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PANDEM

Pandemic Risk and Emergency Management

D4.2 Review and analysis of ethical and human rights issues

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1 Objective

The purpose of this report is to review and analyse ethical and human rights issues in relation to pandemic preparedness in Europe. The report will present the current status and then identify gaps and priority challenges for the European Union.

This will be achieved by

- an introduction and overview of the role and importance of ethical and human rights considerations in pandemic preparedness planning
- a review of ethical and human rights frameworks
- a literature review to identify current priorities and concerns
- a discussion of a recent relevant research project
- identifying disconnects between ethical and human rights concerns and the reality of current governance and policy
- recommending priority challenges for future action.

2 Introduction

2.1 Definitions

“Ethics”:

Moral principles that govern a person’s behaviour or the conducting of an activity;

The branch of knowledge that deals with moral principles: (OED: Oxford English Dictionary).

“Human Rights”:

A right which is believed to belong to every person (OED);

Rights and freedoms to which every human being is entitled. Protection against breaches of these rights committed by a state (including the state of which the victim is a national) may in some cases be enforced in international law (ODL: Oxford Dictionary of Law).

“Ethics” refers to moral behaviour or principles. “Human rights” has a general meaning as defined in the Oxford English Dictionary. The second definition, from the Oxford Dictionary of Law refers to “rights” in legal terms, a definition which also implies obligations and enforceability.

There is considerable overlap between ethics, human rights and law. Modern concepts of “human rights” are based on moral principles. This was recognised by WHO: “All ethical deliberations must take place within the context of the principles of human rights, and all policies must be consistent with applicable human rights laws”[1].

In relation to public health, ethics have been captured as statements of principle or “Ethical Frameworks” whereas human rights principles have been incorporated in legislation or policy documents, both national and international, binding and non-binding.

2.2 Importance of ethics and human rights in pandemic preparedness and response

As the large body of literature attests, for many years public health ethicists worldwide have emphasised the importance of incorporating ethical principles into pandemic planning. Both pandemic preparedness and response require difficult decisions to be made, often very quickly. Poor decisions may have very damaging consequences on many levels, not only as health outcomes, but also in terms of public trust and support. These consequences may be long term and difficult to reverse.

Thompson et al: “Ethics... can make a significant contribution to debates such as what levels of harm the public are prepared to accept, how the burdens of negative outcomes should be distributed across the population and whether or not more resources should be invested in stockpiling antiviral medications” [2].

Bhatia: “It is rightly said that a good and fair decision is one which is based not only on sound scientific reasoning, but also on the moral values and principles of society. If we fail to incorporate ethical guidelines into our planning process or respond purely scientifically to every issue, we may land up being unfair and appear untrustworthy to the public” [3].

Thomas: “Unfortunately, progress in ethics is often spurred by the shame resulting from gross unethical mishaps. Such was the case with the Universal Declaration of Human Rights following the Holocaust and research ethics precautions following the Tuskegee Syphilis Study. In a pandemic of highly pathogenic influenza, there will be little time to sort out complicated issues such as the particular values or needs of minority populations. Some states may be destined to develop their ethics capacities only after unethical damage has been done” [4].

Ethicists have identified some of the following reasons why ethics and human rights are important in pandemic preparedness and response:

- Pandemic management is not purely scientific as it involves decisions which should reflect the moral values of the society;
- Human rights need to be respected not just on moral grounds but also to comply with national and international obligations;
- A pandemic response will often involve decisions which reduce individual rights for the common good. This may be justifiable but only if decisions are based on transparent principles which are clearly non-discriminatory and protect the vulnerable;
- Effective pandemic management requires public trust and support. Ethical principles such as openness and collaboration are necessary to achieve this trust and support, as well as to reduce the likelihood of panic;
- Resources may be scarce and rationing may be necessary, and this will draw upon implicit or explicit ethical principles.

There is much less literature specifically linking human rights with pandemic management as discussed below.

2.3 Ethics and human rights in current pandemic planning

Policy makers, public health specialists and ethicists have produced statements of principles intended to be used as ethical frameworks for pandemic planning. Despite this, as explained in the discussion on national plans later in this report, pandemic management has been treated overwhelmingly as a scientific issue. Ethics and human rights considerations have tended to be included as an afterthought, if at all.

This lack of recognition is apparent both at international and national level. The WHO 2005 checklist for influenza pandemic preparedness planning [5], for example, only includes “Ethical issues” as “Desirable” rather than “Essential” elements and these are only discussed briefly at one paragraph (see below). By 2007 the WHO had prepared more detailed guidance: “Ethical considerations in developing a public health response to pandemic influenza” [1] although it is unclear whether this is being used by Member States for guidance.

In 2005 the EU released its guidance on pandemic planning: “COM (2005) 607: on Pandemic Influenza Preparedness and Response Planning in the European Community”[6]. Nowhere

does this document make any reference to ethical or human rights considerations. The ECDC website dedicates a single page to “Ethical issues” [7]. This page refers to a WHO-EURO meeting in 2007 and includes links to three documents on ethical planning for a pandemic. None of these links were functioning as of 24 May 2016 and no specific European guidance on ethical issues was identified.

Human rights have received even less attention as a specific concept in pandemic preparedness. Where the response to HIV/AIDS was presented, and ultimately recognised, as a rights issue by civil society groups and public health leaders such as Jonathan Mann, the same has not happened with pandemic influenza response. There are many reasons for this, including perhaps that few people have personal experience of restricted individual rights during a severe pandemic. A systematic literature review for “pandemic human rights” (all key words in title), discussed below, produced 24 documents, 22 of which concerned the HIV/AIDS pandemic, leaving only two which related to human rights in a pandemic influenza outbreak [8, 9].

While both HIV/AIDS and influenza outbreaks are (or may become) pandemics involving large loss of life, they require very different public health responses with different ethical and human rights considerations. Unlike HIV/AIDS, a pandemic influenza outbreak is likely to be short-lived and transmission less associated with challenges to conservative moral norms, whilst possibly disrupting normal societal and institutional functioning potentially profoundly [8]. Access to healthcare is more likely to be affected by scarcity of resources rather than stigma or cost (although these may also be factors in some countries).

While we are not suggesting that pandemic influenza management should be a rights issue comparable to HIV/AIDS, it does fundamentally concern human rights, not only as an ethical concept, but also in terms of legal protections. From the evidence of this limited review, “pandemic human rights” beyond HIV/AIDS has received minimal attention from governments or academics. Fully understanding the reason for this will require further research.

3 Review of ethical and human rights considerations and challenges to pandemic planning and response

3.1 Ethical frameworks

As mentioned above, the WHO 2005 checklist for pandemic influenza preparedness planning [5] recommends the inclusion of ethical considerations as “Desirable”. These are discussed at paragraph 1.5.2 of the checklist:

“1.5.2 Ethical Issues

Rationale

Ethical issues are closely related to legal issues as mentioned above. They are part of the normative framework that is needed to assess the cultural acceptability of measures such as quarantine or selective vaccination of predefined risk groups.

Questions to be addressed

Have ethical aspects of policy decisions been considered? Is there a leading ethical framework that can be used during the response to an outbreak to balance individual and population rights?

Check

- Consider ethical questions related to limiting the availability of a scarce resource, such as rationed diagnostic laboratory testing, pandemic strain influenza vaccine or antiviral drugs.
- Consider ethical questions related to compulsory vaccination for healthcare workers and workers from essential services.
- Consider the ethical issues related to limiting personal freedom, such as may occur with isolation and quarantine.
- Ensure the establishment of an ethical framework for research, especially when this involves human subjects.”

WHO recommended that planning should follow “a leading ethical framework” and by 2007 it had drafted its own guidance for Member States: “Ethical considerations in developing a public health response to pandemic influenza” [1]. Governments and academics have also produced lists of ethical principles, variously described as guidance, statements of principles and ethical frameworks. They are intended to guide pandemic

planning, whether at government or local level. A selection of these ethical frameworks is set out below with an outline of their key features.

METHODOLOGY

Ethical frameworks were identified from purposive search, cross referencing and from the “pandemic ethic*” literature search discussed later at 3.3. The frameworks discussed below include both major, influential documents and more local recommendations. This is not an exhaustive list and further frameworks are likely to exist which were not identified during this review. However, they indicate perceived ethical priorities in pandemic preparedness and response. As mentioned above no ethical framework or guidance was found specifically directed at EU Member States as a regional group.

ETHICAL FRAMEWORKS: INTERNATIONAL

SIRACUSA PRINCIPLES: American Association for the International Commission of Jurists, 1985 [10]

The Siracusa Principles is an important instrument by which to measure valid limitations on human rights [11]. It was drafted by a commission of international lawyers in recognition that “one of the main instruments employed by governments to repress and deny the fundamental rights and freedoms of peoples has been the illegal and unwarranted Declaration of Martial Law or a State of Emergency. Very often these measures are taken under the pretext of the existence of a ‘public health emergency which threatens the life of the nation’ or ‘threats to its national security’.”

The International Covenant on Civil and Political Rights allows governments to limit or derogate individual rights in certain circumstances. The Siracusa Principles were designed to clarify the grounds when limitation or derogation might be justified. They are not specific to pandemic influenza or indeed public health emergencies, but rather apply to any declared state of national public emergency. Key features are:

Limitations must be (1) prescribed by law, (2) based on a legitimate objective, (3) strictly necessary in a democratic society, (4) the least restrictive and intrusive means available, and (5) based on scientific evidence and not arbitrary, unreasonable or discriminatory [11].

II. Derogations in a Public Emergency

A. “Public Emergency which Threatens the Life of the Nation

...A threat to the life of the nation is one that:

- a) affects the whole of the population and either the whole or part of the territory of the state; and
- b) threatens the physical integrity of the population, the political independence or the territorial integrity of the state or the existence or basic functioning of institutions indispensable to ensure and protect the rights recognized in the Covenant.”

C. “Strictly Required by the Exigencies of the Situation”

This sets out principles to ensure that limitation or derogation is only where strictly necessary, e.g. “54. Each measure shall be directed to an actual, clear, present, or imminent danger and may not be imposed merely because of an apprehension of potential danger.”

D. Non-Derogable Rights

This sets out rights which are “not derogable under any conditions even for the asserted purpose of preserving the life of the nation.” These include the Covenant’s guarantees of the right to life; freedom from torture, cruel, inhuman or degrading treatment or punishment, and from medical or scientific experimentation without free consent.

It is of note that the Siracusa Principles incorporate intended protections and remedies for individuals:

“55. The national constitution and laws governing states of emergency shall provide for prompt and periodic independent review by the legislature of the necessity for derogation measures.

56. Effective remedies shall be available to persons claiming that derogation measures affecting them are not strictly required by the exigencies of the situation.

57. In determining whether derogation measures are strictly required by the exigencies of the situation the judgment of the national authorities cannot be accepted as conclusive.”

However, it is unclear how such measures could be enforced in practice.

WHO: ETHICAL CONSIDERATIONS IN DEVELOPING A PUBLIC HEALTH RESPONSE TO PANDEMIC INFLUENZA: WHO, 2007 [1]

The WHO Ethical guidance was prepared by the WHO Department of Ethics, Trade, Human Rights and Health Law following a consultative process including workshops and discussion forums with international experts during 2006. Its purpose is “to assist social and political leaders at all levels who influence policy decisions about the incorporation of ethical considerations into national influenza pandemic preparedness plans.”

1. Introduction
2. General ethical considerations
 - Balancing rights, interests and values
 - The evidence base for public health measures
 - Transparency, public engagement and social mobilization
 - Information, education and communication
 - Resource constraints
3. Priority setting and equitable access to therapeutic and prophylactic measures
 - General considerations
 - Criteria for use in prioritization
 - Additional considerations related to priority in access to vaccines
 - Medical and nursing care
4. Isolation, quarantine, border control and social-distancing measures
 - Core governmental responsibilities
 - Considerations related to specific public health strategies
5. The role and obligations of health-care workers during an outbreak of pandemic influenza
 - Establishing the nature and scope of health-care workers’ obligations
 - Reciprocal obligations of governments and employers
 - Promoting compliance with health-care workers’ obligations
6. Developing a multilateral response to an outbreak of pandemic influenza
 - The importance of international cooperation
 - Sharing specimens and promoting equitable access to pharmaceutical interventions
 - Assistance to countries in need
 - Issues for countries receiving assistance
 - Attention to the need of all populations, regardless of their legal status in a country

Communication problems

ETHICAL FRAMEWORKS: NATIONAL

A number of national ethical frameworks or guidance for pandemic planning are understood to exist, for example for the Republic of Ireland and Sweden. However, this review was restricted to frameworks which were publicly available in English and could be easily found by online search.

FRANCE: OPINION NO. 106. ETHICAL ISSUES RAISED BY A POSSIBLE INFLUENZA PANDEMIC: NATIONAL CONSULTATIVE ETHICS COMMITTEE FOR HEALTH AND LIFE SCIENCES (CNNE), 2007 [12]

This document was prepared at the request of the French Defence Ministry and the Interministerial Delegation on Avian Influenza who were working jointly on the French national pandemic preparedness plan and who had “underlined the importance of basing the plan on common ethical values.” According to the ECDC website, two versions of this framework have been produced, but only the first, described here, has been translated into English. The French national pandemic preparedness plan briefly refers to this document at page 17: “For the ethical dimension (ref. Official Notification No. 106 of the National Ethics Consultative Committee)”. Key content:

- “III General ethical issues exacerbated by a pandemic situation
 - III.1 The principle of justice
 - A Solidarity of rich countries with the poorest countries
 - B Solidarity in the face of social inequality
 - III.2 The danger of stigmatisation
 - III.3 Rights and liberties put to the test of the pandemic
 - III.4 Solidarity and autonomy
 - III.5 Ethical issues related to economic considerations
- IV Ethical issues more specific to the influenza pandemic
 - IV.1 Priorities in the allocation of some means of fighting the pandemic
 - A Objectives arriving at conflicting priorities
 - B The system for the allocation of organ grafts as an aid to reflection on prioritisation
 - IV.2 The rights and duties of professional categories with priority
 - IV.3 Ethical issues connected to the impact of the influenza pandemic on the functioning of hospitals”

This document notes that there is a “considerable” need for research, particularly into management, to evaluate measures included in contingency plans, and clinical research “to design pertinent decision-making tools.”

UK: RESPONDING TO PANDEMIC INFLUENZA. THE ETHICAL FRAMEWORK FOR POLICY AND PLANNING: UK DEPARTMENT OF HEALTH, 2007 [13]

This Ethical framework is referenced in the UK national pandemic preparedness plan and it is described as “for use by planners and strategic policy makers at national, regional and local level, both before and during a pandemic. It is also designed to assist clinicians and others (who will also be guided by their own professional codes) in developing policies on clinical issues for use during a pandemic”. Key content:

The individual principles

1. Respect
2. Minimising the harm that a pandemic could cause
3. Fairness
4. Working together
5. Reciprocity, e.g. “if people are asked to take increased risks, or face increased burdens, during a pandemic, they should be supported in doing so, and the risks and burdens should be minimised as far as possible”.
6. Keeping things in proportion
7. Flexibility, e.g. “plans will be adapted to take into account new information and changing circumstances”.
8. Good decision-making
 - i. Openness and transparency
 - ii. Inclusiveness
 - iii. Accountability
 - iv. Reasonableness

The document states that “Equal concern and respect is the fundamental principle that underpins this ethical framework.”

The UK ethical framework includes admirable moral principles with which few people could disagree. However, no concrete examples are given for the applicability of these

principles in a pandemic and the context is both broad and vague. In a devolved health system this might result in a lack of coherent and complementary decision making across health system areas.

US: ETHICAL GUIDELINES IN PANDEMIC INFLUENZA: RECOMMENDATIONS OF THE ETHICS SUBCOMMITTEE OF THE ADVISORY COMMITTEE TO THE DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, 2007 [14]

This document was prepared by Kathy Kinlaw and Robert Levine of the Ethics Subcommittee of the Advisory Committee as an advisory document for the CDC. Key content:

I General Ethical Considerations

- Identification of clear overall goals for pandemic planning;
- A commitment to transparency throughout the pandemic influenza planning and response process;
- Public engagement and involvement are essential to build public will and trust and should be evidenced throughout the planning and response process;
- Public health officials have a responsibility to maximize preparedness in order to minimize the need to make allocation decisions later;
- Sound guidelines should be based on the best available scientific evidence;
- The importance of working with and learning from preparedness efforts globally
- Balancing of Individual Liberty and Community Interests
- Diversity in Ethical Decision Making
- Fair Process Approach (Procedural Justice)

II Addressing Particular Ethical Issues in Pandemic Influenza Planning

A Allocation of Resources

B Ethical Guidelines Regarding Social Distancing and Restrictions on Personal Freedom for Managing Pandemic Influenza

- Is Restricting Personal Freedom in Managing Pandemic Influenza Justified?
- Procedural Conditions in Restricting Personal Freedom
- When are restrictions on personal freedom ethically justified?

This US document is more detailed than any of the previously discussed guidelines, referring to specific examples of scenarios which may arise during an outbreak of pandemic influenza. Nevertheless, the guidelines state that they “are not narrowly

prescriptive, but recognize the need of decision makers in particular communities or regions to transform this guidance into specific decisions.”

US STATE

MCGORTY EK ET AL: STOCKPILING SOLUTIONS: NORTH CAROLINA’S ETHICAL GUIDELINES FOR AN INFLUENZA PANDEMIC, 2007 [15]

This is an example of an ethical framework prepared for specific use at US state level. It was drafted by a Task Force convened by the North Carolina Institute of Medicine and is a comprehensive, 100 page document. The Task Force identified key ethical principles which should guide the state’s response to an influenza pandemic. These include the need to ensure accountability, equitable treatment among similarly situated individuals, proportionality of action, and inclusiveness and timeliness in decision making. “Government must act as the public steward, operate in a transparent fashion, and make decisions that are reasonable and responsive in order to garner the public’s trust. Public trust and cooperation is essential to controlling the spread of disease and maintaining social order.” Specific issues for ethical consideration:

- Responsibilities of and to Health care Workers and Other Critical Workers
- Balancing the Rights of the Individual and the Need to Protect the Public
- Prioritization and Utilization of Limited Resources

ETHICAL FRAMEWORKS: ACADEMIC

Numerous academics have produced ethical guidelines for responses to public health emergencies, including pandemic influenza outbreak. A few examples:

KASS, NE: AN ETHICS FRAMEWORK FOR PUBLIC HEALTH AND AVIAN INFLUENZA PANDEMIC PREPAREDNESS, YALE JOURNAL OF BIOLOGY AND MEDICINE 2005 [16]

This paper proposes a six-step analytical framework “to help public health professionals consider the ethics implications of proposed programs, interventions, research initiatives and policy proposals.” This is then applied to the specific context of a pandemic influenza outbreak. Key content:

Part 1: An Ethics Framework for Public Health

1. What are the public health goals of the proposed intervention, policy, or program?
2. How effective is the intervention, policy, or program in achieving its stated goals?

3. What are the known or potential burdens of the program?
4. How can burdens be minimized? Are there alternative approaches to achieve the same goals?
5. Is the program implemented fairly?
6. How can the public health benefits and the accompanying burdens be balanced? What procedures will best allow for the fair consideration of differing views?

Part 2: Framework applied to avian influenza pandemic preparedness programs

Step 1. What are the goals of the public health program or intervention?

Step 2. What are proposed interventions? How effective are they at achieving stated goals?

Step 3. What are the known or potential burdens of the program?

Step 4. Minimizing burdens and identifying the least restrictive approach.

Step 5. Is the program implemented fairly? Is there justice in the distribution of the plan's burdens and benefits?

Step 6. Fair procedures for creating a preparedness plan and for implementation of a response.

This is an interesting framework in terms of articulating the questions that policy makers need to ask when drafting a pandemic preparedness plan. It is unclear to what extent this framework has been used in practice, but it appears to have been influential for subsequent academics (526 citations according to Google Scholar).

THOMPSON, AK ET AL: PANDEMIC INFLUENZA PREPAREDNESS: AN ETHICAL FRAMEWORK TO GUIDE DECISION MAKING; BMC MEDICAL ETHICS 2006 [2]

This Canadian framework sets out a list of "Ethical values to guide decision-making", with detailed descriptions and examples for each value. The framework drew upon recent experience of SARS in Toronto. The Ethical values are:

- Duty to Provide Care
- Equity
- Individual Liberty
- Privacy
- Proportionality
- Protection of the Public From Harm
- Reciprocity
- Solidarity
- Stewardship

- Trust

While there are recurrent themes, the amount of context and detail in these examples of ethical frameworks varies considerably, with some being essentially lists of moral principles, while others apply principles to specific pandemic scenarios.

3.2 Human rights frameworks

GLOBAL

UNIVERSAL DECLARATION OF HUMAN RIGHTS (UDHR) 1948

In the aftermath of the Second World War, the Universal Declaration of Human Rights was proclaimed by the United Nations General Assembly in 1948. While not itself a formal treaty, it is the foundation of human rights law, setting out for the first time fundamental human rights to be universally protected. “International lawyers widely regard its key provisions as binding - either because the UDHR gives effect to rights guaranteed in the [UN] charter or because it has gained the status of customary international law”[11].

Relevant Articles

Article 3	Right to life, liberty and security of person
Article 7	Right to be treated without discrimination
Article 12	No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence
Article 13	Right to freedom of movement
Article 20	Right to freedom of peaceful assembly and association
Article 25	Right to medical care

INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS (ICESCR)

Ratified 1966/Entry into force 1976

Relevant Covenant Articles

- | | |
|------------|-----------------|
| Article 12 | Right to health |
|------------|-----------------|
1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
 - c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

- d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

INTERNATIONAL COVENANT ON CIVIL AND POLITICAL RIGHTS (ICCPR) 1966/1976

Relevant Covenant Articles

Article 6 Right to life

Article 9 Right to liberty and security of person

Article 10 All persons deprived of their liberty shall be treated with humanity and with respect for the inherent dignity of the human person

Article 12 Everyone lawfully within the territory of a State shall, within that territory, have the right to liberty of movement and freedom to choose his residence

Article 17 No one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence

Article 21 Right of peaceful assembly

Article 22 Right of freedom of association

Article 26 All persons are equal before the law and are entitled without any discrimination to the equal protection of the law

This Covenant should be read together with the Siracusa Principles, discussed above, which clarify the circumstances when derogation and limitation of rights under the Covenant may be justified. All of the rights set out above - apart from the right to life - are derogable in situations of serious emergency.

Although both the ICESR and the ICCPR are intended to be binding, they have weak accountability mechanisms. Their committees can only make recommendations and states are urged to comply, but this cannot be enforced.

CONVENTION ON THE RIGHTS OF THE CHILD (CRC) 1989/1990

Relevant Convention Article

1. States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.

General Comment 15 (Added 2013) Elaborates on the right to health, including the best interests of the child and universal access to quality health services.

As with other human rights conventions it is intended to be legally binding but enforcement would be difficult. The CRC has not been ratified by the United States.

INTERNATIONAL HEALTH REGULATIONS (2005)

The revised version of the IHR, discussed in more detail in D4.1, for the first time included explicit reference to fundamental rights and principles throughout the text.

Article 3 Implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of all persons

Article 23 Informed consent for measures such as medical examination or isolation, except where there is evidence of an “imminent public health risk” (Art.31).

Article 32 States Parties shall treat travellers with respect for their dignity, human rights and fundamental freedoms, and minimise any discomfort or distress associated with such measures

Article 45 Confidentiality and lawful use of personal data collected under the IHR

UNIVERSAL DECLARATION ON BIOTHEMATICS AND HUMAN RIGHTS 2006

This declaration aims to provide a comprehensive framework of principles that should guide biomedical activities, in order to ensure that they are in conformity with international human rights law.

CONVENTION ON THE RIGHTS OF PERSONS WITH DISABILITIES 2007/2008

Article 11 States Parties shall take, in accordance with their obligations under international law, including international humanitarian law and international human rights law, all necessary measures to ensure the protection and safety of persons with disabilities in situations of armed conflict, humanitarian emergencies and the occurrence of natural disaster

Article 25 Persons with disabilities have the right to the highest attainable standard of health without discrimination on the basis of disability

EUROPEAN

EUROPEAN CONVENTION ON HUMAN RIGHTS (ECHR) 1950/1953

The key human rights statute at European level is the European Convention on Human Rights (ECHR). This was drafted in 1950 by the then newly formed Council of Europe and

entered into force on 3 September 1953. All Council of Europe Member States are party to the Convention and new members are expected to ratify the convention at the earliest opportunity (Resolution 1031 ((1994)) on the honouring of commitments entered into by Member States when joining the Council of Europe.

The purpose of the ECHR is to protect human rights and fundamental freedoms in Europe. These are enforced by the European Court of Human Rights.

“Unqualified” rights can never be restricted and are not to be balanced with any public interest arguments.

“Derogable” but “unqualified” rights: the State can derogate from these rights in time of public emergency; otherwise they are unqualified.

“Qualified” rights. These rights are subject to restriction clauses indicating public interest matters to be taken into account.

European Court of Human Rights

The Convention also established the European Court of Human Rights, which is based in Strasbourg. Any individual, group of individuals or state which believes that its rights have been violated under the Convention by a state party can take a case to the Court. The Court can give a judgement or an advisory opinion.

The *European Court of Human Rights* is a different entity to the *European Court of Justice* (ECJ), established in 1952 and based in Luxembourg, which is the highest court in the European Union in matters of European Union law. The ECJ is responsible for with interpreting EU law and ensuring its equal application across all EU Member States.

Relevant Convention Articles

Article 1	The Obligation to Respect Human Rights
Article 2	Right to Life - absolute “unqualified” right
Article 5	Right to Liberty and Security - derogable but “unqualified”
Article 8	Right to Respect for Family and Private Life - qualified right
Article 11	Freedom of Assembly and Association - qualified right

WORLD MEDICAL ASSOCIATION (WMA) DECLARATION OF LISBON ON THE RIGHTS OF THE PATIENT 1981

A declaration rather than a legal instrument but according to the preamble: “The following Declaration represents some of the principal rights of the patient that the medical profession endorses and promotes. Physicians and other persons or bodies involved in the provision of health care have a joint responsibility to recognize and uphold these rights. Whenever legislation, government action or any other administration or institution denies patients these rights, physicians should pursue appropriate means to assure or restore them.”

Relevant Principles

1. Right to medical care of good quality
2. Right to freedom of choice
3. Right to self-determination
4. The unconscious patient
5. The legally incompetent patient
6. Procedures against the patient’s will
7. Right to information
8. Right to confidentiality
9. Right to Health Education
10. Right to dignity
11. Right to religious assistance

CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE, COUNCIL OF EUROPE 1997

This convention aims “to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being” and in recognition that “the misuse of biology and medicine may lead to acts endangering human dignity.” Its relevance to pandemic management includes in research ethics, equity in allocation of healthcare and right to privacy.

Relevant Convention Articles

- | | |
|-----------|---------------------------------|
| Article 2 | Primacy of the human being |
| Article 3 | Equitable access to health care |
| Article 4 | Professional standards |

Article 5	General rule on consent to treatment
Article 6	Protection of persons not able to consent
Article 7	Protection of persons who have a mental disorder
Article 8	Emergency situation
Article 10	Private life and right to information
Article 23	Infringement of the rights or principles
Article 24	Compensation for undue damage
Article 25	Sanctions
Article 26	Restrictions on the exercise of the rights

In the situation of a public health emergency, Article 26 may give the right to restrict the rights granted in all the previous Articles listed above:

“No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.”

CHARTER OF FUNDAMENTAL RIGHTS OF THE EUROPEAN UNION (CFREU) 2000/2009

The Charter of Fundamental Rights of the European Union (CFREU) is the primary legal instrument in Europe which recognises the various personal, civil, political, economic and social rights of EU citizens. Although it was proclaimed in 2000 by the European Parliament, the Council of Ministers and the European Commission, it did not enter into force until the Treaty of Lisbon in 2009 which made it legally binding. The Charter requires the European Union to act and legislate consistently with its Articles. The Charter empowers the EU’s courts to strike down legislation adopted by the EU’s institutions that contravenes it. The Charter applies to the Institutions of the European Union and its Member States when implementing European Union law.

Relevant Charter Articles

Article 1	Human dignity
Article 2	Right to life
Article 3	Right to the integrity of the person
Article 6	Right to liberty and security
Article 7	Respect for private and family life
Article 8	Protection of personal data
Article 11	Freedom of expression and information

Article 21 Non-discrimination

Article 35 Health care

Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.

Article 45 Freedom of movement and of residence

Article 52 Scope and interpretation of rights and principles

1. Any limitation on the exercise of the rights and freedoms recognised by this Charter must be provided for by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others.

NATIONAL

There is an obligation on signatories to the ECHR to incorporate the rights set out in the convention in domestic law. It is beyond the scope of this report to review the national human rights legislation of all 28 EU Member States, but an example is the UK Human Rights Act 1998. The Act makes it unlawful for any public body to act in a way which is incompatible with the Convention, unless the wording of any other Act of Parliament provides no other choice. In this way, national sovereignty is maintained. It also makes it possible to sue for breach of the Convention in UK courts, although individuals still have the option to sue in the European Court of Human Rights in Strasbourg if they so wish.

3.3 Literature review

METHODOLOGY

Feasibility associated with limitations of time and project resources meant we needed to take a pragmatic approach to exploring and synthesising the vast body of literature on pandemic ethics and human rights. As noted earlier in report D4.1, simple key word searches on Google Scholar produced 23,100 results for “pandemic ethic*” and 101,000 results for “pandemic human rights”. (The key word “ethic*” was used to capture all variations, i.e. “ethic”, “ethics”, “ethical”, “ethically”, “ethicist” and “ethicists”).

We therefore limited our literature searches to records with all these words in the title only, in English, and published from 2003 (post the signal event of the SARS outbreak) to the present 21 May 2016.

SYSTEMATIC LITERATURE SEARCH: PANDEMIC ETHICS

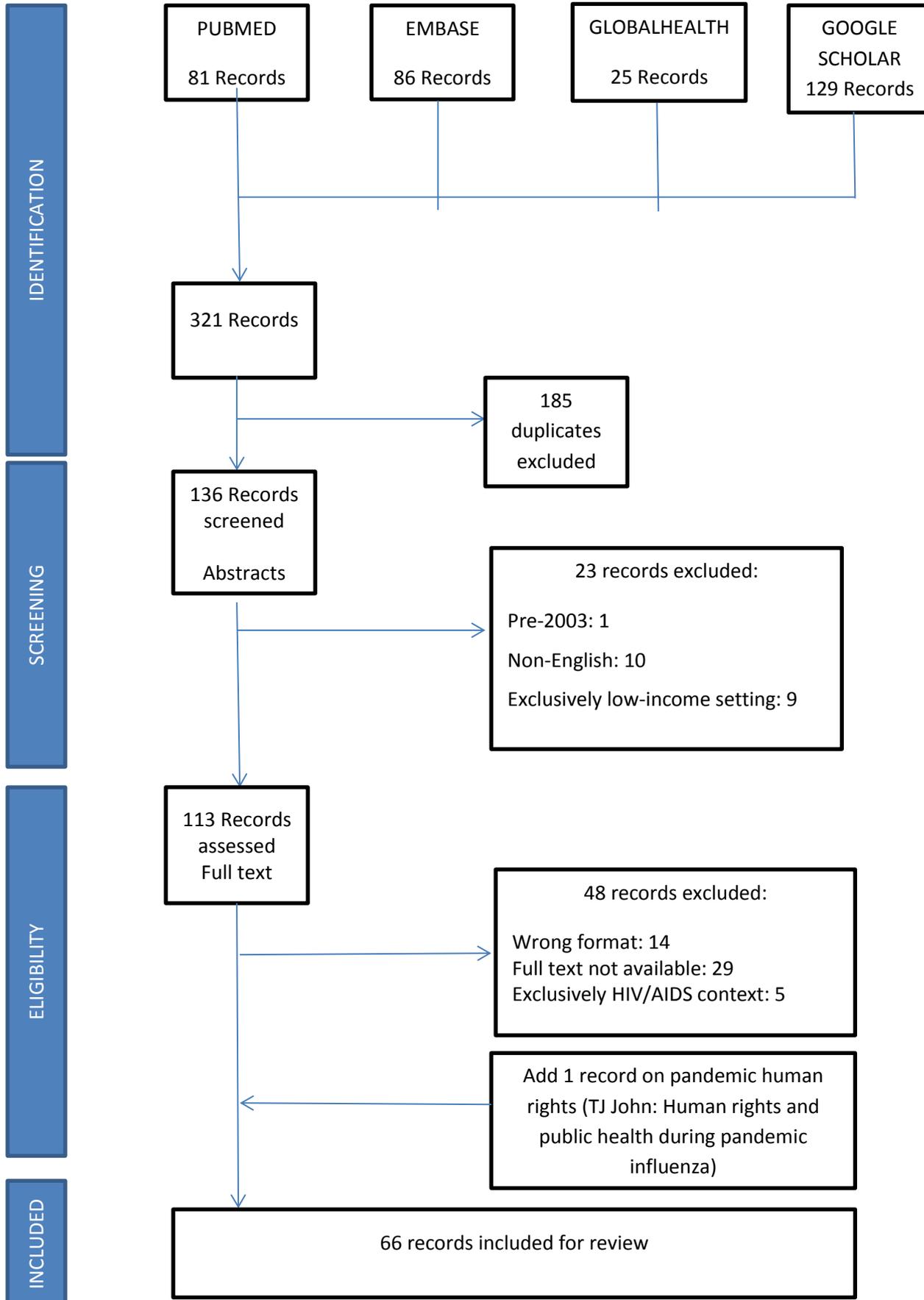
We searched several databases identified below on 21 May 2016. After removing duplicates, 136 records were identified. These were then reviewed by title and abstract. Twenty-three records were excluded as irrelevant, for example because they dealt exclusively with low income countries outside Europe. Full texts of the remaining 113 records were then read and a further 48 records were excluded, either because they were in the wrong format, e.g. they were a book review or conference presentations, if full text versions were not available, or if they discussed pandemic ethics solely in the context of HIV/AIDS. This context is not considered comparable to pandemic influenza for the reasons given earlier at section 2.3. This left 65 records for full review. To this was added the one new record on pandemic human rights identified in the systematic literature search as explained below.

	DATABASES	KEYWORDS [Title only]	DATE OF SEARCH	RESULTS
1	PUBMED	"Pandemic AND Ethic**"	21.05.16	81
2	EMBASE		21.05.16	86
3	GLOBALHEALTH		21.05.16	25
4	GOOGLE SCHOLAR		21.05.16	129
				321

Inclusion criteria: National policy documents/Both peer-reviewed and grey literature/Both published and unpublished literature/English language

Exclusion criteria: Documents before 2003 - but will include major instruments which pre-date this if they are referred to repeatedly and are clearly important.

Figure 1. Flow Diagram: Pandemic AND Ethic*



SYSTEMATIC LITERATURE SEARCH: PANDEMIC HUMAN RIGHTS

This search was also conducted on 21 May 2016. This search used the key words Pandemic AND Human AND Rights with search criteria of all words in the title.

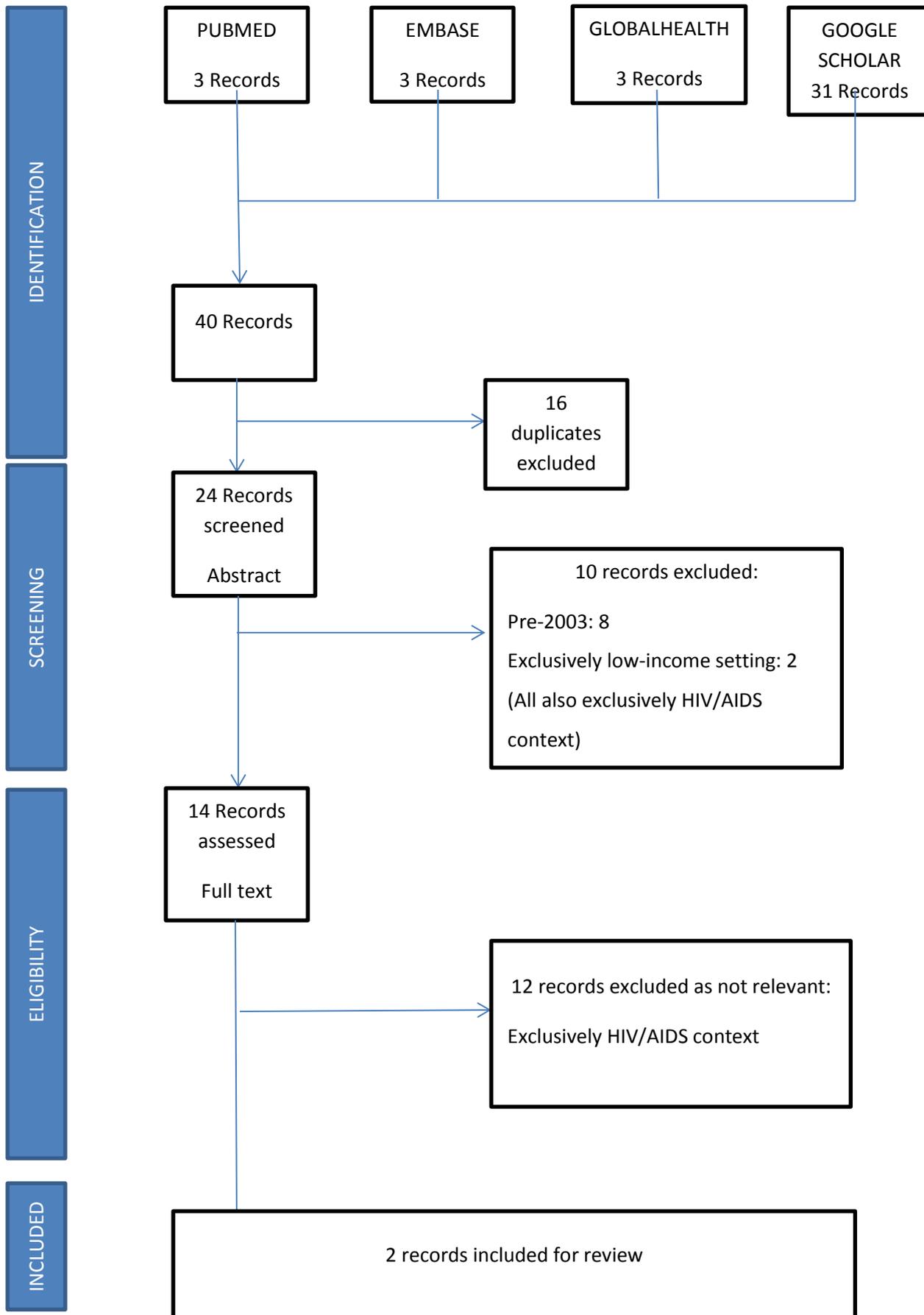
Far fewer records were identified than for the previous search on “pandemic ethic*”, and almost all related to human rights in relation to the HIV/AIDS pandemic. The full texts of some of these were reviewed but the human rights concerns were found not to be comparable to those encountered in a population wide outbreak of pandemic influenza. (For example, access to treatment for HIV/AIDS was affected by issues of stigma and finance rather than scarce resources). After reviewing abstracts, and then full texts, only two records were found to be relevant, one of which was already included in the previous search on pandemic ethic*: Pahlman et al: Pandemic influenza: Human rights, ethics and duty to treat, 2010 [9]. Thus, only one paper was added to the previous search results (TJ John: Human rights and public health during pandemic influenza, 2006 [8]) making a total of 66 records on “pandemic ethic*” and/or “pandemic human rights” for detailed review.

	DATABASES	KEYWORDS [Title only]	DATE OF SEARCH	RESULTS
1	PUBMED	“Pandemic AND Human AND Rights”	15.05.16	3
2	EMBASE		15.05.16	3
3	GLOBALHEALTH		15.05.16	3
4	GOOGLE SCHOLAR		15.05.16	31
				32

Inclusion criteria: National policy documents/Both peer-reviewed and grey literature/Both published and unpublished literature/English language

Exclusion criteria: Documents before 2003 - but will include major instruments which pre-date this if they are referred to repeatedly and are clearly important.

Figure 2: Flow Diagram: Pandemic AND Human AND Rights



RESULTS

Full texts of the 66 records were read to identify origin (from affiliation of the lead author) and key themes. Details of reviewed records are set out in Annex 1. Records were analysed to identify main subject matter, including proposed ethical frameworks, discussion of national pandemic preparedness plans, and/or discussion of one or more of the four key themes identified in D4.1: (1) Communication; (2) Surveillance; (3) Isolation, Quarantine, Border Controls and Social Distancing; (4) Equity and prioritisation of healthcare/scarce resources.

Excluded Records

Records were excluded for pre-dating 2003, non-accessibility of full texts, non-relevance (eg. exclusively low-income setting and/or exclusively dealt with HIV/AIDS pandemic). Ten records were excluded because their full texts were not in English (although their Abstracts were). These records were in French (3), German (2), Spanish (1), Russian (2) and Chinese (2).

Origin

Origin was determined from location of the lead author, with the following results: US: 34; Canada: 13; UK: 8; Australia: 3; NZ: 2; Singapore: 2; India: 2; NL:1; Italy: 1; Germany: 1; Finland: 1; International (WHO): 1

Of 66 reviewed records, the majority (47) were produced by authors in North America with reference to either the US or Canada. Only 12 (18%) were from European countries, mainly the UK. Exclusion of non-English language records will account for some of this, but nevertheless it suggests limited attention from Europe academics.

Common themes

There was a wide variation in the numbers of records focusing on each of the key themes:

1. Communications: 3 records [3, 17, 18]
2. Surveillance: 3 records [19-22]
3. Isolation, quarantine, border controls and social distancing measures: 10 records [18-27]
4. Equity and prioritisation of scarce healthcare: 34 records [3, 17, 18, 20-22, 25-52]

Other common themes:

Planning and Ethics in pandemic preparedness plans: 7 records [3, 4, 53-56]

Duties of healthcare workers: 14 records [3, 9, 17, 18, 26, 27, 30, 36, 43, 44, 57-59]

Research ethics during a pandemic: 4 records [60-62]

Ethical framework: 7 records [2, 14, 16, 43, 63-65]

Human rights: 2 records [8, 9]

The result indicates that by far the most common theme is the allocation of scarce resources, a major theme of 34 records. By contrast, only three records dealt with ethics in relation to communication as a major theme, and the same number covered ethics in pandemic surveillance. Both communications and surveillance are key themes of pandemic planning, prioritized as “Essential” in the WHO checklist and yet on the evidence of this limited literature review, very few academic have tackled the ethical aspects of those issues.

As discussed earlier, only two records dealt with human rights in pandemics as a key theme. One (Jacob John) was a limited, one-page editorial [8]. The other (Pahlman) discussed human rights solely in relation to the duties of healthcare workers during a pandemic (vis a vis their own human right to life) [9].

Findings from this review are:

- The majority of research on ethical considerations in pandemics has been conducted by north American academics;
- The apparent dearth of literature on pandemic ethics from European academics makes it currently difficult to make a study of comparative European approaches to a particular ethical issue;
- Pandemic management as a human rights issue has received very little attention. The reason is unclear;
- The themes covered most by ethicists, while important, do not necessarily reflect themes central to pandemic planning, such as communications and surveillance, which also have important ethical considerations.

3.4 Relevant research projects

Report D4.1 discusses previous and ongoing research projects which have relevance to PANDEM in terms of Work Package 4, i.e. they involve research on governance and legal frameworks in the EU.

Methodology

Using the methodology explained in D4.1 at section 11, for this report we searched specifically for projects which involve ethics and/or human rights in relation to pandemic governance. We were only able to identify two projects: TELL ME and ASSET, which discuss these issues.

TELL ME: Transparent communication in Epidemics: Learning Lessons from experience, delivering effective Messages, providing Evidence 2012-2015

The project

TELL ME was a 36 month collaborative project which aimed to provide evidence and to develop models for improved risk communication during infectious disease crises. TELL ME combined public health, social sciences, behavioural sciences, political sciences, law, ethics, communication and media, in order to develop original communication strategies regarding complicated messages and advice based on uncertainties, also addressing vaccine-resistant groups [66].

Conclusions

D1.6 Report: Human Rights, Stigmatization and Risk of Discrimination Against Specific Population Segments and Target Groups.

This report focuses on the risk of stigmatisation of vulnerable individuals in the context of limited health care resources in a public health epidemic. This risk is discussed with reference to international human rights legislation such as the ECHR, the ICESR and the ICCPR. The report considers that these legal instruments provide important protections, while also noting limitations of enforceability and derogability.

The report was submitted in 2012 at the beginning of the TELL ME project term and while of interest, is limited to one ethical aspect of pandemic response and without specific reference to EU Member States or the EU context. It is unclear to what extent this report contributed to the project's final conclusions.

ASSET: Action plan on Science in Society related issues in Epidemics and Total Pandemics

2014-2017

ASSET is a 3 year, ongoing, EU funded project which is also discussed in report D4.1 at section 10. We reviewed the ASSET Project Report: D2.4: Ethics, Law and Fundamental Rights Report prepared by the Responsible Partner: ZADIG (Eva Benelli) which was submitted 13.04.15. A recorded Skype interview with Eva Benelli and Roberta Vila of ZADIG (report authors) was conducted on 18.04.16. The purpose was to ask more about the project and future intentions.

The “Ethics, Law and Fundamental Rights Report” was prepared at the beginning of the ASSET project with the purpose of “identification and analysis of ethical, legal and fundamental rights considerations in relation to public health crises.” The project partner responsible for the report was ZADIG, an Italian publishing company specialising in communication in medicine, science, nature and the environment.

The report describes the legal framework primarily with reference to the terms of the Charter of Fundamental Rights of the European Union (CFREU) and the European Convention on Human Rights (ECHR). Ethical issues are set out with reference to the WHO ethical framework: “Ethical considerations in developing a public health response to pandemic influenza” [1].

The report stresses that ethical and human rights considerations should be a key component in planning and response to public health crises:

“National governments and local authorities should strive to cultivate a ‘culture of ethics’ across the entire spectrum of societal actors and stakeholders who are likely to be involved - and make or act upon decisions - at different phases of pandemic. A culture of ethics which could be structured on...the promotion of a bottom-up, participatory and inclusive mechanism with a primary focus on restoring and reinventing trust among scientists, researchers, policy makers and the general public” [67].

In the skype interview on 18 April 2016 the report’s authors, Eva Benelli and Roberta Vila of ZADIG, said that while there is no further project deliverable specifically on ethical issues, future work on ASSET includes a “Citizen Consultation” in autumn 2016 when groups of 50 people in each of eight European counties will be asked questions on

pandemics. Ethical issues are expected to be a major part of this discussion. There are also plans for a high level policy forum when senior policy makers can discuss ethical issues in private. A key part of the ASSET project is analysis of communication and public trust during a pandemic.

The authors advised that ASSET is not a research project as such, and does not contain research tasks. Instead it is a “mobilisation and mutual learning” programme. ASSET aims to be a platform where people with different areas of expertise can meet and share knowledge and opinions, in order “to involve people in a more effective way.”

Summary

This finding reflects that there has only been one EU level “research project”: TELL ME which considers ethics and/or human rights. The TELL ME report is both narrow, in focusing on one human rights issue: stigmatisation of vulnerable individuals, and general in discussing the issue in a non-specifically European context. The ASSET project has value in that it is trying to mobilise interest and learning but it did not conduct primary research into ethical issues.

3.5 National pandemic preparedness plan

A review of ethical and human rights considerations in national pandemic preparedness plans was conducted by analysis of the seven EU plans also reviewed in report D4.1 at section 8.1.

The literature review identified a number of papers which analysed ethical aspects of plans, both European and global. Some key findings of these papers are set out below.

Ethical and Human Rights considerations in seven EU national pandemic preparedness plans.

Report D4.1 provides a thematic analysis of the national pandemic preparedness plans of seven EU Member States: Croatia, Czech Republic, France, Hungary, Italy, Spain and the UK. These plans were chosen for their public accessibility on either the WHO or ECDC websites, and because they were published in English.

As explained earlier at section 2.3, the WHO checklist recommends inclusion of ethical considerations as “Desirable” and in 2007 WHO published ethical guidelines for the use of policy makers when drafting national plans. Yet on reviewing these seven plans, it was found that the incorporation of ethical considerations was fairly limited.

ETHICS/HUMAN RIGHTS	
CROATIA 2005	No reference.
CZECH REPUBLIC 2011	Page 6, 3b. <u>Ensuring the ethicalness of pandemic preparedness and response</u> . An influenza pandemic, similarly to any emergency situation in the field of public health, requires making decisions that imply a balancing act between potential conflicts of interest involving individuals on the one hand and the community on the other. The persons responsible for this process may use ethical principles as tools for evaluating and balancing this conflict between interests and values. The ethical approach does not provide a previously set procedure. Rather, it applies principles such as equality, benefit/efficacy, freedom, reciprocity and solidarity. These principles may be used as the basic framework for evaluating and balancing the range of interests in order to achieve the set goal (such as the protection of human rights and the specific needs of vulnerable and minority groups).”
FRANCE 2011	Page 17: “For the ethical dimension (ref. Official Notification No. 106 of the National Ethics Consultative Committee): Be sure to maintain a social consensus around ethical principles...A consensus on shared ethical values is indispensable to preserve social cohesion...Constantly adapt the response as a function of the development of knowledge and the situation.”
HUNGARY 2008	No reference.
ITALY 2010	No reference.
SPAIN 2006	No reference.
UK 2011/14	Not referenced in 2014 plan except that the PHE advice and response will at all times be “based on ethical principles”. Set out in 2011 “UK Influenza Pandemic Preparedness Strategy” pages 30-31: 3.17-3.20: Ethical principles for pandemic preparedness.

Ethics

Only three of the seven plans mentioned ethical considerations (Czech Republic, France, UK 2011). The UK plan referenced the Ethical Framework prepared by the UK Department

of Health, the French plan referenced the ethical guidelines of the National Ethics Consultative Committee. No plan referenced the WHO Ethical Framework.

As explained earlier at page 11, it is possible that other national plans use ethical frameworks, but this report reviews those which were available online and in English.

Human Rights

None of the plans referred to “human rights” although the Spanish plan did refer to protection of “individual fundamental rights”: “The administrative court judges, through prior authorization or ratification, will be the authority that will control the proportionality of any intended health measure insofar as such a measure involves the deprivation or restriction of freedom or of any other fundamental right, thus acting as guarantors of individual fundamental rights” [68].

There are several possible reasons why no plans used the term “human rights”. It may be that preparedness is simply not regarded as a legal or rights issue. It may also be that governments chose not to use the term “human rights” because of its legal implications.

LITERATURE ON ETHICAL ISSUES IN NATIONAL PANDEMIC PREPAREDNESS PLANS

Literature review identified six papers which analysed ethical principles in specific national pandemic preparedness plans. All of these papers were written by North American academics although some included analysis of European plans. Some of their key findings are set out below as they have general relevance to ethical planning.

Preparing for an influenza pandemic: ethical issues: Kotalik, 2005 [69]

Review of pandemic plans of Canada, the UK and the US from an ethical perspective.

“There is no doubt that the aim of the authors of these national pandemic plans was to base their product on the best available science. However, because every discourse about health care has not only a scientific but also a moral dimension, these plans also presuppose certain ethical values, principles, norms, interests and preferences. Yet, for whatever reason...the plans rarely discuss the relevant ethical elements.”

The author considers the following ethical issues particularly pressing and relevant to the implementation of plans: Scarcity; Vaccines and Antivirals; Communications. With regard to the latter: “all sectors of society and all individuals will be affected by a pandemic and everyone’s collaboration will be required...it is essential that plans are developed and

communication programs implemented that will not only inform but also create an atmosphere of mutual trust and solidarity; qualities that at the time of a pandemic will be much needed.”

Ethics in a Pandemic: A Survey of the State Pandemic Influenza Plans: Thomas, 2007
[56]

A review of US state and federal pandemic plans from the perspective of ethical considerations.

“We analyzed the federal and state plans, available on the Internet, for evidence of ethical guidance as judged by the presence of ethical terms. The most striking finding was an absence of ethical language. Although some states acknowledged the need for ethical decision-making, very few prescribed how it should happen. If faced by a pandemic in the near future, we stand the risk of making many unjust and regrettable decisions.”

Wake me up when there's a crisis: progress on state pandemic influenza plans: Thomas, 2007 [4] Review of 50 US state pandemic plans to ascertain progress in ethical preparedness.

Findings were that “7 states had recommended steps to further clarify ethical processes or decisions; 6 states had made some progress but almost exclusively in hospital preparedness. Having a high level public health leader, such as a health department director, committed to ethics was the key determinant of progress. Some state health departments may be destined to gain an appreciation for ethics through ethical mishaps.”

“Although the best time to address and prepare for anticipated ethical challenges is during a nonpandemic period, ‘out of sight, out of mind’ is the reality more likely to come into play.”

Public participation in national preparedness and response plans for pandemic influenza: towards an ethical contribution of public health policies: Farmer, 2010
[70]

Review of 24 pandemic plans, including 8 EU Member States: (WHO, Australia, Belgium, Brazil, Burkina Faso, Canada, Chile, Hong Kong, Czech Republic, France, Germany, Italy, Japan, Korea, New Zealand, Netherlands, Norway, Philippines, Sweden, Switzerland, Thailand, UK, US, Vietnam).

“In spite of the obvious importance of ethical questions associated with issues such as the distribution of resources (vaccines and a shortage of beds for example), or with measures of surveillance or control that could result in restrictions on individual freedom, the majority of the plans studied did not contain an ethical framework. Some indicated the importance of ethics, but without further elaboration (absence of a developed ethical framework). Three plans are an exception to this rule: those of Canada, New Zealand and Switzerland....even in these three plans, which are remarkable in many aspects, public participation *is not* considered an ethical issue or a moral obligation as such.”

A Survey of Ethical Principles and Guidance within Selected Pandemic Plans: McDougall, 2010 [71]

Survey of ethical principles with pandemic plans of Canada, New Zealand, UK, US, France, Australia, Switzerland.

“The ethical frameworks surveyed here overlap to a significant extent at the level of fundamental ethical commitments and principles, and even more so at the level of strategic or operational goals; but on the whole they provide only minimal specific guidance on how to actually realize requirements, for example, that access to vaccine or anti-virals be equitable, or that need and benefit be balanced when it comes to prioritizing groups or individuals for access...more practical guidance is needed about how to implement the ethical commitments and principles endorsed in ethical frameworks, which are not algorithms that mandate particular approaches or decisions, but decision-making tools that need to be adjusted to reflect both the specific biological characteristics of any actual or potential pandemic, and the specific social circumstances in which they are used as part of a coordinated response.”

Ethics for pandemics beyond influenza: Ebola, drug-resistant tuberculosis, and anticipating future ethical challenges in pandemic preparedness and response: Smith, 2015 [55]

Review of ethics in pandemic plans in the context of disease threats beyond influenza.

“Even when ethical frameworks are included in pandemic plans, references to ethical values or principles like reciprocity, trust, or distributive justice often go without much

discussion of how they ought to guide pandemic response activities, like when implementing quarantine measures.”

The author notes that the focus of current pandemic plans on influenza means that they are “ill-equipped to anticipate and facilitate the navigation of unique ethical challenges that may arise in other infectious disease pandemics”. This is of concern because:

- “(1) different infectious diseases have distinct characteristics that challenge anticipated or existing modes of pandemic prevention, preparedness, response, and recovery;
- (2) clear, transparent, context-specific ethical reasoning and justification within current influenza plans are lacking;
- (3) current plans neglect the context of how other significant pandemics may manifest.”

There is “a significant shortfall of meeting our ethical imperative to anticipate and plan for pandemic threats. The EVD outbreak serves as yet another reminder that...we must continue to update our ethical preparedness such that we enumerate anticipated ethical issues that may arise in the context of non-influenza pandemics, devise and install structures that encourage and facilitate inclusive and sustained ethical deliberation on these matters, and begin to address predictable ethical issues that may emerge with future pandemics.”

Summary

Literature on national plans covers the following themes:

- National pandemic plans rarely include ethical consideration although this is extremely important;
- There should be high level commitment to ethical consideration;
- It is important to address ethical considerations in non-pandemic periods, although this rarely happens;
- Public participation in pandemic planning is often not considered an ethical issue: this is an erroneous approach;
- Existing ethical frameworks give minimal guidance. More practical guidance is needed for the implementation of ethical principles;
- It is important to continually review and update ethical preparedness: this is not currently happening.

4 Analysis of common themes and disconnects

While report D4.1 indicates a disconnect between pandemic planning and legal governance to underpin that planning, this review suggests even less attention is given to ethics and human rights considerations in current EU pandemic planning, despite its crucial importance.

ETHICAL AND HUMAN RIGHTS FRAMEWORKS

Many ethical frameworks have been produced, of varying quality and focus, but only two could be easily identified from EU Member States (France and the UK). Ethical frameworks are a valuable tool for and should be central to national pandemic planning. There is little evidence that this is currently the case.

LITERATURE REVIEW

There is a striking disconnect between a large body of literature produced by ethicists, yet ethical considerations not appearing in actual pandemic planning policy. Although pandemic management involves many measures which would infringe on human rights, such as right to life, right to privacy, right to liberty, very few academics seem to have approached it as a human rights issue. The reasons for this are unclear and should be identified.

The majority of research on ethical considerations in pandemics has been conducted by North American academics. The apparent dearth of literature on pandemic ethics from European academics makes it currently difficult to make a study of comparative European approaches to a particular ethical issue.

Themes covered most by ethicists, while important, do not necessarily reflect themes central to pandemic planning, such as communications and surveillance, which also have important ethical considerations.

RELEVANT RESEARCH PROJECTS

Only two projects - TELL ME and ASSET - could be identified which reviewed ethics and human rights in pandemic response. TELL ME focused on just one ethical area (risk of stigmatisation) and this was in a general context (without reference to EU Member States). While useful, ASSET is not a research project, but rather a “mobilisation and mutual learning programme.”

NATIONAL PANDEMIC PREPAREDNESS PLANS

Despite the quantity of literature and many ethical frameworks which have been produced, the European national pandemic preparedness plans reviewed make little reference to these.

5 Priority ethical and human rights issues and challenges for and within the EU

Ethicists are agreed that ethics and human rights should be central to pandemic planning. If not, there is enormous potential for abuse and “gross unethical mishaps” [4]. Yet the findings of this review are that they have been regarded as low priority in Europe. This is reflected in the minimal attention given to them by the EU, the pandemic plans of EU Member States and European academic researchers. Pandemic planning has been largely approached as a purely scientific concern, although many of the measures proposed would involve morally challenging decisions to balance individual and population rights.

The European Union is currently composed of 28 Member States with a range of cultural, political and social contexts and approaches. It is probable that they will also have different responses to ethical questions in pandemic planning. While national sovereignty should be respected, some responses may be on the borderline of what is “ethical”. As discussed in the US Case Study in D4.1, some Member States propose measures which may be in breach of the European Convention on Human Rights (ECHR). While the EU has tried to promote common standards of human rights with the ECHR and also the Charter of Fundamental Rights of the European Union (CFREU), there is little evidence that governments are mindful of these rights when planning for pandemics. The literature on ethics in European plans has been produced by North American authors and is too limited to make a meaningful comparison of approaches across Member States.

PRIORITY CHALLENGES FOR FUTURE ACTION

There is a clear need to recognise and promote the importance of ethics and human rights in pandemic planning. These are some proposed priority challenges which are not mutually exclusive.

Greater prioritisation of ethics and human rights in pandemic planning

- Ethics should be the foundation of pandemic preparedness planning, the spine upon which any strategy and actions are developed and justified;

- Many national plans are drafted by public health experts only. Law, ethics and human rights should be integral to national planning so lawyers and ethicists experienced in public health should be part of the drafting teams.
- Support at EU level of the importance of an ethical framework for pandemic planning, perhaps by producing an EU ethical framework.

Alignment of national pandemic preparedness plans

- Comprehensive review of EU national pandemic plans to identify the ethics and human rights perspective of proposed measures;
- National plans should not be focused narrowly on threat from pandemic influenza alone, but should be broader to include measures to respond to other public health threats. Each of these measures should be assessed from an ethics and human rights perspective.

Increased research into ethics and human rights in pandemic planning

- Research to identify why ethics and human rights are such low priority so this can be reversed;
- Research should consider ethical and human rights issues in all proposed pandemic measures, including communications and surveillance.

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ANNEX 1

ETHICS/HUMAN RIGHTS LITERATURE REVIEW

FULL TEXTS FOR REVIEW: 66 RECORDS

	LEAD AUTHOR	TITLE	DATE	ORIGIN	THEME
1	Anikeeva, O	How will Australian general practitioners respond to an influenza pandemic? A qualitative study of ethical values	2008	Australia	Preparedness of GPs for a pandemic
2	Antommara, AHM	Critical appraisal of: Triage pediatric critical care resources during a pandemic: Ethical and medical considerations	2010	US	4. Equity/prioritisation
3	Bailey, TM	Public engagement on ethical principles in allocating scarce resources during an influenza pandemic	2011	Canada	4. Equity/prioritisation
4	Ball, R	South Carolina prepares for pandemic influenza: An ethical perspective	2015	US	Workforce continuity 3. Isolation, quarantine 4. Equity/prioritisation
5	Barr, H	Ethical planning for an influenza pandemic	2008	UK	Duties of healthcare workers 4. Equity/prioritisation
6	Bennett, B	Law, ethics and pandemic preparedness: the importance of cross-jurisdictional and cross-cultural perspectives	2010	Australia	Legal preparedness, ethical planning, cross-cultural issues
7	Berkman, BE	Mitigating pandemic influenza: the ethics of implementing a school closure policy	2008	US	3. Isolation, quarantine
8	Berkman, BE	Incorporating explicit ethical reasoning into pandemic influenza policies	2009	US	4. Equity/prioritisation
9	Berlinger, N	Pandemic flu planning in the community: what can clinical ethicists bring to the debate	2008	US	Value of ethicists in pandemic planning

10	Bhatia, P	The H1N1 influenza pandemic: need for solutions to ethical problems	2013	India	Ethical planning Duties of healthcare workers 1. Communication 4. Equity/prioritisation
11	Budd, LA	“Value”, “cost” and ethics: UK airports and the governance of pandemic H1N1 risk	2010	UK	3. Border controls
12	Caruso, A	Legal and Political Implications of a Pandemic and Biological Threats. Ethical Dilemmas in Disasters	2010	Italy	Importance of ethics and human rights in an emergency
13	National Ethics Advisory Committee	Ethical values for planning for and responding to a pandemic in New Zealand: A statement for discussion	2006	New Zealand	Statement of ethical values
14	National Ethics Advisory Committee	Getting through together: ethical values for a pandemic	2007	New Zealand	Statement of ethical values
15	Conway, CA	Texas Ethics Group Provides Recommendations on Allocation of Health Care Services During an Influenza Pandemic	2010	US	4. Equity/prioritisation
16	Cook, D	Clinical research ethics for critically ill patients: A pandemic proposal	2010	Canada	Research ethics
17	Cowden, J	Pre-pandemic planning survey of healthcare workers at a tertiary care children’s hospital: ethical and workforce issues	2010	US	Healthcare worker willingness to work in a pandemic
18	Crowcroft, N	The ethics of sharing preliminary research findings during public health emergencies: a case study from the 2009 influenza pandemic	2009	Canada	Research ethics
19	De Bruin, DA	Implementing ethical frameworks for rationing scarce health resources in	2010	US	4. Equity/prioritisation

		Minnesota during severe influenza pandemic			
20	Draper, H	Non-professional healthcare workers and ethical obligations to work during pandemic influenza	2010	UK	Duties of non-professional healthcare workers
21	American College of Obstetricians & Gynecologists. Committee on Ethics	Ethical Issues in Pandemic Planning Concerning Pregnant Women	2013	US	4. Equity/prioritisation
22	Evans, NG	The ethics of biosafety considerations in gain-of-function research resulting in the creation of potential pandemic pathogens	2015	US	Research ethics
23	Farmer, Y	Public participation in national preparedness and response plans for pandemic influenza: toward an ethical contribution of public health policies	2010	Canada	Survey of 24 national plans
24	Faust, HS	The Role of Faith-Based Organizations in the Ethical Aspects of Pandemic Flu Planning - Lessons Learned from the Toronto SARS Experience	2009	Canada	Role of spiritual leaders in ethical pandemic planning
25	Frolic, A	Development of a critical care triage protocol for pandemic influenza: integrating ethics, evidence and effectiveness	2009	Canada	4. Equity/prioritisation
26	Gadd, E	Ethical Issues Related to Pandemic Preparedness and Response	2009	UK	Duties of healthcare workers 4. Equity/prioritisation
27	Garrett, J	The Minnesota Pandemic Ethics Project: sequenced, robust public engagement processes	2011	US	4. Equity/prioritisation
28	Gostin, L	Public Health Strategies for Pandemic Influenza: Ethics and the Law	2006	US	2. Surveillance 3. Isolation

29	Gostin, L	Project on Addressing Ethical Issues in Pandemic Influenza Planning	2006	US	2. Surveillance 3. Isolation, quarantine, border controls and social distancing measures 4. Equity/prioritisation
30	Gostin, LO	Medical countermeasures for Pandemic Influenza: Ethics and the Law	2006	US	Vaccine supply 4. Equity/prioritisation
31	Gostin, LO	Pandemic influenza: ethics, law and the public's health	2007	US	2. Surveillance 3. Isolation, quarantine, border controls and social distancing measures 4. Equity/prioritisation
32	Hobden, D	Flu Pandemic and possible ethical dilemmas: A note for chaplains	2010	UK	4. Equity/prioritisation
33	Kass, NE	An ethics framework for public health and avian influenza pandemic preparedness	2005	US	Ethical framework
34	Kinlaw, K	Ethical guidelines in pandemic influenza: recommendations of the Ethics Subcommittee of the Advisory Committee of the Director, Centers for Disease Control and Prevention	2009	US	Ethical framework for CDC
35	Klopfenstein, ML	Towards an Ethical Community Response to Pandemic Influenza: The Values of Solidarity, Loyalty and Participation	2008	US	Community participation in pandemic response
36	Kotalik, J	Preparing for an influenza pandemic: ethical issues	2005	Canada	Pandemic plans in Canada, UK, US
37	Letts, J	Ethical challenges in planning for an influenza pandemic	2006	Australia	Duties of healthcare workers 3. Isolation, quarantine, social distancing 4. Equity/prioritisation
38	Levin, PJ	Can the health-care system meet the challenge of pandemic flu? Planning, ethical and workforce considerations	2007	US	Duties of healthcare workers 1. Communications 4. Equity/prioritisation
39	Lipsitch, M	Ethical alternatives to experiments with novel potential pandemic pathogens	2014	US	Research ethics
40	Littmann, J	How high is a high risk? Prioritising high-	2014	Germany	Equity/prioritisation

		risk individuals in an influenza pandemic			
41	McDougall, CW	A survey of ethical principles and guidance within selected pandemic plans	2010	Canada	Lists of ethical principles in pandemic plans
42	McGorty, EK	Ethical guidelines for an influenza pandemic	2007	US	Ethical framework
43	McLachlan, HV	A proposed non-consequentialist policy for the ethical distribution of scarce vaccination in the face of an influenza pandemic	2012	UK	4. Equity/prioritisation
44	Melnychuk, RM	Pandemic triage: the ethical challenge	2006	Canada	4. Equity/prioritisation
45	Meslin, EM	Pandemic influenza preparedness: ethical issues and recommendations to the Indiana State Department of Health	2008	US	Ethical framework: Duties of health workers 4. Equity/prioritisation
46	Ng, ES	The Ethics of responding to a novel pandemic	2011	Singapore	2. Surveillance 3. Isolation 4. Equity/prioritisation
47	Pahlman, I	Pandemic influenza: human rights, ethics and duty	2010	Finland	Duties of health workers
48	Pakes, B	The Pandemic Dividend - An Opportunity for Public Health Ethics	2009	Canada	Duties of healthcare workers 4. Equity/prioritisation
49	Rothstein, MA	Currents in contemporary ethics. Should health care providers get treatment priority in an influenza pandemic?	2010	US	4. Equity/prioritisation
50	Schuklenk, U	Confronting an influenza pandemic ethical and scientific issues	2006	UK	Duties of healthcare workers 3. Isolation, quarantine, border controls & social distancing measures 4. Equity/prioritisation
51	Sheather, J	Ethics in the face of uncertainty: preparing for pandemic flu	2006	UK	4. Equity/prioritisation
52	Smith, MJ	Ethics for pandemics beyond influenza: Ebola, drug-resistant tuberculosis, and anticipating future ethical challenges in pandemic preparedness and response	2015	Canada	Ethical planning

53	Strosberg, MA	Allocating scarce resources in a pandemic: Ethical and public policy dimensions	2006	US	4. Equity/prioritisation
54	Tabery, J	The Ethics of Triage in the Event of an Influenza Pandemic	2008	US	4. Equity/prioritisation
55	Thomas, JC	Ethics in a Pandemic: A Survey of the State Pandemic Influenza Plans	2007	US	Ethics in US pandemic plans
56	Thomas, JC	Wake me up when there's a crisis: progress on state pandemic influenza plans	2007	US	Ethics in US pandemic plans
57	Thompson, AK	Pandemic influenza preparedness: an ethical framework to guide decision-making	2006	Canada	Ethical framework
58	Tiong, WW	Ethical considerations in the review of Singapore's H1N1 pandemic response framework in 2009	2013	Singapore	Duties of healthcare workers 1. Communications 3. Isolation, quarantine, border controls and social distancing measures 4. Equity/prioritisation
59	Tuohey, JF	A matrix for ethical decision making in a pandemic. The Oregon tool for emergency preparedness	2007	US	Decision-making matrix for ethics in pandemics
60	Upshur, R	Ethics in an Epidemic: Ethical considerations in preparedness planning for pandemic influenza	2007	Canada	Ethical values in preparedness planning
61	Van't Hoff, G	Prisons' preparedness for pandemic flu and the ethical issues	2009	NL	Prisoners' rights to healthcare in a pandemic
62	Vawter, DE	Allocating pandemic influenza vaccines in Minnesota: Recommendations of the Pandemic Influenza Ethics Work Group	2007	US	4. Equity/prioritisation
63	Vawter, DE	For the good of us all: Ethically rationing health resources in Minnesota in a severe influenza pandemic	2010	US	4. Equity/prioritisation
64	WHO (Verweij, M)	Addressing ethical issues in pandemic influenza planning: equitable access to scarce medical resources	2007	Int'l	4. Equity/prioritisation
65	Zimmerman,	Rationing of influenza vaccine during a	2007	US	4. Equity/prioritisation

	RK	pandemic: ethical analyses			
66	Jacob John, T	Human rights and public health during pandemic influenza	2006	India	Editorial on human rights in relation to pandemic influenza