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PANDEM

Pandemic Risk and Emergency Management

D3.2 Review of Global and EU Initiatives and Research Projects

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1. INTRODUCTION

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.

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 users and stakeholders;
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 recommendations 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. 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 is identifying 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 is also mapping 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.

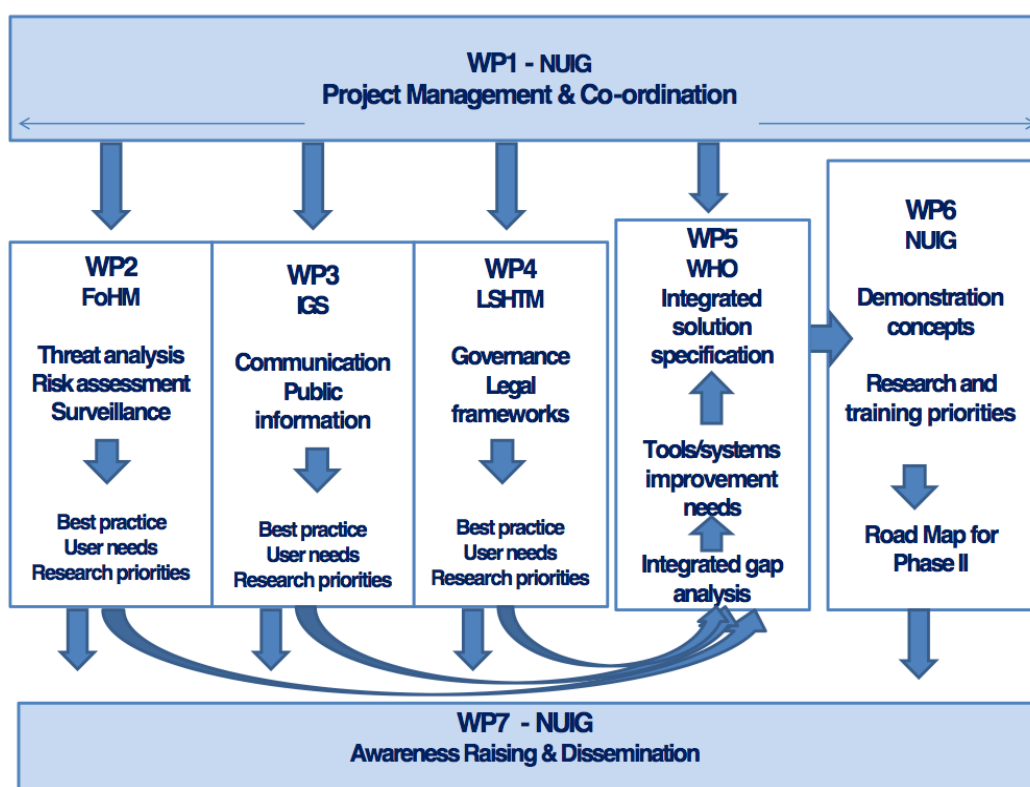


Figure 1. The PANDEM Work Approach.

Specifically the project is:

- Conducting a **comprehensive analysis of current and possible future threats** (air-, water-, food- and vector-borne diseases) including agents with potential for accidental or deliberate release;
- Analysing the actions taken by regional, national, EU and global actors during the Ebola outbreak, the H1N1 pandemic and other major epidemic responses at regional, national, EU and global level;
- Assessing **user needs and gaps** as well as identifying **requirements** to improve pandemic risk and emergency management capacity;
- Leveraging **available tools and systems** developed by research projects for risk assessment, communication, education and governance to improve cooperation between science and society and identifying innovative solutions;

- Examining and developing **mechanisms to strengthen existing networks** in the EU to support member states can work together inter-operably across borders;
- Enhancing **international cooperation** by incorporating input from international research partners to address a major global threat;
- Ensuring **consultation with and participation of a wide number of stakeholders** at regional, national and EU levels including end-users, industry, universities, citizens groups, governments, the EC and its agencies.

Given the cross-border and multi-sectoral context of the health and security challenge for building pandemic management capacity, a systems-based methodology is being applied to:

- Assess current capacity for prevention, preparedness, mitigation, response and recovery;
- Support the gathering of user needs and requirements to improve capacity at transnational level;
- Identify opportunities to improve the process of early detection and response to pandemics.

PANDEM will develop a **roadmap for investments** in research and system developments that result in **demonstrator topics** to be realised in the phase II demonstration project. The objective of the **Phase II project** will be to produce a product, prototype or demonstrator of value to all EU Member States.

1.2. PANDEM expected results and Impact

The review of global and EU initiatives and EU research projects will be conducted to ensure delivery of the expected results and impacts of PANDEM.

The proposed impacts of the project are:

Impact 1: Identification of research gaps and priorities for improving capacity-building at transnational level with a view to prepare for a phase II demonstration project involving all relevant stakeholders, including SMEs;

Impact 2: Identification of innovative concepts that would allow better integration of existing tools and systems to build capacity for health and security protection in case of large-scale pandemics;

Impact 3: Preparation for a future phase II demonstration project on large-scale pandemics;

Impact 4: Increased security for European citizens.

2. OBJECTIVE OF THE REPORT

The objective of this report is to review global and EU initiatives, and to review EU funded research projects relevant to pandemic risk and emergency management. The study includes a review of current initiatives and the policy context for pandemic decision-making at both global and EU levels, such as the International Health Regulations (2005), the UN Secretary-General's High Level Panel on global response to health crises and the EU Decision on serious cross-border threats to health (2013). The report also includes a review of research projects funded by the European Commission under Framework 7 and Horizon 2020 Programmes as well as other European agency programmes. This information forms part of Work Package 3 in PANDEM and will feed into the gap analysis to be undertaken under Work Package 5. The overall aim is to ensure PANDEM takes current global and EU initiatives into consideration and builds on existing EU and international projects in a number of areas including crisis management, information and communication technologies, and health.

2.1. Review Approach

This review is compiled from literature searches, as well as manual searches using the “snowballing” technique to identify relevant global and EU initiatives, and relevant research projects. Consortium members were also consulted for their knowledge of these areas. Together, these approaches have enabled us to construct a broad overview of the context within which PANDEM is operating as a research project combining European funding with global awareness.

Firstly, initiatives and policy frameworks at global and EU levels were considered. Those mentioned in reviewed literature as well as others known to consortium members were cross-checked online, with institutional websites and on PubMed to explore their research profile and any existing academic evaluation of their applications and efficacy. In addition, more specific trends in research outputs at EU and global levels were analysed by topic area, chiefly based on the results of the original literature review.

Secondly, a literature review was conducted using specified search words (see Figures 1-3) to identify research projects relevant to PANDEM funded by the European Commission under Framework 7 and H2020 Programmes in Security, Health and ICT, including studies supported by e.g. DG HOME, DG SANTE and DG CONNECT. Thirdly, additional research projects were identified through consultation with consortium members, targeted searches using key topical terms (such as “Ebola,” “influenza” and “pandemic”) on websites including who.int, the PubMed science and biomedical research search engine, and specialized news sources.

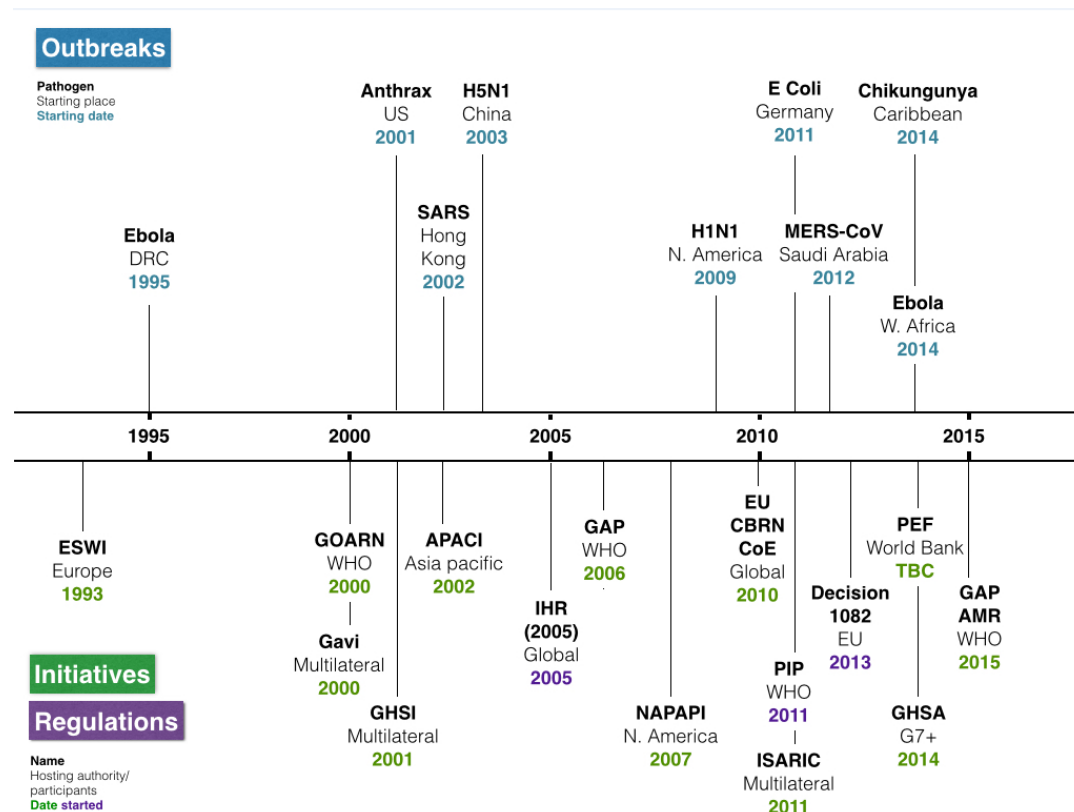
3. GLOBAL AND EU INITIATIVES

3.1. Overview

The Ebola outbreak in West Africa has shone a light on the level of preparedness and response to global emerging and epidemic disease threats. As a result of gaps and inadequacies identified at both regional and global levels, a number of initiatives, reviews and assessments have been established. Each of these was intended to identify lessons learned from the outbreak, and to propose ways in which the world can be better prepared in future. While each initiative is specific to its institutional backer, clear themes are already emerging. These include the need for improved regulatory and governance structures, clear and accountable decision-making at all levels and systems that will ensure swifter and more joined-up response. This is not the first time such lessons have been drawn from disease outbreaks. However, this time there is a sense of urgency and priority being given to implementing the responses.

Figure 2 below provides an overview of key initiatives in global health at the global and EU level over the past 20 years, and indicates how they have evolved in response to high impact disease outbreaks.

The international response to the Ebola outbreak in Kikwit, Zaire (now the Democratic Republic of Congo) highlighted the importance of greater coordination among public health agencies around the world. As a result of discussions begun during that response, WHO and several partner agencies established the Global Outbreak Alert and Response Network (GOARN). Coordinated by WHO, the network served as a surveillance and response hub for disease outbreaks, and became the primary coordination centre for outbreak responses. Subsequent outbreaks, including SARS and the influenza A (H5N1) outbreak in China in 2003 highlighted the need for a stronger legal framework for outbreak surveillance and response. The resulting revision of the International Health Regulations, over a period of several years, placed greater obligations on member states of WHO to put in place systems to monitor, identify and respond to what it defined as Public Health Emergencies of International Concern. Although there are still issues with compliance, the resulting improvement in surveillance and response has been demonstrated as the global community dealt with potentially severe outbreaks of influenza A (H1N1), *E. coli* and the MERS coronavirus.



Key: acronyms & abbreviations

Outbreaks	Initiatives	Regulations
H1N1 Commonly known as swine flu H5N1 Commonly known as avian influenza or bird flu MERS-CoV Middle East Respiratory Syndrome (coronavirus) SARS Severe acute respiratory syndrome	APACI Asia-Pacific Alliance for the Control of Influenza ESWI European Scientific Working group on Influenza EU CBRN CoE European Union Chemical Biological Radiological and Nuclear Risk Mitigation Centres of Excellence Initiative GAP Global Action Plan for Influenza Vaccines GAP AMR Global Action Plan for Antimicrobial Resistance GHSA Global Health Security Agenda GHSI Global Health Security Initiative GOARN Global Outbreak Alert and Response Network Gavi The Vaccine Alliance ISARIC International Severe Acute Respiratory and Emerging Infection Consortium NAPAPI North American Plan for Animal and Pandemic Influenza PEF Pandemic Emergency Facility	Decision 1082 Decision on serious cross-border threats to health IHR (2005) International Health Regulations PIP Pandemic Influenza Preparedness Framework

Figure 2: Overview of key initiatives in global health at the global and EU level.

Disease-specific programmes such as the Global Action Plan for Influenza Vaccines (GAP) and the Pandemic Influenza Preparedness (PIP) Framework have also emerged in response to specific challenges in responding to outbreaks of influenza. Most recently, the United States (through the Centers for Disease Control and Prevention) has promoted a Global Health Security Agenda, and the World Bank has developed and funded a Pandemic Emergency Facility. Each of these initiatives comes in response to a specific challenge of coordination and/or funding. The goal of PANDEM at this stage of the project is to summarise them and then highlight any outstanding gaps.

3.2. Global initiatives

3.2.1. WHO emergency reform in the wake of Ebola

The revised International Health Regulations (IHR) were agreed by 196 countries in 2005, and came into force in June 2007. They are administered by WHO [1]. The IHR require WHO to inform countries about public health risks and give the organization responsibility for declaring a public health emergency of international concern. The IHR also set out minimum capacities which countries must build in order to detect, report and respond to public health events. GOARN (see above) is one part of this response mechanism. It is important to note that each member state is responsible for implementing and assessing the capacities required under the IHR [2].

The Ebola outbreak of 2014-2015 prompted criticism of WHO [3] for not having fully implemented the IHR. So far, fewer than 20% of countries have complied with all the core requirements [4]. In response, WHO is undergoing a reorganization of its' emergency response capacities under the auspices of a UN advisory group. In parallel, a review on the role of the IHR in the Ebola outbreak and response is being conducted by the IHR Review Committee, which has suggested reforms including independent assessment of the development, monitoring and capacity of key IHR measures within each country [5].

3.2.2. Global Health Risk Framework (GHRF)

The GHRF initiative is an independent multinational commission which has been established to build on lessons from the recent Ebola outbreak and other major outbreaks to develop a comprehensive framework for improving the response to future global public health threats. The Commission will analyse options for improving governance, finance, health system resilience and research and development for global health security. The Commission is supported by WHO, World Bank, Gates Foundation and Rockefeller Foundation. It will propose a preparedness and response plan in its final report.

3.2.3. The Global Outbreak Alert and Response Network (GOARN)

Established in 2000, the Global Outbreak Alert and Response Network (GOARN) contributes towards global health security by combating the international spread of outbreaks, ensuring that appropriate technical assistance reaches affected states rapidly and contributing to long-term epidemic preparedness and capacity building [6]. Envisaged as a ‘network of networks’ and hosted by WHO, it is a collaboration of existing technical networks and initiatives in member states, as well as UN bodies and international humanitarian and nongovernmental organisations.

The Network currently is extensive. It was involved in the response to the recent Ebola crisis, although its capacity may have been limited due to funding and staffing cuts at WHO since 2013 [7]. Older reviews suggest that it needed to improve co-ordination and information sharing between members [8], as well as extending its geographical reach [9].

3.2.4. Global Health Security Initiative

The Global Health Security Initiative (GHSI) is a partnership between Canada, the United States, Germany, France, Italy, Mexico, the United Kingdom, the European Commission and the World Health Organisation [10]. It was set up in 2001, with the aim of strengthening preparedness and response to biological, chemical, radiological and nuclear (CBRN) threats and pandemic influenza.

To date, the initiative reports that it has strengthened global preparedness and response for potential outbreaks of smallpox and influenza, improved international communication and risk management, tested and enhanced laboratory capacity, and made efforts to prepare for potential chemical and radiological threats [11]. Through the European Commission, resources and information are conveyed to all EU member states [11].

3.2.5. Sendai Framework for Disaster Risk Reduction 2015-2030

An initiative of the UNISDR, the objective is to adopt a post-2015 framework for disaster risk reduction. With cooperation and support from regional groups, including the European Forum for Disaster Risk Reduction (EFDRR). The framework is to apply to both natural or man-made hazards as well as related environmental, technological and biological hazards and risks. The goal is to prevent new and reduce existing disaster risk through the implementation of integrated and inclusive economic, structural, legal, social, health, cultural, educational, environmental, technological, political and institutional measures

that prevent and reduce hazard exposure and vulnerability to disaster, increase preparedness for response and recovery, and thus strengthen resilience.

3.2.6. ONE Health Initiative

This worldwide initiative recognises and reflects the close links between human, animal and environmental health, and seeks to improve collaboration between professionals working across all these areas [12]. Its specified channels for achieving this are through joint education, communication, clinical care to prevent cross species transmission, research, diagnostic development and public outreach. In practice, ONE Health mostly functions as a repository for information and a particular approach to journals and conferences. Members of the Initiative are mostly national medical, veterinary, research and ecological associations, as well as individuals [13]. It was established in 2006 [14].

3.2.7. Global Health Security Agenda

The Global Health Security Agenda (GHSA) is an effort by nations, international organizations, and civil society to accelerate progress toward a world safe and secure from infectious disease threats; to promote global health security as an international priority; and to spur progress toward full implementation of the World Health Organization (WHO) International Health Regulations 2005 (IHR), the World Organization for Animal Health (OIE) Performance of Veterinary Services (PVS) pathway, and other relevant global health security frameworks. The Global Health Security Agenda (GHSA) broadly aims to prevent, detect and respond to global outbreaks [15]. Prevention work under the GHSA spans the issues of drug resistance, emerging zoonotic diseases, food-borne disease, biosecurity and infectious diseases, and it proposes surveillance, regulation and immunisation as the main channels for addressing these [16]. In practice, this meant establishing four prevention “action packages”, within which to work with a small number of countries and organisations like WHO, FAO and OIE to meet specified targets within a five-year period [17].

GHSA was established to advance implementation of the International Health Regulations, and its 12 technical goals across prevention, detection and response are seen as important in providing clear national pathways for preparedness, especially in the wake of Ebola [18]. Targets also aim to be easily measurable, such as having one trained field epidemiologist per 200,000 people [19]. GHSA focuses more on security/threats as opposed to the public health focus of IHR. There is considerable but not complete overlap between the GHSA assessment tool and the IHR core capacities assessment tool. It is unclear how gaps

identified during assessments will be turned into capacity building, or how this will be coordinated with work done by the governments, WHO and other partners in the countries.

3.2.8. Pandemic Emergency Facility (PEF)

In direct response to the recent Ebola crisis, the World Bank Group is currently working to build the Pandemic Emergency Facility (PEF) in collaboration with WHO, the G7 and G20 countries and other partners [20]. Its aim is to raise and distribute funds specifically for the purpose of quickly responding to the next global health emergency, thereby strengthening capacity for responding to future epidemics or pandemics.

PEF would fund response activities such as rapid deployment of a trained and ready health workforce, medical equipment, pharmaceuticals and diagnostic supplies, logistics and food supplies, and coordination and communication. PEF would not cover pandemic preparedness or reconstruction efforts. Funds would be distributed to WHO, UN bodies or relevant nongovernmental organisations for implementation.

3.3. Influenza-specific global initiatives

3.3.1. National preparedness plans

WHO/Europe recommends that all Member States revise their national pandemic plans to prepare for future influenza pandemics and to strengthen implementation of the International Health Regulations (2005). Furthermore, Member States are strongly encouraged to publish their pandemic plans.

Since the 2009 pandemic, 7 countries in the WHO European Region have published revised national pandemic preparedness plans and other countries are in the process of revising their plans [21]. The plans that have been revised since the 2009 pandemic take into account the national and global experiences from the pandemic. Some of the changes introduced by countries include a more flexible approach to pandemic planning that ensures a response that is proportionate with the severity of the pandemic. Furthermore, pandemic plans emphasize that it will be national risk assessments and the actual situation in the country that dictates the response, rather than WHO pandemic phases. Finally, increased focus on the multisectoral aspect of preparedness planning and incorporation of new evidence are essential new elements in revised plans.

3.3.2. North American Plan for Animal and Pandemic Influenza (NAPAPI)

Originally established in 2007 [22], the 2012 version of this agreement between Canada, the USA and Mexico aimed to promote collaboration for a faster response in the event of an influenza outbreak, building on existing frameworks from the WHO, OIE and FAO [23]. It was revised in order to incorporate lessons from the North American response to H1N1 in 2009 [24].

The plan was chiefly concerned with response protocol within an outbreak, prioritising detection, limiting transmission and casualties, communication between country authorities, prevention of new human influenza strains, maintaining infrastructure and reducing social and economic impacts. It aimed to achieve these goals through the establishment of the North American Senior Coordinating Body, which convened health, agriculture, security and foreign affairs sectors to discuss policy, planning and response activities. A list of implementation actions was produced as their first deliverable [25], but its current state of progress is unclear.

3.3.3. Pandemic Influenza Preparedness (PIP) Framework

This Framework with legally binding components is a unique partnership between Member States, industry and civil society. It was developed following the influenza A (H5N1) outbreaks in mainly South East Asia, and became effective in 2011 [26]. Negotiations commenced in 2007 after concerns that developing countries would not get access to influenza vaccines in the event of a pandemic [27]. As a result, the two underlying principles of the framework are on the one hand that countries will share influenza viruses with pandemic potential with WHO and on the other, that countries most in need will receive benefits that result from the virus sharing through. Benefits are provided through a partnership contribution (PC) by companies that use GISRS materials for vaccine, drug and diagnostics development, and through a standard material transfer agreement when receiving PIP biological materials, companies provide financial or in-kind contributions such as donation of pandemic vaccines during a pandemic and scientific collaboration. The main aim of the agreement is to improve global pandemic influenza preparedness.

Under the PIP Framework, a PC Implementation plan was developed for 2013-2016. A PC of \$28 million was agreed and giving 70% was allocated to preparedness and 30% was put aside for pandemic influenza response. Its key goals include: to improve and strengthen the sharing of influenza viruses with human pandemic potential, and to increase the access of developing countries to vaccines and other pandemic related supplies [28].

3.3.3 Global action plan for influenza vaccines (GAP)

GAP is a strategy led by WHO that aims to reduce the influenza vaccine shortage for both seasonal epidemics and pandemics [29]. GAP was first set up in 2006, but was revised in 2009 to incorporate lessons from the 2009 H1N1 pandemic. A third version will start in 2016, although how the strategy has changed has not yet been announced [30].

GAP intends to affect change through three main objectives. The first is to increase seasonal influenza vaccine usage, both to reduce burden of disease and contribute towards pandemic preparedness [31]. WHO is directly involved in implementing goals related to this objective, such as establishing vaccine stockpiles, surveilling disease burden and strengthening national immunisation advisory committees. The second objective is to increase vaccine production capacity, aiming to produce enough vaccine for 2 billion people by 2015, and by 2020 to build capacity to make a vaccine against a new strain in 6 months for the global population [32]. To achieve this, WHO has given grants for manufacturing to 14 developing countries. The final objective is to work towards more effective influenza vaccines [33], which WHO has so far pursued by reviewing and compiling information about vaccine effectiveness, and making it open access.

3.3.4 Strengthening health security by implementing the International Health Regulations (2005)

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.

3.3.5 Global Influenza Surveillance and Response System (GISRS)

This is a network of 143 institutions across 113 member states coordinated by WHO which has conducted influenza surveillance since 1952 [34]. This includes global partnership of:

- 143 National Influenza Centres in 113 countries;
- 6 WHO H5 reference laboratories;
- 5 WHO collaborating centres for reference and research on influenza (WHO CCs);

- A WHO collaborating centre for studies on the ecology of influenza in animals; and
- 4 WHO essential regulatory laboratories (WHO ERLs).

All EU Member States, with the exception of Cyprus, have a National Influenza Centre that is recognized by WHO and which must comply with WHO Terms of Reference. All EU Member States participate in the ECDC European Influenza Surveillance Network and in the wider WHO European Region network [35].

The main responsibilities of GISRS are to monitor the evolution of influenza viruses and provide recommendations for laboratory diagnostics, vaccines, antiviral susceptibility and risk assessment, and be a key point of contact for WHO related to influenza activity.

FluNet, a global tool for influenza surveillance, functions under GISRS and aims to provide this information in real-time. EU Member States provide their data through Flu News Europe, the joint ECDC-WHO/Europe influenza bulletin (www.flunewseurope.org). GISRS provides an annual EQA program, a shipping fund for sharing viruses with WHO CCs, training and methodological guidelines on RT-PCR and antiviral susceptibility testing for those within its network. Capacity building is also conducted in the EU/WHO European Region context [36].

3.4. Global reviews

The Ebola outbreak in West Africa in 2014-15 has again raised questions about the way the world responds to emerging infectious disease threats. A number of reviews are currently under way into how the response was mounted and managed, and what lessons can be learnt for future outbreaks. Several of the most prominent reviews are outlined below:

3.4.1. UNSG High Level Panel on Global Response to Health Crises

In April 2015, the UN Secretary-General appointed a panel to look into lessons learned from the global response to Ebola, with the President of Tanzania as its chair [37]. The aim of the panel is to make recommendations related to international and national systems that were supposed to support the Ebola response. Early activities indicate that the panel will consider a more field-based perspective on the outbreak, including how respondents interacted within affected countries [38]. The panel is due to submit its report to the Secretary General by the end of December 2015.

3.4.2. WHO Ebola Assessment Panel

A panel of independent experts was chosen to report back to WHO regarding its handling of the Ebola response and to propose areas for improvement. The panel reported back in July 2015.

The report found that member states had largely failed to implement their obligations under the IHR, which would have been crucial to the response, and that WHO's declaration of a Public Health Emergency of International Concern (PHEIC) came far too late. The panel's report recommended that WHO should still be the lead health emergency response agency, but suggested this would require significant organisational change and increased financing. Finally, the panel criticised the fact that WHO and Member States did not coordinate with the humanitarian sector and suggested this as a core area of improvement for future outbreak response [39].

3.4.3. Harvard/LSHTM Independent Panel on the Global Response to Ebola

In November 2015, a team of 19 independent experts brought together by Harvard University and the London School of Hygiene and Tropical Medicine analysed the Ebola outbreak and proposed key reforms. Its recommendations were published in the public health journal *the Lancet* [40].

The report's 10 recommendations provide a roadmap to strengthen the global system for outbreak prevention and response. In addition, WHO is going to publish a Blueprint for R&D on 5-10 priority pathogens in 2016. For industry, these include creating a global fund for accelerated research and development, and a framework for making sure research findings and results are accessible. For national governments, the report suggests a global strategy to enforce IHR core capacities and incentives for early reporting. For WHO, the panel proposed a centre for outbreak response, a neutral Standing Emergency Committee, accountability for prevention and response, as well as better funding and governance. Finally the panel proposed the creation of a Global Health Committee under the auspices of the UN Security Council to keep these issues high on the political agenda [41].

3.5. EU initiatives and policy context

At the European level, there has been a coordinated response to the lessons learnt from the influenza H1N1 pandemic in 2009. These lessons have been put into effect through EU-level decisions and technical guidance documents, including those outlined above. The recent Ebola outbreak in West Africa and its implications for public health, including in Europe,

have not yet been fully incorporated at a policy level. PANDEM is one part of the EU-wide effort to ensure that these measures are now identified and put in place. The project will be looking at the current state of preparedness and planning, including from a governance, legal, surveillance and communications point of view. PANDEM will begin by identifying current gaps, and will then propose ways in which these gaps can be most effectively filled.

3.5.1. Decision 1082/2013/EU on serious cross-border threats to health

In 2013, the EU published a decision [42] in response to analysis of the recent influenza A (H1N1) and *E.coli* outbreaks, which highlighted gaps in the existing health security framework, specifically in risk assessment, preparedness, response planning and crisis management [43]. Under this decision, the EU aimed to provide a common approach for these areas for EU member countries, and to better define the EU's role as coordinator.

The most significant consequences of this decision was that the EU Health Security Committee established its mandate to declare a public health emergency independently from WHO, and to co-ordinate the response. This Decision also established the legal basis for joint procurement across countries to improve access to pandemic drugs and vaccines [44]. The decision was also intended to strengthen preparedness [45], although the mechanisms for doing so were less clear and its impact on EC's pandemic preparedness plan is uncertain (for example, the preparedness planning section links to a 2005 document [46]).

3.5.2. EU Task Force on Biological and Chemical Threats

The first EU Task Force on Biological and Chemical Threats was initiated by DG SANCO in 2002 to support the work of the HSC. The work and the resources was later integrated in the general Commission activities and the work was carried on by the HSC and EC. In 2006, the EC, through the DG Justice Liberty and Security, initiated work on bio-preparedness with a slightly different focus. In 2007, the Commission initiated the Green paper on Bio-preparedness. During 2008, the Chemical, Biological, Radiological and Nuclear materials (CBRN) Task Force was formed, which was composed of approximately 250 experts from throughout Europe. In January 2009 a final CBRN Task Force report was generated that formed the basis for the CBRN Action Plan¹. This Action Plan with many components relevant to pandemic risk management in the EU is being implemented during 2010-2014.

¹ http://europa.eu/legislation_summaries/justice_freedom_security/fight_against_terrorism/jl0030_en.htm

4. EU FUNDED RESEARCH PROJECTS

4.1. Review of EU funded research projects in this area

In the review of EU research projects relevant to PANDEM funded under Framework 7 and H2020 Programmes in Security, Health and ICT, over 1,400 EU-funded projects were identified using the search words pandemic (128), influenza (177), epidemic (282) and surveillance (831). Of these, 84 projects were selected as the most relevant to PANDEM and grouped into seven research areas corresponding to thematic areas in the project. These research areas with associated EU funding are outlined in figure 3 below. Total funding from the EU amounted to close to €450 million over the past 8 years for the 84 projects identified. The figures below illustrate the results in terms of numbers of EU-funded projects within specific research areas.

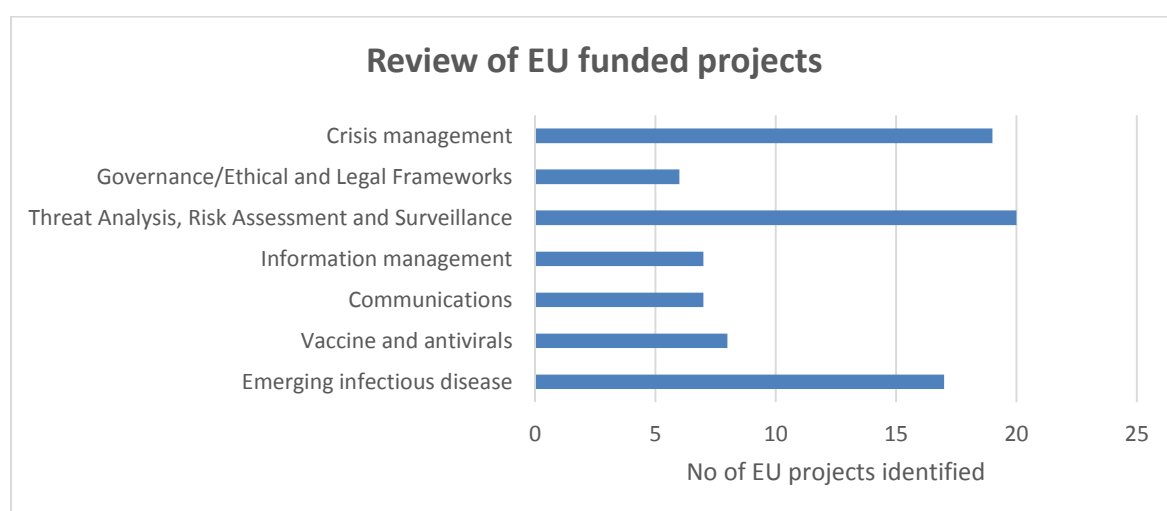


Figure 3. EU funded project areas.

The financial distribution between research areas follow the same pattern as identified above. Crisis management and threat analysis, risk assessment and surveillance projects received most funding, close to 55% (€235 million) of the total. Emerging infectious disease projects receive another 25% of the total funding. Communications, information management, and vaccine and anti-viral projects receive between 5-8% in each area and governance only 2.5% in this review.

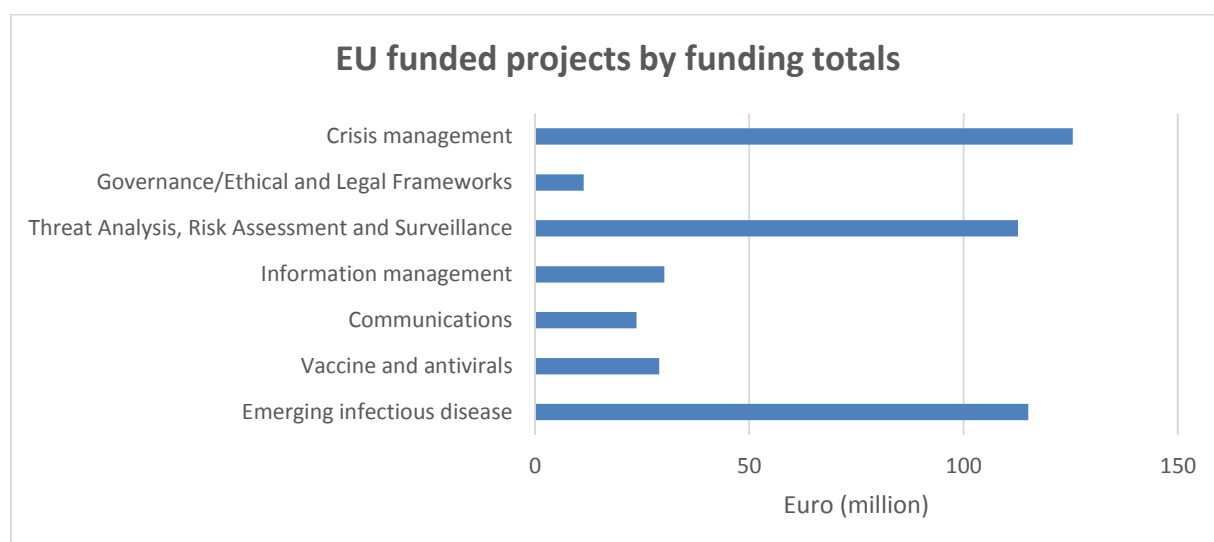


Figure 4. Grants allocated to EU-funded project areas.

When analysing the average budget for the research areas, a different distribution is seen. The difference is less obvious between the areas looking at investment per project. However, if the funds are equally distributed among the 84 projects identified in this report all projects would receive approximately €5.1 million. Governance projects are funded with an average of €1.9 million per project in comparison with crisis management projects which receive €6.6 million on average per project. There seems to be a bias towards crisis management, threat analysis and emerging infectious disease projects in terms of number of projects and funding. Emerging infectious disease projects have an average budget close to €12 million in comparison with €7.5 million for crisis management projects which receive the majority of the funding overall. Security, pandemic/influenza, and food-borne/water-borne projects all have a larger average budget than crisis management projects. Preparedness/public health and research and technology projects have lower average budgets.

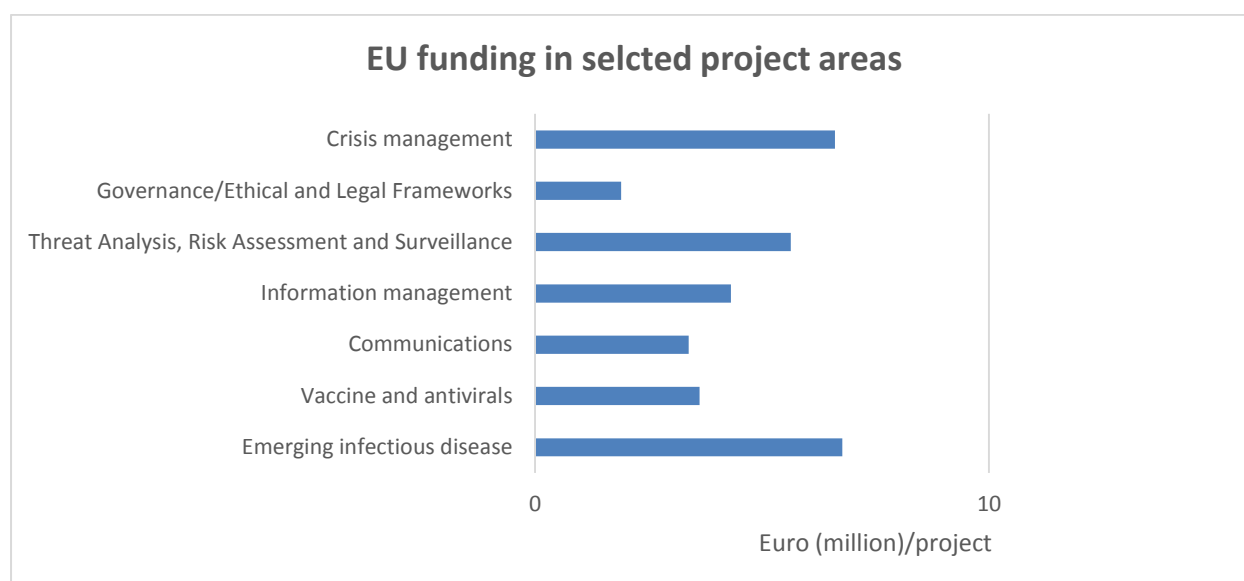


Figure 5. Average EU funding per project in selected project areas.

4.2. Analysis of specific EU-funded projects relevant to PANDEM

The following section explores a number of EU-funded projects of high relevance to PANDEM. Projects are grouped into categories which align with PANDEM Work Packages: *Threat Analysis, Risk Assessment and Surveillance*; *Communications*; *Governance and Legal Frameworks* and *Crisis Management*. Furthermore, vector-borne and zoonotic diseases are grouped under emerging infectious diseases. A number of projects touch on more than one of the categories listed above and are described *Cross-cutting*.

4.2.1. Threat Analysis, Risk Assessment and Surveillance

EUROMOMO (2008-2011): *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 improve risk assessment and management capacity for major health threats including pandemic influenza and other infectious diseases. Weekly European mortality monitoring commenced in 2009 using the EUROMOMO consensus model. During the 2009 influenza pandemic EUROMOMO was able to provide timely measures of excess mortality.

FLUPLAN (2010-2015): 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. Detecting and anticipating possible pandemic influenza strains early can be of vital interest for vaccine development and public health preparedness.

I-MOVE (2012-2017): *The Influenza - Monitoring Vaccine Effectiveness network* aims to measure influenza vaccine effectiveness in Europe. The outcome of monitoring the seasonal influenza vaccine efficiency may be better usage of vaccines, improvement of adjuvants, and a general increased response towards epidemics and pandemics. Also, vaccine strategies and disease burden predictions.

ISSC (2010-2014): *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. The integrated system was developed, implemented and evaluated with a view to the system's translation for early warning of epidemics in similar settings.

MIRACLE (2013-2015): *Mobil Laboratory Capacity for the Rapid Assessment of CBRN Threats Located within and outside the EU* was funded under the security theme 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.

PANDHUB (2014-2017): *Prevention and management of high threat pathogen incidents in transport hubs* was 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 was a cross-border focus and local, national and international practical, legal and ethical implications were 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.

SURVEILLE (2012-2015): 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. The investigation of societal and ethical aspects focussed on undesired side effects of surveillance systems. SURVEILLE addressed legal limitations on the use of surveillance technologies as well as ethical constraints.

4.2.2. Communications

iSAR+ (2013-2015): 'Online and mobile communications for crisis response and search and rescue' (ISAR+) project set out to include citizens in emergency response. It created and tested a system to exchange information between citizens and first responders.

COSMIC (2013-2015): 'The contribution of social media in crisis management' (COSMIC) mapped crises, the use of existing ICT and emerging applications in crises. Findings showed that social media had a positive impact on citizens and emergency response organisations, although a high rate of abuse was also identified. In the end, the project produced guidelines for the use of new media by the public before and during crisis situations, as well as the use of new media by public and private organisations.

SLÁNDÁIL (2014-2017): this project is creating ethical guidelines, strategies for emergency managers and a prototype system to aggregate, analyse, and respond to both verbal and image based social media messages during an emergency situation.

EMERGENT (2014-2017): this project aimed to find ways of identifying and integrating valuable and reliable information from social media into emergency management processes, in order to achieve greater responsiveness. Outputs are anticipated to be new tools for helping to connect citizens with emergency responders, and both communications and ethical guidelines for information use.

SOTERIA (2014-2017): this project is producing recommendations and a toolbox to leverage the positive impact that social media can play in emergencies, enabling public safety organisations (PSOs) and citizens to communicate before, during and after an emergency event.

PHEME (2014-2017): PHEME [47] is an ongoing project that focuses on the challenge of verifying information and communications online. It aims to do this by building algorithms

that will help identify which online information is true and which is not, building on methods for verifying online information, and classifying and processing rumours spread via social media. The platform will then be tested in medical and media settings to understand how users interact with it, and what behavioural implications it might have.

TELL ME (2012-2015) was an integrated EC funded research project involving social sciences, behavioural sciences, communication, media expertise and civil society to develop an evidence-based behavioural and communication package to respond to major epidemic outbreaks [48]. It came to an official end in December 2014, and its outputs included a framework model for outbreak communication, a social simulation model and two e-learning courses for healthcare workers [49]. A key question that emerged centred on the communication gap during the 2009 H1N1 outbreak between global and local health organisations and the public which led to immunization non-compliance and a sense of mistrust.

ECOM (2012-2013): Effective Communication in Outbreak Management: development of an evidence-based tool for Europe (ECOM) [50] is an ongoing project that is aiming to develop an evidence-based behavioural and communications package for health professionals and agencies throughout Europe in case of major outbreaks of infectious diseases. The project's approach includes analysing human behaviour during previous epidemics and using this analysis to determine particular factors, audiences and platforms necessary for developing effective communications strategies. The results of this will feed into communication and behavioural tactics that will be tested with different audiences before the final tool is produced.

FOODRISC (2010-2013) - Food Risk Communication - perceptions and communication of food risk/benefits across Europe. This project aimed to produce a toolkit for policymakers, food authorities and others to aid food communication and to improve public understanding in this area. Researchers gathered new evidence on the challenges of communicating the risks and benefits of food and preventing spread of misleading information across social media, consumer responses to uncertainty, information seeking and deliberation [51]. *FOODRISC came to an end in 2013, and primary conclusions included that there was a limited window during which to communicate with consumers on social media, and that consumers most often started with search engines when considering foodrisk, although channels and depth of research varied by country. The project also developed an online tool called 'Vizzata' to help understand consumer deliberation, as well as a six step strategy for communicating risks and benefits related to food* [52].

4.2.3. Governance and Legal Frameworks

EUROPHEN (2003-2006): Public policies, law and bioethics: a framework for producing public health policy across the European Union by examining concepts of European and universal ethical guidelines. The project aimed to produce an explicit ethical framework for public health. The project compared and contrasted approaches in public health in Member States and documented specific public health priorities. Ethical theories, concepts and traditions were applied to the practice of public health.

Ethical, legal, and social aspects of vaccine research and vaccination policies in Europe (1998-2001): The project aimed to analyse the major reasons for ethical, legal and social concerns surrounding vaccine policies in research and public health. It would establish a European Multidisciplinary Network devoted to monitoring the emerging ethical, legal and social aspects of new vaccines and vaccination policies.

GO4HEALTH (2012-2016): This project aims to assess achievements and shortcomings of the Millennium Development Goals (MDGs) established by the UN in 2000. This is an ambitious set of global goals targeting several topics. The GO4HEALTH consortium focus at health topics and how to achieve the goals agreed upon, addressing problems with national and international responsibility and governance.

HUBBOR (2013-2018): Human Rights Beyond Borders: The extraterritorial application of international human rights law - comparative legal, historical and theoretical approaches. The project will provide an authoritative explanation and critical appraisal of the extraterritorial application of human rights law, covering both civil and political rights and economic, social and cultural rights, including the right to development.

PHLawFlu (2007-2010) - Public Health Law to support pandemic influenza preparedness. The project aimed to strengthen legal tools in support of disease preparedness and the development of coherent European legal responses to pandemic influenza threat. This included the development of an interdisciplinary network of expertise in public health law in relation to communicable disease control, including human pandemic influenza control, across the European Union.

4.2.4. Crisis management

ACRIMAS (2011-2012): *Aftermath Crisis Management system-of-systems Demonstration Phase I*, was funded through the Security theme to develop a roadmap for a subsequent

Demonstration Project Phase II in Crisis Management. The consortium focused on large-scale man-made and natural incidents that would require coordinated response from crisis managers and first responders across Europe. Work involved threat and hazard analysis, development of a set of scenarios, gap analysis for European organisation's capabilities and procedures as well as a roadmap based on specification of infrastructural needs, best practices and demonstration and experimentation topics assessments. Although **ACRIMAS** focused on natural disasters, terrorist attack, industrial accident, humanitarian crisis and CSDP missions the system-of-systems approach and assessment of demonstration topics and roadmap development are very relevant to PANDEM.

DRIVER (2014-2018 planned): *Driving Innovation in Crisis Management for European Resilience* is a Phase II demonstrator based on the findings of **ACRIMAS** and aims to develop a European test-bed enabling bench-marking of new crisis management solutions and actual development of a set of tools that would improve crisis management and member state and EU level.

CBRNEMAP (2010-2011): *Road-mapping study of CBRNE demonstrator*, aimed to create a road-map for the development of a large-scale CBRNE demonstrator project. Similar to PANDEM, the project had a cross-border focus and prioritised demonstration tasks based on end user requirements. End-user requirements were assessed through workshops, questionnaires and stakeholder engagement. Workshops were used to analyse and evaluate gaps, requirements and potential solutions.

S-HELP (2014-2017): *Securing Health. Emergency. Learning. Planning* commenced in 2014 as a small- to medium research topic funded under the Security theme. It aims to enhance protection of public health by advancing the knowledge base required for the development of next generation decision support tools and a user-centred decision support system. It focuses on preparedness, response and recovery in emergency situations and will employ multi-scenario based training for end-users.

4.2.5. Information management

BIG_IDEA (2012-2015): Analysis of genetic data will become more and more important for epidemiology and public health planning. One drawback at the moment is the lack of statistical methods useful to identify transmission routes and spread of epidemics. **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 to process real time data from ongoing outbreaks could unveil transmission routes and be very useful when establishing prevention strategies.

EPIWORK (2009-2013): Establish a framework useful for epidemic forecasts based on non-traditional data sources. This project will develop a tool that uses the increasing amount and availability of social, demographic and behavioural data now available to improve disease surveillance.

EVAg (2015-2019): The goal is to establish an international network around a strong core of European institutes (25) with expertise in a range of virological disciplines. Ultimately increasing the effectivity and usage of the research capacity within this network and making it available for end-users to enhance global research, especially for high level pathogens.

4.2.6. Emerging infectious diseases

ANTIGONE (2011-2016): This project focuses at understanding the underlying mechanisms behind zoonotic pathogens, with an overall goal to identify key factors involved in the zoonotic potential. Increased knowledge regarding zoonotic potential may contribute to better prediction models of possible human pandemics and in the end improved public health and preparedness.

4.2.7. Vaccines and antivirals

REACTION (2010-2014): During a WHO meeting September 2014 regarding the ongoing Ebola outbreak and lack of treatment and vaccines, several therapeutic candidates were highlighted and prompted as prioritized for evaluation. One of those were Favipiravir, an existing antiviral drug with known effect towards other RNA viruses. REACTION will evaluate the possible anti-Ebola effect of Favipiravir in a non-human primate study. As this drug is already approved for human usage and large stockpiles exist, it is a useful candidate for an immediate response.

UNISEC (2013-2017): This consortium will further evaluate recently developed influenza vaccine candidates and hopefully contribute to development of a protective and cost effective universal influenza vaccine, annual and pandemic strains. Three of the most promising candidates will be clinically tested and evaluated based on adequate universal protection and how easy to develop to a marketable product. Several UNISEC partners were previously part of the successful EU FLUSECURE project.

4.2.8. Cross-cutting

ASSET (2014-2017): Action Plan on SIS (Science-in-Society) Related Issues in Epidemics and Total Pandemics was funded under the FP7 Science-in-Society 2013 call. It aimed to forge a complementary partnership to address scientific and societal challenges raised by pandemics; explore and map SIS-related issues in global pandemics; define and test a participatory and inclusive strategy and identify resources to sustain the action in the future. As well as public health, vaccine and epidemiological research, social and political sciences, law and ethics and communication were explored, building on prior work by the **TELL ME** consortium. Of particular relevance to PANDEM, the ASSET consortium submitted a report on Ethics, Law and Fundamental Rights and a Communication Strategy which are both available publically.

Funded as supporting action under the Security's theme, **ARCHIMEDES**, *Support to Security End-Users* aims to build cooperation between researchers and end-users in the security field, as well as to define common operational needs. It has defined barriers to the exploitation of research results.

FLUMODCONT (2008-2011): 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.

PRACTISE (2011-2014): *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 aim was to develop a new toolbox focusing on: investigation of critical elements in event structure through use of scenarios; gap analysis in current response and a system or kit for public information. The response capability functions were considered universal in character and could be applied to EU and member states.

PREPARE (2014-2019): *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.

PULSE (2014-2016): The *Platform for European Medical Support during major emergencies* 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.

4.2.9. CBRN related projects

Member countries of the *Global Partnership Against the Spread of Weapons and Materials of Mass Destruction* is funding several projects of relevance for Article X under the Biological and Toxin Convention (BTWC). The area of biological security has been identified as key priority for the member states. Projects receiving funding from Global Partnership members relevant for Article X mainly focuses on three topics; legal frameworks, Biosecurity, and detection/surveillance. The following projects are of special interest for PANDEM.

EUWAMlab (2014-2015): This project aims to strengthen the capacity to detect and identify infectious disease caused by risk group 4 viruses in countries affected by the Ebola outbreak 2014. The long term goal is to reinforce the capacity and cooperation among the partnership countries to fight biological threats.

Improving biological safety, security and capabilities/capacities in Central Asia to reduce international biological risks (2010-2016): Improving capacities to detect, rapidly identify and diagnose highly dangerous pathogens and EIDs of global concern from a biological safety and security perspective, in Central Asian countries.

Mitigating Biological Security Risks in the ASEAN region (2013-2018): The goal for this project is to increase the capacity to rapidly identify and diagnose highly dangerous pathogens and emerging infectious diseases with pandemic potential in the South-East Asian region.

ViroRed (2010): this is a small project aiming at improving and implementing diagnostic capacities for respiratory and vector borne viruses of global concern in Latin America, Portugal, and Spain.

5. NON-EU RESEARCH FUNDERS

While not directly within this remit of this analysis, institutions both Governmental and non-governmental are funding multiple strands of science and technology research relevant to PANDEM. These include the Bill and Melinda Gates Foundation, the Wellcome trust, NIH and USAID. PANDEM is carrying out a more detailed analysis of research work being supported by these institutions as part of work packages 2, 3 and 4 in the areas of surveillance, communications and governance. The analysis of this research work will be presented at month 9 in the PANDEM product cycle.

The Bill & Melinda Gates Foundation is the largest private foundation in the world with an endowment of 44.3 billion USD (2014). The Foundation aims to enhance healthcare and reduce extreme poverty globally. The Gates Foundation focuses on four research areas, two of which (Global Development and Global Health) are of interest for the PANDEM project. During 2014 the Global Development programme provided funding of 1,923 million USD, nearly 40% of which went on in vaccine projects. The Global Health programme provide 1,114 million USD, close to 80% of which was spent on infectious disease projects. The Gates Foundation was a founding member of Gavi, the Vaccine Alliance, to which it has donated more than 1.3 billion USD over the past five years [53]. Gavi has been positioned as a possible funder of an Ebola vaccine stockpile [54]. Bill Gates has also spoken out about the need for stronger health systems and disease surveillance to prevent future epidemics [55]. The Foundation has recently committed \$75 million to fund a disease surveillance network in Africa to meet this objective [56].

The Wellcome Trust is the second largest private research foundation in the world and largest non-governmental source of funding for biomedical research in the United Kingdom, with annual funding rising from £597 in 2010 to £726 million in 2014. Its ongoing projects of interest to pandemic preparedness and response include funding for influenza research [57], antimicrobial resistance [58], and emergency Ebola research into vaccines, experimental drugs and humanitarian response [59]. The Trust has also recently funded a €25M pandemic crisis management project the London School of Hygiene and Tropical Medicine to direct its research and collaboration with international organisations around epidemic preparedness and response, in the wake of the Ebola crisis [60] [61].

The UK Engineering and Physical Science Research Council (EPSRC) has granted I-SENSE £11 million. This project aims at developing a new generation of early warning systems for disease outbreaks [62]. More rapid detection of outbreaks and identification of causative agents will be of utmost importance to contain epidemics and lower the spread of the disease. The idea is to develop a diagnostic test usable on mobile-phones for diseases and also collect geographical data from the mobile-phone to detect and identify unusual disease clusters.

6. CONCLUSIONS

There is increasing interest in strengthening systems for pandemic preparedness and response globally. However, at present, there is also uncertainty about how to accomplish this task. The apparent lack of overall coordination in the field of pandemics needs to be understood and carefully scrutinized. Coordinating the different organizations and networks within this field is a matter of global interest, as outbreak prevention, preparedness and response management are at the top of national, EU and global agendas following the unprecedented Ebola outbreak in West Africa.

The overall aim of this analysis is to ensure that the PANDEM project takes current international projects and EU initiatives into consideration in a number of areas including crisis management, information and communication technologies and threat analysis. This review of initiatives and research projects relevant to pandemic management funded by the European Commission, as well as other national and international programmes forms a part of Work Package 3 in PANDEM and will feed into the gap analysis undertaken by Work Package 5. By analysing actions taken by the many different actors (for example in relation to the Ebola outbreak, the H1N1 pandemic and other major epidemic responses), this review of global and EU initiatives and of EU research projects will help to ensure that PANDEM delivers the expected results.

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