



H2020-DSR-4-2014

PANDEM

Pandemic Risk and Emergency Management

D5.2 INTEGRATED GAP ANALYSIS AND IMPROVEMENT NEEDS FOR PANDEMIC MANAGEMENT

Authors: Darina O’Flanagan (WHO consultant), Stephanie McKay (WHO intern) and Caroline Brown (WHO Regional Office for Europe).

Coordinator: Máire Connolly, National University of Ireland, Galway (NUIG), Ireland.

Project website: www.pandem.eu.com

Grant Agreement number: 652868

TABLE OF CONTENTS

EXECUTIVE SUMMARY	4
1. INTRODUCTION	5
1.1 The PANDEM Project	6
2. OBJECTIVE OF REPORT	8
3. LITERATURE REVIEW - EFFECTIVENESS & IMPACT OF RESPONSES TO PAST EPIDEMICS & PANDEMICS	9
3.1 Global Health Security	9
3.2 Governance	11
3.3 Surveillance	16
3.4 Diagnostics	19
3.5 Crisis management	20
3.6 Communication	21
4. REVIEW OF CURRENT ARRANGEMENTS	23
4.1 Governance and Legal Frameworks	23
4.2 Risk assessment and surveillance	26
4.3 Communication	28
5. BEST PRACTICE, GAP ANALYSIS, IMPROVEMENT NEEDS AND RESEARCH PRIORITIES ..	30
5.1 Introduction	30
5.2 Risk Management	32
5.3 Governance, Legislation and Ethics	36
5.4 Risk assessment and Surveillance	45
5.5 Information Management and logistics	51
5.6 Diagnostics	54
5.7 Communication	57
5.8 Training/Capacity Building	61
6. PANDEM MATRIX - PRIORITIZATION OF IMPROVEMENT NEEDS & SOLUTIONS	65
7. CONCLUSIONS AND NEXT STEPS	78
8. REFERENCES	79

ANNEX 1 LIST OF ABBREVIATIONS	83
ANNEX 2 TERMS USED AND THEIR UNDERSTANDING IN PANDEM.....	85
ANNEX 3 DECISION 1082/13.....	95

EXECUTIVE SUMMARY

Against a background of emerging and re-emerging infectious disease threats, the Secure Societies Work Programme of the European Commission has funded PANDEM - Pandemic Risk and Emergency Management, a Horizon 2020 crisis management project. The objective of PANDEM is to identify improvement needs for technologies, procedures and systems to build EU capacity for pandemic preparedness and response. Research and innovation priorities for the forthcoming phase II demonstration project will be identified with the ultimate aim to reduce the health, security and economic consequences of future pandemics.

This report D5.2 is based on outputs of a workshop held with stakeholders in February 2016 and findings of WP2-4, which reviewed best practice, user needs and research priorities in threat analysis, risk assessment and surveillance (WP2), communication and public information (WP3) and governance and legal frameworks (WP4). This report includes an assessment of the effectiveness and impact of preparedness and response to past epidemics and pandemics by both national governments and the EU.

The report distils the findings of the previous work packages and looks at the current arrangements, highlights best practice, identifies the gaps and innovation and research needs and outlines the ideal situation in the next 5 years. In each area studied, ongoing work in other relevant projects are reviewed to enable PANDEM to build on and support previous efforts in this area. Lessons learned from reviewing the effectiveness and response to past events are reviewed, including both responses by national governments and EU and Global organisations. Based on these findings, a matrix was developed by all partners in the consortium which examines the current gaps and proposes solutions to address these gaps.

This work will inform the development of an integrated solution specification (D5.3), identification of demonstrator concepts (D6.2) and development of a road map and implementation plan (D6.3).

1. INTRODUCTION

The global health security environment of today recognizes the importance of emerging and re-emerging infectious disease threats and understands the best way of combatting these threats is through harnessing inter-sectoral capacity and collaboration. Factors facilitating emergence and re-emergence are well known and include globalization, climate change, population growth and societal, cultural and behavioural practices that promote disease transmission. Simultaneously, support for infectious disease surveillance and control has diminished and many countries are experiencing deteriorating public health infrastructures. In addition, increasing use of social media enables rapid spread of myths with increased anti- vaccine sentiment and often increased distrust of authorities resulting in further spread of infectious disease.

Figure 1 displays the time line of recent outbreaks, epidemics and pandemics as illustrated in a special report in March 2016 in the New England Journal of Medicine on the neglected dimension of global security - A Framework for countering Infectious -Disease Crises.(1) The report is based on the Commission on a Global Health Risk Framework for the Future and argues convincingly for greater investment in pandemic and epidemic preparedness. Reframing the problem as not just a health issue but rather a risk to economic growth and stability, the investment case made in the paper is compelling. It is against this background that the PANDEM project was established under the Horizon 2020 Secure societies Work Programme.

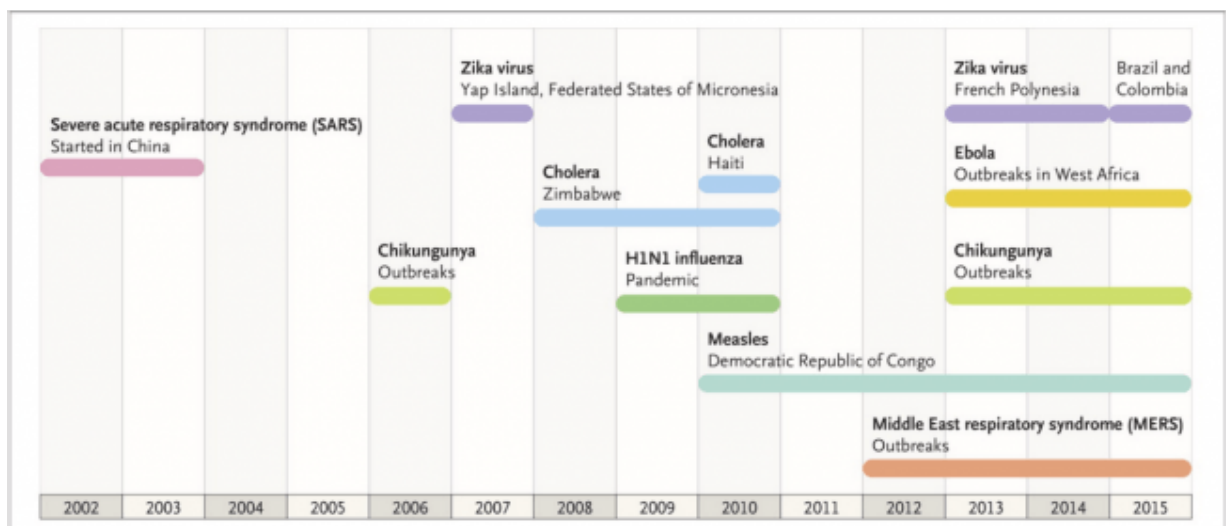


Figure 1 Major Emerging and Re-emerging Infectious Disease Outbreaks, Epidemics and Pandemics, 2002 through 2015

1.1 THE PANDEM PROJECT

The aim of the PANDEM project is to identify innovative concepts to strengthen capacity building for pandemic risk and emergency management in the European Union (EU). The overall objective is to reduce morbidity, mortality, environmental and economic damage from future pandemics by identifying improvement needs for technologies, procedures and systems. Specific attention is being given to enhancing capacity for collaboration on cross-border risk assessment, response and recovery at regional, national and EU level. As pandemics are by definition global events, the project is also looking at the needs for strengthening pandemic management beyond Europe and how the EU can support capacity at international level.

1.1.1 PANDEM objectives

The specific objectives of the project are to:

1. Assess current practice, tools and systems for pandemic management at national, EU and global level in priority areas including risk assessment and surveillance, communication and public information, governance and legal frameworks;
2. Identify gaps and improvement needs through consultation with stakeholders, in particular users;
3. Identify and describe innovative solutions for capacity strengthening, efficient use of resources and better integration;
4. Identify and describe demonstration concepts and future research and development needs to be integrated in a roadmap for the phase II demonstration project.

The project is building on previous research and development efforts and will provide evidence and proposals for the Directorates General (DG) HOME and DG SANTE at the European Commission, in addition to other EC DGs and agencies at a global and national level.

1.1.2 PANDEM work approach

PANDEM has brought a highly skilled group of senior experts from the security, defence, public health, microbiology, communications, information technology and emergency management fields together to develop innovative concepts for pandemic management. The consortium has identified current best practice, user needs and research priorities in three core areas - risk assessment and surveillance, communication and governance. The structure of the PANDEM work approach is shown in figure 1. The project mapped stakeholders and end-users responsible for managing key functions in pandemic

management. This includes policy-makers in national, EU and global public health agencies, security agencies, national laboratories, national communications offices, staff in civil defence units and first responders in health care facilities including paramedics, triage staff and health care workers.

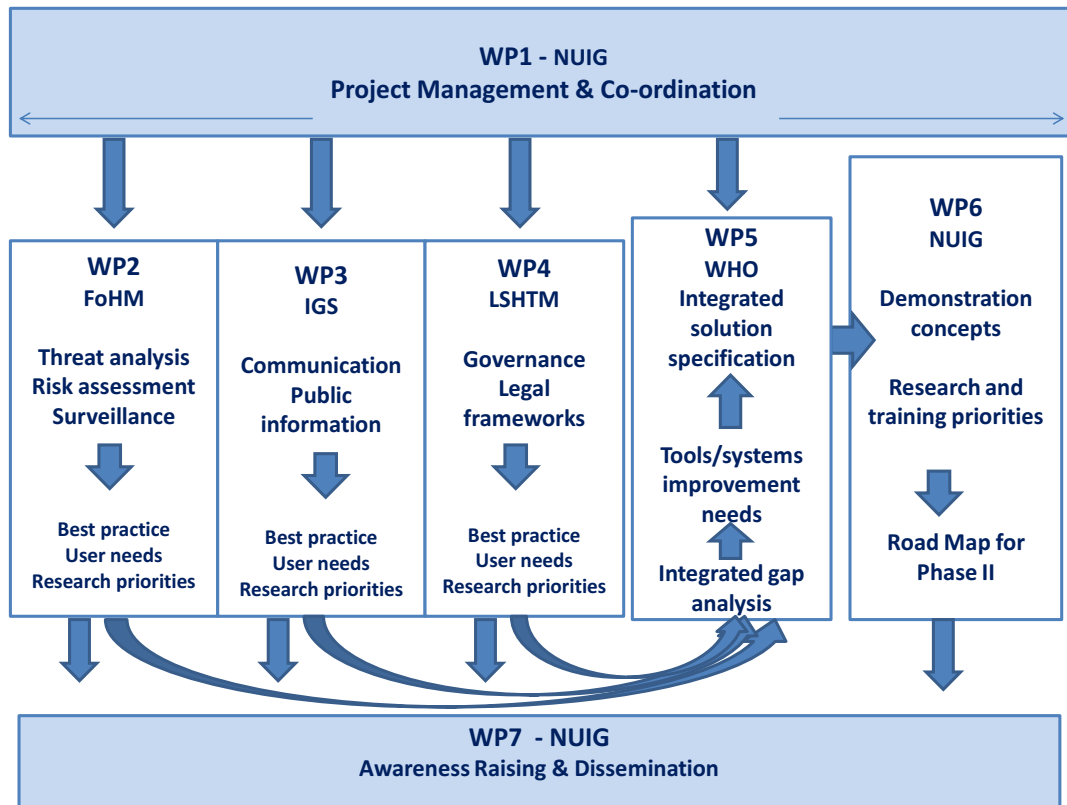


Figure 2 The PANDEM Work Approach

2. OBJECTIVE OF REPORT

The purpose of this report is to present an integrated gap analysis which builds on previous PANDEM reports and the deliberations and discussions at workshop 1. It focuses on current arrangements, best practice, gaps and improvement needs across the key areas addressed by PANDEM and also breaks that analysis down where possible by the level being addressed (National/EU/Global).

The report describes the effectiveness and impact of responses to recent high impact epidemics and pandemics, by national governments and the EU. The outputs of the expert workshop held with stakeholders in February 2016 and findings of WP2-4 are outlined, which reviewed best practice, user needs and research priorities in threat analysis, risk assessment and surveillance (WP2), communication and public information (WP3) and governance and legal frameworks (WP4).

The report identifies improvement needs to fulfill operational requirements for pandemic risk management, with a focus on the systems, practices and tools identified by users necessary to build capacity. Training priorities for capacity strengthening and better integration are also reviewed.

Section 3 examines the lessons learned from reviewing the effectiveness and response to past events, including both responses of national governments and EU and Global organisations. Section 4 of this report distils the findings of the previous work packages and looks at the current arrangements. Section 5 highlights best practice and the ideal situation in the next 5 years, identifying the gaps and innovation and research needs. In each area studied ongoing work in other relevant projects are reviewed to enable PANDEM to build on and support previous efforts in this area.

Finally, in Section 6, a matrix is presented which was developed by all partners in the consortium. This matrix is based on the findings of the previous sections and examines the current gaps and proposes solutions to address these gaps. This work will assist the development of an integrated solution specification (D5.3), identification of demonstrator concepts (D6.2) and development of a road map and implementation plan (D6.3).

3. LITERATURE REVIEW OF EFFECTIVENESS AND IMPACT OF RESPONSES TO PAST EPIDEMICS AND PANDEMICS

The following section examines the literature in relation to assessing the effectiveness and impact of preparedness and response to past epidemics and pandemics. This includes responses by both national governments and the EU. This section supports the systematic literature reviews that have already been undertaken in D3.3 on best practice in communications and digital/social media tools, D4.1 on policy and legal frameworks and D4.2 review and analysis of ethical and human rights issues. The literature on implications for training and research will be discussed in D5.4.

The literature was mainly purposive as many of the reports on lessons learned following epidemics or the 2009 H1N1 influenza pandemic are available from the websites of EU and international organisations (ECDC, EU Commission, EMA, WHO) and not found in formal literature searches. However both PubMed and Embase were searched to answer the question: “What are the results/lessons from evaluations of effectiveness and impact of preparedness and responses by national EU governments and EU institutions” translating to a search on

Lessons OR Learning OR Learn* OR Evaluation OR Effectiveness OR Impact

AND Preparedness OR Planning OR Prevention OR Response OR Control

AND Disease Outbreaks OR Epidemic OR Pandemic

AND European Union OR WHO OR EFSA OR ECDC OR EMA OR Commission OR (Name of each of MS)

Restricted to the past 10 years and the English language.

With the combined purposive search and literature search 38 reports or papers are included in the sections below.

“We should not look back unless it is to derive useful lessons from past errors and for the purpose of profiting from dearly bought experience.”—George Washington

3.1 GLOBAL HEALTH SECURITY

The 2009 H1N1 pandemic was the first Public Health Emergency of International Concern (PHEIC) to be declared under the International Health Regulations 2005 (IHR). The external review of the global response to the 2009 H1N1 pandemic in conjunction with a review of the International Health Regulations (IHR) concluded that the world is ill-prepared to respond to a severe influenza pandemic or to any similarly global, sustained

and threatening public-health emergency (2, 3). Making the case for investment in capacity building under the IHR and subsequent resource mobilization would increase the likelihood that more States Parties could come into compliance with the IHR. Even though the elderly had some cross protection to the H1N1 virus during the 2009 pandemic the risk of death among children and working adults was seven and 12 times greater, respectively, than during typical seasonal influenza. In a more severe influenza pandemic the impact on global health security will be far greater and the review recommended the establishment of a more extensive global, public health reserve workforce.

In the early wake of the Ebola crisis, declared as a PHEIC by WHO on 8 August, 2014, the Commission on a Global Health Risk Framework for the Future was initiated in the spring of 2015 under the leadership of the U.S. National Academy of Medicine (4). The report makes 26 recommendations covering the case for investing in Pandemic preparedness, strengthening Public Health as the foundation of the health system and first line of defence, strengthening the Global and Regional Systems for Outbreak preparedness, alert and response, and finally accelerating research and development to counter the threats of infectious disease. (The response by WHO and the Emergency Reform programme is described in section 3.2). The Global Health Security Agenda (GHSA) was launched in February 2014 and is a growing partnership of over 50 nations, international organisations and non-governmental stakeholders to help build countries' capacity to help create a world secure from infectious disease threats and elevate global health security as a national and global priority.

As always, new threats emerge and global health security continues to be challenged. A major Zika virus epidemic is ongoing in Latin America and the Caribbean (5). There is scientific consensus that Zika virus is a cause of microcephaly and Guillain-Barré syndrome, and links to other neurological complications are being investigated. On 1 February 2016, WHO declared its 4th PHEIC in response to clusters of microcephaly and Guillain-Barré syndrome in the Americas. Locally acquired cases have been reported in Florida and there is potential for further spread not only in the Americas but also Asia, Africa and parts of Europe. Invariably it is pregnant women in low-income countries who are disproportionately infected, living without screens or air conditioning in trash-laden disadvantaged communities. These areas have the highest rates of unintended pregnancies and the lowest resources for mosquito abatement. Up to 6% of infected pregnant women will miscarry and between 1-13 % of surviving infants will have microcephaly and associated hearing, visual and joint defects. Health care costs for affected children will

be enormous. Beyond these direct costs, tourism and travel are reporting multi- billion losses. It is against this background that Brazil, Ecuador and Cuba have deployed military to fight the outbreak. Characterizing the epidemic as a global health security threat could, as Gostin suggested, (5) assist in mobilizing the necessary resources that thus far have been slow to materialize. On 18 November 2016, WHO declared the end of the PHEIC while advising that Zika virus remains a significant enduring public health challenge requiring intense action but no longer represent a PHEIC as defined under the IHR. Many aspects of this disease and associated consequences still remain to be understood, but this can best be done through sustained research. The EC recommended health challenge that this should be dedicated resources to address the long-term nature of the disease and its associated consequences.

In Europe climate change is causing increased vulnerability to vector borne diseases (6). An outbreak of Chikungunya in Italy in 2007 was followed by an outbreak in Montpellier in France in 2014 (7, 8). An outbreak of Dengue in Madeira in 2012-2013 was associated with over 2000 probable cases with 78 linked cases in other European countries (9). All the pre-requisites for autochthonous transmission of both dengue virus and chikungunya virus (vectors, viraemic returned travellers, climatic conditions) are present in Europe. Constant surveillance in areas with competent vectors is imperative (10).

In addition to vector borne threats and emerging viral diseases, antimicrobial resistance is recognized as one of the major global health security treats.

3.2 GOVERNANCE

In new guidance on Managing Ethical Issues in Infectious Disease Outbreaks by WHO, formulated following concern at ethical issues raised by the Ebola outbreak in West Africa in 2014-2016, obligations of governments included ensuring the long term capacity of systems to carry out effective epidemic prevention and response efforts (11). Investment in national public health institutes, their laboratories and the systems that feed into them - is absolutely key (12).

Economically developed countries have a responsibility and interest in assisting the poorer developing states. All countries should review their public health laws and develop preparedness plans for infectious disease outbreaks and other potential disasters and provide guidance to relevant health-care facilities to implement the plans. During an

outbreak the rationale for control measures should be made explicit, and the appropriateness of any restrictions should be continuously re-evaluated in light of emerging scientific information about the outbreak.

WHO/Europe performed an evaluation in 2010 of the usefulness of pandemic plans and preparedness activities (PPA) undertaken by Member States and WHO in the response to the pandemic (13). Issues important for good pandemic preparedness and response at a national level were identified:

1. strong leadership and government engagement in conducting PPA
2. appropriate government funding of PPA
3. effectiveness of the planning process and development of the pandemic plan
4. effective communication among health care professionals, the public and other stakeholders
5. effective strategies for implementing pandemic interventions
6. development of professional capacity for successful implementation of PPA, including greater involvement of family doctors
7. To ensure that regional plans are adaptable to the local situation, there needs to be more community involvement, development of local plans and better coordination between health care specialists and disaster planning groups.

The comments of interviewees in the WHO review suggest that there are common thematic elements that should be considered essential considerations by individual Member States when revising, re-formulating or rejuvenating national pandemic plans (and associated preparedness activities) during the post-pandemic evaluation period. These are:

- communication
- coordination
- capacity
- adaptability (flexibility)
- leadership
- mutual support i.e. **CALM**

Most importantly, it was emphasized that plans were not as important as the process of planning itself.

The EU commissioned the former Health Protection Agency of the UK to review the

response to Pandemic (H1N1) 2009 in Europe by MS, EU Agencies and the EC covering the period 24 April to 31 August 2009 (14). In the survey undertaken in the review, seventeen MS report that consultation occurred between themselves and neighbouring European countries in the development of plans during the preparedness phase. Comments by MS included “By understanding the reasons and rationale taken by other MS on different decisions [and] issues to enable us to decide the best decision to take ourselves”. The authors considered it valuable that MS continue regional and EU-wide cooperation and consultation for pandemic preparedness, and share learning across the EU to enhance pandemic planning and the sharing of relevant practices. Through the survey, it became evident that sectors outside health were generally not affected by the 2009 pandemic. These unaffected sectors should be evaluated to identify gaps as they may be affected by future pandemics or large scale public health crises. They also recommended improving EC inter-service coordination among DGs other than DG SANTE, particularly those with oversight for non-health sectors, and those with an external remit, such as RELEX. It was considered important that the Commission (DG SANTE) and ECDC (in agreement with the EWRS Committee) ensure that the use and role of EWRS is more clearly defined, including the process for notification and collation of information. It was noted that lack of access to the EWRS hindered the European Medicines Agency (EMA) as they had no means of obtaining early information and alerts about the pandemic. It was considered important that the Commission (DG SANTE) establish a process to review and define the use of EWRS, HEDIS, and MediSys, including appropriate usage of these tools.

The EMA undertook an internal evaluation of the outcome of their activities during the 2009 H1N1 pandemic (15). The agency recommended the EMA plan be revised to continue to be complementary to any revised WHO pandemic guidance and any appropriate European guidance, as required. There is also a need for common approaches, such as vaccination strategies and systems for data collection (number of vaccinated people, vaccine effectiveness, pregnancy registries and background incidence rates of diseases). They also advised that the roles of the respective EU partners be clarified and clearly communicated. This was also one of the conclusions of a conference on lessons learned from the 2009 H1N1 pandemic in Brussels, held on 1 and 2 July 2010 (16).

The 2011 External Review of the IHR reported that the most important structural shortcoming of the IHR is the lack of enforceable sanctions (2). Additionally, the review recommended that States Parties should ensure that designated IHR National Focal Points have the authority, resources, procedures, knowledge and training to communicate with

all levels of their governments and on behalf of their governments as necessary.

The Council of the European Union published Council conclusions on Lessons learned from the 2009 H1N1 pandemic - Health security in the European Union in 2010 (17). The Council invited the Commission to revise the Pandemic Preparedness Plan of the EU giving particular attention to the need for inter-sectoral preparedness for a pandemic and to reducing the impact of a pandemic on society, to ensure that the response is flexible, proportionate and adapted to the severity of the threat.

The WHO interim guidance on Pandemic Influenza Risk Management (PIRM) published in 2013 calls for a comprehensive approach to pandemic risk management (18). Figure 3 illustrates the Whole of Society approach to ensure a collaborative effort to sustain essential infrastructure and mitigate impacts of pandemics on health, the economy, and the functioning of society.

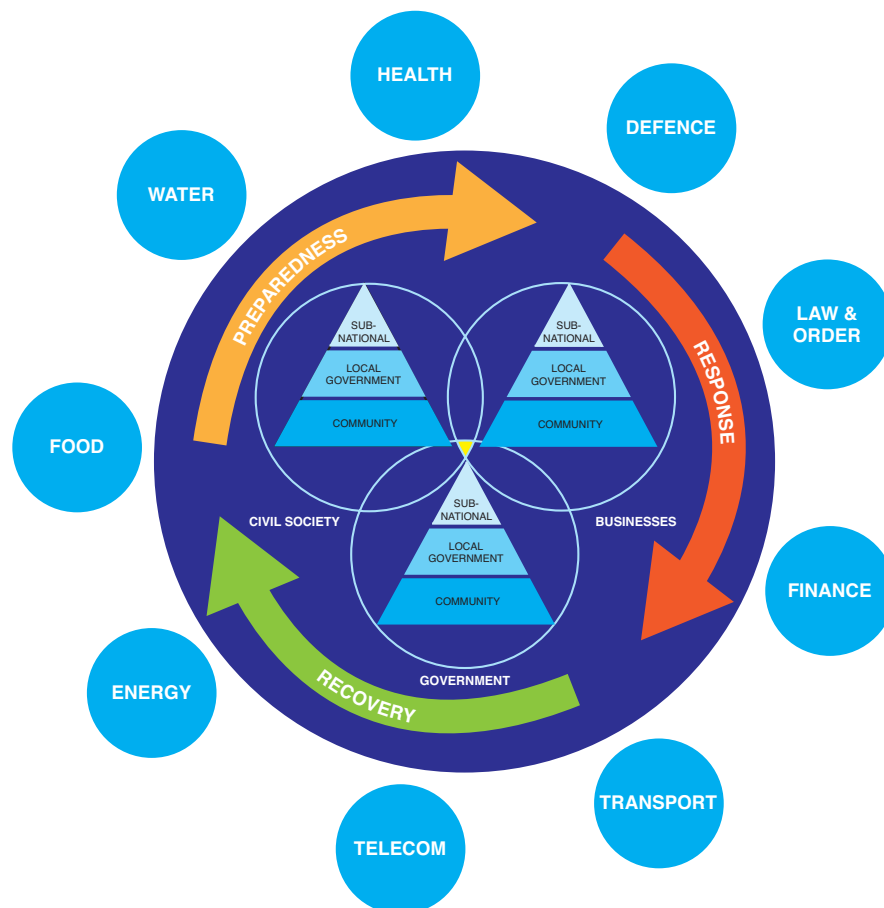


Figure 3 The Whole of Society Approach to pandemic risk management (18)

This guidance is still interim and needs to be finalized to encourage countries to revise their plans. To date, only 8 EU countries and 1 EEA country revised their pandemic plan since the 2009 pandemic (19).

The European Union response to the Ebola outbreak has been reviewed in D4.1. In January 2015 the Executive Board of WHO requested an interim assessment of the WHO response to the Ebola outbreak (20). Significantly, the panel reported that if many of the recommendations made following the Pandemic (H1N1) 2009 been implemented, the global community would have been in a far better position to face the Ebola crisis. Among the 21 recommendations, the importance of improved funding for WHO was emphasized as was the need for all countries to develop the core capacities required under the IHR. The disconnect between the humanitarian approach and the health emergency system was problematic, partly due to different approaches to risk assessment. It was recommended that WHO and its partners should have a better understanding of the humanitarian system.

The United Nations established a high-level panel on the Global Response to Health Crises and the report *Protecting Humanity from Future Health Crises* in February 2016 made 26 recommendations, a central recommendation of the Panel's work is to establish a High-level Council on Global Public Health Crises within the General Assembly to provide political leadership on global preparedness, monitor the implementation of reforms, and help prepare for a Summit on Global Public Health Crises in 2018 (21). In the most recent report on the implementation of the IHR of May 2016 the development of a global strategic plan to improve public health preparedness was recommended as was the creation of an Intermediate Public Health Alert (IPHA) (22). (This had also been recommended in the report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola (23)).

In a paper on Ebola: lessons learned and future challenges for Europe, Quaglio *et al.* called for the EU's responsibilities in global health emergencies to be clearly defined. They argued that the role of the military also needs to be redefined when public health systems are overwhelmed and that a pool of European medical and scientific teams be established and deployed at short notice (24).

As a result of the many reviews undertaken following the pandemic and high impact epidemics such as Ebola many organisations are in the process of reforming to better meet

future challenges. The new WHO Health Emergencies Programme represents a fundamental development for the Organization, complementing WHO's traditional technical and normative role with new operational capacities and capabilities for its work in outbreaks and humanitarian emergencies. All WHO's work in emergencies is brought into a single programme (25, 26). The Advisory Group on Reform of WHO's work in outbreaks and emergencies recommended the expansion of the current Emergency Response Framework to cover all phases of the emergency management cycle - preparedness, alert, response, recovery and prevention (27). A key task will be demonstration of the cost effectiveness of the expanded operations (28). The high level panel on the global response to health crises also recommended external assessments of a country's core capacity on a periodic rolling basis and also that regional organisations facilitate simulation exercises for health crises responses, especially in border areas (21). In light of this and other IHR review recommendations, 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 (29).

The EU has also responded to meet the challenge and established a European Medical Corps as part of the European Emergency response capacity (30).

3.3 SURVEILLANCE

ECDC commissioned an external evaluation of their own response to the H1N1 influenza pandemic 2009-2010 (12). The review found that overestimation of disease severity occurred in several recent large epidemics and is a recurrent bias of early outbreak communications: special care should be taken in assessing the clinical severity of a disease; a possible solution can be an analysis of the first few 100 laboratory confirmed cases. Daily counting of cases or deaths are often demanded by the media and politicians, but aggregate counts at the EU level are liable to distortion due to differing extent of case ascertainment and reporting systems among the Member States. Even when using an agreed case definition, interval-based (e.g. weekly) counts tend to be more reliable and should be adopted in future pandemics, in the early stages of the pandemic. (This is standard practice in the US - this step alone would relieve a lot of unnecessary pressure on both MS and international organisations.) The reviewers also advised that the analysis of the risk level that justifies public investment in developing and deploying new vaccines - either for the population as a whole or for specific risk groups - needs to be improved. The external review of the global response to the 2009 H1N1 pandemic in

conjunction with a review of the International Health Regulations (IHR) also recommended that WHO develop and apply measures to assess severity of every influenza epidemic (2).

The WHO Regional Office for Europe Recommendations for good practice in pandemic preparedness advised the capacities required for effective pandemic response are built by: (a) strengthening routine surveillance for severe disease in hospitals (sentinel SARI surveillance); (b) developing monitoring systems for influenza vaccine uptake; (c) having capacity to perform risk assessment including severity at the local/ regional/ national level; (d) using established and tested information systems rather than having to develop new ones during the pandemic (13). The Council of Europe in 2010 called for increased investment in research to be able to better assess and predict the impact of influenza both in the inter-pandemic period and at the very early stages of a pandemic. Functional mathematical models should be promoted and developed at the European level (17). The dangers of unrealistic expectations of modelling, which could not be reliable in the early phases when there was insufficient data, was emphasized in the Independent review of the UK response to the 2009 pandemic (31). This report urged training of key ministers and senior officials to understand the strengths and limitations of likely available scientific advice as part of their general induction. Drawing on a conference on surveillance for decision making held in the US in 2010, the surveillance approaches required to inform public health responses are well described in an article by Lipsitch *et al.* including the merits and difficulties associated with real time predictive modelling (32). Surveillance systems for emerging respiratory viruses are described by Al-Tawfiq *et al.* and they emphasise the importance of capacity building in both developing and developed countries (33).

The importance of country collaboration in the development of comprehensive risk assessments was reiterated in the WHO advisory group on reform (27).

EMA advised Collaboration of the Agency with the ECDC and Member States to revise the "European Strategy on Influenza A/H1N1 vaccines Safety Monitoring" in the context of a future pandemic taking into account the experience of the 2009 pandemic (15). Rapid assessment of influenza vaccine effectiveness using analysis of an internet-based cohort was an innovative method to determine vaccine effectiveness while the epidemic/pandemic is on-going (34).

The United Nations report "Protecting Humanity from Future Health Crises" recommended that all State Parties to the IHR establish a "One Health" surveillance mechanism to

collect and analyse public health information in near-to-real time, combining data from all segments of society (21). Such a one health approach is essential for surveillance of diseases such as West Nile virus (35). West Nile transmission is known to be present in Europe for many years: The first large outbreak in humans was reported from Bucharest, Romania in 1996-1997 and again in 2010 (36). A human outbreak was reported from the Central Macedonia Region in northern Greece and human cases were reported from Romania, Hungary, Italy and Spain in August-September 2010.

Integration of surveillance systems with laboratory data and local public health response data, including contact tracing was identified as a need in lessons learned from SARS as experienced by the HPA in the UK (37).

The WHO ethical guidelines underline the importance of protecting the confidentiality of personal information, assessing the importance of universal mandatory participation in surveillance and also of ensuring a transparent process to ensure individuals and communities are aware of the type of information that is collected about them (11). Rapid data sharing is essential during a public health emergency and efforts should be made to ensure that rapid sharing of information with immediate implications for public health does not preclude subsequent publication in a scientific journal.

The production of an ethical framework to assist planners, strategic policy-makers and healthcare professionals with the ethical dimensions of decisions they would face before, during and after an influenza pandemic - drawn up by an independent body, the Committee on Ethical Aspects of Pandemic Influenza (CEAPI) - was considered a vitally important step in the UK review of the pandemic (31).

In May 2011, a large outbreak of the hemolytic- uremic syndrome associated with the rare *E. coli* serotype O104:H4 occurred in Germany (38). The outbreak involved 4321 cases, 50 of whom died. Initial investigations showed an association with the consumption of salad items, in particular cucumbers. Subsequent detailed analysis of menu items in some of the affected restaurants demonstrated that side salads had been garnished with sprouts - understandably these had not been recalled during interview of many of the affected patients. The investigators in their report of their experience suggest food items or ingredients that are deemed to be hard to remember should be included in analytical studies, even if such items are mentioned by less than 50% of cases surveyed (contrary to international guidelines). The communication issues around this outbreak have been explored in the case study in D4.1. - suffice it to say that the dilemma of whether or not

to report early findings is well known to public health investigators - communicate early and subsequently wrong may damage trade; communicate late when conclusive results subsequently show early results correct and lives may be lost.

3.4 DIAGNOSTICS

To ensure the rational use of laboratory testing capacity, the prioritization of testing for surveillance versus clinical diagnostic purposes, especially within a limited resource environment, should be determined according to the different stages that might occur during a pandemic (e.g. period of detection of first cases, period of trying to delay spread, period when there is widespread community transmission), and depending on the severity, through authorities communicating changes in testing priorities to clinicians and the different laboratories in a timely fashion (13). Better use of sero-epidemiological studies should be developed for future pandemics (31, 39): in fact, important scientific and public health-related information was obtained from the 2009 pandemic, but due to the delayed activation of the system, most of this was provided too late to be of practical use (12). The Council of Europe in 2010 called for investment in national surveillance centres, both in the area of epidemiological surveillance on the number of people afflicted, deaths, etc., and in the area of virological surveillance on the genetic characteristics of the virus: mutations and resistance but also serological surveillance to be able to determine whether many cases are asymptomatic (17).

The United Nations report “Protecting Humanity from Future Health Crises” recommended the WHO convenes its Member States to re-negotiate the Pandemic Influenza Preparedness Framework with a view to including other novel pathogens, and making it legally binding (21).

Long term storage of biological specimens taken at the time of outbreaks is considered in the new WHO ethical guidelines (11). When feasible informed consent for use of biological specimens should be obtained either from individuals or through policies developed in collaboration with the involved communities. If specimens are shared outside of the country, agreements should specify that the benefits accruing from any subsequent use of the specimens are shared with the communities of origin. The 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, also known as the Nagoya protocol on Access and Benefit Sharing (ABS) is a 2010 supplementary agreement

to the 1992 Convention on Biological Diversity (CBD). This protocol sets out obligations to take measures in relation to access to genetic resources and benefit sharing.

3.5 CRISIS MANAGEMENT

As in most member states and international organisations involved in the response to the pandemic, many ECDC staffers in critical positions were subjected to severe stress over prolonged periods (12). However, ECDC's innovative strategy of allowing the observation and review of ongoing efforts at an early stage during the pandemic contributed to the capacity of the organisation to rapidly discover and correct problems/dysfunctionalities in the crisis organisation during the event. Business continuity management (BCM) was an underdeveloped function at ECDC in the period in question and efforts have been made to remedy this since the pandemic. Recommendations in the review included ensuring multiple potential occupants of key roles are available to avoid role overload. In particular, the role of the Director should be delimited. The review recommends that crisis staff structures should learn from designers of military and "blue light" response organisations with a few key participants protected from the intense operational tempo and tasked with an enhanced strategic analysis. Business continuity was also described as problematic in WHO in the report from the External Review of the IHR (2). The European council in 2010 called for a "BCP for Dummies" to explain how companies should prepare for pandemics (16).

In an independent review of the UK response to the 2009 influenza pandemic it was noted that the UK's current central government crisis management arrangements have been in place since 2002, and have been tested in various crises and exercises and refined through those experiences. As a result many decisions had already been made in principle prior to the pandemic and that key personnel had already had the opportunity to work together (31). Again it was noted that due to the prolonged nature of a pandemic resilience arrangements were tested.

Tools have been developed to assist countries prepare for surges in resource demand during future pandemics (40). These, as yet, are not widely available in Europe.

3.6 COMMUNICATION

The WHO ethical guidelines outline the importance of early and ongoing community engagement in establishing and maintaining trust and preserving social order (11).

In the review commissioned by ECDC on the response to the pandemic the reviewers noted the changing communication landscape with growing use of social media by self-appointed alternative “experts” of dubious credentials and urged more research to determine the most effective methods of dissemination of accurate information and interaction with target audiences (12). The WHO regional Office for Europe review advised follow-up and evaluation need to be performed on how information is received and perceived by health care providers, the public and other stakeholders. In addition to the above, effective communication with health professionals is developed by using existing channels that are effective and trusted (e.g. via medical professional societies); and making information more concise, clear, and customized to different health care worker audiences, including developing a web site where health professionals can ask questions and get timely answer. (13). Having convinced health care workers is essential to improve vaccine delivery and compliance with pandemic responses (15).

In an assessment report on EU-wide pandemic vaccine strategies and communications issues arising in the MS, the majority of respondents from the MS reported pandemic vaccination goal shortfalls: experiencing difficulties in reaching their vaccination coverage goals for pregnant women, persons with underlying chronic diseases, and health care workers. The main reasons for these shortfalls were attributed to scepticism and/or limited interest on behalf of the health care workers and the general population (41). One of the biggest challenges facing communicators was the sheer volume of media and public queries.

Contingency measures need to be in place for additional staffing in times of crisis. Public polling and survey activities were broadly considered to be valuable to the work of communicators in MS; however, some concerns were raised. Five examples include: 1) carefully wording questions in order to be confident that the responses appropriately reflected the issue of interest; 2) carrying out surveys in waves in order to monitor changing public opinions over time; 3) systematically monitoring online sources; 4) starting the communication monitoring process as early as possible; and 5) having contracts and plans in place to be able to prepare and execute polls quickly in order to be able identify future needs. The findings also noted that the use of new media should not replace the

traditional means of communications (e.g., conventional media, leaflets, brochures, letters, billboards, etc.) since several population groups continue to rely on these approaches.

A report on the response to the 2009 pandemic in Italy echoed these findings with a very low vaccine coverage among both HCWs and the public. Confusion about the severity of the pandemic coupled with concerns regarding adverse events contributed to the poor uptake. Building awareness of the importance of the active involvement of all health professionals (at local, regional and national level) in influenza pandemic preparedness was one of the key lessons (42). The report described excellent surveillance data and modelling suggested the early containment efforts may have contributed to delaying and reducing the impact during the initial summer period.

In contrast the relatively high uptake of pandemic vaccine in Sweden was compared with a low uptake in Australia, examining the role of the media in framing health messages and the resulting public perception of risk and related behaviour (43). As such, governments need to more actively incorporate the media in pandemic communication planning.

The first EU assessment report on the pandemic describes some innovative techniques for targeting vulnerable groups, including developing partnerships with organisations such as homeless charities and migrant groups, as well as distributing leaflets and posters in religious buildings and social areas (14). They also describe how in a few MS 24/7 helplines were initiated for HCWs to access. However, 9 of the 17 responding MS had no system in place to ensure HCWs had received and understood the messages. The European Council in 2010 advised that the Health Security Committee (HSC co-ordinating committee of DG SANTE and member states) must take into account communication factors, which can be obtained through the collection of the comments, the feedback and the experiences of the HSC Communicators' Network. (For the role of the HSC see 4.1.3). The existing tools available to the Network must be improved and adjusted (like HEDIS and Medisys) (16).

The use of certain terms in the UK response was considered to be unclear in the UK review (31). In particular, 'containment' was used to describe a strategy which was not intended to contain the disease but to slow the spread. However, the use of weekly briefings, Q&A sessions and regular release of facts and figures was considered to constitute examples of best practice.

In the review on response to the Ebola epidemic, community engagement was considered as an essential core function when managing a health emergency (20).

4. REVIEW OF CURRENT ARRANGEMENTS

Following the review of preparedness and response to recent high-impact epidemics pandemics, an analysis of the findings and results from work undertaken in work packages 2-3 was conducted. Current arrangements, best practice, gaps and improvement needs, and research priorities are identified in sections 4 and 5.

4.1 GOVERNANCE AND LEGAL FRAMEWORKS

4.1.1 Role of DG HOME and DG ECHO

In line with the IHR and Decision No 1082/2013/EU of the European Parliament and the Council of 22 October 2013 on serious cross-border threats to EU (Decision 1082) pandemic planning and response is no longer confined to the health sector. The WHO interim guidance on Pandemic Influenza Risk Management (PIRM) published in 2013 calls for a comprehensive approach to pandemic risk management.

DG HOME plays an important role in preparedness and response planning by:

- Developing EU-policy for internal security. DG HOME carries out risk assessment by means of its strategic analysis capacity (STAR: Strategic Analysis and Response) in order to provide support for EU policies. STAR functions as a crisis centre and a risk analysis methodology provider. It conducts situational monitoring, but depends on intelligence from others to produce situational awareness during a crisis e.g. Frontex for external border crises.

- Piloting EU-research for secure societies. This is undertaken through the Horizon 2020 program which funds research and innovation activities which have been prioritised in order to protect citizens, society and economy as well as infrastructures and services.

This includes, but is not limited to, protection of European borders, enhancement of societal resilience to natural and man-made disasters, and development of novel solutions for the protection of critical infrastructure and innovative medicines.

DG ECHO 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. In September 2014, the Director General of DG ECHO, Christos Stylianides, was appointed EU Ebola Coordinator.

The Emergency Response Coordination Centre (ERCC) of DG ECHO (formerly known as the Monitoring and Information Centre (MIC)) plays key operational roles in a major crisis. The Union Civil Protection Mechanism facilitates cooperation in civil protection assistance interventions in the event of major disasters inside and outside the EU. This was also illustrated during the 2014 Ebola outbreak with Ebola Task-Force meetings organized at the ERCC and involving the HSC.

WHO also advises governments to work with local and international humanitarian agencies to identify how the basic needs of vulnerable populations will be met in a pandemic (18).

4.1.2 Role of Member States

Under Decision 1082, Member States have been called to further develop, strengthen and maintain their capacities to monitor, identify (early warning and assessment) and respond to serious cross-border threats to health.

The IHR, which entered into force on 15 June 2007, require countries to report certain disease outbreaks and public health events to WHO. Building on the unique experience of WHO in global disease surveillance, alert and response, the IHR define the rights and obligations of countries to report public health events, and establish a number of procedures that WHO must follow in its work to uphold global public health security.

In practice, many MS in the EU often report events through the EWRS simultaneously to WHO, ECDC, DG SANTE and all other EU MS.

4.1.3 Role of DG SANTE and Health Security Committee

The Directorate General for Health and Food Safety (DG SANTE) plays a major role in EU public health crisis management (generic preparedness planning, stockpiling, vaccination strategies, training and table top / command exercises, etc.). The Emergency Operations

Facility (HEOF) which is part of the Health Threats Unit of DG SANTE, is an operational centre intended to monitor and respond to pandemic outbreak, as was the case during the 2009 H1N1 influenza pandemic.

The Health Security Committee co-ordinates health-security measures in the EU.⁽⁴⁴⁾ It was set up in the aftermath of the 2001 terrorist attacks in the US and formalized under Decision 1082. Over the years, the Committee has established a solid base for preparedness activities, by: enabling EU governments to exchange information and evaluate health events, functioning as a discussion forum that advises health ministers, and facilitating coordinated crisis response by EU governments.

A rapid alert system for notifying at Union level alerts in relation to serious cross-border threats to health, an ‘Early Warning and Response System’ (EWRS), was established in 2013 and continued the role of the previous EWRS in relation to reporting of Communicable disease events. The EWRS enables the Commission and the competent authorities responsible at national level to be in permanent communication for the purposes of alerting, assessing public health risks and determining the measures that may be required to protect public health.

4.1.4 Role of ECDC

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 21 April 2004 established a European Centre for disease prevention and control (45). The regulations state that within the field of its mission, the Centre shall:

- (a) search for, collect, collate, evaluate and disseminate relevant scientific and technical data;
- (b) provide scientific opinions and scientific and technical assistance including training;
- (c) provide timely information to the Commission, the Member States, Community agencies and active international organisations within the field of public health;
- (d) coordinate the European networking of bodies operating in the fields within the Centre’s mission, including networks arising from public health activities supported by the Commission and operating the dedicated surveillance networks; and
- (e) exchange information, expertise and best practices, and facilitate the development and implementation of joint actions.

4.1.5 Role of WHO

WHO are the directing and coordinating authority on international health within the United Nations' system (46). They do this by: providing leadership on matters critical to health and engaging in partnerships where joint action is needed; shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge; setting norms and standards and promoting and monitoring their implementation; articulating ethical and evidence-based policy options; providing technical support, catalysing change, and building sustainable institutional capacity; and monitoring the health situation and assessing health trends. The International Health Regulations (2005) are one of six leadership priorities for the organization. WHO is working to support countries to put in place the capacities required by the IHR and report on progress. A major re-organisation is currently underway to strengthen WHO systems and networks to ensure a rapid and well-coordinated response to public health emergencies.

4.2 RISK ASSESSMENT AND SURVEILLANCE

4.2.1 Role of Member States

The national competent authorities designated to the commission under Decision 1082 shall communicate the following information to the participating authorities of the epidemiological surveillance network:

- (a) comparable and compatible data and information in relation to the epidemiological surveillance of communicable diseases
- (b) relevant information concerning the progression of epidemic situations;
- (c) relevant information concerning unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries.

Under the founding regulation of ECDC, the Obligations of the Member States are specified:

- (a) provide to the Centre in a timely manner available scientific and technical data relevant to its mission;
- (b) communicate to the Centre any messages forwarded to the Community network via the early warning and response system; and
- (c) identify, within the field of operation of the mission of the Centre, recognised competent bodies and public health experts who could be made available to assist in Community responses to health threats, such as field investigations in the event of disease clusters or outbreaks.

When reporting information on epidemiological surveillance, the national competent authorities shall, where available, use the case definitions adopted in accordance with those agreed under Decision 1082. MS report routine surveillance data into the ECDC platform The European Surveillance System (TESSy database). All unusual and serious events which could have cross border implications are initially alerted through the EWRS.

Under the World Health Organisation (WHO) International Health Regulation of 2005, countries are committed to further build their capacities to detect, assess and notify, and report on public health emergencies of international concern. At the national level, States Parties are required to assess all reports of urgent events within their territories within 48 hours by applying a specific algorithm contained in Annex II of the IHR (2005); the decision instrument. This instrument provides States Parties with the parameters used to decide whether or not a specific event needs to be notified to WHO under the IHR (2005). When a State Party identifies an event as notifiable, it must be notified to WHO immediately, i.e., within 24 hours after having carried out the assessment of public health information related to the event. Such notification will include details of any health measure employed in response to the event as well as accurate and sufficiently detailed public health information available, including case definitions, laboratory results and number of cases and deaths. Any event that is notifiable under Annex II of the IHR will also be reportable to the EWRS.

4.2.2 Role of DG SANTE and Health Security Committee

Decision 1082 describes how the epidemiological surveillance network shall bring into permanent communication the Commission, the ECDC, and the competent authorities responsible at national level for epidemiological surveillance.

4.2.3 Role of ECDC

The European Centre for Disease Prevention and Control (ECDC) was established in 2005. It is an EU agency aimed at strengthening Europe's defences against infectious diseases. It is seated in Stockholm, Sweden. According to the Article 3 of the Founding Regulation, ECDC's mission is to identify, assess and communicate current and emerging threats to human health posed by infectious diseases (45). In order to achieve this mission, ECDC works in partnership with national health protection bodies across Europe to strengthen and develop continent-wide disease surveillance and early warning systems. By working with experts throughout Europe, ECDC pools Europe's health knowledge to develop

authoritative scientific opinions about the risks posed by current and emerging infectious diseases.

4.2.4 Role of WHO

The International Health Regulations, or IHR (2005), represent an agreement between 196 countries including all WHO Member States to work together for global health security. Through IHR, countries have agreed to build their capacities to detect, assess and report public health events. WHO plays the coordinating role in IHR and, together with its partners, helps countries to build capacities. IHR also includes specific measures at ports, airports and ground crossings to limit the spread of health risks to neighbouring countries, and to prevent unwarranted travel and trade restrictions so that traffic and trade disruption is kept to a minimum.

4.3 COMMUNICATION

4.3.1 Role of Member States

Risk communication is one of the 8 core capacities identified by the IHR as essential for responding to public health emergencies. Under the new Joint External Evaluation tool of the IHR, countries are assessed in 5 domains of emergency risk communication by 5 levels of capacity (29).

4.3.2 Role of DG Sanco and Health Security Committee

The Health Security Committee has established a network that brings together communicators from national risk-management authorities, the Commission and EU agencies.

Within the EU, the network helps communicators cooperate with each other:

During a crisis - share information in the early stages and coordinate common strategies and messages to the public.

Longer-term - exchange best practice on health risks/crisis communication and recommendations for preventing diseases caused by the threats.

Globally, the network is an important channel for containing and mitigating global health threats. It enables the EU to spread information rapidly worldwide, by connecting with existing communicators' networks under the Global Health Security Initiative and the WHO network under the International Health Regulations (IHR).

4.3.3 Role of ECDC

Article 12 of the founding regulation of ECDC states that the independence of the Centre and its role in informing the public mean that it should be able to communicate on its own initiative in the fields within its mission, its purpose being to provide objective, reliable and easily understandable information to improve citizens' confidence (45). The Centre shall act in close collaboration with the Member States and the Commission to promote the necessary coherence in the risk communication process on health threats.

The Centre shall cooperate as appropriate with the competent bodies in the Member States and other interested parties with regard to public information campaigns.

ECDC activities in the area of health communication stem from the mandate given to ECDC in Article 12 of its Founding Regulations. They have three directions:

Efficiently communicate the scientific and technical output of ECDC to professional audiences: The main scientific output from ECDC is disseminated through technical and scientific reports, which are authored by internal and external experts.

Communicate key public health messages and information to the media and the European public: Health problems and concerns differ from country to country. ECDC therefore works closely with national authorities to ensure its public health messages have maximum impact.

Support the development of Member States' health communication capacities: ECDC supports Member States' communications activities by delivering training in health communication skills, providing adaptable tools and guidance, and facilitating the share of best practices on health communication.

4.3.4 Role of WHO

WHO provides global guidance on best practices for risk communication and is supporting countries to build up capacities through establishing the right policy, strategy and plans for risk communication, providing training for key personnel, engaging and training journalists on how to report on health emergencies, and running simulation exercises to test national systems. In emergencies, WHO provides hands on support for response by deploying its Emergency Communications Network (ECN) to affected countries and regions to work hand-in-hand with national and local authorities. Established in 2013, the ECN has grown to become 104-strong, and is one of the most frequently used deployment mechanisms in WHO. While principles, good practices and training programmes already exist in the field of risk communication, there is no single, comprehensive, evidence-based, up-to-date, systems-focused WHO guidance for Member States in this area. In order

to address this gap, WHO is embarking on a project to develop guidance on emergency risk communication. The guidance is expected to cover: 1) communicating during public health emergencies; and 2) building and sustaining local capacity. WHO provides on line training in emergency risk communication (47). Shortly WHO will launch a new web-based knowledge exchange platform for outbreaks and infectious disease management called OpenWHO.

5. BEST PRACTICE, GAP ANALYSIS, IMPROVEMENT NEEDS AND RESEARCH PRIORITIES

5.1 INTRODUCTION

Task 5.2 of WP 5 “Gap analysis and Integrated solutions” focuses on developing an inventory of best practice, based on outputs of the workshop and findings of WP2-4. This task includes assessing the effectiveness and impact of responses to past events, both preparedness and response to past epidemics and pandemics. This includes responses by both national governments and the EU. In addition, this task identifies improvement needs to fulfil operational requirements for pandemic risk management as defined by the project. This focuses on the systems, practices and tools identified by users necessary to build capacity. Training priorities for capacity strengthening and better integration are also reviewed.

One approach to this task was to use qualitative analysis software *Atlas.ti* to review the previous deliverables 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, 4.1, and 4.2. Each deliverable was coded based on 10 categories: outbreak and event detection, outbreak investigation, surveillance, risk management, risk communication, risk assessment, information management, governance, ethics and capacity building. Within each category, items were organized into 5 sub-categories: current arrangements, best practice, gaps and improvements, planned work, and innovations and research needs. A small summary was written for each coded item on the *Atlas.ti* software, after which all coded items were arranged visually in "networks" on the software to further understand relationships between categories, items with duplicate codings and gaps that needed to be addressed. A

final gap analysis was written from these summaries and networks. See figure 4 for example of visual display of the ethics category studied.

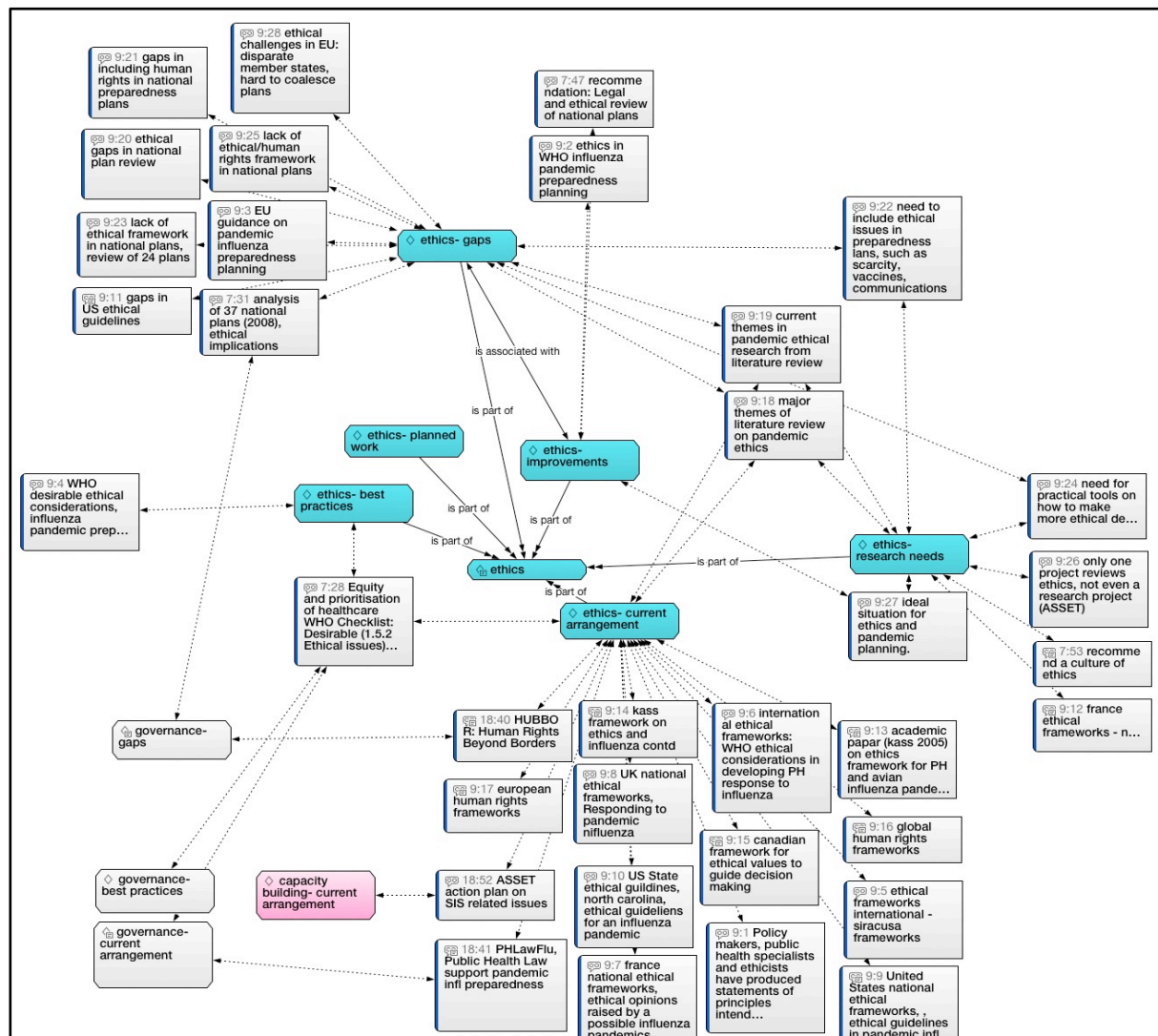


Figure 4 Example of visual display of the ethics category analysed by Atlas software

The second approach to this task was by a traditional manual review of the outputs of the previous deliverables 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, 4.1, and 4.2. Both approaches were conducted by separate individuals. It was found that the traditional method validated the outputs of the *Atlas.ti* approach. The sections below represent the merged analysis of these two approaches.

In the analysis of the earlier deliverables presented below we include information given on similar projects. In this way PANDEM wishes to build on previous research and avoid duplication.

5.2 RISK MANAGEMENT

5.2.1 Current arrangements

The key functions in pandemic risk and emergency management are indicated in D3.1 (see figure 5).

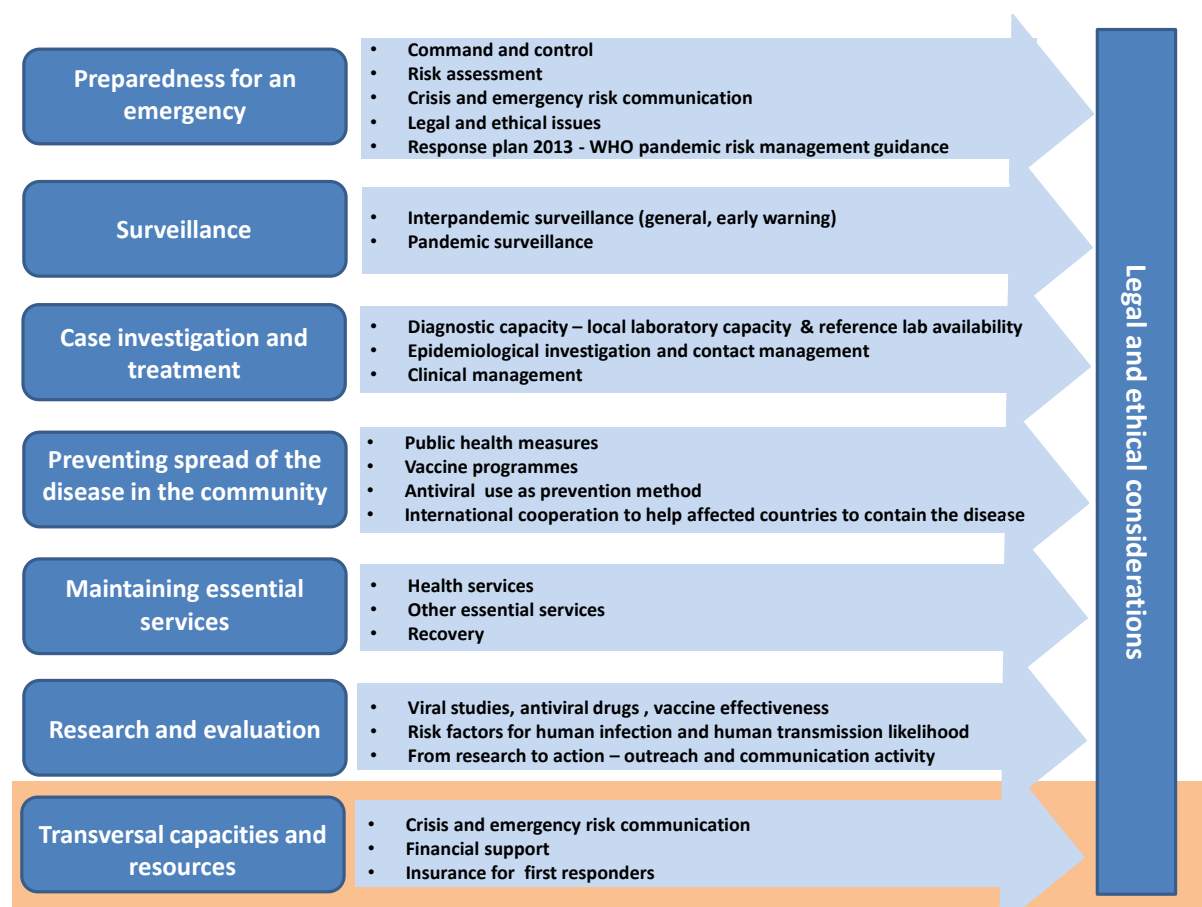


Figure 5 Pandemic Risk and Emergency management (Source: WP3, D3.1 Figure 2).

The key stakeholders at International, European and National level are described in D3.1 (See figure 6).

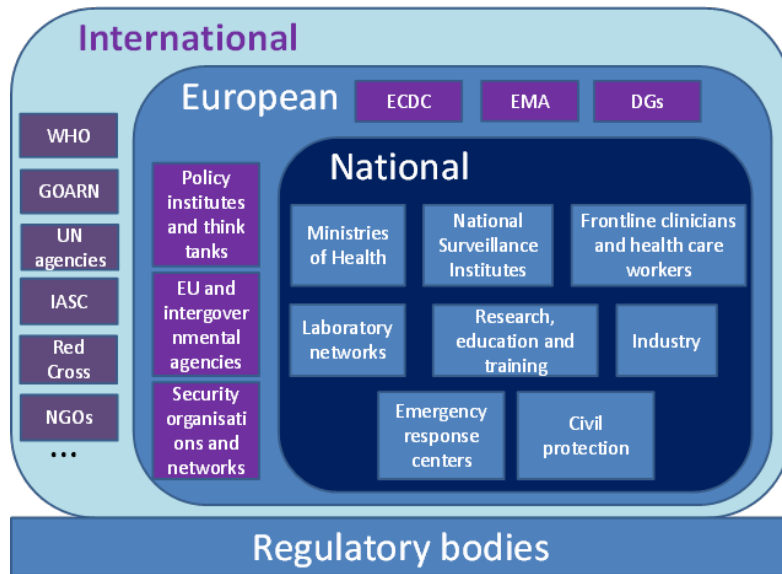


Figure 6 Overview of some key international, European and national (Member States) pandemic stakeholders (Source: WP3, D3.1 Figure 4)

In the EU region the Health Security committee of DG SANTE plays a key role in coordinating the response of the EU Member States. The European Centre for Disease Prevention and Control provides technical advice to the Commission and the Member States. WHO plays a pivotal role in the global response to a pandemic and the response in and by EU countries is coordinated with the WHO Regional Office for Europe. The interaction between the various players is again illustrated in D3.1 figure 5.

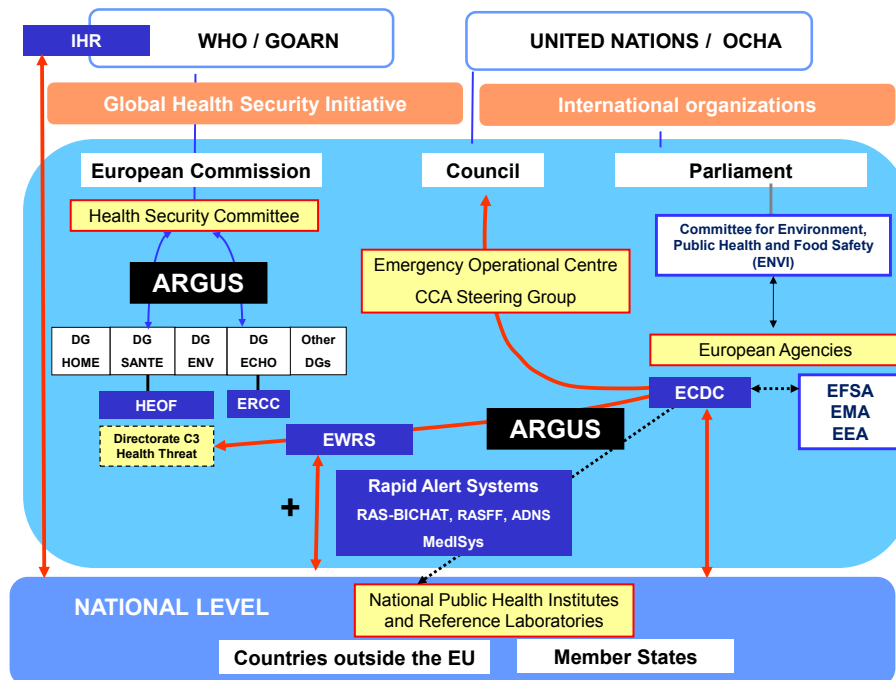


Figure 7 Overview of the European early warning mechanism (Source: WP3.1 Figure 5).

5.2.2 Highlights of best practice, ideal situation in next 5-10 years

More so than any previous infectious disease outbreak or pandemic, the response to the Ebola outbreak in West Africa was truly intersectoral. As described in the case study in D4.1

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, 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.

5.2.3 Gaps identified and improvement needs

5.2.3.1 Global level

There has been much written about the poor global response to Ebola and the necessity for a more rapid response when facing future pandemics or serious epidemics. The current approach for mobilizing resources is slow and fragmented.

D4.2 highlights the need for further research to evaluate measures included in pandemic contingency plans and for clinical research to design pertinent decision making tools. The review of D3.3, D4.1 and D4.2 highlights the need for an integrated risk management approach, incorporating ethical, legal and communication skills at all stages of pandemic preparedness and response.

5.2.3.2 Regional level

Again at a European level during the Ebola event while information exchange was timely and relevant there was a delay in mobilizing a response from both regional and MS authorities.

There are difficulties in communication between disaster management (first responders) and health emergency management (public health sector). The two groups use different terminologies for the same things, which make collaboration difficult.

5.2.3.3 National level

Currently many EU countries lack advanced data management tools for contact tracing that would link data at local, national and international levels, and also confirmed laboratory results.

MS did not have information on the availability of rare disease specific experts at a European level. ECDC should provide a roster of relevant experts for severe and unusual

outbreaks, and for bioterrorism events such as smallpox, botulism, ricin, etc., that would be available if such an outbreak occurs.

In situations where extra staffing is needed, one of the EU MS cases studies noted that there are no procedures in place to recruit necessary staff. It was also noted that personnel burnout in an emergency remains a challenge.

5.2.4 Overview of ongoing and planned work in other projects

There are several EU funded projects currently in operation with relation to risk management. **PRACTICE: Preparedness and Resilience against CBRN Terrorism using Integrated Concepts and Equipment** was funded in 2011 under the Security theme as a large collaborative project. The response capability functions were considered universal in character and could be applied to EU and member states.

PREPARE: Platform for European preparedness against (re-)emerging epidemics commenced in 2014, funded under the Health theme. **PREPARE** establishes a Europe-wide clinical research framework for harmonised large-scale clinical research studies on infectious disease. This framework will respond to any severe infectious disease outbreak providing real-time evidence for management of patients and informing public health responses. It is a large-scale clinical project aiming to provide a one-stop shop for policy-makers, public health agencies, regulators and funders of research into pathogens with pandemic potential.

ACRIMAS (Aftermath Crisis Management systems-of-systems Demonstration Phase I) developed a roadmap for a Demonstration Project Phase II in Crisis Management which focuses on large-scale man-made and natural incidents that would require a coordinated response. Though this project focused on natural disasters, terrorist attacks, and industrial accidents, the systems-of-systems approach is relevant to pandemic preparedness. The **DRIVER** project, Driving Innovation in Crisis Management for European Resilience, is a Phase II demonstrator project based on the findings of ACRIMAS.

PULSE, the Platform for European Medical Support during Major Emergencies, focuses on preparedness in both a biological attack and a major stadium “crush,” and how cross border support would be coordinated. This project seeks to develop a standardized response to such events across Europe.

CBRNEMAP, Road-Mapping study of CBRNE demonstrator, aimed to create a road-map for a large-scale CBRNE demonstrator similar to PANDEM.

S-HELP, Securing Health. Emergency. Learning. Planning, is a research project that focuses on preparedness, response and recovery in emergency situations.

5.2.5 Innovation and Research needs

Establishing a shared nomenclature for disaster management and health emergency management would improve collaboration and response to pandemics. However, this may be a challenge due to the fact that these actors work separately and may operate under separate legislative frameworks.

There also needs to be a discussion regarding the definition of the military role when health systems are overwhelmed. There needs to be a multi- agency / departmental input into pandemic plans to agree on, and ensure inclusion of any required interaction procedures with military organizations. Tools to support Interdisciplinary co-ordination and collaboration at national and regional level are required.

We need to ensure research is done to monitor the effectiveness and safety of public health interventions.

At a local level, data tools are required incorporating GIS, audit and performance management of follow-up of contacts. This would enable timely interventions on individual level with prophylaxis, quarantine, isolation and treatment to limit expansion of the high-impact epidemic/pandemic. The tool would incorporate procedures for timely management at local level coupled with audit at local and national level, and potential to conduct effective cross-border contact tracing.

5.3 GOVERNANCE, LEGISLATION AND ETHICS

The PANDEM project deliverable 4.1 reviews the policy and legal frameworks underpinning governance related to pandemic preparedness and response. 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.

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. The importance of good pandemic governance is described in D4.2 by which it can ensure that in the event of a pandemic, response measures:

- Are evidence based and therefore a more effective response to an epidemic;
- Have a legal base? and are 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

5.3.1 Current arrangements

At the global level, the International Health Regulations 2005 (IHR) (48) is the international legal instrument designed to respond to threat of all-hazards, including infectious disease. The key terms of the IHR are outlined in D4.1.

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 WHO IHR contact points that are in the WHO Regional Offices
- 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 and trade. 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:

- to constitute a public health risk to other States through the international spread of disease, and
- to potentially require a coordinated international response

The legal frameworks covering the transportation of specimens, bio-safety, biosecurity, diagnostics and virus sharing are outlined in D4.1, including both EU and global governance arrangements.

Articles 3, 23, 32 and 45 of the IHR all indicate ethical considerations which must be considered in any interactions with persons under application of the IHR.

There are various ethical and human rights frameworks that would or could be guiding documents in pandemic preparedness planning. The Siracusa Principles are a legal instrument, drafted by the American Association for the International Commission of Jurists, to clarify when and how any individual rights may be limited and to designate when such repression is illegal. Human rights frameworks include the Universal Declaration of Human rights, the International Covenant on Economic, Social and Cultural Rights, the International Covenant on Civil and Political Rights, the Convention on the Rights of the Child, the Universal Declaration on Bioethics and Human rights and the Convention on the Rights of Persons with Disabilities.

There are outbreak and disease specific programs, such as the Global Outbreak and Response Network (GOARN), Global Health Security Initiative (GHSI), Global Health Security Agenda (GHSa), Global Action Plan for Influenza Vaccines (GAP), the Global Action Plan for Antimicrobial Resistance (GAP AMR), and the Pandemic Influenza Preparedness Framework (PIP) that have arisen to combat specific challenges.

At a regional level within Europe, DECISION 1082/13 on serious cross-border threats to health and repealing Decision No 2119/98/EC is a key decision of recent years. It confirms the commitment in Article 168 TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION (TFEU) of Member States to coordinate their policies and programmes in public health. The Decision extends this. Key provisions include are listed in Annex 3.

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.

In addition there are also EU governance mechanisms (agencies, systems and tools) that pertain to pandemics prevention and control (- all detailed in D4.1). These include ECDC, the European Medicines Agency, the European Food safety Authority, the EU Health Security Committee, the Health Emergency Operations Facility, the Early Warning and Response System, Medical Information System, Health Emergency and Disease Information System and European Medical Corps. There are also several other international governance initiatives that pertain to pandemic threats.

European ethical frameworks include the European Convention on Human Rights, the WMA Declaration of Lisbon on the Rights of the Patient and the Charter of Fundamental Rights of the European Union.

At a national level, D4.1 describes the arrangements for governance and ethical frameworks which were accessible and available in English.

5.3.2 Highlights of good practice, ideal situation in next 5-10 years.

Effective pandemic governance needs to be national, regional and international and countries' responses need to be coordinated and collaborative. Pandemic plans ideally will, as recommended by WHO, have a greater focus on intersectoral cooperation, collaboration and leadership and include strategies for exchanging information and communicating risk. A coordinated, standardised response would seem the ideal response for maximum efficiency and effectiveness. While D4.1 discusses the tensions inherent in any such approach due to sovereignty/subsidiarity issues and also to the political priority differing among EU MS, the report argues that effective network governance is crucial to achieve effective outcomes.

WHO Interim Guidance on Pandemic Influenza Risk Management 2013 replaces the *2009 Pandemic Influenza Preparedness and Response: a WHO guidance document*. The new guidance focuses upon risk assessment at national level to guide national level actions, provides a revised approach to global phases, advises flexibility through uncoupling of national actions from global phases and included principles of emergency risk management for health. The new guidance includes updated annexes on planning assumptions, ethical considerations, whole-of-society approach, business continuity planning, representative parameters for core severity indicators, and containment measures.

Ideally over the next 5 years all EU MS will have updated their pandemic plans and will ensure that the full legal authority and legislation required to sustain and optimize pandemic preparedness, capacity development and response efforts across all sectors is in place. Ideally, there will be underpinning evidence based research to support recommended interventions.

It can be argued that an example of good practice during the recent Ebola epidemic were the many examples of multi-sectoral co-operation observed at global, regional and national levels. Securitisation of outbreak planning in severe major epidemics or pandemics can improve political leverage and justify military and security focussed measures in response.

Feedback from MS indicated that the Health Security Committee of the European Commission, coupled with risk assessments from ECDC and weekly situation reports from WHO were useful during the Ebola epidemic.

Christos Stylianides, the Commissioner for Humanitarian Aid and Civil Protection of the European Commission has highlighted the deployment of European mobile laboratories in West Africa as an example of what worked well in the European response to the Ebola epidemic.

There are a few publicly available documents in place regarding ethics and pandemic influenza, including WHO's "Ethical Considerations in Developing a Public Health Response to Pandemic Influenza," the UK Department of Health's "Responding to Pandemic Influenza. The Ethical Framework for Policy and Planning", the French OPINION NO. 106. "ETHICAL ISSUES RAISED BY A POSSIBLE INFLUENZA PANDEMIC: NATIONAL CONSULTATIVE ETHICS COMMITTEE FOR HEALTH AND LIFE SCIENCES" and the US CDC's "Ethical Guidelines in Pandemic Influenza: Recommendations of the Ethics Subcommittee of the Advisory Committee to the Director."

Ideally public engagement and involvement will be embedded in the planning and response process which will work to build and maintain public trust.

5.3.3 Gaps identified and Improvement needs

5.3.3.1 Global level

Coordinating the many regional, national and international actors during a pandemic remains a challenge. 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. 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.

Much has been written about the challenges at the national and international level during the Ebola outbreak. This involved a lack of clarity involving directives, a lack of leadership, slow response to the outbreak, how funding was raised, and the prioritization of healthcare. The weaknesses of the affected countries exacerbated these issues. There is a need to improve coordination and response to international outbreaks, which WHO is addressing through its emergency reform.

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. A legal framework that promotes sharing of

pathogenic material for research 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. The 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, also known as the Nagoya protocol on Access and Benefit Sharing (ABS) is a 2010 supplementary agreement to the 1992 Convention on Biological Diversity (CBD). This protocol sets out obligations to take measures in relation to access to genetic resources and benefit sharing.

5.3.3.2 Regional level

There is a dearth of expertise and training in public health law across Europe. This suggests an urgent need for improved training in public health law in both the legal and healthcare sectors. The results of research undertaken in D4.1 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.

During the recent Ebola crisis, it was reported that DG ECHO requested staff from other involved agencies to act as liaison officers. Due to the increased work pressures due to the crisis this was not possible, indicating the lack of surge capacity in European agencies.

The mandate of ECDC to respond to outbreaks outside of the EU was reported as causing delays in permitting ECDC staff to travel to assist in West Africa. In addition, deployment of medical teams from EU MS has been criticised as delayed.

5.3.3.3 National level

There are many discrepancies in pandemic policies and plans across Europe. These strategic differences may prove problematic should a cross-border outbreak occur. Also, review of legislation in D4.1 suggests inadequate legal underpinning for proposed pandemic control measures in many member states. Legislation may be outdated and/or in breach of ECHR. Further, there does not seem to be a correlation between national strategies (e.g. public health interventions, vaccination, antiviral use, risk communication etc.) and pandemic influenza outcome measures. This highlights the need for applied research to evaluate effectiveness of response measures. Plans also often lack attention to disadvantaged populations, which are typically disproportionately affected by pandemics.

While it is essential that plans are flexible enabling adaptation to the specifics of each situation, the possible options to be applied in a severe or mild pandemic should be ideally outlined in the inter-pandemic period. Many plans were also out of date.

Of 28 EU countries, 16 had national pandemic preparedness plans which were publically available from the ECDC or WHO website, 12 were updated since 2009 and 7 were available in English - 4 of which were updated since 2009. Other countries should revise their plans in line with WHO guidance and in coordination with WHO and EU/ECDC. Plans, or agreed components thereof (relevant to cross-border coordination) should be publicly available. Plans should include evidence-informed strategies and be subject to legal and ethical review.

In a review of eight European plans the authors note “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.”(49)

One of the major gaps is that many national plans do not address ethical and human rights concerns. Several literature reviews of European or global plans found that even when ethical issues were mentioned, they were not discussed in detail. None of the plans reviewed discussed human rights. Further, when ethical issues are discussed, there is no guidance for health professionals on how to realize the requirements set out.

Additionally, the EU is composed of 28 member states, and these states may have disparate understandings of what is considered ethical. While the Charter of Fundamental Rights of the European Union provides some binding guidance, there has been little work done with all EU member states to establish a set of uniform ethical principles with regard to a pandemic.

D4.2 mentions the need for more practical guidance about how to implement the ethical frameworks and the need for decision making tools that can adapt to reflect the specifics of a particular pandemic and the social settings in which it occurs.

Much of the planning done at all levels relates to preparedness for pandemic influenza. The challenge is to anticipate and plan for both governance and ethical issue which also arise in the context of non-influenza pandemics.

In reviews of the response to the *E.coli* O104:H4 outbreak in Germany the US CDC states that “lessons learned” are that it is of critical importance for “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 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.

5.3.4 Overview of ongoing and planned work in other projects

The work of previous/ current EU projects such as PHLAWFLU and CELESTE (ISS) and CELESTE (PHE), ASSET and Sharing data for Public Health have been described in D4.1 and all cover some aspect of policy and legal frameworks in European pandemic preparedness. It is clear that continued work needs to build upon the output of these projects.

The ASSET programme has reviewed ethics and human rights response, though ASSET does not consider itself a project, but a “mobilization and mutual learning program.” ASSET is an EU funded program that aims to “forge a complementary partnership to address scientific and societal challenges raised by pandemics, explore and map Science in Society (SiS)-related issues in global pandemics; define and test a participatory and inclusive strategy and identify resources to sustain the action in the future.” (50)

HUBBOR, Human Rights Beyond Borders, is an EU-funded project that looks at comparative legal, historical and theoretical approaches of international human rights law.

SURVEILLE: Surveillance: Ethical Issues, Legal Limitations and Efficiency. A project to assess the impact of different surveillance systems. A multi-disciplinary project combining law, ethics, sociology and technology analysis. SURVEILLE assessed surveillance technology for its actual effectiveness in fighting crime and terrorism, for its social and economic costs, and surveyed perceptions of surveillance in the general public and certain identified target groups. SURVEILLE addressed legal limitations on the use of surveillance technologies as well as ethical constraints.

Other ongoing work includes the EU Task Force on Biological and Chemical threats, initiated in 2002, which began to implement its Action Plan in 2010-2014. The Task Force focused on bio-preparedness.

5.3.5 Innovation and Research needs

There are several recommendations with regards to EU’s international response to pandemics. One option proposed in D4.1 is to develop a European Model Act which is flexible enough to be used in different legal systems and which provides guidance for national emergency legislation with safeguards for individual rights. This would describe the legal framework/basis for response within and across member states which provides legal authority and safeguards to both public health authorities and individual citizens. In addition it is proposed that capacity building in public health law should take place across

EU Member states, enabling better cross-border understanding, coordination and coherence in national legislation.

To enhance accessibility of national pandemic preparedness plans across the EU, plans should be made available online and the availability of a repository of translated national plans, or agreed parts of plans, would be useful. Countries with sufficient resources are encouraged to make their plans available in multiple/common languages.

It has been suggested in D4.1 that **A Declaration of International responsibilities or principles** would assist in defining more clearly the responsibility of the EU in global health emergencies.

Much of the research that needs to be done in ethical underpinning of pandemic response pertains to the development of pandemic plans to include an ethical dimension. As mentioned, very few plans include a detailed discussion of ethics, if it is included at all. Many plans presuppose a set of ethical values without any explicit mention on what those values are. Because the EU has 28 member states with their own distinct cultures and values, it is critical to be frank and detailed about what an ethical response to a pandemic would mean.

Most research that has been done with regard to ethics and pandemic preparedness has been done in North America, notably in the USA and Canada. More research needs to be done on this issue with specific regard to Europe.

In the future development of ethical and human rights approaches to pandemic planning, it is important to take several concerns into account. A comprehensive overview of all EU national plans from an ethics and human rights perspective is needed, supported at the EU level. Research should be done on why ethics and human rights are such a low priority and aim to make ethical concerns a foundation of pandemic planning rather than an ancillary concern at both national and international levels. Research should also review ethical issues that pertain to all aspects of pandemic planning and response, such as communication and surveillance. National plans should eschew a narrow focus on influenza, rather they should take into account all pathogens that may cause a serious cross-border threat to health.

5.4 RISK ASSESSMENT AND SURVEILLANCE

Work Package 2 in PANDEM conducted a threat analysis and developed pandemic scenarios for use by all work packages to identify gaps, needs and solutions and test potential demonstrator concepts. The threat analysis described threats from infectious agents with pandemic potential from air-borne, vector borne and zoonotic pathogens, food and water borne pathogens and the emergence of novel pathogens. Building on work of previous EU-funded projects such as PRACTICE and FLURESP the responsible partners from the Public Health Agency of Sweden (FoHM) and the Swedish Defence Research Agency (FOI) developed four pandemic scenarios:

- a natural outbreak of pandemic influenza
- an emerging respiratory disease other than influenza (SARS/MERS-CoV)
- a deliberate release of small pox
- an accidental release of Venezuelan Equine Encephalitis from a vaccine plant.

Work package 2 conducted an analysis of knowledge, capacity and capability gaps, priorities and candidate solutions to strengthen surveillance and risk assessment and define research priorities. Utilizing the pandemic influenza scenario, deliberate release of smallpox scenario and the emergence of an unknown disease scenario, D2.2 assessed current systems and practices for surveillance and risk assessment at national, EU and global level identifying best practice for pandemic preparedness and response. D2.3 reviewed current diagnostic technologies and identified requirements for future competitive and innovative solutions.

5.4.1 Current arrangements

All countries reviewed in D2.2 (Sweden, Ireland, England and the United States) have the capacity to detect diseases with pandemic potential/serious outbreaks through numerous routes - clinical notification (which is most likely), event detection systems which use epidemic intelligence to monitor media and journal reports from their own or other countries, Early Warning and Response System (EWRS) reporting in EU MS and WHO International Health Regulations (IHR) reporting. All countries highlighted the importance of good relationships with clinical and laboratory colleagues enabling astute clinicians to discuss unusual events with public health authorities. All described close collaboration between the public health authorities, veterinary institutions and the department of agriculture, vital for a one-health approach to disease surveillance. All described the importance of a national zoonotic committee.

Case studies demonstrated a high capacity for outbreak and event detection of an unknown disease and detection of novel causes of pandemic influenza. All countries have systems in place to collaborate with law enforcement agencies in the event of suspected bioterrorism.

5.4.2 Highlights of best practice, ideal situation in next 5-10 years

In Sweden, there is a strong infectious disease clinics network that maintains close collaboration between local authorities and hospitals as well as necessary public health and veterinary agencies, so disease detection may be easily communicated between all stakeholders. In the United Kingdom, the UK Zoonosis Animal Disease and Infections group (ZADI) meets every quarter. Though this collaboration is not regulated by law, there is consistent sharing of data between sectors responsible for animal and human health. The Human Animal Infections and Risk Surveillance (HAIRS) group conducts risk assessment processes for zoonotic and risk to UK population.

Ireland's National Public Health Outbreak Response (NPHOR) is used for major events. Local areas regularly investigate disease outbreaks, and the central Health Protection Surveillance Centre will only become involved if an outbreak affects more than one area. A National Public Health Outbreak Response Team (NPHORT) can be initiated in the case of a severe outbreak to invoke emergency procedures, have regular meetings, conduct first few hundred cases surveillance and produce regular situation reports. Best practice for outbreak detection also included having cases of unknown severe disease be notifiable in Ireland whereby any illnesses of unknown cause that might cause public health concern are mandatorily reported enabling early detection of emerging diseases.

In England, PHE has its own risk assessment mechanism for an unknown disease, in which it evaluates the transmissibility of vectors, the severity of infection, the interventions available and the predicted population impact. England has a standard approach to establish a diagnosis for an unknown disease, in which a local clinician will notify the local health protection team and that team will work with the clinician to establish necessary epidemiological data, demographics, travel history, etc. If there are concerning features present, the local team will work with the regional and national level, including Public Health England (PHE). All EU countries use EWRS and the IHR mechanisms to report and discuss concerning outbreaks of infectious disease with ECDC, the European commission and WHO. Sharing of microbiological findings with the scientific community, such as the sequence data of MERS-CoV, allows for rapid outbreak investigation. PHE has protocols in

place for rapid investigation of the first few hundred cases (FF100) of an influenza pandemic and their close contacts and the sharing of information appropriately throughout the department of health and other sectors of government. During the 2009 pandemic, strong local capacity and resources were considered essential as were having predefined teams and standardized processes for outbreak investigation; and regular exercises. PHE has a team in charge of developing annual exercises and training programs with multiple stakeholders, and involves simulations of events of severe disease outbreak (such as deliberate anthrax release). With regards to influenza, PHE's risk assessment process for emerging infections would be utilized in a new emerging influenza virus to evaluate predicted impact. The risk assessment team would include professionals with epidemiology, microbiology, virology and emergency response expertise. ECDC and WHO risk assessments are also valuable tools for member states.

In the United States, in the case of domestic situations, it is feasible for CDC to form a team for investigation within 24-48 hours. In specific situations, CDC has pre-configured groups of 10 that can be deployed urgently if required. Internationally, the US Global Rapid Response Team has the capacity to form a group anywhere in the world within 24 hours, a second group 24-72 hours later and a larger group after a longer lead time. Collaboration between different sectors and agencies was seen as essential for outbreak investigation. Memorandums between those responsible for animal health, food safety, water safety and weather experts enabled a one health approach.

Other well-established surveillance systems highlighted include ICU surveillance of influenza or other serious respiratory illnesses and having syndromic surveillance, in which certain disease signs and symptoms are reportable before a laboratory diagnosis has been made. Having surveillance procedures in place, including computerized notifiable disease reporting systems that can be rapidly adapted to incorporate a new emerging threat were highlighted as essential for an effective response capacity.

5.4.3 Gaps and Improvement needs identified

The FOI and FOHM work package leaders noted that gaps in outbreak detection and surveillance were not uniform in the MS studied and that each of the countries studied had their own gaps and weaknesses that oftentimes other countries could meet. This suggests that there is capacity to improve by peer to peer learning.

5.4.3.1 Global level

D4.1 noted in their literature review that pandemic plans only have weak linkages between human and animal surveillance. Some plans do not specify adapting surveillance during the pandemic. Nor did plans address the selection or prioritization of surveillance indicators. However, surveillance system requirements for both seasonal and pandemic influenza are currently being reviewed. A key requirement will be the development of IT systems to collect the required parameters both at community (mild cases) and hospitals (severe cases and real-time mortality data).

5.4.3.2 Regional level

Technology must be improved to accommodate a major event. In Europe, it was noted that the EWRS system can be overwhelmed when many countries are entering situation reports and updates during a time of crisis, which makes it difficult for many stakeholders to access real-time information.

5.4.3.3 National level

In Sweden, it was noted that there should be further instructions for unusual event reporting, including “better instructions on how the current reporting paragraph can be used, and [increase] awareness on the possibility and responsibility of reporting unusual reporting of diseases”. There is also concern that current surveillance would not detect an unknown disease. In Ireland, while HPSC educates the medical students at one of the medical colleges about IHR and the need to notify public health officials about certain disease scenarios, this education does not cover the entire country. IHR and event notification needs to be extended to all at undergraduate level.

All countries were concerned that rare diseases may not be initially picked up at presentation. As smallpox does not occur in nature, it would difficult for a clinician to immediately identify the disease, especially if he or she were too young to have had previous experience. Again, the responsibilities of each sector must be explicitly outlined for such an outbreak, especially the relationship between the health and security sectors. Smallpox trainings and stress tests would improve clinical awareness about unusual and severe disease outbreaks and help gauge a country’s ability to respond to such a threat.

In order to assess the severity of a pandemic or serious epidemic it is necessary to obtain data on illness severity at both ends of the spectrum i.e. what proportion are infected but

so mild they do not need to attend medical care and also what proportion are admitted to hospital and need intensive care. Many MS have a lack of baseline knowledge at community level data on people who do not seek health care but who nevertheless are impacted by the pandemic and fail to attend work. This may be due to themselves experiencing mild illness, attending a sick relative or minding children if there are school closures. There is poor capacity to estimate and monitor spread of infection and impact on essential services in society e.g. data on school and work absenteeism.

Another indicator of those infected but not overtly symptomatic may be obtained through serological surveys but again this is expensive and not routinely available in all MS. Some MS face ethical barriers in accessing residual blood samples which have been taken for another purpose and using these samples for serology investigations.

For influenza, communication between ICUs and public health authorities needs to be improved so that all necessary authorities have access to real-time data. Some MS still rely on paper-based systems, which are slow and inefficient. National automated data entry systems with linkages between relevant systems would alleviate these concerns.

5.4.4 Overview of ongoing and planned work in other projects

D3.2 undertaken by FOI and IGS reports on the specific EU projects related to PANDEM. Many of these projects relate to threat analysis, risk assessment and surveillance.

EUROMOMO: *European monitoring of excess mortality for public health action*, aimed to develop and operate a coordinated approach to real-time mortality monitoring across Europe in order to identify excess deaths that may be associated with seasonal-influenza, improve risk assessment and management capacity for major health threats including pandemic influenza and other infectious diseases. However, this important project struggles to maintain a secure source of funding.

I-MOVE: *The Influenza - Monitoring Vaccine Effectiveness network* aims to measure seasonal influenza vaccine effectiveness in Europe.

ISSC: *An integrated surveillance system for infectious disease in rural China: generating evidence for early detection of disease epidemics in resource-poor settings* was funded under the FP7 Health theme. The project aimed to improve the early detection of epidemics in rural China by integrating syndromic surveillance with case report surveillance systems.

PANDHUB: *Prevention and management of high threat pathogen incidents in transport hubs* is funded under the Security theme and aimed to create a toolbox to aid transport operators in the development of pandemic preparedness and response plans. There is a

cross-border focus and local, national and international practical, legal and ethical implications are being reviewed.

The *Platform for European Medical Support during major emergencies* or **PULSE** project was funded under the 2013 FP7 Security call. It focuses on European Health Services and their preparedness to deal with major emergencies and uses two pilot scenarios: a biological attack and a major stadium ‘crush’. Both scenarios involve cross border support. **PULSE** aims to develop standard and consistent response procedures for use across Europe and provide a framework for decision makers providing access to timely data, planning and decision support tools.

Governments and non-governmental institutions have also pledged funds to improve outbreak and event detection. The Wellcome Trust in the United Kingdom has several projects in pandemic preparedness and response, specifically in influenza research, antimicrobial resistance and emergency Ebola research into vaccines, experimental drugs and humanitarian response. The Trust has also committed €25M towards a project in pandemic crisis management. The UK Engineering and Physical Science Research Council (EPSRC) has granted I-SENSE £11M to “develop a new generation of warning systems for disease outbreaks.” Mobile phone-connected diagnostic devices aim to widen access to testing in GP surgeries, in the community in the developing world and in the home. The capability to detect infections and then wirelessly connect test results to healthcare systems will help patients gain faster access to treatment, and support public health efforts to map indicators of emerging infections in real-time.

I-Sense is also using the vast amount of web-based information on Google, Facebook and Twitter to identify indicators of disease outbreaks, before people attend clinics, or from geographical regions that are not covered by traditional public health systems (51).

5.4.6 Innovation and Research needs

Training and modules on rapid risk assessment are needed. WHO already conducts training on how to use the WHO guidance for the rapid risk assessment of acute public health events. ECDC plans to improve its rapid risk assessment methodology, after which, this methodology could also be utilized throughout Europe. Standardized, ready-to-use templates would be especially useful for risk assessments of an unknown disease. For influenza, risk assessment would be facilitated by countries taking a common approach to determining severity, e.g. based on FF100 cases and the work being done by WHO on the Pandemic Influenza Severity Assessment (PISA), as well as standardizing parameters so that modellers can share and compare data. There should also be established sites for

intensive monitoring of the FF100 cases, as this data could be shared and would not be necessary from every country.

Where not currently available, countries should consider establishing systems to routinely monitor outbreaks in institutions, absenteeism from work and schools, as well as web-based self-reporting systems to increase the availability of community level data. Ideally such a system would incorporate the addition of laboratory sampling to estimate accurately the proportion of such cases that have been truly infected. This would provide the MS with the ability to quickly assess the impact of a pandemic at community level, identify implications for essential services and plan response in real-time. Influenzanet is a system to monitor the activity of influenza-like-illness (ILI) via the internet with the aid of volunteers and allows people in 11 countries in the EU to report influenza-like symptoms (52).

Accessing hospital data requires the development of innovative IT systems to collect the required parameters. Data tools are required to automate collection and transfer of data from hospitals, including ICUs. Collaboration with hospital physicians, microbiologists, intensivists, public health physicians and IT specialists are required to agree protocols.

5.5 INFORMATION MANAGEMENT AND LOGISTICS

5.5.1 Current arrangements

Member states, regional and global authorities depend on two sources of data both pre and during a pandemic. The first and most traditional source of data is that of notifiable disease data that is statutorily based and is dependent on notifications of specified diseases from clinicians and in many MS also from laboratories. EU MS collect this data in their own national databases and then forward to ECDC via TESSy and also to the WHO Regional Office for Europe on a specified list of diseases. Increasingly, there is close collaboration between ECDC and WHO to enable a joint data collection for both authorities from the MS, thus avoiding duplication. Secondly, data is collected on events of potential public health concern. These events are reported both to the EWRS and also to WHO through the IHR. Both ECDC and WHO and the websites of many of the national institutes of the MS provide a wealth of information and guidance on preparedness for and management of serious outbreaks and pandemics.

5.5.2 Highlights of best practice, ideal situation in next 5-10 years

Both Sweden and Ireland described strong national databases as examples of best practice for infectious diseases that could be adapted at very short notice to incorporate a new emerging pathogen with pandemic potential. In Ireland data from clinicians on notifiable diseases is merged at a local level with data from laboratories to enable a single data set.

5.5.3 Gaps identified and improvements needs

5.5.3.1 Global level

User friendly platforms are required to promote the collection, analysis, and dissemination of pandemic data and information. At both global and regional level knowledge sharing with MS could be improved. Increasingly MS are unaware of the excellent material that is available from both ECDC and WHO and from the many projects resourced by the commission.

5.5.3.2 Regional level

At the EU level, MS have reported in the case studies in WP2 that data flows in the EWRS can be overwhelming in major events. Simplified data processing and data fusion for decision makers could reduce the cognitive load.

5.5.3.3 National level

Countries generally rely on traditional sources of data (surveillance and laboratory, clinical data) to describe an outbreak, conduct risk assessment and response. Few countries currently have the capacity to predict the evolution or outcome of an outbreak, e.g. by applying mathematical modelling.

There are several gaps in laboratory information management and resulting communication. Registration of samples is not always consistent or clear, which complicates retrospective epidemiological analysis. Sample tracking is also not efficient, as there is no established chain of custody which assures traceability of samples and data. Improvements must also be made with the data request forms; as clinical samples often arrive without all necessary data. Further, paper based systems in regular mail for specimen form and testing results are inefficient and slow. The lack of a tracking and tracing system is a great biosafety risk. With regards to technology, the development of a laboratory information management system (LIMS) to be used in both reach-back and mobile laboratories would improve data storing and sharing issues. An electronic platform for results and data requests could also be added to the LIMS system, or built separately. Such a platform would avoid the mistakes and slow process of a paper-based system. Laboratories must also take advantage of the latest developments of computational power, data transmission and storage needs and develop the use of meta-data, such as

photo, video and positioning data (GIS). While these concerns were expressed in D2.3 in the review of diagnostic technologies and some of the problems identified occurred in mobile laboratories during the Ebola outbreak some problems were also reported from some of the European laboratories.

5.5.4 Overview of ongoing and planned work in other projects

EPIWORK: EPIWORK (2009 -2013) was a project sponsored by the Future and Emerging Technologies program of the European Community aimed at developing the appropriate framework of tools and knowledge needed for the design of epidemic forecast infrastructures. The research considered the development of modelling, computational and ICT tools such as: the foundation and development of the mathematical and computational methods needed to achieve prediction and predictability of disease spreading in complex social systems.

FLUMODCONT: was funded under the specific call for the ‘Development of pandemic influenza containment and mitigation strategies’. As such, it aimed to support development of evidence-based and publicly-acceptable policy, planning and response procedures to mitigate potential impacts of future pandemics. In addition to improving contact and travel patterns in epidemiological models, behavioural responses to epidemics and social acceptance of restriction measure as well as the impact of intervention measures for containment and mitigation were evaluated

ANTIGONE (ANTicipating the Global Onset of Novel Epidemics, from 2011-11-01 to 2016-10-31) seeks to identify key factors involved in understanding underlying mechanisms behind zoonotic pathogens in order to improve prediction modelling and health preparedness.

FLUPLAN: Is a research project aiming at understanding the reassortment phenomena for influenza. Increased knowledge of this mechanism can become a valuable tool for risk assessment and threat analysis.

5.5.5 Innovation and Research needs

A system that can quickly deliver useful predictive data during or before an event is required to provide an informed analysis for policy makers. Such a system would be based on integrated “big data” encompassing a wide spectrum of information feeds. This data Includes demographics, environmental data including vector data, individual and traditional human and animal data sources as well as climactic factors and climate change data.

There is a need for greater use of transdisciplinary one health collaborative research to identify likely scenarios with increased risk of pandemic/high-impact epidemic potential.

Further development of the EWRS could improve visualization and presentation of epidemiological data (including dashboards) at the EU-level during a high impact epidemic or pandemic. Requirement analysis, usability study etc. could be implemented as a demonstrator/pilot for evaluation in a small number of countries. This would enable a common understanding of the decision-making challenges faced by stakeholders, and a suite of customisable decision support tools designed to support stakeholder requirements. Other modelling supports are required in Europe, such as tools and models to estimate requirements for pre-pandemic stockpiling. A flexible resource model, which allows MS to select mild or severe pandemic scenarios and indicates the implications for resource requirements such as antivirals, ICU beds, ventilators etc., could improve pandemic planning capacity in Europe. These type of models are applied in other regions of the world but have not been developed for use in the European region (40). Such an evidence-based tool could be utilized in simulation exercises and training workshops

While the next section reviews issues relating to diagnostics, there is of course a big overlap with information management and diagnostics. Mobile laboratories aim to have diagnostic capacities as close as possible of the patient care unit to perform rapid detection and identification of a pathogen, while respecting quality standards.

Methods need to be developed to integrate the work between mobile laboratories and reach-back facilities. This effort would include mobile data sharing, cloud computation, real-time data processing and innovating task sharing. Mobile laboratories should also increase their use of satellite communications and Global Navigation Satellite Systems (GNSS) data for geo-location. The use of satellite communication tools is a strong asset for mobile laboratories that allow for real-time data transfer.

5.6 DIAGNOSTICS

5.6.1 Current arrangements

In the review of diagnostic technologies, D2.3 described current methodologies for detecting and identifying known pathogenic agents and how serology and PCR are the main used techniques in the case of an outbreak of a new emergent disease. In D2.1 on Threat analysis and scenarios, the importance of biosafety was noted recalling a number of escapes of the SARS pathogen from laboratories in Asia. In the smallpox deliberate release scenario, interaction between European Union's Judicial Cooperation Unit, Europol

and the European Network of Forensic Science Institutes and MS authorities are advised to ensure results can be used during legal prosecution (e.g. accredited sampling and measurement procedures; chain of custody *etc.*).

5.6.2 Highlights of best practice, ideal situation in next 5-10 years

The WHO Guidelines for the collection of clinical specimens during field investigation of outbreaks, WHO laboratory biosafety manual and the Biorisk manual and laboratory biosecurity guidance were mentioned as demonstrating best practice. Concerns were expressed however that many front line workers were not aware of their contents. Most laboratories studied in D2.3 participated in European laboratory networks.

5.6.3 Gaps identified

5.6.3.1 Global level

There were few global laboratory networks identified in D2.3 and the authors considered this a gap in pandemic management. There are a number of EU laboratory networks for emerging and high threat pathogens.

5.6.3.2 Regional level

There is no standard for the communication of results (data produced, type of reported data, communication channels). In the case of a pandemic, there is a need to integrate data from different labs in order to have a global view of the situation for appropriate pandemic management. This is very difficult if the level of information in each report and report formats are different and if communication channels and reporting systems (having each different reporting characteristic) are disparately used.

5.6.3.3 National level

Lack of common laboratory information management system (LIMS) at MS and EU level. If available in some MS, there is no standard program (all have different home-made or commercial solutions).

Lack of biosafety measures at laboratories was identified as a gap. Though all laboratories assessed have decontamination procedures, they vary in terms of methods and agents.

In mobile labs, there is a need to train workers in the prevention of accidents, as well as the proper response when an accident does occur. There is also a lack of training for locally trained individuals in the concept of biosafety. More funding is also needed to develop and maintain capacity in this area.

In the questionnaire study performed by D2.3 no lab reported any robust track and trace system (tracing only by sticker or by specific carrier forms). (Details of the participating

laboratories by country, laboratory type and involvement in laboratory networks are provided in D2.3. This represents a major gap as the transportation of highly infectious material holds biosafety and biosecurity risks. It would be therefore very important to know who has been exposed to the sample during transport (biosafety risk) and to know exactly where the samples are collected (geolocation) and located at all times during transport (biosecurity risk).

In the study the lack of suitable accreditation by some of the participating laboratories is a concern. Many laboratories develop their own tests and without accreditation there is no guarantee about validation and robustness of home-made tests in those laboratories.

5.6.5 Overview of ongoing and planned work in other projects

There are also several other projects in place to improve outbreak and even detection described in D3.2. **EWAMlab** is a project which aims to strengthen capacity to detect and identify infectious disease caused by high threat pathogens (viruses) in countries affected by the 2014 Ebola outbreak. The project **“Mitigating Biological Security Risks in the ASEAN region”** is working to increase the capacity to identify and diagnose pathogens with pandemic potential in the South-East Asian region. **ViroRed** is working to improve and implement diagnostic capabilities for respiratory and vector borne viruses in Latin America, Portugal and Spain. These projects are all funded through member countries of the *Global Partnership Against the Spread of Weapons and Materials of Mass Destruction*, specifically Article X under the Biological and Toxin Convention (BTWC). **MIRACLE: Mobil Laboratory Capacity for the Rapid Assessment of CBRN Threats Located within and outside the EU** was funded in 2013. One aim is to identify the needs and solutions for deployment of a CBRN mobile laboratory in- and outside of the EU. It uses a multidimensional matrix including threat type and societal impact to define scenarios and missions and will undertake a gap analysis to identify improvement actions. The role of national and international regulatory authorities will be assessed for inclusion as CBRN mobile capacity stakeholders. Communication and legal issues will also be investigated.

BIG_IDEA aims to develop a novel framework to analyse sequence data of multiple strain epidemics and focus at closest ancestries among samples instead of most recent common ancestors. This approach would process real time data of ongoing outbreaks and could unveil transmission routes, facilitating the development of prevention strategies.

EVAg: EVAg aims to establish a European network among institutions with virology expertise, facilitating communication between experts and promoting research collaboration.

5.6.6 Innovation and Research needs

There must be an increase in the number of fully-trained workers capable of deployment to European mobile laboratories and a development in training of local lab workers in developing countries, especially in outbreak conditions. Training must involve biosecurity and biosafety and their distinctions, PPE, self-protection and management stress and hazards, and accident avoidance and management.

Other innovations recommended in D2.3 include:

- Development of a secured, traceable, priority and affordable transport of samples.
- Implementation of high-tech and up-to-date equipment in European laboratories [especially “open detection” equipment: electron microscopy, next generation sequencing and matrix assisted laser desorption ionization-time of flight (MALDI-TOF) mass spectrometry].
- Development of more rapid molecular based tests (e.g. genetic testing by isothermal amplification, protein detection on lateral flow) and their implementation in POCT format in order to use them in any environment (patient bedside and reach-back laboratories). The automatic results transmission from POCT to local databases by Bluetooth or Wi-Fi would be an asset.
- *Specific for mobile lab*: Generalise the use of small size true deep sequencing equipment (for instance portable NGS technologies) in the field for rapid unknown threat identification and for epidemiological surveillance (evolution of the pathogen: genetic drift, acquisition of resistance mechanism) during the outbreak.
- Establish procedures to respect a chain of custody ensuring traceability of samples and data from sampling to results communication and sample storage/destruction. This could be an adaptation of the forensic chain of custody developed in the “Generic Integrated Forensic Toolbox (GIFT)” project, taking into account ethics and patient data confidentiality.
- Set-up of electronic platform for sharing the request form and test results, which could be completed online by the requester and by the lab, in order to avoid mistakes linked to the re-transcription of data. This system could be a part of the LIMS or should be linked to it to allow direct and easy information transfer.
- Widen the European implementation of One Health/(my care net) systems to link the lab to patient meta-data (complete patient medical file).

5.7 COMMUNICATION

5.7.1 Current arrangements

Over the past decade, the crucial role of risk communication in pandemic and epidemic control has been increasingly recognized and it has become a specialized area of public health science. Recent Ebola and Zika outbreaks show the importance of early risk communication for outbreak management.

Globally WHO plays a leading role in risk communication on pandemics and epidemics. The WHO emergency risk communication learning course aims to provide WHO Member states with an introductory set of self-use learning material on risk communication for epidemics, pandemics and other health emergencies (53).

In Europe the Communicators network has been set up under the Health Security Committee Decision 1082 /2013/EU of the European parliament and of the Council on serious cross-border threats to health to discuss communication strategies, and with an aim to provide consistent and reliable messages to the citizens, especially during public health crisis situations (54).

D3.3 details examples of processes in selected EU countries. In Sweden, there are detailed plans for communication that were in place even before 2009. Since 2009, the communications department has greatly expanded. The pandemic influenza communications guidelines were written in 2009. An operational plan is currently under preparation. In the UK, there is an outbreak preparedness plan that was developed in 2014 and involves a risk communication strategy. The UK consults risk assessments from ECDC and PHE and these are shared with the media.

Several belief models are mentioned in D3.3 to model health behaviour and design risk communication strategies. The most common ones include the health belief model, health protection theory, risk communications, protection motivation theory, and theory of planned behaviour.

5.7.2 Highlights of best practice, ideal situation in next 5-10 years

An extensive literature review on risk communication in D3.3 looked at best practices in the EU and in specific countries. Risk communication was most effective when messages were tailored to specific groups of the population. A multi-channel approach to communicate clear and consistent messages worked well. Transparent communications and involving the public were valued.

There are several principles with regards to risk communication and governance. Decisions regarding risk communication should follow principles of honesty, stewardship, transparency, openness and be science-based. All decisions on the response should engage civil society and collaborate with national and regional levels. Pandemics involve sectors of government beyond healthcare and should involve different layers of public

administration. Key points included the importance of response partners clearly agreeing on goals and ethical framework for their communications, engaging with the media as early as possible, and planning before the outbreak begins. D3.3 reports that in terms of the IHR, Europe has a high compliance with risk communication as a core capacity compared with other WHO Regions; in 2015, based on self-assessment, 85 % of MS of the WHO European Region reported to WHO to have implemented its risk communications core capacity, which should mean that countries have or are working to acquire a range of skills, establish practices and strategies for using risk communications in outbreak and health emergency settings. Responding to recent global health crises, implementing the IHR and preparing for pandemic influenza, have stimulated the need for specialized training in emergency risk communications. Experts from 28 countries in the European Region were trained to communicate health risks in emergencies. An expert interviewed in D3.3 described how authorities in some European countries are now becoming more open and available to talk to media - more aware that in a globalised world, you need to be ready not only to react to the media, but also to foster relations proactively.

Social media, websites, email and mobile technology are all used for risk communication. Websites updated frequently also allow for the public and expert parties to stay up-to-date on information regarding an outbreak. SMS technology is also an efficient way to spread information quickly.

5.7.3 Gaps identified and Improvement needs

Much of the published literature on risk communication described in the review in D3.3 focuses on the national level and here the biggest gaps were noted to occur in skills required for risk communication.

5.7.3.1 Global level

Continued support to countries to help them to utilize WHO global guidance on outbreak communications is needed, as is research to interpret and understand differences in perceptions and risk amplifications across different countries. Expand research on effectiveness of risk communication.

5.7.3.2 Regional level

D3.3 found that regional stress tests or exercises for communication were useful, though not common enough. Front-line healthcare workers were sometimes not well included or well briefed in the required communications response through their regional networks.

5.7.3.3 National level

The WHO pandemic preparedness checklist deems risk communication as essential for national pandemic preparedness plans. However D3.3 reported that in European countries, understanding and measuring both perceptions and behaviour was a common skills gap among national authorities. Methodologies to identify and target specific groups, monitor public opinion and communicate uncertainties were needed. Decision making tools for risk communications, strategies and messages with pre-tested effectiveness were often absent. The review found that there was not always sufficient numbers of skilled staff available during outbreaks.

5.7.5 Overview of ongoing and planned work in other projects

WHO communications guidelines and training platform available on the WHO website (shortly to be available on the OpenWHO platform for MOOCs;

EU-funded Seventh Framework (FP7) collaborative research projects:

FoodRisC (2010-2013), aimed to produce a toolkit for policymakers, food authorities and others to aid risk communication related to food safety and to improve public understanding in this area (55).

CommHERE (2011-2014) aimed to improve communication on the outcome of EU funded health research projects to the media, the general public and other target groups including the EC in all of Europe. The final evaluation showed mentoring, local networking and outreach to researchers at conferences to be particularly effective, and presented some guidelines for strengthened research communications based on this (56).

TELL ME, 2012-15 aimed to provide evidence and develop models for improved risk communication during infectious disease crises (57). Several members of the TELLME consortium are now part of the [ASSET project](#).

ECOM, 2012-2016 has compiled an evidence based communications package for use in major outbreaks (58). Tools like apps and infographics were developed based on these findings, including a standardised risk perception questionnaire, and a guide to designing a choice experiment around vaccinations examining acceptance under differing conditions of known disease severity, vaccine effectiveness etc. These are used to help measure public opinion during an epidemic.

INfluENCE, 2013 -2015 was funded by the Department of Health in the UK, and aimed to examine the factors behind pandemic vaccine uptake and the communications consequences on the back of the 2009 H1N1 pandemic (59).

PHEME (2014-2017) and **ASSET** (2014-2018) examine respectively the detection of rumours on social media and scientific and societal challenges raised by pandemics (50, 60).

5.7.6 Innovation and research needs

We need to develop a higher quality evidence base to enable better design, monitoring and evaluation of pandemic communication interventions for MS. Public health authorities have limited visibility over social media “outbreaks” of misinformation. Early warning systems for social media disinformation are required to enable mechanisms to react in a timely manner and reassure the general public in relation to myths and unfounded rumours. Competencies must also be developed in promoting messaging that is targeted towards specific populations, rather than general risk communication strategies.

Globally, research needs to be done into how countries, governments and organizations can be most effective, clear and consistent in their messaging. There are also questions of the competing priorities in risk communications, and how one can balance the political, technical, policy and legal pressures on decision-makers. Communications need to be embedded in the response at all levels with adequate and appropriate staff assignments.

On a regional level, regular stress tests on risk communication procedures would allow for better preparedness between countries. Regional networks should also explore how information and updates can be shared to enhance country decision making and best align and/or understand messaging with neighbouring countries.

Research is needed into how the impact of national communications on an outbreak response can be better measured and evaluated using pre-defined methodologies.

5.8 TRAINING/CAPACITY BUILDING

5.8.1 Current arrangements

Both ECDC and WHO provide a range of activities (workshops, training, guidance and manuals) to countries aimed at strengthening pandemic preparedness and response.

Other organisations involved in training include: Associations of Schools of Public Health in the EU Region (ASPHER), Centre for Health Sciences Training, Research and Development (CHESTRAD), Global Health Action (GHA), Institute for International Medical Education (IIME), Training Programs in Epidemiology and Public Health Interventions Network (TEPHINET), World Federation for Medical Education (WFME), European Union Institute for Security Studies (EUISS). The European Programme for Intervention Epidemiology Training (EPIET) and the European Public Health Microbiology Training Programme (EUPHEM) are 2-year training fellowship programmes co-ordinated through ECDC and highly valued as demonstrated by the high number of applicants for each place.

5.8.2 Highlights of best practice, ideal situation in next 5-10 years

The WHO Regional Office for Europe evaluation of the usefulness of pandemic preparedness in the response to the 2009 pandemic demonstrated that countries found a range of activities highly useful - the planning process itself, participation in meetings, workshops, network meetings and trainings organized by ECDC and WHO, ECDC and WHO guidance and guidance developed by countries.

5.8.3 Gaps identified and improvements needs.

It has proven difficult to map the current capacities and capabilities in pandemic and epidemic preparedness and response across Europe. Efforts by ECDC to identify training gaps were frustrated by differing terminologies, structures and systems in European member states. There is a high and often unmet demand for places in ECDC summer schools and both WHO and ECDC courses

5.8.3.1 Global level

One of the key problems identified in the case studies was the difficulty that global institutions have in ensuring that the guidance they produce reaches, and is utilised by, the first line responder or Health Care Workers.

3.8.3.2 Regional level

As stated in D3.1 at the EU and Member State level, states are required to regularly provide the EC with an update of their preparedness and response planning at the national level, in accordance with the implementation of the IHR (IHR core capacities), interoperability between the health sectors and other sectors, and business continuity plans containing details on planning, response and recovery through all stages of a pandemic. However, cooperation and coordination between Member States and agencies could be improved and strengthened (i.e., country specific assessment of preparedness, cross-border exercises, coordinated funding, implementing a shared IT-platform to facilitate information flow among stakeholders, etc.). D4.1 urged WHO and the EC to support MS to meet their obligations. Indeed this is now being developed by WHO as part of the joint external evaluations on the implementation of the IHRs.

New efforts to map capacity and capabilities in Europe are required to address the unequal resource allocation across Europe. As mentioned in section 5.4.6, training should include how to conduct rapid risk assessment.

5.8.3.3 National level

Gaps identified D2.2 “Analysis of risk assessment and surveillance: current systems, practices, technologies and research needs” included training of medical students and qualified clinicians in relation to requirements of IHR and the need to report any events causing public health concern to the appropriate public health authorities. Similarly, it was mentioned that there is a need to conduct regular, cross-sectional exercises, as this would have the benefit of both training individuals in event detection and connect experts before an event should occur. Joint civil-military exercises including cross border events would improve inter-sectoral working. A particular concern was expressed in relation to rare diseases including CBRN and diseases such as smallpox, where unfamiliarity with the presenting signs and symptoms may cause a delay in diagnosis and alerting of the authorities. This can result in nosocomial and community spread in the absence of the required infection control procedures.

As stated in D2.3, laboratory workers also need to be trained in issues related to biosafety and biosecurity. In European laboratories, more up-to-date, high-tech equipment needs to be implemented, such as MALDI-TOF, and the speed of generic diagnostic methods should be improved. Rapid molecular based tests are needed, as well as their implementation in POCT format for application in the field. Training in the use of these new technologies should be facilitated through laboratory networks. Training in containment, inactivation and decontamination procedures needs to be improved.

D4.2 highlighted the need for guidance on how to implement the ethical commitments and principles in ethical frameworks. Similarly, D4.1 highlighted the requirements for training in public health law, including the obligations implicit in Decision 1082.

5.8.4 Overview of ongoing and planned work in other projects

TELL ME, 2012-15 aimed to provide evidence and develop models for improved risk communication during infectious disease crises (57). It has developed 2 e-learning courses for health care workers. D4.1 describes the CELESTE project which facilitates exchange of information and expertise between specialists in Public Health law.

PREPARE (Platform for European Preparedness Against (Re-) emerging Epidemics) is establishing a European clinical research framework for harmonised large-scale clinical research studies on infectious diseases, prepared to rapidly respond to any severe ID outbreak, providing real-time evidence for clinical management of patients and for

informing public health responses. It does incorporate a training element (virtual learning centre) on its website (www.prepare-europe.eu) including powerpoints from conferences and publications. PREPARE is funded by the European Commission's FP7 and has formally commenced its activities on 1 February 2014.

5.8.6 Innovation and Research needs

D2.2 proposed the development of online and e-learning resources for training of health care professionals and first responders. Linking these to continuing professional development requirements in the MS would encourage early adoption. Serious gaming was also suggested as a user friendly and innovative method for training. This has the added advantage of enabling training to take place without the added cost of travel and could be translated into commonly used languages. Joint public health and military exercises with cross border components should be developed and implemented. Systems and structures to allow training in public health law are required.

6. PANDEM MATRIX - PRIORITIZATION OF IMPROVEMENT NEEDS AND POSSIBLE SOLUTIONS

Following extensive review and analysis of the outputs of previous deliverables, outcomes of PANDEM workshop(s) and review of the literature and of current practice, the PANDEM consortium developed a matrix to prioritise identified gaps, describe possible solutions and their potential impact and ideal situation within the next 5-10 years. The gaps identified in the previous deliverables and from the matrix are presented below. During the discussions and literature review new gaps and potential solutions became apparent and these are also included in this section. These gaps and possible solutions were presented to the workshop in September and further refined at that meeting.

The project aims at producing generic solutions i.e. not disease specific but taking aboard any disease or even unknown new ones (unless specified otherwise). The basic criteria for selection of research topics (i.e. potential research projects for phase II demonstration project) were as follows:

- Fulfils a clear gap/need by EU and MS
- Likely to achieve useful results within the budget available
- Topic supports capacities of MS to respond to cross-border threats to health. Topic not already covered, or only partially, by EC, ECDC or WHO, or by other EU-funded projects
- Impact defined in terms of: reducing mortality, morbidity, socio and economic and security consequences of the next influenza pandemic or large scale outbreak.

TOPIC 1 SURVEILLANCE & INFORMATION MANAGEMENT

1.1 Interactive resource modelling tool

CURRENT GAPS: Tool to estimate requirements for pre-pandemic stockpiling and lack of understanding of implications of resource shortages in the response.

POSSIBLE SOLUTIONS: Flexible tool that incorporates different pandemic scenarios eg. Mild, moderate or severe, and indicates the implications for resource requirements such as antivirals, hospital and ICU beds, Ventilators etc.

POTENTIAL IMPACT: A resource planning tool would enable MS to prepare for surges in resource demands during future pandemics and large scale outbreaks.

IDEAL SITUATION WITHIN 5-10 YEARS: Evidence-based tool available for estimation of demands for policy makers and for use in simulation exercises.

1.2 Integrated predictive modelling tool incorporating One Health disciplines

CURRENT GAPS: Analysis of possible development of an epidemic is based on information from traditional sources (sentinel, laboratory). Predictive information is often missing or showing a wide variation of possible outcomes.

POSSIBLE SOLUTIONS: Transdisciplinary collaborative research used to identify multiple data sources to produce likely scenarios with likely developments of an ongoing pandemic/high-impact epidemic.

POTENTIAL IMPACT: Provision of information to implement countermeasures in an efficient way during a pandemic and flatten the epidemic curve. Give a baseline to enable identification of the most efficient measures and later evaluation of measures used.

IDEAL SITUATION WITHIN 5-10 YEARS: System that can quickly deliver useful predictive data during an event. Based on an integrated “Big Data” system encompassing wide a spectrum of information feeds. Includes demographics, environmental data including vector data, individual and traditional data sources.

1.3 Community-based surveillance

CURRENT GAPS: Lack of baseline knowledge of community level data and information on impact of a pandemic. Little data available on people who do not seek health care. Poor capacity to estimate and monitor spread of infection and impact on essential services in society.

POSSIBLE SOLUTIONS: People-friendly platforms to promote the collection, analysis, and dissemination of pandemic data and information. Identify methodology, data sources available and determine feasibility/usefulness in different MS. Include Absenteeism work and schools. Addition of laboratory sampling to estimate the impact.

POTENTIAL IMPACT: Enables rapid risk assessments and estimate of impact of a new threat and thereby enables best possible use of counter measures.

IDEAL SITUATION WITHIN 5-10 YEARS: Ability by all MS to quickly assess impact of a pandemic at community level, identify implications for essential services and plan response in real-time.

1.4 Visual Analytics

CURRENT GAPS: Lack of common tool for visualization and presentation of epidemiological data (including dashboards) at EU during a high impact epidemic or pandemic. Current data flows can be overwhelming in major events.

POSSIBLE SOLUTIONS: Analysis of current data sharing in place strengths and weaknesses. Software design, implementation, maintenance planning legal issues etc. Constant monitoring and situational awareness, dynamic adaptability to the evolving situation, real time information sharing, linked data approach. Requirement analysis, usability study etc. could be implemented as a demonstrator/pilot for evaluation in a small number of countries.

POTENTIAL IMPACT: Provides MS with a common situational awareness tool, enabling better and faster communication and improved decision making. Simplified data processing and data fusion for decision makers, thus reducing cognitive load.

IDEAL SITUATION WITHIN 5-10 YEARS: Common data visualization tool to be used by all MS and system to enable appropriate access of outputs at all levels and across all sectors.

1.5 Surveillance of severe infections

CURRENT GAPS: Key recommendation post 2009 pandemic is to improve the timeliness of data collection and analysis on the severity of a pandemic/high impact epidemic. Utilization of intensive care resources recognized as an unforeseen bottle neck in the management of a pandemic. Data needed to optimise use of scarce resources.

Accomplished by measuring proportion of cases hospitalized, admitted to intensive care, or died.

POSSIBLE SOLUTIONS: Data tools are required to automate collection and transfer of data from hospitals, especially ICUs. Collaboration with hospital physicians, microbiologists, intensivists, public health physicians and IT specialists to agree protocols. Problems re data sharing pre-publication need to be explicitly addressed.

POTENTIAL IMPACT: Better decision making by senior policy makers at global regional and national levels enabling a flexible and proportionate response to the event in real-time. Better use of intensive care resources which would save lives.

IDEAL SITUATION WITHIN 5-10 YEARS: Tools in place for a timely analysis of the severity of the event to enable a proportionate response by decision makers. Possibility to follow utilization of critical resources in health care to maximize use of these resources.

1.6 Contact tracing

CURRENT GAPS: Currently many EU countries lack advanced data management tools for contact tracing that would link data at local, national and international levels, and also confirmed laboratory results.

POSSIBLE SOLUTIONS: Data tools are required incorporating GIS, audit and performance management of follow-up of appropriate contacts. Legal aspects on quarantine management and on sharing data needs to be further clarified.

POTENTIAL IMPACT: Timely interventions on individual level with prophylaxis, quarantine, isolation and treatment to limit expansion of the high-impact epidemic/pandemic.

IDEAL SITUATION WITHIN 5-10 YEARS: Procedures in place for timely management at local level coupled with audit at local and national level, potential to effectively do cross-border contact tracing.

1.7 Development of a laboratory information management system (LIMS)

CURRENT GAPS: Lack of common LIMS at MS and EU level. If available in some MS, no standard program (all have different home-made or commercial solutions).

POSSIBLE SOLUTIONS: Can be used in both reach-back and mobile laboratories. Linked to other lab programs (sample tracking system, analytical programs) for direct and easy information transfer. Development of the ontology to unify operational functions from different stakeholders and to align the terminology.

POTENTIAL IMPACT: Better management system will have positive impact on laboratories turn-around-time. Improvement and harmonisation of data recording will facilitate data sharing and data analysis.

IDEAL SITUATION WITHIN 5-10 YEARS: LIMS available on-line with specific restricted access. The LIMS will be compatible with the information systems of other stakeholders (e.g., other laboratories, field hospitals) and will be integrated that the information sharing process is harmonized and transmission of relevant data facilitated. Harmonisation and alignment of terminology will be ensured by the ontology.

1.8 Sample tracking and tracing (from sampling to storage/destruction)

CURRENT GAPS: Lack of system for the tracing of samples from sampling to storage. Poor tracing - if any - during transport, and disparate methods for sample tracing in the laboratory. Security and preservations of samples is not guaranteed.

POSSIBLE SOLUTIONS: Effective transport mechanisms for samples to improve securitisation and tracking. Transport conditions ensured for sample preservations. Tracking of samples during transport. Information system integrating tracking system to the LIMS.

POTENTIAL IMPACT: Securitisation and tracking of sample during transport will enhance biosecurity. Prevention of loss or theft during transport. More affordable transport will increase material sharing, which is crucial for new test development and validation. Better transport conditions will increase/preserve quality of the shared material (important for appropriate identification of unknown agent or for test development).

IDEAL SITUATION WITHIN 5-10 YEARS: Barcoding, RFID tagging of all the samples and/or geolocation using GPS data. Secured, traceable, prioritised and affordable transport of the samples.

1.9 Risk-assessment

CURRENT GAPS: Rapid risk assessments are provided by WHO and ECDC and then utilized and adapted by individual countries. Usefulness is appreciated - utilization unknown. Currently no system to resolve conflicts in messages.

POSSIBLE SOLUTIONS: Coordination of template sharing and development and implementation of an agreed upon risk assessment template. Create project that collects and collates templates and produces a draft model template. Develop plan for implementation.

POTENTIAL IMPACT: Easy and quick communication and interpretation of risk assessments and saved resources by avoiding duplication of work.

IDEAL SITUATION WITHIN 5-10 YEARS: Risk assessment templates have been shared and a model template that is easy to use and interpret between countries is being applied e.g. within EU/EEA.

TOPIC 2 COMMUNICATIONS

2.1. Develop a higher quality evidence base to enable better design, monitoring and evaluation of pandemic communication interventions for MS

CURRENT GAPS: Overall lack of high quality evidence about how, why and what works best in field of communication. Targeting specific groups can be difficult, given lack of baselines and prior systematic knowledge. Value of communications not as widely acknowledged as other areas of pandemic response. Lack of high quality evidence and monitoring prompts a vicious cycle, as difficult to prove efficacy of interventions to secure investment. Pre-testing and measurement to be able to effectively monitor impact of pandemic communications.

POSSIBLE SOLUTIONS: Designing interventions and understanding the different variables for success would enable MS to design better interventions Communications acknowledged as core component of pandemic response.

POTENTIAL IMPACT: Communications acknowledged as core component of pandemic response MS communicators would also be able to systematically report on the impact of their communications interventions, which they cannot currently do. This could have high impact in the long term, but could face a lag time between research and implementation.

IDEAL SITUATION WITHIN 5-10 YEARS: A higher quality scientific evidence base showing the variables for effective communication interventions, including baselines and protocols established before the event itself.

2.2. Making better use of evidence from social and behavioural science for pandemic communications

CURRENT GAPS: Often instructions from authorities are not engaged with or acted upon by populations. Difficult to target at risk groups without tailored approaches. Behavioural, social science and anthropology are not often integrated in the design of communications interventions.

POSSIBLE SOLUTIONS: Social science expertise in outbreak communications staff, and recognition of how important this is by wider pandemic community. Better dissemination

of existing and new guidelines including multidisciplinary one health and all hazard approach

POTENTIAL IMPACT: Higher community engagement with pandemic responses and greater uptake of protective behaviours. This could achieve very high impact in a pandemic/high-impact epidemic setting, but would need to be prepared beforehand and begin early on.

IDEAL SITUATION WITHIN 5-10 YEARS: Pandemic communications bring about effective behaviour change that can be measured and analysed in terms of impact.

2.3. Enabling risk communications principles to be better used in pandemic communications, including on social media / digital tools

CURRENT GAPS: International guidance on risk communication widely known, but not often enacted. Communicators often fail to follow risk communications principles, creating lack of trust when they are found to have been over-confident or to not have revealed full details to the population upon request.

POSSIBLE SOLUTIONS: Authorities listening to communities. Greater use of feedback mechanisms and tools for monitoring risk perception and other elements of risk communications during outbreaks. The relevant skills or decision-making structures that would allow principles to be implemented in place in all MS and specially trained risk communicators embedded in emergency response / all hazard function. Political concerns do not compromise the communication of uncertainty. Engage with top level EG PM department at an early stage.

POTENTIAL IMPACT: Greater trust and openness between public and authorities. Public feel more listened to, and become more resilient against panic and misinformation. Principles of risk communication already exist and are well known and guidance exists, meaning that impact could be achieved on a shorter timescale.

IDEAL SITUATION WITHIN 5-10 YEARS: Governments and other pandemic responders confident and effective at communicating uncertainty, communicating early, and listening to communities. Risk communication is an ongoing act of community engagement and participation, even at times of low threat, allowing the public to become familiar with decision-making processes and principles. High public health literacy through engagement. Risk communication function embedded at all levels from at Prime Minister departmental Level down to local level

2.4 System to identify in peacetime key trusted communicators during pandemic/major epidemic

CURRENT GAPS: Family doctors and other front line workers often giving contradictory messages.

POSSIBLE SOLUTIONS: Identified trusted HCWs can be used as conduit for risk communication messages.

POTENTIAL IMPACT: Disconnect between messages from policy makers and frontline will be overcome by engaging and listening to concerns of HCWs on the ground.

IDEAL SITUATION WITHIN 5-10 YEARS: Less contradictory messages.

TOPIC 3. GOVERNANCE

3.1 Model Legal framework for Pandemic Response

CURRENT GAPS: Inadequate legal underpinning for proposed pandemic control measures in many MS. Incoherent response across member states and some legislation may be outdated and/or in breach of ECHR.

POSSIBLE SOLUTIONS: Updated national legislation to underpin planned public health measures. Authority for potential emergency measures including protection for individual human rights. Research will require an initial detailed mapping (inventory) of the status of national planning and underlying legislation in 28 member states. A feasibility study will follow re a model framework. This will then enable the development of a model framework in collaboration with MS. Research is also required on public acceptability of proposed measures.

POTENTIAL IMPACT: Clarity of response within and across MS which provides legal authority and safeguards to both public health authorities and individual citizens. Adoption of modern international frameworks into national legislation.

IDEAL SITUATION WITHIN 5-10 YEARS: Model Act which is flexible enough to be used in different legal systems and which provides guidance for national emergency legislation with safeguards for individual rights.

3.2 Increasing trust in PH institutions

CURRENT GAPS: Research would include developing an understanding of levels of trust in PH institutions, where challenges, exist, and what their implications are in relation to pandemic preparedness and response. Recognised potential problem of loss of public trust in public health institutions and spokespeople. Public trust is essential in an emergency to ensure compliance and support for response measures. At the same time there is a lack of ethical and/or human rights input in pandemic planning.

POSSIBLE SOLUTIONS: Management and resolution of loss of public trust and confidence in public health authorities. Ensuring that ethics and protection of human rights is at the heart of pandemic preparedness and response planning. Clear plans on how to reach marginalised populations.

POTENTIAL IMPACT: Greater public trust and cooperation will make public health response more effective and ethically acceptable. Less risk of public panic which can undermine measures. The process of collaborating with stakeholders to develop an EU Ethical Framework will encourage greater transparency and trust.

IDEAL SITUATION WITHIN 5-10 YEARS: Increased public trust, knowledge of, and involvement in pandemic response planning. An EU Ethical Framework which has been developed following a European-wide collaborative process, which is used by MS and which has public support and understanding.

3.3 Defining the EU's international governance role in pandemics

CURRENT GAPS: The role and responsibilities of the EU and its institutions in relation to global governance is unclear, as seen in the response to the recent Ebola outbreak. Current structures are primarily inward-facing. This is inappropriate for humanitarian reasons and because future public health threats are likely to come from outside Europe.

POSSIBLE SOLUTIONS: Clarity, outward-looking institutions, when future health threats are likely to arise beyond Europe. A clear declaration would provide a mandate for EU agencies and structures to respond beyond Europe.

POTENTIAL IMPACT: A declaration would be a statement of ethical and practical principles to support international emergency response.

IDEAL SITUATION WITHIN 5-10 YEARS: Clarity on the role and responsibilities of the EU in the event of an international public health emergency. This might involve a widening of the mandate of current EU agencies.

Possible new topic:

3.4 Investment model for preparedness and response (based on principles of good governance).

CURRENT GAPS: Needs to be determined by literature review. Currently some important systems not securely funded (e.g. Euro Momo). Cases needs to be made for investment in these systems and in preparedness in general. Investment case for risk communication.

POSSIBLE SOLUTIONS: Development of investment models for different threats. This would need to link epidemiological transmission modellers to economists and frame resource allocation scenarios based on existing and potential governance arrangements.

POTENTIAL IMPACT: Countries able to respond more effectively to threats.

IDEAL SITUATION WITHIN 5-10 YEARS: Increased investment in preparedness, better use of scarce resources.

3.5 Involvement of local level and all sectors in preparedness planning

CURRENT GAPS: National plans are not known, accessible at all levels. Lines of communication missing. Roles and responsibilities at local level unclear.

POSSIBLE SOLUTIONS: Involve and promote use of pandemic/all hazard plans Exercise as M&E tool.

POTENTIAL IMPACT: Improved understanding of key elements of pandemic planning at all levels.

IDEAL SITUATION WITHIN 5-10 YEARS: All levels have developed suitable plans based on the over-arching national and international plans

3.6 Interdisciplinary co-ordination

CURRENT GAPS: One health approach not always considered.

POSSIBLE SOLUTIONS: Interdisciplinary tools, legislation SOPs EOC National Coordinating body to include one health.

POTENTIAL IMPACT: Greater involvement of whole of society to pandemic planning and response.

IDEAL SITUATION WITHIN 5-10 YEARS: All stakeholders in different sectors understand the role they will play in a pandemic.

TOPIC 4. TRAINING/ CAPACITY BUILDING

4.1 E- Learning and Game-based Learning (Immersive Training Technology for pandemic preparation)

CURRENT GAPS: Knowledge gap particularly among first responders / clinicians / lab workers/ public health physicians/ communications staff etc. in relation to rare causes of infectious disease pathogens (including CBRN). Delayed outbreak detection with consequent poor infection control leading to disease amplification Training is required on appropriate steps to take (who to tell, what infection control precautions to take, etc.) Training for clinicians on appropriate interpretation of diagnostics. Current training systems require significant hands-on interventions, which serve as a resource bottleneck in terms of rapid knowledge transfer.

POSSIBLE SOLUTIONS: E-Learning and Game based Learning Reinforcement of multisectoral approach with health and defence sectors and include ethical and legal dimensions. E-Learning could also target the public. Populations understand why measures such as surveillance, quarantine, social distancing, mass interventions (e.g. vaccination, chemoprophylaxis) are necessary.

POTENTIAL IMPACT: Early recognition of rare diseases. Getting ahead of the outbreak curve and improved resilience in fighting EID. Reduction in transmission and improved morbidity and mortality outcomes.

IDEAL SITUATION WITHIN 5-10 YEARS: More timely ascertainment of rare diseases to enable early intervention. Immersive collaborative gaming technologies can be used to rapidly train and upskill front line health practitioners. Certificates and continuing professional development points can incentivize participation and be used for audit purposes. Certification could be provided through international organisations such as EUPHA.

4.2 Capacity and Capability Mapping

CURRENT GAPS: Resources and skills are unevenly distributed across EU countries. Even the most well -resourced MS struggle at times of epidemics.

POSSIBLE SOLUTIONS: No mapping currently available.

POTENTIAL IMPACT: Reduction in inequalities of planning and response capacity across Europe.

IDEAL SITUATION WITHIN 5-10 YEARS: Public Health infra-structure is mapped and countries can prioritise allocation of resources (staff and training) based on accurate description of gaps. This includes ensuring adequate communications, legal, ethical resources embedded at all appropriate levels and phases of the planning and response processes.

4.3. Capacity building (training) in public health law across EU member states***

CURRENT GAPS: Very few public health lawyers in Europe and policy documents (e.g. national plans) being drafted by public health specialists without input from lawyers or ethicists.

POSSIBLE SOLUTIONS: Limited knowledge of public health legislation among policy makers. Limited or no knowledge of public health issues among lawyers. Need for public health law expertise to guide policy in each MS.

POTENTIAL IMPACT: Increased legal capacity which will lead to sounder national legislation, and across Europe, better cross-border understanding, coordination and coherence.

IDEAL SITUATION WITHIN 5-10 YEARS: A pool of public health lawyers in each member state forming part of a coordinated network across Europe. This network is being set up under decision 1082.

4.4 Knowledge Sharing Repository for outputs from key projects

CURRENT GAPS: Learning from Projects often lost after projects finish. Also not available to all as not translated into MS languages.

POSSIBLE SOLUTIONS: Repository which is maintained and updated with long term funding. Existing guidance needs better dissemination.

POTENTIAL IMPACT: Better use of project material by Member States

IDEAL SITUATION WITHIN 5-10 YEARS: MS have immediate access to portal that enables easy retrieval of work of previous projects

4.5 Translation of lessons learned into actions

CURRENT GAPS: Currently no systematic methodology to follow up assessments.

POSSIBLE SOLUTIONS: Development of a strategy to ensure incorporation of lessons into identifiable actions.

POTENTIAL IMPACT: Quality improvement seen in pandemic / major epidemic management.

IDEAL SITUATION WITHIN 5-10 YEARS: Systems in place to ensure recommendations from reviews have been followed and implemented subject to prioritisation by the MS.

4.6 Risk communication training

CURRENT GAPS: Lack of RC planning.

POSSIBLE SOLUTIONS: Support MSs with guidance and mentoring and template to developing implementing and measuring RC plans.

POTENTIAL IMPACT: Improved adherence to effective interventions as public understand and appreciate the rationale of responses initiated by their governments

IDEAL SITUATION WITHIN 5-10 YEARS: Well trained cadre of risk communicators supporting pandemic planning and response in all EU MS.

TOPIC 5. LOGISTICS

5.1 Optimal design of Pandemic Supply Chains at EU or MS level?

CURRENT GAPS: Improvements and coordination amongst EU MS possible, with excessive operational pressure on current delivery systems.

POSSIBLE SOLUTIONS: Reduce the time taken to fulfil order requirements for pandemic response products (PPE, anti-virals, vaccines).

POTENTIAL IMPACT: Reduce cycle times, greater availability of key resources, cost efficient and flexible capacity.

IDEAL SITUATION WITHIN 5-10 YEARS: Pandemic response aligned with key stakeholders, and additional capacity and requirements met through innovative ways.

5.2 Procurement platform

CURRENT GAPS: Inadequate knowledge of common procurement policies/ problems across EU MS.

POSSIBLE SOLUTIONS: Better implementation of Decision 1082 on joint procurement.

POTENTIAL IMPACT: More secure and cost-effective access to vaccine and pandemic supplies.

IDEAL SITUATION WITHIN 5-10 YEARS: Inequalities in relation to vaccine access will be reduced across EU MS.

TOPIC 6. DIAGNOSTICS

6.1 Rapid diagnostic test (RDT) / point-of-care testing (POCT) and new sequencing technologies

CURRENT GAPS: Most current POCT are simplex (only one target), however one syndrome can be caused by more than one agent (need to test for all agents causing the syndrome). This is a general gap evidenced during the Ebola and again during the Zika outbreak.

POSSIBLE SOLUTIONS: Emerging diagnostic tools enabling a rapid and thorough characterization of existing and new emerging agents (e. g. new sequencing technologies coupled with rapid bed-site diagnostic tests).

POTENTIAL IMPACT: This will decrease the time needed for pathogen identification. Therefore accelerate the gathering of Information necessary for decision making (risk assessment, clinical management of patients,...).

IDEAL SITUATION WITHIN 5-10 YEARS: Having multiplex RPD/ POCT targeting the most prevalent agents and use as a screening test before using more expensive and sophisticated resources. Used in deployable analytical capacity as a help when the diagnosis does not confirm the target-like disease / syndrome.

7. CONCLUSIONS AND NEXT STEPS

The PANDEM consortium has identified a number of key gaps in European preparedness for pandemics and serious epidemics across the various targets of PANDEM enquiry and analysis. These gaps and potential solutions have been further discussed in a second workshop in Brussels in September 2016 with key stakeholders and priorities agreed which will be addressed in the next phase of the PANDEM project.

This body of work forms the basis of and will assist the development of an integrated solution specification (D5.3) and identification of demonstrator concepts (D6.2) and development of a road map and implementation plan (D6.3) to be presented for Phase II.

As demonstrated in this review new and emerging infectious diseases pose threats which transcend geopolitical boundaries and therefore require efficient and effective responses. The solutions and demonstrator concepts will help steer the European Member States in this direction.

8. REFERENCES

Bibliography

1. Sands P M-SC, Dzau VJ. The Neglected Dimension of Global Security – A Framework for Countering Infectious-Disease Crises. NEJM. 2016;374(13):1281-7.
2. WHO Report from the Director-General to the 64th World Health Assembly. Implementation of the International Health Regulations (2005) Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009 Report by the Director-General. 2011.
3. Fineberg HV. Pandemic Preparedness and Response – Lessons from the H1N1 Influenza of 2009. NEJM. 2014;370(14):1335-42.
4. GHRF Commission (Commission on a Global Health Risk Framework for the Future). The neglected dimension of global security: A framework to counter infectious disease crises.
5. Gostin LO, Hodge JG, Jr. Zika virus and global health security. Lancet Infect Dis. 2016;16(10):1099-100.
6. Bezirtzoglou C, Dekas K, Charvalos E. Climate changes, environment and infection: Facts, scenarios and growing awareness from the public health community within Europe. Anaerobe. 2011;17(6):337-40.
7. Report JEW. CHIKUNGUNYA IN ITALY
Joint ECDC/WHO visit for a European risk assessment 17 - 21 September 2007. 2007.

8. Delisle E, Rousseau C, Broche B, Leparç-Goffart I, L'Ambert G, Cochet A, et al. Chikungunya outbreak in Montpellier, France, September to October 2014. *Euro Surveill.* 2015;20(17).
9. European Centre for Disease Prevention and Control. Dengue outbreak in Madeira, Portugal, March 2013.; 2014. Report No.: 978-92-9193-564-2.
10. Tomasello D, Schlagenhauf P. Chikungunya and dengue autochthonous cases in Europe, 2007-2012. *Travel Med Infect Dis.* 2013;11(5):274-84.
11. WHO. Guidance for Managing Ethical Issues in Infectious Disease Outbreaks. Spain2016.
12. Greco D SE, Marks G. Review of ECDC's response to the influenza pandemic 2009-2010. Stockholm: ECDC; 2011. Stockholm, August 20112011.
13. WHO Regional Office for Europe LJ-G, Michala Hegermann-Lindencrone, Caroline Sarah Brown, University of Nottingham, Ahmed Hashim, Ian Shaw, Jonathan Nguyen-Van-Tam. Recommendations for Good Practice in Pandemic Preparedness Identified through evaluation of the response to pandemic (H1N1) 2009.
14. Health Protection Agency Assessment Report on the EU-wide Response to Pandemic (H1N1) 2009 (TOR1). Health Protection Agency United Kingdom; 2010.
15. European Medicines Agency. Pandemic report and lessons learned Outcome of the European Medicines Agency's activities during the 2009 (H1N1) flu pandemic. 2011.
16. . Decision No 1082/2013/EU of the European Parliament and the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC:.
17. Council of the European Union. Council conclusions on Lessons learned from the A/H1N1 pandemic - Health security in the European Union. Brussels, September 2010; 2010.
18. WHO. WHO Pandemic Influenza Risk Management.
19. WHO. WHO/Europe | Influenza - Plans revised after 2009 pandemic [Available from: <http://www.euro.who.int/en/health-topics/communicable-diseases/influenza/pandemic-influenza/pandemic-preparedness/national-preparedness-plans2/new-plans-revised-after-2009-pandemic>.
20. WHO. Report of the Ebola Interim Assessment Panel. WHO.
21. UN Report of the High-level Panel on the Global Response to Health Crises. Protecting Humanity from Future Health Crises. 2016.
22. Director General WHO. Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response. 2016.
23. Moon S, Sridhar D, Pate MA, Jha AK, Clinton C, Delaunay S, et al. Will Ebola change the game? Ten essential reforms before the next pandemic. the report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola. *The Lancet.* 2015;386(10009):2204-21.
24. Quaglio G, Goerens C, Putoto G, Rubig P, Lafaye P, Karapiperis T, et al. Ebola: lessons learned and future challenges for Europe. *The Lancet.* 2016;Infectious diseases. 16(2):259-63.
25. WHO. Reform of WHO's work in health emergency management [Available from: http://www.who.int/about/who_reform/emergency-capacities/RC_Reform-who-work-health-emergency-management-en.pdf.
26. WHO. Recommendations to WHO on its work in health emergencies and WHO's response to those recommendations [Available from: http://www.who.int/about/who_reform/emergency-capacities/emergencies-recommendations-response.pdf
27. WHO. ADVISORY GROUP ON REFORM OF WHO'S WORK IN OUTBREAKS AND EMERGENCIES First report [Available from: http://www.who.int/about/who_reform/emergency-capacities/advisory-group/first-report.pdf?ua=1.

28. WHO. ADVISORY GROUP ON REFORM OF WHO'S WORK IN OUTBREAKS AND EMERGENCIES Second report [Available from: http://www.who.int/about/who_reform/emergency-capacities/advisory-group/second-report.pdf?ua=1].
29. WHO. JOINT EXTERNAL EVALUATION TOOL INTERNATIONAL HEALTH REGULATIONS (2005).
30. DG ECHO. European Medical Corps 2016 [Available from: http://dppi.info/sites/default/files/DG_ECHO_European_Medical_Corps.pdf].
31. Hine DD. The 2009 Influenza Pandemic An independent review of the UK response to the 2009 influenza pandemic. 2010.
32. Lipsitch M, Finelli L, Heffernan RT, Leung GM, Redd SC. Improving the evidence base for decision making during a pandemic: The example of 2009 influenza A/H1N1. *Biosecurity and Bioterrorism*. 2011;9(2):89-115.
33. Al-Tawfiq JA, Zumla A, Gautret P, Gray GC, Hui DS, Al-Rabeeh AA, et al. Surveillance for emerging respiratory viruses. *Lancet Infect Dis*. 2014;14(10):992-1000.
34. Eames KT, Brooks-Pollock E, Paolotti D, Perosa M, Gioannini C, Edmunds WJ. Rapid assessment of influenza vaccine effectiveness: analysis of an internet-based cohort. *Epidemiol Infect*. 2012;140(7):1309-15.
35. Chaintoutis SC, Dovas CI, Papanastassopoulou M, Gewehr S, Danis K, Beck C, et al. Evaluation of a West Nile virus surveillance and early warning system in Greece, based on domestic pigeons. *Comp Immunol Microbiol Infect Dis*. 2014;37(2):131-41.
36. European Centre for Disease Prevention and Control/WHO Regional Office for Europe. West Nile virus infection outbreak in humans in Romania, 2010.2011.
37. Goddard NL, Delpech VC, Watson JM, Regan M, Nicoll A. Lessons learned from SARS: The experience of the health protection agency, England. *Public Health*. 2006;120(1):27-32.
38. Buchholz B MD, M.P.H., Helen Bernard, M.D., Dirk Werber, D.V.M., Merle M. Böhrer,, Cornelius Remschmidt MD, Hendrik Wilking, D.V.M., Yvonne Deleré, M.D., Matthias an der Heiden, Ph.D., Cornelia Adlhoch, D.V.M., Johannes Dreesman, Ph.D., Joachim Ehlers, D.V.M., Steen Ethelberg, Ph.D., Mirko Faber, M.D., Christina Frank, Ph.D., Gerd Fricke, Ph.D., Matthias Greiner, D.V.M., Ph.D., Michael Höhle, Ph.D., Sofie Ivarsson, M.Sc., Uwe Jark, D.V.M., Markus Kirchner, M.D., M.P.H., Judith Koch, M.D., Gérard Krause MD, Ph.D., Petra Lubber, Ph.D., Bettina Rosner, Ph.D., M.P.H., Klaus Stark, M.D., Ph.D., and Michael Kühne, D.V.M., Ph.D. German Outbreak of *Escherichia coli* O104:H4 Associated with Sprouts. *NEJM*. 2011;365(19):1763-70.
39. Broberg E, Nicoll A, Amato-Gauci A. Seroprevalence to influenza A(H1N1) 2009 virus--where are we? *Clin Vaccine Immunol*. 2011;18(8):1205-12.
40. Stein ML, Rudge JW, Coker R, van der Weijden C, Krumkamp R, Hanvoravongchai P, et al. Development of a resource modelling tool to support decision makers in pandemic influenza preparedness: The AsiaFluCap Simulator. *BMC Public Health*. 2012;12:870.
41. Health Protection Agency CRISMART. Assessment Report on EU-wide Pandemic Vaccine Strategies 2010 [Available from: http://ec.europa.eu/health/communicable_diseases/docs/assessment_vaccine_en.pdf].
42. Rizzo C, Rota MC, Bella A, Giannitelli S, De Santis SD, Nacca G, et al. Response to the 2009 influenza A (H1N1) pandemic in Italy. *Eurosurveillance*. 2010;15(49):6.
43. Sandell T, Sebar B, Harris N. Framing risk: communication messages in the Australian and Swedish print media surrounding the 2009 H1N1 pandemic. *Scandinavian journal of public health*. 2013;41(8):860-5.
44. EU Commission. Health security Committee [Available from: http://ec.europa.eu/health/preparedness_response/risk_management/index_en.htm].
45. Parliament E. REGULATION (EC) No 851/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 April 2004

establishing a European centre for disease prevention and control. Official Journal of the European Union. 2004.

46. WHO. WHO: What we do [Available from: <http://www.who.int/about/what-we-do/en/>].

47. WHO. Emergency Risk Communication Training [Available from: <http://www.who.int/risk-communication/training/en/>].

48. International Health Regulations (2005). Second Edition, (2008).

49. Holmberg M LB. Framing post -pandemic preparedness: Comparing eight European plans. Global Public Health. 2016;1-16.

50. ASSET. Description of Work 2012 [Available from: <http://www.asset-scienceinsociety.eu/pages/about>].

51. I-Sense. EPSRC IRC in Early-Warning Sensing Systems for Infectious Diseases [Available from: <https://www.i-sense.org.uk/about-us>].

52. Guerrisi C et al Participatory Syndromic Surveillance of Influenza in Europe. The Journal of Infectious Diseases. 2016;214(S4):S386-92.

53. WHO. Risk communication learning course <http://www.who.int/risk-communication/training/en/> [Available from: <http://www.who.int/risk-communication/training/en/>].

54. European Union. DECISION No 1082/2013/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 October 2013

on serious cross-border threats to health and repealing Decision No 2119/98/EC [Available from:

http://ec.europa.eu/health/preparedness_response/docs/decision_serious_crossborder_threats_22102013_en.pdf.

55. Barnett J AMA, Kennedy J, Raats M, Shepherd R, Verbeke W, Fletcher J, Kuttschreuter LimaL, Wills J, Wall P. Development of strategies for effective communication of food risks and benefits across Europe: Design and conceptual framework of the FoodRisC project. Development of strategies for effective communication of food risks and benefits across Europe: Design and conceptual framework of the FoodRisC project. 2011;11:308.

56. CORDIS. CommHERE Description 2015 [Available from: http://cordis.europa.eu/project/rcn/101317_en.html].

57. TELL_ME. [Available from: <http://www.tellmeproject.eu/content/project-summary>].

58. CORDIS. E-com@EU Result in Brief 205 [Available from: http://cordis.europa.eu/result/rcn/92767_en.html].

59. Han YKJ, et al. Predictors of influenza vaccine uptake during the 2009/10 influenza A H1N1v ('swine flu') pandemic: Results from five national surveys in the United Kingdom. Prev Med. 2016;84:57-61.

60. PHEME. About PHEME 2016 [Available from: <https://www.pheme.eu/>].

61. ICDRM/GWU Emergency Management Glossary of Terms. Institute for Crisis, Disaster, and Risk Management, The George Washington University; 2010.

62. IBM. What is Big Data Analytics? [Available from: <https://www-01.ibm.com/software/data/infosphere/hadoop/what-is-big-data-analytics.html>].

63. Oxford Reference. [Available from: <http://www.oxfordreference.com/>]

64. Power DJ, Sharda R, Burstein F. Decision Support Systems. Wiley Encyclopedia of Management: John Wiley & Sons, Ltd; 2015.

65. Lilienfeld DE, Stolley PD. P.D. Foundations of Epidemiology 3rd ed: Oxford University Press, New York, N.Y.

66. Homeland Security Presidential Directive 2007 [Available from: <http://fas.org/irp/offdocs/nspd/hspd-21.htm>].

67. Public Health Emergency Glossary. [Available from: <http://www.phe.gov/Preparedness/planning/mscc/healthcarecoalition/Pages/glossary.aspx>.
68. Risk Steering Committee, DHS Risk Lexicon 2010 [Available from: <https://www.dhs.gov/xlibrary/assets/dhs-risk-lexicon-2010.pdf>.
69. National Response Framework al, [accessed 31.05.2016]. [Available from: <https://aglearn.usda.gov/customcontent/APHIS/APHIS-FY14-IS800/glossary.htm> - l.
70. World Health Organization, Laboratory biosafety manual. Third edition 2004 [
71. World Health Organization, Biorisk management - Laboratory biosecurity guidance 2006 [
72. Business Dictionary [Available from: <http://www.businessdictionary.com/definition/model.html> - ixzz4AumPDeVM
73. WHO. Glossary of terms used (Health Impact Assessment). [Available from: <http://www.who.int/hia/about/glos/en/index2.html>.
74. Last J. A dictionary of epidemiology. 4th ed: Oxford University Press 2001.
75. NFPA 1600, Standard on Disaster/Emergency Management and Business Continuity Programs 2004 [Available from: <http://www.nfpa.org/codes-and-standards/document-information-pages?mode=code&code=1600>.
76. Visitask.com 2016 [Available from: <http://www.visitask.com/best-practice-g.asp>.
77. The Institute of Medicine. The Future of Public Health. 1988.
78. WHO. Human Health Action. [Available from: <http://www.who.int/hac/about/definitions/en/>.
79. Gratt LB. The Definition of Risk and Associated Terminology for Risk Analysis. In: Bonin JJ, Stevenson DE, editors. Risk Assessment in Setting National Priorities. Boston, MA: Springer US; 1989. p. 675-80.
80. Fischhoff B. Adapted from: Risk Perception and Communication Unplugged: Twenty Years of Process¹. Risk Anal. 1995;15(2):137-45.
81. Tomaszewski B. Situation awareness and virtual globes: Applications for disaster management. Computers & Geosciences. 2011;37(1):86-92.
82. Brugha R, Varvasovszky Z. Stakeholder analysis: a review. Health Policy Plan. 2000;15(3):239-46.

ANNEX 1 LIST OF ABBREVIATIONS

ARI: acute respiratory infections

ASPHER: Associations of Schools of Public Health in the EU Region

CBRN: Chemical Biological Radiological and Nuclear

CCA: Crisis Coordination Arrangements

CDC: Centre for Disease Control and Prevention D2.1

CHESTRAD: Centre for Health Sciences Training, Research and Development

DG-DEVCO: International Cooperation and Development Directorate-General

DG-ECHO: Humanitarian aid and Civil Protection Department Directorate-General

DG-ENV: Environment Directorate-General

DG-HOME: Migration and Home Affairs Directorate-General

DG-MOVE: Mobility and Transport Directorate-General

DG-SANCO: Health and Consumers Affairs Directorate-General

DG-SANTE: Health and Food Safety

ECDC: European Centre for Disease Prevention and Control

ECN: Emergency Communications Network WHO

EID: Emerging Infectious Diseases

EMA: European Medicines Agency

EMC: European Medical Corps

EPIET: European Programme for Intervention Epidemiology Training

ERC: Emergency risk communication

ERCC: Emergency Response Coordination Centre

EUISS: European Union Institute for Security Studies

EUPHEM: European Public Health Microbiology Training Programme

EPIS: Epidemic Intelligence Information System

ERCC: Emergency Response Coordination Centre (ERCC) of DG ECHO

EWRS: Early Warning and Response System

FRONTEX: European Agency for the Management of Operational Cooperation at the External Borders

GHA: Global Health Action

GHSA: Global Health Security Agenda

GHSI: Global Health Security Initiative

GOARN: Global Outbreak Alert and Response Network

HCW: Health Care Worker

HEOF: Health Emergency Operations Facility

HPSC: Health Protection Surveillance Centre of Ireland

HSC: Health Security Committee

IHR: International Health Regulations

IIME: Institute for International Medical Education

MERS: Middle East respiratory syndrome coronavirus

NPHOR: National Public Health Outbreak Response

PCR: Polymerase chain reaction

PHEIC: Public Health Emergency of International Concern

SARS: Severe acute respiratory syndrome

TEPHINET: Training Programs in Epidemiology and Public Health Interventions Network

TESSy: European Disease Surveillance Platform

WFME: World Federation for Medical Education

WHO: World Health Organisation

ANNEX 2 TERMS USED AND THEIR UNDERSTANDING IN PANDEM

Acceptable Risk: That level of risk (likelihood of occurrence and consequence of impact) for any activity or situation that is sufficiently low that society (or an organization within society that is managing the risk) is comfortable with it. Society (and an individual organization) does not generally consider expenditure in further reducing such risks justifiable (61).

Actor: Individual simulating a victim, victim family, media, perpetrator, or other person within the exercise scenario to prompt realistic action/reaction from the exercise players. (61).

Analysis: A method of studying the nature of something or of determining its essential features and their relationships (61).

Big data: Term applied to data sets whose size or type is beyond the ability of traditional relational databases to capture, manage, and process the data with low-latency. And it has one or more of the following characteristics - high volume, high velocity, or high variety. Big data comes from sensors, devices, video/audio, networks, log files, transactional applications, web, and social media - much of it generated in real time and in a very large scale (62).

Biological agents: A microorganism that causes disease in personnel, plants, or animals or causes the deterioration of material (63).

Bioterrorism: The unlawful use of biological agents, such as a deadly virus or bacteria, to kill or harm people, animals, or plants. See also biological warfare, biosecurity, terrorism (63).

Capability, Surge: The ability to manage patients requiring unusual or very specialized medical evaluation and care. Surge requirements span the range of specialized medical and health services (expertise, information, procedures, equipment, or personnel) that are not normally available at the location where they are needed (e.g., pediatric care provided at non-pediatric facilities or burn care services at a non-burn center). Surge capability also includes patient problems that require special intervention to protect medical providers, other patients, and the integrity of the medical care facility (61).

Capacity, Surge: The ability to evaluate and care for a markedly increased volume of patients—one that challenges or exceeds normal operating capacity. The surge requirements may extend beyond direct patient care to include such tasks as extensive laboratory studies or epidemiological investigations.

Case (HHS media definition): A person in the population identified as having a particular disease, health disorder, or condition under investigation (61).

Case, Confirmed: A case that is classified as confirmed for reporting purposes (61).

Case, Suspected: A case that is classified as suspected for reporting purposes (61).

Communicable disease : An infectious disease caused by a contagious agent which is transmitted from person to person by direct contact with an infected individual or by indirect means such as exposure to a vector, animal, fomite, product or environment, or exchange of fluid, which is contaminated with the contagious agent (54).

Contact tracing: Measures implemented in order to trace persons who have been exposed to a source of a serious threat to health, and who are in danger of developing or have developed a disease (54).

Crisis (management definition): A major event involving business organizations that has potentially negative results for the organization. The event and its aftermath may significantly damage a business and its employees, products, services, financial condition, and reputation. “Crisis” is a term used historically in business management to designate events equivalent to “emergency” in public safety (61).

Cross-border: A transaction where the two parties are domiciled in different countries.

Decision Support Systems: Decision support systems (DSS) are a class of computerized information system that support decision-making activities. Decision support systems are designed artifacts that have specific functionality. Five more specific Decision Support System types include i) communications-driven, ii) data-driven, iii) document-driven, iv) knowledge-driven, and v) model-driven systems (64).

Declaration, Disaster (emergency management): A declaration based upon legislation that triggers the greatest availability of spending and resource assignment authority at the relevant government level (61).

Declaration, Emergency (emergency management): A declaration based upon legislation, that is generally more limited in scope and resource amount compared to a disaster declaration (2).

Disease: The biological dimension of nonhealth, an essentially physiological dysfunction (63).

Emergency risk communication: The real-time exchange of information, advice and opinions between experts or officials and people who face the threat (from a hazard) to their survival, health or economic or social well-being.

Epidemic: Epidemic refers to an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area. Outbreak carries the same definition of epidemic, but is often used for a more limited geographic area. Cluster refers to an aggregation of cases grouped in place and time that are suspected to be greater than the number expected, even though the expected number may not be known. Pandemic refers to an epidemic that has spread over several countries or continents, usually affecting a large number of people (CDC).

Epidemiology (public health application): The study of the distribution and determinants of disease & other adverse health factors in human populations by time, place and person (65).

Epidemiological Surveillance: the process of actively gathering and analyzing data related to human health and disease in a population in order to obtain early warning of human health events, rapid characterization of human disease events, and overall situational awareness of disease activity in the human population (66).

Expert: An individual who meets some defined level of knowledge, skills and abilities (i.e., competencies) that usually have been demonstrated by the expert's past experiences (61).

Food and water-borne diseases: A disease caused by consuming contaminated food or drink.

Hazard: (i) A potential or actual force, physical condition, or agent with the ability to cause human injury, illness and/or death, and significant damage to property, the environment, critical infrastructure, agriculture and business operations, and other types of harm or loss (67). (ii) Natural or man-made source or cause of harm or difficulty (68).

Interoperability: The ability of emergency management/response personnel to interact and work well together. In the context of technology, interoperability also refers to having an emergency communications system that is the same or is linked to the same system that a jurisdiction uses for nonemergency procedures, and that effectively interfaces with national standards as they are developed. The system should allow the sharing of data with other jurisdictions and levels of government during planning and deployment (69).

Isolation: The separation and confinement of individuals known or suspected (via signs, symptoms, or laboratory criteria) to be infected with a contagious disease to prevent them from transmitting disease to others. Isolation may be further qualified as respiratory, contact, bodily secretions, in contrast to “full” isolation (61).

Laboratory biosafety: containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release (70).

Laboratory biosecurity: protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release (71).

Mitigation: Activities providing a critical foundation in the effort to reduce the loss of life and property from natural and/or manmade disasters by avoiding or lessening the impact of a disaster and providing value to the public by creating safer communities. Mitigation seeks to fix the cycle of disaster damage, reconstruction, and repeated damage. These activities or actions, in most cases, will have a long-term sustained effect (61).

Modelling: Graphical, mathematical (symbolic), physical, or verbal representation or simplified version of a concept, phenomenon, relationship, structure, system, or an aspect of the real world. The objectives of a model include (i) to facilitate understanding by eliminating unnecessary components, (ii) to aid in decision making by simulating 'what if' scenarios, (iii) to explain, control, and predict events on the basis of past observations (72).

Monitoring: The continuous observation, detection or review of changes in a condition, in a situation, or in activities, including a continuous function that uses systematic collection

of data and analysis on specified indicators relating to serious cross-border threats to health (54).

Outbreak: A disease outbreak is the occurrence of cases of disease in excess of what would normally be expected in a defined community, geographical area or season. An outbreak may occur in a restricted geographical area, or may extend over several countries. It may last for a few days or weeks, or for several years.

A single case of a communicable disease long absent from a population, or caused by an agent (e.g. bacterium or virus) not previously recognized in that community or area, or the emergence of a previously unknown disease, may also constitute an outbreak and should be reported and investigated (WHO).

Outcomes: The effect the process has had on the people targeted by it. These might include, for example, changes in their self-perceived health status or changes in the distribution of health determinants, or factors which are known to affect their health, well-being and quality of life (73).

Outputs: The products or results of the process. These might include, for example, how many people a project has affected, their ages and ethnic groups or the number of meetings held and the ways in which the findings of the project are disseminated (73).

Pandemic: An epidemic occurring worldwide, or over a very wide area, crossing international boundaries and usually affecting a large number of people (74).

Pathogen: An organism that causes disease (63).

Plan, Emergency Management: An emergency management plan using 'management by objective' explains an organizational structure and defines how the participants in the organization operate to achieve the end goal and interim objectives. A 'plan' may be guidance that is triggered by a defined set of circumstances (such as an Emergency Operations Plan) or may be guidance for actions over a defined time interval (such as an annual Preparedness Work Plan). This contrasts with an Emergency Management Program. (61)

Policy: A policy can be defined as an agreement or consensus on a range of issues, goals and objectives which need to be addressed (Ritsatakis et al., 2000). In the context of

pandemic management (i) activities, programs, and systems developed and implemented prior to a disaster/emergency that are used to support and enhance mitigation of, response to, and recovery from disasters/emergencies (75). (ii) A continuous cycle of planning, organizing, training, equipping, exercising, evaluating, and taking corrective action in an effort to ensure effective coordination during incident response. Within the National Incident Management System, preparedness focuses on the following elements: planning; procedures and protocols; training and exercises; personnel qualification and certification; and equipment certification.

Practice, Best: A superior method or innovative practice that contributes to the improved performance of an organization, usually recognized as “best” by other peer organizations. It implies accumulating and applying knowledge about what is working and not working in different situations and contexts, including lessons learned and the continuing process of learning, feedback, reflection and analysis (what works, how and why) (76).

Practice, Good: Good Practice means to carry out a function or testing using only recommended or approved methods (e.g., food regulation) (76).

Preparedness: (i) The phase of Emergency Management that encompasses actions designed to build organizational resiliency and/or organizational capacity and capabilities for response to and recovery from disasters and emergencies. (ii) Activities, programs, and systems developed and implemented prior to a disaster/emergency that are used to support and enhance mitigation of, response to, and recovery from disasters/emergencies (75). (iii) A continuous cycle of planning, organizing, training, equipping, exercising, evaluating, and taking corrective action in an effort to ensure effective coordination during incident response. Within the National Incident Management System, preparedness focuses on the following elements: planning; procedures and protocols; training and exercises; personnel qualification and certification; and equipment certification (61).

Probability: likelihood

Public Health: The science and practice of protecting and improving the overall health of the community through disease prevention and early diagnosis, control of communicable diseases, health education, injury prevention, sanitation, and protection from environmental hazards (66). What we, as a society, do collectively to assure the conditions in which people can be healthy” (77).

Public Health Emergency: A public health emergency (the condition that requires the governor to declare a state of public health emergency) is defined as "an occurrence or imminent threat of an illness or health condition, caused by bio terrorism, epidemic or pandemic disease, or (a) novel and highly fatal infectious agent or biological toxin, that poses a substantial risk of a significant number of human fatalities or incidents or permanent or long-term disability (WHO/DCD, 2001). The declaration of a state of public health emergency permits the governor to suspend state regulations, change the functions of state agencies (78).

Public Health Surveillance: Systematic, ongoing collection, collation, and analysis of health-related information that is communicated in a timely manner to all who need to know which health problems require action in their community. Surveillance is a central feature of epidemiological practice, where it is used to control disease. Information that is used for surveillance comes from many sources, including reported cases of communicable diseases, hospital admissions, laboratory reports, cancer registries, population surveys, reports of sickness absence from school or work (in which a sudden sharp rise in numbers may signal the onset of an epidemic), and reported causes of death, in which again a sudden rise in numbers, for instance of deaths from pneumonia, may signal the onset of epidemic influenza (63).

Public Health Measure: means a decision or an action which is aimed at preventing, monitoring or controlling the spread of diseases or contamination, combating severe risks to public health or mitigating their impact on public health

Public Trust: The "community" confidence in its government and governmental agencies (61).

Quarantine: The compulsory physical separation, including restriction of movement, of populations or groups of healthy people who have been exposed to a contagious disease. This may include efforts to segregate these persons within specified geographic areas (61).

Regulatory body, regulatory authority, regulatory agency or regulator is understood as a public authority or government agency responsible for exercising autonomous authority over some area of human activity in a regulatory or supervisory capacity.

Response: Activities that address the short-term, direct effects of an incident. Response includes immediate actions to save lives, protect property, and meet basic human needs. Response also includes the execution of emergency operations plans and of mitigation activities designed to limit the loss of life, personal injury, property damage, and other unfavourable outcomes. As indicated by the situation, response activities include applying intelligence and other information to lessen the effects or consequences of an incident; increased security operations; continuing investigations into nature and source of the threat; ongoing public health and agricultural surveillance and testing processes; immunizations, isolation, or quarantine; and specific law enforcement operations aimed at pre-empting, interdicting, or disrupting illegal activity, and apprehending actual perpetrators and bringing them to justice (61).

Recovery: The development, coordination, and execution of service- and site-restoration plans; the reconstitution of government operations and services; individual, private-sector, nongovernmental, and public assistance programs to provide housing and to promote restoration; long-term care and treatment of affected persons; additional measures for social, political, environmental, and economic restoration; evaluation of the incident to identify lessons learned; post incident reporting; and development of initiatives to mitigate the effects of future incidents (61).

Risk: (i) The likelihood of the occurrence and the likely magnitude of the consequences of an adverse event during a specified period. (ii) The expectation of loss from hazards and their impact. Risk is a function of probability (likelihood) of a hazard occurrence and the impact (consequences) of a hazard 83 on the target of the risk assessment. It connotes a relationship between the hazard and the target's vulnerability to the hazard. Risk can be addressed by managing probability (through mitigation) and/or managing impact (through mitigation, preparedness, response and recovery). (iii) Potential for an unwanted outcome resulting from an incident, event, or occurrence, as determined by its likelihood and the associated consequences (61).

Risk Analysis: (i) A detailed examination performed to understand the nature of unwanted, negative consequences to human life, health, property, or the environment; an analytical process to provide information regarding undesirable events; the process of quantification of the probabilities and expected consequences for identified risks (79). (ii) Systematic examination of the components and characteristics of risk. In practice, risk analysis is generally conducted to produce a risk assessment. Risk analysis can also involve

aggregation of the results of risk assessments to produce a valuation of risks for the purpose of informing decisions. In addition, risk analysis can be done on proposed alternative risk management strategies to determine the likely impact of the strategies on the overall risk (68).

Risk Assessment: (i) The process, including both risk analysis and risk management alternatives, of establishing information regarding an acceptable level of that risk for an individual, group, society, or the environment (79) (ii) Product or process which collects information and assigns values to risks for the purpose of informing priorities, developing or comparing courses of action, and informing decision making. A risk assessment can be the resulting product created through analysis of the component parts of risk (68).

Risk Communication: (i) The process of providing concise, comprehensible, credible information, as needed to make effective decisions regarding risks. In emergency management/incident response, risk communication is generally considered to be providing a service to those outside of the incident command system, with the goal of influencing behaviour (80). (ii) Exchange of information with the goal of improving risk understanding, affecting risk perception and/or equipping people or groups to act appropriately in response to an identified risk. Risk communication is practiced for both non-hazardous conditions and during incidents. During an incident, risk communication is intended to provide information that fosters trust and credibility in government and empowers partners, stakeholders, and the public to make the best possible decisions under extremely difficult time constraints and circumstances (68).

Serious cross-border threat to health: A life- threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection (54).

Situation Awareness: Situation awareness, in its most simple and vernacular form, is the idea of people knowing “what is going on” (81).

Stakeholders: Actors who have an interest in the issue under consideration, who are affected by the issue, or who - because of their position - have or could have an active or passive influence on the decision-making and implementation processes (82).

Threat: The possibility of a hazard occurrence; something that has the potential to cause harm (61).

Training: Training is instruction that imparts and/or maintains the skills (and abilities such as strength and endurance) necessary for individuals and teams to perform their assigned system responsibilities. Training objectives should be competency-based and specify a level of proficiency that relates to the relevant competencies (“awareness, operations, or expert”). As much as possible, training should address skills function under the conditions likely when the skill must be conducted (61).

Vector-borne disease: A large and miscellaneous class of diseases that are transmitted to humans by vectors, predominantly insects. They include mosquito-borne diseases caused by viruses, bacteria, protozoa, and helminths; diseases spread by blackflies and other biting and blood-sucking flies, ticks, lice, fleas, etc.; and diseases in which the intermediate hosts are fish, freshwater snails, and mammals (63).

ANNEX 3 DECISION 1082/13

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

This decision confirms the commitment in Article 168 TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION (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))