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WP2 STUDY & ANALYSIS D2.4 ETHICS, LAW AND FUNDAMENTAL RIGHTS REPORT

ASSET Project • Grant Agreement N°612236

ASSET

Action plan on SiS related issues in Epidemics And Total Pandemics

7th RTD framework programme

Theme: [SiS.2013.1.2-1 Sis.2013.1.2-1]

Responsible partner: **ZADIG**

Contributing partners: -

Nature: **Report**

Dissemination: **PU**

Contractual delivery date: **2014-11-30 (m11)**

Submission Date: **2015-04-13 (m16)**

This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement no 612236



co-funded by the EU. GA: 612236

www.asset-scienceinsociety.eu



DOCUMENT MANAGEMENT

PROJECT FULL TITLE	Action plan on SiS related issues in Epidemics And Total Pandemics
PROJECT ACRONYM	ASSET
	Coordination and Support Action: project funded under Theme SiS.2013.1.2 "Mobilisation and Mutual Learning (MML) Action Plans"
GRANT AGREEMENT	612236
STARTING DATE	01/01/2014
DURATION	48 months

D2.4 Ethics, Law and Fundamental Rights Report

Task: 2.4

Leader: ZADIG – Other contributors: -

History of changes:

Vn	Status	Date	Organisation / Person responsible	Reason for Change
V1	Draft	16/03/2015	ZADIG / Eva Benelli, Dimitris Dimitriou	First draft version
Vf	Final	13/04/2015	ZADIG / Eva Benelli, Dimitris Dimitriou	Approved version



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EXECUTIVE SUMMARY

The present report contributes to the accomplishment of a major objective of the ASSET project, which is the establishment of baseline knowledge on *Science-in-Society* related issues about pandemics, within the wider scope of Work Package 2 (WP2: Study & Analysis). The principal focus of this report is to provide an overview and discuss relevant ethical, legal and fundamental rights considerations in situations of public health emergencies, such as epidemics and pandemics. There is a saying that goes, “extraordinary circumstances demand extraordinary measures”, and on this basis the report extends further to offer an array of practical recommendations on how fundamental human rights and ethical considerations can better inform the decision-making process in the need to apply these “extraordinary measures”. Exceptional circumstances must not provide an alibi for pandemic planners and policy makers to ignore fundamental human rights and ethical tensions that can arise at different phases of a pandemic.

The first part of the report presents the international policy landscape on what constitutes fundamental human rights, both at EU and world level. More specifically, the Charter of Fundamental Rights of the European Union (CFREU) is presented as a legally binding instrument that sets out the basic rights that must be respected both by the European Union and the Member States when implementing EU law, and the provisions of which are discussed, under the prism of public health emergency situations. In recognition of the fact that the rights and principles listed in the CFREU are not always specific or relevant to public health emergencies, the report further explores the way in which fundamental human rights find application in the healthcare and medical context, with examples used from international policy documents, such as the WHO International Health Regulations (2005), the Universal Declaration on Bioethics and Human Rights (2006), and the WMA Declaration of Lisbon on the Rights of the Patient (1981).

These international policy instruments do provide a concrete framework for the formulation of national policies in the event of a large scale public health emergency, however, there are occasions in which specific decisions or the implementation of certain measures may come to direct conflict with ethical principles and values, even if these decisions or measures are in accordance with established policies and laws. Ethical principles and societal norms may often come into tension with priorities and needs in a state of emergency, and decision makers are required to critically assess and timely take decisions on the best available evidence at every phase of the pandemic. Although it would be impossible as a task to cover every possible pandemic scenario, the section on “ethical issues and considerations in pandemics” addresses key points and promotes ethical best practice in the event of public health emergencies. Key principles and values are presented that should be considered in addressing fundamental rights (e.g. restriction of personal freedoms), ethical issues (e.g. duty to provide care), societal issues (e.g. priority-setting) and political issues (e.g. international cooperation) in pandemic preparedness and response. These principles are described as “key principles” since they inform every activity and decision at all phases of a pandemic.

It should be noted that this report draws on existing evidence from the scientific literature, international agencies’ technical reports and policy documents to offer an insight on ethics-related issues and generic approaches, instead of creating a promise for solutions to ethical problems, which problems can rarely be solved in the absence of specific contextual details. It is envisaged with this report to provide to policy makers, health care professionals and citizens stakeholders an additional platform for deliberation on science-in-society related issues in epidemics and pandemics.



1. INTRODUCTION

ASSET (Action plan on Science in Society related issues in Epidemics and Total pandemics) is a 48-month Mobilisation and Mutual Learning Action Plan (MMLAP), co-funded by the European Commission, and comprises an international group of experts in public health, social and political sciences, vaccine and epidemiological research, science communication and media. Overall, the ASSET project aims to address a wide array of issues around major infectious disease outbreaks toward the creation and elaboration of a consolidated action plan, which comprises the following steps/objectives:

1. To forge a transdisciplinary partnership to effectively address epidemics and pandemics.
2. To explore and map science in society related issues in epidemics and pandemics.
3. To define and test a participatory and inclusive strategy for successful action.
4. To identify resources necessary to make the action sustainable after project completion.

Each of the abovementioned steps/objectives manifests a critical phase in the life-cycle of the ASSET project. The present report links directly and contributes to the accomplishment of the second step/objective of ASSET, within the wider scope of **Work Package 2** (WP2: Study & Analysis), the purpose of which is to carry out a comprehensive exercise in order to establish baseline knowledge on *Science-in-Society* related issues about pandemics, including:

- Governance of pandemics and similar crises
- Unsolved scientific questions regarding pandemics
- Participatory governance
- Ethical, legal and fundamental rights implications
- Gender issues
- Research and innovation context
- Risk of intentionally caused outbreaks

As noted above, the identification and analysis of ethical, legal and fundamental rights considerations in relation to public health crises, constitutes a key component of this exercise. Accordingly, this report aims to identify, present and discuss ethical and fundamental rights issues or considerations that arise as a result of contextual or situational factors (e.g. pandemic phase, geographic spread, severity of disease etc.) in the event of a major infectious disease outbreak, notably an influenza pandemic. It is envisaged for the contents of this report to serve as input for the development of the ASSET Action Plan Handbook (WP3: Action Plan Definition), and offer a solid base for dialogue and deliberation among policy makers, health care providers and citizens in the context of a series of consultations to be organised by the Danish Board of Technology, in the scope of Work Package 4 (WP4: Citizen Consultation).



2. LEGAL CONTEXT AND INTERNATIONAL POLICY LANDSCAPE

Ethical principles, societal norms and fundamental rights issues are closely interwoven with infectious disease outbreaks, and more generally, any cross-border public health crisis. Critical ethical questions commonly arise in pandemic influenza planning, preparedness and response, which also enter the public healthcare discourse due to the fact that every action taken or decision made in the context of a major infectious disease outbreak has a moral dimension attached to it, except the scientific or political one. According to Selgelid (2009), the moral dimension and importance of ethical considerations in pandemics, is revealed by the fact that consequences of infectious diseases are almost unrivalled, as historically “[...] they have caused more morbidity and mortality than any other cause, including war” (p. 255). As observed in the most recent Ebola epidemic in West Africa, the subtle presence of ethical and fundamental rights implications was manifested in reported cases of stigmatisation and discrimination against the most vulnerable groups of society, the provocation of negative emotions such as fear and panic, and a series of measures implemented for the protection of both national and international security.

Exactly how ethical content should enter into activities and decisions in a pandemic context, is difficult to say in the abstract. Ethical principles and societal norms may often come into tension with priorities and needs in a state of emergency, and decision makers are required to critically assess and timely take decisions on the best available evidence at every phase of the pandemic. Any pandemic event can have a severe impact for both individuals and societies at large, since it can invariably cause significant morbidity and mortality for populations worldwide, and produce serious disruptions in the economy and the social infrastructure. At international level, there is general consensus that exceptional measures may be acceptable in extraordinary circumstances – this includes restriction of some fundamental rights. The World Health Organization (WHO), for example, says that “International human rights principles stress the importance of individual rights and freedoms, but make it clear that these freedoms can be restricted when the public’s health is threatened” (WHO, 2008:36). However, any such measures should be “[...] reasonable, proportional, equitable, non-discriminatory, and in full compliance with national and international laws” (WHO, 2007:3).

The **Siracusa Principles** (UN Commission of Human Rights 1984) describe the general circumstances in which human rights may be restricted in the interests of a public health objective. These particularly highlight the following conditions:

- The restriction must be provided for and carried out in accordance with the law;
- The restriction must be in the interest of a legitimate objective of general interest;
- The restriction must be strictly necessary in a democratic society to achieve the objective;
- There must not be any less intrusive and restrictive means available to reach the same objective;
- The restriction must not be drafted or imposed arbitrarily, that is, in an unreasonable or otherwise discriminatory manner.

From the above, it is evident that although ethical principles and fundamental human rights provide a solid framework for the formulation of policies in the event of a public health emergency, there are occasions where the implementation of certain measures may not be in accordance with applicable human rights laws and principles, which may be compromised for the benefit of the greater good. However, it should be noted that decisions or actions may still have been informed by ethical deliberations within the context of those principles. Despite all, what should constitute an imperative for decision makers and pandemic planners is *not to ignore* fundamental human rights under the deceptive context of exceptional circumstances (Prieur, 2012).



At this point, it would be necessary to move deeper and provide more context on what constitutes fundamental human rights within the wider legislative framework of the European Union, with the aim to put into perspective those principles and human rights most likely to be challenged in situations of pandemics or any public health emergency. It is important to note that the European legislative and policy framework is itself grounded in the underlying European principles and values, so inevitably legal and ethical considerations converge in this case.

There are two main documents that set out the fundamental human rights framework in Europe: (1) the **Charter of Fundamental Rights of the European Union** (CFREU), and (2) the **European Convention on Human Rights** (ECHR). The next section briefly discusses those articles of the CFREU and the ECHR which are most likely to be relevant in the midst of a pandemic event or generally, an international public health emergency, and further draws attention to other international policy instruments which makes explicit reference to fundamental rights in a healthcare context.

2.1 The EU Fundamental Rights Framework

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. Its roots can be traced back in the UN Universal Declaration of Human Rights, which was adopted and proclaimed by the UN General Assembly in 1948, and the European Convention on Human Rights (ECHR).

As mentioned in the preamble of the UN Universal Declaration of Human Rights, one of the principal aims was to recognise the “inherent dignity and [...] equal and inalienable rights of all members of the human family to freedom, justice and peace in the world”. The ECHR is an instrument of the Council of Europe adopted in 1950, which draws on the UN Universal Declaration of Human Rights and enshrines a number of human rights and civil liberties. The ECHR establishes (at Article 19) the European Court of Human Rights (ECtHR), at which individuals (or states) may ask for judgment when they feel their rights have been abused by another state bound by the ECHR.

The CFREU enshrines the human rights and civil liberties described in the ECHR, and also the economic and social rights described in the Council of Europe’s European Social Charter¹ and the European Union’s Community Charter of Fundamental Social Rights of Workers². The CFREU was formally proclaimed in 2000, and entered into force with the Lisbon Treaty of 2009, which made it legally binding. The overarching goal of the CFREU is to provide legal certainty with respect to fundamental rights in the EU. The preamble to the CFREU is worth mentioning, since it encapsulates most of what is – from the point of view of ethics and fundamental rights – important when thinking about the critical situations, questions, and dilemmas that arise in the course of a pandemic:

“Conscious of its spiritual and moral heritage, the Union is founded on the indivisible, universal values of human dignity, freedom, equality and solidarity; it is based on the principles of democracy and the rule of law. It places the individual at the heart of its activities, by establishing the citizenship of the Union and by creating an area of freedom, security and justice. [...] The Union contributes to the preservation and to the development of these common values while respecting the diversity of the cultures and traditions of the peoples of Europe as well as the national identities of the Member

¹ Council of Europe. (1996). “The European Social Charter”. Available at: <http://www.coe.int/T/DGHL/Monitoring/SocialCharter/Presentation/ESCRBooklet/English.pdf>

² European Union. (1989). “Community Charter of Fundamental Social Rights of Workers”. Available at: http://www.aedh.eu/plugins/fckeditor/userfiles/file/Conventions%20internationales/Community_Charter_of_the_Fundamental_Social_Rights_of_Workers.pdf



States and the organisation of their public authorities at national, regional and local levels; it seeks to promote balanced and sustainable development and ensures free movement of persons, goods, services and capital, and the freedom of establishment.”³

The CFREU is divided into seven chapters, each of which comprises a number of articles/fundamental rights and principles, as presented in Table 1.

Table 1: Summary of CFREU core values, fundamental rights and principles.

Charter of Fundamental Rights of the European Union (2000)		
Chapter	Core values	Fundamental rights and principles (CFREU Articles)
I	Dignity	<u>Human dignity; Right to life; Right to the integrity of the person; Prohibition of torture and inhuman or degrading treatment or punishment, prohibition of slavery and forced labour.</u>
II	Freedoms	<u>Right to liberty and security; Respect for private and family life; Protection of personal data; Right to marry and found a family; Freedom of thought, conscience and religion; Freedom of expression and information; Freedom of assembly and association; Freedom of the arts and sciences; Right to education; Freedom to choose an occupation and the right to engage in work; Freedom to conduct a business; Right to property; Right to asylum; Protection in the event of removal, expulsion or extradition.</u>
III	Equality	<u>Equality before the law; Non-discrimination, Cultural, religious and linguistic diversity; Equality between men and women; Rights of the child; Rights of the elderly; Integration of persons with disabilities.</u>
IV	Solidarity	Workers’ right to information and consultation within the undertaking; Right of collective bargaining and action; Right of access to placement services; Protection in the event of unjustified dismissal; Fair and just working conditions; Prohibition of child labour and protection of young people at work; Family and professional life; Social security and social assistance; <u>Health care</u> ; Access to services of general economic interest; Environmental protection; Consumer protection.
V	Citizens’ Rights	Right to vote and stand as a candidate at elections to the European Parliament and at municipal elections; Right to good administration; Right of access to documents; Ombudsman; Right to petition; Freedom of movement and residence; Diplomatic and consular protection.
VI	Justice	Right to an effective remedy and a fair trial; Presumption of innocence and the right of defence; Principles of legality and proportionality of criminal offences and penalties; Right not to be tried or punished twice in criminal proceedings for the same criminal offence.
VII	General Provisions	Scope; Scope of guaranteed rights; Level of protection; Prohibition of abuse of rights.

³ European Union. (2000). “Charter of Fundamental Rights of the European Union”. *Official Journal of the European Communities*, 2000/C 364/01; preamble. Available at: <http://www.europarl.europa.eu/charter/pdf/text_en.pdf>



Not all fundamental rights and principles listed above are directly relevant or could apply to a pandemic situation and generally, any large-scale public health emergency. In the following pages are presented and briefly discussed those CFREU articles which are crucial to take under careful consideration in the preparedness and response phase of a pandemic.

Chapter I – Dignity

Human dignity

Article 1 of the CFREU proclaims that human dignity is “inviolable” and “must be respected and protected”. Dignity is at the heart of the European fundamental rights framework. The official “Explanations Relating to the Charter Of Fundamental Rights” declare that “dignity of the human person is not only a fundamental right in itself but constitutes the real basis of fundamental rights” (p. 1).⁴

As the core of the European fundamental rights framework, dignity is central to all aspects of pandemic preparedness and response.

Right to life

Article 2 - Paragraph 1, secures the right to life. It should be noted that due to the fact that the “meaning and scope” of the rights contained in the CFREU is (through Article 52 Paragraph 3) “the same as” the corresponding rights contained in the ECHR, the following aspects of the ECHR (Article 2) must also be taken into account:

Deprivation of life shall not be regarded as inflicted in contravention of this Article when it results from the use of force which is no more than absolutely necessary:

- (a) in defence of any person from unlawful violence;
- (b) in order to effect a lawful arrest or to prevent the escape of a person lawfully detained;
- (c) in action lawfully taken for the purpose of quelling a riot or insurrection.

In situations of public health emergencies and pandemics, some decisions may be taken (perhaps only indirectly or unintentionally) which endanger life. An infectious disease outbreak may require from authorities to enforce quarantine measures on people in full awareness of the threat such a decision could pose to certain individuals or small communities, especially in the absence of any immediate plans for intervention. In the case of public health emergencies, Article 2 of the CFREU is closely associated with Article 35, i.e. the right of access to health care and medical treatment.

Right to the integrity of the person

Article 3 is also important in relation to public health emergencies. Paragraph 1 assures everyone’s “right to respect for his or her physical and mental integrity”. Paragraph 2 demands that in the fields of medicine and biology, “the free and informed consent of the person concerned, according to the procedures laid down by law” must be respected.

There are different possible interpretations of “integrity”. Integrity of a person is linked to dignity, but also to the values of autonomy and privacy. Specifically in the case of autonomy and privacy, it is not difficult to see how threats to integrity could occur at various phases of a pandemic (e.g. mandatory vaccination, or sharing of personal or medical data).

⁴ European Union. (2007). “Explanations Relating to the Charter Of Fundamental Rights”. *Official Journal of the European Communities*, 2007/C 303/02. Available at: <<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2007:303:0017:0035:en:PDF>>



Prohibition of torture and inhuman or degrading treatment or punishment

Article 4 is of interest here mainly with respect to inhuman and especially, degrading treatment. In a public health emergency there may be cases where compulsory medical procedures are implemented for individuals, such as mandatory vaccination or screening tests. Under all circumstances, individuals must be treated with respect and not become subject to humiliation or be submitted to enforced treatment, if they have not provided any kind of consent.

Chapter II – Freedoms

Right to liberty and security

Article 6 corresponds to Article 5 of the ECHR, and is highly relevant in the case of public health emergencies. That article describes certain limitations to the right to liberty (including lawful detention after conviction by a competent court; lawful detention on reasonable suspicion of having committed an offence, and so on). These limitations include an explicit reference to the situation of an infectious disease outbreak:

No one shall be deprived of his liberty save in the following cases and in accordance with a procedure prescribed by law:

[...]

(e) the lawful detention of persons for the prevention of the spreading of infectious diseases [...].

Detention or restriction of liberty (movement) could then be consistent with Article 6 of the CFREU, if such detention is lawfully done in order to contain an infectious disease.

Respect for private and family life

Article 7 protects the “right to respect for [...] private and family life, home and communications”. The reference to communication is interesting and important in the context of pandemics, since informal surveillance via monitoring of social networks is a potentially useful tool which increasingly receives more attention by public health authorities in response to an infectious disease outbreak.

At first instance, the question to raise is whether or not posts, tweets or updates on social media constitute communication per se, however it certainly entails the provision of information, even if unilateral. In any case, any kind of information that is communicated by a person should be evaluated of its purpose and whether the intention is to reach a specific audience.

A second point is to note that Article 8 Paragraph 2 of the ECHR runs as follows: “There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic wellbeing of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.” Thus, in a situation of a public health emergency, public health authorities may be justified in not respecting privacy of communication, especially in circumstances where there is a threat for national security, public safety, and the economic well-being of the country.

Protection of personal data

Article 8 affirms the right to data protection. The official “Explanations Relating to the Charter Of Fundamental Rights” make explicit that the Article on protection of personal data is based on the European Data Protection Directive (95/46/EC) which sets out general rules on the lawfulness of the processing of personal data and is,



therefore, subject to the same restrictions as the latter Directive⁵. These include public security, defence, State security (including economic well-being), and criminal matters (cf. 95/46/EC Article 3, Paragraph 2).

It should be noted that in 2012 the European Commission proposed a comprehensive reform of the existing data protection rules with the introduction of the General Data Protection Regulation (GDPR), which aims at strengthening online privacy rights for EU citizens. The proposed Regulation has received criticism that it conflicts with other non-European laws, regulations and practices (e.g. surveillance by governments).

Freedom of thought, conscience and religion

Article 10 could be particularly relevant in a public health emergency or pandemic, if an individual's beliefs or communities' customs are at odds with protective measures and recommendations put forward by health authorities (e.g. refusal to vaccinate on ideological or religious grounds, burial practices, etc.). According to the corresponding Article of the ECHR (Article 9), this right is subject to possible limitation "in the interests of public safety, for the protection of public order, health or morals, or for the protection of the rights and freedoms of others".

Freedom of expression and information

Article 11 protects, inter alia, the freedom and pluralism of the press and media. The corresponding Article of the ECHR (Article 10) states: "The exercise of these freedoms, since it carries with it duties and responsibilities, may be subject to such formalities, conditions, restrictions or penalties as are prescribed by law and are necessary in a democratic society, in the interests of national security, territorial integrity or public safety, for the prevention of disorder or crime, for the protection of health or morals, for the protection of the reputation or rights of others, for preventing the disclosure of information received in confidence, or for maintaining the authority and impartiality of the judiciary."

But it is to be noted that such restrictions as may be necessary in the event of a public health emergency are highly likely to be already catered for in existing law. Any further restrictions of the right to freedom of expression and information that surpass existing law would be highly controversial.

Freedom of the arts and sciences

Article 13 declares that scientific research should be free of any constraints. This Article protects the right of academics to conduct and publish scientific research studies, and specifically in the case of pandemics, protects the right of scientists to work for the development of vaccines. A sensitive issue concerns the publication of scientific studies with dual-use potential (i.e. research pursued for scientific and peaceful purposes could also be used in warfare or terrorism), which has been a source of controversy even within the scientific community circles. Academic freedom should be respected, but it may be necessary to strike an appropriate balance between public safety and respect for rights.

Chapter III – Equality

Articles 20-26 of the CFREU can be discussed together. Collectively these Articles declare that everyone is equal before the law (Article 20) and that there should be no "discrimination based on any ground such as sex, race,

⁵ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. Available at: <<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31995L0046&from=en>>



colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation” (Article 21; Article 23 as regards gender equality) – cultural, religious and linguistic diversity are to be respected (Article 22); the rights of children (Article 24) and the elderly (Article 25) are affirmed; as is the integration of persons with disabilities (Article 26).

These rights could be threatened in situations of a public health emergency, especially in the case of the most vulnerable groups of societies, such as ethnic, religious and linguistic minorities whose needs may not receive the same level of attention or access to resources may be limited.

Chapter IV – Solidarity

The fundamental rights contained in Chapter IV relate to employment, professional life, the family, welfare, and consumers. Article 35 (Health care) is the most relevant to discuss for situations of public health emergencies.

Health care

Article 35 (Health care) gives everyone “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”. This provision is relevant in situations of major infectious disease outbreaks, where hospitals and emergency services run to capacity as an increasing number of patients need to be admitted to hospitals to receive care. This also suggests possible implications in terms of provision of vaccines and more generally, provision of emergency healthcare provision. The Article therefore has serious implications for the preparedness phase of a pandemic.

Chapter V – Citizens’ Rights

The Articles in Chapter V of the CFREU are not specifically applicable to public health emergencies or pandemics.

Chapter VI – Justice

The Articles in Chapter VI of the CFREU are not specifically applicable to public health emergencies or pandemics.

Chapter VI – General Provisions

The Articles in Chapter VII of the CFREU are not specifically applicable to public health emergencies or pandemics.



2.2 Human Rights in the Medical and Healthcare Context

WMA Declaration of Lisbon on the Rights of the Patient (1981)

As already mentioned, the Charter of Fundamental Rights of the European Union (CFREU) and the European Convention on Human Rights (ECHR) constitute the primary legal instruments at European level. Both the CFREU and the ECHR set out fundamental rights and principles in a wide policy framework, however there are only a few direct references to public health related issues. In an effort to provide more substance on those fundamental rights from a medical perspective and for the purposes of the present report, it is important to draw attention to the WMA Declaration of Lisbon on the Rights of the Patient (WMA, 1981)⁶, which touches upon many of the fundamental rights and freedoms discussed earlier in the context of the CFREU, under the lens of medical ethics and within the broader healthcare context from the patients' perspective. It is evident that some of the principles and provisions set out in the WMA Declaration of Lisbon also correspond to Articles from the CFREU (see Table 2).

Table 2: Key principles and provisions set out in the WMA Declaration of Lisbon (1981) and correspondence to Articles from the Charter of Fundamental Rights of the European Union.

Principle	Key provisions	Relevant CFREU Article(s)
Right to medical care of good quality	<ul style="list-style-type: none"> Every person is entitled to appropriate medical care without discrimination. The patient should always be treated in accordance with his/her best interests. The treatment applied shall be in accordance with generally approved medical principles. 	Article 21 Article 35
Right to self-determination	<ul style="list-style-type: none"> The patient has the right to self-determination, to make free decisions regarding himself. The physician will inform the patient of the consequences of his/her decisions. A mentally competent patient has the right to give or withhold consent to any diagnostic procedure or therapy. The patient has the right to the information necessary to make his/her decisions. The patient should understand clearly what is the purpose of any test or treatment, what the results would imply, and what would be the implications of withholding consent. 	Article 3 Article 4
The legally incompetent patient	<ul style="list-style-type: none"> If a patient is a minor or otherwise legally incompetent, the consent of a legally entitled representative is required in some jurisdictions. Nevertheless the patient must be involved in the decision-making to the fullest extent allowed by his/her capacity. If the legally incompetent patient can make rational decisions, his/her decisions must be respected, and he/she has the right to forbid the disclosure of information to his/her legally entitled representative. If the patient's legally entitled representative, or a person authorized by the patient, forbids treatment which is, in the opinion of the physician, in 	Article 21 Article 24

⁶ The World Medical Association (WMA) is a global decision-making body that produces policies in the form of Declarations, Statements and Resolutions, relevant to fundamental rights and ethical issues, within the medical and healthcare context. These policies function as normative codes and lack enforcement authority.



	<i>the patient's best interest, the physician should challenge this decision in the relevant legal or other institution. In case of emergency, the physician will act in the patient's best interest.</i>	
Procedures against the patient's will	<ul style="list-style-type: none"> • <i>Diagnostic procedures or treatment against the patient's will can be carried out only in exceptional cases, if specifically permitted by law and confirming to the principles of medical ethics.</i> 	Article 3 Article 4
Right to information	<ul style="list-style-type: none"> • <i>The patient has the right to receive information about himself/herself recorded in any of his/her medical records, and to be fully informed about his/her health status including medical facts about his/her condition.</i> • <i>Exceptionally, information may be withheld from the patient when there is good reason to believe that this information would create a serious hazard to his/her life or health.</i> • <i>Information should be given in a way appropriate to patient's culture and in such a way that the patient can understand.</i> • <i>The patient has the right not to be informed on his/her explicit request, unless required for the protection of another person's life.</i> • <i>The patient has the right to choose who, if anyone, should be informed on his/her behalf.</i> 	Article 8
Right to confidentiality	<ul style="list-style-type: none"> • <i>All identifiable information about a patient's health status, medical condition, diagnosis, prognosis and treatment and all other information of a personal kind must be kept confidential, even after death. Exceptionally, descendants may have a right of access to information that would inform them of their health risks.</i> • <i>Confidential information can only be disclosed if the patient gives explicit consent or if expressly provided for in the law. Information can be disclosed to other health care providers only on a strictly "need to know" basis unless the patient has given explicit consent.</i> • <i>All identifiable patient data must be protected. The protection of the data must be appropriate to the manner of its storage. Human substances from which identifiable data can be derived must be likewise protected.</i> 	Article 8
Right to dignity	<ul style="list-style-type: none"> • <i>The patient's dignity and right to privacy shall be respected at all times in medical care and teaching, as shall his/her culture and values.</i> • <i>The patient is entitled to relief of his/her suffering according to the current state of knowledge.</i> • <i>The patient is entitled to humane terminal care and to be provided with all available assistance in making dying as dignified and comfortable as possible.</i> 	Article 1 Article 6 Article 7 Article 21
Right to religious assistance	<ul style="list-style-type: none"> • <i>The patient has the right to receive or decline spiritual and moral comfort including the help of a minister of his/her chosen religion.</i> 	Article 10 Article 22

It is evident from the above that fundamental rights become yet more solid and substantial in the appropriate context, i.e. the healthcare context in this case. It is important to highlight the relevance of these fundamental rights and principles in the event of a pandemic, where a large proportion of people may be at risk to become infected and consequently, become patients.



WHO International Health Regulations (2005)

In 2005, the World Health Organisation adopted and released at the 58th World Health Assembly, a revised version of the International Health Regulations (IHR), which provided guidance for Member States to assess and manage serious health threats with a potential to spread beyond borders (WHO, 2005). In Article 3 of the IHR, it is clearly stated that “implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of all persons” (p. 10)⁷. This is unlike the previous version of the IHR that was solely concerned with restrictions on trade and not on restrictions of individual rights (Gostin, 2004). The revised version of the IHR makes explicit reference to fundamental rights and principles throughout the text. For instance, Article 42 states that implementation of health measures shall be “[...]applied in a transparent and non-discriminatory manner” (p. 28). Article 23 puts emphasis on the need for public health authorities to first obtain an informed consent from international travellers, before any protective measures (e.g. medical examination, vaccination) or restrictive measures (e.g. isolation) are implemented to individuals, except in circumstances where there is evidence of an “imminent public health risk”, as mentioned in Article 30. It is also stated that public health authorities should carry out “[...] the least intrusive and invasive examination that would achieve the public health objective of preventing the international spread of disease” (p. 20).

Moreover, the Regulations state clearly in Article 32 that travellers must be treated with respect for their dignity, human rights and fundamental freedoms, and minimise any discomfort or distress associated with implemented health measures. According to the Regulations, the following conditions must be respected for the treatment of travellers (p. 24):

- (a) treat all travellers with courtesy and respect;
- (b) take into consideration the gender, socio-cultural, ethnic or religious concerns of travellers;
- (c) provide or arrange for [...] appropriate medical treatment, means of necessary communication if possible in a language that they can understand and other appropriate assistance for travellers who are quarantined, isolated or subject to medical examinations or other procedures for public health purposes.

The Regulations also provide some protection as to confidentiality and lawful use of personal data collected under the IHR (Article 45).

Differently to the CFREU and the ECHR – or even the WMA Declaration of Lisbon to a certain extent – the IHR touch upon, but only make a superficial approach, to fundamental rights issues, and do not provide clear guidance as to how these could be safeguarded in actual situations of a public health emergency. Nonetheless, the references made to specific human rights and fundamental freedoms throughout the document offer insight as to which of those issues link back to certain provisions of the CFREU and ECHR and thus, are important to address in the context of public health emergencies or pandemics.

In sum, the IHR as a legal instrument, explicitly requires that the following fundamental human rights and principles are respected, in accordance with what has been presented already:

- Right to dignity
- Right to confidentiality and privacy

⁷ It should be noted that the Constitution of the World Health Organization had been the first international instrument to enshrine the enjoyment of the highest attainable standard of health as a fundamental right of every human being (“the right to health”), without distinction of race, religion, political belief, economic or social condition (WHO, 1946).



- Right to protection of personal data
- Right to access to medical care
- Right to self-determination (Informed consent to treatment)
- Right to equal treatment (Non-discrimination)

Universal Declaration on Bioethics and Human Rights (2006)

In October 2005, the General Conference of UNESCO adopted by acclamation the Universal Declaration on Bioethics and Human Rights (2006). This Declaration aims to provide a universal framework of principles and procedures to be respected with regards to ethical issues in the field of medicine, life sciences and associated technologies as applied to human beings. This Declaration is based on a *rights-based ethics* approach⁸ and demonstrates how transversal some principles are in the broader medical and healthcare context. Furthermore, it is important since it makes reference both to fundamental human rights and key ethical issues which are absolutely relevant in situations of a large-scale public health emergency, such as pandemics. The most relevant articles have been selected to be presented from the Universal Declaration on Bioethics and Human Rights (See Table 3), which reflect for the most part the provisions set out in the CFREU and the ECHR.

Table 3: Description of Articles from the Universal Declaration on Bioethics and Human Rights (2006).

Article	Principle (Article title)	Description
Article 3	Human dignity and human rights	<ul style="list-style-type: none"> • <i>Human dignity, human rights and fundamental freedoms are to be fully respected.</i> • <i>The interests and welfare of the individual should have priority over the sole interest of science or society.</i>
Article 4	Benefit and harm	<ul style="list-style-type: none"> • <i>In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximised and any possible harm to such individuals should be minimised.</i>
Article 5	Autonomy and individual responsibility	<ul style="list-style-type: none"> • <i>The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.</i>
Article 6	Consent	<ul style="list-style-type: none"> • <i>Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.</i> • <i>Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned.</i>

⁸ As suggested by its name, rights-based ethics attempts to ground its principles not in philosophic or medical tradition, but in human rights, particularly those that have been agreed upon in international conventions. This would suggest that the stated principles are not vague ethical obligations but rather binding legal rights.



Article 8	Respect for human vulnerability and personal integrity	<ul style="list-style-type: none"> <i>In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.</i>
Article 9	Privacy and confidentiality	<ul style="list-style-type: none"> <i>The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.</i>
Article 10	Equality, justice and equity	<ul style="list-style-type: none"> <i>The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.</i>
Article 11	Non-discrimination and non-stigmatisation	<ul style="list-style-type: none"> <i>No individual or group should be discriminated against or stigmatised on any grounds, in violation of human dignity, human rights and fundamental freedoms.</i>
Article 12	Respect for cultural diversity and pluralism	<ul style="list-style-type: none"> <i>The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, not to limit their scope.</i>
Article 13	Solidarity and cooperation	<ul style="list-style-type: none"> <i>Solidarity among human beings and international cooperation towards that end are to be encouraged.</i>
Article 14	Social responsibility and health	<ul style="list-style-type: none"> <i>The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.</i> <i>[...] progress in science and technology should advance access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good; [...]</i>

Following the identification and reflection on the fundamental human rights presented in policy-related documents at international level, the report continues to identify and explore further substantial considerations that arise in the event of major infectious disease outbreaks and pandemics, from both an ethical and societal perspective, since decisions for action often need to be based on the moral codes, norms and principles set out by individuals or societies at large.

3. ETHICAL ISSUES AND CONSIDERATIONS IN PANDEMICS

Prior to the identification and analysis of ethical issues and considerations which are pertinent in different phases of pandemic event, it would be important to take under consideration the dynamic relationship that exists between ethical principles and fundamental human rights, which at core constitute two distinct systems at the level of decision-making in situations of public health emergencies, despite the fact that these systems are very similar in substance.



In general terms, ethical norms and moral considerations determine how one ought to behave and act in order to show due respect to others in accordance with what is *good* and what is *right* on the basis of a set of moral values and principles which are endorsed by the society at large. In other words, ethical norms and moral considerations construct a conceptual, yet robust, framework of guiding principles and values which need to be respected by individuals to ensure cohesion within a community. Many of these values and principles, such as respect for dignity, autonomy and non-discrimination, commonly apply to different cultures and societies across Europe. This provides an appropriate context and form the basis for the eventual incorporation of ethical norms and principles into a broader policy framework, such as the case of the Charter of Fundamental Rights of the European Union (CFREU). This is an international legal instrument that conceptually encodes and mirrors shared values and principles which at the very end, are representative of the European ethos. Thus, it is apparent that ethical norms have a prominent role and require to receive much attention since the European policy framework is itself grounded in a wider European ethical framework.

It should be noted that in the preparedness and response phase of public health emergencies, ethical considerations and decision-making implications extend far beyond the provisions and principles set out in legal instruments, which in many occasions can be open to interpretations and cannot possibly cover all ethical implications raised at local, national and international level. Conflicting interests, contextual parameters and critical questions that arise in the course of an outbreak, necessitates the identification and analysis of the various ethical considerations and implications at different phases of a pandemic. The WHO report “Ethical Considerations in Developing a Public Health Response to Pandemic Influenza” (WHO, 2007), presents five general ethical considerations for different phases of a pandemic, which require decision-makers attention. These ethical considerations point toward the direction of a number of procedural and substantive values which are presented and discussed next.

1. **Balance rights, interests & values** – Competing claims based on different principles must be evaluated through ethical deliberations designed to reach appropriate decisions, which, if they infringe on individual liberties, “must be necessary, reasonable, proportional, equitable, non-discriminatory, and legal”.
2. **Use best available evidence, but remain flexible** – Because little may be known for certain about a pandemic in its early phases, judgments about public health measures must be made based on their likely effectiveness and benefits, but they must also be constantly re-evaluated in light of new evidence.
3. **Seek transparency, public engagement & social mobilization** – All aspects of planning should involve relevant stakeholders, and “[policy decisions and their justifications should be publicized and open to public scrutiny]” in order to foster public awareness, confidence, assent, feedback on local conditions, trust, legitimacy and compliance.
4. **Inform, educate & communicate** – Advance planning is needed to develop strategies to reach the entire population in linguistically and culturally appropriate ways during all phases of pandemic preparedness and response (and especially to enable public participation in policy development, and public understanding both of the risks related to pandemic spread, and of the individual and collective measures that are justified and appropriate to respond to those risks).
5. **Justify resource constraints and allocations** – Although what counts as “reasonable efforts to prepare” for a pandemic will vary according to the available resources and competing health priorities in any specific country, difficult allocation decisions (including contributions to the international cooperation necessary to overcome resource constraints in developing countries) should be informed by public engagement processes and have clearly communicated rationales.



3.1 Procedural and substantive values

As already discussed, any kind of a public health emergency can potentially raise a number of ethical considerations and produce situations where public health officials and healthcare professionals are required to take action outside the boundaries of an already established policy framework, and make certain decisions which will be based on ethical codes and principles instead⁹. There is a number of ethical values and principles that can inform decisions in the event of a public health emergency, whose importance may vary according to situational or contextual factors in the event of a pandemic. On broad terms, ethical values can be divided into two categories in the frame of pandemics: *substantive* and *procedural* values. The substantive values are those which inform *what decisions to make*, whereas the procedural values are those which inform *how to make decisions*. Typically, the **procedural values** that guide ethical decision-making in the event of a public health emergency are:

- Be open and transparent
- Be inclusive
- Be reasonable
- Be responsive
- Be accountable

Table 4 presents descriptions for each of the five procedural values, on the basis of information retrieved from reports published the Pandemic Influenza Working Group from the Joint Centre for Bioethics at the University of Toronto (JCB, 2005) and the National Ethics Advisory Committee of New Zealand (NEAC, 2007). It is important to note that the UK Department of Health in the document “Responding to Pandemic Influenza: The Ethical Framework for Policy and Planning” (UK Department of Health, 2007) considers these procedural values as components of a core ethical value, which is *good decision-making*.

Table 4: Description and actionable recommendations of procedural values in pandemics.

Procedural value	Pandemic Influenza Working Group	National Ethics Advisory Committee
Open and transparent	<i>The process by which decisions are made must be open to scrutiny, and the basis upon which decisions are made should be publicly accessible.</i>	<ul style="list-style-type: none"> • <i>Let others know what decisions need to be made, how they will be made and on what basis they will be made</i> • <i>Let others know what decisions have been made and why</i> • <i>Let others know what will come next</i> • <i>Be seen to be fair</i>
Inclusive	<i>Decisions should be made explicitly with stakeholder views in mind, and there should be opportunities to engage stakeholders in the decision-making process.</i>	<ul style="list-style-type: none"> • <i>Include those who will be affected by the decision</i> • <i>Include people from all cultures and communities</i> • <i>Take everyone’s contribution seriously</i>

⁹ There are three principal ethical theories in the tradition of Western philosophy, which provide an ethical framework within which decisions are made under different circumstances in the context of public health emergency. These ethical approaches are: (a) the *virtue ethics* approach, (b) the *deontological* approach, and (c) the *consequentialist* approach. Broadly speaking, *virtue ethics* stresses the importance of one’s character and the virtues that one’s character embodies for determining or evaluating ethical behaviour, the *deontological approach* judges the morality of an action based on the action’s adherence to a set of rules, and the *consequentialist approach* holds that the rightness of an action is absolutely to be judged according to its consequences.



<p>Reasonable</p>	<p><i>Decisions should be based on reasons (i.e., evidence, principles, and values) that stakeholders can agree are relevant to meeting health needs in a pandemic influenza crisis. The decisions should be made by people who are credible and accountable.</i></p>	<ul style="list-style-type: none"> • <i>Work with alternative options and ways of thinking</i> • <i>Work with and reflecting cultural diversity</i> • <i>Use a fair process to make decisions</i> • <i>Base decisions on shared values and best evidence</i>
<p>Responsive</p>	<p><i>There should be opportunities to revisit and revise decisions as new information emerges throughout the crisis. There should be mechanisms to address disputes and complaints.</i></p>	<ul style="list-style-type: none"> • <i>Be willing to make changes and be innovative</i> • <i>Change when relevant information or the context changes</i> • <i>Enable others to contribute whenever they can</i>
<p>Accountable</p>	<p><i>There should be mechanisms in place to ensure the decision makers are answerable for their actions and inactions.</i></p>	<ul style="list-style-type: none"> • <i>Act on our responsibility to others of our decisions and actions</i> • <i>Help others to take responsibility for their decisions and actions</i>

In brief, the procedural (ethical) values and principles that should be respected and applied in the process of decision-making for balancing and restricting rights can be summarised in the form of actionable recommendations, as follows:

- **Proportional, evidence-based, accountable decision-making.** As far as possible, decisions should be taken on the basis of solid, reliable evidence. Restrictions of rights should be proportional to the risks those restrictions are intended to mitigate. Where reliable evidence (e.g. risk assessment or situational awareness) is not available, this should be acknowledged. Decision-making processes should have clear lines of accountability so that the rationale for any decision can be examined afterwards.
- **Fairness, Impartiality, Neutrality, Non-discrimination.** Decisions should be, and be seen to be, fair, equitable, impartial, and non-discriminatory. Some decisions may be, in certain senses, unfair (e.g. prioritising one group over another), so as far as possible such prioritising should be planned and established in advance. Once planned and established, decisions taken within that framework should be, and be seen to be, fair, equitable, impartial, and non-discriminatory.
- **Inclusiveness, participation, and shared-values-based decision-making.** Decisions that can be taken in advance of an event should be informed by a wide base of those people and communities likely to be affected by them. Everyone's contribution should be taken seriously. Decision-making should be guided by the shared values of a society. It is important that people who do not agree with a decision, are nonetheless supportive of the method by which that decision was arrived at.
- **Responsiveness and Flexibility.** Decision-making procedures should be flexible enough to be able to respond to whatever circumstance might arise. Plans should be revisable in the light of emerging factors and information. Yet the grounds on which plans will be revised, and the principles and shared values that will guide the revisions, should be clear in advance to all stakeholders.

These procedural values comprise a collection of guiding principles – in the form of actionable recommendations – which should be incorporated into national pandemic preparedness plans, and be already in place before a pandemic event occurs. It should be noted that procedural values are not only relevant to public health emergencies, but rather are representative and key components of good governance from the side of the authorities, which contribute to cultivate a relationship of trust and credibility with the general public.



Besides the procedural values, there are also the **substantive values**, which can be described as criteria or principles that inform and guide the decision-making process to do the right thing. This suggests that substantive values are crucial to consider during different phases of a public health emergency where a timely decision has to be made. The Joint Centre for Bioethics Working Group at the University of Toronto (JCB, 2005) identifies ten substantive values which are critical in pandemic preparedness planning.

Individual liberty

Some restrictions to individual liberties (i.e. personal autonomy and freedom) may be necessary to apply in order protect the public from serious harm in the event of a public health emergency. Nonetheless, competent authorities need to ensure that any restrictions are proportional and absolutely necessary, while alternative ways to mitigate the impact of restrictive measures need to be identified for clinicians to act in their patients interests (Lo and Katz, 2005). In addition, any restrictions of individual liberties should apply equitably to people.

Duty to provide care

Healthcare professionals and workers have the duty to provide care, protection and support in public health emergencies. It is the responsibility of healthcare providers to weigh demands of their roles against other against other competing obligations to their own health, and to family and friends. There is a broad spectrum of duties and responsibilities that healthcare providers may need to respond, ranging from resource allocation to workplace conditions. According to Clark (2005), healthcare providers have a duty to provide care in the context of an infectious disease outbreak for the following reasons: (a) the ability of physicians and healthcare professionals to provide care is greater than that of the public, thus increasing the obligation to provide care, (b) by freely choosing a profession devoted to care of the ill, healthcare professionals have assumed the risk, (c) the profession is legitimated by social contract and therefore its members should be available in times of emergency.

Privacy

In many ways, preparedness for and response to public health emergencies, and pandemics in particular, can pose a threat to privacy. Any such threats should be proportionate to the gains reasonably likely to arise. If personal information is required to be disclosed in the context of the emergency, this should be relevant to achieve legitimate and necessary public health goals. It should be determined whether the good that is intended is significant enough to justify the potential harm that can derive from suspending privacy rights (Thompson et al, 2006). Surveillance should be as discreet and targeted as possible in order to gather the minimum amount of personal data necessary to inform a decision.

Protection of the public from harm

Should there be a need for competent authorities to apply restrictions to individual liberties, decision makers should reflect on the imperative for compliance and provide reasons for public health measures to encourage compliance. It is important to consider the potential harm arising from pandemic control strategies, such as the decision to proceed with mass vaccination in the absence of substantial evidence about the predicted risk-benefit ratio.

Proportionality

Interventions made in the name of safety and security in the event of a public health emergency should be proportionate to the risks. When rights are compromised, the imposed burden on individuals should be proportionate to the security need. Any intervention should be necessary, likely to be effective and efficient, and fairly imposed. It is essential to recognise that judgements of what is proportional should be



informed by risks and threat levels and that these will vary at the different phases of a pandemic event. The principle of proportionality requires that the least intrusive means possible is used (Singer et al, 2003).

Reciprocity

Societies have an ethical responsibility to support those who face a disproportionate burden in protecting the public good. Typically, it is the healthcare providers who have heavier responsibilities and may be due extra support, but should also consider the need to support patients and vulnerable members of a society.

Equity

The principle of equity holds that all patients have an equal claim to receive needed health care. During a pandemic, there are difficult decisions that need to be made about which health services to maintain and which to defer because of extraordinary circumstances. Nonetheless, all efforts should be made to ensure that patients receive treatment in a fair and non-discriminatory manner. Decision-makers must strive to preserve as much equity as possible between the interests of patients and those who need urgent treatment for other diseases (Thompson et al, 2006).

Trust

Procedural ethical values such as openness, transparency, responsiveness and accountability contribute to the development of trust between different actors involved in the event of a pandemic. In particular, trust is an essential part of the relationship between government and citizens, between health care workers and patients, between organizations and their staff, between the public and health care workers, and among organizations within a health system.

Solidarity

The necessity for nations to develop a sense of solidarity at international level, is more evident than ever. Pandemics can materialise into a world threat and challenge conventional ideas of national sovereignty, security or territoriality. Within societies, representative community actors and organisations should join forces to increase resilience and collectively protect fundamental rights of the most vulnerable groups in society.

Stewardship

Those entrusted with governance should be guided by the notion of stewardship, which includes protecting and developing one's resources, and being accountable for public well-being. Also inherent in stewardship are the notions of trust, ethical behaviour and good decision-making. It is the responsibility of decision makers to avoid and/or reduce collateral damage that may result from resource allocation decisions, and protect and develop resources where possible.

It is essential to note that both substantive and procedural values cannot be ranked according to their level of importance, as they all need to be taken into serious consideration, on equal terms, when it comes to decision making. However, it is the *relative* importance of each value that may shift according to contextual or situational factors in the course of a public health emergency, so more attention may be given on how to safeguard one value over another, within the wider policy and legislative framework. Perhaps, a more critical question to address concerns the way in which different values and principles should be balanced against one another to reach to a decision, should they be in tension at any point. For example, decisions may have to be taken by public health authorities on whether to place at risk the lives of health care workers in order to save the lives of others. The



question of what would be an acceptable level of risk to expose health care workers to is, at least in part, the question of how to balance health care workers' rights against the rights of individuals of the same community.

Similarly, decisions may have to be made on whether to prioritise resources in such a way as to benefit a particular group of individuals at the possible expense of another. In other cases, interventions may be imposed, which restrict civil liberties (e.g. isolation, quarantine etc), and such decisions can be seen as involving either the restriction of one of a person's rights to secure another of that person's rights (e.g. the right to freedom of association may be restricted in order to ensure the right to security), or the restriction of some people's rights to ensure the rights of other people. Such decisions are likely to raise controversies and should receive particular attention. As described earlier, such decisions which involve the balancing of rights – in effect, the restriction of rights – should be taken in accordance with the Siracusa Principles (UN Commission on Human Rights 1984). Nonetheless, it should be noted that the Siracusa Principles describe when it is acceptable to restrict rights, not which rights should be restricted in any given scenario.

3.2 Areas of ethical tension in pandemic events

Further to the identification and analysis of the most important values and principles that provide an ethical framework for decision-making in public health emergencies, this section takes a step closer to discuss areas of tension and specific ethical concerns which may surface from the onset of a pandemic, and can have a major influence on the implementation of a public health response at later phases. More specifically, this section presents the following issues from an ethical perspective:

- **Restriction of personal freedoms**
- **Duty to provide care in pandemics**
- **Priority setting and resource allocation**
- **International cooperation and global governance**

Restriction of personal freedoms

Restriction of personal freedoms	
Procedural values (<i>most applicable</i>)	Substantive values (<i>most applicable</i>)
<ul style="list-style-type: none"> • Be open and transparent • Be inclusive • Be reasonable • Be responsive • Be accountable 	<ul style="list-style-type: none"> • Liberty • Protection from public harm • Proportionality • Privacy • Reciprocity

As discussed earlier, the restriction of personal freedoms in the alert and response phase of a pandemic is an intervention which aims to control the spread of the disease, and can take several forms, which include quarantine, isolation, border control and social-distancing measures. To avoid any ambiguities in future reference to these terms, their definitions are presented below, adapted from the 4th and 5th edition of the *dictionary of epidemiology* (Last, 2001; Porta, 2008):



Isolation: Separation, for the period of communicability, of infected persons or animals from others under such conditions as to prevent or limit the transmission of the infectious agent from those infected to those who are susceptible or who may spread the agent to others.

Social distancing¹⁰: A range of community-based measures to reduce contact between people (e.g. closing schools or prohibiting large gatherings). Community-based measures may also be complemented by adoption of individual behaviours to increase the distance between people in daily life at the work site or in other cautions (e.g. substituting phone calls for face-to-face meetings, avoiding shaking hands).

Quarantine: The restriction of the movement and activities of healthy persons or animals who have been exposed to a suspected or confirmed case of communicable disease during its period of communicability (i.e., contacts) to prevent disease transmission during the incubation period if infection should occur.¹¹

Border controls: Measures that are designed to limit/control spread of infection across entry points to the country. They can include travel restrictions, entry or exit screening, reporting, health alert notices, collection and dissemination of passenger information, travel advisories or restrictions, etc.

These kinds of measures are likely to apply to individuals or entire communities on the basis of less than conclusive evidence about the infection and other epidemiological characteristics of the virus. Consequently, there is considerable potential for ethical issues to arise. Kinslaw et al. (2007) pose the question directly, i.e. *when are restrictions on personal freedom ethically justified?* In broad terms, legitimate restrictions on personal freedoms may occur if, in exercising one's freedom, one places others at risk. It is perhaps isolation and quarantine the two situations which have the most serious ethical implications as they directly impose restrictions on personal freedoms and challenge fundamental rights for citizens. Quarantine and isolation represent the tension between the interests of society in protecting and promoting the health of its citizens and the interests of individuals in civil liberties such as privacy, non-discrimination, freedom of movement, and freedom of arbitrary detention. Nonetheless, coercive public health measures such as isolation and quarantine can be legitimate when justified when balancing the public health interests of society against the freedom of the individual (Gostin et al., 2002).

Authority for isolation and quarantine should be clear and lawful, with fair procedures and criteria based on risk, and procedural mechanisms need to be in place to challenge the unjustified use of the quarantine or isolation power and make any objections to be heard (Gostin and Berkman, 2008). Moreover, requirements for mandatory liberty-limiting and social distancing interventions should be imposed only in cases in which voluntary actions seem unlikely to be effective. Any restriction of personal freedoms should be the outcome of carefully controlled research, although this may not be feasible under circumstance of a public health emergency. As specified by WHO (2008), symptomatic, potentially exposed, and non-exposed person should be treated differently since they pose different level of risk for others. Nonetheless, some individuals may be subject to some sort of intervention on the basis of suspicion rather than knowledge: "It may be necessary to employ some interventions which have little or no scientific support. The model we recommend is that of 'evidence-informed' decision-

¹⁰ It is noteworthy to mention that the definition for "social distancing" only appears in the older – 4th – version of the dictionary of epidemiology. According to the WHO *Guidelines for Humanitarian Agencies - Pandemic Influenza Preparedness and Mitigation in Refugee and Displaced Populations* (WHO, 2008), social distancing is particularly important to consider, as one of the main prevention measures for individuals and communities to reduce or delay disease caused by pandemic influenza.

¹¹ The word *quarantine* comes from the Italian *quaranta*, meaning forty, and refers to the 40 days arbitrarily (or empirically) believed to be an adequate isolation period, perhaps based on the biblical 40 days. The clinical distinction between **isolation** and **quarantine** is that isolation is the procedure for persons already sick, whereas quarantine is often applied to (apparently) healthy contacts. This has legal and ethical implications if apparently healthy persons must submit to restrictions upon their freedom to move at large in society.



making, a model that is somewhat less rigorous than ‘evidence-based’ decision making but something that has to do until more satisfactory validation becomes available.” (Kinslaw, Barrett and Levine, 2007).

As a general rule “[...] the enactment of restrictive measures should be based on the best available scientific evidence and should be exceedingly clear why particular individuals or communities are being restricted and that the criteria that justify a restriction would be equally applied to any and all individuals meeting these same criteria” (Kinslaw, Barrett and Levine, 2007). Thus, the public should be clearly informed that restrictions on personal freedom are anticipated, that these limitations may be important to the individual’s own protection, and that they are also necessary to limit the spread of disease throughout the community. In 2006, WHO organised a global consultation on addressing ethical issues in pandemic influenza planning, with four main ethical considerations and challenges identified in relation to isolation and quarantine measures implemented by public health authorities. These included:

- *Understanding viral transmission patterns:* In any outbreak, it is paramount to understand the relationship between the transmission of a virus and the effectiveness of isolation.
- *Sensitivity to circumstances:* Any policy on isolation and quarantine must consider the circumstances and conditions in which people live. For example, in societies where people live alone or detached from their families and other support mechanisms, home-based confinement could be especially burdensome.
- *Risks to cohabitants:* The decision to isolate infected persons at home may delay the spread of the virus to other households and members of the community, but, if done improperly, it may also increase the risk of infection to other household members. Public health policies should ensure that all conditions of confinement are safe and humane.
- *Need for legal authority:* Countries should evaluate their laws and, if necessary, create explicit legal authorisation for non-pharmaceutical public health measures, such as quarantine and isolation.

According to the WHO document on *Ethical Considerations in Developing Public Health Response to Pandemic Influenza* (WHO, 2007), there are several factors that need to be taken into account in the context of planning actions and measures related to the isolation or quarantine of symptomatic individuals. In particular, any isolation or quarantine measures should:

- be voluntary to the greatest extent possible; mandatory measures should only be instituted as a last resort, when voluntary measures cannot reasonably be expected to succeed, and the failure to institute mandatory measures is likely to have a substantial impact on public health;
- provide for infection control measures appropriate to each confinement context (such as hospitals, temporary shelters, or homes) in order to protect others from infection;
- ensure safe, habitable, and humane conditions of confinement, including the provision of basic necessities (food, water, clothing, medical care, etc) and, if feasible, psychosocial support for people who are confined;
- consider the development of mechanisms to address the potential financial and employment consequences of confinement
- protect the interests of household members of individuals who are isolated and treated at the household level, including recommending or providing alternative housing if living with the isolated patient is likely to put them at significant risk of illness;
- provide fair procedures for making decisions about affected individuals; in extraordinary circumstances, exceptions to normal procedural protections may be appropriate where immediate action is essential to protect the health of others, but in all cases legal recourse should be available to individuals to challenge their isolation or quarantine.



The effectiveness of quarantine measures should constantly be evaluated and monitored and there should be clear procedures for legal challenge (WHO, 2008; 2009). It should also be pointed out that different measures can be considered for the enforcement of quarantine. Mandatory quarantine measures are not necessarily effective and different countries have applied different enforcement measures; for example, during the SARS outbreak, Canada relied mostly on voluntary compliance, but Hong Kong used barricades and tape to confine people; Singapore used surveillance cameras and electronic monitoring devices; China imposed penalties like imprisonment (Ries, 2004). The most appropriate measures should be employed according to the circumstances, following execution of an accurate assessment on the likelihood for people to try and “break” the quarantine, the foreseeable consequences if they proceed as such, but also other factors such as the levels of trust that exist between those subjected to quarantine and the authorities imposing it.

As mentioned before, the isolation and quarantine measures in the event of a pandemic are particularly delicate and complex issues to handle both from an ethical and legal perspective, and in the case where such interventions are required to be implemented often dominate the public discourse around their necessity, effectiveness and consequences for these interventions. Due to their characteristics, isolation and quarantine measures can be perceived to be more of a threat for the maintenance of social cohesion and infringement of fundamental human rights, as compared to social-distancing or travel restrictions and border controls measures, for instance. Nonetheless, social distancing and travel restrictions can also have a deep and long-term impact both on communities and individuals.

Social distancing measures include steps to avoid crowding and to reduce physical interaction by closing public spaces and meeting places, such as schools, theatres, etc. (Vukotich et al., 2010). There is a number of important questions that public health officials need to consider before any social distancing measures are implemented, such as “*Who has the power and under what criteria to order closure and for what period of time?*”, “*What threshold of disease should trigger closure and should thresholds be different for different entities (e.g. schools, events etc.)?*”, “*Under what circumstances should compensation for closures be paid?*”, “*Should there be penalties for non-compliance, and if so, which ones?*” (Gostin and Berkman, 2008). These are important issues that concern the day-to-day function of society, so it is paramount to carefully consider the implications of such social distancing measures before they are introduced. For example, a decision to close workplaces could have serious economic impacts on individuals, families, and communities. In a similar way, the prevention of access to public or community meeting places could raise difficult cultural questions with respect to, say, attendance at funerals, religious worship, access to education, and so on (WHO, 2008).

From the side of the government, what should be avoided at all costs is to use social distancing in a discriminatory fashion, targeting ethnic or religious minorities. Instead, clear procedures should be in place to identify early warning signs of discrimination. As noted by Gostin and Berkman (2008:50), “[...] this will not only take into account important ethical considerations, but also improve the likelihood that the public will accept social distancing as a means to slow disease transmission. Given that compliance with social distancing instructions will be difficult to enforce, acceptance is critical to the success of the measures”.

WHO (2006) provides few recommendations for governments on how could ethical tensions be overcome with regards to social distancing measures, specifying that any such measures should:

- to the extent possible, provide means of mitigating adverse cultural, economic, social, emotional, and health effects for individuals and communities;
- provide employment protection for workers who comply with social-distancing measures against the wishes of their employers;



- incorporate the input of employers, unions, and other relevant stakeholders, particularly with respect to plans for work closure procedures and the use of alternative work schedules;
- be made available in advance to the key actors who will be charged with implementing these measures so that they can adapt them to the local culture and context and prepare for their implementation.

In the case of travel restrictions and border controls, the situation is slightly different as decision made by national governments are informed directly by the WHO International Health Regulations (WHO, 2005). More specifically, before and during a pandemic, WHO issues transparent and clearly justified travel recommendations in accordance with IHR, which countries are expected to follow. It is the responsibility of national governments to use whatever policy instruments they have available to ensure that they can comply with the IHR requirements. Relevant to the ethical implications of travel restrictions, and in an effort to avoid unwarranted travel disruptions and economic burdens, governments have the responsibility to honestly disclose credible scientific information as early as possible.

International travel restrictions and border controls can infringe upon fundamental rights in relation to freedom, and, in particular, such measures can present serious ethical implications for privacy. For example, containment measures may require the travel industry to collect and disclose passenger data. According to Gostin and Berkman (2008), to avoid discrimination and to ensure proportionality, public health officials should inform the affected individuals about the reasons for the infringement of privacy, the intended use of the information and the extent to which third parties will have access to the data. Finally, it is suggested by the WHO (2006) that authorities need to ensure they have obtained informed consent of affected travellers for examinations, prophylaxis, and treatment, in accordance with the IHR (2005).

Box 1: Recommendations to overcome ethical considerations on the restriction of personal freedoms

- 1) Governments and the healthcare sector should ensure that pandemic influenza response plans include a comprehensive and transparent protocol for the implementation of restrictive measures. The protocol should be funded upon the principles of proportionality and least restrictive means, should balance individual liberties with protection of public from harm.
- 2) Governments and the healthcare sector should ensure that the public is aware of: (a) the rationale for restrictive measures; (b) the benefits of compliance; (c) the consequences of non-compliance.
- 3) Governments and the healthcare sector should include measures in their pandemic preparedness plans to protect against stigmatisation and to safeguard the privacy of individuals and/or communities affected by quarantine or other restrictive measures.
- 4) Governments and the healthcare sector should institute measures and processes to guarantee provisions and support services to individuals and/or communities affected by restrictive measures, such as quarantine orders, implemented during a pandemic emergency. Plans should state in advance what backup support will be available to help those who are quarantined.

Adapted from the Joint Centre for Bioethics report (JCB, 2005)



Health care workers and the duty to provide care

Health care workers and the duty to provide care

Procedural values <i>(most applicable)</i>	Substantive values <i>(most applicable)</i>
<ul style="list-style-type: none"> • Be open and transparent • Be inclusive • Be reasonable • Be responsive • Be accountable 	<ul style="list-style-type: none"> • Duty to provide care • Reciprocity • Trust • Solidarity

As discussed previously in the report, health care workers (HCWs) have a critical and prominent role in pandemic planning for preparedness and response. It is common that extraordinary demands are made on HCWs over the course of a pandemic, as they are expected to dutifully perform an array of tasks under the most difficult working and psychological conditions. But how far does the “duty of care” extent for HCWs? In other words, is there an unlimited duty of HCWs to provide care under any circumstances?

The departure point and key ethical concern to raise is whether HCWs should actually tolerate the risk of getting infected themselves. There is a widespread conception that healthcare workers “implicitly consent to the risk of getting infected as this is part of their job” (Sokol, 2006). A further explanation suggests that since HCWs have greater capacities to provide care than other people and members of the public, they therefore have a stronger obligation to commit to the provision of care (Ruderman et al., 2006). Basically, the duty to provide care is established via a (unwritten) social contract; HCWs receive special education and training and they are granted other privileges by society, and the expectation is that they will provide health care, when needed, in return (Huber and Wynia, 2004).

While these arguments do strongly suggest that HCWs have a responsibility to contribute to a public health emergency, and more so in response to a pandemic, this issue is nonetheless more complex. First, people often have to fulfil multiple roles, with different consequent duties which may come into conflict with each other. For example, a HCW has a professional duty to care for a patient infected by a virus; but also has a familial duty to his family not to expose himself (and hence them) to attendant risks (Sokol, 2006). Moreover, if a HCW becomes ill as a result of treating a particular patient, then s/he may not be able to treat other patients to whom s/he has also duties, and further may not be able to fulfil duties to family members or the loved ones (Selgelid, 2009). HCWs also have duties to co-workers, health care provision requires teamwork so if one refuses to work then someone else will be called in to do the job. It is important then for HCWs to have solidarity embedded as one of the values (Reid, 2005).

Also important to note is the value of reciprocity; as highlighted by WHO (2008:77) “[...] If workers are to take high risks, there is a duty upon society, in particular on their institutions, to support them”. Such support could take various forms, including priority access to prophylactic means (e.g. antivirals, vaccines etc.), increased remuneration, access to dedicated insurance schemes, and psychosocial support for the front-line responders and their families. It should also include measures designed to identify the signs of stress in HCWs, and mitigate stress as and when it arises, either during or in the aftermath of a pandemic event. The WHO report on *ethical considerations in developing public health response to pandemic influenza* (WHO, 2007) summarises in four points the reciprocal obligations of governments to minimise risks to health care workers (HCWs):



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

It is noted that these risk reduction methods are important for the protection both of HCWs and of the public. From their end, HCWs have an ethical obligation not only to use the protective measures that are offered to them, but also to report if they become infected and to accept temporary exclusion from work until they are no longer infectious.

To summarise, it is widely accepted that society has responsibilities toward HCWs in exchange for those individuals' willingness to assume risks for the benefit of others (WHO, 2006). These responsibilities include:

- *Obligations of governments and employers:* Governments and employers have a duty to minimize the risks to workers exposed to heightened risks by providing adequate training, access to protective measures and other methods of infection control. Workers at heightened risk are not limited to health care professionals but may also include other health care workers and providers of essential services other than health care.
- *Education about risk:* It is often argued that individuals who enter the health care professions have voluntarily assumed to take risks to their own health. This argument only holds true, however, if the potential risks associated with providing health care are clearly disclosed to health care providers as part of their training.
- *Education about methods of transmission:* Workers should be given timely and comprehensive access to information about the methods of avoiding transmission of an infection. This information is important not only for their own benefit, but also to protect public health. It was noted that lack of knowledge about methods of transmission created significant problems in the early years of the HIV pandemic.
- *Legal protections:* During a pandemic, health care providers may be forced to make difficult triage decisions or to provide treatment beyond pre-existing standards of care. Providers should be protected from inappropriate civil or criminal penalties. One participant noted that professional associations of health-care workers can contribute to this effort by developing guidelines for providing care during a pandemic that could be cited as evidence of a legal standard of care.
- *Access to vaccines and treatment:* The fact that health care workers are likely to assume greater risks to their own health than other members of society is an argument in favour of giving them priority access to pandemic vaccination to prevent infection and to antivirals if they become sick. Some participants noted that this argument could be applied now, during the pandemic alert period, for workers such as animal cullers who could become exposed to avian influenza viruses that can cross species and infect humans.
- *Access to insurance and other benefits:* Workers who become infected as a result of caring for others should be guaranteed adequate health and disability insurance coverage. If they die, their families should be eligible for death benefits. Countries should consider whether they will be able to assume the entire burden of providing these benefits or whether private insurers should be asked to contribute to the effort.



A final point to be made is that the duty to provide care also depends on the effectiveness of treatment, so evidence regarding likely efficacy of treatment against the particular strain of flu is necessary to provide. Early in a pandemic which involves a novel strain of a virus however, such evidence may be unavailable. So, in a situation of uncertainty it is also unclear what expectations should there be for HCWs. A difficult question to answer is *what risk of infection is acceptable for sending a HCW to treat a patient?* This depends on the outcomes of a focussed assessment about the expected effectiveness of treatment. It is reasonable to state that HCWs should not be expected to face as much risk when treatment is likely to be futile or merely palliative (Selgelid and Chen, 2008).

Box 2: Recommendations to overcome ethical considerations on the duty to provide care

- 1) Professional colleges and associations should provide, by way of their codes of ethics, clear guidance to members in advance of a major communicable disease outbreak, such as pandemic flu. Existing mechanisms should be identified, or means should be developed, to inform college members as to expectations and obligations regarding the duty to provide care during a communicable disease outbreak.
- 2) Governments and the health care sector should ensure that:
 - a. Care providers’ safety is protected at all times, and providers are able to discharge duties and receive sufficient support throughout a period of extraordinary demands; and
 - b. Disability insurance and death benefits are available to staff and their families adversely affected while performing their duties.
- 3) Governments and health care sectors should develop human resource strategies for communicable disease outbreaks that cover the diverse occupational roles, that are transparent in how individuals are assigned to roles in the management of an outbreak, and that are equitable with respect to the distribution of risk among individuals and occupational categories.

Adapted from the Joint Centre for Bioethics report (JCB, 2005)

Priority-setting and allocation of scarce resources

Priority-setting and allocation of scarce resources	
Procedural values (<i>most applicable</i>)	Substantive values (<i>most applicable</i>)
<ul style="list-style-type: none"> • Be open and transparent • Be inclusive • Be reasonable • Be responsive • Be accountable 	<ul style="list-style-type: none"> • Equity • Solidarity • Trust • Stewardship

Any public health emergency of pandemic scale requires from governments to make difficult decisions regarding prioritisations and allocation of scarce resources, which include therapeutic and prophylactic measures. What is characteristic of any pandemic event, is the fact that an extraordinary high number of people over a large geographic area will require care at the *same time*, with an immediate impact on the availability of both human and material resources (Kotalik, 2005). Thus, national public health authorities are required to develop and have



in place some criteria for resource allocation (rationing) and how priorities are set, much before a pandemic event occurs. According to WHO (2007), policy makers need to establish standard procedures for setting priorities and promoting equitable access, based on two main axes. First, considering that a pandemic is a worldwide emergency where all of almost all individuals are susceptible and therefore threatened, it requires that civil society and other major stakeholders in the decision-making process are involved, to ensure that criteria established for the allocation of resources are made in open, transparent and inclusive manner. Second, to incorporate clear, pre-established mechanisms for revising decisions based on new evidence, when appropriate. The uncertainties about who will most at risk of severe illness and death in a pandemic might necessitate focussing on general principles and arguments, instead of giving priority to specific groups or persons.

According to WHO (2004), setting goals and choosing priorities will requires the consideration of logistic, ethical, moral, cultural, legal and other issues that surround decisions to allocate scarce resources. At the level of priority-setting and more generally, prioritisation of goals and policies by pandemic planners and decision makers, there are two general principles that inform and guide the process: **efficiency** (or **utility**) and **equity**.¹² The principle of *efficiency* seeks to maximise protection of the population with the available means, driven by a consequential concept that the greatest number of human lives ought to be saved, on the grounds that human life constitutes an ultimate value. The principle of *equity* is concerned with giving equal weight to equal claims and supports the rejection of discrimination, minimisation of unfairness, prioritisation of those at risk, the vulnerable and those of a younger age (Verweij, 2008).

Some of important questions to be considered by public health authorities in their distribution plans, include:

- What scarce goods are involved in the distribution plan?
- Who will decide about prioritisation and distribution?
- Who is eligible to be a recipient?
- What morally relevant criteria will be employed for priority-setting?

With reference to the last point made above, we arrive to the question of how should allocation of resources be made available under the circumstances, taking into account both the efficiency and equity principles within a frame of fair procedures to be followed for the prioritisation of specific groups. According to WHO (2004), vaccination priorities may differ from those during the interpandemic period, so it is essential to clearly define priority groups, from local to national level. On the basis of a WHO global consultation for addressing ethical issues in pandemic influenza planning (WHO, 2006), the prioritisation of groups to receive vaccination in the event of a public health emergency can be made as follows: 1) health care workers, 2) essential service providers, 3) persons at high risk of a fatal outcome, 4) healthy adults, 5) children of 2-18 years of age.

Prioritisation of healthcare workers may be justified on the grounds of social utility, since healthy healthcare workers will be needed to in order to find a pandemic - more generally could be prioritised “pandemic responders” which would include anyone with a role to fulfil during a pandemic for the benefit of society (Selgelid, 2009). Extreme caution is required however for that matter, since this type of prioritisation raises the issue of “social worth” for the group of HCWs, which is only justified under the special circumstances of a pandemic, and should not extend beyond that (WHO, 2006).

It is important to highlight at this point the tension that can be created regarding decisions for prioritisation of children and young adults over older adults, or generally whether it appropriate to consider the “age” factor in

¹² It should be noted that these two principles can conflict if priorities are to be set, and so is important that there are also *fair procedures for accountability* in place (Verweij, 2008).



making prioritisation decisions (WHO, 2007). As suggested, age-based prioritisation could be controversial as an issue, and if some government wishes to adopt this, then it should be after extensive consultation with the public. Any criteria should rely on broad life stages (e.g. child, young adult, older adult etc) rather than ranking individuals based on differences of only a few years. There is a theory that vaccination should be focussed on groups of people known to be central to spreading infection, and such a group could be children of school age (Verweij, 2008). For others, it is the young people should receive priority when a decision is made for the allocation of resource. Emmanuel and Wertheimer (2006) for example, argue for prioritisation of the young on the grounds of a “life cycle allocation principle [...] based on the idea that each person should have an opportunity to live through all the stages of life”. A similar idea underlies what is sometimes referred to as the “fair innings” argument, which suggests that everyone is entitled to some “normal” span of life years. Nonetheless, it should not be assumed that a policy of taking age into account would necessarily lead to the prioritization of younger people. Some countries may decide, instead, to favour persons who are older, particularly in cultures that have a tradition of placing greater value on elderly people. Regardless of the approach, pandemic planners need to ensure that criteria for priority-setting are not discriminatory or unfair against individuals on the basis of characteristics such as gender, race and ethnicity, religion, political affiliation and so forth (WHO, 2007).

As discussed, the principle of equity is central in decision making for prioritisation and allocation of resources. These are some important points to also consider with reference to “equity” as presented by experts following the WHO global consultation on addressing ethical issues in pandemic influenza planning (WHO 2006):

- *Social justice and protecting the vulnerable:* It is inappropriate to prioritize certain groups leaving vulnerable groups aside, i.e. conferring privilege on those who are already considered to have a higher value to society, such as health-care workers, at the expense of people who are disabled, poor, or otherwise vulnerable.
- *Global justice:* Most countries' national plans focus on protecting their own citizens, an approach that advantages countries that are economically powerful at the expense of resource-limited countries. Many participants stressed the importance of directing resources to developing countries and considering mechanisms such as patent exceptions, compulsory licensing and technology transfer that would enable developing countries to produce their own antivirals.
- *Equity in access to information:* Broad dissemination of information about the pandemic and about access to treatment, prophylactic and preventive means is essential. Information should be made available even in resource limited settings and plans should ensure that information is equally available to those with literacy or other communication impediments.
- *Equity in identification of "high-risk" persons:* If countries prioritize persons based on their risk of infection or death, they should ensure that judgments about risk are made fairly and objectively. For example, the heightened risks faced by pregnant women or persons with compromised immune systems should be taken into account.

As a final point, it should be noted that often national influenza preparedness plans allude to scarcity of resources and when they do, there often seems to be an explicit or implicit assumption that the scarcity is unavoidable and that the planning for a full complement of all resource needs during a pandemic would be impossible. As highlighted by Kotalik (2005), “The assumption that scarcity of a particular resource is unavoidable is (with the exception of anti-virals and vaccines) an assumption that is usually not scrutinised [...] There is the financing concern of preparedness measures that seems to permeate many sections of these plans. This concern should not interfere with careful determination of all measures and all resources that likely would be required for the optimal response to this health threat. Any decision that is likely to have an effect on every citizen, such as the



limited availability of resources to cut costs, should be put to public consultation. Open democratic societies and their people have the right to know and ought to have a say in the decision making process.”.

Box 3: Recommendations to overcome ethical considerations on priority setting and allocation of scarce resources

- 1) Governments and the health care sector should publicize a clear rationale for giving priority access to health care services, including antivirals and vaccines, to particular groups, such as front line health care workers and those in emergency services. The decision makers should initiate and facilitate constructive public discussion about these choices.
- 2) Governments and the health care sector should engage stakeholders (including staff, the public, and other partners) in determining what criteria should be used to make resource allocation decisions (e.g. access to ventilators during the crisis, and access to health services for all illnesses), should ensure that clear rationales for allocation decisions are publicly accessible and should provide a justification for any deviation from the pre-determined criteria.
- 3) Governments and the health care sector should ensure that there are formal mechanisms in place for stakeholders to bring forward new information, to appeal or raise concerns about particular allocation decisions, and to resolve disputes.

Adapted from the Joint Centre for Bioethics report (JCB, 2005)

International cooperation and global governance

International cooperation and global governance	
Procedural values <i>(most applicable)</i>	Substantive values <i>(most applicable)</i>
<ul style="list-style-type: none"> • Be open and transparent • Be inclusive • Be reasonable • Be responsive • Be accountable 	<ul style="list-style-type: none"> • Protection of public from harm • Solidarity • Trust • Proportionality • Reciprocity

Any pandemic event calls for international cooperation and coordination in the development and implementation of pandemic preparedness plans, due to its inherently global impact. As a principle, cross-border and transnational cooperation between governments help to ensure that national plans are kept transparent, and further contribute to their legitimacy. Nonetheless, national governments may be required to face an array of moral dilemmas and challenges in their international relations with other governments, when core values such as solidarity, reciprocity and trust are not bilaterally manifested during public health emergencies of international concern.

The United Nations organization has a leading role in this respect, as one of the strategic objectives is to achieve international cooperation for effectively dealing with international humanitarian issues, which require a multilateral approach. The Universal Declaration of Human Rights (UN, 1948) guarantees respect for social,



economic, and cultural rights, which also refer to issues around health that are indispensable for human dignity, and it proclaims that these rights should be realised through national effort and international cooperation. The ethical duty has been codified into a legal duty of international cooperation and assistance between States expressed in many international human rights instruments, such as the United Nations Covenant on Economic, Social and Cultural Rights (UN, 1966). Article 12 of that Covenant places particular emphasis on that obligation in the context of the prevention, treatment and control of epidemic diseases.

It should also be acknowledged the decisive role of international organisations in providing not only a legal framework, but also the appropriate conditions for international cooperation at different levels. For instance, international disease surveillance is conducted under the WHO International Health Regulations (2005) and more specifically, and the establishment of the WHO Global Influenza Surveillance Network across the world, while the European Commission continuously seeks to strengthen cooperation between Member States, with most recent example the introduction of Decision No 1082/2013/EU on serious cross-border threats to health, which “[...] aims to support cooperation and coordination between the Member States in order to improve the prevention and control of the spread of severe human diseases across the borders of the Member States, and [...] clarifies the methods of cooperation and coordination between the various actors at Union level” (Article 1). From an ethical perspective, it is of special interest the fact that this EC Decision No 1082/2013/EU gives legal effect and enables Article 21 of Regulation (EC) No 1234/2008 to apply in situations of public health emergency of international concern, whereby “the Commission may exceptionally and temporarily accept a variation to the terms of a marketing authorisation for a human influenza vaccine, where certain non-clinical or clinical data are missing”.

Despite the fact that international legal instruments and principles are already in place, there are some ambiguities as to what international cooperation really entails, what should be role of national governments and international organisations in addressing cross-border risks and obligations, and so on. According to Archer (2008), it is a responsibility of the national governments “[...] to take steps to ensure that adequate international assistance is made available so that all countries can contribute to the international and national efforts that will be necessary to prevent a pandemic from occurring and to minimize its effects in all societies if it does occur” (p. 103). As a general rule, core human rights and ethical principles and international legal obligations should inform decisions and initiatives taken by WHO and other international organizations during a public health emergency. Archer (2008) continues to suggest that “[...] during each phase of a pandemic, national governments will respond best to policy recommendations that draw together arguments based on national interest, human rights principles (and other bodies of international law), and ethical values”.

Of particular concern when implementing international human rights laws is keeping the focus on those persons who are especially vulnerable. This condition of vulnerability is not only determined by some biological characteristics, but it may also be determined by societal or political circumstances. To give an example, if someone is a citizen of a country that does not have the ability to mount a well-organised response to a pandemic, s/he will be at a greater risk than a person in a country where a virus is equally prevalent but which is better prepared to respond (Archer, 2008). There is an additional risk that vulnerable groups within countries, such as foreign residents, travellers, and members of minority groups may be victimised. As emphasised by WHO (2007), international and national monitoring should pay particular attention to the needs of all populations, such as displaced persons, refugees, asylum seekers and migrants. This dimension of governments’ obligation to meet the needs and safeguard the rights of all populations, regardless of their legal status, forms the basis of a principle that is a central element for international cooperation, which is the principle of solidarity.



Solidarity is often – falsely – associated with wealthy countries' response for help and support requested by poorer countries in times of an emergency or a crisis. The countries that benefit from such efforts have an obligation to help compensate the frontline countries. While it is possible that countries to be affected most during a pandemic are likely to be poor countries, however, in the course of a pandemic even wealthy countries may lack sufficient resources for protecting their own citizens. According to the US Institute of Medicine (2007), the correlate of this is that the governments with greater resources ought to make clear in advance how these essential activities will be rewarded through efforts to help the first-affected countries deal with their own health problems and contain the spread of the virus as long as possible (including fair access to vaccines), as well as through financial aid to mitigate harm caused by disruption of trade, loss of tourism, and so on. The countries that benefit from such efforts have an obligation to help compensate the frontline countries.

WHO (2006) provide some recommendations for the minimisation of the global impact of a pandemic, on the basis of some mechanisms that can be established to strengthen international cooperation:

- *Special needs of developing countries:* On the one hand, developing countries provide benefits to the entire global community by sharing virus specimens for research and engaging in surveillance. On the other hand, limited resources and immediate health-care needs make it difficult for these countries to develop and implement adequate pandemic preparedness and response plans. Wealthy countries should help developing countries establish stockpiles of drugs or set up mechanisms by which drugs and vaccines could be provided in case of need.
- *The importance of regional cooperation:* Countries have a particular responsibility to consider the needs of other countries in the same region. Countries should develop preparedness and response plans at the regional level.
- *Cross-border issues:* Countries should attempt to avoid situations where care is available in one country but not immediately across its borders. Avoiding disparities in care across borders will require regional collaboration.
- *Threats to governmental stability:* In a severe pandemic, the strain on health services and disruption of society might be so severe that some governments will collapse. Countries and international organizations should consider how they will contribute to rebuilding efforts in these situations.

Box 4: Recommendations to overcome ethical considerations on international cooperation and global governance

- 1) The World Health Organization should remain aware of the impact of travel recommendations on affected countries, and should make every effort to be as transparent and equitable as possible when issuing recommendations.
- 2) Federal countries should utilise whatever mechanisms are available within their system of government to ensure that relationships within the country are adequate to ensure compliance with the WHO International Health Regulations.
- 3) The developed world should continue to invest in the surveillance capacity of developing countries and should also make investments to further improve the overall public health infrastructure of developing countries.

Adapted from the Joint Centre for Bioethics report (JCB, 2005)



3.3 Stigmatisation and vulnerability

This section presents separately two other issues with implications for pandemic preparedness and response: stigmatisation and vulnerability.

Stigmatisation

The issue of stigmatisation has often been common in epidemics and pandemics, with more recent examples the H1N1 (2009) influenza pandemic, as well as the Ebola epidemic in 2014. As already discussed briefly in this document, in the context of epidemics and pandemics there are individuals or entire communities that can become the target of stigmatisation for a number of reasons, such as the perceived connection with the geographic origin of the outbreak in question, or their actual connection to perceived animal origins of an outbreak, and finally due to the fact that those individuals have actually become infected themselves¹³.

Pandemic planners and decision makers should always consider that a number of individuals or groups are susceptible to stigmatisation, and should take all measures to avoid this from occurring not simply as a moral obligation toward the others, but also because any such behaviour may cause uncontrolled effects with negative consequences for both the individuals involved, but also for society as a whole. In order to avoid unnecessary stigmatisation, pandemic planners and decision makers can focus efforts on trying to ensure that provision of healthcare services is made on an equal basis for everyone, disregarding the political cost or any criticisms made by society. Such an approach would contribute to the prevention of vertical discrimination of people under the threat of discrimination; it should be considered that the active act of discrimination does not need to be present in order for stigmatisation and its negative effects to occur.

It was pointed out earlier that restrictive measures such as isolation and quarantine may result in possible stigmatisation of individuals. Therefore it is a responsibility of pandemic planners and decision makers to take measures to reduce this effect to the extent that is possible. For example, during the quarantine procedures, people must not be made to feel as criminals or a threat to society. Instead, they should understand that they fulfil a civic duty by accepting the quarantine conditions, and should accordingly be treated with respect. Once the quarantine is lifted, particular attention should be given to ensure that people are not left with any residual stigma. The government should use available mechanisms and strategies to help in the re-integration of quarantined people back to society, and ensure access to on-going medical support and counselling services over a specified period of time.

Vulnerability

Respect for human vulnerability is very important, as stated explicitly on Article 8 of the Universal Declaration on Bioethics and Human Rights (UNESCO 2006). In public health emergencies, vulnerable groups may require priority treatment: "Allowing for local circumstances and without prejudice to the priority assistance to be given to all who have a chance of survival, priority for humanitarian assistance, first aid and any emergency evacuations go in priority to the most vulnerable people, such as pregnant women, children, people with disabilities, elderly people, the ill and the wounded" (Prieur, 2012:29).

It is therefore essential for vulnerable groups to be identified in advance, also in order to assess whether preparations and plans are capable of meeting their special requirements and needs (Prieur, 2012). Other individuals or groups that may require additional assistance of some kind include those with special language

¹³ TELL ME Project: D1.6 – Report on human rights, stigmatisation and risk of discrimination. Available at <<http://www.tellmeproject.eu/content/d16-human-rights-stigmatisation-and-risk-discrimination>>



requirements (non-native speakers), tourists and other visitors, the institutionalised people, refugees, asylum seekers, displaced people, undocumented migrants, some indigenous populations, ethnic, cultural and religious minorities, the socio-economically disadvantaged, and so on. The condition of vulnerability may appear in many different forms, and efforts should be made to identify it, always considering that determinants of vulnerabilities will differ across societies, and may change within societies over time. Health care workers ought to be trained in identifying the signs of vulnerability in order that, in the midst of an event, they can adapt to circumstances in whatever ways are needed.

One concern is that implementing special measures for vulnerable groups may be in tension or come into conflict with the principles of equity and non-discrimination. Prioritising vulnerable groups could be seen as giving them an unfair advantage. Considerations of equity could be applied in two ways. On one application, the principle is taken as implying that everyone should be treated equitably, regardless of any advantage or disadvantage they may have; on the other application, equity is taken as implying that the end-state should be as equitable as possible – in which case disadvantage should be taken into account at the outset, in order to ensure that those starting from the disadvantaged, vulnerable positions, are given additional support. Whilst both applications of the principle of equity have some merit, the latter approach, which takes vulnerabilities and disadvantage into account from the outset, is more in accord with other important principles, notably those of distributive justice, reciprocity, and welfare.

It should be noted that new forms of vulnerability may emerge at the response phase of a pandemic. For example, people subject to quarantine, isolation, or other forms of social distancing may have special requirements and needs in the absence of which feel vulnerable. Existing and identified vulnerabilities may change in nature or be exacerbated by interventions at the response phase. Groups like asylum seekers, refugees, or internally displaced people are vulnerable in various respects anyway, but at the response phase of a public health emergency, their vulnerability could be worsened with respect to, for example, access to basic healthcare (WMA, 1998). Therefore, public health authorities, front-line responders and medical staff in general, need to be attentive and responsive to the signs of vulnerability from members of the community or different segments of the society.



4. CONCLUDING REMARKS

This report identified and drew attention to the various ethical, legal and fundamental rights implications in situations of public health emergencies, such as epidemics or pandemics. The relative abundance of national guidelines, international policy instruments, technical reports and scientific papers that discuss fundamental rights issues and different types of ethical considerations in pandemic preparedness and response, reveals the importance and the need to place those issues in the right context and the right proportions.

A state of emergency is an extraordinary event which can lead to major disruptions for the functioning of society, and as an of different factors and variables, some basic democratic structures, principles and values may be compromised for the benefit of the *common good*, i.e. the continued existence of society as such. The various international policy instruments that have been presented over the last decades by international organisations and institutions do provide a solid basis for the formulation of national policies for emergency situations, with fundamental human incorporated at the core of decision-making processes. It should be noted however that the due to the element of uncertainty and timeliness of actions during a public health emergency, some decisions and measures may come into tension with well-established ethical principles and societal norms, even if these decisions and measures are in accordance with the national or international policies and regulations.

Ethical considerations should not be seen as part of a problem, but rather as part of a solution with shared value for both individuals and key stakeholder groups within society. Policy and decision makers should take into account ethical considerations to *inform* and *colour* all aspects of pandemic planning for preparedness and response. More importantly, 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 basis of one of the driving concepts of the ASSET project supports, i.e. 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.

The existence of such a culture of ethics would support an overall appreciation of the significance and value of “injecting” ethical considerations in the decision-making process, on issues such as the restriction of personal freedoms, the duty to provide care, priority-setting and resource allocation, and international cooperation. The ASSET project can certainly provide this platform and build a collective mechanism (a community of practice) in which fundamental rights issues and ethical considerations in public health emergencies could become issues for open deliberation with all relevant actors from society, whether at local or international level.



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