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Pandemic Risk and Emergency Management

D4.1 Review of Policy and Legal Frameworks

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Table of Contents

1 Objective 4

2 Introduction 4

2.1 Definitions 4

2.2 Background/Overview 5

2.3 Network Governance 9

3 Methodology 11

4 Governance frameworks and mechanisms: Global 12

4.1 International Legal Instruments 12

4.1.1 International Health Regulations (2005) 12

4.1.2 Nagoya Protocol 14

4.1.3 Pandemic Influenza Preparedness Framework 2011 14

4.2 Global Governance Mechanisms 16

4.2.1 World Health Organization (WHO) 16

4.2.2 Global Outbreak Alert and Response Network (GOARN) 18

4.2.3 Global Health Security Initiative (GHSI) 18

4.2.4 Global Health Security Agenda 18

4.2.5 WHO Global Influenza Surveillance and Response System (GISRS) 19

5 Governance Frameworks and Mechanisms: European Union 19

5.1 EU Legal Instruments 19

5.1.1 Article 152 (5) EC 19

5.1.2 Article 168 Treaty on the functioning of the European Union (TFEU) 20

5.1.3 Article 222 Treaty on the functioning of the European Union (TFEU) 20

5.1.4 Decision 2119/98/EC 21

5.1.5 Decision 2000/57/EC 21

5.1.6 Regulation 851/2004 21

5.1.7 EU COM (2005) 605: Strengthening coordination on generic preparedness planning for public health emergencies at EU level 21

5.1.8 EU COM (2005) 607: Pandemic influenza preparedness and response planning in the European Community 21

5.1.9 Schengen Agreement 21

5.1.10 Decision 1082/13 on serious cross-border threats to health and repealing Decision No 2119/98/EC 22

5.2 EU Governance Mechanisms 24

5.2.1 WHO Regional Office for Europe 24

5.2.2 EU Agencies 24

5.2.3 EU Health Security Committee (HSC) 25

5.2.4 Health Emergency Operations Facility (HEOF) 26

5.2.5 Early Warning and Response System (EWRS) 26

5.2.6 Medical Information System (MEDISYS) 26
5.2.7 Health Emergency & Disease Information System (HEDIS) 27
5.2.8 European Medical Corps (EMC) 27
6 Governance Frameworks and Mechanisms: International initiatives 27
6.1 North American plan for animal and pandemic influenza (NAPAPI) 27
6.2 Sendai Framework for disaster risk reduction (2015-2030) 28
6.3 Global Health Risk Framework (GHRF) 28
6.4 Global challenge initiative on the future of health 28
7 Governance Frameworks and Mechanisms: International commonalities and disconnects 29
8 Governance Frameworks and Mechanisms: Member States 30
8.1 National Pandemic Influenza Preparedness Plans 30
9 Governance Frameworks and Mechanisms: Transportation of specimens, bio-safety, bio-security, diagnostics and virus-sharing 53
9.1 Safety and the regulation of transport of specimens 53
9.1.1 Regulatory bodies 53
9.1.2 Legal instruments for the regulation of dangerous goods transport 54
9.1.3 Nature of biological material: Dangerous Goods – Infectious substances 56
9.1.4 Packing, Marking and labelling instruction of Dangerous Goods 57
9.2 Diagnostics 61
9.3 Bio-safety and bio-security 61
9.3.1 Definitions 61
9.3.2 Legal framework 62
9.4 Sharing pathogenic biological material 63
10 Literature Review 65
10.1 Methodology 65
10.2 Results and analysis of commonalities and disconnects 68
11 Relevant research projects 71
12 Expert Workshop on Pandemic Governance, Brussels: Workshop Outputs 77
13 Case study: European Union response to Ebola outbreak 2014-2015 83
14 Case study: Germany E. coli outbreak 2011 93
15 Case study: US Model Emergency Health Powers Act 105
16 Priority legal and governance issues and challenges for & within the EU 114
16.1 Summary of Challenges, Recommendations, Gap Analysis and Research Questions 114
16.2 Commonalities and disconnects for further investigation 121
References 122

1 Objective

The objective of this report is to review the current status of pandemic governance (policy and legal frameworks) at global, regional (European) and, to the extent possible, national (European Member State) level. This information is used to identify priority governance issues and challenges for and within the European Union.

This objective is achieved by an examination of key legal and policy frameworks and mechanisms at global, European and national level. Commonalities and challenges are identified from literature review, consideration of relevant recent and ongoing research projects and input from public health governance experts, both from a workshop held in Brussels on 17-18 February 2016 and from individual interviewee interviews. Three case studies, two from Europe and one from the US illustrate challenges and proposed solutions.

This report should be read with report D4.2 on ethical and human rights issues in pandemic governance. Both reports inform report D4.3 where we report a more detailed gap analysis and feasibility review of issues identified in D4.1 and D4.2.

2 Introduction

2.1 Definitions

"**Governance**" is the process for governing a country or organisation. For this project, "governance" includes consideration of policy and legal frameworks [report D4.1], ethics and human rights [report D4.2]. "Governance" may also be interpreted more broadly to include the features of good governance, such as monitoring, transparency, civil society engagement and accountability [see section 11].

A **legal framework** is the broad system of rules that governs and regulates decision making, agreements and laws. This can include both policy and law, also known as "soft law" and "hard law" respectively. There are important differences between these [1]:

Policy

- A statement of principles/intentions
- Can be used to create new laws but must comply with existing laws
- Non-binding and non-enforceable – only influential in weight
- Can be public (e.g. published national pandemic preparedness plan), or may be kept as an internal document

- Less rigid than law and can be decided ad hoc to meet immediate emergencies
- "Soft law": the usual basis of governance for pandemics.

Law

- Jurisdictional: rarely goes beyond national sovereignty
- Binding and enforceable (usually)
- Results from a legislative or judicial act
- Can be inflexible and slow to react
- "Hard law".

2.2 Background/Overview

Importance of pandemic governance

A pandemic or outbreak of infectious disease caused by a high threat pathogen is one of the most serious threats a country can face. Historically, pandemics have been enormously disruptive, not only to the health of individuals, but to the functioning of society as a whole. An epidemic which is out of control can become a security threat, damaging national institutions, the economy and international relations.

A pandemic due to a rapidly transmissible infectious agent is a fast moving emergency which needs a rapid response. Without rules in place, ad hoc measures may be taken without detailed consideration. As a result, they risk being ineffective or unjust, failing to respect human rights and worsening the impact of the epidemic.

Pre-pandemic preparedness planning can establish a legal and ethical framework within which to respond to an emergency situation. Law and policy which is transparent, evidence based and respects civil rights can enable an effective and efficient response which maintains the trust and support of the population.

As explained by the US academic Lawrence Gostin: "Pandemics can be deeply socially divisive, and the political response to these issues not only impacts public health preparedness, but also is important to a good and decent society. It is for these reasons that it is particularly important to show respect for public health ethics and international law – particularly human rights law – when developing national policy for pandemic influenza"[2].

In summary, pandemic governance can ensure that in the event of a pandemic, response measures:

- Are evidence based and therefore a more effective response to an epidemic;
- Are legally and ethically sound ;
- Reach a correct (or justifiable) balance between individual rights and "the common good";
- Maintain societal functioning, thereby reducing the risk of public panic and economic loss;
- Enable coordination and collaboration with neighbouring countries.

Global and regional institutions have recognised and emphasised the importance of pandemic governance. The World Health Organization (WHO) in its role as the specialized agency of the United Nations concerned with international public health has led this with a key international legal instrument: the revised International Health Regulations (IHR) (2005). The IHR explicitly obliges its 196 signatories to have national preparedness plans in place, underpinned by national legislation.

Similarly both the EU and the US have recognised the importance of pandemic governance as noted by Brattberg:
"Each has vowed to take extraordinary action to protect societies from a threat that easily sweeps across borders. Moreover, similar policies, structures, and operational capacities focusing on surveillance, early warning and control have emerged in both the EU and the US over the past decade or so. In particular, both have succeeded in establishing some sort of minimum standards for pandemic preparedness and response." [3]

Challenges of governance

Governance to successfully prepare for and respond to global public health threats is both particularly important, and also particularly challenging to achieve.

What is "good governance"?

"Good governance" (at national, regional and global levels) would contribute to reducing morbidity/mortality, economic loss etc. But achieving "good governance" is exceptionally challenging. The evidence base for many scientific measures is limited and it can be a challenge to evaluate and test "principles of public good" [workshop participant: see section 11].

Inherent tensions

It is a truism that infectious diseases do not respect country borders, and pandemics are by definition international events. Effective pandemic governance needs to be national, regional and international and countries' responses need to be coordinated and collaborative. A coordinated, harmonized response would seem the ideal response for maximum efficiency and effectiveness. This is the aim of the IHR which is the legal basis upon which WHO and signatories (States Parties) prepare for and coordinate the response to public health emergencies of public health concern (PHEIC) caused by any hazard, whether of chemical, biological or radionuclear origin. Given the large number of countries and stakeholders this is challenging, although regional organisations such as the EU are moving to encourage this. Such a coordinated and harmonized response is rarely achievable because of inherent tensions:

- Overarching harmonized response v sovereignty/subsidiarity

Pandemics are global phenomena yet governance needs to be flexible to respect national sovereignty and the evolving nature of the demands of containment. Individual states have differing political, cultural and socio-economic backgrounds. Public health responses may vary across countries and it is a major challenge for a lead organisation, whether regional or global, to ensure coordination and coherence of responses.

- Individual rights v the common good

Pandemic control may require measures which, in other circumstances, would be considered a breach of human rights, e.g. restriction of movement (isolation, quarantine), loss of privacy (access to confidential medical records). A public health emergency is one of the few instances where such a curtailment of rights may be justified. But governance needs to be carefully drafted to be transparent, ethical and set clear rules for balancing these conflicting rights, and provide safeguards for individuals whose rights must give way to the public good. Different countries will have different views on where the balance should lie and the extent of individual restrictions which will be publicly tolerated or acceptable.

- Political will

Although there are 196 signatories to the IHR and 28 EU Member States are committed to EU Decision 1082/13, countries will differ as to the priority they give to pandemic planning. This was clearly seen in the sometimes slow response to the Ebola outbreak from both affected countries, and responding EU countries [see case study]. It is also

apparent from analyses of publicly available national pandemic preparedness plans [see section 8]. As EU Member States are, broadly, high income countries, this seems more likely due to a lack of prioritisation and political motivation, than to a lack of capacity.

Multiple stakeholders

Pandemic governance involves multiple stakeholders, many of whom may have competing interests and it is extremely challenging to accommodate all of these. These stakeholders cross regions, countries and sectors within countries:

Bennett captures this notion well: "governance is not solely the preserve of government, but also the responsibility of wider society. The major stakeholders in society powerfully influence health, including business (pharmaceuticals and biotechnology), employers (conditions of work and pollution controls), academia (researching for solutions), foundations (philanthropy for health), the media (health information and risk perception) and civil society (caring, support, advocacy). Harnessing the energy of these stakeholders and coordinating their activities are essential for a healthy society."[4]

Brief history of pandemic governance

The first steps towards international pandemic governance began with the International Sanitary Conference of 1851 when a few countries recognised that a common approach was needed to tackle deadly infectious diseases which did not respect borders [5]. Progress since then has been fitful and largely reactive.

Key dates:

1851	International Sanitary Conference
1948	WHO founded
2003	SARS outbreak
2004	Establishment of the European Centre for Disease Control (ECDC)
2005	Revised International Health Regulations
2009	Influenza H1N1 pandemic
2011	Pandemic Influenza Preparedness Framework
2013	EU Decision 1082/13 on serious cross-border threats to health
2014	Ebola virus outbreak in west Africa
2015-16	Independent assessment of WHO's reponse in the Ebola outbreak. The Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response and new Health Emergencies Program agreed at WHA69 May 2016.

Scope of "governance"

We considered two potential aspects in our review of governance:

1. The process of making pandemic governance, laws and policy, i.e. how an issue gets on the agenda
2. The actual governance, laws and policy

We took the second approach, namely a review of governance itself.

This is specifically a review of "**pandemic governance**". A "pandemic" is an epidemic occurring worldwide, or over a very wide area, crossing international boundaries and usually affecting a large number of people. Therefore, "pandemic governance" refers specifically to **public health governance**, and to governance **which affects more than one country**. This report will review governance at international, regional (specifically European) and national levels (insofar as it impacts on neighbouring countries).

A very substantial body of literature has already been produced on "governance", in relation to communicable diseases alone. A Google Scholar search on 14 May 2016 produced the following: "Pandemic law": 60,700 results; "Pandemic governance": 30,800 results; "Pandemic ethic*": 23,100 results; "Pandemic human rights": 101,000 results. PHLawFlu project carried out a scoping exercise with public health experts across Europe and identified 24 different themes for legal policy and governance for pandemic preparedness and response [6]. It was beyond the scope of this project to review all these themes, although we have focused on a few key themes in respect of national pandemic planning [section 7].

We do not attempt here to duplicate previous work or to provide a comprehensive review of pandemic governance. Instead, we focus on current challenges and issues which impact on the European Union and merit further investigation to identify potential solutions.

2.3 Network Governance

This report describes current key pandemic governance frameworks and mechanisms. All have the same goal of contributing to an improved pandemic response. However, this goal cannot be achieved by any single organisation and there is a need for a high level of collaboration and coordination. This requires multilateral cooperation across countries and across organisations within countries. It also involves coordination and resolution of complex (and sometimes competing) demands.

"The task of preparing a vast, multi-level governance system for the onslaught of a complex safety and security problem is a major public policy challenge today. This is as true for the EU as for the US in which multiple actors operating with considerable latitude and with different kinds of authority can complicate a coherent response" [3].

This is governance at network level and effective network governance is crucial to achieve effective outcomes. This is discussed in Provan: *Modes of network governance* [7]:

"Addressing complex issues that demand multilateral coordination, as is often the case in the public and non-profit sectors…requires more than just achieving the goals of individual organizations. It requires collective action and the governance of these activities."

Provan identifies different forms of network governance and explores which might be most appropriate for different settings in order to achieve the desired goal. Network governance should not be hierarchical and it need not involve legal structures, but it is crucially important:

"For goal-directed organizational networks with a distinct identity … some form of governance is necessary to ensure that participants engage in collective and mutually supportive action, that conflict is addressed, and that network resources are acquired and utilized efficiently and effectively."

Shared governance is possible and appropriate where there is a small number of different entities working closely together with a high level of trust. Shared governance can build community capacity and all members of the group participate on an equal basis so they will all be committed to the goals of the network. However, where there are multiple network participants with a common goal but perhaps a lower level of mutual trust, a Network Administrative Organisation (NAO) may be more effective. This form of network governance will be led by an administrative organisation, (such as the European Commission), which is capable of handling large numbers of diverse participants. It will be better able to achieve a balance between efficient operation and inclusive decision making. However, even with this form of network governance, a compromise and balance needs to be reached between administrative efficiency, inclusivity, and flexibility. A stable, bureaucratically efficient network may have less committed members and be less flexible to change. This model can be seen in the example of the European Commission and the EU Member States.

3 Methodology

In order to identify the current status of policy and legal frameworks relevant to pandemic governance, it was necessary to collect data from a number of different sources to achieve a range of perspectives. Specific methodologies are detailed in particular sections.

- Review of existing governance frameworks and mechanisms at international, EU and national (EU Member State) levels. Identification of commonalities and disconnects [sections 4-8]
- Literature Review. Purposive and systematic literature reviews
    - Purposive literature search of relevant documentation on governance frameworks and mechanisms, relevant research projects and of three case studies.
    - Limited systematic literature review for journal articles not identified in purposive search. To identify common themes and approaches of interest in current scholarship [section 10]
- Review of recent and ongoing relevant research projects. To identify and learn from work already carried out, and avoid duplication [section 11]
- Brussels Workshop of the PANDEM Consortium: 17-18 February 2016. Input of leading experts in public health governance to identify gaps and research questions [section 12]
- Interviews. Ten individual interviews (phone-based or in person) with leaders of other research projects, workshop attendees and key interviewees [contributions to several sections as indicated in the text]
- Case studies. Selected on recommendation of experts as illustrating specific governance problems/issues in recent years. Two at European level (EU and Germany), one US (comparison with EU) [sections 13-15]
- Summary and review of priority legal and governance issues and challenges for and within the European Union. For each area of research (above), common themes and disconnects were identified. From these common themes, priority issues and challenges are suggested [section 16]. These issues, together with those identified in report D4.2, will be investigated further for report D4.3.

4 Governance frameworks and mechanisms: Global

4.1 International Legal Instruments

4.1.1 International health regulations (2005)

The International Health Regulations 2005 (IHR) [8] is the key international legal instrument designed to respond to threat of all-hazards, including infectious disease.

History

The IHR can be traced back to the International Sanitary Regulations of 1851 which recognised the need for international cooperation in public health. In 1969 the WHO adopted and renamed these as the International Health Regulations. They underwent minor modifications in 1973 and 1981 but the 48th World Health Assembly in 1995 called for a major revision of the regulations as a formal, internationally-coordinated mechanism was needed to respond to changing global circumstances, particularly a substantial increase in cross-border travel and trade, and the threat of emerging and re-emerging infectious diseases.

In 2005, the revised IHR (2005), which came into force on June 2007, created an international legal instrument which is legally binding on the 196 signatory countries. This includes all WHO Member States and thus all EU Member States. The importance of the IHR is explained in IHR Brief No.1:

"A critical contribution to international health security. The entry into force of the International Health Regulations (2005) (IHR (2005)) on 15 June 2007 is a public health landmark for the World Health Organization (WHO) and its Member States. The global community has a new legal framework to better manage its collective defences to detect disease events and to respond to public health risks and emergencies that can have devastating impacts on human health and economies. The successful implementation of the IHR (2005)…will contribute significantly to enhancing national and global public health security."

Purpose and scope: Article 2

"The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."

Key terms

The IHR sets out obligations for both signatory countries and for the WHO. Key obligations for Member States are:

- Notification. Requirement to notify WHO of events following use of a decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern (PHEIC)
- National IHR focal point responsible for communicating urgent events with regional WHO IHR contact points
- Capacity. Core Capacity requirements for national surveillance and response and for designated airports, ports and ground crossings.

Key obligations of the WHO are:

Article 5.4: WHO shall collect information regarding events through its surveillance activities and assess their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Articles 11 and 45 where appropriate.

- Technical assistance and advice to Member States
- Declaration by the Director General of a PHEIC.

The IHR define a PHEIC as an extraordinary event which is determined:

(i) to constitute a public health risk to other States through the international spread of disease, and

(ii) to potentially require a coordinated international response.

Legal Status and Compliance

While the IHR is undoubtedly a major advance in coordinating and formalising the international response to pandemic disease it has two critical weaknesses. One is the poor public health capacity of many low income Member States, making compliance difficult. The second is the lack of an enforceability mechanism.

The IHR came into force in 2007 and Member States were required to have achieved the minimum core capacities within 5 years, i.e. by 2012. WHO subsequently granted a 2 year extension for achieving core capacity to 2014 and then "final 2-year extensions (for exceptional circumstances)" to 2016. Events such as the recent Ebola outbreak demonstrate that many countries are still some way to achieving core capacity, and will need significant international support to do so.

The WHO recognised the lack of enforceability and in 2009 published "IHR (2005): Toolkit for implementation in national legislation: Questions and answers, legislative reference and assessment tool and examples of national legislation" [9]. WHO also put reliance on peer pressure to have some influence, as explained in their 2009 Factsheet: "Frequently asked questions about the International Health Regulations (2005)" [10]:

"Although the IHR (2005) do not include an enforcement mechanism per se for States which fail to comply with its provisions, the potential consequences of non-compliance are themselves a powerful compliance tool. Perhaps the best incentives for compliance are 'peer pressure' and public knowledge. With today's electronic media, nothing can be hidden for very long. States do not want to be isolated. The consequences of non-compliance may include a tarnished international image, increased morbidity/mortality of affected populations, unilateral travel and trade restrictions, economic and social disruption and public outrage."

The Joint External Evaluation tool for the IHR (2005) Monitoring and Evaluation framework, discussed further at 4.2.1 below, is a recent initiative to support compliance with the IHR (2005).

4.1.2 Nagoya protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the convention on biological diversity 2010/2014

The Nagoya Protocol [11] was adopted in 2010 and entered into force in 2014. It applies to genetic resources covered by the Convention on Biological Diversity (CBD). The EU and all its Member States are parties to the CBD. The Protocol sets out core obligations in relation to genetic resources, benefit-sharing and compliance. Its objectives are to protect the rights of countries and of indigenous and local communities that allow their genetic resources and associated traditional knowledge to be used, while also giving researchers in Europe improved access to genetic resources.

4.1.3 Pandemic Influenza Preparedness Framework 2011

The Pandemic Influenza Preparedness ("PIP") Framework [12] was endorsed by the World Health Assembly in 2011. The PIP Framework brings together Member States, industry other stakeholders and WHO to implement a global approach to pandemic influenza preparedness and response. Its key goals include:

- To improve and strengthen the sharing of influenza viruses with human pandemic potential; and

- To increase the access of developing countries to vaccines and other pandemic related supplies.

It is the result of intergovernmental negotiations initiated with a view to regaining trust of developing countries, such as Indonesia. In 2005 Indonesia had been particularly badly hit by the H5N1 avian flu outbreak in South East Asia. Indonesia stopped sharing A (H5N1) viruses with WHO collaborating centres because the resulting vaccines produced by commercial companies were likely to be unavailable to developing countries such as itself.

While this position generated much criticism of Indonesia in some quarters, it exposed the inequitable position of lower income countries which tend to be more vulnerable to infectious disease outbreaks, while being least able to purchase vaccines or compete with high income countries for medications in an influenza pandemic when supplies will be limited.

The "PIP Framework" is considered an important step forward in global pandemic preparedness. Its goals are (1) to improve and strengthen the sharing of influenza viruses with human pandemic potential; and (2) to increase the access of developing countries to vaccines and other pandemic related supplies. The WHO and its Member States commit to virus sharing obligations, in return for benefits in vaccine access. It is innovative in involving the private sector which is required to provide benefits to low income countries (via the WHO) in exchange for access to biological materials which support industry research and development.

Views differ on the benefit of the PIP framework. It enables cash benefits to be channelled through WHO to countries most in need and there are in-kind contributions, including pledges of pandemic vaccine and antivirals in real time in the event of a pandemic and capacity building.

Some weaknesses of the framework are that it applies only to "H5N1 and other influenza viruses with human pandemic potential", so seasonal influenza outbreaks are excluded. It is also non-binding "soft law" so it does not impose a legal obligation to share virus samples, although it should encourage state cooperation.

Gostin has pointed out that while a step in the right direction, the framework "secured the norm of virus sharing while providing only weak benefit sharing in return. The PIP

Framework will likely fall short in meeting vaccine demand during a pandemic, and it provides no guidance on equitable rationing during scarcity" [13]. The framework is not set up to cover total demand for pandemic vaccine in a pandemic, but rather to enable developing countries to receive an early supply of donated vaccine.

Any list of legal instruments relevant to pandemic governance should include those which concern human rights. The following human rights legislation is discussed in report D4.2:

Human Rights Legal Instruments

Universal Declaration of Human Rights (UDHR) 1948
International Covenant on Economic, Social and Cultural Rights (ICESCR) 1966/1976
International Covenant on Civil and Political Rights (ICCPR) 1966/1976
Siracusa Principles 1985
Convention on the Rights of the Child 1989/90
Universal Declaration on Bioethics and Human Rights 2006
Convention on the Rights of Persons with Disabilities 2007/2008

4.2 Global Governance Mechanisms

There are a vast number of governance mechanisms operating at global, regional, national and local level. The following are some key mechanisms relevant to pandemic preparedness.

4.2.1 World Health Organization (WHO)

We do not attempt here to give a detailed evaluation of the World Health Organization (WHO) but simply to briefly set out its role as the key international body for health, specifically in respect of infectious disease.

The WHO was established in 1948 as the health agency of the United Nations. It is headquartered in Geneva, with six regional offices and 147 country offices. The current Director-General is Dr Margaret Chan.

The WHO has had responsibility for responding to the international spread of infectious diseases since the first World Health Assembly (WHA) in 1948. A core responsibility has been to provide disease alert and response assistance to countries.

Key Achievements

The eradication of smallpox is considered one of WHO's greatest achievements. It was declared as an objective at the 1959 World Health Assembly and following a global

immunization campaign led by WHO, smallpox was declared eradicated in 1980. WHO is currently working to eradicate polio, a goal which is close to achievement.

Challenges/controversies

WHO has fundamental challenges in its governance and funding mechanisms which are complex and will not be explored here but which are considered to have contributed to the inability of WHO to mount a rapid scale-up of the response to the Ebola outbreak in 2014. WHO has been the subject of heavy criticism and calls for major structural reform culminating with the endorsement at the WHA69 in May 2016 of the WHO Health Emergencies Programme (http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_30-en.pdf). The new Health Emergencies Programme aims to complement WHO's traditional technical and normative role with new operational capacities, so that WHO can continue in the role of the global coordinating health body during outbreaks and humanitarian emergencies.

Future initiatives

Recent initiatives are intended to respond to weaknesses identified in high level external evaluations of the WHO Ebola response.

Global Strategic Plan

The WHO Secretariat is currently committed to development of a Global Strategic Plan "to ensure implementation of the IHR, especially the establishment and monitoring of core capacities. The Global Strategic Plan should inform the development of regional office and national plans." [14]

The Joint External Evaluation Tool

The IHR Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation (WHA 68/22 Add.1) recommended "…to move from exclusive self-evaluation to approaches that combine self-evaluation, peer review and voluntary external evaluations involving a combination of domestic and independent experts."

In light of this, WHO, in collaboration with partners and initiatives such as the Global Health Security Agenda (GHSA), developed the Joint External Evaluation (JEE) process as part of the IHR (2005) Monitoring and Evaluation framework.

4.2.2 Global outbreak alert and response network (GOARN)

The Global Outbreak Alert and Response Network (GOARN) is a collaboration of technical institutions and networks who pool human and technical resources to contribute and participate in internationally coordinated responses to infectious disease outbreaks [15]. The network comprises 153 institutions/technical partners and 37 additional networks. The WHO coordinates the network and provides a secretariat.

GOARN was established in 2000 and has played a major role in organizing the global response to infectious disease outbreaks. GOARN's primary aims are to:

- Assist countries with disease control efforts by ensuring rapid and appropriate technical support to affected populations;
- Investigate and characterize events and assess risks of rapidly emerging epidemic disease threats;
- Support national outbreak preparedness by ensuring that responses contribute to sustained containment of epidemic threats [1].

4.2.3 Global health security initiative (GHSI)

The Global Health Security Initiative (GHSI) was established in November 2001 and is an informal partnership of eight countries (France, Germany, Italy, Japan, Mexico, the UK and the US) and the European Union to strengthen global preparedness and response to threats to health security, including pandemic influenza. The WHO acts as technical advisor to the group. The GHSI is intended to work with, rather than replace or duplicate the work of other groups. The EC's membership of the group means that EU Member States are kept informed of the results of the GHSI's work.

The GHSI has five working groups including a Pandemic Influenza Working Group. According to the GHSI website this group "is responsible for sharing and comparing respective national approaches to pandemic preparedness, including vaccine and anti-viral stockpiling and use, surveillance and epidemiology, diagnostics, and public health measures. During the H1N1 Pandemic, the Working Group coordinated the regular exchange of information among GHSI members on the status of the pandemic response."

4.2.4 Global Health Security Agenda

The Global Health Security Agenda (GHSA), launched in 2014, is a partnership of nearly 50 countries with the aim of facilitating collaborative efforts to deal with infectious disease threats. The GHSA encourages concrete commitments and to raise global health security as a priority for national leaders. It has identified 11 Action Packages towards specific

[1] http://www.who.int/csr/outbreaknetwork/goarnenglish.pdf?ua=1

goals, e.g. Antimicrobial Resistance, Real Time Surveillance, Workforce Development. All GHSA member countries participate in one or more Action Package, and each Action Package includes a 5-year target, indicators and monitoring and evaluation activities.
Apart from individual country members, advisory partners include the WHO and the EU. IT was endorsed by the G7 in June 2014.

4.2.5 WHO Global influenza surveillance and response system (GISRS)

Known as the Global Influenza Surveillance Network (GISN) until 2011, the WHO GISRS monitors the evolution of influenza viruses and provides recommendations in area including laboratory diagnostics, vaccines, antiviral susceptibility and risk assessment. WHO GISRS also serves as a global alert mechanism for the emergence of influenza viruses with pandemic potential. GISRS receives data from its National Influenza Centres (NIC) and other national influenza reference laboratories which collaborate with GISRS [2].

5 Governance Frameworks and Mechanisms: European Union

5.1 EU Legal Instruments

5.1.1 Article 152 (5) EC

This article (which replaced and expanded on Article 129 of the Maastricht Treaty 1992 and Article 129 of the Treaty of Amsterdam 1997) gives the EC a mandate in protecting public health at Community level. It is the legal basis for addressing health threats at EU level:

"1. Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their transmission and their prevention, as well as health information and education. The Community shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

[2] WHO website: http://www.who.int/influenza/gisrs_laboratory/en/.

3. The Community and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.
4. The Council…shall contribute to the achievement of the objectives referred to in this Article through adopting:
(c) Incentive measures designed to protect and improve public health, excluding any harmonisation of the laws and regulations of the Member States."

The EC role is to coordinate national health policies and the Article makes clear that responsibility for public health lies with the Member States. The EC is to encourage cooperation and coordination between states but it explicitly excludes any efforts at "harmonisation of the laws and regulations of the Member States": 4(c).

5.1.2 Article 168 Treaty on the functioning of the European Union (TFEU)

This revised Article 152 slightly, establishing the fight against major health threats as a Community public health objective:

"1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.
Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health."

5.1.3 Article 222 Treaty on the functioning of the European Union (TFEU)

This is a "Solidarity Clause" which when invoked, triggers the EU Integrated Political Crisis Response arrangements (IPCR). This is a "Political Coordination Tool" which aims to enable a coherent and coordinated joint response from the EU and its Member States, in the event of a major crisis:
"1. The Union and its Member States shall act jointly in a spirit of solidarity if a Member State is the object of a terrorist attack or the victim of a natural or man-made disaster. The Union shall mobilise all the instruments at its disposal, including the military resources made available by the Member States, to:
(b) assist a Member State in its territory, at the request of its political authorities, in the event of a natural or man-made disaster."

The Article was most recently invoked as a result of the migrant crisis although the value of the IPCR is yet to be established.

5.1.4 Decision 2119/98/EC: Setting up a network for the epidemiological surveillance and control of communicable diseases in the Community

Established the Community Network for the Epidemiological Surveillance and Control of Communicable Diseases in the Community. Superseded by Decision 1082/13 (below).

5.1.5 Decision 2000/57/EC

Creation of the Early Warning and Response System (EWRS) for the prevention and control of communicable diseases

5.1.6 Regulation 851/2004

Establishment of a European Centre for Disease Prevention and Control (ECDC)

5.1.7 EU COM (2005) 605: Strengthening coordination on generic preparedness planning for public health emergencies at EU level

The EC's generic preparedness plan

5.1.8 EU COM (2005) 607: Pandemic Influenza Preparedness and Response Planning in the European Community

The EC's Pandemic Influenza Preparedness and Response Plan

5.1.9 Schengen Agreement

The Schengen Agreement is a European treaty signed in 1985 which led to the formation of the Schengen Area. It was supplemented by the Schengen Convention in 1990. The Schengen treaties were incorporated into EU law by the 1997 Treaty of Amsterdam and now apply to 26 countries (all EU Member States except Bulgaria, Croatia, Cyprus and Romania, which would like to join, while the UK and Ireland are opt-outs). Iceland, Liechtenstein, Norway and Switzerland are also signatories. All new EU Member States are required to become signatories.

The Schengen treaties abolished internal border controls for the signatory European countries and this is of relevance to public health and the control of infectious disease in a number of respects. The Schengen Information System means that countries consent to share information about people moving from one country to another. Also, Article 2.2 of

the Schengen Agreement allows countries to temporarily reinstate borders in the interest of national security, which might include a public health emergency. Under the Schengen Borders Code, nationals of third countries can be refused entry if considered a public health threat [16].

Martin, in *The role of law in pandemic influenza preparedness in Europe* 2009, [16] discusses the possibility that in a pandemic, EU citizens from countries with weak health systems (particularly central and eastern Europe) might cross borders to countries with better health resources:
"this could mean an influx of persons who are possible disease carriers from poor states with a frail public health system and with insufficient medicines, to other EU states, putting citizens at risk and draining health resources in those states. This creates difficult choices for host countries in terms of the assistance they offer. Should they fail to offer healthcare services to mobile populations, these populations will put state population health at risk. Should they offer healthcare services to mobile populations, this will strain resources and drain services from home populations."

Schengen countries have closed borders on a number of occasions, most recently in response to the migrant crisis. As of March 2016, eight EU countries had re-instated border checks and there are concerns that the Schengen commitment to open borders across Europe may not survive further pressure [17].

5.1.10 Decision 1082/13 on serious cross-border threats to health and repealing Decision No 2119/98/EC

This is a key decision of recent years [18]. It confirms the commitment in Article 168 TFEU of Member States to coordinate their policies and programmes in public health. The Decision extends this. Key provisions include:

- The legal framework of Decision 2119/98/EC for epidemiological surveillance and control is extended to cover additional public health threats: "in particular related to other biological or chemical agents or environmental events, which include hazards related to climate change" (Article (3))
- The role of the Health Security Committee is formalised and strengthened (Article (4))
- The mandate of the ECDC is confirmed to cover "surveillance, detection and risk-assessment of threats to human health from communicable diseases and outbreaks of unknown origin." (Article (5))
- Recognition of and compliance with the IHR 2005 and the WHO (Articles (6), (12), (26))

- Member States must consult and coordinate "in order to promote interoperability between national preparedness planning in view of the international standards, while respecting Member States' competence to organise their health systems. Member States should regularly provide the Commission with an update on the status of their preparedness and response planning at national level." The Commission is required to compile and exchange this information through the HSC. Member States are also required to inform the Commission of any substantial revisions to national preparedness planning. (Article (12))
- Strengthening of cooperation and procedures to ensure vaccine coverage across the EU (Article (13), (15))
- Extension of the EWRS to all serious cross-border threats to health (Article (16))
- In recognition of the negative impact of "inconsistent or confusing communications with the public and stakeholders such as healthcare professionals, a coordinated response within the HSC should "encompass rapid information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on robust and independent evaluation of public health risks, to be adapted to national needs and circumstances. Such exchanges of information are intended to facilitate monitoring of the clarity and coherence of messages to the public and to healthcare professionals." (Article (22))
- Cooperation in control or contact-tracing measures where there is a serious cross-border threat to health may require the exchange of sensitive personal data (Article (25)). The EWRS should provide for specific safeguards for the safe and lawful exchange of personal data (Article (27))
- Encouragement of cooperation with third countries and international organisations, such as the WHO. "It could be in the interests of the Union to conclude international cooperation agreements." (Article (26)).

Central to Decision 1082/13 is an extension of the definition of public health threats, and an emphasis on cooperation and coordination between Member States, international organisations and third countries.

European legal instruments to protect human rights are discussed in report D4.2:

<u>Human Rights Legal Instruments</u>

European Convention on Human Rights 1950/53

WMA Declaration of Lisbon on the Rights of the Patient 1981

Convention on Human Rights and Biomedicine, Council of Europe 1997

Charter of Fundamental Rights of the European Union (CFREU) 2000/2009.

5.2 EU Governance Mechanisms

5.2.1 WHO Regional Office for Europe

One of the WHO's six regional offices. Based in Copenhagen, it is the headquarters for the WHO European Region comprising 53 Member States, including all 28 EU countries. There is high level collaboration with the European Commission (DG-SANTE) and with the ECDC with joint planning and many joint activities, e.g. the joint WHO/Europe ECDC influenza bulletin Flu News Europe (www.flunewseurope.org), joint risk assessment etc.

5.2.2 EU Agencies

There are a number of EU agencies which may be involved in different capacities in the event of a high impact epidemc or pandemic in Europe. These are some of the most relevant:

EUROPEAN COMMISSION

- **DG SANTE (Previously DG SANCO until 2015): Health and Food Safety**

DG SANTE aims to improve quality of life in the EU through policies laws and programmes in its three main areas of activity: public health, food safety and consumer protection.

- **DG ECHO: Humanitarian Aid and Crisis Management**

DG ECHO provides emergency assistance and relief to the victims of natural disaster or armed conflict outside the EU.

- **DG DEVCO: International Cooperation and Development**

DG DEVCO is responsible for designing European international cooperation and development policy and delivering aid throughout the world.

- **DG RESEARCH: Research and Innovation**

DG RESEARCH is responsible for the EU's research and innovation policy and coordination of research and innovation activities.

- **DG HOME : Migration and Home Affairs**

The role of DG HOME is to ensure the EU's security. As well as promoting police cooperation through Europol, it deals with border management, civil protection, disaster management and the creation of a common EU migration and asylum policy.

ECDC

Established in 2004 by Reg (EC) 851/2004 and operational in 2005. The ECDC is an agency of the EU based in Stockholm with the aim of strengthening Europe's defences against infectious diseases.

According to Article 3 of the Founding Regulation, the ECDC's mission is to identify, assess and communicate current and emerging threats to human health posed by infectious diseases. It is an advisory body which provides scientific opinions and technical advice on risks posed by current and emerging infectious diseases.

EUROPEAN MEDICINES AGENCY (EMA)

EU agency for the evaluation of medicinal products. Previously (1995-2004) known as the European Agency for the Evaluation of Medicinal Products (EMEA). One of its key roles is a central authorisation procedure so that new medicines may be marketed and made available throughout the EU. Pharmaceutical companies submit a single marketing-authorisation application to the EMA which carries out a scientific assessment of the application and gives a recommendation on whether the medicine should be marketed or not. The EMA has established mock-up and emergency procedures to speed up assessment and authorisation of vaccines for use during a flu pandemic.

EUROPEAN FOOD SAFETY AUTHORITY (EFSA)

Provides scientific advice on request for the EC, the European Parliament and EU Member States. The EFSA played a key role during the German E.coli outbreak in 2011 [see case study].

5.2.3 EU Health Security Committee (HSC)

The EU Health Security Committee was established in 2001 as an informal advisory group on health security at EU level. It is composed of representatives of the ministries of health from all Member States. The role of the HSC is to provide a forum for Member States to cooperate in addressing common health threats. Plenary meetings take place in Luxembourg. At times of emergency it may meet on a daily basis, such as during the 2009 H1N1 pandemic. According to its website "the HSC was the key body for coordinating the response in the EU. It was a platform for sharing information on countermeasures (e.g. vaccination strategies) and for coordinating communication to health workers and for EU citizens." Its role has been strengthened by Decision 1082/13.

5.2.4 Health Emergency Operations Facility (HEOF)

The Health Emergency Operations Facility (HEOF) was established in 2001 as a central coordinating body in the event of a pandemic emergency. It consists of a crisis and communication facility in Luxembourg for the management of alerts and emergencies notified by Member States. It is intended as a "mechanism for information exchange, consultation and coordination for the handling of health-related issues linked to attacks in which biological and chemical agents might be used or have been used."[3]

Tools developed by the HEOF have included the EWRS, MEDISYS and HEDIS, discussed below.

5.2.5 Early Warning and Response System (EWRS)

The aim of the Communicable Diseases Network is to promote cooperation and coordination between the Member States to improve the prevention and control of communicable diseases in the EC. The Early Warning and Response System (EWRS) is part of this network. The EWRS is a means to bring together the EC and the competent public health authorities in each Member State in permanent communication. Member States are required to notify other Member States and the EC via the EWRS in the event of:

1. Outbreaks of communicable diseases extending to more than one Member State of the Community;
2. Spatial or temporal clustering of cases of disease of a similar type, if pathogenic agents are a possible cause and there is a risk of propagation between Member States within the Community.
3. Spatial or temporal clustering of cases of disease of a similar type outside the Community, if pathogenic agents are a possible cause and there is a risk of propagation to the Community.
4. The appearance or resurgence of a communicable disease or an infectious agent which may require timely coordinated Community action to contain it.
5. Manifestation of a disease or an occurrence that creates a potential for a disease pursuant to Article 1 of the International Health Regulations (2005) which is a communicable disease pursuant to Annex to Decision No 2119/98/EC and related measures to be notified to the World Health Organization under Article 6 of the International Health Regulations (2005)

5.2.6 Medical Information System (MEDISYS)

MediSys is an internet monitoring and analysis system providing event based surveillance to rapidly identify potential threats to the public health using information from the

[3] http://ec.europa.eu/health/preparedness_response/generic_preparedness/planning/heof_en.htm

internet. It displays only those articles with interest to Public Health, grouped by disease or disease type. It analyses the news and warns users with automatically generated alerts. The information processed by Medisys is derived from the Europe Media Monitor (EMM)[4].

5.2.7 Health Emergency & Disease Information System (HEDIS)

HEDIS is a situation awareness tool which is used to provide an overview of the situation on an identified health threat to the Commission and Member States. HEDIS is a Web-based portal with restricted access offering a central destination and jumping off point for all the information derived from various sources (with real-time updates from MediSys, WHO, OIE,…), communication tools, access to Geographic Information Systems (GIS) and modeling applications allowing European stakeholders responsible for health threats response to consult and exchange health-related information in a structured and predictable manner. [5]

5.2.8 European Medical Corps (EMC)

Launched in February 2016 to improve the EU's preparedness and response to global health emergencies, the European Medical Corps (EMC) has been established as a direct result of "lessons learned" from the Ebola outbreak. At the time of its launch nine Member States had offered teams and equipment for the use of the EMC: Belgium, Luxembourg, Spain, Germany, Czech Republic, France, Netherlands, Finland and Sweden.

6 Governance Frameworks and Mechanisms: International Initiatives

It is beyond the scope of this report to capture all current international governance initiatives in relation to pandemic threats. This is a selection of global and regional frameworks and mechanisms which have been recently launched or are still being developed. Some, such as the Global Health Risk Framework and the European Medical Corps, have been developed to address weaknesses which became apparent in the Ebola response.

6.1 North American Plan for Animal and Pandemic Influenza (NAPAPI)

A joint initiative of the USA, Canada and Mexico, the North American Plan for Animal and Pandemic Influenza (NAPAPI) was launched in 2012. It is a regional and cross-sectoral health-security framework which outlines how the three countries will strengthen their

[4] https://ec.europa.eu/jrc/en/scientific-tool/medical-information-system
[5] http://ec.europa.eu/health/preparedness_response/generic_preparedness/planning/hedis_en.htm

emergency response capacities, and also collaborate to ensure a quick and coordinated response to outbreaks of pandemic influenza or animal influenza.

6.2 Sendai Framework for disaster risk reduction (2015-2030)

The Sendai Framework is an international Treaty and 15 year, voluntary, non-binding agreement. Its implementation has been supported by the United Nations Office for Disaster Risk Reduction (UNIDSR). It sets four priorities for action: understanding disaster risk, strengthening disaster risk governance to manage disaster risk; enhancing disaster preparedness for effective response, and to "Build Back Better" in recovery, rehabilitation and reconstruction.

6.3 Global Health Risk Framework (GHRF)

The Global Health Risk Framework is an initiative resulting from the lessons of the Ebola outbreak response [19]. A Commission of 18 experts in global public health has been established to recommend a more effective global architecture for mitigating the threat of epidemic infectious diseases. The Commission will analyse options for improving governance, finance, health system resilience, and research and development for global health security. It aims to develop a comprehensive framework to improve the response to future global public health threats. The US National Academy of Medicine is the secretariat for the commission but it is intended that the framework will not be influenced by politics or the interests of any one country or organisation [19].

6.4 Global Challenge initiative on the future of health

Launched in January 2016, the Global Challenge is a two year initiative of the World Economic Forum to respond to future epidemics through optimized public-private partnerships. "The initiative's efforts will harness the capabilities of the healthcare, mining, telecommunications and mobility industries, among others, to work with national governments, international organizations and civil society to create solid, preventative action plans for emerging outbreaks." [6]

[6] https://www.weforum.org/press/2016/01/preparing-for-the-next-pandemic-fear-cannot-be-our-motivation/

7 Governance Frameworks and Mechanisms: International Commonalities and Disconnects

If WHO is regarded as the leader of international pandemic governance, and the EC as the leader of European pandemic governance (within its obligation to comply with WHO and the IHR), common themes and issues can be identified.

The IHR and Decision 1082/13 are the key legal instruments at international and European level and both the IHR and 1082/13 have expanded on previous legislation with similar terms:

- Widening of governance to include new and re-emerging infectious diseases, as well as other public health threats;
- An emphasis on achieving more coherent and coordinated responses from Member States;
- An emphasis on reporting obligations.

Both the WHO and the EC face similar challenges in achieving these objectives:

Enforceability. The WHO and the EU are both membership organisations. Thus they are ultimately run by those members and must respect sovereignty and subsidiarity. They may give guidelines, and both IHR and Decision 1082/13 are described as binding legal instruments, but ultimately enforcement would be very difficult.

Capacity. As organisations of Member States with different economies and health system capacities both WHO and the EC must find ways to support states which cannot meet their obligations. Without this support an effective coordinated response will not be achievable.

Political will. Member States may have different public health priorities and be unwilling to address resources to pandemic governance, even where they have capacity to do so. The WHO and the EC both need to convince Member States of the extent to which pandemic preparedness should be prioritized against other competing health system demands.

Following the theory of Provan [7], discussed earlier, it could be argued that the WHO and the EC are examples of network administrative organisations: leaders of network governance. They are each trying to manage large numbers of network members. They face competing challenges to maintain stability but also to be flexible enough to respond quickly to a crisis.

8 Governance frameworks and mechanisms: Member States

It is beyond the scope of this report to assess and compare the governance frameworks and mechanisms of all 28 EU Member States in relation to pandemic threats. To date the most detailed evaluation was made by the 3 year PHLawFlu project, described later in this report, which explained the challenges of attempting such an assessment. The CELESTE project (discussed at section 10 below) is currently attempting "an exhaustive mapping/survey of the legal framework within Member States in relation to the IHR and the implementation of Decision 1082/13." They also aim to "identify commonalities, inconsistencies and gaps in national laws to facilitate the harmonisation of actions targeted at improving preparedness for serious cross-border threats to health". This is a major undertaking which is due for completion in October 2016.

Examples of national laws are the Civil Contingencies Act 2004 in the UK, which grants emergency powers to make temporary legislation to respond to serious emergencies. These are defined as "an event or situation which threatens serious damage to human welfare". The French Public Health Code authorizes isolation and quarantine and grants powers to close facilities such as schools in a public health emergency.

8.1 National Pandemic Influenza Preparedness Plans

INTRODUCTION

International legislation is important and is intended to be binding. Its signatories agree to comply with certain commitments. However, the principles of national sovereignty and subsidiarity mean that in reality such international law is unenforceable and those national signatories can comply with its terms in variable ways. This is inevitable: there is no international enforcement body, and the 196 national signatories to the IHR for example have a wide range of political, social and economic contexts which will require flexible responses.

WHO sought to manage this unenforceability and variability by requesting its Member States to develop or update national influenza preparedness plans. Also, each country was requested to put in place national legislation to underpin their national plan. This would enable measures to be enforced at the national level. WHO provided guidance and a recommended model "global influenza preparedness plan" published in 2005. In 2009 it also provided guidance on implementation of the IHR in national legislation [9]. The aim was to achieve "international harmonization of preparedness measures, as this is the key to success in reducing the risk of spread of an influenza pandemic" [20].

All 28 EU Member States are signatories to the IHR and members of WHO. They all agreed to develop national preparedness plans. These plans are therefore key policy documents. While they cannot prove national capacity to carry out those plans, they are an indicator of preparedness and intended response measures.

BACKGROUND

During 2005 several key initiatives drove efforts for stronger global preparedness for a pandemic. The WHO took the lead:

- Resolution 58.3 at the World Health Assembly 2005 revising the International Health Regulations (2005). These were signed by 196 nations, including all the 25 EU Member States at that time;
- WHO global influenza preparedness plan. A model to encourage greater coordination and predictability of national responses;
- WHO national preparedness plan checklist. This aimed to "provide an outline of the essential minimum elements of preparedness, as well as elements of preparedness that are considered desirable" [21].

At the European level, in 2005 the ECDC became operational as an EU agency with a mission "to identify, assess and communicate current and emerging threats to human health posed by infectious diseases." [Art 3, Reg 851/2004].

Through 2005, WHO Europe and the ECDC held a number of joint workshops to encourage and advise EU states on drafting national plans. A questionnaire was sent to all Member States and according to a workshop summary report "the results of this questionnaire indicated that all 25 Member States had a plan either available and published (19 countries) or in draft form (6 countries)".

Following the 2009 H1N1 pandemic, the WHO advised Member States to review and update their plans to reflect lessons learned. During 2011, joint workshops were again held by WHO Europe and the ECDC with the participation of the 45 European Member States in the WHO Regional Office for Europe (WHO/EURO). Recommended changes to plans included greater focus on "intersectoral cooperation, collaboration and leadership" and "strategies for exchanging information and communicating risk".

These workshops were reportedly successful: “32 countries reported that they were in the process of revising their national pandemic plans and the revised reports have been published for two countries” (France and the UK) [22]. This report also mentioned the new “Cross Border Threats Initiative, one of whose aims was to “coordinate EU Member States’ activities for implementation of IHR core capacities (sharing experiences and resources, interoperability of national preparedness plans)”. EU Decision 1082/13 also stresses the importance of interoperability of written preparedness plans.

In 2013 the WHO published updated guidance for Pandemic Influenza Risk Management [23]. Chapter 5 on National pandemic influenza risk management states that countries should:
“Review or develop national pandemic risk management programmes, including preparedness activities and response plans, and establish, as needed, the full legal authority and legislation required to sustain and optimize pandemic preparedness, capacity development and response efforts across all sectors.”

Most recently, and in the aftermath of the Ebola outbreak, in 2016 the WHO published a Joint External Evaluation Tool to test national capacity and compliance with the IHR. The first criterion for evaluation is the requirement for “National legislation, policy and financing”:
P.1.1 Legislation, laws, regulation, administrative requirements, policies or other government instruments in place are sufficient for implementation of IHR;
P.1.2 The state can demonstrate that it has adjusted and aligned its domestic legislation, policies and administrative arrangements to enable compliance with the IHR (2005) [24].

Thus, for more than a decade there have been considerable efforts to encourage Member States to develop comprehensive written national pandemic preparedness plans, following a standard WHO model as far as possible, and supported by national legislation. Yet it is unclear how successful those efforts have been. There have been only a few published studies of the plans and to date there has been no complete inventory of national plans or legislation for all 28 EU Member States. The most successful effort so far was by the PHLawFlu project, which is discussed at section 10 of this report.

The CELESTE project carried out an inventory of generic EU national plans in 2013-2014. These were plans in respect of serious cross-border threats covered in EU Decision 1082/13, e.g. biological, chemical and environmental, but specifically excluding threats to

health[7]. Another team within the CELESTE consortium is now attempting an "exhaustive mapping/survey of the legal framework" with respect to Member State compliance with EU Decision 1082/13, to include threats to health. This project is due to end in October 2016 [25].

AIM

Limitations of time and resources mean that it is not possible here to conduct a detailed study of national pandemic preparedness plans or supporting legislation. Instead an audit was made of the accessibility of plans, and where they could be accessed, brief analysis of plans in the following respects:

1. Reference to national legislation underpinning measures in the plan;

Proposed measures with regard to four identified key themes:

2. Communication (excluding reporting obligations);
3. Surveillance;
4. Isolation, quarantine, border controls and social distancing measures;
5. Equity and prioritisation of healthcare.

Review was also made of reference to ethical and human rights considerations in the national plans and these findings are set out in report D4.2.

METHODOLOGY

Literature review: National pandemic preparedness plans

National pandemic preparedness plans are listed in two publicly accessible repositories, namely the websites of the WHO and the ECDC. As this was a review of accessibility the plans were sought only on these sites.

Inclusion criteria

Plans publicly accessible on either the WHO or ECDC websites. Accessed on 03.11.15.

WHO Regional Office for Europe:

http://www.euro.who.int/en/health-topics/communicable-diseases/influenza/pandemic-influenza/pandemic-preparedness/national-preparedness-plans2/full-list-of-national-preparedness-plans

http://www.euro.who.int/en/health-topics/communicable-diseases/influenza/pandemic-influenza/pandemic-preparedness/national-preparedness-plans2

[7] Telephone interview 05.05.16

ECDC:
http://ecdc.europa.eu/en/healthtopics/pandemic_preparedness/national_pandemic_preparedness_plans/Pages/influenza_pandemic_preparedness_plans.aspx

Published since 2005.
In English.

Exclusion criteria

Plans published elsewhere. While some national plans were found on other sites, for example by Google search, it was unclear if these were official, current or final versions.
Plans not in English.
Plans in English, which have been superseded by more recent versions not in English.

Other literature

Published papers on these plans were found by purposive literature search of Google Scholar using key words "Pandemic Plans".

Brussels workshop: 17-18 February 2016

A summary of the accessibility search was presented and briefly discussed with the work group at the workshop held in Brussels.

Key interviewee interviews

Interviewees were asked for their opinion on national plans with regard to language, accessibility and updating.

RESULTS

National Pandemic Preparedness Plans: Accessibility

See results Table 1

An audit on 3 November 2015 attempted to access national plans on the WHO and ECDC websites. This identified that many of the links were broken and there were discrepancies between the two websites. Of 28 Member States, only 16 had plans which were accessible from either the ECDC or WHO websites. Of these 16 plans only 7 were published in English (not a requirement of either the WHO or EU), and only 4 of those had been updated since 2009 (recommended). The 7 plans in English which were downloaded and reviewed are:

- **Croatia 2005** [26]
- **Czech Republic 2011** [27]
- **France 2011** [28]

- **Hungary 2008** [29]**.** Between the audit on 03.11.15 and review in April-May 2016, the English language version of the Hungarian plan became unavailable from either the WHO or ECDC websites.
- **Italy 2010** [30]. This plan is undated, no authorship is given or even reference to the country. The ECDC website names it as the Italian plan of 2010 although an Italian interviewee advised that it was a version from 2006 [8].
- **Spain 2006** [31]
- **UK 2011/2014** [32, 33]**.** The 2014 Pandemic Influenza Response Plan states that it "links to the PHE National Incident and Emergency Response Plan (2013)" but the 2013 plan is not on either the WHO or ECDC websites. Instead the "UK Influenza Pandemic Preparedness Strategy 2011" is posted and most measures for review were in that 2011 document.

National Pandemic Preparedness Plans: Review of themes

The WHO pandemic preparedness checklist sets out "Essential" and "Desirable" elements of a national pandemic preparedness plan. WHO published revised guidance in 2013 but since of the reviewed plans only the UK plan was updated after 2013, they were compared to the original 2005 WHO guidance.

A summary of the results is given at Table 2

1. National Legislation

WHO Checklist: Essential. "Is there a legislative framework in place for the national response plan?"

The plan for Croatia only refers to veterinary laws. Three other plans (Italy, Spain, UK) refer to relevant legislation. No copies of the statutes are provided and it is unclear if these laws are still current.

Four identified key themes:

2. Communication (excluding reporting obligations)

WHO Checklist: Essential

The plan for Croatia makes only one brief reference: "Organise communication with the media and the public, i.e. appoint an individual or organising body to be exclusively authorised to release reports for the media and public about the pandemic…inform the public through the media." All other plans give lengthy attention to communication strategies.

[8] Telephone interview with Caterina Rizzo, ISS on 05.05.16

3. Surveillance

WHO Checklist: Essential

All seven plans discussed surveillance in some detail, the majority in alignment with the WHO phases of a pandemic. (The identified six phases of the original WHO plan were revised to four phases in the revised 2013 guidance, with the phases based on risk assessment rather than geography. The national response should also be based on risk assessment of the actual situation rather than pre-determined.)

4. Isolation, quarantine, border controls and social distancing measures

WHO Checklist: Essential (4.1.3 Public health measures)

All plans, except that of Croatia, discussed the possibility of measures, but mainly in non-specific terms with little detail of how this might be achieved. The plan for Hungary seems the most stringent, e.g. "in order to contain the spread of the epidemic, hospital visiting will have to be prohibited" and refers to using police forces to control movement of persons: "With contributions from the police, NPHMOS shall intensify control of persons arriving from areas in danger of epidemic at the border crossing points, screening and isolation of suspect influenza cases." Citing a lack of evidence for effectiveness, the UK plans states that "there are no plans to attempt to close borders" and that "the working presumption will be that the Government will not impose any such restrictions."

5. Equity and prioritisation of healthcare

WHO Checklist: Desirable (1.5.2 Ethical issues)

The plan of the Czech Republic does not discuss prioritisation. Five of the other plans (Croatia, France, Hungary, Italy, Spain) prioritise health workers and/or high risk groups among the population, e.g. chronically ill and children. The UK plan states that pandemic vaccine will be prioritised dependent "on the emerging profile of at-risk groups."

Other literature

Systematic and purposive literature search identified only a few papers which analysed specific EU national plans. A summary of some of their key findings is given below.

How prepared in Europe for Pandemic Influenza? An Analysis of National Plans: Mounier-Jack, Coker; 2006 [34]

Twenty-one national plans from the European region were analysed in comparison with the WHO checklist[21]. Measures were of "completeness" depending on how many of the checklist criteria were included and of "quality" according to the perceived importance of those criteria.

Average completeness score for all surveyed plans: 54%

Average quality score: 58% (range 27%-86%)

"Overall, plans are satisfactory in addressing areas such as surveillance and communication. However, other areas are less than satisfactory, and there are a number of gaps common to many plans."

"The target audience of the preparedness plans is often unclear."

"The defined purpose of many national plans remains obscure."

"There is considerable variation between the plans of different countries in Europe, and some important gaps are present in many plans."

Identified gaps:

- Many plans document only weak linkages between human and animal surveillance and response systems;
- Many countries fail to identify appropriate strategies to ensure early containment of the disease in case the pandemic originates at home;
- Few countries are explicit in how they cooperate, and will do so in the future, with other EU countries, including near neighbours;
- Roles and responsibilities of different levels of government, including regional and central government are not always clear;
- Planning and prioritization of laboratory testing capacities during the pandemic phase are not properly addressed;
- Plans do not consider adapting (or discontinuing) surveillance during the pandemic. The selection and prioritization of surveillance indicators are poorly addressed;
- Little attention has been given to the distribution and supply of antivirals to defined populations. Many plans fail to distinguish between treatment and prophylaxis;
- Plans are not always specific on their operational strategy and on how and when to procure vaccines;
- Few plans address how patients will be managed and where they will be treated;
- Fewer than half of the plans address the maintenance of essential services.

Discourses of disease, discourses of disadvantage: A critical analysis of National Pandemic Influenza Preparedness Plans: Garoon, Duggan; 2008 [35]

Review of 37 plans, including 16 from Europe and central Asia.

"Policies proposed in the plans, like preparedness policies in general, are rife with ethical challenges…underscoring the important role that ethical review should play in pandemic preparedness planning."

"While pandemic influenza poses dangers to every population, it represents an especially dire threat to disadvantaged groups…disadvantage may stem from a variety of individual and group characteristics, including socioeconomic position, place of residence, gender, religion, race, ethnicity, an/or sexual orientation. Past influenza pandemics have disproportionately impacted disadvantaged populations, and without particular attention, future pandemics will likely follow suit."
"None of the plans explicitly referenced disadvantaged groups as such, and the plans paid scant attention to the particular needs and interests of disadvantaged individuals and populations."

Pandemic influenza control in Europe and the constraints resulting from incoherent public health laws: Martin et al; 2010 [6]
Review of national public health laws in 32 European countries in relation to pandemic influenza and to national plans.
"Results of this study show differences across Europe in the extent to which national pandemic policy and pandemic plans have been integrated with public health laws. We found significant differences in legislation and in the legitimacy of strategic plans…Some states propose use of emergency powers that might potentially override human rights protections while other states propose to limit interventions to those authorized by public health laws."

Analysis of 2009 pandemic influenza A/H1N1 outcomes in 19 European countries: association with completeness of national strategic plans: Meeyai et al; 2014 [36]
Plans of 19 European countries were analysed to compare overall "completeness" of plans with health outcomes from the 2009 H1N1 pandemic.
"There was no clear pattern of correlation between overall completeness of national strategic plans and pandemic influenza outcome measures and no evidence of association between these outcomes and components of pandemic plans that might plausibly affect influenza outcomes (public health interventions, vaccination, antiviral use, public communication)."
"The diversity of pandemic influenza outcomes across Europe is not explained by the marked variation in the completeness of national plans."

Framing post-pandemic preparedness: Comparing eight European plans: Holmberg, Lundgren; 2016 [37]
Review of 8 European plans (6 EU countries plus Norway and Switzerland).

"The preparedness plans in the Member States diverge in ways that will challenge the ambition of the European Union to make the pandemic preparedness plans interoperable and to coordinate the Member States during future pandemics."

Brussels workshop 17-18 February 2016

The findings of the accessibility audit were presented at the workshop in Brussels and discussed very briefly. Several participants who were involved in drafting national plans in their home countries stated that regardless of published plans, they knew the procedures to follow in the event of a pandemic.

That may be the case at high level but there is no evidence that this knowledge has filtered down to local or even sub-national level in many countries.

None was supportive of the plans being published in English as a common language for greater accessibility:

"We are completely allowed to write our national plan in our own language. And if anyone is not able to read these languages…I don't care…that's not a criteria for evaluation."

"Q: Responses to pandemics is a matter of national sovereignty. But we also know that individual countries border other countries, and sometimes they have different languages. So how do they communicate? As well as through the EU institutions do they also communicate bilaterally, and how do they do that?

A: I take point of what you said but there are official languages in the EU, working languages. There are official languages at the WHO and I think we have to stick to that. And I have no problem to discuss with our neighbouring countries."

Key interviewee interviews

Questions 3 of the questionnaire relates to the national plans:

"*3. As of late 2015, only 4 (of 28) national pandemic preparedness plans of EU Member States were publicly available, in English and up-to-date (i.e. post 2009). Should any of the following be a requirement of EU Member State national plans?*

- *3.1 In English*
- *3.2 Publicly accessible*
- *3.3 Up-to-date – if so, how would this be evaluated?*

In contrast to the workshop participants, all interviewees who expressed a view, stated that the plans should be either in English or in a common language or languages, to be agreed after open discussion.

"We all know that the working language is English in all of these things in the international arena…I think there's a strong argument for it, but I'm not sure what the legal basis would be for doing it in the European Union. It's common sense that it should be done, but the mechanism for getting it done is more problematic."

With regard to question 3.3 on updating of plans:

"You can't say every 5 years or something like that. I think that there should be a mechanism at European level to say that whenever new evidence emerges, then they should issue a call for them to be updated…probably the Commission would have to do it, rather than the ECDC. The Commission is the executive agency and would need to issue a call for updating in the light of significant new evidence becoming available. The ECDC doesn't have any executive powers."

Several interviewees also stated that countries with low capacity should have extra support from the EU.

DISCUSSION

This limited analysis of 7 plans identified issues similar to those identified by other authors.

- A lack of common format or structure. Plans seem to have different target audiences. The Croatia plan is highly technical and focuses on scientific surveillance. The French plan carries many illustrations and seems directed to the public. The UK plan (2011) is stated to be for a target audience of health workers. Many considerations stated as "Essential" in the WHO checklist are not included in plans. Some plans are aligned to the 6 WHO pandemic phases (later revised to 4 phases). For the UK "the use of WHO phases to trigger different stages of the local response were considered confusing and inflexible" and this plan develops its own phases: detection, assessment, treatment, escalation and recovery (DATER).

- A lack of specifics, particularly in relation to the sensitive area of isolation and quarantine measures. For example the plan of the Czech Republic speaks of "activating alternative plans for ensuring isolation and provision of medical care, if the situation so demands." The French plan mentions "implementation of exceptional

structures for specific reception of isolated people with influenza". This is extremely vague and provides little indication of what measures are contemplated.

- Intentions to design measures (authorizations, guidelines, training procedures) when a pandemic is actually in progress, although this may be impractical. For example: Croatia (page 16): "develop guidelines for health workers and laboratories on patient management and infectious material handling"; Italy: "prepare emergency plans to maintain health services and other emergency services; Spain: "the administrative court judges through prior authorization or ratification, will…control the proportionality of any intended health measure." Again, there is a lack of specifics. It would be helpful to be able to define what can be prepared beforehand and what can only be done during the actual pandemic.

- Out of date plans. Several plans state that there will be annual review of the plan and updating as necessary, e.g. Hungary (page 26) but there is no indication that this is being done. (The Hungarian plan is from 2008 and no longer accessible in English). Only 10 of 28 plans and only four of these reviewed plans had been updated since the H1N1 outbreak in 2009 (as requested by WHO and the ECDC). This suggests either lack of capacity or lack of prioritization, or both.

Good practices

There are some aspects of the plans which may be taken as examples of "good practice", e.g.

- Emphasis on communication. Apart from the Croatian plan which barely mentions communication, all plans discuss the importance of communication with stakeholders, including the public. Several plans contain "communication strategies" demonstrating that this is regarded as important.
- Emphasis on surveillance. All plans include substantial discussion of surveillance measures, again recognizing its importance.
- Public information websites. Both the UK and Spanish plans include public websites giving information to the general public on health emergencies.

LIMITATIONS

Only 7 plans were reviewed and these may not be representative. While there are many aspects which may be criticized, these plans are at least publicly available and have been translated into English, unlike the majority of other plans. The fact that so many plans

are only available in their national language restricts accessibility and the possibility of review.

Limitations of time and resources meant that this could only be a brief review. There are many other aspects of national plans which merit further and deeper study. For example, coherence and coordination of plans between neighbouring countries, review of national legislation (if it exists) to see to what extent it genuinely supports national plans, and above all, capacity to carry out planning intentions, i.e to what extent those intentions are realistic.

RECOMMENDATIONS

Accessibility

- National Pandemic Preparedness Plans should be current and publicly accessible. Ideally, this would be set out as a formal EC principle which all EU Member States should endorse.
- Each Member State needs to submit the following in an agreed common repository:
  - National pandemic preparedness plan;
  - National legislation underpinning measures in the plan;
  - The chain of command for pandemic response.
- Following open discussion, national plans need to be published in agreed common working language (s)

Coordination/Collaboration

- There need to be more collaborative exercises between Member States and with the WHO and the EU/ECDC.

  "Member States requested that intercountry collaboration continue in the following areas, supported by ECDC and WHO Europe: Continued sharing of pandemic preparedness plans, best practices and experience between countries, through the organization of meetings and/or working groups focused on specific topics, and through networks of experts."[22]

- Better coordination between WHO and the ECDC to ensure coherent management of lists of plans.

- More support for EU Member States with low capacity, and at least providing translation services for plans.

Plans fit for purpose

- Evidence base. The UK plan is the only one to stress the importance of an evidence base for proposed measures. This plan therefore rejects many measures for isolation and quarantine as of unproven benefit. It could be argued that the UK plan is too narrowly focused on pandemic influenza as these measures may be appropriate for other health threats. However, it is correct that there is little evidence for commonly recommended measures such as face masks or school closures. Research failed to find a correlation between the "completeness" or "quality" of plans (in comparison with WHO criteria), and health outcomes [36]. This undermines arguments for compliance. Therefore evidence should be prioritized.
- Legal and ethical review. Although Member States are allowed flexibility over the content and format of plans, the proposed measures must still be legal under European and national laws, and respect ethics and human rights. They should therefore be independently reviewed, perhaps by a central EU advisory body.

CONCLUSIONS

Although all Member States have signed up to the IHR and committed to its terms, they are clearly failing to comply in terms of developing up to date and accessible national pandemic preparedness plans. This is important. Plans are only one indicator of preparedness, but in the absence of any better test, they are a key one. Also, a failure to make plans publicly accessible is an impediment to coordination and transparency. It would appear from previous research, from discussions at the Brussels workshop, and from the brief audit carried out for this study, that plans are not being prioritized by Member States.

TABLE 1 NATIONAL PANDEMIC PREPAREDNESS PLANS: SEARCH RESULT 3 NOVEMBER 2015

	Accessed 3 November 2015: **ECDC Website:** http://ecdc.europa.eu/en/healthtopics/pandemic_preparedness/national_pandemic_preparedness_plans/Pages/influenza_pandemic_preparedness_plans.aspx Web page states: "*Updated 22 October 2015*" **WHO EUROPE Website:** http://www.euro.who.int/en/health-topics/communicable-diseases/influenza/pandemic-influenza/pandemic-preparedness/national-preparedness-plans2/full-list-of-national-preparedness-plans http://www.euro.who.int/en/health-topics/communicable-diseases/influenza/pandemic-influenza/pandemic-preparedness/national-preparedness-plans2			
ID	**COUNTRY**	**DATE** According to ECDC website (WHO only gives a few dates)	**LANGUAGE** According to ECDC/WHO websites	**SEARCH RESULT** (Unless stated, same result on both websites)
1	AUSTRIA	2006	German, English (3rd Edition)	Link gives message that website is unavailable. Redirected to website of Austrian Federal MOH. English version of website but unable to locate plan. [Subsequent Google search found English version at http://dev.ersnet.org/uploads/Document/42/WEB_CHEMIN_4946_1251467747.pdf]
2	BELGIUM	2006	French, Flemish, German (WHO), English (ECDC)	Link goes to file not found.
	BULGARIA[1]	2006	Bulgarian	Link goes to Bulgarian MOH page. Entirely in Bulgarian so unable to locate plan. [Subsequent Google search found English version at: http://www.fao.org/docs/eims/upload/221619/n

				ational_plan_ai_bgr_en.pdf].
4	CROATIA	2005	Croatian, English	Link goes directly to plan in English which can be accessed and downloaded.
5	CYPRUS	2005	Greek English (ECDC)	Link goes to file not found.
6	CZECH REPUBLIC	2011	Czech, English	Link goes directly to relevant Czech MOH webpage where both language versions can be accessed and downloaded.
7	DENMARK	2013	Danish	Link goes directly to relevant Danish MOH webpage. Plan can be accessed and downloaded but only available in Danish.
8	ESTONIA	2007	Estonian, Russian, English	Link goes to file not found. [Subsequent Google search found 2005 plan in English at: rahvatervis.ut.ee/bitstream/1/.../Sotsiaalministerium2004_3_inglisek.doc].
9	FINLAND	2012	Finnish	ECDC: Link goes directly to relevant Finnish MOH page. Plan of 2012 and further documents of 2013 and 2014 can be accessed and downloaded, but are only available in Finnish. WHO: Link goes to file not found.
10	FRANCE	2011	French, English (ECDC)	ECDC: Direct links to both French and English versions which can be accessed and downloaded. WHO: Link to French version only.
11	GERMANY	2007	German	Link goes to file not found.
12	GREECE	2009	Greek	Link goes to plan in pdf but page froze and impossible to access or download from either ECDC or WHO websites.
13	HUNGARY	2008	Hungarian, English (ECDC)	ECDC: Link goes directly to relevant MOH page where both language versions can be accessed and downloaded. WHO: Link goes to Hungarian version only.
14	IRELAND	2007	English	Both ECDC and WHO linked to page which does not

				exist: www.dohc.ie so impossible to access plan. [The correct Irish MOH address is www.health.gov.ie from which the 2007 plan could be accessed and downloaded.]
15	ITALY	2010	Italian, English (ECDC)	ECDC: Links go directly to plans in both languages which can be accessed and downloaded. Neither plan is dated but ECDC website gives date as 2010. WHO: Link to Italian version only.
16	LATVIA	2006	Latvian	Both ECDC and WHO linked to http://phoebe.vm.gov.lv which is an incorrect address and does not exist.
17	LITHUANIA	2008	Lithuanian[ii]	ECDC: Link goes directly to plan on relevant Lithuanian government web page. Plan is in Lithuanian only. WHO: Link goes to general Lithuanian government web page. Entirely in Lithuanian so not possible to locate plan in any language version.
18	LUXEMBOURG	2006	French English (ECDC)	Links go directly to relevant MOH web page from where the plan in French only can be accessed and downloaded. No English version found.
19	MALTA	2007	English	Links go to Maltese government website in English and Maltese. Searched for plan but unable to locate.
20	NETHERLANDS	2011	Dutch	Links go to Dutch MOH website. English version of website available but unable to locate plan.
21	POLAND	2005	Polish	ECDC: Link goes to Polish Department of Sanitation from which the plan in Polish can be accessed and downloaded. WHO: Link goes to Polish MOH website. English version of website available but unable to locate plan.
22	PORTUGAL	2006	Portuguese	Links go directly to plan in Portuguese which can be accessed and downloaded.
23	ROMANIA	2009	Romanian	Links go directly to plan in Romanian which can be

				accessed and downloaded.
24	SLOVAKIA	2001/2008	Slovakian	Both links go to plan at www.uvsr.sk but cannot access document. [Subsequently found 2001 plan on general WHO website at: http://www.who.int/influenza/preparedness/plans/influenza_preparedness_plan_slovakia/en/]
25	SLOVENIA	2006	Slovenian	ECDC: Link goes directly to plan version 1.2 in Slovenian. WHO: Link goes to Slovenian MOH website and then to plan version 0.01 in Slovenian.
26	SPAIN	2005/2006	Spanish, English	Links go to Spanish MOH website with 2005 plans and 2006 updates in Spanish and English. All can be accessed and downloaded.
27	SWEDEN	2012	Swedish, English	ECDC: Link goes to file not found. WHO: Link goes to plan in Swedish only, which can be accessed and downloaded.
28	UK	2011/2014	English	ECDC: Links directly to 2011 and 2014 plans which can be accessed and downloaded. WHO: Link to 2011 plan only, which can be accessed and downloaded.

TABLE 2 NATIONAL PANDEMIC PREPAREDNESS PLANS: REVIEW OF THEMES

1. NATIONAL LEGISLATION	
CROATIA 2005	Page 42. In reference to avian influenza surveillance and control: "Veterinary Medicine Act (Official Gazette of the Republic of Croatia, OGRC, 70/97, 105/01, 172/03) and the Mode and Procedure for Notification of Suspicion and Cancellation of Infectious Animal Disease and the Requisite Forms Form and Contents Regulation (OGRC 179/04)."
CZECH REPUBLIC 2011	No reference.
FRANCE 2011	No reference.
HUNGARY 2008	Page 10: "List of effective relevant regulations at Annex 3." Link to Appendix no longer accessible [as at 30.04.16].
ITALY 2010	Page 26: "Legislation applicable to ensure the coordination of interventions needed to confront and overcome the emergency phase is covered by Law 225/92, D.L. 343/2001, converted into Law 401/2001, D.L. 245/2002, converted into Law 286/2002, D.L. 90/2005 converted into Law 152/2005. On the basis of this cited legislation, coordination functions will be the responsibility of the Prime Minister, under advice from the Department for Civil Protection, which in turn will initiate action by the National Civil Protection Service."
SPAIN 2006	Page 45: "Establishment of the legal basis for the implementation of special public health measures in the context of influenza with pandemic potential." Act 3/86 on Special Public Health Measures "has been given a sufficient legal rank in order to enable its direct application by the Health Authorities with powers and responsibilities in the area of Public Health, provided that the circumstances stipulated in that legal provision have actually arisen…The health measures that may be adopted in accordance with this Act must be proportionate to the ends pursued, be limited to the time strictly necessary in order to overcome the crisis situation and be implemented under the control of the jurisdictional bodies entrusted with the protection of individual rights. The administrative court judges, through prior authorization or ratification, will be the authority that will control the proportionality of any intended health measure insofar as such a measure involves the deprivation or restriction of freedom or of any other fundamental right, thus acting as guarantors of individual fundamental rights."
UK 2011/14	Not referenced in 2014 plan but set out in 2011 "UK Influenza Pandemic Preparedness Strategy" pages 62-63: "taking legislative action." 7.25: "There is no intention to use legal powers to require people to undergo vaccination or treatment." 7.26: "The Public Health (Control of Disease) Act 1984…provides powers for a justice of the peace to impose restrictions or requirements (other than vaccination or treatment) on a person, if their behaviour is putting others at risk of significant harm from infectious disease. The Act also allows the government to make regulations specifically to address a 'serious and imminent' threat to public health, if this should arise. This is intended as a contingency provision in the event that legal powers are needed to deal with a substantial threat (such as SARS). Any regulations made could, for example, in extreme circumstances enable a local authority to impose requirement for medical examination, or for isolation or quarantine." 7.29: Part two of the Civil Contingencies Act 2004 established a new generic framework for emergency powers. Emergency powers allow the Government to make special temporary

	legislation (emergency regulations). However, emergency powers are for use in only the most serious of emergencies when existing powers may be insufficient, and there is not time to either take new powers through the usual route of new legislation, or to see if existing legislation is sufficient. The use of emergency powers is very much viewed as a last resort option and a number of robust safeguards exist to restrict their use." 7.30: "Even if emergency powers are enacted, they are still limited in their scope to the direct amelioration of the effects of the emergency. In addition, emergency regulations are designed to be time bound and will either lapse after 30 days or as otherwise specified in the regulations."

2. COMMUNICATION	
CROATIA 2005	Page 16: One reference: "Organise communication with the media and the public, i.e. appoint an individual or organising body to be exclusively authorised to release reports for the media and public about the pandemic…inform the public through the media."
CZECH REPUBLIC 2011	Discussed in alignment with 6 WHO phases (pages 20-21, 30-31, 36-37, 41-47).
FRANCE 2011	Discussed in relation to each measure. Page 26. "Elements of communication strategy."
HUNGARY 2008	Discussed in alignment with 6 WHO phases, eg. "Communication plan" at pages 15-17, 19, 21, 23.
ITALY 2010	Pages 21-22: "Prepare adequate communication strategies."
SPAIN 2006	Page 33: The Communications Subcommittee "has prepared a communication plan for avian influenza…the plan includes the preparation of communication strategies, attention to journalists, information to the public and information coordination with other institutions, national as well as international…this plan also focuses on keeping the internal lines of communication activated, within the Ministry as well as within the Government itself, and with the Autonomous Communities." Pages 38-39: "Communication of the risk to the general public along with the measures to be adopted to avoid this risk." Reference to website giving advice: www.gripeaviar.es [active as at 01.05.16] and www.msc.es [link redirects to www.msssi.gob.es which is active].
UK 2011/14	2014 Plan pages 51-54: sets out tasks of Communications Directorate. 2011 pages 45-49, 5. Communication and public and professional engagement. Clear and specific advice. Public website: www.direct.gov.uk/preparingforemergencies. Can go to your local area (only England & Wales) although pandemic outbreak is not necessarily listed as a potential emergency.

3. SURVEILLANCE	
CROATIA 2005	Pages 22-49. Detailed technical discussion.
CZECH REPUBLIC 2011	Pages 10-11 and then in alignment with 6 WHO phases
FRANCE 2011	Discussed in alignment with 4 WHO phases.
HUNGARY 2008	Discussed in alignment with 6 WHO phases.
ITALY 2010	Pages 11-13
SPAIN 2006	Pages 40-44: "Strengthening the Early Warning System…Intensify Rapid Containment Activities." Pages 52-53: "Revision of the indicators and surveillance systems necessary for pandemic Phase 6."
UK 2011/14	2011 Detection & Assessment pages 34-36.

4. ISOLATION, QUARANTINE, BORDER CONTROLS & SOCIAL DISTANCING MEASURES	
CROATIA 2005	No reference.
CZECH REPUBLIC 2011	Page 29: "Implementing potential measures relating to international travel", page 41: "Activating alternative plans for ensuring isolation and provision of medical care, if the situation so demands"
FRANCE 2011	Discussed in alignment with 4 WHO phases, e.g. page 41: "recommendations for quarantine of contact cases at home, quarantining of contact cases, suspension of air and maritime links from affected areas." Page 49: "implementation of exceptional structures for specific reception of isolated people with influenza." No details specified.
HUNGARY 2008	Discussed in alignment with 6 WHO phases. Page 7: "In order to contain the spread of the epidemic, hospital visiting will have to be prohibited." Page 19: NPHMOS, in collaboration with the Police, implements controls of persons coming from areas of outbreak, the identification and isolation of persons suspected of having influenza, at the designated border crossing stations and points." Page 20: "With contributions from the police, NPHMOS shall intensify control of persons arriving from areas in danger of epidemic at the border crossing points, screening and isolation of suspect influenza cases in accordance with the relevant recommendation of the WHO and the European Communities ECDC."
ITALY 2010	Page 13: "the following measures are required: public health measures such as limitation of movement, isolation and quarantine for cases and contacts". Page 14: "assess the opportunity of restricting movement from and to other countries where epidemic clusters have been ascertained…isolation of patients with suspected symptoms…quarantine and active surveillance of contacts
SPAIN 2006	Nothing specified, apart from page 45 reference to authority of administrative court judges to "control the

	proportionality of any intended health measure, insofar as such a measure involves the deprivation or restriction of freedom or of any other fundamental right."
UK 2011/14	2011 Pages 38-40: International travel, border restrictions and screening. Discussed in some detail and largely rejected as measures to take, eg. 4.18: "there are no plans to attempt to close borders in the event of an influenza pandemic", 4.21-4.22 "there is very limited evidence that restrictions on mass gatherings will have any significant effect on influenza virus transmission…the working presumption will be that the Government will not impose any such restrictions."

5. EQUITY & PRIORITISATION OF HEALTHCARE	
CROATIA 2005	"Vaccination is recommended primarily to: • People aged 65+ years • Chronic patients • Groups that would exhibit increased exposure to the risk in the pandemic situation. …Health workers should come next…Services vital to the functioning of the state should also be covered by the vaccination. It would be optimal for vaccination continuation to cover the whole population as well."
CZECH REPUBLIC 2011	No reference.
FRANCE 2011	Page 17. "Health care professionals and those in related fields have priority access to the vaccine and are strongly encouraged to receive the vaccination to avoid propagating the virus to the people they treat; The Government must allow access to the vaccine and to other health care products, in an order of priority defined through a transparent and publicly-announced procedure." Page 70. "Priorities must be established for vaccination, for example: • Protect the populations that are most at risk medically, • Limit the infectiousness of the virus by giving priority to protection of the populations who promote infection (especially children), • Protect specific personnel whose activity absolutely must not be interrupted."
HUNGARY 2008	Page 20: "OCMO reviews and updates the plan for distributing vaccines required to vaccinate high-risk population groups and population groups to be provided increased protection." Page 21: "vaccination of healthcare workers and employees of sectors providing essential services shall begin. In the event of the non-availability of the necessary vaccines, NPHMOS considers the launch of antiviral prevention for healthcare workers and for employees working on key areas essential for the operation of the national economy, until such time as vaccination may begin."

ITALY 2010	Page 17: "The present plan identifies 6 categories, listed according to priority: 1. Health care personnel and other workers; 2. Personnel connected with services essential for security and emergency needs; 3. Personnel in public utility services; 4. Persons with a high risk of severe or fatal complications due to influenza; 5. Healthy children and adolescents aged between 2-18 years; 6. Healthy adults. The priority scale, for points 4-6 can be subjected to revision during pandemic alert phase 5, on the basis of the epidemiological characteristics of the virus in circulation."
SPAIN 2006	Page 46: Prioritisation set out in Annex IV, which is not in English. Prioritization is understood to be given to highest risk groups which are specified as children and adults with chronic illnesses. The next priority is health workers and workers in emergency services (specified as police and security services, public utilities, funeral services, telecommunications, public transport and transport of basic foodstuffs).
UK 2011/14	2011 page 41, 4.30: "In the light of scientific and clinical advice at the time, antiviral treatment may be limited, for part or all of the pandemic, to those in at risk groups if the pandemic proves to be very mild in nature or if antiviral medicine supplies are being depleted too rapidly." 4.33 "the Government does not plan at the current time to adopt a general strategy of household prophylaxis. 4.39 Pre-pandemic vaccines, if useful "would be prioritised for the protection of frontline healthcare workers and those in clinically at-risk groups." 4.46 Pandemic vaccination programme: "the presumption should be that the prioritisation of vaccine will depend on the emerging profile of at-risk groups for a new pandemic virus, with priority given to clinical risk groups and front-line health and social care workers. There are no plans to prioritise vaccine for any other specific groups or sectors for business continuity reasons."

9 Governance Frameworks: Transportation of specimens, bio-safety, bio-security, diagnostics and virus-Sharing

9.1 Safety and the regulation of transport of specimens

The transport of biological material presents risks for human health (of the transporters, of the laboratory workers and of neighbouring populations), for the environment and for the wellbeing of transported animals.

Measures have therefore been taken by regulatory bodies to ensure that such transport is carried out under the best possible conditions.

The legislation governing the transport of biological material depends on the following three elements:

- The nature of the biological material;
- The mode of transport used; and
- The territory on which the biological material is transported.

This document focuses on the transport of biological material for scientific purposes. The regulation of the transport of food for human or animal consumption is beyond the scope of this document.

9.1.1 Regulatory bodies

The United Nations provides recommendations for the safety and regulation of the transport of dangerous goods. These recommendations apply to model organizations, regional bodies and national governments in a form that can be adopted with little or no modification directly into their regulations.

In line with the "*United Nations Recommendations*" on the "*Transport of Dangerous Goods and the Model Regulations*", the model regulations (i.e. ADR, AND, IMDG, RID and IATA DG) are organized on the same basic scheme of provisions. This scheme allows uniform development of national and international regulations governing the various modes of transport. Yet the model regulation remains flexible to accommodate any special requirements that might have to be met. The scheme of provisions provided by the UN Model Regulations consists of:

- A principle of classification of dangerous goods;
- A list of the principal dangerous goods;
- General packing requirements;

- Testing procedures;
- Marking and labelling instructions; and
- Template of transport documents.

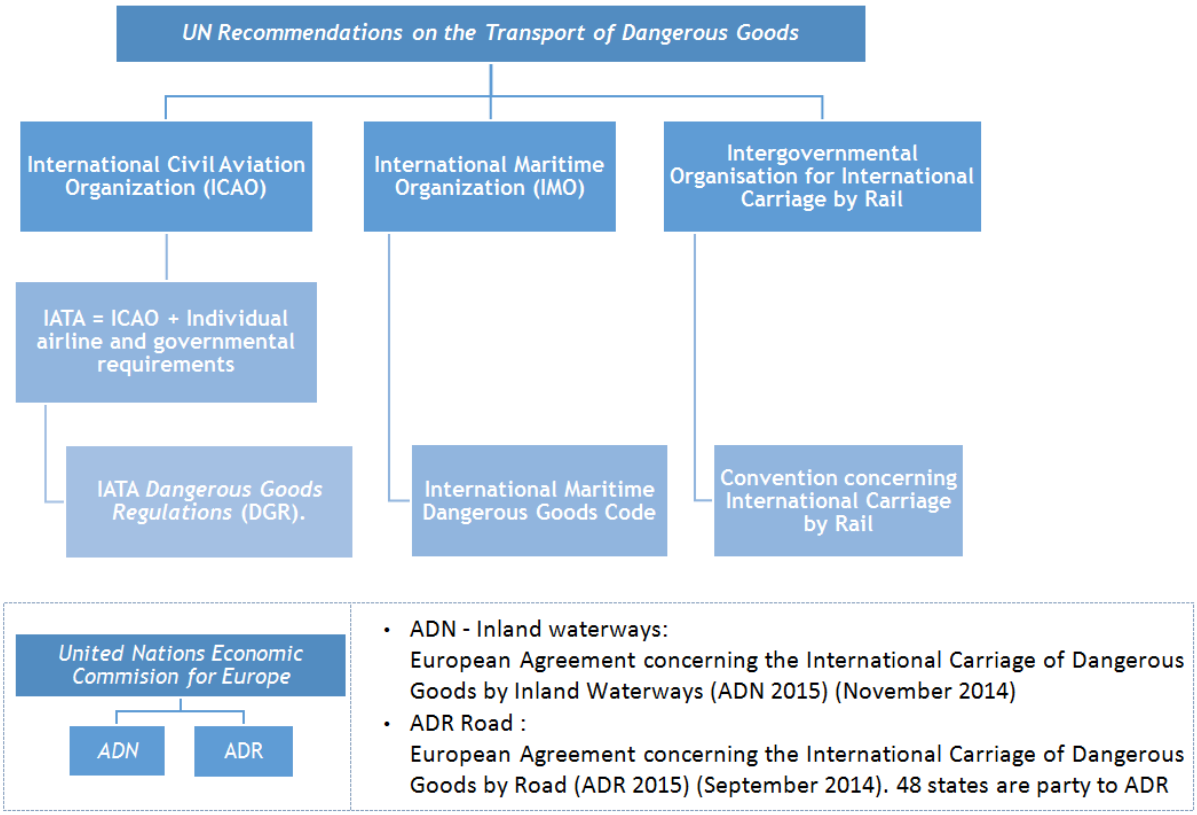


Figure 1. Model regulation body and regulation codes.

9.1.2 Legal instruments for the regulation of dangerous goods transport

International regulations

- **IMDG Code (International Maritime Dangerous Goods Code)**
  IMDG Code is an international guideline for the safe transportation or shipment of dangerous goods or hazardous materials by sea. The IMDG Code is intended to protect crew members and to prevent marine pollution in the safe transportation of hazardous materials by sea. The current version of the IMDG Code is the 2014 Edition since 1 January 2016 for two years.

- **Regulation concerning the International Carriage of Dangerous Goods by Rail (RID)**
  This regulation is written by the Intergovernmental Organisation for International Carriage by Rail (OTIF). The objective of this Governmental Organisation is principally to develop the uniform systems of law which apply to the carriage of passengers and freight in international through traffic by rail.

- **International Air Transport Association (IATA)**

  IATA aims to represent, lead, and serve the airline industry. This association additionally links third parties and the airline industry. IATA works closely with local governments, International Civil Aviation Organization (ICAO) and airlines in the development of regulations and working standards for the aviation industry.

  The IATA Dangerous Goods Regulations (DGRs) are similar to the "Technical Instructions for the Safe Transport of Dangerous Goods by Air" published by the International Civil Aviation Organization (ICAO). However, the DGRs include additional requirements that are more restrictive than the Technical Instructions, to reflect standard industry practices or operational considerations. The current version of the DGRS is the 57th Edition which is effective since 1 January 2016.

European Union legal instruments

The European Union uses different types of legal instruments to implement policy regulating the transport of biological material:

- **ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road**

  The European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) was signed at Geneva on 30 September 1957 under the auspices of the United Nations Economic Commission for Europe, and it entered into force on 29 January 1968.

  Since 1 January 2015, a 2015 edition (ECE/TRANS/242, Vol. I and II), and corrigenda is applied. Dangerous goods may be carried internationally in road vehicles if they comply with the conditions described in the Annexes A and B of the ADR.

- **ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways**

  The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) was signed at Geneva on 26 May 2000 on the occasion of a Diplomatic Conference held under the joint auspices of the United Nations Economic Commission for Europe (UNECE) and the Central Commission for the Navigation of the Rhine (CCNR). It entered into force on 29 February 2008.

  The Regulations annexed to the ADN contain provisions concerning dangerous substances and articles, provisions concerning their carriage in packages and in bulk on

board inland navigation vessels or tank vessels, as well as provisions concerning the construction and operation of such vessels.

- **Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods**
  This directive lays down common rules for the safe and secure transport of dangerous goods within and between EU countries by road, rail or inland waterway. Directive 2008/68/EC covers aspects such as loading and unloading, the transfer to and from another mode of transport, as well as the stops in the course of the transport process. In addition, the directive extends the application of international rules to national transport of dangerous goods such as ADR, RID and ADN.

National rules

For reasons other than safety during transport (e.g. environmental protection or national security), EU countries are entitled to regulate or exclude the transport of dangerous goods within their own territory. They may also set down specific safety requirements for the national and international transport of dangerous goods within their own territory with regard to:

- The transport of dangerous goods by vehicles, wagons or inland waterway vessels not covered by this directive;
- The use of prescribed routes, where justified, including the use of prescribed modes of transport; and
- Special rules for the transport of dangerous goods in passenger trains.

9.1.3 Nature of biological material: Dangerous Goods – Division 6.2 Infectious substances[9]

A classification of dangerous goods has been established by the United Nations. The division 6.2 covers infectious substances. Infectious substances are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsia, parasites, and fungi) and other agents such as prions, which can cause disease in humans or animals.

[9] Source: ADR, United Nations Economic Commission for Europe Committee on Inland Transport, European Agreement Concerning the International Carriage of Dangerous Goods by Road. New York and Geneva 2010 (applicable as from 01 Jan 2011) § 2.2.62.1.1 p 230

In the Dangerous Goods (DG) regulations, a substance is identified by its class (here 6.2 Infectious substance), by its UN number and by its "proper shipping name". In the class 6.2 Infectious substance, there are four different proper shipping names (cf. Table 1).

The UN number and the proper shipping name of a substance depend on the answers to the questions displayed on Table 1.

Note 1: Genetically modified microorganisms and organisms, biological products diagnostic specimens and infected live animals shall be assigned to this class if they meet the conditions for this class.

Note 2: Toxins from plant, animal or bacterial sources which do not contain any infectious substances or toxins that are not contained in substances which are infectious substances should be considered for classification in Class 6.1 Toxic substances and assigned to **UN 3172**.

Table 1: Definition of the proper shipping name of a substance of division 6.2 Infectious substance

Is the infectious substance carried in a form that, when exposure to it occurs, the substance is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals?	
If Yes (category A)	Then there is a second question: Does this infectious substance cause disease in humans or both humans and animals? • If yes, then **UN No. 2814** and the proper shipping name is **"Infectious substance, affecting humans"**. • If not, then **UN No. 2900** and the proper shipping name is **"Infectious substance affecting animals only"**.
If not (category B)	Then the infectious substances will be assigned to **UN No. 3373** and its proper shipping name is **"Biological substance category B"** except if the substance is a clinical waste. In case of clinical waste, the **UN No. is 3291** and the proper shipping name is **"Clinical waste, unspecified, N.O.S"**.
Is the substance a medical or clinical waste which is reasonably believed to have a low probability of containing infectious substances?	
	If yes then UN **No. 3291** and the proper shipping name is **"Clinical waste, unspecified, N.O.S"**.

9.1.4 Packing, Marking and labelling instruction of Dangerous Goods

The packing, marking and labelling instructions depend on the transport mode but the procedure to find those instructions is similar for the different transport mode. This procedure will be illustrated in case of transport by road.

A table called “Dangerous Goods list” lies in the model regulation e.g. ADR (applicable from 1 January 2011). This table provides for each proper shipping name of a dangerous good the instructions concerning the packing group (if applicable), the labels, and the packing instruction. Instructions for the “Infectious substance, affecting humans” (UN No. 2814) are presented in

UN No.	Name and description	Class	Classification code	Packing group	Labels	Special provisions	Limited and excepted quantities		Packaging			Portable tanks and bulk containers	
									Packing instructions	Special packing provisions	Mixed packing provisions	Instructions	Special provisions
	3.1.2	2.2	2.2	2.1.1.3	5.2.2	3.3	3.4.6	3.5.1.2	4.1.4	4.1.4	4.1.10	4.2.5.2 7.3.2	4.2.5.3
(1)	(2)	(3a)	(3b)	(4)	(5)	(6)	(7a)	(7b)	(8)	(9a)	(9b)	(10)	(11)
2814	INFECTIOUS SUBSTANCE, AFFECTING HUMANS	6.2	I1		6.2	318	0	E0	P620		MP5		
2814	INFECTIOUS SUBSTANCE, AFFECTING HUMANS, in refrigerated liquid nitrogen	6.2	I1		6.2 +2.2	318	0	E0	P620		MP5		
2814	INFECTIOUS SUBSTANCE, AFFECTING HUMANS (animal material only)	6.2	I1		6.2	318	0	E0	P620		MP5	BK1 BK2	

Figure 2 and

UN No.	Name and description	Class	Classification code	Packing group	Labels	Special provisions	Limited and excepted quantities		Packaging			Portable tanks and bulk containers	
									Packing instructions	Special packing provisions	Mixed packing provisions	Instructions	Special provisions
	3.1.2	2.2	2.2	2.1.1.3	5.2.2	3.3	3.4.6	3.5.1.2	4.1.4	4.1.4	4.1.10	4.2.5.2 7.3.2	4.2.5.3
(1)	(2)	(3a)	(3b)	(4)	(5)	(6)	(7a)	(7b)	(8)	(9a)	(9b)	(10)	(11)
2814	INFECTIOUS SUBSTANCE, AFFECTING HUMANS	6.2	I1		6.2	318	0	E0	P620		MP5		
2814	INFECTIOUS SUBSTANCE, AFFECTING HUMANS, in refrigerated liquid nitrogen	6.2	I1		6.2 +2.2	318	0	E0	P620		MP5		
2814	INFECTIOUS SUBSTANCE, AFFECTING HUMANS (animal material only)	6.2	I1		6.2	318	0	E0	P620		MP5	BK1 BK2	

Figure 2.

UN No.	Name and description	Class	Classification code	Packing group	Labels	Special provisions	Limited and excepted quantities		Packaging			Portable tanks and bulk containers	
									Packing instructions	Special packing provisions	Mixed packing provisions	Instructions	Special provisions
	3.1.2	2.2	2.2	2.1.1.3	5.2.2	3.3	3.4.6	3.5.1.2	4.1.4	4.1.4	4.1.10	4.2.5.2 7.3.2	4.2.5.3
(1)	(2)	(3a)	(3b)	(4)	(5)	(6)	(7a)	(7b)	(8)	(9a)	(9b)	(10)	(11)

2814	INFECTIOUS SUBSTANCE, AFFECTING HUMANS	6.2	I1		6.2	318	0	E0	P620		MP5		
2814	INFECTIOUS SUBSTANCE, AFFECTING HUMANS, in refrigerated liquid nitrogen	6.2	I1		6.2 +2.2	318	0	E0	P620		MP5		
2814	INFECTIOUS SUBSTANCE, AFFECTING HUMANS (animal material only)	6.2	I1		6.2	318	0	E0	P620		MP5	BK1 BK2	

Figure 2. Extract of the ADR Dangerous Goods list table.

P620	PACKING INSTRUCTION	P620

This instruction applies to UN Nos. 2814 and 2900.

The following packagings are authorized provided the special packing provisions of **4.1.8** are met:

Packagings meeting the requirements of Chapter 6.3 and approved accordingly consisting of:

(a) Inner packagings comprising:

(i) leakproof primary receptacle(s);

(ii) a leakproof secondary packaging;

(iii) other than for solid infectious substances, an absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if multiple primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated so as to prevent contact between them;

(b) A rigid outer packaging. The smallest external dimension shall be not less than 100 mm.

Additional requirements:

1. Inner packagings containing infectious substances shall not be consolidated with inner packagings containing unrelated types of goods. Complete packages may be overpacked in accordance with the provisions of 1.2.1 and 5.1.2; such an overpack may contain dry ice.

2. Other than for exceptional consignments, e.g. whole organs which require special packaging, the following additional requirements shall apply:

   (a) Substances consigned at ambient temperatures or at a higher temperature: Primary receptacles shall be of glass, metal or plastics. Positive means of ensuring a leakproof seal shall be provided, e.g. a heat seal, a skirted stopper or a metal crimp seal. If screw caps are used, they shall be secured by positive means, e.g., tape, paraffin sealing tape or manufactured locking closure;

   (b) Substances consigned refrigerated or frozen: Ice, dry ice or other refrigerant shall be placed around the secondary packaging(s) or alternatively in an overpack with one or more complete packages marked in accordance with 6.3.3. Interior supports shall be provided to secure secondary packaging(s) or packages in position after the ice or dry ice has dissipated. If ice is used, the outer packaging or overpack shall be leakproof. If dry ice is used, the outer packaging or overpack shall permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used;

   (c) Substances consigned in liquid nitrogen: Plastics primary receptacles capable of withstanding very low temperature shall be used. The secondary packaging shall also be capable of withstanding very low temperatures, and in most cases will need to be fitted over the primary receptacle individually. Provisions for the consignment of liquid nitrogen shall also be fulfilled. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the liquid nitrogen;

   (d) Lyophilised substances may also be carried in primary receptacles that are flame-sealed glass ampoules or rubber-stoppered glass vials fitted with metal seals.

3. Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging shall be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa and temperatures in the range -40 °C to +55 °C.

4. Other dangerous goods shall not be packed in the same packaging as Class 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 ml or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances. These small quantities of dangerous goods of Classes 3, 8 or 9 are not subject to any additional requirements of ADR when packed in accordance with this packing instruction.

5. Alternative packagings for the carriage of animal material may be authorized by the competent authority of the country of origin [a] in accordance with the provisions of 4.1.8.7.

[a] *If the country of origin is not a Contracting Party to ADR, the competent authority of the first Contracting Party to the ADR reached by the consignment.*

Figure 3. "Infectious substance, affecting humans" (UN No. 2814) packing instruction.

9.2 Diagnostics

In Europe, in vitro diagnostic (IVD) medical devices are regulated following the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998. IVD devices are not subjected to a pre-market authorization, but to a conformity assessment by 'notified bodies' that issue a certificate of conformity ('CE' mark).

New European legislation is currently in progress to update the legal framework for medical devices and in vitro diagnostic medical devices in concertation with stakeholders (industry, patient and consumer association) *(Scholz* N., EU Legislation in Progress: Medical devices and in vitro diagnostic medical devices, European Parliament Think Tank Members' Research Service, 07-12-2015).

In follow up to Directive 98/79/EC implementation, the EC published a list of titles and references of harmonised standards under Union harmonisation legislation (2015/C 226/03, Official Journal of the European Union, 10-07-2015).

In addition to commercial IVD products, a number of diagnostic tests can be home-made. A subset of the Directive's essential requirements could be considered applicable to in house tests and the institution offering the testing service should have a quality system in place (ISO 15189 [for diagnostic testing], ISO 17025 [for clinical study testing] or ISO 13485 [for commercial IVD product development and distribution]).

9.3 Bio-safety and bio-security

9.3.1 Definitions

Laboratory bio-safety describes "the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release" (World Health Organization, 2004. *Laboratory biosafety manual*. Third edition).

Laboratory bio-security describes "the protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release" (World Health Organization, 2006. *Biorisk management - Laboratory biosecurity guidance*).

9.3.2 Legal framework

Biosecurity policy measures haven been reviewed by the the European Biosecurity Awareness Raising Network (EUBARnet) (Revill, J. (2012). Biosecurity Policy Measures at the International, Regional and Local Levels, *European Biosecurity Awareness Raising Network, Review Series on Policy, Ethics and Security*, paper n°8).

At the international level, a biosafety legal framework is set by the international agreement, "*Cartagena Protocol on Biosafety to the Convention on Biological Diversity*", adopted on 29 January 2000 and entered into force on 11 September 2003, which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. The Cartagena protocol is complemented by the "*Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress*". This Supplementary Protocol provides for international rules and procedure on liability and redress for damage to biodiversity resulting from LMOs.

Biosafety can also be regulation by taking into account the WHO *Laboratory biosafety manual*.

At the international level, biosecurity governance relies on a series of documents:

- **The Biological Weapons Convention (BWC)**: This convention entered into force on 26 March 1975. It is a treaty banning the development, production and stockpiling of bacteriological (biological) and toxin weapons and regulating their destruction.
- **United Nations Security Council Resolution 1540**: This resolution stablishes legally binding obligations on all UN Member States to have and enforce appropriate and effective measures against the proliferation of nuclear, chemical, and biological weapons (WMD), their delivery systems, including by establishing controls.
- WHO has published a series of "laboratory biorisk management guidance" documents in the frame of the Alert, response, and capacity building under the **International Health Regulations (IHR).**

In Europe, laboratory biosafety is regulated by a number of legislative texts:

- The Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

- The Council Directive 98/81/EC of 26 October 1998 amending 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms.
- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration

These directives also take biosecurity aspects into account (knowledge on which facilities and personnel can handle dangerous materials and obligation of inspection of such facilities). Moreover, biosafety and biosecurity are addressed together as "biorisk" through standard form the European committee:

- "Laboratory biorisk management standard" (CEN workshop agreement CWA 15793, published in 2008 and revised in 2011).
- "Laboratory biorisk management - Guidelines for the implementation of CWA 15793:2008" (CWA16393 published in 2012).

9.4 Sharing pathogenic biological material

Access to and sharing of biological material with human pathogenic potential is important for the development of new diagnostic tests, drugs and vaccines. Legal frameworks for biological material sharing currently exist:

- The Convention on Biological Diversity (CBD): The Convention on Biological Diversity (CBD) entered into force on 29 December 1993.

  "*The objectives of this Convention, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.*

  States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction." (Citation from the "Convention on Biological Diversity" text, United Nations 1992)

- The Pandemic Influenza Preparedness (PIP) Framework: The Framework was developed by WHO Member States. It became effective on 24 May 2011 when it was unanimously adopted by the Sixty-fourth World Health Assembly
  "*The objective of the Pandemic Influenza Preparedness (PIP) Framework is to improve* ***pandemic influenza*** *preparedness and response, and strengthen the protection against the pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system ("WHO GISRS"), with the objective of a fair, transparent, equitable, efficient, effective system for, on an equal footing:*

  (i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and

  (ii) access to vaccines and sharing of other benefits." (Citation from the "Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits" text, World Health Organization 2011).

- Trade-Related Aspects of Intellectual Property Rights (TRIPS): The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, issued by the WTO, is in force since 1995. It introduces global minimum standards for protecting and enforcing nearly all forms of intellectual property rights (IPR). IPR have to be taken into account for protection and access of biological material, and for the fair dividing of benefits issued form research and development based on shared biological material.

However, a *global legal framework regulating the access, protection and sharing of* biological material with human pathogenic potential (not only Influenza), and the fair repartition of benefits issued from that material, *is lacking*. This represent a big challenge as IPR provides strong incentives to hold knowledge and to protect biological materials, while CBD that affirms the sovereignty of states over their resources and claims a share on the benefits arising from such resources.

In the case of a global health emergency, the human right to health could be used to provide access to pathogen materials as it is for access to medicine (ethical beyond legal obligation). Therefore, a legal framework that promotes sharing of pathogenic material for research, outside of the pandemic phase, is essential in order to improve pandemic preparedness (diagnostic, drug and vaccines development). This legal framework should regulate not only biological strains but also sequencing genetic data sharing, which are currently out of scope of the PIP framework.

10 Literature Review

A literature review was conducted with the objective of identifying commonly recurring themes in pandemic governance literature and the nature of the debate on these themes. This was not intended to be an exhaustive search but rather as a scoping exercise to review recent academic scholarship on pandemic governance.

10.1 Methodology

DATA COLLECTION: PURPOSIVE LITERATURE SEARCH

Literature review combined purposive and systematic literature searches. A purposive literature search was conducted between September 2015 and June 2016 for the purpose of this report. Documents were identified through research into legal instruments, governance frameworks and mechanisms (including national pandemic preparedness plans) and case studies. Full texts were downloaded from open-source websites including WHO, CDC, ECDC and EUR-LEX, Ministries/Departments of Health of EU Member States and the LSHTM library.

Personal email communication was made with organisations, researchers and implementers identified from purposive search documents to request further information. Contacted organisations included WHO Regional Office for Europe and DG SANTE.

Inclusion criteria: National policy documents/Both peer-reviewed and grey literature/Both published and unpublished literature/English language/Pandemic disease scenario: airborne, human to human transmission

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

Purposive search identified 168 records which were stored in an EndNote Reference library programme. Reference types were:

Audiovisual material, i.e. ECDC presentation on Decision 1082/13:	1
Blog	1
Book	3
Conference proceedings	2
Government document, e.g. national pandemic plan:	33
Journal Article:	76
Legal Rule or Regulation/Statute:	14

Newspaper Article	10
Report, e.g. research project report	23
Unpublished work, i.e. advance high level panel report on Ebola:	1
Web Page	4

For the purpose of this literature review, analysis was conducted on the 76 journal articles only. To these were added a further 30 journal articles identified by systematic literature review.

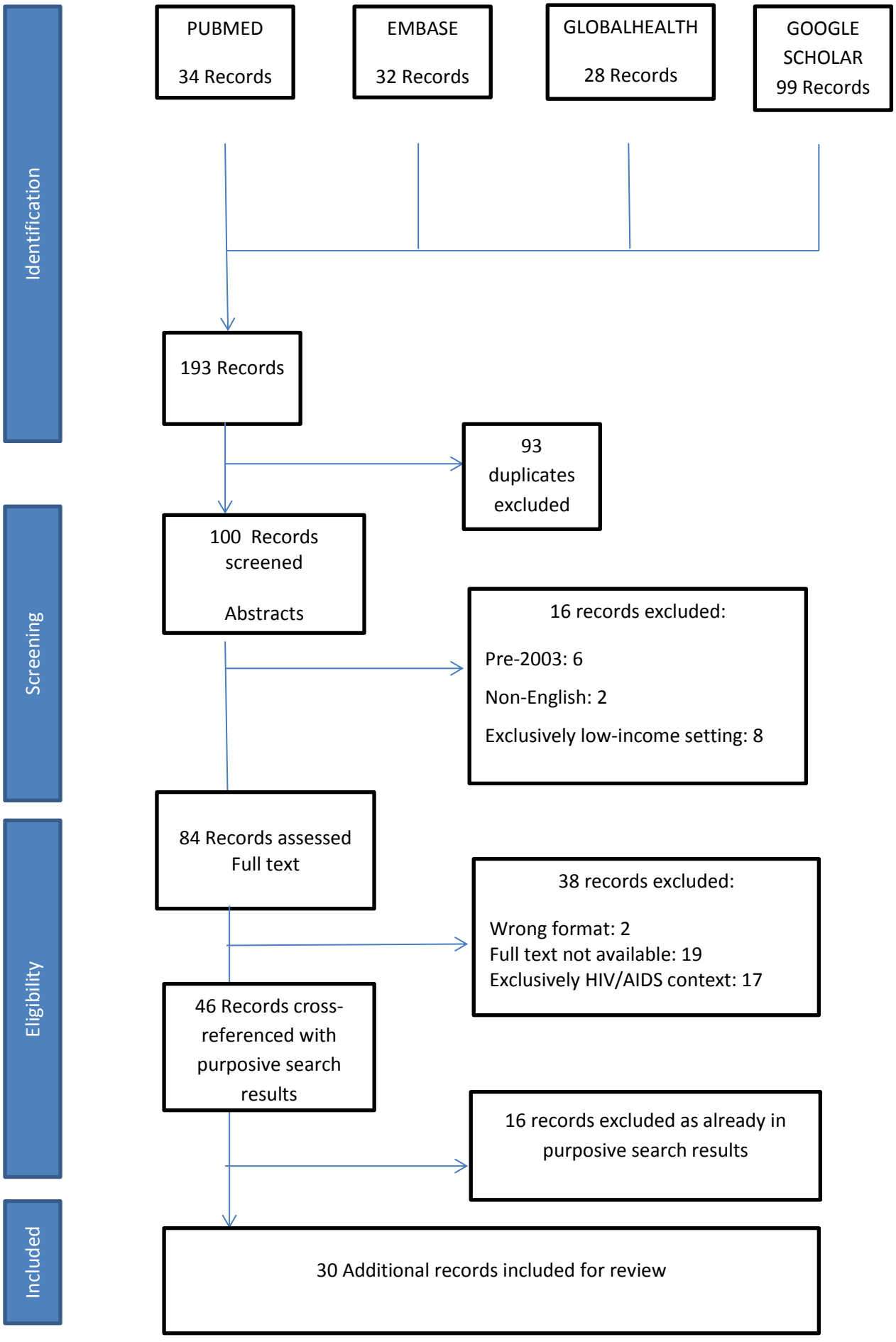
SYSTEMATIC LITERATURE SEARCH

Systematic literature search was conducted on 26 May 2016 to identify further journal articles not already captured by purposive search. As explained in the introduction to this report, a search by key words produced thousands of results. Therefore it was decided to search by key words in the titles only, with the search terms used being "Pandemic AND Law", "Pandemic AND Legal", "Pandemic AND Governance". After excluding duplicates and irrelevant records (see flow diagram below) this resulted in a total of **30** additional records, making a total of **106** journal articles identified by purposive and systematic literature search for review.

Table 3: Systematic Literature Search Results: Pandemic AND Law; Pandemic AND Legal; Pandemic AND Governance

	DATABASES	KEYWORDS [Title only]	DATE OF SEARCH	RESULTS
1	PUBMED	Pandemic AND Law Pandemic AND Legal Pandemic AND Governance	26.05.16	34
2	EMBASE		26.05.16	32
4	GLOBALHEALTH		26.05.16	28
5	GOOGLE SCHOLAR		26.05.16	99
TOTAL			**193**	

Figure 4: Flow Diagram: Pandemic AND Governance; Pandemic AND Law; Pandemic AND Legal



10.2 Results and analysis of commonalities and disconnects

The 106 journal articles were reviewed for the following information:

- Country of origin of lead author: to see where most academic research on pandemic governance is being conducted
- Common themes/concerns, and perspectives on those themes

Country of origin of lead author

US:48; UK: 32; Australia: 8; Germany: 3; Italy: 3; Belgium: 2; Canada: 2; Sweden: 2; Switzerland: 2; Mexico: 1; New Zealand: 1; Philippines: 1; Singapore: 1

We found that 80 of 106 academic papers on pandemic governance (75%) originated from two countries, the US and the UK. Only 10 papers originated from EU Member States (excluding the UK). This small sample was insufficient to make any valid comparison of approaches across different EU countries.

This result is likely to have been skewed by the literature search being confined to English language articles only. It was noticeable that many records were due to a few prolific authors, e.g. Gostin (9 records), Bennett (4 records), Hodge (4 records). Nevertheless, it does suggest that outside the US and the UK, pandemic governance is a neglected area of research.

Common themes

The 106 journal articles included records purposely retrieved for sections of this report which had already been reviewed elsewhere, for example in relation to national pandemic preparedness plans, or for the case studies. These were excluded from further review.

The remaining literature covered a wide range of aspects of pandemic governance. However, these were some of the more popular themes of academic authors:

<u>The importance of law and policy in pandemic preparedness</u>

While the subjects varied widely, nearly all papers stressed the role and importance of law in pandemic preparedness. This was an overarching theme, whether the specific topic was surveillance, communication or any other aspect of pandemic management.

Of relevance to the EU context, Bennett argues that given the challenge of legal and ethical pandemic planning, particularly when it is cross-jurisdictional and cross-cultural,

policy or "soft law" is more appropriate than a "one size fits all" approach: "international guidance that leaves plenty of room for each nation to construct its response in conformity with its own cultural and value requirements". [38]

Ebola outbreak 2014-2015

The amount of literature on the recent Ebola outbreak is evidence of the profound impact this had on international public health. Senior figures such as Bill Gates [39], David Heymann [40], Lawrence Gostin [41] and the high-level Harvard-LSHTM panel [42] have all written on the need for structural governance reform to create an international framework able to respond effectively to another major infectious disease outbreak.

EU Pandemic Governance

Relatively few authors deal specifically with EU pandemic governance: "The EU…despite its increased relevance for European pandemic cooperation activities, is often neglected in governance studies of global health threats." [3].

Many of the papers that did, arose from conclusions from the PHLawFlu project, discussed in more detail at section 10 of this report. A common theme was the lack of coherence across Europe in pandemic planning and the need for greater coordination [1, 6, 43]. Although Article 152 of the European Treaty explicitly forbids harmonisation of state laws some "convergence of legal powers" is necessary to achieve an "appropriate legal response to disease threats" [16].

Greer writes of the challenge of transferring EU health law to national law (not solely in relation to pandemic governance): "The act of transposition, whereby EU law is written into national law and policy, is an inexact process. Member States will often overshoot or undershoot, adding policies they wanted to make anyway or failing to comply. It takes time for such failures to be picked up by legal processes and some never are. Implementation—making the legislation real—is also hard…Every stage offers opportunities to make health of Europeans worse, or better." [44]

For these writers, achieving coordinated, coherent governance across EU Member States is the most significant challenge to effective planning and implementation.

Securitisation of Pandemic Response

Several authors noted how in recent years, pandemic influenza has been framed as a security threat by politicians. This has had the advantage of increasing political prioritisation and making it easier to implement policy: "securitizing a public policy problem can increase political leverage over administrative processes of implementation" [3].

According to Brattberg both the EU and the US "encounter a similar set of governance challenges when confronting new, complex, and boundary spanning security threats such as pandemic influenza. Both blocs have securitized the issue and made it a policy priority, and we have seen a certain degree of follow through from strategic intent to policy and practical capacity building." [3]

Koenig explains that "if an epidemic outbreak is presented as an imminent political and security threat that requires rapid protection, its prioritisation can be effectively justified…a sense of crisis fosters the need for public leadership and acceptance of related policy responses. It likewise justifies military and security-focussed measures to solve problems." [45]

Kamradt-Scott argues that while the framing of pandemic influenza as a security issue "opened up a pathway for exceptional responses" such as increased emergency preparedness planning, the focus was on national protection. Policies "were driven by national priorities and not the need for a coherent global public health response." [46]

If major reforms are needed to make pandemic governance "fit for purpose" these may only be possible by stressing the security threat of pandemic influenza. However, having done so, decisions then need to be made as to what "security" to protect: "Should policymakers prioritise national or international security? Or should they focus efforts on protecting human security?" [45].

Legal Immunity for Pandemic Response Actions

Protecting government employees and institutions from legal liability for actions taken to respond to a public health emergency was a theme of a number of US academics. This seemed to be a particularly American concern not tackled by European authors and is perhaps a reflection of a more litigious US legal environment.

Abbot argues that although the law protects individuals who are victims of negligence "it is critical that this system not interfere with government's efforts to control and limit the total harm suffered by its residents as a result of a public health or other emergency" [47].

Koch argues that health workers need protection from litigation in the form of "binding immunity-conferring rules" as these "would go a long way toward encouraging physicians, nurses, and other health care workers, as well as hospitals and other health care entities, to comply with the [New York State Ventilator] Guidelines." [48]

Mariner takes a contrary view, pointing out that "there is no evidence that immunity from liability has any significant effect on the number of qualified health professionals who volunteer to help in disasters." She argues that "there is no need for new laws blaming individuals for spreading disease or absolving officials from accountability." But rather that the public trust would be restored by public health programmes that are consistent with the nation's values and the US Constitution [49].

While perhaps less of a concern to Europeans because of a different legal environment, this does overlap with questions about the limits of health workers duties to work in a public health emergency.

11 Relevant research projects

AIM

To identify recent or ongoing research projects with themes relevant to European pandemic governance, including ethical or human rights issues. The purpose of this is to identify relevant commonalities and, where research was still ongoing and not yet in the public domain, make contact with research leaders to learn more of policy and legal development efforts.

SEARCH STRATEGY

Inclusion criteria: Research projects which dealt with issues of governance in relation to pandemics or infectious disease control. "Governance" included legal and policy issues, and ethical and human rights issues.

Exclusion criteria: Research projects not in English which concluded prior to 2010.

- Review of EU Documents:

- *Influenza Research EU Funded Projects 2001-2007*. 38 Results
- *European Commission supported research projects on Influenza 2008-2012*. 33 Results

- Search of Europa Cordis website: http://cordis.europa.eu. 11.04.16. Search terms: "pandem* + governance". 142 Results
- Email enquiry of Agnes-Marta Molnar at DG Sante: 23.03.16. 6 Results
- Brussels workshop discussion: 17-18.02.16. 2 Results
- PANDEM Consortium report D3.2: Review of Global and EU Initiatives and Research Projects. 6 Results.

After excluding duplicates and reviewing project summaries, nine potentially relevant recent or ongoing projects were identified. Full project reports (where available) were then read and a further four projects were excluded as not relevant. One of these: TELL ME, focused on human rights and stigmatization of specific population groups during a pandemic and is discussed in report D4.2. This left five projects which reviewed some aspect of policy and legal frameworks in European pandemic preparedness:

1. PHLAWFLU
2. ASSET
3. STRENGTHENING DATA SHARING FOR PUBLIC HEALTH
4. CELESTE (GENERIC NATIONAL PLANS)
5. CELESTE (COMPLIANCE OF NATIONAL PLANS WITH 1082/13)

Project leaders were contacted by email and interviewed either in person or by telephone to obtain further details [50]. Those aspects of the projects relevant to pandemic governance are detailed below.

RESULTS

1 PHLAWFLU: Public Health Law to support Pandemic Influenza Preparedness 2007-2010

The project

The PHLawFlu project examined the role of law in supporting or constraining pandemic disease preparedness across the European Union plus the states of Croatia, Turkey, Iceland, Liechtenstein and Norway. (Croatia subsequently joined the EU in 2013). In addition, the project developed a sustainable network of public health law expertise across Europe, and a repository of on-line literature addressing law as a tool for public

health (www.ephln.org). The uniqueness of the PHLawFlu project lies in the application of legal research to a public health concern in relation to Europe.

Conclusions

There are significant differences in legislation and in the legitimacy of conduct across states in Europe. Some states propose use of emergency powers that might potentially override human rights protections while other states propose to limit interventions to those authorized by public health laws. These differences could create a problem for European strategies.

There is a dearth of expertise and training in public health law across Europe. Most pandemic planning in Europe is undertaken by public health practitioners with no input from persons with expertise in law, and there is limited understanding of the relationship between law and public health practice in the management of disease prevention and control. This suggests an urgent need for improved training in public health law in both the law and healthcare sectors.

The results of our research suggest that states would welcome further guidance from the EU on management of a pandemic, and guidance to assist in greater commonality of legal approaches across states. There will be ramifications of incoherence of laws across states for movement of populations, transportation of drugs, access to healthcare and for human rights and data protection. There is a need for further analysis to determine the public health implications of differences in laws, and whether regions beyond Europe are more coherent in their legal responses to pandemic influenza [51].

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

2014-2017

The project

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.

Work Package 2: 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

The identification and analysis of ethical, legal and fundamental rights considerations in relation to public health crises constitutes a key component of this exercise.

Conclusions

D2.4 Report: Ethics, Law and Fundamental Rights Report

- Legal Context and International Policy Landscape
- Ethical Issues and Considerations in Pandemics

This report gives an overview of the legal context and ethical issues, recommending a "culture of ethics" in pandemic preparedness. In interview, the authors advised that ASSET is not a research project as such, but rather a "mobilisation and mutual learning" programme. ASSET aims to be a platform where people with different areas of expertise can meet and share knowledge and opinions, in order "to involve people in a more effective way." [52]. [See also D4.2]

3 STRENGTHENING DATA SHARING FOR PUBLIC HEALTH

2014-2016

The project

This project will produce practical guidance to facilitate the negotiations for the sharing of public health surveillance data across borders. The guidance will target the needs and expectations of data generators, secondary data users, and those who wish to facilitate data sharing, such as multilateral organisations. The guidance will also address technical good practice to overcome obstacles to data sharing once an agreement to share has been

reached. With a focus on providing actionable solutions, draft guidance will be piloted in various global contexts. It will be reviewed and revised on the basis of feedback from these pilots, before its launch towards the end of 2016.

Conclusions

Ongoing project but findings to date are that data-sharing should follow principles of reciprocity which are embedded in governance. These should not be legally based, but rather creating a virtuous cycle of trust sharing and building networks [53].

4 CELESTE: Case Studies, Exercises, Learning, Surveys and Training across Europe (ISS: Generic Preparedness Plans)

[2013-2014]

The project

This CELESTE project carried out an inventory of generic EU national plans in 2013-2014. These were plans in respect of serious cross-border threats covered in EU Decision 1082/13, e.g. biological, chemical and environmental, but excluding infectious threats to health. They reviewed legal underpinning of plans, but not ethical issues.

Conclusions

The findings were that there is variability of preparedness across Europe with countries in the north and west better prepared than those in the south and east. A need for much better coordination and collaboration between neighbouring countries, for example:

- A common language for plans
- Better identification of contacts in neighbouring countries
- Need for training across all sectors, including health, on how to improve plans
- Need for sharing of plans across neighbouring countries.

They argue that health should be regarded as a security issue and there should be more governance at EU level to create a model, harmonized plan for all Member States.

5 CELESTE: Case Studies, Exercises, Learning, Surveys and Training across Europe (PHE: Compliance of national laws with EU 1082/13)

2015-2016

The project

1. To provide a study on national laws supporting or constraining defined issues of health threats identified under Decision 1082/13 across Europe.

2. To facilitate the exchange of information and expertise on law between specialists in Public Health law interested in forging closer connections.
3. To identify gaps in national laws that could jeopardize the implementation of coherent preparedness planning in the EU Member States.
4. To provide a resource to support PH law reform and PH policy making in Europe.

Conclusions

Ongoing. Current activities include a workshop for European public health lawyers, a survey going to health policy makers in Member States, and work on a web forum for public health lawyers.

DISCUSSION

All the above named projects include reports on aspects of pandemic governance although in some cases this is peripheral to another primary theme such as surveillance (STRENGTHENING DATA SHARING) or communication (ASSET)

The following projects or reports have a central theme of pandemic governance and are of especial interest. They will be referred to elsewhere in this report.

PHLAWFLU: Brought together policy makers from all Member States and partially mapped national legislation underpinning pandemic preparedness in Member States. Identified a Europe-wide lack of knowledge of public health law and a desire among policy makers for greater communication and guidance from the European Union. Established a web forum for public health lawyers (discontinued after 2012 due to lack of funding).

CELESTE (ISS): Conducted an inventory of generic preparedness plans. Identified lack of coordination and collaboration across neighbouring countries.

CELESTE (PHE): Building on PHLAWFLU this project is currently attempting to further map national legislation underpinning Decision 1082/13/EU and plans to reinstate a web forum for European public health lawyers.

CONCLUSIONS

It is unlikely that all relevant projects have been identified as the content was not always apparent from the project title. Some projects have only recently begun, are

unpublicised and were not found online, despite a lengthy search of EU websites. This was the case of the projects "STRENGTHENING DATA SHARING" and "CELESTE" which were brought to our attention by participants at the Brussels workshop 17-18 February 2016.

With the caveat that there may be more, and more relevant, recent and ongoing projects which were not identified, these findings indicate that compared to other areas of pandemic research, relatively little investment has gone into research into pandemic governance. Nevertheless, the two completed projects PHLAWFLU and ASSET produced valuable insights, and it is hoped that the two ongoing projects, together with PANDEM, while smaller briefs, will continue this progress.

12 Expert Workshop on Pandemic Governance, Brussels: Workshop Outputs

As part of the PANDEM project, a workshop was held at the Metropole hotel in Brussels on 17 and 18 February 2016. The aim was to gather a broad cross-section of experts and stakeholders in the areas of risk assessment, surveillance, communications and governance to discuss the current state of the art, best practice, gaps, user needs and to formulate research topics, possible solutions and innovations. The focus of the workshop was from an EU perspective and how global, EU and national gaps and challenges might affect EU preparedness.

WORKING GROUP 3: GOVERNANCE AND LEGAL FRAMEWORKS

Discussion in Working Group 3 was a scoping exercise to obtain the input of leading governance and ethics experts on pandemic governance issues. The overarching aim of the discussion was to better understand how governance arrangements might enhance public health responses. There is general agreement on the importance of governance to ensure an effective and efficient response to a pandemic emergency, which is both legal and ethical. However, it can be a challenge to evaluate and test "principles of public good". By "governance" we include consideration of legislation, policy, ethics and human rights. "Governance" may also be interpreted more broadly to include the features of good governance, such as monitoring, transparency, civil society engagement and accountability.

Given the potential magnitude of the subject "pandemic governance" the workshop discussion focussed on pandemic governance in relation to the themes of

"Communication" and "Surveillance". This was both because of the identified importance of these themes, and also to be directly relevant to the other two work packages.

Key questions (suggestions to be developed further by the Working Group experts)
In a pandemic, what are the legal/governance and ethical/human rights issues regarding:
1. Communication – both with the public and with pandemic stakeholders?
2. Surveillance?

Factors important for public health settings: governance principles, legal issues, collective responsibility in case of outbreak, political context.

Discussions took place during three separate workshop sessions held over the two days. These were preceded and followed by plenary sessions with participants in the other two working groups.

PARTICIPATING INSTITUTIONS

LSHTM, UK; Georgetown University, USA; WHO Europe; Chatham House, UK; Ministry of Health, Bulgaria; Federal Public Health Service, Belgium; DG ECHO; DG SANTE; ECDC; Wageningen University, NL; George Washington University, USA.

WORKSHOP OUTPUTS

The 2 day workshop discussion was recorded and this recording was subsequently transcribed verbatim. A draft list of outputs had been prepared during the workshop and this was subsequently revised using the discussion transcript to ensure accuracy. Chatham House Rules applied so individual speakers are not identified. A "Workshop outputs" document was then sent to all workshop attendees for verification and further input. The final version is set out below. The list of "Gaps and Research Questions" was used as the basis of an Interview Questionnaire for key interviewees (Annex 2).

SCOPE

1. The European Union as an actor at national, regional and global levels in the sense of protection of EU Member States and of the EU in general. European interests are interlinked with global interests, including those of low and middle income countries;
2. An all biological hazards approach;

3. Considering actors beyond national governments: encompassing civil society, health professionals and other stakeholders.

GENERAL GAPS AND RESEARCH QUESTIONS

1. How does the European Union relate to global shifts in pandemic governance?
2. What is the EU's role in protecting itself, including its global health responsibilities?
3. How and where do you allocate scarce resources in an effective, efficient and equitable manner to gain the optimal public health benefit?
4. How can we create a standardised reporting system (whether at EU or country level) for what resources are mobilised and where they are mobilised?
5. How can we monitor the implementation of pandemic response in a standardised way so that we can see what works and start to learn best practice?
6. How can we evaluate and "stress-test" pandemic preparation and response measures?
7. How can public health authorities work more effectively with institutions such as the military and the police force?

<u>GOVERNANCE OF COMMUNICATIONS</u>

DEFINITION

Communication:

- Between governing bodies and with the public
- In preparation for outbreaks and during outbreaks

GOVERNANCE PRINCIPLES

1. Decisions should follow principles of honesty, stewardship and be based on the best available evidence at the time;
2. Decisions should follow principles of transparency and openness;
3. Decisions should incorporate engagement with civil society;
4. Aim for collaboration and coordination at national and EU levels; a pandemic goes beyond the public health sector and is likely to involve sectors such as Foreign Affairs, Defence and Health in all the layers of public administration;
5. Communication should be as local as possible, and use effective and appropriate channels and voices;
6. Trust is critically important. Who is the voice? Are they trusted?
7. Timeliness, accuracy, uncertainty are all challenging for authorities to deal with;

GAPS AND RESEARCH QUESTIONS

1. How can we ensure better coordination and collaboration between:
   - Agencies of the EU;
   - The EU and Member States:
   - EU Member States?
   - With the WHO and other international bodies
   - How can we pre-establish such connections for better preparedness?
2. How can we ensure effective and efficient communications across institutions and organisations? How to better use the existing Health Security Committee communicator's network to support preparedness and during the response phase?
3. How can we evaluate and respond to questions of public trust and panic?
   How can we evaluate and respond to questions of trust and panic among decision makers across the sectors? How can we prevent them from making overly protective decisions?
4. What is causing the unravelling of public trust and how can we ensure and maintain trustworthiness of public health advice? What is the role of "other voices" such as social media and how can public health authorities respond to other voices in a trustworthy way?
5. How can we better understand the public, in terms of their behaviour, how they may react, what they want to know and how they want to hear it?
   How, and how far, can we bring civil society and public health professionals' organisations into the communication process?
   What is the role of training issues (adult learning schemes) and adult education about pandemics and health security?
6. What is it that triggers panic, i.e. irrational behaviour that is counter-productive?
7. Given better understanding of public trust and behaviours, are there any actionable interventions that can ensue from this knowledge?
8. Should we educate the public in pandemic response and risk during the pre-pandemic or inter-pandemic phase? If so, how?
   "*I would argue that this is not just a matter of education (which sounds one-way) but also of engaging the public (in prepandemic times) so as to promote public legitimacy of controversial measures that may be considered when a pandemic occurs.*" [10]
9. How do we find a common understanding of roles and responsibilities for communication in an emergency? How do we (or should we) respond to messages

[10] Comment subsequently added by working group participant.

from individual health professionals, or politicians, which may deviate from the official message?

10. Is there a place for consortia of "trusted individuals" to relate official messages in times of emergency?
11. How can social media be used more effectively to communicate official messages in an emergency?
12. How can civil society participate more effectively in communication, particularly at local level?

GOVERNANCE OF SURVEILLANCE

DEFINITION

"Surveillance" is potentially very broad, as it may include reporting, epidemiological research, virus sharing and genetic sequencing, watch lists, monitoring of social media and a range of other activities.

GOVERNANCE PRINCIPLES

1. Accountability is key: both along formal and informal lines;
2. Surveillance needs to inform actions: only collect data that is likely to be acted upon;
3. Privacy is key and needs to be particularly re-examined in light of different forms of data that are increasingly becoming available;
4. Surveillance data needs to be coherent, needs to allow comparisons to be made (and not be undermined by lack of coherence, solidarity) across countries (and regions?)
5. Participation of communities, and other stakeholders in surveillance actions should be considered (including incentives to report);
6. Surveillance needs to move beyond the traditional reporting systems to take account of, for example, big data that informs emerging patterns of epidemic origin, health services response capacity/capability, inform lessons learnt during and after events.

GAPS AND RESEARCH QUESTIONS

1. How can surveillance data be better shared across organisations and between Member States?
    - Community objections and sensitivities to data sharing
    - Do we need better ethical framework questions?

- Do we need agreements for reciprocity?

2. Assuming digital data is valid, how could that information be used? How can it be linked to response capacity and to what extent can it be used within formal surveillance?
3. What does the public consider an acceptable level of surveillance in terms of balancing security with privacy? Is health surveillance to be governed (or regarded by the public) by the same criteria as military and police surveillance data?
4. How can governance be used to incentivise reporting?
5. How can we ensure that there is a functional purpose to the collection of data and that it serves the public good? How to understand the public good in this context? For example, what types of scientific research may be considered as serving the public good?
6. How can we ensure that surveillance data is used for the benefit of the provider of the information, rather than for the benefit of the recipient of the information, whose needs are secondary?
7. How can we oblige national or regional organisations to respond appropriately to reported data? What should be the mechanisms for actionability?
8. How can civil society participate more effectively in surveillance, particularly at local level?

Need for an online platform facilitating decision making (for sharing information at an early stage, sharing protocols, tools, standardized parameters, situation reports including maps, analysed data, infographics, and for coordination and communication).

SUMMARY

Governance might be regarded as a "special case" and should be assessed differently to other work packages or technical objectives. It is very hard to research the validity of a governance principle or to demonstrate how effective it is to achieve a particular goal. Nevertheless it is agreed that there are a number of very important governance principles and we need to understand them more, and better, to see how they might be put into operation.

Discussions identified apparent gaps and research questions which might test these principles. Further analysis is now required to ascertain work already carried out on these areas and where research might be usefully carried out.

13 Case study: European Union response to Ebola outbreak 2014-2015

The recent Ebola outbreak in West Africa has been one of the greatest global health challenges of recent years. This case study will briefly review the EU response mechanisms, highlighting some weaknesses which became apparent during the outbreak, measures which have been taken to tackle some of those weaknesses and further solutions which have been proposed. Information is taken from literature review, interviews with interviewees working in or with the relevant agencies at the time, and follow up emails to clarify certain points. The case study does not seek to provide a comprehensive analysis, for which see the EU Conference summary report [54], or "Ebola: lessons learned and future challenges for Europe"[55].

INTRODUCTION

The Ebola outbreak began in Guinea in December 2013, but it was March 2014 before WHO received notification. The outbreak rapidly spread to neighbouring Liberia and Sierra Leone. By January 2016 the outbreak had infected 28,637 people, killing 11,315, according to WHO figures. Around 500 deaths were of local health workers.

During 2014, appeals from Médecins sans Frontières (MSF), together with the WHO formal declaration of a public health emergency of international concern (PHEIC), called on the global community, including the European Union and individual Member States, to provide support to the affected countries. The EU has established agencies to provide emergency humanitarian aid, whether financial or in terms of human or material support. Yet it has been acknowledged that the EU response was slow [53, 58], and few European health personnel and equipment arrived in West Africa until the epidemic had already passed its peak.

Table 4: Brief Chronology of EU response to Ebola outbreak

December 2013	Index case: death in Guinea of 2 year old child
22.03.14	Guinea confirms 59 deaths from Ebola virus
31.03.14	First Ebola cases confirmed in Liberia
03-04.14	DG DEVCO deploys three mobile laboratories to Guinea
26.05.14	First cases and deaths reported in Sierra Leone
21.06.14	MSF reports that the outbreak is "totally out of control" and calls for international support

08.08.14	WHO Declaration of PHEIC
15.09.14	EU meeting to discuss response and pledge support [56]
16.09.14	MSF appeal for international support at UN Briefing, Geneva
18.09.14	Resolution of the European Parliament [57]
16.10.14	Ebola high level coordination meeting [57]
23.10.14	Designation of Christos Stylianides as EU Ebola Coordinator
11.14	Launch of "Ebola Communication Platform for Clinicians"
03.03.15	High level conference "Ebola from Emergency to Recovery"
8-9.10.15	G7 Health Ministers' Commitment: "Lessons Learned"
12-14.10.15	EC Conference: "Lessons learned"
17.12.15	Council conclusions
14.01.16	Official end of the Ebola epidemic
02.16	Launch of European Medical Corps

RESPONSE

March-April 2014

When the Ebola outbreak was first reported to WHO by the Ministry of Health in Guinea in March 2014, the initial European response was useful and timely. European experts were part of the WHO-GOARN team which investigated the initial reports of virulent haemorrhagic fever and the diagnostic testing which confirmed Ebola was made in a laboratory in Lyon, France. DG DEVCO, the EU agency responsible for development and cooperation, had three mobile laboratories in the region, and transferred these to Guinea in April 2014. However, in the following months, further EU support was slow to materialise.

The mandated EU agency to respond was DG ECHO, which combines civil protection and humanitarian action. While the "humanitarian action" component is primarily responsible for allocating funds to partners in the field, "civil protection" works to combine in-kind assistance from the Member States. Typical DG ECHO operations are to arrange assistance for regions affected by natural disasters such as floods or earthquakes. The agency is a well-trained, tightly knit group which has been very successful in rapidly deploying overseas assistance in the past.

April-September 2014

From April 2014 DG ECHO had one or two field experts in each of the three affected West African countries (4-5 experts in total) who spent several months trying to coordinate

response efforts as well as exchanging information between the Commission and the African authorities. Attempts to do so "ran into complications with different languages and standards in the Member States" according to sources. Instead, the Member States sent out teams bilaterally.

Thousands of people continued to be infected and die of Ebola in West Africa. In June the MSF director of operations, Bart Janssens announced that the outbreak was "totally out of control" and called for massive global support. It wasn't until 8 August that, upon advice of the first Emergency Committee meeting convened under the IHR, WHO declared a Public Health Emergency of International Concern. This is defined in the International Health Regulations 2005 as "an extraordinary event which is determined, as provided in these Regulations:

- to constitute a public health risk to other States through the international spread of disease; and
- to potentially require a coordinated international response". This definition implies a situation that: is serious, unusual or unexpected; carries implications for public health beyond the affected State's national border; and may require immediate international action.

The European Commission pledged financial support early on, with the figure standing at nearly €150 million by September 2014. But MSF made it clear that what was needed on the ground was not money but health workers.

<u>September 2014-February 2015</u>

A Commission statement from DG ECHO dated 15 September 2014 states: "The EU is gravely concerned by the Ebola epidemic in West Africa, where the situation continues to deteriorate…Today we have discussed with EU Ministers how to coordinate further steps in a European-wide response to the epidemic…We support the shaping of a joint solution for medical repatriation coordinated at European level and appeal to Member States to share national capacity to this end."

A resolution of the European Parliament on 18 September pledged further support.

A high level coordination meeting was held on 16 October 2014 and on 23 October the Director General of DG ECHO, Christos Stylianides was appointed Ebola Coordinator. This gave a focus and confirmed DG ECHO as the lead response agency.

On 11 November 2014 on online platform “Ebola Communication Platform for Clinicians” was launched. This platform had been developed by the ECDC to link European experts on Ebola. The following day, Commissioner Stylianides, and the Commissioner for Health, Vytenis Andriukaitis embarked on a 4 day tour of the affected countries: “This is a sign of the political commitment of the European Commission to help bring to an end the Ebola epidemic which has already claimed more than 5000 lives. ”[58]

A joint effort financed the Dutch vessel *Karel Doorman* which in November 2014 delivered 5000 tons of assistance (including ambulances, trucks, mobile hospitals and protective equipment) from nine Member States to the three affected countries [59].

However, the greatest response came not from the EU but from the eventual mobilisation of individual EU Member States such as the UK, Denmark, France and Germany which called on their military forces, deploying thousands of military personnel to the affected countries.

As the outbreak passed its peak, efforts moved towards investing in lasting improvements to healthcare capacity, the subject of a conference held in March 2015: "Ebola, from Emergency to Recovery."

This brief chronology suggests a slow response. We will now look more closely at the efforts which were made during this time.

COORDINATION OF EU AGENCIES

DG ECHO took the lead in the EU response but EU agencies needed to work together to combine their expertise. Although DG ECHO is responsible for civil protection and humanitarian action, its staff does not include any health experts and for this it relied on support from DG SANTE (Health and Food Safety) and the ECDC. But SANTE's offices are in Luxembourg and the ECDC is based in Stockholm. Despite coordination efforts, this distance had a negative impact: “it’s very difficult to get the right people at the right time at the right table…the physical, geographical distance between the different DGs definitely hampered the overall coordination.”

Agency guidelines do provide a solution. DG ECHO’s Crisis Centre in Brussels maintains empty offices ready to host external staff. DG ECHO requested liaison officers from other agencies to be temporarily based in Brussels to help with coordination, but were told that

the higher workload caused by the crisis meant that staff could not be released. It is unclear whether guidelines are enforceable. A liaison officer was sent from the World Food Programme (WFP) and he stayed in Brussels for several months working closely with DG ECHO. This was very successful and was a key factor in the commissioning of the military vessel, the *Karel Doorman*: "He was a very senior person who had a large network and he was physically there with us and made it happen. I'm pretty sure if we'd only had our own resources, the military vessel wouldn't have been the success it was."

COORDINATION WITH OTHER ACTORS

Given the nature of the crisis, many more agencies and state actors became involved, and integrating these was a major challenge. Apart from humanitarian and health agencies, the Ebola response also became the concern of foreign affairs, internal affairs, defence and security. This involvement took place not only at commission level but also at national levels. EU staff in civil protection were no longer working with their counterparts in Member States but needed to forge new relationships with staff in other sectors. To achieve a response it was necessary to bring all these sectors together and attempt to find common ground.

Efforts were made to achieve better communication and an Ebola Task Force was established which held regular meetings. The Health Security Committee (HSC), with public health experts from all Member States, was also playing an advisory role and held regular audio meetings. From August 2014 the HSC held weekly meetings, many of which laid the groundwork for higher level EU Council meetings when strategic decisions were made. David Nabarro, who had been appointed UN System Coordinator for Ebola also participated in HSC meetings to ensure everyone was informed. Smaller logistical meetings needed to be held with representatives of stakeholders such as WHO, UNICEF and the WFP, or to deal with specific technical issues such as Medevac.

The appointment of Christos Stylianides as Ebola Coordinator in October 2014 was beneficial and a stimulus to action. Existing Task Force meetings were expanded to include more stakeholders and held daily conference calls to improve communication and coordination between the different sectors.

Within the constraints of the Commission structure these efforts did at least maintain an information flow. Feedback from sources is that the HSC meetings were well-run and ensured that Member States were kept up-to-date. Nevertheless, it could be a long

process for decisions to be made. The Commission works for the Member States, it does not have supranational powers. So a Council meeting and conclusions are needed in order to allocate funding and take action. Council meetings are attended by representatives of different Member States and it can take weeks to set up a meeting of all the people who need to attend.

HUMAN RESOURCES

As mentioned above, the EU was generous with financial support and by July 2015 the total contribution stood at €1.8 billion. This included funding from individual Member States and over €869 million from the European Commission [55]. However, MSF's call for health workers on the ground proved to be a far greater challenge to organise.

The ECDC is a centre of expertise in infectious diseases but like DG SANTE, its main focus is the protection of health within the European Union. It is charged with "strengthening Europe's defences against infectious diseases" [11] and its role is advisory only. So while the ECDC has many epidemiological experts able to provide authoritative technical opinions on infectious disease risk, there is no mandate for those experts to respond directly. Therefore, when the Ebola outbreak occurred they had no means for their personnel to travel to West Africa to assist. "They were very capable of writing extremely informative, high quality reports but they weren't able to transfer that knowledge. Eventually they went to the field, but for a long time they couldn't do that. They are based in Europe, for Europe."

Sending health workers from Member States was also problematical. It needed countries to agree to release health workers, which many (while supportive in other respects, including financially) were unwilling to do because of concerns that infections would be imported into home countries. It required the provision of specialised evacuation services (Medevac) to bring health workers back to Europe in the event of infection. It also required designated hospitals in Europe able to treat Ebola-infected patients. All of this took several months of difficult negotiations with Member States to organise. Sometimes authorisation had to be obtained from several different departments of a Member State.

Medevac was particularly difficult to set up as commercial airlines had halted flights to the affected countries. Ministries of defence were approached but few responded. "It's

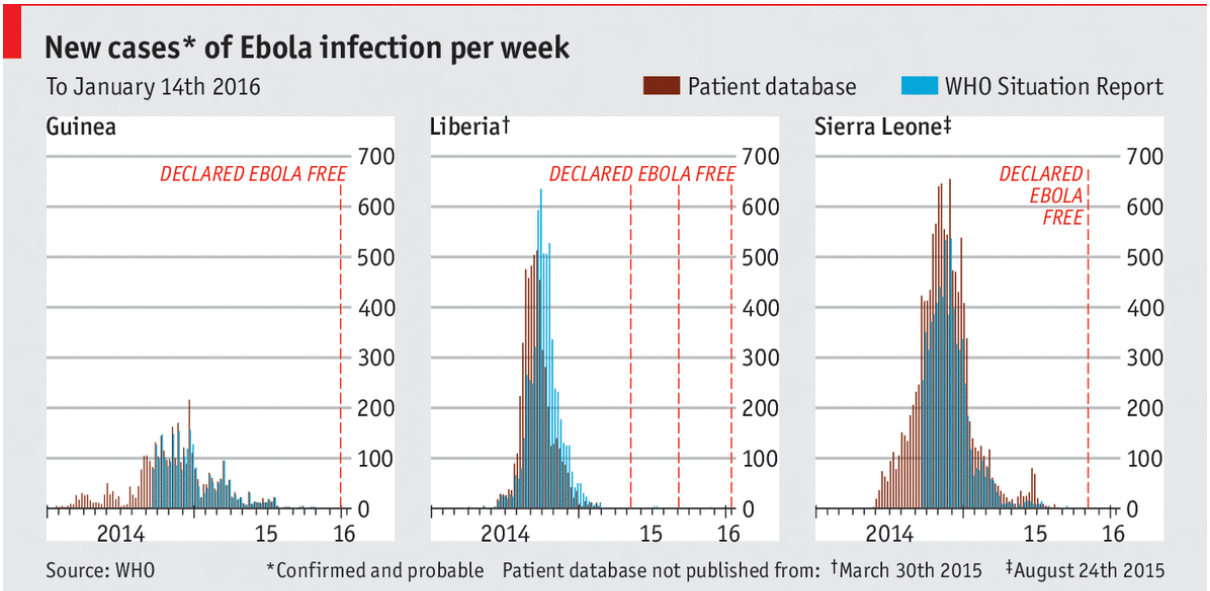
[11] http://ecdc.europa.eu/en/aboutus/what-we-do/Pages/Mission.aspx

not necessarily unwillingness from the ministries of defence...I think that the message just didn't come across. If we could have pre-established this, we would have been able to make better use of the military capacity. Just trying to organise this from Brussels and not speaking face to face with the right people proves that." The Medevac facility was not available until December 2014.

IMPACT

It is not possible to accurately evaluate the impact of these delays on outcomes. However, it is of interest to compare the differing levels of international intervention in the three affected countries. Liberia has historically close ties with the United States, and when the first Liberian Ebola cases appeared, President Ellen Johnson Sirleaf made a direct call to President Obama for assistance. The response was rapid and effective, coordinated by the CDC and with huge operational support from the US military which organised an air bridge from the US via Senegal, flying in materials and building treatment units and laboratories. The Liberian outbreak was the quickest to be brought under control and the first to be declared over.

Figure 5: New cases of Ebola infection per week: To January 14th 2016



As a former British colony, Sierra Leone has historical links with the UK, and the British military was used to provide effective assistance here, if not quite as quickly as the US operation in Liberia.

The outbreak in Guinea was the last to end, with sporadic new cases still appearing in March 2016. Although a former French colony, Guinea had not maintained close relations with France and international assistance was slower to arrive. There was a high demand for French-speaking epidemiologists and people looked to France, Belgium, Switzerland – or the ECDC. But mobilisation was slow: "it's really just this question about insurance and money. Who's going to pay and how are we going to set this up. So you're limited by all these little rules. And they prevented the ECDC from deploying." Ultimately Guinea received more French-speaking epidemiologists from the US than from any European country[12].

DISCUSSION

It is important to acknowledge the extremely challenging context in which this occurred. Firstly, the European Commission is a vast set of institutions for 28 Member States with different languages, capacities, political and cultural perspectives. An organisation on this scale requires exceptionally good structures in place to respond quickly and effectively to a major global health emergency. It is apparent that at the time, huge efforts were made by many EC staff to overcome these organisational challenges.

Secondly, all EU Member States are signatories to the International Health Regulations and the EU explicitly supports this. As such, it looks to the World Health Organization for leadership in global health. The declaration by WHO of a public health emergency of international concern on 8 August may thus have impacted on the speed of the EU's mobilisation of support.

However, the Ebola outbreak exposed a lack of preparedness within EU agencies to respond to an emergency of this nature, and in this context. The earlier SARS outbreak of 2005 was in more developed Asian countries. Europe had never before been asked to respond to an infectious disease outbreak in countries with little healthcare capacity of their own.

Internal Review

To date, Christos Stylianides has produced three reports to the European Council. These acknowledge that "the usual international emergency response structures did not kick in as they would normally do."[59] He gives his assessment of what worked, what worked –

[12] Telephone interview 13.05.16

eventually, and “areas where we should have done better” [60]. Among efforts receiving praise are the funding mechanism, the deployment of the Dutch naval ship and the deployment of the European mobile laboratories: “the first of which was on site in Guinea in the first week of the epidemic, and two of which remain operational on the ground.” The slow mobilization of Medevac is acknowledged: “in the summer of 2014, when the need for such a system became acute, there was very little specialised capacity available”. Singled out as the greatest failure and “the main operational lesson from the crisis” was the failure to rapidly mobilise medical teams to work in West Africa: “we should have looked at deploying multidisciplinary response and assistance teams from the start of the crisis”. His explanation for the delay is that “at the height of the crisis, in late 2014, it was tremendously difficult to mobilize broader support – at a time when this was clearly the biggest gap in the international response.”

In October 2015 the EU held a high level conference attended by the Director General of WHO: "Lessons learned for public health from the Ebola outbreak in West Africa - how to improve preparedness and response in the EU for future outbreaks". Over three days the conference produced a long list of recommendations [54]. Council conclusions published on 17 December 2015 stress the need to strengthen national preparedness and response [61]. Also to strengthen coordination and collaboration.

European Medical Corps (EMC)

The European Medical Corps (EMC) was launched in February 2016 in recognition of the particular difficulty in sending European health workers to West Africa. The EMC comprises pre-defined health workers ready to be deployed at short notice in response to emergencies within Europe and elsewhere. It incorporates Medevac and support in the field. By January 2016 nine Member States had committed their support [62]. This is a promising innovation but is as yet untested.

RECOMMENDATIONS FOR FUTURE RESPONSE

Several commentators have suggested that the limited EU response arose from critical, structural weaknesses, which were not debated at the conference. These require more deep-seated changes.

External Review

The only review of the EU response has been internal. Several interviewees criticised this as insufficiently independent or fundamental. A **high level external review** was

considered more appropriate, perhaps similar to the series of reviews conducted on the WHO response.

International Approach, Beyond Europe

The EU is committed to support for the IHR and WHO, there was a declared willingness to respond to the call for international aid and efforts to do so. But this was hampered by the structure of the EU which is primarily inward facing. EU agencies such as DG SANTE and the ECDC in particular, have a mandate only to protect the EU Member States.

The EU does have a governance mechanism for enhanced coordination in major crises – the Integrated Political Crisis Response (IPCR) - but this only operates for threats to Member States. Similarly, the ECDC designed "Ebola Communication Platform for Clinicians" was stated to be "of particular value in sharing experience in case persons suffering from Ebola are hospitalised in the European Union".

A response beyond Europe makes sense not only for humanitarian reasons, but also because most infectious disease threats are likely to come from outside the continent.

This would require a wider mandate for EU institutions, particularly the ECDC. As a starting point, the EU's responsibilities in global health emergencies need to be clearly defined [55]. This could be by means of a **Declaration of international responsibilities or principles**.

Another proposal was for a **European-African consortium** focusing on novel and re-emerging infectious diseases threatening global health security [63].

Redefinition of the Military Role

The most effective response to the crisis came from the mobilisation of military resources of individual countries. Despite little or no training in humanitarian response, the military demonstrated a deep operational capacity. This could be harnessed more quickly in the future but will require the **military's role to be redefined** when public health systems are overwhelmed [55].

Structural Reform

This was a crisis which demanded a quick response and rapid mobilisation. The European Commission showed that it is structurally unsuited to do this. Crises will arise again so for a better response, interviewees considered that **structural reform** is needed. While

interviewees acknowledged that these changes would be politically challenging and complex, involving the balance of powers between the European Commission and Member States, the proposals might be justified as in Europe's strategic interests as a security issue, apart from other valid reasons.

In particular:

- The European Commission should have more executive authority so it can take a greater leadership role;
- Flexibility and willingness to deploy Commission staff, both across EU agencies and outside Europe;
- Comprehensive review of the role and mandate of the ECDC;
- Much closer coordination between the different EU agencies;
- Better coordination between the European Commission and WHO. "It's all about governance. It's all about getting a coordinated mechanism for speaking together."

CONCLUSIONS

However challenging, the EU needs to find ways to respond more effectively to infectious disease outbreaks such as Ebola. This is important as a humanitarian response and as an affirmation of global commitment. It may also be justified through self-interest because future pandemic threats are likely to arise outside Europe and improving the health security of EU citizens was a core aim of the second EU Health Programme (2008-2013)[61]. A flexible approach is needed, given that new and unpredictable threats may arise. Focusing on the particular circumstances of Ebola may be "fighting the last war." The EU's own review has produced a list of recommendations, now being carried out. If introduced, it still remains to be seen how successful these will be.

14 Case study: Germany E. coli outbreak 2011

The German E.coli (Escherichia coli) outbreak of 2011, also known as the "Spanish cucumber crisis" related to foodborne illness focused in northern Germany during May-July 2011. By the time the outbreak ended it had infected 3950 people and killed 53, worsened international relations within Europe and beyond, damaged public trust and cost billions of Euros in lost revenue and compensation payments. This case study will review the outbreak, what went wrong, and consider how better governance might have helped. The methodology used was purposive literature search and input from interviewees at the Brussels workshop 17-18 February 2016.

Introduction

First signs and development of the outbreak

From early May 2011 a number of people in northern Germany began falling sick from an unusual strain of E.coli. The outbreak was food-borne apart from a few cases contracted from close contact with an infected person [64]. Most of the cases were in adults aged between 16 and 60 with adult women being particularly affected [65]. E.coli is relatively common but this strain caused severe symptoms with a high proportion of patients suffering haemolytic-uraemic syndrome (HUS) which can lead to kidney failure and death. Treatment includes administration of corticosteroids, dialysis and blood transfusion[66].

The first indication of a public health incident was on 19 May 2011 when the Hamburg medical officer asked the Robert Koch Institute (RKI) in Berlin to investigate three cases of HUS in children. The Koch institute is the federal body responsible for disease control and prevention in Germany. Further cases emerged and on 22 May 2011 Germany used the European Early Warning Response System (EWRS) to report 30 cases of HUS to the World Health Organization.

On 25 May 2011 the E.coli strain was identified "in record time" [67] as O104:H4, an extremely rare serotype which had only been found once before: a single case of HUS in South Korea in 2005 [68]. O104:H4 is particularly aggressive as it combines with another group of E.coli called enteroaggregative E.coli and also Shiga toxin to cause bloody diarrhoea, kidney damage, and sometimes also damage to the nervous system. Initial epidemiological analysis suggested the outbreak was caused by the consumption of raw vegetables such as tomatoes, cucumbers and lettuce, although it could not be narrowed down any further at that stage. The outbreak in Germany "was the country's biggest food-borne bacterial outbreak for 60 years"[69]. In Europe the O104:H4 outbreak has been described as "the deadliest foodborne illness in history"[68].

Attempts to identify the source

Four days after reporting the outbreak, on 26 May 2011 the Hamburg authority for health and consumer protection announced in a press release that they had traced the bacterium to two samples of cucumbers originating from Spain. The mass media published the German findings the same day [70].

Based on information received from the German authorities, on 27 May 2011 the European Commission issued a press release and notification to the 27 EU Member States through its Rapid Alert System for Food and Feed (RASFF). This stated that two provinces of Spain were one of the confirmed sources of the E.coli outbreak.

Spanish cucumbers were withdrawn from the market and the suspected Spanish greenhouses were closed for further investigation. Spanish authorities vigorously denied the claims, arguing that there was no proof that the outbreak originated in Spain. On 30 May 2011 the German government warned against consumption of all raw cucumbers, tomatoes and lettuce to prevent further cases [71].

Laboratory tests on 31 May 2011 showed that the sample cucumbers were infected with E.coli (possibly during transportation across Europe) but not with the O104:H4 variant responsible for the outbreak. The following day the European Commission removed the alert notification on Spanish cucumbers but the damage had already been done [70].

The next suspect was locally (German) grown bean sprouts, and on 5 June 2011 a spokesman for the agricultural ministry in Lower Saxony warned people to stop eating these. However, there was initial uncertainty when, like the cucumbers, sprouts samples tested negative for the O104:H4 strain [66]. Then on 10 June 2011 the head of the RKI confirmed that sprouts were indeed the cause of the outbreak.

Final identification

On 24 June 2011 a second outbreak of HUS was reported in Bordeaux by French authorities. A joint risk assessment issued by the European Food Safety Agency (EFSA) and the ECDC on 29 June 2011 confirmed that the French outbreak was from the same O104:H4 variant and the same source as the German cases, namely bean sprouts. The EFSA set up a Task Force which included specialists from Member States, the European Commission, the ECDC, WHO and the Food and Agriculture Organization (FAO). On 5 July 2011 this Task Force delivered a report which narrowed down the source to one lot of organic fenugreek seeds imported from Egypt as the likely cause of the outbreaks in Germany and France [66, 69]. The seeds had been imported in November 2009 and distributed to 70 different companies, 54 in Germany and 16 in 11 other European countries where they were used to grow bean sprouts [72].

The peak of the outbreak was later shown to have been on 22 May 2011. The last newly reported case was on 4 July and on 26 July 2011 the RKI formally declared the outbreak to be over.

Table 5: E.Coli outbreak timeline: May-July 2011

Early May:	Commencement of outbreak
19.05.11	Hamburg medical officer notifies the Robert Koch Institute (RKI) of three cases of haemolytic-uraemic syndrome (HUS)
20.05.11	RKI sets up a team of 15 investigators to carry out a first case study
22.05.11	RKI notifies WHO of the outbreak using the Early Warning Response System (EWRS). Peak of the outbreak.
25.05.11	E.coli is identified as variant O104:H4
26.05.11	Hamburg health authority press release attributes the outbreak to imported Spanish cucumbers
27.05.11	European Commission (EC) issues a press release and EU-wide notification through its Rapid Alert System for Food and Feed (RASFF) attributing the source to producers in two Spanish provinces
30.05.11	German government warns against consumption of all raw cucumbers, tomatoes and lettuce
31.05.11	Laboratory tests show that sample Spanish cucumbers do not carry E.coli variant O104:H4
01.06.11	EC removes the alert against Spanish cucumbers via RASFF
02.06.11	Many countries cancel orders or impose restrictions on imported produce, Russia bans imports of all fresh produce from Europe
05.06.11	Agricultural ministry in Lower Saxony issues a public warning against consumption of bean sprouts
06.06.11	EC calls on the European Food Standards Agency (EFSA) to assist
10.06.11	RKI confirms that bean sprouts are the cause of the outbreak
24.06.11	Outbreak of HUS reported in Bordeaux by French authorities
29.06.11	French outbreak confirmed as O104:H4
04.07.11	Last new case reported
05.07.11	EFSA Taskforce identifies the source as organic fenugreek seeds imported from Egypt in 2009 by a German distributor
26.07.11	RKI declares outbreak over

Impact

The impact of the outbreak was enormous and long lasting.

Human

An internal investigation team of the RKI noted that in an average year, Germany experiences about 1000 patients per year with E.coli, of whom about 70 per year develop HUS. During this outbreak, there were over 3000 cases, of whom 855 developed HUS [72]. This put enormous strain on the German health system and hospitals struggled to cope with large numbers of patients requiring dialysis [73]. While the majority of cases were in five northern German states, there were also a significant number of international cases in Sweden (35), Denmark (15), France (10), the US (2) and single cases in 12 other European countries and Canada. Most of these patients had visited northern Germany during the peak of the outbreak [72].

Economic

The declaration of a health alert followed by warnings against such a broad range of vegetables (tomatoes, lettuces, cucumbers) and then specifically against Spanish cucumbers caused a temporary collapse in the market. On 2 June 2011 Russia banned imports of all fresh vegetables from Europe, orders were cancelled all over the EU and many other countries imposed stricter rules for importation [70]. Losses were suffered by farmers across Europe as produce had to be destroyed or given away. The Spanish government estimated that their farmers were losing up to €200 million per week. Dutch farmers calculated their own loss at €70 million per week.

The WHO calculated that in total, farmers and industries lost $1.3 billion because of the outbreak, with emergency aid to 22 European Member States costing another $236 million[74]. In the immediate aftermath, in June 2011, EU Member States agreed to a compensation package of €210 million for farmers who had suffered loss [75]. Litigation is still ongoing. In October 2015 German courts accepted the claim of a Spanish agricultural cooperative to be compensated by the City of Hamburg although the amount is still to be decided. The claim is for €2.3 million [76].

International relations

Accusations made by Germany against Spain had an extremely detrimental effect on international relations between the countries, already weakened by a recent history of economic bailout:

"The accusations, which were unproven and now appear to have been unfounded, have not only damaged the important Spanish and Dutch horticultural export industries – forcing angry farmers to throw away unsold produce – they have also deepened Spanish resentment of German politicians towards their southern partners in the eurozone…The 'cucumber crisis' has contributed to this sense of resentment, leaving Spaniards feeling that the Germans look down on them as unhygienic peasant farmers, even though most vegetables for export are produced by large, modern agro-industrial enterprises" [77].

DISCUSSION

This was a relatively short outbreak in a high income country with very experienced infectious disease experts, regional support from bodies including the ECDC, EFSA, as well as global expert advice such as from the CDC. Despite this, the outbreak response was flawed in many respects.

Surveillance: Considerable literature has been produced on the scientific investigation into this outbreak. Some commentators have criticised a delay of a week between confirmation of the first cases of HUS and notification to the RKI on 19 May 2011 [78]. Epidemiological analysis subsequently showed that the outbreak had actually begun at the beginning of May [72] and by the time the RKI were notified, a large number of infections had already occurred. However, once the RKI received notification they acted rapidly, using a team of 15 investigators to produce a first case-control study within days. Meat and dairy products were quickly ruled out, with lettuce, tomato and cucumbers being identified as possible causes. A major international effort was mobilised to work on the problem: "Microbiological research laboratories around the globe began pooling resources to coordinate the world's first 'open source' analysis of a microbial genome. In turn, this spurred an unprecedented level of focused study by international collaborators…Thanks to recent technological advancements in DNA sequencing, researchers around the world were able to map the genome of O104:H4 within days" [68].

It is not the purpose of this case study to review the standard of surveillance procedures in this particular outbreak except to note that there appears to have been an avoidable notification delay at the outset, but subsequent investigations were rapid and meticulous. However, the critical importance of surveillance means that these processes need to be subject to rigorous and continual scrutiny. The quality of surveillance impacts not only on the speed of outbreak control in terms of human health, but on public anxiety and trust

in health officials. It is an enormous challenge for surveillance to keep pace with the complex food distribution chains in Europe but it is essential that it does keep pace.

This also highlights the persisting tension between timeliness and accuracy. The rapidly conducted case control study was able to identify salad vegetables as the probable cause, but could not yet narrow it down to bean sprouts. The precautionary principle meant that authorities had to act on this preliminary information. People were dying and they therefore they had a duty to discuss possible causes even if this was subsequently overturned.

Communication

Communication management received some of the heaviest criticism, with many commentators arguing that it exacerbated the crisis. According to a Lancet editorial at the time "communication surrounding the outbreak has been haphazard at best, dismal at worst"[79]. A PANDEM project interviewee described it as: "a classic case of miscommunication, of a failure of everybody to get their act together."

It is a challenging task to give clear public health messages which will inform and protect, yet not induce panic. A key criticism was that there were too many spokespeople giving inconsistent, and occasionally contradictory information.

UK Professor of Bacteriology, Hugh Pennington, had a similar comment reported in the Lancet "In Hamburg there was the agricultural minister for Lower Saxony. Another agricultural minister in the east talked about cucumbers in a rubbish dump. In the UK we usually have a single well briefed authoritative person, someone the public can trust, not lots of different voices"[65].

Refuting this criticism, an RKI investigator argued that "different specialties have different things to communicate. A chief medical officer may be too authoritative. If official agencies communicate in a conservative way it creates a media vacuum which is quickly filled by a doctor with too much time or too little information on his hands" [65].

A German study reviewed how the outbreak was reported in leading German news media and how this might have affected perception of risk. This found that having different government spokespeople amplified the risk: "In a multi-level governance system, risk communication is not controlled by a single authority and...divided responsibilities act as

a constraint on the various health authorities…the reluctance of the central federal health agencies to critically comment on the Hamburg agency's press releases opened up a discursive space for further speculations and premature proposals that had economic consequences"[80].

It is important to recognise that the priority of these health agencies was to prevent people eating possibly harmful food, in which case economic damage was an unfortunate but justifiable consequence. However, evaluation suggests that in this case the different messages from German health agencies did create some unnecessary confusion.

Proportionality: government response

It might be considered that both the official and media responses were disproportionate to the issue, exacerbating the problem and creating panic in the population. This outbreak caused a conflict between two key principles of the EU, namely the free movement of goods [81] and the need to protect human life and health. However, it has been argued that public health must always take precedence over economic interests [70] and the EU allows Member States to take measures to prevent potential risks to human health, even if these may involve restricting free movement [70]. In the middle of an unprecedented health crisis it can be difficult to gauge when these measures are proportional. Within this context, the WHO expressed concerns about recommendations of the German authorities:

"What was unusual about this event was the broad recommendation to avoid eating three entire groups of foods. There are many varieties of lettuce, tomatoes and cucumbers and it would be very unlikely that all types of all three groups of foods would be the source of the outbreak. While such broad warnings can be justified, having them in place for an extended period of time can inflict economic damage and destroy livelihoods, even outside the affected country, as seen in this case. However, it must be stressed that public health authorities must always balance the health risk to the population against other undesirable consequences…The priority must always be on protecting public health and thus economic considerations should never compromise public safety"[82].

Proportionality: public response

The response of the European public to the health threat may also be considered disproportionate. Compared to the risk of other infectious diseases such as TB, malaria or HIV, the threat from this outbreak was relatively low. This public alarm has been

attributed to the "surprisingly high number of fatalities while health authorities could not identify the source of the contamination" [67].
A survey by the magazine Stern found that "a majority of Germans were not satisfied with their government's response to the crisis. About 44% of those surveyed said there were too many warnings; 21% felt they didn't have enough information" [78]. At the height of the outbreak, in late May 2011, the measure of worldwide searches on Google for information on E.coli "was extremely high, approaching the celebrity status" [67].

Role of the media

There are concerns that the media may amplify perceptions of risk and thereby induce panic in the population but that may be a simplistic interpretation. One study analysed the impact of Belgian online news coverage on consumers' perception of risk from the outbreak, and behavioural intentions as consumers of fresh produce. This found that while perceptions of risk and severity were high "the consumers thought they could prevent the risk from happening, which stresses the importance of increasing consumers' knowledge of emerging food safety risks. Furthermore, analyses showed the moderating role of government trust and its influence on the way consumers perceived the risk, how worried they were, and their behavioural intentions" [83].

Although there was much criticism within Spain of their portrayal in the German press, once it was apparent that the Spanish cucumbers were not the source of the outbreak, German media became "restrained and even self-critical" [77].

German researchers found that "health agencies need to be aware of the diversity of voices and legitimate claims. Risk communication is not just a technical expert discourse but – at best – a vivid dialogue on how best to handle the various threats to health. The news media and different institutional actors are crucial for an open debate as they cover the risk differently and thus provide alternative interpretive patterns for the public" [80].

This research stresses the need for public health authorities to recognise the role of the media and themselves participate in this public debate.

Involvement of EU Agencies

From the moment that the German authorities announced the crisis via the EWRS, both European and global institutions became involved in the outbreak response. But there were doubts as to how well this joint approach was coordinated.

European Commission

The role of the EC during the outbreak has drawn criticism. When German authorities placed the blame on Spanish cucumbers on 26 May 2011, this accusation was accepted by the Commission which issued an EU-wide alert the following day. Spanish Prime Minister Zapatero criticized both the German authorities and the Commission, calling for compensation for damages incurred. During the outbreak, it was argued that since it was EU taxpayers who were immediately liable for the German mistake, the Commission should take greater control of the outbreak, rather than leaving it to German authorities.

The EU food safety regime is based on a shared competence between the EU and Member States [84]. The EU does have power to take central regulatory action under EU General Food Regulation (GFR) and Article 53 gives it the authority to introduce emergency food measures. That was not done, possibly due to the difficulty of pinpointing the source of the outbreak at that time. However, Article 56 of the GFR confers authority to "set up a crisis unit immediately" in "a situation involving a serious direct or indirect risk to human health deriving from food." It is not known if this particular Article was invoked, but on 6 June 2011 the Commission called upon the EFSA for support, and it was the EFSA which set up the Task Force which eventually traced the source of the outbreak to imported fenugreek seeds.

ECDC: While the outbreak was still in progress in June 2011 the Lancet questioned the role of the ECDC:

"Where was the European Centre of Disease Prevention and Control?...From the public's point of view, no visible collaboration seems to have taken place. The latest events in Germany point to a chronic predicament facing many European institutions. Although a European spirit of cooperation is welcome and apparent, its practice often falls short of expectations. ..there is a strong case for a European-wide review of national and continental responses to infectious-disease outbreaks. Europe can do much better" [79].

ECDC senior scientists had in fact travelled to Germany to assist in the outbreak investigation and Marc Sprenger, then Director of the ECDC refuted the Lancet criticism, stating that "ECDC has played an essential part in providing the scientific and technical information for those engaged in risk management during this outbreak and we have also made our information available to all on our website" [85].

WHO Regional Office for Europe

The WHO Regional office for Europe monitored the outbreak and published regular updates on its website [86]. This stated that it was "working closely with national health authorities and international partners to detect the unusual bacterial strain and track down its source".

EFSA

The European Food Safety Authority (EFSA) report: "E.coli: Rapid response in a crisis" [69] states that the EFSA worked with German risk managers and assessors, the European Commission and the ECDC. It provided scientific assistance and advice in the form of senior staff and risk assessment reports. The EFSA also set up a joint Task Force "in response to an urgent request from the Commission". It was this Task Force which traced the implicated fenugreek seeds through the EU supply and distribution chain, reporting its findings on 5 July 2011.

What could be improved?

Post-outbreak studies have tended to focus on the surveillance response. An article from the CDC states that "lessons learned" are the critical importance of "continuous public health surveillance to detect disease outbreaks; rapid epidemiological investigation of outbreaks; public health reference laboratories that can examine and identify uncommon organisms that sometimes cause disease; and food safety authorities that take appropriate measures to control the source of the infection and to prevent similar events from happening in the future"[64].

The outbreak highlighted the very complex distribution networks for agricultural products across Europe and beyond. Increasing globalisation and interconnectedness brings economic benefits but also increased challenges to maintaining food safety. It also means that economic shocks have wide impacts across many countries.

- Prevention: This crisis "raises serious questions about the EU food safety regime" [84]. Stringent food safety standards must be maintained on imported foods, including seeds, to minimise the risk of bringing in infected products.
- Surveillance: It is clear that accurate, rapid tracing and diagnosis is critical as every day of uncertainty was enormously costly both in human and financial terms. Once authorities were notified, surveillance systems seem to have worked quickly, but there is a continual need to respond to the challenge of ever more complicated trade links and to maintain a high level of research and investment to improve surveillance.

Improving technology creates greater possibilities for highly effective surveillance systems but many governments may find this prohibitively expensive [68].

- Communication: While the source was unknown, it was appropriate that public health authorities prioritised health over economic or political concerns. Even then, it can be a difficult balance to alert the public to a health risk in order to avoid preventable casualties, while also exercising caution to avoid panic [67], particularly where new information is being received on an ongoing basis. However, to maintain public trust it is essential that the "official" message is evidence based, consistent and transparent. If not, there can be a huge loss of public trust which may be long lasting. In this case, having several official spokespeople was deemed to be detrimental.

  In a modern democratic society, there will inevitably be "alternative voices", including social media. However, the evidence is that an official, authoritative voice can be a moderating influence in the public debate. Common perceptions are that in the case of the O104:H4 outbreak, communication was not handled well. While this will always be a challenge it is argued that "scientists could help by establishing channels to provide timely and scientifically reliable information that can be conveyed in a language accessible to the layman"[67].
- Leadership and coordination: it may be that the European Commission could take a greater leadership role early on and coordinate representation from Member States and relevant agencies, such as the ECDC and the EFSA. Apart from the benefit of shared scientific expertise, an even greater benefit may be derived from leadership from a single coordinating source. The Commission can be a moderating force to manage tensions between individual Member States. EU and Member States need to work together to shape the narrative and quickly disavow any signs of xenophobia.
- Governance. This outbreak underlines the importance of having robust governance systems in place before an outbreak. The enormous pressure of responding to a fast moving crisis means that roles, responsibilities and triggers for action need to be as clear and comprehensive as possible in advance. All of the measures listed above: prevention, surveillance, communication, leadership and coordination need forward planning. Arguably, many aspects of the flawed response could have been improved had clearer rules and procedures been in place, whether in respect of reporting obligations, communication strategies or Commission responsibilities. Advance planning would also ensure that this governance is within an ethical framework which respects human rights.

It is unclear whether Germany or other EU states have effected governance changes to make future outbreaks less likely – or to achieve a better response if they do occur.

CONCLUSION

This case study illustrates the importance of leadership to provide a coordinated response, the need for transparency and consistency in communications, and the critical role of constant vigilance in surveillance. It also underlines the importance of comprehensive and robust governance to cover all these aspects. Overall lessons of the outbreak are of the fragility of international relations, economic vulnerability and interdependence, and the increased risk of rare or unknown infections in a globalising world.

15 Case study: US Model Emergency Health Powers Act

This case study will review the United Stated Model State Emergency Health Powers Act (MSEHPA) as an example of emergency public health legislation and consider whether a similar model would be appropriate within the European Union context. Data to inform this study was collected by purposive literature search and email communication with two authors of the MSEHPA, Professor Lawrence Gostin of Georgetown University and Professor James Hodge of Arizona State University.

INTRODUCTION

For the United States, the events of late 2001 were an unprecedented wake up call to strengthen its national security. The catastrophic attacks of 11 September were followed by bioterrorism when letters containing anthrax spores were posted to several news media offices and two US Senators, leaving 5 people dead, infecting 17 others, and requiring months of expensive environmental clean-up of multiple federal and other facilities.

The U.S. Centers for Disease Control and Prevention (CDC) commissioned a joint team from Georgetown and Johns Hopkins Universities, led by Professor Lawrence Gostin, to draft model state legislation which could support a more effective response to future emergency public health threats. Following a rapid collaborative effort, the Model State Emergency Health Powers Act (MSEHPA)[87] was published in December 2001. The emergency powers which it proposed, including temporary measures to curtail civil liberties in certain specific circumstances, were intended to give officials the authority to act decisively and quickly in the event of a bioterrorist attack, major disease outbreak, or other public health emergencies. The MSEPHA was controversial but many of the

provisions were subsequently adopted and enacted into state laws. According to the Network for Public Health Law, as of March 2016, provisions of the MSEHPA had been enacted in the public health legislation of 34 US states. State governors have invoked their powers for a range of public health emergencies.

BACKGROUND

The events of 11 September 2001 and subsequent anthrax attacks in the United States led to urgent consideration of the risk and appropriate response to threats to public health from infectious disease, whether deliberate bioterrorism or pandemic disease outbreaks of the type historically experienced.

While 9/11 brought urgency to the debate, deliberations had already begun years earlier. A report of the National Intelligence Council of the Central Intelligence Agency in 2000 identified that infectious diseases would have significant implications for US national security, and that "emerging and re-emerging infectious diseases…will continue to kill at least 170,000 Americans annually."[88]

Outdated state legislation

There was recognition that many state public health laws were outdated, inconsistent or inadequate. Some appeared to be unconstitutional and to conflict with laws in neighbouring states, for example in disclosure of health information. In 2002, Lawrence Gostin et al. noted that US state laws "often do not reflect contemporary scientific understandings of disease (e.g. surveillance, prevention and response) or legal norms for protection of individual rights...At the same time, many existing public health laws predate the vast changes in constitutional (e.g. equal protection and due process) and statutory (e.g. disability discrimination) law that have transformed social and legal conceptions of individual rights."[89]

Purpose

The MSEHPA was drafted "to facilitate the detection, management, and containment of public health emergencies while appropriately safeguarding personal and proprietary interests" [89].

It could not be mandated but was instead a model for state legislation. In the United States, federal powers are limited to those specified in the constitution, such as the need to regulate interstate commerce. Most public health powers are constitutionally reserved to the 50 states under what is known as the "police powers."

The MSEHPA - Content

The basic premise of the Act is that each state is responsible for safeguarding the health, well being and security of its population. Therefore, state and local governments must be able to respond quickly and effectively to public health emergencies and the MSEHPA grants specific emergency powers to state governors and public health authorities to enable them to do so.

The Act first requires the state to have a comprehensive plan to respond to a public health emergency. It allows for immediate investigation by granting access to individuals' health information in specified circumstances. It sets out a procedure for declaring a public health emergency, and during such an emergency state and local officials are authorized to use and appropriate property as necessary for the treatment of patients, and to destroy contaminated facilities or materials. They are also empowered to provide care, testing, treatment and vaccination to people who are ill or who have been exposed to infectious disease, and to isolate infected people from the rest of the population to prevent further disease transmission.

The Act stresses that in exercising these emergency powers the state must respect the dignity and rights of individuals and groups. Actions must be grounded in scientific evidence and promote the common good. Civil rights and liberties must be protected to the fullest extent possible consistent with the primary goal of controlling serious health threats. The Act claims to strike a balance. It "seeks to ensure a strong, effective and timely response to public health emergencies, while fostering respect for individuals from all groups and backgrounds" [87].

Table 6: Table of Contents for the Model Act

Article I	**Title, Findings, Purposes and Definitions**
Section 101	Short title
Section 102	Legislative findings
Section 103	Purposes
Section 104	Definitions
Article II	**Planning for a Public Health Emergency**
Section 201	Public Health Emergency Planning Commission
Section 202	Public Health Emergency Plan
Article III	**Measures to Detect and Track Public Health Emergencies**
Section 301	Reporting
Section 302	Tracking

Section 303	Information sharing
Article IV Section 401 Section 402 Section 403 Section 404 Section 405	**Declaring a State of Public Health Emergency** Declaration Content of declaration Effect of declaration Enforcement Termination of declaration
Article V Section 501 Section 502 Section 503 Section 504 Section 505 Section 506 Section 507	**Special Powers During a State of Public Health Emergency: Management of Property** Emergency measures concerning facilities and materials Access to and control of facilities and property, generally Safe disposal of infectious waste Safe disposal of human remains Control of health care supplies Compensation Destruction of property
Article VI Section 601 Section 602 Section 603 Section 604 Section 605 Section 606 Section 607 Section 608	**Special Powers During a State of Public Health Emergency: Protection of Persons** Protection of persons Medical examination and testing Vaccination and treatment Isolation and quarantine Procedures for isolation and quarantine Collection of laboratory specimens: performance of tests Access to and disclosure of protected health information Licensing and appointment of health personnel
Article VII Section 701 Section 702	**Public Information Regarding Public Health Emergency** Dissemination of information Access to mental health support personnel
Article VIII Section 801 Section 802 Section 803 Section 804 Section 805 Section 806 Section 807 Section 808 Section 809 Section 810	**Miscellaneous** Title Rules and regulations Financing and expenses Liability Compensation Severability Repeals Saving clause Conflicting laws Effective date

The MSEHPA stresses the importance of communication and coordination. Articles II and III are concerned with the pre-emergency stage. Here the law is used to:

- Give a defined role for public health, law enforcement and emergency management agencies; and
- Require planning and sharing of information [89].

Article IV sets out the circumstances in which a state governor can declare a public health emergency: (1) an occurrence or imminent threat of an illness or health condition, that (2) is caused by bioterrorism or a new or reemerging infectious agent or biological toxin previously controlled and that (3) also poses a high probability of a large number of deaths, a large number of serious or long-term disabilities, or widespread exposure to an infectious or toxic agent that poses a significant risk of substantial future harm to a large number of persons [89]. These are intended to be "demanding threshold conditions" [89] but they are also flexible so that a declaration can be made whether for cases of mass epidemic/pandemic or for bioterrorism. States can also adapt the clause, for example to add further threshold conditions, or to choose an all-hazards approach, rather than just biological threats.

Articles V and VI concern post-declaration powers and it is these which are most controversial since they grant special powers over property or persons. However, the authors argued that it is precisely these powers which may be necessary in a public health emergency. In the case of property, this may take the form of appropriation of medicines or hospital beds. Or perhaps facilities are urgently needed, for example for quarantine or for the disposal of corpses. Similarly, it may be necessary to exercise powers over individuals to enforce measures such as vaccination, physical examination or isolation in order to help contain the spread of infectious diseases. While it is expected that the majority of people will willingly comply with these measures, some may not. And compulsory powers are needed for those who will not.

According to Gostin "provided those powers are bounded by legal safeguards, individuals should be required to yield some of their autonomy, liberty, or property to protect the health and security of the community." His argument is that these are powers which health agencies have always had, but that the safeguards contained within the MSEHPA mean that it "affords explicit protections…that go beyond most existing state laws."[89]

A further sensitive provision is Article VIII, Section 804, which gives immunity from liability to persons exercising these powers except where there has been gross negligence or willful misconduct.

While these may seem extreme measures, they are intended only for extreme situations. The MSEHPA stresses repeatedly the importance of individual rights, but where there is a severe threat to public health, the rights of the public must prevail. The Act is a pragmatic attempt "to identify and legitimize critical public health functions against a framework of personal rights and freedoms protected by law."[89]

Enactment

The draft MSEHPA published on 21 December 2001 succeeded in opening up a vigorous debate about the extent to which state powers to "promote the common good"[89] should be permitted to outweigh individual rights to liberty and property. A minority of commentators criticized it for insufficient protection of civil liberties, saying that the Model Act gave "tremendous powers to unnamed and unaccountable public health officials to order people examined, treated, vaccinated or quarantined and do it with immunity unless acting with willful malice"[90]. An opposition petition from the Association of American Physicians and Surgeons stated that "the proposal allows government authorities to ration and commandeer drugs and other items, including firearms and private property. And yet what constitutes a real or possible 'emergency' is left subject to wide interpretation, leaving the governors little or no accountability" [91]. Reich argued that in an open democratic society the ideal and most effective response is strong leadership supported by civil cooperation. However, "the MSEHPA presents the necessary tools for dealing with situations in which the ideal response does not take effect"[92].

Despite this controversy, many states rapidly drew on the MSEHPA in revising their public health laws. The MSEHPA was also later incorporated into the broader Turning Point Model State Public Health Act, published in September 2003.

The US Network for Public Health Law, an initiative of the Robert Wood Johnson Foundation, tracks the number of number of states which feature public health emergency laws based in part on the MSEHPA. As at 15 March 2016 this applied to 34 US states.

Declaration of Public Health Emergency

The authors of the MSEHPA envisaged that a public health emergency declaration (and the powers such a declaration would enable) would only be made in extreme and rare circumstances. As one author, James G. Hodge, Jr., noted in 2012:

"A public health emergency declaration may be issued only when it can be shown that an act of bioterrorism or other public health threat poses a 'high probability' of a large

number of deaths, disabilities, or exposures to agents that could cause future harms. These definitional limits confine a declaration of public health emergency to those rare cases where quickly developing factors militate a rapid and effective public health response."[93]

In fact since 2001 declarations of public health emergency have been made in many and varied circumstances. Some were disasters such as Hurricane Katrina, the H1N1 outbreak and many cases of local environmental contamination. Others have been perhaps more surprising, such as "prescription drug abuse related deaths" (Florida 2011), "food insecurity" (Hawaii 2012) and "opioid addiction epidemic" (Massachusetts). Declarations of public health emergency may be made by federal, state, local and tribal representatives. They need to provide a justification, geographic scope and overall goal of the declaration[13].

A MODEL FOR THE EUROPEAN UNION?

We do not here give a view on whether the MSEHPA achieved the correct balance between individual rights and the "common good". It was drafted for the US context and to standardise US state laws and traditions. One of the main authors, James Hodge Jr has admitted many challenges remain: "issues related to interjurisdictional coordination, duplicative legal declaration of emergency, disaster, and public health emergency; real-time legal decision making; and liability protections for emergency responders and entities remain unresolved"[93]. However, even one of its critics admits that the MSEHPA is "an important piece of model legislation" and "a great step forward in laying the groundwork for debate on reconsideration and improvement of state quarantine laws" [92].

So might a model act be beneficial to preparedness and response planning in the EU context? There are considerable political differences which would make this a complex process, although not necessarily an impossible one.

Justification

Public health threats and outdated laws

Many of the public health threats which led to the drafting of the MSEHPA also threaten the Member States of the European Union. In terms of health security, the impact of a pandemic, whether caused by bioterrorism or naturally occurring infectious disease is

[13] Data as of March 15 2016 provided by Professor James Hodge, Director, Network for Public Health Law – Western Region, Sandra Day O'Connor College of Law, Arizona State University.

potentially more serious given the larger population and greater population density in Europe compared to the United States.

It is currently unclear what, if any, national legislation is currently in place to underpin pandemic planning in EU Member States. To date there has been no complete mapping and gap analysis of national laws, although the PHLawFlu project achieved a partial assessment. This found that "few states have an adequate legal framework to support the measures they intend to implement during a pandemic [1]." Where legislation does exist, the project identified many of the same problems as with the US states: "…many [EU member] states have public health laws that originate in the nineteenth century. In some cases attempts have been made to amend laws in recognition of IHR obligations and pandemic planning, without addressing the outdated science and jurisprudence that underlay old legislation, resulting in an inaccessible collection of uncoordinated and unconsolidated laws [6]." Another similarity was that just as some US state laws were possibly unconstitutional, in the European Union, a number of national plans seemed to have given little consideration to human rights and might not meet the obligations of the European Convention of Human Rights [94].

As mentioned above, the United States has a federal government and states have power to make their own public health laws. Similarly, under the principle of subsidiarity the EU's members are sovereign states which create their own laws. However, a key finding of PHLawflu was that there is a lack of public health law expertise throughout Europe and "states would welcome further guidance from the EU on management of a pandemic, and guidance to assist in greater commonality of legal approaches across states"[94].

Ethics and human rights

Apart from the benefit of a more coherent legal response across the EU, a model law should incorporate ethical principles and safeguards to ensure respect for human rights. This is essential in an open democratic society where potentially coercive measures will need public understanding, trust and support. It would concord with the "culture of ethics" promoted by the ASSET project "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" [95].

Preparedness

A key aspect of preparedness is having good governance in place well before a public health emergency arises. "Good governance" being policy underpinned by laws which have been carefully considered and debated with relevant stakeholders, and which is legal, ethical and flexible enough to respond to a range of circumstances. The exercise of emergency powers may require a careful weighing up of individual rights against the public good. Policy or law created in the midst of a public health emergency will not allow for proper debate and is at much greater risk of being unethical and/or ineffective. A full and transparent debate on emergency powers in the pre-pandemic stage is also more likely to gain public trust and support.

Challenges

Principle of subsidiarity

Despite the similarities between a federal US and the European Union, gaining acceptance of a model emergency powers act is likely to be more difficult in the EU context.

Under Article 168 of the Treaty on the functioning of the European Union, human health protection must be privileged in the definition and implementation of all EU policies and activities [1]. The EU also has a particular obligation to encourage cooperation between Member States "to improve the complementarity of their health services" [96]. However these measures explicitly exclude "any harmonisation of the laws and regulations of the Member States." Any model law would need to be very carefully framed as advisory only, maintaining the subsidiarity principle.

Different legal systems

Apart from the challenge of different languages, cultures, politics and capacities, a fundamental hurdle to drafting model legislation would be that the 28 Member States incorporate a range of different legal systems. The majority follow different versions of codified civil law, while others, including the UK and the Republic of Ireland are founded on common law. Some countries combine the two systems. Any model law would need to be flexible enough to be adopted by either. Model legislation would need to take as a starting point, compliance with Decision 1082/13/EU, the key EU instrument on cross-border threats to health. At present the extent of compliance with Decision 1082/13/EU in the national laws of Member States is not known although the CELESTE project is currently attempting to map this. Furthermore, drafting a model act would require the collaboration of public health lawyers from all Member States, when there is a dearth of public health law expertise across the continent [94].

Political Will

For a model act to be adopted by Member States would require political will from both within the EC and from national governments. The response of US states to the model Turning Point Act (which incorporated the MSEHPA) was found to depend on multistate partnerships and participation in the drafting process, the conducting of formal gap analyses and recognition of legislative need. "Assuming that the mere presence of model legislation is sufficient to stimulate change is erroneous."[97]

Lack of political will may prove to be one of the greatest obstacles judging by the example of the national pandemic plans all Member States are required to have in place. As discussed elsewhere in this report, a majority of these policy documents are outdated or inaccessible despite support from WHO Europe and the ECDC, a WHO model and a clear obligation. It is unclear whether this is due to low capacity or low prioritization or both. The United States was galvanized by the catastrophic events of 9/11 to draft a model act, the EU and its Member States have not experienced an impetus on this scale. However, this perspective may change in the current climate of European terrorist attacks and migrant crisis.

CONCLUSION

The most immediate benefit of the MSEHPA was that it opened up the debate on many difficult legal and ethical issues which arise in a public health emergency. For this reason, despite the many challenges, a model emergency powers act for Europe would be a positive measure. It would be a means to bring together legislators across Europe, it would encourage debate and it could be a first step towards setting out the principles which the European Union wants to represent.

16 Priority legal and governance issues and challenges for and within the EU

16.1 Summary of Challenges, Recommendations, Gap Analysis and Research Questions

This report has collected data on the current status of pandemic governance from many sources which show a range of challenges, gaps and potential questions for further research. There have also been many recommendations in the literature and from interviewees with ideas to resolve some of these issues. These are summarised below.

GOVERNANCE FRAMEWORKS AND MECHANISMS [4-8]

Regional and International Level

Challenges

As the leaders of networks of Member States, both the WHO and the EC face similar challenges:

Lack of enforceability of obligations in the IHR and Decision 1082/13.

Capacity. Both WHO and the EC must find ways to support states which cannot meet their obligations. Without this support an effective coordinated response will not be achievable.

Political will. The WHO and the EC both need to convince Member States why pandemic preparedness should be a priority in spite of other competing health system demands.

National Level

Challenges

Review of a selection of national pandemic preparedness plans indicated the following problems:

- A lack of common format or structure
- A lack of specific scenarios
- Intentions to design measures when a pandemic is actually in progress, although this may be impractical
- Out of date plans

Recommendations

Accessibility. As a formal EC principle, for endorsement by all Member States, plans should be:

- Current and publicly accessible
- Submitted in an agreed common repository, with copies of national underpinning legislation, and the chain of command for pandemic response
- Published in a common language (or languages), to be agreed following open discussion

Coordination/Collaboration

- More collaborative exercises between Member States and with the WHO and the EU/ECDC.
- Better coordination between WHO and the ECDC to ensure coherent management of lists of plans.
- More support for EU Member States with low capacity, at least example in providing translation services for plans.

Plans fit for purpose

- Emphasis on the importance of a scientifically sound evidence base for proposed measures.
- Consider widening plans for other public health threats beyond pandemic influenza.

Legal and ethical review. Plans should be independently reviewed (perhaps by a central EU advisory body) to ensure proposed measures are legal under European and national laws, and respect ethics and human rights.

LITERATURE REVIEW [9]

Common Themes

The importance of law and policy in pandemic preparedness

The profound impact of the Ebola outbreak 2014-2015 as a catalyst for structural reform

EU Pandemic governance: the significant challenge of achieving coordinated, coherent governance across EU Member States

Securitisation of Pandemic Response: Framing pandemic influenza as a security threat can achieve political prioritisation and thereby improve implementation of preparedness planning. But it is necessary to clarify how to respond to the security threat.

Legal immunity for pandemic response actions: a need to protect organisations and health workers from legal liability for actions taken during a pandemic.

RESEARCH PROJECTS [10]

Challenges and Recommendations

There has been little research into pandemic governance in Europe. Results of the few relevant research projects are:

PHLawFlu

- A dearth of expertise and training in public health law across Europe. Most pandemic planning in Europe is undertaken by public health law practitioners with no input from persons with expertise in law, and there is limited understanding of the relationship between law and public health practice
- Incoherent laws across Europe will have ramifications for movement of populations, transportation of drugs, access to healthcare and for human rights and data protection. There is a need for further analysis to determine the public health implications of differences in laws, and whether regions beyond Europe are more coherent in their legal responses to pandemic influenza

- Member States would welcome further guidance from the EU on management of a pandemic, and guidance to assist in greater commonality of legal approaches across states.

STRENGTHENING DATA SHARING FOR PUBLIC HEALTH

Ongoing project, but findings to date are that data-sharing should follow principles of reciprocity which are embedded in governance. These should not be legally based, but rather creating a virtuous cycle of trust sharing and building networks

CELESTE (ISS:GENERIC PLANS)

- Variability of preparedness across Europe with countries in the north and west better prepared than those in the south and east.
- A need for much better coordination and collaboration between neighbouring countries, for example:
    - A common language
    - Better identification of contacts in neighbouring countries
    - Need for training across all sectors, including health, on how to improve plans
    - Need for sharing of plans across neighbouring countries.

- Health should be regarded as a security issue and there should be more governance at EU level (whether the EC or the ECDC) to create a model, harmonized plan for all Member States.

BRUSSELS WORKSHOP [11]

Gaps and Research Questions

GENERAL: EU STRUCTURE

1. How does the European Union relate to global shifts in pandemic governance?
2. What is the EU's role in protecting itself, including its global health responsibilities?
3. How and where do you allocate scarce resources in an effective, efficient manner to gain the greatest public health benefit?
4. How can we create a standardised reporting system (whether at EU or country level) for what resources are mobilised and where they are mobilised?
5. How can we monitor the implementation of pandemic response in a standardised way so that we can see what works and start to learn best practice?

6. How can we evaluate and “stress-test” pandemic preparation and response measures?
7. How can public health authorities work more effectively with institutions such as the military and the police force?

COMMUNICATION

1. How can we ensure better coordination and collaboration between:
   - Agencies of the EU;
   - The EU and Member States:
   - EU Member States?
2. How can we ensure effective and efficient communications across institutions and organisations?
3. How can we evaluate and respond to questions of public trust and panic?
4. What is causing the unravelling of public trust and how can we ensure trust and cooperation with public health advice? What is the role of “other voices” such as social media?
5. How can we better understand the public, in terms of their behaviour, how they may react, what they want to know and how they want to hear it?
6. What is it that triggers panic, i.e. irrational behaviour that is counter-productive?
7. Given better understanding of public trust and behaviours, are there any actionable interventions that can ensue from this knowledge?
8. Should we educate the public in pandemic response and risk during the pre-pandemic or inter-pandemic phase? If so, how?
9. How do we find a common understanding of roles and responsibilities for communication in an emergency? How do we (or should we) respond to messages from individual health professionals, or politicians, which may deviate from the official message?
10. Is there a place for consortia of “trusted individuals” to relate official messages in times of emergency?
11. How can social media be used more effectively to communicate official messages in an emergency?
12. How can civil society participate more effectively in communication, particularly at local level?

SURVEILLANCE

1. How can surveillance data be better shared across organisations and between Member States?
    - Community objections and sensitivities to data sharing
    - Do we need better ethical framework questions?
    - Do we need agreements for reciprocity?
2. Assuming digital data is valid, how could that information be used? How can it be linked to response capacity and to what extent can it be used within formal surveillance?
3. What does the public consider an acceptable level of surveillance in terms of balancing security with privacy? Is health surveillance to be governed (or regarded by the public) by the same criteria as military and police surveillance data?
4. How can governance be used to incentivise reporting?
5. How can we ensure that there is a functional purpose to the collection of data and that it serves the public good? Does "public good" include "research"?
6. How can we ensure that surveillance data is used for the benefit of the provider of the information, rather than for the benefit of the recipient of the information, whose needs are secondary?
7. How can we oblige national or regional organisations to respond appropriately to reported data? What should be the mechanisms for actionability?
8. How can civil society participate more effectively in surveillance, particularly at local level?

CASE STUDY: EU RESPONSE TO EBOLA [12]

Challenges

- Limited mandate to respond to public health emergencies outside Europe
- Lack of preparedness resulting in a slow, uncoordinated response
- Lack of coordination between EU agencies and between the EC and Member States

Recommendations

- High level external review of the EU response to the Ebola outbreak
- Drafting of an EU Declaration of International Responsibilities
- Redefinition of the role of the military when public health systems are overwhelmed
- Structural reform of the EC:

    Greater executive authority

    Flexibility and willingness to deploy EC staff

Review of the mandates and governance of EU agencies and how they can achieve better coordination with each other, with Member States and with the WHO

CASE STUDY: GERMANY E.COLI OUTBREAK [13]

Challenges

- Increasingly complex food distribution networks require stringent food safety standards
- Sophisticated surveillance systems required – may be too expensive for some countries
- Communication needs to be evidence-based, consistent and transparent to avoid loss of public trust. Need to participate in open debate with news media and "alternative voices"

Recommendations

- Review of the role of the European Commission in leading and coordinating efforts by Member States and relevant agencies
- Review of existing governance for reporting obligations, communication strategies, Commission responsibilities

CASE STUDY: US MODEL EMERGENCY HEALTH POWERS ACT [14]

Commonalities and challenges for US and EU

- Public health threats and outdated laws
- Need for pandemic response to respect ethics and human rights
- Need for preparedness: having good (legal, ethical, flexible) governance in place well before a public health emergency arises
- Need for a common (or coordinated) approach while respecting the principle of subsidiarity
- Different legal systems requiring a flexible approach
- Lack of political will to make necessary pandemic planning decisions

Recommendations

A model emergency powers act for Europe would be a means to bring together legislators across Europe, it would encourage debate and it could be a first step towards setting out the principles which the European Union wants to represent.

16.2 Commonalities and disconnects for further investigation

There are common themes and disconnects across these different aspects of pandemic governance. These are categorized below and will be further investigated for report D4.3 to identify research already carried out, feasibility and prioritization. The latter will be assessed by need and potential impact on improving pandemic governance in the EU.

Data collection

Full inventory and analysis of national pandemic preparedness plans

Full inventory and analysis of domestic legislation underpinning pandemic preparedness

Improved cross-border coordination, collaboration and interoperability

Sharing of planning measures (accessible plans) and relevant stakeholders

Improved coherence and harmonization of planning (while still respecting sovereignty)

Structural reform of EU bodies

Review of the role and mandate of the ECDC

Review of the executive role of the EC during a pandemic

Improved collaboration and coordination across EU agencies

Declaration of EU's role and responsibilities in the event of an international public health emergency

Capacity

Training in public health law, including obligations under 1082/13

Model legal and policy documents

Model emergency powers act

Model pandemic preparedness plan

Security

Define the military's role in a public health emergency

Define public health threats as a security issue

Civil society

Review how to gain and maintain public trust and support in a public health emergency

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[i] An English language version of the 2006 Bulgarian plan was found by purposive web search. WHO Europe advised in response to email enquiry that there is an updated, 2013 Bulgarian plan but this is only in Bulgarian and may not yet be online.

[ii] The WHO Europe website lists a Lithuanian plan in English but WHO Europe advised in response to email enquiry that it was only available in Lithuanian.