National Consultative Ethics Committee for Health and Life Sciences

OPINION N°106

Ethical issues raised by a possible influenza pandemic

Members of the Working Group:
Annick ALPEROVITCH (rapporteur)
Frédérique DREIFUSS-NETTER
Anne Marie DICKELE
Patrick GAUDRAY
Pierre LE COZ (rapporteur)
Philippe ROUVILLOIS
Michel ROUX
Philippe WAQUET

Persons heard:
Reza LAHIDJI
Isabelle BONMARIN

CONTENTS

The avian influenza epizootic caused by the H5N1 virus, which is affecting a number of Asian countries, is reason for concern regarding the possibility of pandemic influenza in humans. The "*Espace Ethique de l'AP/HP*" (Ethics Group of the Paris Public Hospitals), referred the matter of ethical issues in connection with this possible pandemic to CCNE. The concern of the Espace Ethique de l'AP/HP is shared by two bodies working jointly on a contingency plan for the management of the "*Pandémie grippale en France*" (Pandemic Influenza in France). They are the *Secrétariat général de la défense nationale* and the *Délégation interministérielle contre la grippe aviaire* (Defence Ministry and the Interministerial Delegation on Avian Influenza), who have underlined the importance of basing the plan on common ethical values[1].

In the view of the Committee, the essential issue at stake is whether the emergency situation caused by pandemic influenza includes the possibility of giving less precedence to certain fundamental ethical principles. Should individual liberties be subordinated to other values more conducive to effective management of this major health threat? To what extent can personal mobility be restricted? What conditions would society insist on before accepting that some of its members would have priority for inoculation in the phase when vaccines were in short supply?

I. DEFINITION OF THE SCOPE OF CCNE'S DELIBERATION

Three times in the 20th century, the number of influenza cases caused by a new virus breaking out worldwide rose very sharply: 1918, 1957 and 1968. Forty years elapsed between the first influenza pandemic of the 20th century and the one which followed it, whereas a mere ten years or so separated the second and third pandemic. We cannot forecast the date when the next influenza pandemic will strike, nor can we be sure of where it will come from. We cannot even be confident that it will be due to a mutation of the H5N1 avian virus. Some other virus, hosted by another animal species, could just as well be the cause of it. However, strategies to fight the pandemic would be just as pertinent and some of these measures could serve a useful purpose in other kinds of health crises.

In response to the recommendations of the World Health Organization (WHO), contingency plans are being put together in various countries to define the measures which, applied collectively, could limit the consequences of the next influenza pandemic. Several countries already have a plan prepared and the French plan is one of the most advanced of them, but information to French citizens of its existence and of what it contains is close to zero.

There are uncertainties: the number of cases, the duration of the epidemic and the virulence of the virus. To such uncertainties regarding the amplitude of the epidemic are added further doubts concerning the impact of the various measures on the number of hospitalisations and fatalities. Models produced by various research groups do not provide precise evaluations. The best they can do is to compare the effectiveness of the various

[1] Document n° 40/SGDN/PSE/PPS, dated January 9, 2007

measures. The authorities are therefore confronted with the difficulty of decision making in an uncertain situation. And yet, ethical reflection must also integrate this uncertainty.[2]

In this uncertain situation, however, some points meet with a large degree of consensus.

In the absence of any strategy to fight the epidemic, a very high proportion of the population exposed to a new virus (as many as 50% in some assessments) would be affected by the disease. As regards the dynamics of the epidemic in France, the time elapsing between the first cases and the peak of the first wave of the epidemic[3] would be about six weeks. Furthermore, a specific vaccine (so-called "pandemic vaccine") would only be available in quantities sufficient to cover all priority needs some weeks after the onset of the pandemic. In consequence, the major portion of the first pandemic wave would probably have to be managed in a situation where vaccine supplies were in very short supply.

The amplitude and the speed of extension of the epidemic and the unavailability (at least temporarily) of some of the possibilities of fighting it, militate in favour of defining, before the outbreak of the pandemic, the measures which will need to be taken. A management plan will only be fully effective if it is accepted by the population as a whole and if all members of the community are aware of the individual contributions they must make to the plan, in both their home and social environments. It is therefore very obvious that efficient communications, planned from the outset, are of primary importance. Information should bear not only on the public health measures included in the plan. Ethical aspects must also be stressed so that the flu pandemic does not give rise to panic reactions and antisocial behaviour.

In such an exceptional situation, there could be a need to review the hierarchy of values which are the foundation of ethical recommendations, as far as health is concerned in particular. Should we go as far as considering that a review of our priorities is an ethical necessity?

CCNE does not seek to make an ethical case for the essential decisions that the authorities will be required to take. Our purpose is to provide food for thought in the full knowledge that, inevitably, these decisions will be unwelcome to a large proportion of those concerned. Nevertheless, the Committee points out that these decisions, regardless of their nature, must comply with the principle expressed in CCNE's Opinion n° 8, i.e. *"The basic requirement on which the respect for human dignity is based is the highest of all values, and must be translated into the actual de facto situations."* The dignity of individuals is independent of their social standing or of their usefulness to others.

[2] To take but one example, the ethical aspects of issues relating to access to hospital care could be debated without attempting to include a precise quantitative dimension. But the constraints weighing on ethical reflection differ, depending on whether, for instance, there is a need to postpone a few thousand or 100,000 hospitalisations, or of managing an increase in requests for admission to intensive care units of a few hundred or several thousand patients.

[3] In an influenza epidemic, the number of new cases per week increases very substantially in the first six weeks (approximately), after which there is a gradual decrease, with the whole outbreak lasting some three or four months. In the case of some influenza pandemics, like the one in 1918-1919, two epidemic outbreaks, separated by several months, were observed.

To foster reflection on the subject, this Opinion will begin with a summary of some of the results of epidemiological models of the pandemic which have a bearing on ethics (II). Next will be discussed general ethical considerations which pandemic influenza would throw into sharper relief (III), then the more specific problems such as priorities in the allocation of resources and access to care, hospital care in particular (IV) and, finally research needs (V).

II. SOME EPIDEMIOLOGICAL FINDINGS AS A CONTRIBUTION TO ETHICAL REFLECTION

Various international research teams, including the *Institut de Veille Sanitaire* (InVS)(French Institute for Public Health Surveillance)[4] and the Scientific Pandemic Influenza Advisory Committee[4] (SPIAC) in the United Kingdom, did some modelling to evaluate, in a variety of well-defined scenarios, the epidemiological indicators for the severity of the epidemic in the absence of any prophylactic or therapeutic action. The models also compared the impact of diverse strategies to fight the pandemic. Some of the work is specific to measures of a purely national application and some tries to evaluate the measures that could be recommended for international use. The studies are based on the current status of scientific knowledge and the accepted degree of uncertainty. It must never be forgotten that results are based only on statistical evaluations. They do, however, provide the most accurate global view of the pandemic available to us at this point. We will be referring to some components of these studies which could throw light on the ethical considerations that arise in such circumstances.

A. Epidemiological specificity of the influenza pandemic

An influenza pandemic is caused by the emergence of a new virus that no one, regardless of his or her age, is immune to. While this definition is an over simplification of a situation that can be altogether more complex, it does give an understanding of why the age breakdown of the people who may be infected by the virus — and therefore at risk of being affected by the pandemic influenza syndrome — is not what is usually observable in common seasonal winter outbreaks when a part of the population is already immunised. Another point is that there may appear, in a pandemic, viral variants for which those people most at risk of severe complications are not the same population as those who are usually most vulnerable to infection. For example, at the time of the 1918/1919 Spanish flu, the adult working population was the most severely tried by the disease. Finally, it is important not to confuse the risk of being infected by the pandemic virus and the risk of severe complications which may not be caused by the same factors. As regards a future influenza pandemic, the epidemiological models are based on the assumption that the majority of cases, of both hospitalisation and death, could involve sectors of the population which, *a priori*, are not at any particular risk (adults in good health). The situation is therefore not at all the same as during the recent heat wave, in which, with a few extremely rare exceptions,

[4] InVS Report 2005: *Estimation de l'impact d'une pandémie grippale et analyse de stratégies* (Doyle A, Bonmarin I, Lévy-Bruhl D, Le Strat Y and Desenclos JC) (An evaluation of the impact of an influenza pandemic and an analysis of strategies)

[4] Scientific Pandemic Influenza Advisory Committee (subgroup on modelling) February 2008: Modelling Summary

the only people who suffered severe complications and those who died, were particularly vulnerable initially because of advanced age, poor health or living in socially deprived circumstances.

B. Multiplicity and complementarity of individual possibilities for fighting the pandemic

Existing models are mainly concerned with medical measures to be taken (antiviral treatments, pre-pandemic and pandemic vaccines) for which data on efficacy — to be extrapolated with caution to a future influenza pandemic — is available. Measures for individual protection, such as wearing a mask, have not as yet been evaluated in sufficient detail to determine their impact on numbers of cases. Moreover, the effects of individual medical protective methods on the severity of the epidemic, both preventive and curative, are measured each in isolation. We do not currently have available any more pertinent methods of evaluating strategies, nor do we have more sophisticated instruments which could examine several of these measures in optimal combinations. And even if the data necessary for such an evaluation were to become available, the global operating model would still be extremely complex.

C. Collective measures - national and international

Models have been developed to study the impact of possible national or international measures for the purpose of slowing the progression of the pandemic and limiting its scale. Some of them show that massive and multiple measures, medical and non medical, if they were initiated very swiftly in the area of onset of the earliest cases, could contain the epidemic, at least temporarily, on the condition that it begins in a rural environment. Another advantage is that the virus could be identified and the vaccine prepared before the disease had had a chance to spread. However, from a global viewpoint, few countries and in particular, few of the Asian countries primarily concerned by the avian flu at this point, own the healthcare and social structures required for fighting an emerging epidemic effectively. British studies suggest that restricting national and international travel, setting up sanitary check systems at borders and regulating public gatherings would have only a limited effect on the international and national (i.e. within the United Kingdom) dissemination of the disease. On another front, while many plans include the closing of schools, the potential impact on the number of cases (the children themselves and their families) has not been evaluated.

III. *GENERAL ETHICAL ISSUES EXACERBATED BY A PANDEMIC SITUATION*

III.1. The principle of justice

The values which society holds in high regard must remain foremost in our minds when we are fighting the spread of the virus while seeking to combine strategic efficacy with ethical

principles. Everyone agrees that formulating a plan to fight a pandemic must not aggravate existing injustice. Justice is a principle which can accept two meanings: equality and equity.

- To be just in the meaning of *equality*, is to act so that individuals are recognised in their dignity, that is so that their individual value is recognised as absolute. From the viewpoint of *egalitarian* justice, decision makers must help those whose dignity is endangered by precarious living conditions. It is this principle of egalitarian justice which inspires policies to counter social discrimination and measures designed to protect the weak and the minorities.

- Justice in the meaning of *equity* moderates absolute egalitarianism with an effort to provide the whole community with the same life expectancy and quality of life. It does not contradict the requirement for equality; the objective is to avoid a situation where unconditional respect for the value of a person leads to the investment of collective resources in that person without any regard for the consequences on the quality of life of other members of society. Equity is of particular concern when resources are scarce. Since in an influenza pandemic, there would certainly be a limited time when medical resources were in short supply, equity would have to moderate egalitarianism. From an ethical point of view, the Committee considers that the plan to fight such a health scourge should be based on a requirement for justice in the egalitarian sense of the concept, moderated by the temporary need to place a priority on resources.

A. Solidarity of rich countries with the poorest countries

Can the ethical issues raised by a pandemic be addressed without dealing first with the duty of providing assistance and justice?

Intrinsically, fighting a pandemic could act as lever against exclusion[5]. National and international anti-pandemic containment strategies all make a plea for a duty of solidarity on the part of the richest countries in favour of the poorest. But there is reason to fear that international solidarity could be limited to a display with which the demand for justice would not be content, unless the actions it implicates are readied well before the start of the pandemic. Experience shows that solidarity is always founded on a convergence of interests, so that a call for universal solidarity runs the risk of being inadequate to meet the needs of equity if the expectation is assistance provided to other countries without any hidden agenda, in particular an economic one.

We find, in the example of the influenza pandemic, that countries owning appropriate means of containment have, in most cases, built up stocks of antiviral medicines sufficient to respond to their own prevention and treatment needs, for the most plausible attack rates[*]. If the attack rate is lower than expected, medicines will be on hand for countries unable to build up stocks. But if the attack rate is equal to what was expected, and even more so if it is higher than expected, countries — the most economically developed countries among them in particular — will use up all available stocks for their own nationals.

It seems likely therefore that we would not live up to the duty of justice and assistance to the poorest countries when a pandemic breaks out, unless we can prepare for the event

[5] Ameisen J.-C. : La lutte contre la pandémie grippale : un levier contre l'exclusion. Esprit, 2007, 336 :78-95

[*] Proportion of people taken ill with influenza

long in advance and set aside a small portion of the resources invested in our own epidemic-containing strategies. France is committed to preparing for swift distribution of such stocks to the poorest populations. This is reinforced by the evidence of some epidemiological models which suggest that **sharing stocks of antiviral medication with the poorest countries, as prescribed by the duty of assistance, could also help to reduce the severity of the epidemic in donor countries[6].** Sharing with poor countries appears therefore as a necessity in the fight to contain the spread of disease in donor countries.

B. Solidarity in the face of social inequality

The attention that is needed for people who are isolated, excluded or living in particularly precarious conditions is not specific to an influenza pandemic situation. But compared to other crises (heat waves, extreme cold, etc.) organised social welfare services and individual solidarity could be less efficient because of the very high numbers of potential helpers who would be sick themselves. Some work, anticipating the kind of problem with which we would be confronted, arrived at an estimated 30 to 35% of professionals or relatives unable to work at the peak of the first wave of the pandemic, which includes the people who would have to stay home to look after sick relatives or because schools would be shut.

Closing schools for weeks at a time, a measure which many countries plan to take, will be a source of inequalities. Single-parent and low-income families will suffer more than most if they have to stay away from work to look after their children. To give substance in this respect to the egalitarian concept of justice, solidarity from neighbours or relatives will be playing an essential role in this kind of situation. Furthermore, the impact of this measure, designed to reduce the exposure of children to the flu virus, will depend on their social environment. It is important to give careful consideration, before the pandemic, to what could be done so that such a step could be of benefit to all children.

Because of crowding and poor sanitation in their living conditions, some people, prison inmates in particular, would be at risk of very high attack rates and complications. Such sectors of the population must be the object of specific measures in containment plans to avoid the dangers of seriously compromised law and order.

III.2. *The danger of stigmatisation*

A pandemic may provoke stigmatising behaviours and these must be anticipated. To avoid such reactions must be one of the objectives of communication with the public. It must be emphasised once again that there is no individual characteristic which could predict those who are most at risk of being infected by the flu virus: the majority of cases may well arise among the young and healthy. To prevent collective fear, which would be inevitable and understandable in such a situation, from degenerating into ungovernable panic, the mass media must use to the full their power of influence on individual and collective behaviour. The considerable weight of their involvement in the intensification of collective emotional reactions, with stigmatisation as a possible result, should be an incentive to

[6]Colizza V. et al. Modelling the worldwide spread of pandemic influenza. PLos Med. 2007, 4(1) : "*International sharing of antiviral stocks might reduce attack rates more than countries retaining their own stockpiles for their own use"*.

engage without delay in consultation with them. A special working group could devote its attention to the role of the media, as regards anticipation and responsibility, in the event of an influenza pandemic.

III.3. *Rights and liberties put to the test of the pandemic*

France is a country where the rule of law prevails. This means that the authorities are governed by principles of legality. But to quote Montesquieu "*There are cases in which a veil should be drawn for a while over liberty, as it was customary to cover the statues of the gods".*

Two situations can justify this parenthesis in the enforcement of legislative law: a state of siege and emergency, on the one hand, and the theory of exceptional circumstances, on the other.

- The states of siege or emergency are decreed to react to "extraordinary" circumstances. The law dated April 3, 1955, n° 55-385, would be used by the Council of Ministers to order a state of emergency. The situation would allow, inter alia, by order of the "Préfet", for protection or security zones to be defined, in which the presence or residence of persons would be regulated. A state of emergency therefore authorises an extension of the normal powers of authority so that they can cope with the situation.

- The theory of exceptional circumstances, devised by the *Conseil d'Etat* (Council of State), is based on the finding that, sometimes, in certain circumstances, the authorities are not able to comply with the ordinary principles of legality. In that event, in order to satisfy the needs of national defence, the restoration of order and the continuity of public services essential to national or local needs, the authorities may take, on a temporary basis, the decisions and steps required by circumstances without complying with normal procedures and existing legislation. The Government may in such case, by decree, suspend the enforcement of a law (CE 28 June 1918 Heyries); or encroach on liberties (CE 18 May 1983 Rodes); citizens may even replace defaulting authorities and edict temporary measures to be observed by the community (CE 5 mars 1948 Marion).

Clearly, in the event of a serious and sudden pandemic, the Government could take steps such as requisitions, confining certain categories of citizens and restricting travel, either on the basis of a decree proclaiming a state of emergency or supported by the theory of exceptional circumstances.

General or particular restrictions which may apply to citizens, according to the jurisprudence established by the *Conseil d'Etat* and which are also set out in the so-called Siracusa Principles[7] established by WHO, must:

- be provided for and carried out in accordance with the law;

- be in the interest of a legitimate objective of general interest;

[7] The Siracusa principles on the Limitation and Derogation of Provisions in the International Covenant on Civil and Political Rights. E/CN.4/1985/4,

- be strictly necessary to achieve the objective, be based on scientific evidence and not drafted or imposed arbitrarily, i.e. in an unreasonable or otherwise discriminatory manner.

Finally, it is worth mentioning that legislators made a preventive move in the March 5, 2007 law, n° 2007-294, relating to the preparedness of the public health system for major health hazards, in particular in articles L 3131-1 and L 3131-2 in the *Code de Santé Publique* (Code of Public Health)[8]. A national plan for the prevention and control of the influenza pandemic, updated in 2007[9], considers measures for limiting travel, regulating public gatherings and educational, cultural and economic activities in order to prevent contagion.

While CCNE is well aware that such restrictions on fundamental liberties might be necessary in the circumstances, we wish to draw attention to the risk of extending them beyond what is strictly required to contain the influenza pandemic, either because of a maximalist (and therefore inappropriate) conception of the precautionary principle or as a demagogic concession.

By the same token, it must be remembered that all rights and liberties, which are not specifically excluded, must continue to apply. This is the purpose of article L 3131-1 of the *Code de la Santé Publique* stating that a state of health-related emergency does not affect rules of respect for privacy and the confidentiality of personal medical data.

III.4. *Solidarity and autonomy*

The consideration of ethical issues often leads to a confrontation between principles of autonomy and the need for solidarity. The two concepts are not mutually exclusive unless the idea of autonomy is reduced to meaning selfish freedom of action. To be autonomous means to be free among other free agents, not being in opposition to them. Conversely, solidarity consists in allowing the greatest number of people to exercise their autonomy.

---

[8] *Article L3131-1 :*In the event of a major health hazard requiring emergency action, in particular a possible epidemic, the Minister for Health may, by order with justification and in the interests of public health, prescribe measures proportionate to the risk incurred and appropriate to circumstances of time and venue, in order to prevent and limit the consequences of the possible threats on the health of the population.*
The Minister may empower the territorially competent representative of the State to take all the measures required for the implementation of these provisions, including individual measures which are immediately reported to the public prosecutors.
The departmental representative of the State and those acting under his/her authority are bound to preserve the confidentiality of information collected concerning third parties.
The representative of the State reports to the Minister for Health on action taken and results of the implementation of this article.
*Article L3131-2 *Justification for measures taken in implementation of article L. 3131-1 is periodically reviewed by the "Haut Conseil de la santé publique" (Public Health Council) as decreed by the Conseil d'Etat (Council of State). Such measures are abrogated as soon as they are no longer necessary.*

[9] Document n° 40 /SGDN/PSE/PPS dated January 9, 2007.

But, although in theory, it is only to a depleted view of autonomy that solidarity is opposed, it must be noted that, in practice, the requirement of solidarity is sometimes experienced as a coercive limitation on individual liberty. There are, for example, people who are opposed to the very principle of vaccination, by personal conviction or for ideological reasons, who claim respect for their autonomy.

Be that as it may, autonomy necessarily implies knowledge. Consent is only free when it is informed. As regards the influenza pandemic, respect of autonomy includes — for each and everyone of us — the right to precise information regarding the risks and the protective measures (antiviral treatment, vaccination) which could be made available to us and we must have the opportunity of rejecting them. Refusal would take on a particular significance. People choosing to refuse benefit directly from the protection that is provided by all those who accept what they themselves are refusing. It is true that in other circumstances, refusing vaccination could be interpreted in the same way. However, **during an influenza pandemic, a confused understanding of autonomy leading to rejecting treatment, the effect of which would be to facilitate the spread of the disease, would be unlikely to be acceptable by society as a whole. Autonomy would have to bow to solidarity.** Naturally, and complying with codes of deontology, this would not exempt health providers from their duty to hear and dialogue with those who are reluctant, in order to try and persuade them to accept preventive or curative treatment.

III.5. *Ethical issues related to economic considerations*

Ethical problems generated by the cost of disease management can be classified into three categories: contracts between Pharmaceutical companies and States, the involvement and regulation exercised by international political authorities on the pharmaceutical market and choices regarding the allocation of resources.

- The media reported on a 'viral strains for vaccines' contract signed between a country particularly affected by the avian influenza epizootic and a pharmaceutical company. The contract incurred WHO disapproval as the organisation wants samples to be shared out free of charge. This policy may be the result, at least in part, of fears that the need for vaccines might not be covered in those countries which would be most affected by the pandemic. As yet, it would seem that WHO has not obtained international agreement on the principle it is defending. Through such confiscation, fundamental ethical values are flouted.

- To give substance to the *egalitarian* meaning of justice, States cannot remain indifferent to some of the effects of a market economy when human lives are at stake. They must commit to an adaptation of the international production of vaccines to global demand which would be both large and relatively limited in time. The question therefore is can industry respond to such demand and set up production systems capable — once the pandemic vaccine is developed — of immunising the entire global population in a short time. If not, who should take on this pressing obligation?

- To satisfy the dimension of *equity* that the principle of justice upholds, States will need to reflect on priorities for the allocation of assets: what resources should be devoted to fighting the pandemic in the presence of other crying needs, be they medical, related to public health or of a different kind altogether? Moreover, some of the items needed to fight

the epidemic, such as antiviral drugs and masks, deteriorate over time so that stocks would need to be replenished if the pandemic outbreak is delayed. When out-of-date stocks need replacing, ethical issues linked to the opportunity cost[10] will have to be discussed, and thought given to the prospect of using resources invested in fighting a future epidemic for major health hazards as yet left unfunded.

IV. *ETHICAL ISSUES MORE SPECIFIC TO THE INFLUENZA PANDEMIC*

IV.1. Priorities in the allocation of some means of fighting the pandemic

Some of the means of fighting the pandemic (including antiviral drugs) must be available at the start of the pandemic, and in sufficient quantities, if exceedingly difficult allocation problems are to be avoided. This is not true of the vaccine, which can only be developed once the pandemic virus emerges, so that production, however intensive, will only be able to respond progressively to considerable demand. When health care items are too scarce to be made available to everyone, the egalitarian sense of justice which requires conduct adjusted to the needs of individuals, without regard for their particularities, will be competing with justice in a social sense which requires the setting of priorities. If society cannot cover all the needs, it must establish a ranking for demands.

Everyone will have to be satisfied that no favouritism is involved and that the authorities are acting solely for the purpose of containing the extension of the pandemic. Conforming to the egalitarian sense of justice, the first idea that has to be made clear is that the aim is to protect the *entire* population, regardless of social position and age. **The concern for equality is qualified by the requirement for equity, which only comes second and on a temporary basis, while the vaccine is being developed and until it can be made available to all members of the community.** From the point of view of justice in the sense of equity, defining priorities for the allocation of vaccines is a necessity to which there is no alternative temporarily since making them available to all at the same time is a physical impossibility. Even though they cannot be applied mechanically to the reality of the situation, the ethical principles of justice (in the dual sense of equality and equity) can govern the practice of public health management.

A. Objectives arriving at conflicting priorities

Those who are at a high risk of complications and those whose activity is necessary for looking after patients and for keeping the country operational during the pandemic are generally considered, in most contingency plans, as a priority for protection. At first sight, there seems to be nothing in such a plan that would undermine the ethical requirement for equity. But as soon as the various options for applying these priorities are considered, it becomes obvious that their objectives must be more clearly defined.

For example, selecting people to be protected as a priority solely on the basis of their "economic" value, present or future, i.e. their social "usefulness", is unacceptable. People's

[10] Presentation by J.P. Moatti, Journées nationales d'éthique, Paris, November 2007

dignity does not depend on their usefulness which, for that matter, is extremely difficult to define, particularly in the circumstances.

If the attack rate of the next pandemic were to be comparable to those of the three episodes in the 20th century, and in the absence of any measures to fight the disease, the next influenza pandemic would cause tens of thousands of deaths, if only on a purely national basis. Should the first objective of countermeasures, and of inoculation in particular, be to reduce the total number of deaths? Any strategy limiting the number of deaths also reduces to more or less the same extent the number of serious complications and hospitalisations. Choosing to aim at saving the greatest number of people means recognising that each human life has the same value, which would seem to satisfy the egalitarian requirement inherent to the principle of justice.

What, however, would be the consequences if this objective were to be put into practice? For a given (and limited) number of doses of vaccine, the reduction in the number of deaths would be all the greater if the people benefiting from priority protection were also those members of the community most likely to die in the event of infection. Choosing such an objective would therefore lead to vaccinating as a priority the sick and elderly as well as neonates.

The limitations on such a choice of priorities are that many of the people qualifying for priority inoculation would be those whose life expectancy was the shortest (independently of the extra risk caused by influenza). For this reason, although it has some legitimacy in its own right, the above objective would lead to priorities which would be ill-received by some sectors of society. Think, for example, of inter-generational bonds within families and how grandparents would feel when they discovered they were given priority while their children and grandchildren would not have access to the vaccine.

Could an alternative be to place a premium on life expectancy? The objective would then be not so much preserving the greatest number of lives, but rather the greatest number of days of life. Very young children, whose life expectancy is the longest, would be the group with the strongest priority for vaccination. On the negative side, this would mean not giving priority to those most vulnerable to infection, the very old in particular. Would it perhaps be even conceivable to go a step further in that direction and take into consideration not just life expectancy, but life expectancy in good health, as seems to be the trend in the evaluation of public health programmes?

This dilemma confronts us with society's existing exclusions: in such a situation, the elderly, the sick, the disabled could be deprived of treatment. The other limitation on the criterion of life expectancy is that giving priority to children only is hardly a sensible course if the health of those who can look after them is not protected.

B. The system for the allocation of organ grafts as an aid to reflection on prioritisation .

The *"Agence de la Biomédecine"* is faced with a chronic medical problem, the cause of 250 deaths every year: the shortage of donor organs. While on several counts this chronic shortage of resources is not identical to the situation which would be facing us in an influenza pandemic, it is worth looking into the way in which ethical criteria were weighed by the agency since it is probably the authority whose thinking on the subject of priorities is

the most advanced. Could we draw a few lessons on how to deal with a flu pandemic from this collective acceptance of completely transparent choices made by one public health authority?

Despite all the differences between the two situations (social emergency versus individual emergency) some findings seem to have educational value:

- If the criterion of time spent on the waiting list is excluded (it has no pertinence in the case of an influenza pandemic since everyone would be in the same need), we find that the concern for an equitable allocation of the resource is expressed via a set of factors weighing life expectancy, efficacy and the degree of urgency. Drawing lots is not considered an acceptable *modus operandi* even though it is certainly true that it would have the advantage of giving everyone an equal chance of obtaining an item appropriate to their needs, without the characteristics most likely to be chosen as a reason for discrimination (age, nationality, state of health, productive capacity, etc.), being allowed to bias decisions. But the arbitrary nature of a lottery, when a medical decision is involved, is unacceptable to a majority of the population[11]. Fairly spontaneously, as in any society (past or present), there is a consensus in favour of giving priority to new generations over their elders. It would seem that, when resources are scarce and we reach the end of our lives, our claim for treatment is not on a footing of total equality with, for instance, a child. Rejection of the egalitarian criterion in drawing lots is probably at least partly due to society's hazy feeling that it must grant priority to those most likely to ensure that it survives, even though putting this in formal terms is not an easy task.

- Public health authorities responsible for the allocation of grafts grant a good deal of prominence to the criterion of prospective efficacy, giving priority to patients whose state of health would *a priori* offer the best chances of survival with reference to their quality of life. Regardless of age, an individual candidacy can be rejected when the prognosis is poor. This criterion aims to put available resources to the best possible use through an evaluation of risks of complications, possible failure and the probability of extended survival. In an ordinary situation, it would seem fairer to give priority for the allocation of scarce resources to those with the worst level of well-being. But an exceptional and critical situation can force society to consider the egalitarian sense of justice and give preference to a more radical condition: keeping alive the greatest possible number of people for the longest possible time of survival.

Generally speaking, we can consider that in a shortage, a good level of social acceptability is conditioned by the fact that no principle is subordinated to any other principle. Applying any single principle (equality, life expectancy, quality of life) to the detriment of any other is not the method we should choose to arrive at a just decision. Justice is to be found in the weighing of excesses that could be generated by giving absolute precedence to one criterion to the detriment of all others.

[11] In a different context, the antiprotease drugs issue, when they began to be used to treat AIDS, is a demonstration of the low degree of social acceptability of drawing lots, to the extent that it triggered a protest movement (*Conseil National du Sida*). (National Council on AIDS). Report on the availability of antiprotease drugs and on the problems raised by supply not matching demand, February 26, 1996.

The example of an equitable management of vital resources, in the context of the allocation of organ transplants, is interesting in that it shows that there is always tension between the object of efficacy (level of life expectancy and quality of life of people) and the concern for equality (as regards medically and/or socially recognised needs). There is no technical solution to this conflict between ethical criteria when we must decide on a method of allocating health-related resources. Our only choice is between two levels of arbitrariness, partial with predefined criteria, and absolute in the absence of criteria, in which latter case, solutions are imposed rather than accepted.

Ethical criteria to provide a standard are a necessity. They give citizens peace of mind regarding the existence of rules applicable to all and the respect of ethical principles (neither money nor "queue jumping"). This climate of trust must be created before the crisis situation is upon us, which means before the flu pandemic strikes our country. One way of doing this would be to have the people know that ethical rules have been defined, inspired by existing, transparent and validated methods of regulation.

The mismatch between the supply and the collective demand for care in the event of a flu pandemic will oblige the authorities to implement a strategy involving a plurality of competing ethical principles: equality, protection of the most vulnerable, efficacy, individual liberties, equity and solidarity. The complexity of attempting to weigh these criteria against each other is aggravated by our ignorance of some major decision parameters.

IV.2. The rights and duties of professional categories with priority

On top the priorities involving the population as a whole, contingency plans include provisions to give special protection to key personnel engaged in activities which are considered essential to the conduct of the country's affairs during the pandemic. Health professionals, more particularly health carers, would of course be the first to be protected. On an individual basis, because of the work they do, they are more at risk of being infected by the disease than the population as whole. If only for that reason, there are grounds for granting them priority. Furthermore, for the sake of the community, protection of health workers is essential if the healthcare system is to cope with the crisis and remain sufficiently organised to avoid untimely deaths and serious complications.

Apart from the healthcare system, the authorities are legitimately concerned with maintaining essential activities in the country (transport, security, energy production, etc.) so that certain people working in these sectors will be protected as a priority. The process of selecting the professional categories singled out for protection should be widely advertised.

Protected people will have many duties but also rights. Respect for their autonomy implies that they receive, in good time, precise information on the prophylactic treatment they are being offered, that they are allowed to refuse it, but if they do, are informed of the risks their community could be running as a result. An essential duty of the professionals concerned is to use the means of protection the community makes available to them with the greatest parsimony. The fact that one sector, such as security, transport or energy, has a priority does not mean that everyone working in the sector has a priority. Responsible and concerted reflection will be necessary, long before a pandemic, in each professional group

with priority to decide collectively how many and which people will need to be protected. The need to define collective behaviour in a pandemic is not, for that matter, solely restricted to essential sectors. Some companies and government departments have already begun to reflect on these difficult decisions. In such a crisis, who could stay home and thereby reduce to some extent their own risk of becoming infected? Who should continue to come to work?

Finally, it is essential to emphasise that the ***special priority*** **granted to people belonging to a group that society considers should be protected before others, is a *collective priority* for the protection of everyone** (and not a *value* placed on an individual). And also that it is specific to the pandemic situation.

Moreover, steps will need to be taken to fight the disinformation which might lead people to believe that the vaccine is the only way of overcoming the pandemic. Contingency plans mention vaccines but also measures such as wearing a mask, isolation and prophylactic treatment. For those people advised that they should best stay at home, steps must be taken to provide them with the necessary assistance.

IV.3. Ethical issues related to the impact of the influenza pandemic on the functioning of hospitals

The referral by the *Espace Ethique de l'AP-HP* indentifies two problems raising ethical issues: the deferment of some hospitalisations and the triage of patients on admissio n to (or release from) resuscitation units. Neither of these problems is inherently specific to the influenza pandemic, but in a pandemic their dimension modifies their nature, so that solutions which may have been judged, in another context, incompatible with the ethical principle of equality of access to care for all, will have to be reviewed.

In the most favourable scenario considered by the *Institut de Veille Sanitaire* (InVS)(French Institute for Public Health Surveillance), hospitals would admit over 300,000 extra new patients in just a few weeks. To cope with this inflow, a large number of planned hospitalisations would have to be postponed. Is it up to each health carer (or team of carers) to make this selection? In an influenza pandemic crisis, the stakes are so high that this general principle might need to be reappraised. For the selection procedure to be acceptable from the dual point of view of public health and ethics, should not criteria for the ranking of health problems, depending on the acceptability (medically, ethically) of the deferment, be defined, discussed and evaluated in advance in a spirit of total transparency? On this specific issue, as on other crucial points, the State is responsible for defining the major guidelines of the public health policies to be implemented at all levels and for making available the resources to do so.

The second issue, that of the selection of patients in intensive care units, raises problems which are close to the ones we have just mentioned, but they are amplified by the gravity of the medical consequences.

Every admission to an intensive care unit is in fact the ultimate step in a process of selective decision, which may go to the lengths of removing one patient to make room for another. For doctors in the resuscitation unit, this is an extremely difficult, but routine, decision they have to take. A number of criteria enter into the decision: objective clinical criteria, some of which may even be quantified (various severity indices have been defined for use in resuscitation), subjective criteria and values which, in an emergency, cannot be totally explicit nor entirely egalitarian.

In theory, quantified predictive criteria are designed to characterise groups of patients, not to predict the future of any individual patient. However, in particular for vascular risks, these indices are frequently used by clinicians for decisions concerning individuals. In an influenza pandemic situation, for 'comparable' patients to benefit from 'comparable" care, is it ethically acceptable to consider a selection which would be partly based on severity indicators defining a sick person by age and on a set of biological and clinical signs? If so, can we go as far as to recommend the use of such an index in the decision-making process, in the name of the principle of equal access to care? Since many such triage decisions could take place in call reception centres directing patients brought in by emergency services, should they be supplied with the tools which could contribute to giving every patient the same chance of receiving the best care?

Conditions of extreme tension and fatigue brought on by an influenza pandemic can affect clinicians' capacity for analysis and, above all, the time they can afford to spend on it. In such a context, anything which could contribute to improving the quality of medical decisions should be made available to health carers, it being clear that they would be entirely free to use, or not to use, such tools.

Other pathologies and routine healthcare needs will not be made to disappear by the onset of the pandemic. The sick and those suffering from traumatic injury requiring immediate help must be given the care they need. Should then a part of our public health system be dedicated to other pathologies besides the pandemic flu? A decision of this kind by the authorities to try and prevent avoidable fatalities, which would be added to the deaths caused by the pandemic, would seem sensible. But such a decision — with as a result, refusing ICU admission to a patient who could benefit today to preserve the chances of survival of a hypothetical patient tomorrow — seems hardly acceptable.

Places where people gather, among which hospitals would be prominent, are certainly more vulnerable than most. How will hospitals admitting infected patients manage to avoid becoming a focus of disease propagation? The same question arises in retirement homes, nursing homes for the handicapped, etc. Will an infected person be isolated or confined together with other infected patients? Sidestepping such questions can pave the way for social utilitarianism with unacceptable ethical consequences.

V. RESEARCH NEEDS

Underlining the need for research programmes is not an ethics-related recommendation, but it does have major implications for the respect of ethical principles in the management of an epidemic. Due to the extension of the avian flu epizootic, research programmes, focusing particularly on the environment and animal influenza, have been funded. The origin of the next influenza pandemic may, however, not be the one on which current efforts are concentrating. Furthermore, fundamental research should feature prominently in these programmes.

On a number of points raised in this Opinion, it would seem there is a lack of information and the need for research is considerable. Perhaps the most urgent requirement is for research on management. The type of information produced by such research is also important for ethical reflection, as we pointed out in respect to hospitalisation deferrals.

Measures included in contingency plans have not been sufficiently evaluated. This is the case, for example, for the effectiveness of wearing masks, which could do with improved

evaluation in real-life conditions. If wearing masks is to be recommended, everyone must be accurately informed of the degree of protection it provides.

There is also a need for clinical research, in particular to design pertinent decision-making tools. Uncertainty as to the date of onset of the pandemic may mean that the results of today's research are out of date when the first cases are diagnosed. But one of the research objectives could be to design and make available systems for updating results at any time without delay. The epidemiological and clinical characteristics of the disease and the actual efficacy of treatment will only be available for study when the epidemic is with us. Information provided by the very first cases will be essential to improve the quality of care and optimise counter strategies. In order to launch research instantly when the time comes, protocols must be ready and already approved by regulatory authorities so as to avoid a conflict of ethics between protocols designed to protect individuals and the urgency of implementing measures to fight the pandemic. On this point, a useful example could be the steps taken by the European Medicines Agency for the establishment of pre-registration procedures to accelerate marketing authorisation for pandemic vaccines.

While an extreme emergency may justify some degree of relaxation in the enforcement of principles and regulations, its nature and extent as regards research and other matters must be clearly defined beforehand. All crisis situations can give rise, in the name of the principle of beneficence, to misuse. This must be anticipated.

VI. CONCLUSION AND RECOMMENDATIONS

The situation, however critical, cannot be allowed to alter ethical values. In a time of emergency, they must just be ranked, temporarily.

The proportions and the speed of extension of a possible pandemic influenza requires management plans to be defined before the onset of the early cases, despite the current gaps in our knowledge of how the pandemic will develop.

A crisis management plan, to be fully effective, must be accepted jointly by the population as a whole. Everyone must be aware of the part they must play in the implementation of the plan in their own family and social environment.

For this reason, information to the public on the pandemic should be given and repeated at regular intervals, so that when the pandemic is announced there are no panic-stricken reactions which could, apart from other possible consequences, aggravate several ethical problems and be all the more damaging for being, at least partially, avoidable. Messages from the authorities must help to dispel the apprehension that stigmatising behaviour can generate. Media commitment to fighting the pandemic will be of supreme importance.

Should there be, following flawed information or individualistic behaviour, a conflict between autonomy and solidarity, priority must be given to the value of solidarity. The right to refuse treatment must be qualified by the overriding duty to avoid contaminating others. As autonomy and solidarity are complementary on the whole, rather than incompatible, it would probably be constructive to show that solidarity effectively protects everyone.

In step with other countries in the northern hemisphere, France has responded to the appeal launched by the World Health Organization and is committed to helping countries in the south fight the pandemic. Such a commitment implies that the utmost care must be taken in preparations for making available stocks of medicines to underprivileged populations at very short notice. To be worthy of our duty of justice and assistance to the poorest countries when the pandemic strikes, we must work on our preparedness well in advance.

On a national level, pandemic influenza would create a situation in which care for people who are isolated, excluded or living in highly precarious circumstances and those who are particularly vulnerable to complications because of crowded living conditions and poor hygiene (in particular, prison inmates) would be all the more defective because those who would normally provide that care would also be affected by the disease. Outstanding efforts at communication will be needed to ensure that such people get equitable access to care and this cannot be improvised.

Every effort must be made to prevent the population from behaving unethically as a result of the pandemic. However, the precaution principle, the need to reassure or, *a fortiori,* wanting to show in a favourable light how committed the authorities are to fighting the epidemic, can in no way justify measures restricting fundamental liberties (travel, assembly), or those reinforcing discrimination, unless they have been the subject of prior consultation and consensus based on the argument of their efficacy.

Ranking access to prophylactic or preventive care is a major issue. The example derived from the equitable management of vital resources in the context of organ transplant reveals that there is always tension between the twin objectives of efficacy and equality. In choosing between two arbitrary solutions — the limited arbitrariness of pre-defined criteria, or the absolute arbitrary nature of an absence of criteria — where choices would be imposed rather than accepted, criteria which set a standard have the advantage of reassuring citizens regarding the existence of rules applicable to all and compliance with ethical principles (neither money nor "queue jumping"). The probable shortage, at least in the short term, of several means of prevention will oblige the authorities to adopt strategies based on multiple ethical criteria: equality, protection for the most vulnerable, efficacy, individual liberties, equity and solidarity. The difficulty of weighing all these factors is compounded by our ignorance of the major decision parameters. However difficult this may be currently, it has to be done.

That certain people who must keep the country's essential activities running (foremost among them health carers, but also in other sectors: transport, security, the production of energy, etc.) should be protected as a priority is only legitimate. Responsible and concerted thought must be given within each professional group benefiting from such priority, so that a collective decision can be taken as to how many and which individuals should be protected.

Priority is in no way an individual value judgment. This is not, and cannot be, a hierarchy of dignity, since dignity is consubstantial with the human being. Nor is it a ranking based on any criterion of social utility, a concept which it is impossible to determine with any degree of accuracy. The only aim is to reconcile ethical demands with the strategic purpose of halting the progress of the epidemic for the common good.

In conclusion of this analysis of ethical issues in connection with pandemic influenza, which could apply to any other epidemic with the same characteristics, CCNE wishes to formulate the following recommendations:

1. However unpredictable may be time of onset of a future influenza pandemic and, by reason of this very uncertainty, there is an urgent need to inform the public more fully:
    a. Of the possible nature and consequences of influenza caused by a new virus. One of the essential objectives of the authorities, with the support of the major communication networks, must be to reassure, prepare and avoid as much as possible panic-induced reactions and their violent corollaries. Pragmatic and strategic efforts to contain the pandemic's extension at the earliest stage are not incompatible with ethical demands. On the contrary, the population's awareness of the ethical rules which will apply in the event of a pandemic crisis, determines the effectiveness of the measures taken to counter viral propagation.
    b. Of the contents of the French crisis management plan, so that everybody is aware of the part they must play in the implementation of the plan, in their own family and social context.
    c. Of the need to define priorities for access to immunisation or to any other form of prevention, the criteria underlying these priorities and the rules of ethics that were taken into consideration for their establishment.

    To be effective, this information must be communicated via different channels and in various forms, and must also be repeated on occasions, along the same lines as were followed by the authorities for other major public health information campaigns, such as the recommendations to moderate the prescription of antibiotic medicines.

2. Since the pandemic may spread extremely swiftly, procedures for the implementation of countermeasures must be very precisely defined as soon as possible. This recommendation concerns both the availability of antiviral medicines for countries unable to build up stocks of their own, and measures which apply nationally. In order to respect the principles of autonomy, transparency and efficacy, all those concerned by such measures must be informed of their rights and duties.

3. The chronic difficulties affecting certain component parts of our public health system (emergency services in particular) militate in favour of ad hoc studies for an in-depth evaluation of the impact of an influenza pandemic on the public hospital system. Priority areas of research could be organisation and management, medical decision-making assistance tools in a pandemic, with some degree of uncertainty, as well as research to evaluate the efficacy of non medical measures of fighting the pandemic.

4. Finally, a state of medical emergency cannot justify, except in circumstances of exceptional gravity, sacrificing respect for people's personal privacy and the confidentiality of their health-related data.

Paris, February 5, 2009