EUROPEAN COMMISSION

pulse

Platform for European Medical Support During Major Emergencies

D8.1 Plan for Ethical Impact Assessment

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Abstract:
This deliverable comprises a plan for the Ethical Impact Assessment that will be carried over the course of the PULSE project. First, the plan sets out the main steps comprising the Ethical Impact Assessment (EIA). Second, the deliverable provides an overview of the policy initiatives to be taken into account across a number of areas, including protection of ethical principles, major emergency management, physical systems and critical information systems and data protection. Third, it sets out the security codes of practice and standards relevant for PULSE. Fourth, the deliverable specifies the PULSE data controller. Further areas of research and analysis are indicated in all sections.

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Ethical Impact Assessment, ethical, legal and societal impact

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1 Introduction

1.1 Purpose and scope of the Document

This document comprises the first deliverable of Work Package 8 (Legal, ethical and societal impact), setting out the plan for the Ethical Impact Assessment (EIA) that will be carried out during the course of the PULSE project. It sets out the process of the EIA, that is, the main steps that will be pursued in the EIA. In addition, this document provides an overview of the policy initiatives and legislation that will be analysed as to their impact on the PULSE project.

1.2 Structure of the Document

Section 2 offers a glossary of the key terms used in this document. Section 3 sets out the main steps comprising the Ethical Impact Assessment (EIA). Section 4 provides an overview of the policy initiatives to be taken into account across a number of areas, including protection of ethical principles, major emergency management, physical systems and critical information systems and data protection. Section 5 sets out the security codes of practice and standards relevant for PULSE. Section 6 specifies the PULSE data controller. Section 7 refers to the EIA report that will be completed as the final outcome of WP8. Further areas of research and analysis are indicated in all sections.

2 Glossary

Terms	Definitions	Notes
Ethical Impact Assessment	An EIA is a process during which an organisation – or project consortium, as in the case of PULSE – together with stakeholders (and, in particular, end-users) considers the ethical issues or impacts posed by a new project, technology, service, programme, legislation, or other initiative, to identify risks and solutions.	
Ethical issues	Ethical issues refer to the issues concerning some aspect that raise ethical questions	
Ethics	Ethics is the systematic reflection on right and wrong conduct according to norms and values that we think should be adhered to	

EMS	Emergency Medical Service	
ICT	Information and Communication Technology	
Legislation	A law or a body of laws enacted	e.g. The Charter of Fundamental Rights
Phase	A subset of a Scenario. It may be, for instance, identified, in terms of time (e.g. before the incident) and/or location (e.g. hospital) and/or type of population involved (e.g. people in "uncertain" status in a SARS-like epidemic) and/or purpose (prepare, recover)	Each PULSE Scenario is split into two Phases: Preparedness and Response.
Platform	See PULSE Platform	
Policy	Document that provides high-level guidelines, in terms of actors and responsibilities	The "Decision No. 1082/2013/EU of European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health" is an example of policy
Preparedness phase	Activities that prepare and train responders and ensure that the required mix of resources are ready to respond in case of adverse events	
Procedure	A document describing a series of actions that, in the end, produce an output; a procedure normally specifies the flow diagram (logic and time sequence of the actions), the actors (who does the action) and the software tools used to carry out the action	Classification rule for separating people "assaulting" a hospital
PULSE	Platform for European Medical Support during major emergencies	
PULSE End-user	Any actor that is expected to interact with the PULSE Platform. Interaction with the Tools may consist of: providing input, launching simulations, elaborations, receiving input	
PULSE Platform	PULSE System + PULSE SOP	
PULSE Project	The Project that will specify, design, implement and validate the PULSE platform.	

Response phase	Activities that are triggered by the adverse event, with the purpose to diminish/contain its effects	
Requirements	Justified characteristic needs, formulated by users and experts. For IT systems, usually one distinguishes between technical and operational (possibly strategic) requirements	
SARS	Severe Acute Respiratory Syndrome	
Stakeholder	A person or group that has a stake or interest in something	
System	Collection of interrelated components	
Tool	Any helping software instrument, including input/output interfaces with users or other Tools or Systems (mostly software). A Tool may use Modules. A software Tool may also be identified with the set of functionalities	

Table 1: Glossary

3 Introduction to the Ethical Impact Assessment Plan

3.1 The purpose of an ethical impact assessment (EIA)

Ethical impact assessment (EIA) is a means of ensuring that ethical implications are examined by stakeholders prior to the deployment of a new technology or project in order that mitigating measures can be adopted as necessary. An EIA is a process during which an organisation – or project consortium, as in the case of PULSE – together with stakeholders (and, in particular, end-users) considers the ethical issues or impacts posed by a new project, technology, service, programme, legislation, or other initiative, to identify risks and solutions.

The main objectives of an EIA for the PULSE project are as follows:

- Investigate the critical infrastructure (and the critical infrastructure information system) that will form the physical framework conditions for the development of the PULSE platform, specifically with regard to legal and regulatory concerns and data security and data protection issues.
- Conduct an ethical impact assessment of the tools, technologies and procedures to be developed in the PULSE project so as to ensure

that they comply with ethical standards as well as relevant national and European regulations regarding security of information systems, privacy and data protection and confidentiality.
- Consider the ethical issues arising from two pilot scenarios
- Develop an informed consent policy, procedure and form.

3.2 Project description

PULSE is an end-user driven project, the concept of which is the implementation of a comprehensive study regarding the needs of the emergency services when faced with a major crisis. PULSE aims to develop a sustainable pan-European technical and operational platform for the health services. This platform will provide stakeholders within the health services (i.e. ambulance personnel, hospitals and national agencies) with access to key data and medical information to enable them to prepare and to respond effectively during a major medical crisis.

The PULSE project involves a comprehensive study of the procedures, processes and training requirements in current operation in the European Health Services (EHS) with the support of end-users. The PULSE project will carry out the following activities:

- Develop standard and consistent response procedures and processes.
- Provide tools to support decision-making in both preparedness and response phases.
- Provide a framework to facilitate decision-makers' access to timely key data, planning and decision support tools and to international best practice and lessons learned.
- Present innovative training techniques to improve personnel response training.
- Develop an 'emergency app' for smart phones to enable users fast and flexible access to emergency resource availability information.

The PULSE framework solution will be validated by two pilot scenarios based on multiple exercises and demonstrations: a) a SARS-like virus epidemic in Italy and b) a major stadium 'crush' at a Dublin concert. Both will involve cross-border support from neighbouring countries. The project team will present and discuss these scenarios with representatives of the core stakeholders in order to validate and to complement the scenarios. Stakeholders include, inter alia, health care institutions, emergency services, medical personnel, industry, businesses, data protection authorities, and organisations representing citizens' interests (normally non-government organisations).

The EIA will take place through the pilot scenarios as the tools, technologies and procedures will be tested in the scenarios. An ethical, legal and societal analysis will also be carried out on the specific features of the scenarios themselves.

3.3 The EIA team

Expertise for the EIA can be found within the consortium. Partners have the following responsibilities:

- TRI will function as LEPPI (Legal, Ethical, Privacy and Policy Issues) officer and oversee all activities on legal and ethical aspects of PULSE across all PULSE work packages.
- Onest Solutions and UCSC will contribute expertise in the area of systems and information security, by facilitating the identification of ethical factors to be considered in developing systems for the support of the emergency healthcare service.
- In consultation with Onest Solutions, UCSC and Skytek, TRI will carry out a preliminary assessment of the impacts of the identified ethical factors on the implementation of PULSE.

An Ethical Review Committee (ERC) comprising three external, independet experts has been established. The members of the ERC are

- Dr. Javier Arias Diaz, Subdirector General - Instituto de Salud Carlos III
- Prof.dr. Philip Brey, Department of Philosophy of Technology, Universiteit Twente
- Ms. Zuzannna Warso, Helsinki Foundation for Human Rights

The LEPPI Officer will provide a copy of the draft EIA report to the Committee at month 12, month 24 and month 29, and invite comments from the Ethical Review Committee (ERC). Members of the consortium will meet with the ERC at approximately month 13 and month 25. In addition, as part of its terms of reference, the consortium, via the LEPPI, will seek the views of the ERC on key ethical issues and seek their Committee's support in disseminating relevant project deliverables.

3.4 Terms of reference

In a normal EIA, its terms of reference may be determined by the EIA plan which is formulated by the EIA team. It is very important that the EIA team's terms of reference have been explicitly agreed between the EIA team and senior management.

In the case of the PULSE EIA, the terms of reference have been prescribed by the project's Description of Work (DoW) which forms part of the contract between the PULSE consortium and the European Commission.

PULSE proposes to conduct a legal, ethical and societal impact assessment in WP8 which will engage all project partners as well as external stakeholders to assess any impacts or risks that might directly or indirectly arise from the project and to collaborate with Trilateral Research, the task leader, to identify possible solutions to the identified risks.

3.5 Budget

The budget for the PULSE ethical impact assessment has been determined in the context of the project budget. Normally, in an ethical impact assessment, the EIA team will plan EIA activities within a prescribed budget or, in some instances, the EIA team may feel it needs a somewhat larger budget in order to conduct an appropriate EIA. If so, it will put its case to senior management, who may or may not increase the budget accordingly. An adequate and clearly identified budget is important so that the EIA team can carry out the activities it deems necessary, especially, for example, in order to consult adequately with stakeholders.

3.6 Timeframe

The duration of an EIA may be determined by some practical exigencies. In the case of the PULSE project, the EIA needs to be conducted before the project ends. In a commercial environment, the duration of an EIA may be driven or affected by the wishes of a market development or marketing department who want to see ethical issues resolved before a new technology or service or pharmaceutical is put on the market.

The two tables below set out a timeline for WP8 activities for 1) a specific topic (allocation of resources) and 2) general consultation with end-users.

The consortium will take into account the allocation of medical resources in public health emergencies in large scale crisis in the context of the following tasks:

Task	Period	Partners involved	Deliverable	Delivery date
2.1 - Health service user requirements gathering and reviewing including threat analysis	Months 1-4 (completed)	UCSC, SKY	D2.1 Requirements specification	4
3.3 – Design and test of healthcare facilities model	Months 4-15	UCSC, SES	D3.1 Context models	15
4.1 – Health service preparedness Decision Support and Validation Tool (DSVT)	Months 15-19	SES, SKY	D4.1 Decision support validation tool	18
4.4 Surge Capacity Generation support tool (SGCT)	Months 9-19	UCSC	D4.4 Surge capacity tool	18
5.1 – Status quo analysis	Months 9-19	CESS	D5.1 Procedures and status quo report	18
5.2 Identification of improvement potential	Months 9-18	UCSC	D5.2 PULSE SOP	18

Table 3: Timeline for WP8 activities regarding the topic of allocation of medical resources across a variety of areas.

The partners will interview ministry of health policy-makers, medical associations, national ethics committee representatives and other health care officials in order to gather their views on the allocation of medical resources. Trilateral will contribute to coordinating data collection for this sub-task.

TRI will carry out an analysis of the issues regarding allocation of resources for each task.

The table below sets out those tasks in which it is envisaged that end-users will be involved.

Task	Period	Partners involved	Deliverable	Delivery date
2.1 - Health service user requirements gathering and reviewing including threat analysis	Months 1-3 (completed)	UCSC, SKY	D2.1 Requirements specification	4
2.5 – Individual application requirements	Months 1-9	UCSC, SKY	Input to D2.2 Use case specification	8
3.4 – Scenario generation	Months 4-19	SSI, SKY	D3.2 Scenario generator	18
5.5 External stakeholders	Months 9-19	UCSC	-	18
7.3 Benchmarking and evaluation and assessing public acceptance	Month 30	UCSC, OST	D7.4 Trials final report	30
7.6 External stakeholders	Months 25-30	OST	Input to D7.4	29
8.7 External stakeholders	Months 1-30	TRI, OST	Input to D8.2	30

Table 4: Timeline for WP8 activities regarding discussion of ethical, legal and societal issues with end-users.

External stakeholders will be consulted in working sessions to request their input into the discussion of legal and ethical issues.

3.7 Stakeholders

One important objective of an ethical impact assessment is to engage stakeholders in order to identify, discuss and find ways of dealing with ethical issues arising from the development of new technologies, services or products. Engaging stakeholders will enable the assessor to identify risks and impacts that she/he may not otherwise have considered.

A good EIA will include consultation with internal and external stakeholders. Internal stakeholders (in the case of PULSE) include the consortium partners. External stakeholders include others such as the following:

- hospitals
- community health services
- pre-hospital emergency care services
- medical suppliers
- rescue services
- health-related voluntary services
- fire-fighters
- paramedics
- international organisations
- civil society organisations
- policy-makers and regulators (e.g., data protection authorities)
- industry (those who might commercialise the emergency app)
- etc.

For the EIA, the relevant stakeholders include potential end user groups. These stakeholders will be the direct users of accessible services, procedures and applications resulting from PULSE, in addition to accessible services and applications that will be developed in the future by the Consortium partners or other service/application developers using the PULSE results and tools.

See Table 4 above for information regarding the specific tasks in which end users are involved.

3.8 Consultation with stakeholders

In the PULSE project, we envisage consultation with internal and external stakeholders by various means, notably as follows:

- End user workshops convened in PULSE work packages where user requirements of various stakeholders will be considered. At least four workshops will be organised and the members of the end user group and other key stakeholders invited to contribute crucial inputs to the project.

  At least four workshops will be organised:

  Workshop Description Audience
  Workshop 1 Validation of preliminary user requirements Users group
  Workshop 2 Validation of PULSE First Prototype Users Group
  Workshop 3 Validation of PULSE Second Prototype Users Group and General Public
  Workshop 4 Presentation of the project results Users Group and General Public

- Interviews conducted via telephone or skype or other similar means.
- E-mails.

TRI will interact with policy-makers, for example, through consultations issued by the European Commission, to make recommendations for amendments to existing legislation or inclusions for future legislation regarding ensuring preparedness and response during a major crisis.

3.9 Compliance with legislation

TRI, as LEPPI officer, will ensure that PULSE research complies with the European Charter of Fundamental Rights, avoiding any negative impacts. The European Convention on Human Rights and the relevant case-law of the European Court of Human Rights, especially regarding Article 8 (Right to Respect for Private and Family Life)[1] may be an important point of reference for a legal/ethical review. This may be particularly given the upcoming accession of the EU to the Convention.

TRI will ensure that the PULSE data controller is acting in compliance with Directive 95/46/EC and with the Article 29 Working Party Opinion 8/2010.

The draft General Data Protection Regulation [2]will also be taken into account. While the final version is still unavailable, the proposed amendments will be monitored and checked for their potential impact on PULSE.

Moreover, TRI will lead activities for an ethical impact assessment of the tools and technologies to be developed in the PULSE project so as to ensure that they comply with national and European regulations regarding protection of physical systems and critical information systems.

In line with the following provision in the PULSE DoW – "Prior to the commencement of the relevant research and where applicable, copies of ethical approvals/notifications/opinions by the competent legal local/national Ethics Boards/Bodies/administrations on the informed consent procedure, must be submitted to the EC/REA and reported as a deliverable" – the PULSE coordinator will submit the informed consent procedure formulated by the Consortium to the Project Officer.

3.10 Ethical issues, risks and possible solutions

In this section, we set out a list of ethical principles which has a heuristic status, that is, it will help to identify and locate ethical issues in consultation with both PULSE partners and stakeholders. The EIA team, in consultation with stakeholders, will endeavour to assess the impact of

[1] http://www.echr.coe.int/Documents/Convention_ENG.pdf

[2] http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf

ethical issues on the PULSE initiatives, the kinds of risks these ethical issues might pose for the PULSE initiatives, and possible solutions to the risks. Again, the ethical risk management strategies set out below also have a heuristic function.

Proposed ethical issues include:

- Loss of privacy control
- Data security
- Accessibility to health and medical records
- Transparency
- Storage and processing of personal data; confidentiality
- Delegation of control
- Incidental findings
- Fairness and justice
- Nondiscrimination

Ethical and social risks	Description	Ethical risk management
Loss of privacy control	Storage and process of personal data, confidentiality.	Anonymity, access only by authorised persons.
Data security	Difficulty in ensuring the security of shared personal health data.	Highest possible data security standards.
Accessibility	Third parties' interest in access to electronically recorded and stored personal health data. Participant/ patients own access to his or her medical record.	• Data protection. • Limited storage of medical record. • Access to medical data strictly denied to any other than the authorised persons.
Transparency	Lack of transparency: • The analysis of health data and the respective outcome. • Work of healthcare professionals/therapeutic concept.	• Informed consent (given in a clear and comprehensive language) • Transparency (including openness about uncertainties and knowledge gaps) is essential for public trust in new technologies.
Storage and process of personal data, confidentiality	• Measurements from various sensors will be transmitted wirelessly. • Difficulty in ensuring the security of shared personal health data.	• Highest possible data security standards.
Delegation of control Privacy incidental findings	• Notify proper authorities • Monitoring module will decide (on their own) • Emotional state will be supervised.	• Informed consent • Danger that the user will lose autonomy. This loss of personal control will be carefully checked.

Table 5: Ethical risk management

Following identification of ethical issues, risks and appropriate risk management strategies, WP8 partners and TRI will oversee the

implementation of appropriate procedures and processes by PULSE consortium partners throughout the duration of the project.

TRI has already identified legal, ethical and societal issues for both scenarios (i.e., a SARS-like virus pandemic and a stadium crush), with a particular focus on the ethical values relevant to decision-making in a pandemic situation, ethical issues and problems in resource triage and resource allocation and issues in public health law. [3] An overview of these issues was used as input for the first end-user workshop (Task 2.1 Health service user requirements gathering and reviewing including threat analysis).

3.11 Report of the EIA

The EIA team will post the EIA report on the PULSE project website and will invite comments or further contributions from stakeholders.

4 Overview of policy initiatives and legislation

Sections 4.1 and 4.2 comprise an overview of policy initiatives in the field of protection of ethical principles and the field of major emergency management. Further research will provide an analysis and assessment of how initiatives in these different areas impact on each other (e.g., with regard to how one may enable or constrain the other). The aim is to identify any constraints from a policy perspective that could limit the effectiveness of the PULSE project. Section 4.3 provides an overview of relevant EU legislation regarding protection of physical systems and critical information systems. Analysis of specific pieces of legislation will be carried out in order to facilitate the identification of legal and ethical factors to be considered in developing systems for the support of the emergency healthcare service. Finally, section 4.4 offers an overview of the most salient points of the EU Data Protection Directive for PULSE, in addition to a list of relevant national legislation and competent authorities. Further research will investigate differences in national legislation in the area of data protection and the ways in which such differences might impact the development of the PULSE platform. Using the findings of the above tasks, the partners will make a preliminary assessment of the impacts of the identified ethical and legal factors on the implementation of PULSE.

4.1 Protection of ethical principles

The Seventh Framework Programme for Research and Technological Development was announced in 2006 by Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013).[4] This Decision sets out the following: "Research activities supported

[3] See Appendix 1
[4] http://cordis.europa.eu/documents/documentlibrary/90798681EN6.pdf

by the Seventh Framework Programme should respect fundamental ethical principles, including those reflected in the Charter of Fundamental Rights of the European Union. The opinions of the European Group on Ethics in Science and New Technologies are and will be taken into account." Article 6 further sets out that "All the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles".

The Charter of Fundamental Rights of the European Union (2010/C 83/02)[5] sets out the rights, freedoms and principles of the citizens of the EU Member States. The core values of the Union are described as human dignity, freedom, equality and solidarity. Article3 (2) and Article 8 of the Charter are particularly relevant for the PULSE project.

Article 3

Right to the integrity of the person

1. Everyone has the right to respect for his or her physical and mental integrity.

2. In the fields of medicine and biology, the following must be respected in particular:

(a) the free and informed consent of the person concerned, according to the procedures laid down by law;

(b) the prohibition of eugenic practices, in particular those aiming at the selection of persons;

(c) the prohibition on making the human body and its parts as such a source of financial gain;

(d) the prohibition of the reproductive cloning of human beings.

Article 8

Protection of personal data

1. Everyone has the right to the protection of personal data concerning him or her.
2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data that has been collected concerning him or her, and the right to have it rectified.
3. Compliance with these rules shall be subject to control by an independent authority.

The Seventh Framework Programme provides additional information on ethics related to undertaking ICT research in FP7. [6] These resources will be used in the development of the EIA.

In addition, important ethical issues found in the following Opinions released by the European Group on Ethics in Science and New Technologies:[7]

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[5] http://www.europarl.europa.eu/charter/pdf/text_en.pdf
[6] http://cordis.europa.eu/fp7/ethics-ict_en.html

Opinion n°28 - 20/05/2014 - Ethics of Security and Surveillance Technologies

Opinion n°26 - 22/02/2012 - Ethics of information and communication technologies

Opinion n° 13 - 30/07/1999 - Ethical issues of healthcare in the information society

4.2 Principles of major emergency management

The principles of emergency management developed by the International Association of Emergency Managers (IAEM)[8] and widely accepted across the emergency management field will be taken into account in the development of the scenarios. According to the IAEM, emergency management must be:

1. Comprehensive – emergency managers consider and take into account all hazards, all phases, all stakeholders and all impacts relevant to disasters.
2. Progressive – emergency managers anticipate future disasters and take preventive and preparatory measures to build disaster-resistant and disaster-resilient communities.
3. Risk-Driven – emergency managers use sound risk management principles (hazard identification, risk analysis and impact analysis) in assigning priorities and resources.
4. Integrated – emergency managers ensure unity of effort among all levels of government and all elements of a community.
5. Collaborative – emergency managers create and sustain broad and sincere relationships among individuals and organisations to ensure trust, advocate a team atmosphere, build consensus and facilitate communication.
6. Coordinated – emergency managers synchronise the activities of all relevant stakeholders to achieve a common purpose.
7. Flexible – emergency managers use creative and innovative approaches in solving disaster challenges.
8. Professional – emergency managers value a science and knowledge-based approach based on education, training, experience, ethical practice, public stewardship and continuous improvement.

Reference will also be made to the EU Civil Protection Mechanism in the ethical, social and legal analysis of the two scenarios.

The new EU Civil Protection Mechanism came into effect at the beginning of 2014. The revised legislation builds on an established system which was set up to enable coordinated assistance from 31 participating states (28 EU

[7] http://ec.europa.eu/bepa/european-group-ethics/publications/opinions/index_en.html

[8] http://www.iaem.com/page.cfm?p=about/em-principles

Member States, along with Norway, Iceland and the former Yugoslav Republic of Macedonia) to victims of natural and man-made disasters in Europe and elsewhere. [9] The new legislation places a greater emphasis on disaster prevention, risk management, and disaster preparedness, including the organisation of training, simulation exercises and the exchange of experts, in addition to developing new elements such as a voluntary pool of pre-committed response capacities by the Member States. [10]

The revised legislation includes the following elements:

- A European Emergency Response Capacity which will facilitate a voluntary pool of response capacities and experts available for immediate deployment as part of a collective European intervention.
- An Emergency Response Coordination Centre (ERCC) which provides a full 24/7 capacity to monitor and respond to disasters ensuring that Member States are fully appraised of the situation and can coordinate regarding the provision of resources and financial and in-kind assistance.
- Member States are asked to contribute to risk management planning by sharing summaries of their risk assessments and refining their risk management planning.
- The importance of prevention and preparedness actions is now legally embedded into the EU Civil Protection Mechanism. EU assistance regarding training will be provided to enable improved inter-operability of the Member States' teams on the ground.

4.3 Protection of physical systems and critical infrastructure systems

The following legislation is relevant:

- **Directive 2001/20/EC** of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

- **Council Directive 83/570/EEC** of 26 October 1983 amending Directives 65/65/EEC,75/318/EEC and 75/319/EEC on the approximation laid down by law, regulation or administrative action relating to proprietary medicinal products

- **Directive 98/44/EC** of the European Parliament and of the Council of 6 July 1998 on the Legal protection of biotechnological inventions

[9] http://ec.europa.eu/echo/en/what/civil-protection/mechanism

[10] http://ec.europa.eu/echo/files/aid/countries/factsheets/thematic/civil_protection_legislation_en.pdf

- **Convention of the Council of Europe on Human Rights and Biomedicine** signed in Oviedo on 4 April 1997, and the Additional Protocol on the Prohibition of Cloning Human Beings signed in Paris on 12 January 1998.

- **UN Convention on the Rights of the Child**, 2002.

- **Universal Declaration on the human genome and human rights adopted by UNESCO**,1997.

- **Directive 99/5/EC** on Radio Equipment, Telecommunications Terminal Equipment and the Mutual Recognition of Their Conformity. Access to control devices and control is a key issue from the viewpoint of the person

- **Directive 2001/95/EEC** includes the general safety requirements for manufacturers and

distributors. The manufacturers must put on the market products that comply with the general safety requirement. They must also provide consumers with necessary information

- **Low Voltage directive (LVD) 73/23/EEC** seeks to ensure that electrical equipment within certain voltage limits provides a high level of protection

- Proposal for a **DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL** concerning measures to ensure a high common level of network and information security across the Union /* COM/2013/048 final - 2013/0027 (COD) */

- **Handbook on European data protection law** - European Union Agency for Fundamental Rights, 2014 - Council of Europe, 2014

- **EU compliance and regulations for the IT security professional** - A White Paper by Bloor Research (Author : Nigel Stanley, Publish date : March 2009)

- **Directive 2013/40/EU** of the European Parliament and of the Council of 12 August 2013 on attacks against information systems and replacing Council Framework Decision 2005/222/JHA

- **The Directive on attacks against information systems - A Good Practice Collection for CERTs on the Directive on attacks against information systems** - ENISA P/28/12/TCD, Version: 1.5, 24 October, 2013

- **Directive 2004/108/EC** relating to electromagnetic compatibility and repealing Directive 89/336/EEC OJ L 390 of 31 December 2004

- **Directive of 9 March 1999** of the European Parliament and of the Council on Radio Equipment and Telecommunications Terminal Equipment and the mutual recognition of their conformity OJ L 91 of 7 April 1999

4.4 Data protection

Currently the Europe Union is undergoing a major revision of its data protection framework. The European Commission proposed a new framework, including a new Data Protection Regulation (GDPR), in January 2012. The GDPR introduced new features and new principles not contained in the existing Data Protection Directive (95/46/EC), which has been in place for almost 15 years.

The Data Protection Directive sets out the following principles relating to data quality, for which the data controller is responsible.

Personal data must be:

(a) processed fairly and lawfully;
(b) collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes. Further processing of data for historical, statistical or scientific purposes shall not be considered as incompatible provided that Member States provide appropriate safeguards;
(c) adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed;
(d) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that data which are inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed, are erased or rectified;
(e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data were collected or for which they are further processed. Member States shall lay down appropriate safeguards for personal data stored for longer periods for historical, statistical or scientific use.

National and European documents on privacy and data protection in selected countries

The undermentioned competent authorities and legislations are related to data protection:

- **Europe**: Competent Authority: European Commission Legal Advisory Board Data Protection. 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. European Data Protection Supervisor (https://secure.edps.europa.eu/EDPSWEB/edps/EDPS)
- **Albania:** Law no. 8517/1999 on the protection of personal data.

- **Austria:** Competent Authority: Bundeskanzleramt Österreichische Datenschutzkommission. Bundesgesetz über den Schutz personenbezogener Daten "Datenshutzgesetz 2000. BGBI. I no.165/1999.
- **Belgium:** Competent Authority: Commission de la protection de la vie privée. O.J. 3.2.1999, 11.12.1998.
- **Bulgaria**: The Constitution of Bulgaria recognizes the right to privacy. Bulgaria signed (Strasbourg, 28.1.1981) Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (CE Convention no. 108/1981). Since 1996, the law is being processed for the protection of citizens' personal data, in transposition of the EU Directive 95/46.
- **Croatia**: The Act on Personal Data Protection-Official Gazette n.105/2004.
- **Cyprus**: Law No.8517/1999 about personal data protection.
- **Czech Republic:** Competent Authority: Office for Personal Data Protection. Law No. 101/2000 on Personal Data Protection.
- **Denmark**: Act no. 429 del 31/5/2000, on Processing of Personal Data. Competent Authority: Datatilsynet.
- **Estonia**: Competent Authority: "Andmekaitse Inspektsion". The Estonian Constitution recognizes the right to privacy. In 1996, the "Riigikogu" (the Estonian Parliament) adopted the Law on the Protection of Personal Data.
- **Finland**: Competent Authority: "Tietosuojavaltuutetun toimisto". Law No. 523/1999, The Finnish Personal Data Act.
- **Germany**: Competent Authority: Der Bundesbeauftragte für den Datenschutz. Federal Data Protection Act, 2001.
- **Greece**: Competent Authority: Hellenic data protection Authority - Commission pour la protection des données à caractére personnel. Law No. 2472/1997 about Protection of individuals with regard to the processing of personal data.
- **Iceland**: Competent Authority: Persónuvernd - Icelandic Data Protection Agency. Law No. 77/2000, "Protection of individuals with regard to the processing of personal data".
- **Ireland**: Competent Authority: Data Protection Commissioner. Data Protection Act, 1988.
- **Italy**: Competent Authority: Garante per la Protezione dei Dati Personali. Data Protection Code: Legislative Decree no. 196/2003.
- **France**: Competent Authority: Commission Nationale de l'Informatique et des Libertés. Loi Informatique et Libertés (French Data Protection and Freedoms Act), 6 Jan 1978.
- **Hungary**: Competent Authority: Data Protection Commissioner of Hungary, Parliamentary Commissioner for Data Protection and Freedom of Information. Law on protection personal data no. 63, 1992; 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; Convention for the Protection of

Individuals with regard to Automatic Processing of Personal Data (CE Convention no. 108/1981).

- **Lithuania**: Competent Authority: State Data Protection Inspectorate. Personal Data Protection Act, 1996.
- **Luxembourg**: Competent Authority: Commission nationale pour la protection des données. "Protection des personnes ˆ l'Žgard du traitement des donnŽes ˆ caractŽre personnel", 2002.
- **Macedonia**: Law on the Protection of Personal Data - adopted by Parliament January 25, 2005. Article. 18 of the 1991 Constitution guarantees the protection of personal data.
- **Netherlands**: Competent Authority: Registratiekamer. "Wet bescherming persoonsgegevens" (O.J. 302/2000), 6 July 2000.
- **Norway:** Competent Authority: Datatilsynet. Law on personal data protection, 2000.
- **Poland:** Competent Authority: Biuro Geneeralnego Inspektora. Law on personal data protection, 1997.
- **Portugal:** Competent Authority: Comissão Nacional de Proteccão de Dados. Lei da proteccào de dados pessoais" N0. 67/1998.
- **Romania:**
- **Slovak Republic:** Competent Authority: Department of Informatics - Data Protection. Law on the protection of personal data information systems, 1998.
- **Spain**: Competent Authority: Agencia de Protección de Datos. Ley Orgánica n.15 del 13 diciembre 1999, de Protección de Datos de Carácter Personal (LOPD); Real Decreto 1720/2007, de 21 de diciembre, por el que se aprueba el Reglamento de desarrollo de la Ley Orgánica 15/1999, de 13 de diciembre, de protección de datos de carácter personal.
- **Sweden**: Competent Authority: Datainspektionen. Personuppgiftslagen (SFS 1998:204).
- **Switzerland**: Competent Authority: Eidgenössischer Datenbeauftragter (Data Protection Commissioner of Switzerland). CE Convention no.108/1981; Federal Law on Data Protection, 1992.
- **UK**: Competent Authority: Information Commissioner. The Data Protection Act, 16 July 1998.

Article 29, Data Protection Working Party (2000). Privacy on the Internet – An integrated EU approach to On-line Data Protection, 5063/00/EN Final.

Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector

5 Overview of security codes of practice and standards

The ISO 27000[11] series of standards regarding information security matters are relevant to PULSE, and specifically:

- ISO/IEC 27000: 2014: Information security management systems – Overview and vocabulary
- ISO/IEC 27005: 2011 Information security risk management which provides guidelines for information security management

The ISO/IEC WD 29134 Privacy impact assessment – methodology draft standard is also relevant. [12]

These standards will be reviewed in the coming months as part of work for WP8.

6 PULSE data controller

The people or organisations that collect and manage personal data are referred to as "data controllers". Data controllers must respect the privacy rights of individuals supplying their personal data. The Data Protection Directive (Directive 95/46/EC)[13] sets out a series of rights and duties regarding personal data when it is collected and processed.

In many Member States, the data protection authority (DPA) require those organisations that create and maintain databases of personal data to register with the DPA. Hence, as PULSE intends to gather personal data from some stakeholders, it will need to register its database with the local DPA, which will be confirmed at a later stage.

7 Looking ahead: Findings and recommendations

Trilateral Research will produce an Ethical Impact Assessment report including recommendations as an outcome of work package 8. The EIA report will be distributed to project partners, in addition to stakeholders. The EIA will be updated if changes are made to the project.

[11] http://www.iso.org/iso/catalogue_detail?csnumber=56891

[12] http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=62289

[13] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML

Annex 1 – Informed consent procedures

Service providers (medical/fire, etc.) will be asked to sign an informed consent form prior to their participation in the stadium crush event.

Informed Consent

Informed consent is the process by which a participant will be fully informed about the research in which the participant will be involved. It originates from the legal and ethical right participants have to direct what happens to their body and personal data and from the ethical duty of the investigators to involve the participants in research.

Seeking the consent of an individual to participate in research reflects the right of an individual to self-determination and the individual's fundamental right to be free from interference, whether physical or psychological, and to protect the individual's personal data. These are ethical principles recognised as legal rights.

Respect for persons requires that participants are given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied. General requirements for informed consent imply that the persons who are invited to participate in research:

- Are given clear and adequate information in a form that is accessible and intelligible.
- Are competent and understand the purpose of the project and the consequences of participation.
- Can assess their situation.
- Can make an independent and voluntary decision whether to participate on the basis of information and their preferences and values
- Voluntarily communicates their decision.
- Can withdraw from the research at any time without penalty.
-

Guidelines for Informed Consent Process

It is important to see informed consent as a process, not just a form to be filled in. Information should be presented to enable persons to voluntarily decide whether or not to participate in the research. The following comments may guide investigators about this process.

Educate the prospective participant

In order to respect the requirement of informed consent, it is important to ensure that there is genuine understanding of what the research is about and what the foreseeable outcomes will be and what direct, immediate, and tangible benefits the participants can expect. One must be sure to communicate in ways that are easily understandable and accessible for the participants. The use of scientific jargon and legalese is not appropriate. The document is primarily thought of as a teaching tool, not as a legal

instrument. The investigator should be aware of the fact that the use of the first person (e.g., "I understand that…") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a participant.

Give information in an appropriate form

The potential participants must be given information about the project and what participation means in a form that the person can perceive and understand (for example, in the case of visually impaired people and dyslexic people they will get information orally in addition to in writing). To send an information letter as an attachment in an e-mail is not necessarily enough. One cannot take it for granted that all informants have actually opened and read an attachment in an e-mail. It is therefore a good rule to repeat the information before asking the informants to sign the consent form. The researcher should have a copy of the information sheet and offer to read it aloud, or make sure that the informants get enough time to read it themselves. Furthermore, the informant will have the opportunity to ask questions and get answers to these before any signing. In uTRUSTit, this will be achieved by starting each session with an offer to read the information out loud to the participants and offering explanations until the information is fully understood.

Underscore that the participation is voluntary

Participation in research must be voluntary and the participant has the right to withdraw at any time without having to give any explanation or reason for doing so. The participant must not incur any penalty or loss of benefits as a result of either not participating or withdrawing at any time during the experiment.

Include only people able to give a valid informed consent

User groups should not include people unable to give valid consent. Some groups may not be able to read a consent form on paper, for example, those who have severe visual problems and those who suffer from severe dyslexia. Since the recruitment of visually impaired and dyslexic people will go through user organisations, the recruitment assistant in each organisation should assist in giving information to and answering questions from potential participants. Researchers hould provide the consent form in an accessible electronic form in advance. Before the research encounter, the researcher should collect a signature on a paper version of the consent form from the participant. The practicalities of the signing for those who cannot see will be taken care of by helping them in placing the pen, signing frame or stamp (whatever tool they will use) on the right place on the sheet prior to the signing. There should be two researchers present to witness the consent.

Keep the information safe and in accordance with the informed consent

It will be the responsibility of the partner conducting the respective research to ensure that all uses of data and samples are in accordance with data protection laws and the consent obtained from the participant.

Checklist for compiling the informed consent form

The informed consent form consists of two parts, first, information on the research study, followed by documentation of consent, i.e., date, place and the identity of the person (name and age) and his or her signature.

The following pieces of information should be covered by the information section of the informed consent form:

- The **title** of the study.
- Who is **funding** the study.
- What is the **purpose** of the study.
- **Who can take part in** the study and who is invited to participate.
- The approximate **number of participants** involved in the study.
- Describe the **overall experience** that will be encountered, the expected duration, and procedures.
- Describe the **right to decline** to participate and to **withdraw** from the research once participation has begun and the foreseeable consequences of declining or withdrawing; the information must state that the participation is totally voluntary and that the prospective participant can stop at any point without having to give any explanation or reason. Further, no penalty or loss of benefits will occur as a result of either not participating or withdrawing from the research at any time.
- Information on any **reasonably foreseeable injuries**, discomforts, inconveniences and risks that are associated with the research activity. *(This should not be the case in Trials.)*
- There should be an explanation about the **confidentiality (and limits) of the data collected**. This means that the participants shall be told of the extent to which their personally identifiable information will be held in confidence. They shall be informed about what kind of data will be recorded and stored, who will have access to the data, for what it will be used, and where and for how long it will be stored.
- Researchers should give details of **contact persons** who are able to answer questions from participants about the research and the rights of the research participant.
- Researchers should give details on who is the data controller and how the participant can revoke consent.

Currently, the partners envisage the use of informed consent forms in the context of some or all of the following tasks:

- **Task 2.1** – Health service user requirements gathering and reviewing including threat analysis
- **Task 2.5** – Individual application requirements
- **Task 5.5** – External stakeholders
- **Task 7.3** – Benchmarking and evaluation and assessing public acceptance
- **Task 7.6** – External stakeholders
- **Task 8.7** – External stakeholders

Ethical Compliance

The consortium have developed a set of procedures and controls to ensure that all requirements with respect to informed consent are adhered to:

Participants must have the right:
- To know that participation is voluntary
- To ask questions and receive understandable answers before making a decision
- To know the degree of risk and burden involved in participation
- To know who will benefit from participation
- To know the procedures that will be implemented in the case of incidental findings
- To receive assurances that appropriate insurance cover is in place
- To know how their data will be collected, protected during the project and either destroyed or reused at the end of the research, if a plan to reuse the data exists, information must be provided in order to insure that the involved minors will be re-asked for their consent as soon as their reach legal majority, in compliance with the Article 29 Working Party document WP 147 00483/08/EN
- To withdraw themselves and their data from the project at any time
- To know of any potential commercial exploitation of the research.

Annex 2 – Informed consent forms and information sheets

INFORMATION SHEET FOR PARTICIPANTS

Platform for European medical support during major emergencies (PULSE)

We would like to invite you to participate in this EU-funded collaborative research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

In Europe, one of the core emergency response services to deadly threats such as pandemic disease and major terrorism attacks is the European Health Services (EHS). Key EHS stakeholders comprise hospitals, community health services, pre-hospital emergency care services, medical suppliers, rescue services, health related voluntary services and others. The EHS must remain in an excellent state of preparedness supported by first-class planning and decision support tools. Moreover, in the response phase, EHS need consistent, co-ordinated and standardised tools providing support in critical tasks like early threat detection, common operational picture, creation of surge capacity, etc. At a pan European level, EHS also need an interoperable framework with the ability to provide a co-ordinated European response to any major medical incident. PULSE aims to meet these challenges. The project will begin with a comprehensive study of the procedures, processes and training requirements in current operation at the EHS using the support of end users available to the project. It will then:

- Develop standard and consistent response procedures and processes;
- Provide tools to support decision making in both preparedness and response phases;
- Provide a Framework that ensures decision makers have access to timely key data, planning and
- decision support tools and to international best practice and lessons learnt;
- Present innovative training techniques to improve personnel response training;
- Develop an 'emergency app' for smart phones that will allow users fast and flexible access to emergency resource availability information;

The PULSE Framework will be validated by exercises and demonstrations based on two scenarios: (1) a biological attack in Italy and (2) a major stadium 'crush' at a Dublin concert. Both will involve cross border support from neighbouring countries.

The project team will present and discuss these scenarios with representatives of the core stakeholders in order to validate and to complement the scenarios. Stakeholders include, inter alia, health care institutions, emergency services, medical personnel, industry, businesses, data protection authorities, and organisations representing citizens' interests (normally non-government organisations).

With your participation, you have the opportunity to be involved in the European Commission's attempt to support and improve emergency healthcare preparedness. The project team will use the insights gained from the workshops as an important input to the PULSE project. You will get a paper copy or PDF of the workshop report and the final project report.

When you agree to participate, you will be invited to a workshop which will be held in **xxxxxx** on **xx xxxx 2014**. A few days before the workshop takes place, you will receive an outline of the scenarios. Interviews will be recorded, subject to the participants' permission. Recordings of interviews will be deleted upon transcription. For the further course of the project, only anonymised data will be used.

It is up to you to decide whether to take part or not. Participation is entirely voluntary. You are entitled to ask questions and receive understandable answers from the PULSE project partners before you make your decision about whether to participate. If you decide to take part, you are free to withdraw at any time and without giving a reason. In addition to withdrawing yourself from the study, you may also withdraw any data or information that you might already have provided up until it is transcribed for use in the final report.

If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form.

If this study has harmed you in any way, you can contact Sarah Bourke, PULSE project co-ordinator, sarah.bourke@skytek.com or tel: +353 6787660

PULSE Interview Participant Consent Form

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Project Title: Platform for European Medical Support during major emergencies

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

Please tick/ initial box

- I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data up to the point of publication. ☐
- I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of Data Protection Directive (Directive 95/46/EC) and its national implementations. ☐
- I consent to the workshop being recorded. ☐
- The information you have submitted will be published as a report and you will be sent a copy. Please note that confidentiality and anonymity will be maintained and it will not be possible to identify you from any publications. ☐

Participant's Statement:

I,

_____

(name in print)

agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project, and understand what the research study involves.

Signed Date

Appendix 1 – Key ethical values and legal issues in the two scenarios

Ten key ethical values relevant to decision-making for a SARS-like pandemic [Scenario 1][14]

Individual liberty

- What are the justifications for balancing individual liberties against the value of the protection of the public from harm?
- Are restrictions to individual liberty proportional to the risk of harm?
- Are restrictions applied without discrimination?

Proportionality

- Are emergency management powers and public health powers exercised in a way that is relevant, legitimate and necessary?
- Are least restrictive methods used in limiting individual liberties?
- In circumstances in which less restrictive measures have failed to achieve their purpose, what kinds of (more) coercive measures might be implemented? What are the implications of using more coercive measures?
- Are restrictions applied without discrimination?

Privacy of personal information and the public need to know

- If personal information is to be made public, is there a clear and well-defined public health goal for doing so?
- Are there less intrusive means – other than the disclosure of personal information – available to protect public health?
- Are there mechanisms in place for protecting communities from undue stigma?
- Is the good intended significant enough to justify the potential harm that can arise as a result of suspending privacy rights (e.g., the harm from stigmatisation of individuals or particular communities)?

Duty to steward resources

- Are good efforts made to protect and develop resources where possible?
- Are benefits maximised on the allocation of resources?

[14] Adapted from Thompson, Alison, K., Karen Faith, Jennifer L. Gibson and Ross E.G. Upshur, "Pandemic influenza preparedness: an ethical framework to guide decision-making", *BMC Medical Ethics*, Vol. 7, No. 12, 2006.
Adapted from Singer, Peter A., R. Benatar Solomon, Mark Bernstein, Abdallah S. Daar, Bernard M., Susan K. MacRae, Ross E.G. Upshur, Kinda Wright and Randi Zlotnick Shaul, "Ethics and SARS: lessons from Toronto", *BMJ*, Vol. 327, 6 December 2003, pp. 1342-1344.

- Are efforts made to avoid and/or reduce collateral damage that may result from decisions about resource allocation (e.g., denial of surgery/treatment for patients with cancer or heart disease)?
- Are both good outcomes (i.e., benefits to the public good) and equity (i.e., fair distribution of benefits and burdens) considered in decision-making processes?

Trust

- Are steps taken to build trust before the crisis hits?
- Are decision-making processes made according to the values of accountability, inclusiveness, openness and transparency, reasonableness and responsiveness?
- Are decision-making processes transparent to affected stakeholders?

Duty to provide care

- To what extent should healthcare workers and/or emergency workers fulfil their duty to care given imminent health risks to themselves and their family?
- Are there mechanisms in place to ease the moral burden of those with the duty to care?
- Are there facilities in place (e.g. access to an effective vaccine to prevent illness) to protect and care for emergency workers who take on risks when treating others?

Protection of the public from harm

When making the decision to quarantine individuals, protection of the public from harm must be weighed against individual liberty.

Decision-makers should address the following:

- Ensure stakeholders are made aware of the medical and moral reasons for public health measures
- Ensure stakeholders are made aware of the benefits of compliance and the consequences of non-compliance
- Establish mechanisms to review these decisions as the public health situation changes and to address stakeholders' concerns or complaints

Reciprocity

Questions for decision-makers and institutions:

- Are mechanisms in place with which to ease the burden of health care workers/emergency workers, patients and patients' families in their hospitals and in coordination with other health care organisations?
- Are measures taken to ensure the safety of workers, particular when redeploying staff in areas beyond the usual scope of practice?

Equity

Decision makers must strive to

- Preserve as much equity as possible between the interests of patients [afflicted with the virus] and those who need urgent treatment for other diseases
- Ensure procedural fairness in decision-making

Procedural values guiding ethical decision-making for a SARS-like outbreak[15]

Procedural value	Description
Reasonable	Decisions should be based on reasons (i.e., evidence, principles and values) that stakeholders agree are relevant to meeting health needs in such a situation. Decisions should be made by people who are credible and accountable.
Open and transparent	The process by which decisions are made must be open to scrutiny and the basis on which decisions are made should be publicly accessible.
Inclusive	Decisions should be made explicitly with stakeholder views in mind and stakeholders should be engaged in the decision-making process.
Responsive	There should be opportunities to revisit and revise decisions as new information emerges. Mechanisms with which to address disputes and complaints should be in place.
Accountable	Mechanisms should be in place to ensure that decision-makers are accountable for their actions and inactions.

[15] Adapted from: University of Toronto Joint Centre for Bioethics Pandemic Influenza Working Group, "Stand on Guard for Thee: Ethical considerations in preparedness planning for pandemic influenza", November 2005. http://www.jointcentreforbioethics.ca/people/documents/upshur_stand_guard.pdf

Core components of ethical decision-making for disaster triage situations[16] [Scenario 2]

Fairness	The process is inherently just to all individuals and the process itself treats all individuals equally who have equal needs
Duty to care	Physicians have a duty to care as best as they can for all victims of an incident
Duty to steward resources	Physicians have a duty to attempt to obtain the best outcome for the greatest number of people with the resources available.
Transparency	Notwithstanding the difficulty of reactive triage decisions, the process and criteria should be as transparent as possible
Consistency	The process should be applied in the same way to all presenting for care
Proportionality	The degree of resource restriction should be proportional to the demands
Accountability	Triage officers and others should be able to defend their decisions and be answerable for them. This may involve documentation and potential review of decisions by the institution and possibly outside agencies.

Problem areas that need to be considered in times of resource triage[17]

Type of problem	**Description**
The fair chances/best outcome problem	To what degree should we favour producing the best outcome with our limited resources?
The priorities problem	How much priority should we give to treating the sickest or the most disabled patients?
The aggregation problem	When should we allow an aggregation of modest benefits to larger numbers of people to outweigh more substantial benefits to fewer people?
The democracy problem	When must we rely on a fair democratic process as the only way to determine what constitutes a fair rationing outcome?

[16] Adapted from: Hick, John, L., Dan Hanfling and Stephen V. Cantrill, "Allocating Scarce Resources in Disasters: Emergency Department Principles", *Annals of Emergency Medicine*, Vol. 59, No. 3, March 2012, pp. 177-186.
[17] Adapted from O' Laughlin, Daniel, T. and John L. Hick, "Ethical Issues in Resource Triage", *Respiratory Care*, Vol. 53, No. 2, February 2008, pp. 190-200.

Factors influencing resource allocation[18]

May consider (add description of different elements)	Should not consider
Likelihood of benefit	Sex
Change in quality of life	Race
Duration of benefit	Ability to pay
Amount of resources required	Social worth
	Perceived obstacles to treatment
	Patient contribution to illness
	Past resource use

Legal issues: scope of public health law and general issues[19]: BOTH SCENARIOS

- The public health (emergency management) workforce *lacks input into and knowledge* regarding legal and ethical decision-making in emergencies
- Lawyers, public health practitioners, emergency managers and others must *prioritise and resolve legal issues on the basis of incomplete information and guidance* during declared emergencies
- Dual states of emergency can lead to a *confused response* as a variety of government agencies and actors try to respond simultaneously according to different legal authorities
- Emergency laws tend to offer a menu of legal powers and options as opposed to a manual for how to respond. In a *vacuum of affirmative legal direction*, public health practitioners and emergency managers may act outside legal boundaries.
- "Legal triage" refers to the prioritisation by emergency managers, public health practitioners and their legal counsel of legal issues and solutions in real time in order to facilitate legitimate public health responses that balance communal and individual interests in declared states of emergency. Legal triage requires responders to make critical legal decisions in emergencies in which facts may be unclear, resources scarce and communal wellbeing seriously threatened.
- Public health emergency law "offer government and the private sector flexible powers to protect the public's health, allows government to suspend legal regulations that impede emergency responses, encourage volunteers' or others' efforts by limiting liability, facilitate transitions to a crisis standard of care and

[18] Ibid.

[19] Hodge, James G. Jr., Timothy Lant, Jalayne Arias and Megan Jehn, "Building Evidence for Legal Decision Making in Real Time: Legal Triage in Public Health Emergencies", *Disaster Medicine and Public Health Preparedness,* Vol.5, No.2, 2011, pp. 1-10.

authorise alterations in professional licensing standards or scopes of practice" (p.1)

- Disaster and emergency declarations empower public and private entities to address the public health aspects of emergencies through enhanced and expedited powers to implement social distancing measures (e.g. set curfews, order quarantine or isolation) and conduct testing, screening, treatment and vaccination programmes.

Legal issues related to implementing crisis standards of care[20]

Subject	**Legal issues**
Organisation of personnel	• How are employees, independent contractors and volunteers legally distinguished for the purpose of coordinating services and benefits? • Have appropriate contractual or other mechanisms been executed to facilitate the delivery of services by employed or volunteer personnel, ensure worker safety, or make available workers' compensation or other benefits?
Access to treatment	• Has the entity assessed its strategy for conducting medical triage under legal requirements for treating existing and forthcoming patients?
Coordination of health services	• Are health care personnel aware of the legal effects of a shift to crisis standards of care and changes relating to scopes of practice during an emergency? • Are legal issues concerning the use of volunteer health professionals during an emergency addressed via the entity's emergency plan?
Patients' interests	• Are there appropriate measures to ascertain patients' informed consent? • Barring waiver, are the entity and its personnel prepared to respect patients' health information privacy rights?
Allocation of resources	• Are state or local policies regarding resource allocation followed? • Can government appropriate existing resources (with just compensation) for communal purposes during an emergency?
Liability	• When may the entity and its personnel be liable for their actions in treating patient in a major

[20] Adapted from Hodge, James, G. Jr., Dan Hanfling and Tia P. Powell, "Practical, Ethical, and Legal Challenges Underlying Crisis Standards of Care", *Journal of Law, Medicine and Ethics*, Spring 2013, pp. 50-55.

	emergency situation? • What legal protection from liability for entities, their health care personnel, independent contractors or volunteers (including insurance coverage) apply?
Interjurisdictional cooperation	• Have agreements been made in order to facilitate interjurisdictional coordination of emergency health services? • Are these agreements consistent with governmental requirements? • Have state or local governments on international borders addressed specific concerns through lawful agreements?