2002).

Some scholars maintain that each individual physician has to learn how to balance the dual duties to patients and to the health care system and public interest (Minogue, 2000). Others criticize this position as unrealistic, and fear that imperfect judgment in this balancing will lead to a compromise of physicians' loyalty and damage their integrity. They advocate an enhanced effort to develop practice guidelines and monitor their use (Carson, 2000). The latter approach is the one that clearly is most applicable to a pandemic situation. Clear and explicit guidelines for preventive and therapeutic interventions, particularly if created with public participation and widely disseminated, would be helpful both for the protection of the trust and integrity in the patient-physician relationship and an assurance of fairness in acting in the public interest.

Finally, in this section it will be useful to briefly examine the idea of accountability, which seems particularly important in situations where the physician must act in response to both the individual personal care and the public health care. A model of stratified accountability was proposed that possibly could be adapted to an influenza pandemic situation. This model includes three major components (the accountable parties, the subject matter and the process for accountability) and eight content areas for accountability of ethical conduct, such as fiduciary obligations and equity among patients. The methods for assessment of accountability in this fashion are still being developed (Emanuel, 1996).

8.2 Triage

Given the expected number of sick people during an influenza, all pandemic health care facilities and health care workers will likely be overwhelmed and unable to provide care for all who will need it. Hence, all methods available to deal with this situation need to be considered. The triage of patients during mass disasters, epidemics or other mass emergencies is a difficult and complex area. This review can only provide an outline of some main issues and concerns that have implications for understanding the ethics of this activity.

The term triage comes from the French word *trier*, meaning to sort, pick or select and it was used for wool and coffee beans before it was applied to injured soldiers in the Napoleonic wars. Triage refers to sorting out who should be getting treatment first when not all can receive it immediately because of discrepancy between the resources, including personnel or supplies, and the number of persons in need of care. In disaster situations, the triage procedure also often includes distribution of patients to various facilities, selecting various forms of transportation for them, and deciding on the type of care the patients will be offered (Auf der Heide, Erik, 2002). The authors who documented the history of this procedure also suggested that it is important to distinguish between the egalitarian triage and utilitarian triage. But they observed that this separation is not maintained in most discussions of triage, creating confusion and a difficulty to plan for the future. According to these scholars, while egalitarian triage is widely and successfully practiced during war and in hospital emergency rooms and in IDU, utilitarian triage has been practiced only sporadically and usually was rejected when it subjected to scrutiny (Baker & Strosberg 1992).

There are other bioethicists, however, who believe that all forms of triage are utilitarian. Childress stated: "Systems of triage, whether informal or formal, all have an implicit or explicit utilitarian rationale – they were designed to produce the greatest good for the greatest number by meeting human needs most effectively and efficiently under conditions of scarcity" (Childress, 2003).

The fully egalitarian approach to rationing utilizes the use of lottery or queuing, and some ethicists indeed favour it (Ramsey as quoted by Childress) (Childress, 2003 p. 83). But the egalitarian notion that all human lives have equal worth would not be served if an opportunity to save the life of one person would be lost because of the non-urgent treatment of another person. Therefore, sorting persons based on medical needs (severity of patient's condition and urgency of care) is also considered by many to be non-controversial triage of an egalitarian type. In this case, equality of opportunity is provided and justice is clearly served because equals are treated equally and similar cases similarly.

When triage also includes social utility, that is, the criterion of some usefulness of the person to society, then triage becomes more ethically problematic. Here it appears to be useful to make a distinction between broad social utility (e.g., creating a triage group of all politicians, or all health care workers), and narrow social utility (e.g., creating a triage category group of political decision makers who are needed to control pandemic response, or front-line health care workers who are essential for patient care delivery). Thus Childress says: "Judgment of broad social utility infringe on equal regard, and it is not justifiable to use them as a basis for rationing in general or in emergency, such as a bioterrorism attack" (Childress, 2003 p. 85).

The most ethically problematic are those triage systems that make full use of the utilitarian calculus and the imperative to produce the greatest good for the greatest number of people, and take into consideration also the persons' likelihood of benefiting from medical interventions. Using this parameter, some very ill person, whose life is most threatened, will not be given the benefit of a trial of aggressive intervention that could possibly be life-saving. Some documents on triage fully accept and defend this approach. A policy of the World Medical Association explains that there are: "victims, whose condition exceeds the available therapeutic resources, who suffer from extremely severe injuries...to such an extent and degree that they cannot be saved in the specific circumstances of time and place, or complex surgical cases requiring a particularly delicate operation which would take too long, thereby obliging the physician to make a choice between them and other patients. For these reasons, all such victims may be classified as 'beyond emergency care'. The decision to 'abandon an injured person' on account of priorities dictated by the disaster situation cannot be considered 'failure to come to the assistance of a person in mortal danger'. It is justified when it intends to save the maximum number of victims" (The World Medical Association, 1994).

Other writers are very concerned by triage systems that designate some patients as 'unsalvageable'. As an example, a US disaster response manual is critical of a proposed 5-category triage system, that designates one category of persons as "catastrophic", and instructs to place in that group, not only persons who are moribund, but also those who could be saved if extensive resources were diverted from more salvageable cases. The report points out that even in the Vietnam War, all living casualties were considered potentially salvageable, and it lists the following problems with the 'catastrophic' category:

- a) this triage is applicable only to situations where there are truly massive numbers of casualties
- b) psychologically it is untenable to condemn living casualties to such a category, particularly by persons not experienced in making such decisions,
- c) treating 'catastrophic' cases last means that people who would survive for days without treatment may be given preference over persons who still may be saved, once the resources needed are finally mustered (Auf der Heide, Erik, 2002).

Some statements on triage do not explicitly mention that patients could be placed into an 'unsalvageable' category when there is a lack of resource to attempt to salvage them. For example, one Consensus Statement identified the following factors "that should be considered in determining benefit and utility for triage decisions":

- a) likelihood of successful outcome
- b) patient's life expectancy due to disease
- c) anticipated quality of life
- d) wishes of patient or surrogate
- e) burdens (psychological, financial, missed opportunities to treat others) for those affected
- f) health and needs of community
- g) individual and institutional moral and religious values (Society of Critical Care Medicine Ethics Committee, 1994).

In order to categorize patients according to the probability that they will benefit from medical intervention, we need objective, verified and highly predictive indicators that could be used in rapid patients' assessment. Such criteria and classification systems were proposed for mass casualty involving burn patients (Saffle *et al.* 2005). Developing such reliable criteria of triage for influenza pandemic is important but it will be difficult, given that clinical findings can identify patients with influenza-like illness but are not particularly useful for confirming or excluding the diagnosis of influenza (Call *et al.* 2005), and access to laboratory tests to confirm influenza will be very limited. Yet, most observers agree that criteria are needed. "Physicians should never be placed in a position of individually deciding to deny treatment to patients without a guidance of a policy or a protocol" (Pesik *et al.* 2001, quoted by Childress) (Childress, 2003).

It could be because of the lack of such reliable criteria, or for deeper ethical and psychological reasons, that a large survey (1988) of American critical-care professionals concluded that in daily practice, these physicians and nurses are disinclined to make choices based on estimates of who might benefit most. The authors of the study interpreted results as indicative of less than optimal use of critical-care resources (Society of Critical Care Medicine Ethics Committee, 1994). One might speculate that at the present time, 18 years later, the professionals did become more utilitarian in their approach, but a more recent study of this type was not located.

Triage centres operating during a pandemic situation could benefit from an advanced design of entry process that would include patient identification tracking, integrated computer interfaces to eliminate up-front registration tasks, immediate placement of patients in open emergency department beds and physicians-directed ancillary testing and care at triage when no beds are available. Such process was found to decrease wait times and decrease the fraction of patients who leave before being seen in a busy emergency department (Chan *et al.* 2005). American emergency physicians expressed concerns about the tendency of overcrowded emergency departments to triage patients outside of these departments even prior to complete evaluation and treatment (SAEM Ethics Committee, 1995). Similar concerns could be raised about makeshift triage centres for influenza patients outside hospitals, not equipped and staffed to provide full patients evaluation.

One recent paper addressed the triage of persons for mechanical ventilation in an epidemic. It advocated "in resource poor environment, the traditional bioethical focus on patient autonomy...shifts to a utilitarian or "distributive justice" model that attempts to do the "greatest good for the greatest number" with the resources available." Some of the advice provided by these authors:

- a) triage criteria should be designed for use of individual physicians, to reduce the need for definition and defense of individual strategies for individual cases;
- b) criteria should be implemented on regional, not institutional basis, with a government agency providing support for implementation;
- c) legal liability protection for providers should be assured;
- d) criteria should be implemented in a step-wise fashion, so that as resources are exhausted, another, stricter tier of exclusion criteria is implemented;
- e) tiers should be based on objective determinations of effectiveness of care (Hick & O'Laughlin 2006).

Some countries, like United Kingdom and Canada, do have, as part of their national pandemic plans, national clinical guidelines for patients, but these do not address rationing of critical care, access to ventilation, and admission to intensive care units (British Thoracic Society *et al.* 2005; Public Health Agency of Canada, February 2004 Annex G). They focus on rapid clinical diagnosis of pandemic influenza as opposed to other respiratory and febrile illnesses, on decision-making concerning types of patients who need to be admitted as opposed to being cared for at home, and on the diagnostic tests and basic care measures that will be useful. The search carried out for this report did not locate any other papers on triage guidelines specifically formulated for influenza conditions or advising on use of existing triage systems. It was noted that currently, no Europe-wide agreement exists on triage and ethics, and it was suggested that a universal classification system must be adopted in order to facilitate international cooperation and coordination (Domres *et al.* 2001).

8.3 Public justification of standards of care

As all the above material indicates, the triage and subsequent care of patients during a pandemic at times will be very different from conventional triage in emergency rooms that our population is used to. A bioethicist suggested that under such circumstances any proposals for procedures and standards for care during pandemic need to be articulated publicly and adopted with public participation. It is essential both for assuring public voluntary cooperation and for maintaining trust in the health care system. The process ought to be transparent and inclusive. It will be particularly important if any triage or rationing criteria should be partially social utilitarian, because "determining which functions are essential requires broad societal participation..." (Childress, 2003). Similarly, critical care physicians advised: "Triage policies should be disclosed in advance to the general public and, when feasible, to patients and surrogates on admission. Triage decisions may be made without patient or surrogate consent. Disclosure of triage decisions may help to facilitate communication, understanding and cooperation among patients, surrogates and physician" (Society of Critical Care Medicine Ethics Committee, 1994).

8.4 Institutional responsibility for critical care during a pandemic

Critical care will play a key role in decreasing morbidity and mortality during a pandemic. Survival of critically ill patients will depend on availability of treatment that supports failing organ systems, such as mechanical ventilation, haemodynamic support, renal replacement therapy. Under normal ICU conditions, nearly three quarters of patients with severe sepsis and half of the patients with acute respiratory distress syndrome survive. Without access to ICU, or similar units, survival of these patients would be very small. Therefore, a recommendation was made that hospitals have an obligation to be ready to expand their ICU facilities (Gomersall *et al.* 2006), and develop a set of practices that could be implemented in the event that critical care capacity of that hospital is exceeded. The practices that were proposed are: conversion of some of the wards into crucial care units; training of additional staff in critical care; guidelines for restriction of range of critical care procedures. Some members of the working group that produced this recommendation also advocated strongly for hospitals to stockpile ventilators (Rubinson *et al.* 2005).

It was pointed out that because of the global 'just-in-time delivery' economy, hospitals have no surge capacity for health care and could run out of common drugs, antibiotics, food supplies and other products within days of a pandemic, which would paralyze transportation or lead to border closures (Osterholm, May 5, 2005). Stockpiling of these supplies and others, such as disinfectants and oxygen was recommended (Rando).

In 1997, British medical specialists expressed a concern that during a pandemic, there would be "a demand for ventilation hugely in excess of the provision currently available" and made a representation to the Department of Health to have this issue addressed (Goodman & Anderson 1997). More recently this issues has emerged in United States. It was noted that USA has only 105,000 mechanical ventilators, which are all in use during a regular influenza seasons (Osterholm, May 5, 2005). In a pandemic, the country many need over 700,000 ventilators. National Strategy Stockpile of USA apparently holds another 5000 units. Some hospitals are already stockpiling disposable emergency ventilators; many other organizations are examining various technical and fiscal options of how to acquire this equipment. To acquire enough ventilators for a pandemic like the one in 1918 would necessitate an investment of 18 billion dollars (McNeil, 2006).

Another task that hospitals and other institutions were advised to undertake is the preparation and training of their staff, particularly those who, like respiratory therapists, will play a crucial role during a pandemic when respiratory distress and respiratory death will be common (Rando).

8.5 Summary

It appears from the surveyed literature that so far, ethical aspects of clinical care of patients during a pandemic have received only very limited attention. The changing role of physicians, as precipitated by an infectious disease outbreak, needs further discussion. There is an urgent need to thoroughly examine triage methods and criteria that could be applicable during a pandemic, especially, criteria for possible triage of a highly utilitarian nature, which may be required under conditions of extreme scarcity of resources. This work requires, not only, professional input, but also public participation. High demands for critical care and supplies during pandemic was recognized, and lack of capacity to deal with expected numbers of influenza patients is startling. Health care organizations are beginning to address their related ethical responsibilities.

9. Ethics of traditional public health measures

9.1 Introduction

Measures, such as, isolation of patients, quarantine of persons (who had or could have had contact with an infected person), travel restrictions, wearing face masks, prohibitions of engaging in a trade, closing of schools, and prohibition of holding public gatherings have been used for centuries to protect people and communities and to limit infectious disease spread (Gensini *et al.* 2004). With the emergence of vaccination and antibiotics, these measures have been rarely used in the past 50 years in developed countries (Sato & Frantz 2005), but their usefulness have been recently re-evaluated (Day *et al.* 2006; Kerrod *et al.* 2005). At the time of the SARS outbreak, public health authorities and the public had not been prepared for quarantine (Gostin, 2003). However, when facing a new disease with a high mortality rate and unresponsive to therapy, authorities had no other means available to control the very grave situation, except for quarantine of contacts, isolation of patients and other traditional measures. These measures were extensively used and eventually succeeded in terminating these very worrisome outbreaks and eradicating the virus from human hosts.

9.2 Applicability of traditional public health measures to influenza pandemic

Transmission of influenza has not been sufficiently studied, but it was recommended that persons infected and initially admitted with a newly emergent influenza subtype with pandemic potential should not only be isolated in ordinary rooms but placed in negative pressure rooms to further reduce chances for virus transmission (Buxton Bridges *et al.* 2003). WHO recently examined the evidence available for the use of so called classic or traditional measures to combat influenza spread (Bell & World Health Organization Writing Group. 2006). The WHO report recommends use of isolation and quarantine during a pandemic alert period in an attempt to prevent an outbreak. In a pandemic phase, various population-based measures are recommended in order to delay the spread and reduce the effects of pandemic. The report calls for additional research and suggests that legal authority and procedures for implementing interventions should be understood and agreed to in advance and should respect cultural differences and human rights.

9.3 Recent experience with these measures

Compliance with quarantine, and risk perception of people who were placed in quarantine during the SARS outbreak in Toronto was investigated (Cava *et al.* 2005a). It appears that participants wavered between fear and denial about their risk. Reported compliance was high, but adherence to household quarantine protocols was uneven. Attitudes toward quarantine were examined in four other countries (Hong Kong, Singapore, Taiwan, US), and it was found that a sizeable proportion of responders in all these countries were opposed to compulsory quarantine (Blendon *et al.* 2006). There was some resentment and complaints about over-surveillance in Singapore where public health measures were used very aggressively and it was suggested that the social implications of these strategies need to be addressed (Teo *et al.* 2005).

Concerns were expressed about inability to communicate with families, lack of health care, as well as other factors. Other investigators noted that it was important to prove the legitimacy of quarantine and to share with those affected the criteria used for making the decisions (DiGiovanni *et al.* 2004). It was concluded that public health authorities have a dual role of monitoring compliance and providing support to people in quarantine (Cava *et al.* 2005b).

Research done in Taiwan, where more than 150,000 patients were quarantined, proved that the onset-to-diagnosis time in quarantined persons was significantly shortened compared to those people who were not in quarantine. Thus quarantine lead to more rapid diagnosis, hospitalization and treatment, thereby improving the chance of successful outcome. Traditionally, the perception has been that people in quarantine derive no benefit from their confinement to home or institution, that it has been done only for benefit of others. This study suggests that quarantined persons may derive a personal benefit, providing that they have prompt access to medical care if the disease become manifest (Hsieh *et al.* 2005).

Mathematical modeling indicated that screening for SARS at international borders, while not likely to have a major effect on ultimate spread of infection, is capable of providing a delay of spread up to one week, this way providing one weeks' additional time to improve methods of early isolation of cases (Glass & Becker 2006).

9.4 Health Law and traditional public health measures

Law has had a longstanding interest and involvement in traditional measures used to control infections. "States have an inherent authority to protect, preserve, and promote the health, safety, morals, and general welfare of the people, termed police powers" (Gostin, 2000). Expressions of these powers are quarantine acts and related regulations that are in force in many countries (e.g. Die Bundesversammlung der Schweizerischen Eidgenossenschaft, 1974).

Also, in many countries, it is held that the infected individual has a responsibility, in law, to protect others. For example, according to the United Kingdom Public Health (Control of Diseases) Act, a person suffering from a notifiable disease commits a criminal offense if he, in a public place, exposes others to infection, or if he continues with a trade, business or occupation where he risks exposing others to infection. A concern was expressed that this law does not protect people from unjust discrimination and it needs to be re-examined (Brazier & Harris 1996).

A pandemic may represent many legal challenges. "Many of our laws are out of date and they have not been tested in the crucible of real public health emergencies" (Gerberding, Fall 2002). Health lawyers are also concerned about large scale surveillance activities, collecting sensitive health information, possible continuous monitoring of health care workers, immigrants and travelers, lack of voluntariness during case contact investigations and other interventions that may diminish civil liberties. Politicians and economists are concerned about travel and border controls that require a trade-off between maximization of health or maximization of trade (Gostin, 2004). There is a large legal literature on the United States "Model" State Emergency Health Powers Act, which is considered appropriate by some and excessive by others; involuntary quarantine provisions were among more contestable sections of this act (Annas, Winter 2003). This Model Act's powers given to public health authorities include testing, treatment, vaccination programs, isolation, quarantine and travel restrictions, that may infringe on such liberties as rights to due process, speech, assembly, travel and privacy. However, the exercise of these powers according to the act is to be constrained in time, duration and scope and limited to least restrictive means necessary (Gostin *et al.* August 7, 2002).

9.5 Bioethics of traditional public health measures

For a long time, public health specialists and officers have been aware that one of their critical tasks is to use prudently their powers of imposing public health measures. "The rights of individuals have to be balanced against the needs of communities in...control of communicable diseases" (Last, 1992 p. 1188). As discussed in the section 2 of this review, bioethicists has been lagging behind in the examination of these issues. One of the limitations of bioethics, until recently, has been the lack of recognition for the individual, not only as a victim of an illness, or, a patient in need of service, but also, as a vector of diseases and potential source of harm to others (Francis *et al.* 2005). As a result, there are at the moment only very few papers dealing with traditional public health measures as they affect individuals and groups.

Many types of ethical theories recognize a principle of nonmaleficence, most simply formulated as 'we ought not to intentionally inflict evil or harm', but legitimate disagreement exists among philosophers about the nature and stringency of the obligation (Beauchamp & Childress 2001 p. 115). Some writers stress that it is impossible to avoid all evil, and we need to make a judgment based on factors like probability, certitude and causal influence of the agent (Garrett *et al.* 1998 p. 55-76). The situations that people have encountered with the emergence of HIV and AIDS has led to the formulation of a moral obligation not to infect others (Harris & Holm 1995), grounded in the principle of nonmaleficence.

An argument was presented that all people with a communicable disease, be it the common cold or HIV, have a strong *prima facie* obligation to not knowingly communicate the disease to others, or put them at risk of acquiring the infection. Authors suggest that communicating the disease is to inflict harm proportionate to the severity of the disease. They distinguish between the duties that a person with common cold or flu has toward those who live under the same roof and those who could get infected at a workplace and in social contacts. In the first case, they believe that the infected individual can stay home, because it is his or her last refuge, and because household contacts would likely become infected by the time the disease became manifest. Only if the danger of infection would be great, should the infected person seek complete isolation. In the second case, authors suggest that the infected person has an obligation to temporally isolate herself from all social and work contacts or seek specific consent of those with whom she associates. "This must, of course apply to health care workers who expose themselves to infection and then see other patients. Now, of course, the risk to those other patients of not receiving the health care they need may be greater than the risk of being infected by their health care worker. When there are no non-infected health carers available, those who carry infection can at least obtain consent to exposure as they would and should obtain consent to treatment". The authors believe that expecting people to accept this obligation in the absence of a system of compensation for lost income is unreasonable, particularly if honoring the obligation would create a severe financial burden. (Harris & Holm 1995 p. 6).

A more recent paper that postulates that we have a duty not to infect others, asks how far this duty goes, and what ethical theory may best be able to assist in setting limits to that duty (Verweij, 2005). This paper argues that the duty to avoid infection creates requirements not only on persons who know that they carry a disease, but also on persons who are at increased risks, and even on those who are known to be healthy. The writer applied a social contract theory and concluded that this theory may make excessive demands on the infected individual. The utilitarian theory, the author suggested, is better able to set the limit on precautions against infection.

9.6 Recommendations for influenza pandemic planning

Restriction of liberty in the interest of public health by measures such as quarantine has been one of the key ethical issues that emerged from analysis of the SARS outbreak. The following recommendations were made to governments and health care sectors:

- A. Ensure that pandemic influenza plan include a comprehensive and transparent protocol for the implementation of restrictive measures. The protocol should be founded upon the principles of proportionality and least restrictive means, should balance individual liberties with protection of public from harm, and should build in safeguards such as the right to appeal.
- B. Ensure that public is aware of the rationale for restrictive measures, the benefits of compliance and the consequences of non-compliance
- C. Include measures to protect against stigmatization and to safeguard the privacy of individuals and communities affected
- D. Institute measures to guarantee provisions and support services to those affected by restrictive measures and hold discussion of appropriate levels and source of compensation in advance (University of Toronto Joint Centre for Bioethics and Pandemic Influenza Working Group, November 2005 p. 12-15)

Quarantine that may be required after an international biological weapons attack, was the theme of a conference held in January 2004 at the Wilton Park Conference Centre, Sussex, England. Many issues discussed at the conference are applicable to influenza pandemic (Defense Threat Reduction Agency, 2004).

10. Communications before and during a pandemic

10.1 Historical perspective

As we have seen in Section 3, lack of communication and improper style and content of communications were serious problems during the pandemic of 1918, the pandemic threat in 1976 and to some extent in the SARS outbreaks. Typically, when the US Congress investigated what went wrong during the 1976 aborted attempt to vaccinate Americans against possible pandemic influenza, a senior administrator concluded that the most important thing would have been a “more comprehensive widespread discussion with all sectors of the public” (Viseltear, 1977 p. 50). The impressions and memories of the public as concerns these events were greatly shaped by printed and visual messages, reports, news, recommendations and statements that were produced by governments, public health authorities (officials and experts), and by mass media.

On the other hand, those organizations and professional groups which passed unscathed through a crisis like SARS outbreak, attributed this in great part to effective communication and resulting trust between management and employees (Tseng *et al.* Mar 2005).

A view was expressed that the overall communication of risks and benefits of vaccination to the US population during the past decade has been unsatisfactory (May, 2005). Evidence cited is the public reaction to shortage of influenza vaccine in USA in 2004-2005. The shortage, caused by a manufacturing problem in England, generated irrational public fear, disregard for distribution standards favoring people at high risk and price gouging. Another example (provided by the same author) of communication lapse is the ‘anthrax by mail’ episode. An exaggerated risk perception led to some 30,000 Americans taking wide spectrum antibiotics, which may have rendered some microorganisms resistant to the antibiotic and increased future risks. The author argued that the fear, which was motivating irrational behavior, was the result of the media coverage of vaccine shortage and anthrax attacks. The media coverage was shaped largely by competition to make these stories newsworthy in order to be published. In addition to the trend of ‘sensationalization’, there is also a trend to personalization and dramatization which often leads to exaggeration of risks. Official communications, on the other hand, frequently lack historical and social context, respect for cultural, economic and experiential diversities, and fail to provide packaging that would make the facts understood and retained by the greatest number of people. The writer proposed to develop a sound ‘communication infrastructure’ designed to accurately convey health information (May, 2005).

Low rates of influenza vaccination among elderly in Sweden in the past decade were attributed mainly to lack of knowledge of recommendations. “The results clearly demonstrate that the single most important factor needed to attain high coverage is information, both to the people defined to be at risk and to health care professionals” (Dannetun *et al.* 2003). An influenza vaccination study involving over 20 000 of individuals, including health professionals, across five European countries concluded that recommendation of family doctors are critical and that “people would be more likely to be vaccinated if they had more information on the efficacy and tolerance of the vaccine, as well as the disease” (Szucs & Muller 2005).

10.2 Communication Issues in Pandemic Plans

The principles of transparency and accountability require that those who are going to be affected must be informed. Besides, the lack of communications at the pre-pandemic stage increases risk of confusion and lack of collaboration of stakeholders when the pandemic is declared (Kotalik, 2005). Given the current enhanced level of citizens' expectations as concerns the government's performance and saturation of our lives by a constant flow of media messages, the role of communications will be even important in the next pandemic. It must be understood that communications will be one of the more time-consuming and complex activities during a pandemic (Fukuda). Pandemic plans often, but not always, recognize that communication is a distinct set of tasks, related to all other inter-pandemic and pandemic activities. But the communication needs that received attention in the national pandemic plans are mostly those between the various levels of governments and participating institutions. Pandemic plans may be available on the Internet, but there is a lack of distinct programs for communicating with health care professionals, all other health care workers and with the public and private sectors.

If the future ethical framework for pandemic influenza planning will include some criteria for ethical decision-making process, then communications with and involvement of affected stakeholders will become mandatory (University of Toronto Joint Centre for Bioethics and Pandemic Influenza Working Group, November 2005).

US Department of Health and Human Services recently "initiated outreach to engage the public and obtain a broader perspective into decisions on priority groups for pandemic vaccine and antiviral drugs" (United States Department of Health & Human Services & Leavitt November 2005 Appendix D p. 1). In July 2005, 14 US public and private organizations initiated The Public Engagement Pilot Project in Pandemic Influenza (PEPPI). The purpose was to obtain an enhanced public input into vaccine policy decisions and also to test the feasibility of such public engagement on a complex policy issue. A series of meetings was held in six states with over 300 participants with diverse backgrounds. This pilot project was interpreting as providing a proof that a diverse group of citizens and stakeholders can be recruited to learn about a technical subject, interact respectfully and make a recommendation on an important policy question (Bernier & Marcuse 2005).

10.3 Various concerns and suggestions about communication

A survey of family physicians in the aftermath of SARS outbreaks showed that they attach a great deal of importance to communication issues, the timeliness of information and information delivery mechanism (Hereeg *et al.* 2005). Better communication, including development of a Web-based data collection tool was credited with improvement of vaccine distribution so that it could be made available to those at the greatest risk of complications (Ehresman, 2005). Credible and effective communications to a population of mixed cultures and languages was found to be critical for effective voluntary quarantine during the SARS epidemic (DiGiovanni *et al.* 2004).

Communication can be used not only to inform but also to change behavior. It was suggested that the reliance of infection control professionals on didacticism to affect behavior is in our era producing disappointing results. A 'socioethical approach' was suggested as an alternative and described as consisting of movements

- From individualism to community
- From rationality to rhetoric
- From productivity to praxis
- From monologue to dialogue (Mah & Myers 2006)

Communication within a nation could be hindered by concerns about possible negative impact on security or negative political impact. Examples of that kind of communication problem would be a controversy whether or not a publication of the reconstruction of 1918 Spanish influenza virus should be made public (Kennedy, 2005), and recent revelation by an off duty WHO advisor that China may have concealed hundreds of human bird flu deaths (Enserink, 2005). Well functioning communication channels within each state, a challenge for states with federal structure where provinces or cantons are responsible for health affairs, is also a pre-condition of a good international communication, discussed at a recent international conference (Sibbald, 2005).

Guttman and Salmon (Guttman & Salmon 2004) identified the following ethical issues raised by public health communications:

- Targeting and tailoring public health messages to particular population segment
- Obtaining an equivalent of informed consent
- The use of persuasive communication tactics
- Messages on responsibility and culpability
- Messages on harm reduction

These authors pointed out that there are three types of unintended adverse effects of public health communications: labeling and stigmatizing, expansion of social gaps, and promotion of health as a value. They suggest that ethical analysis should be applied to each phase of public health communications.

Communications about pandemic will be affected by the overall communication culture in the country. Roadblocks in communications appeared to have caused much delay in the reporting of SARS. "Chinese government's rigid control of information and its strict bureaucracy have hindered efforts to halt the deadly disease that seems to have originated on Southern China and is threatening the public health around the world and hurting economies across Asia" (de Castro, Leonard, D. *et al.* 2003). Some observers charge that even in democratic industrial countries there is an unjustified tendency to secrecy. "Fundamentally, all information belongs to the public and it should be in the public domain unless compelling reasons exist to withhold it" (Pope, Feb 6, 2003 p. 16). Nevertheless, communication of risks requires special attention, and its own risk assessment (Editorial, 2004).

10.4 Final Comment on Communications

It appears from the publications available for review that as yet there has not been much attention paid to communication about pandemic directed to various sectors of society and the public in general. However lessons from recent history, the current demands for fair, open and inclusive decision-making process, and practical necessity of a coordinated action all suggest that a well structured and comprehensive communication plan will emerge as one condition for ethically satisfactory influenza pandemic planning.

11. Conclusion

This review of literature was created to provide background information for discussion of ethical aspects of influenza pandemic preparedness plans and related public health policies. The interpretation of the material collected here is understandably reader-dependent. This reviewer's impression is that when insights of contemporary bioethics are combined with ethos of discipline of public health and with reflected experiences with infectious outbreaks of the past, a picture of desirable ethics of preparedness measures for the upcoming influenza pandemic is starting to emerge. The picture is still hazy and has a number of dark spots. It will require a considerable intellectual interdisciplinary work to obtain more precision and clarity of the vision. Nevertheless, even now, appraisal of existing pandemic plans and commentary on various policy options from an ethical perspective appears feasible and useful. Eventually, focused attention to this new domain of bioethics may allow us to offer a comprehensive bioethics framework for new or revised pandemic plans and for response at the time of influenza pandemic.

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