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PANDEM

Pandemic Risk and Emergency Management

D4.3 Identification of knowledge, capability and capacity gaps, priorities and candidate solutions for pandemic governance

Responsible partners: LSHTM

Authors: Elizabeth Speakman, Richard Coker, LSHTM, UK

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

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1 OBJECTIVE

The objective of this report is to provide a synthesis paper on knowledge, capability and capacity gaps, priorities and candidate solutions to strengthen pandemic governance in the European Union.

2 BACKGROUND

This report is a synthesis of research already conducted for reports D4.1: Review of policy and legal frameworks, and D4.2: Review and analysis of ethical and human rights issues. These earlier reports examined existing key legal, ethical and policy frameworks at global, European and national levels with the aim of identifying commonalities, disconnects and priority challenges for future research.

During the process of this research it quickly became apparent that "pandemic governance" is a vast field. Limitations of time and resources meant that it was not possible to cover all areas encompassed by this description. For example, in terms of governance frameworks, key global and EU documents were identified and briefly reviewed, but it was not possible to review relevant national governance arrangements of all 28 Member States as this would have required more resources and time, including translation facilities. Similarly, pandemic governance includes many important individual preparedness and response subjects (a previous project: PHFluLaw identified 24 themes), any one of which could justify detailed review on its own.

Pandemic governance is multi-layered and complex, involving issues of politics, law, ethics, economics, public health, inter-sectoral working, and more. A comprehensive review is not feasible within this 18 month project. Nevertheless, within these limitations, research for reports D4.1 and 4.2 identified many priority challenges in pandemic governance. This was achieved through literature reviews (systematic and purposive), key informant interviews, input from an expert workshop in Brussels held 17-18 February 2016, review of previous relevant research projects, and research for three case studies based in Europe and the United States.

These findings from D4.1 and D4.2 were summarised at D4.1:16.2: Summary of commonalities and disconnects for further investigation; and D4.2: 5: Priority challenges for future action. This report explains how this large number of proposals has been analysed further to prioritise a limited number of topics for further work.

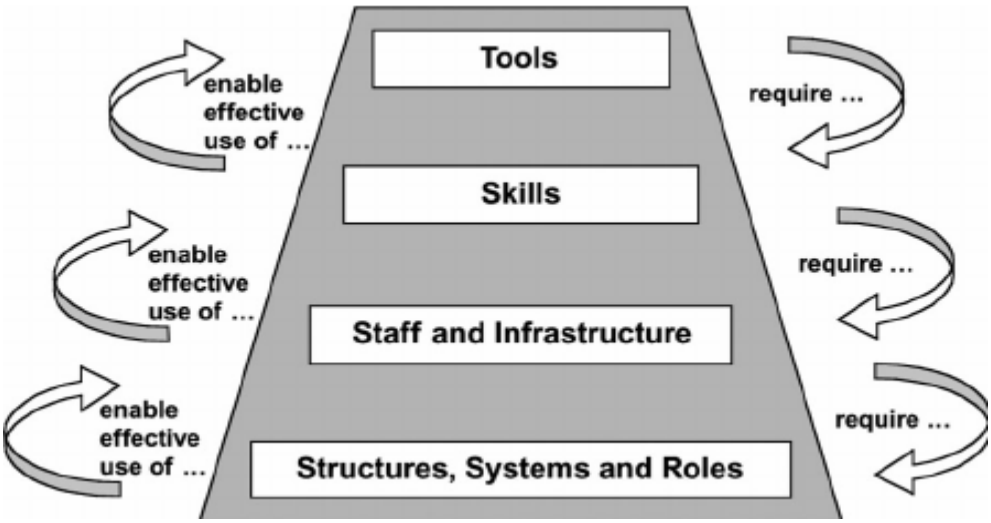
3 METHODOLOGY

Priority areas identified in reports D4.1 and D4.2 were reviewed in consultation with consortium members to narrow these down to four key areas. These four areas were then investigated further by means of:

- Purposive literature review of issues identified after June 2016
- Input and feedback from an expert workshop held in Brussels 21-22 September 2016
- Further key informant interviews. Eleven interviews were conducted with key informants in public health governance between March and May 2016. These contributed to reports D4.1 and D4.2 which were submitted in June 2016. The questionnaire and ethics approval are set out in those reports. A further four interviews were conducted between July and October 2016 using an abbreviated version of the same questionnaire and referring to specific proposals.

Methodological Framework

The results of this research are analysed drawing upon the conceptual framework developed by Potter and Brough, their Capacity Pyramid:



Potter and Brough: Capacity Pyramid

4 RESULTS

4.1 FINDINGS FROM REPORTS D4.1 AND D4.2

Report D4.1: Review of policy and legal frameworks

16.2: Summary of commonalities and disconnects for further investigation

Data collection

- Full inventory and analysis of national pandemic preparedness plans
- Full inventory and analysis of domestic legislation underpinning pandemic preparedness.

Improved cross-border coordination, collaboration and interoperability

- Sharing among countries of planning measures (accessible plans) and relevant stakeholders
- Improved coherence and harmonisation of planning among countries (while still respecting sovereignty).

Supporting the EU's role in international pandemic governance

- Coordination and cooperation between the EC and Member States with regard to support and assistance to affected States outside the EU
- Coordination and cooperation between EC agencies.

Capacity

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

Model legal and policy documents

- Model emergency powers act
- Model national pandemic preparedness plan.

Security

- Define the military's role in a public health emergency
- Define public health threats as a security issue.

Civil society

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

Report D4.2: Review and analysis of ethical and human rights issues

5: Priority challenges for future action

Greater prioritisation of ethics and human rights in pandemic planning

- Ethics should be the foundation of pandemic preparedness planning, the spine upon which any strategy and actions are developed and justified
- Many national plans are drafted by public health experts only. Law, ethics and human rights should be integral to national planning so lawyers and ethicists experienced in public health should be part of the drafting teams
- Support at EU level of the importance of an ethical framework for pandemic planning, perhaps by producing an EU ethical framework.

Alignment of national pandemic preparedness plans

- Comprehensive review of EU national pandemic preparedness plans to identify the ethics and human rights perspective of proposed measures
- National plans should not be focused narrowly on threat from pandemic influenza alone, but should be broader to include measures to respond to other public health threats. Each of these measures should be assessed from an ethics and human rights perspective.

Increased research into ethics and human rights in pandemic planning

- Research to identify why ethics and human rights are such low priority so this can be reversed
- Research should consider ethical and human rights issues in all proposed pandemic measures, including communications and surveillance.

4.2 POTENTIAL PANDEMIC GOVERNANCE RESEARCH TOPICS FOLLOWING CONSORTIUM DISCUSSION

Reports D4.1 and D4.2 were disseminated for discussion and feedback from other PANDEM consortium members. The list of challenges was then synthesised into four potential pandemic governance research topics, which incorporated many of the key suggestions of D4.1 and D4.2:

1 Model legal framework for Pandemic Preparedness and Response

To incorporate:

- Capacity building in public health law

- Mapping of existing EU Member State legislation and policy.

2 Increasing trust in public institutions

To incorporate review of:

- Communication (including risk communication) with the public
- Public health authorities working with the media
- Managing population apathy and panic
- Community education
- Ethics and transparency in public health planning and response.

3 Supporting the EU's role in international pandemic governance

This might include to incorporate an EU Global Health Strategy consistent with Decision 1082/13 which could consider the following areas:

- Coordination and cooperation between the EC and Member States with regard to support and assistance to affected States outside the EU
- Coordination and cooperation between EC agencies.

4 Resource allocation model for preparedness and response

5 ANALYSIS: POTENTIAL PANDEMIC GOVERNANCE RESEARCH TOPICS

As explained in the Methodology section above, the proposals identified by the consortium were subjected to further scrutiny. This was done by means of purposive literature search and input from public health experts in individual recorded interviews, and in the expert workshop held in Brussels 21-22 September 2016. Verbatim comments from interviewees are given at each relevant section. Comments illustrate the views of senior public health experts at this time, but do not necessarily imply endorsement by the PANDEM consortium.

For the purpose of this report, themes have been separated into four separate proposals for further action. However, there is a certain amount of overlap and research for one topic may benefit others. For example, data collected on national legislation (5.1) could be useful for other research topics, such as exploring how to increase trust in institutions (5.2), or to achieving better coordination and cooperation for an international governance role (5.3). The global strategy plan proposed for 5.3 might incorporate any of the other proposals made in this report.

5.1 MODEL LEGAL FRAMEWORK FOR PANDEMIC PREPAREDNESS AND RESPONSE

The benefit of a European model legal framework for pandemic preparedness and response was considered when researching the case study: *United States Model State Emergency Health Powers Act*. (This case study was suggested by experts at the first Brussels workshop, held 17-18 February 2016). The full case study is at section 15 of report D4.1 and a shorter version, currently submitted for publication, is included at Appendix 8.1 of this report: *Personal View: Can the US Model State Emergency Health Powers Act be a guide for Europe?*

5.1.1 THE VALUE OF A MODEL EMERGENCY ACT

The background to this proposal is that all 28 EU Member States are signatories to the International Health Regulations 2005 (IHR) and EU Decision 1082/13 which set obligations for pandemic management. These are legally binding. However, a key weakness of these and other international legal instruments are the difficulties of enforceability at international level. The terms of the IHR and Decision 1082/13 need to be incorporated into domestic legislation which can be enforced by national governments. A further challenge is that the principles of national subsidiarity and sovereignty mean that countries can comply with international obligations in variable ways and according to the

resources available to them. As pandemic management, by definition, concerns management of a cross border threat, this may create difficulties of coordination and coherence.

Previous research by the PHLawFlu project: 2007-1010[1] found that representatives of Member States were unclear what national legislation for pandemic management, if any, was in force in their countries. Furthermore, some existing legislation appeared to be outdated, illegal and/or unethical (in breach of the European Convention on Human Rights). Most policy documents had been prepared without input from public health lawyers

The more limited research conducted for PANDEM found that national pandemic preparedness plans made very few references to supportive legislation, and even where this was stated to exist, it was not easily accessible [Section 8.1, D4.1].

Creating a model legal framework flexible enough to be acceptable to all Member States would be extremely challenging but the development process would of itself provide a number of important benefits.

The case study sets out the potential benefits of a model legal framework for EU Member States. In brief, if adopted into national legislation, this would help to ensure measures which were coherent, coordinated and transparent across states. Equally important, the measures would be evidence-based, reflecting current scientific knowledge, they would provide a legal basis for pandemic management, and they would incorporate consideration of ethical issues and protection of human rights. Individual Member States could use or adapt measures in the model framework to their own particular country context so that they were culturally and socially acceptable, while also enforceable.

Interviewees were largely supportive of the concept of a model act, while noting the political challenges to achieving this:

"*There is a lack of interoperability but countries and national laws are sovereign.*"
"A model act would be useful. It can open dialogue between countries but would be politically difficult."

5.1.2 REQUIREMENTS TO CREATE AN EFFECTIVE MODEL ACT

1. Political commitment
2. Representatives from 28 Member States to design a model act
    - Capacity in public health law
    - Understanding of existing legislation
3. Adoption/Sustainability.

1. Political commitment

The example of the MSEHPA shows that a model act will only achieve acceptability if governments recognise legislative need and are part of the drafting process. This was confirmed by interviewees:

"They need to understand what they want to do as Europe. Then once they understand that, they can put it into legislation…What you need to tell them is 'sit down and talk and figure out how you're going to do a better job next time, and then put it into legislation'."

"Legal systems are so very different from state to state. And what they considered necessary to be put into law in one state, would not be in another. And the way they go about enforcing law is very different. So we found it very difficult to get a common approach to public health law across the states."

2. Representatives from 28 Member States to design a model act

The process of bringing country representatives together, by itself, would be beneficial to achieving better cooperation. This was the experience of PHLawFlu researchers:

"The meetings we had were incredibly helpful. Once we'd identified someone who had enough knowledge to be representative of their state, they got to know each other, they interacted with each other, they sent us information online. It works much better to have one institution that collaborates, where you have representatives of each state. That works better than having lots of different agencies…

…A lot of them were public health people because there were no public health lawyers. But they were people who administered the public health and they would tell us whether or not there was any legal framework for them to work in. Or if there wasn't any, they would say "we're a bit worried that there isn't a legal framework. Because firstly we don't know what we can and can't do. Also because there are people who do things that

we would regard as not ethical. But because there's no legal framework there's nothing we can do about it."

2a Capacity in public health law

Both PHLawFlu and PANDEM found that there is a serious shortage of public health lawyers in many Member States [1, 2]. Although in some cases, such as Ireland and Sweden, we were informed that law and ethics are an important part of the policy drafting process, there was no evidence that this is the situation Europe-wide. Much policy appeared to have been drafted by public health staff without input from legal or ethical experts. This was reflected in policy documents, including national plans, which made little reference to legal underpinning or ethical considerations. There is therefore a pressing need to build public health law capacity by means of training courses throughout Europe. These could be directed to train lawyers in public health issues, or to train public health practitioners in relevant laws.

"The EC needs to increase capacity in public health law – fund a programme for training lawyers."

2b Understanding of existing legislation

To create a model act it would be necessary to review existing legislation to identify examples of both good and bad practice. A key issue, identified by both PHLawFlu and PANDEM, is that there has been no mapping of relevant legislation in the Member States to identify compliance with the IHR or Decision 1082/13. PHLawFlu found that even representatives of Member States were not always sure of what legislation existed in their own countries. There was a lack of transparency and some legislation appeared to be outdated and unethical.

Mapping of Member State legislation would be challenging, given the different languages and legal systems, but it would be possible. One example would be to use LawAtlas: http://lawatlas.org, a policy surveillance programme funded by the Robert Wood Johnson Foundation which teaches policy surveillance methods and legal mapping. It also maintains datasets of legislation and resources for researchers. The ultimate purpose of LawAtlas is to make the case for laws that improve the public's health:

"Legal mapping can help policy-makers, advocates and researchers understand what the laws are on a given topic, know how the laws differ over time and across jurisdictions, and provides data so they may evaluate their impact."

The procedure for rigorous mapping of legislation is set out in Annex 3. In brief, the procedure to follow is:

- Define the Scope
- Conduct background research
- Question development
- Collect and Build the Law
- Code the law for each jurisdiction
- Quality Control.

5.1.3 THE US MODEL STATE EMERGENCY POWERS ACT (MSEHPA) AS A PRECEDENT

The case study proposed using the US Model State Emergency Powers Act (MSEHPA) as a precedent and we consider that this would be a valid model for consideration. However, there may be other European examples to follow, and any European model would need to reflect different cultural priorities. This was the view of interviewees:

"The US is a fantastic place to look at from the point of view of state and federal structures. And every state is completely different. So a bit like the EU in a sense. More homogenous than the EU would be, but I think nevertheless there are a lot of similarities."

"It's nice to say the US has a good model, and there are many other countries that might also have models, like the UK which has a fairly decent model for flu. And it might be useful for the Commission to get a review of these done. And then to take this into their discussions at a high level, cross-sector within the European Commission."

"I think it wouldn't be politically acceptable to say follow the US model. What we do as academic institutions is tell them, here are some options to consider."

3. Adoption/Sustainability

As discussed above, although the process of creating a model act would have benefits in increasing public health law capacity, and gaining a proper understanding of existing legislation, for European states to incorporate the terms of a model act (in part or fully) in national legislation, would require political commitment.

To help ensure sustainability, some interviewees recommended that legal and ethical advice be provided to policy makers across Europe. This could be an advisory Legal and

Ethical Committee which would sit at the heart of the EC and provide advice, or else perhaps an advisory website:

"A committee maybe, where each state was represented. Where they could input into the content of any laws that were passed and any principles. I think that would be quite viable."

"[On a model act] It has to be backed up by some sort of European information support. It's not just a piece of legislation, because the people who are not lawyers will find the legislation very difficult to understand. So what they really want is advice. So what we really need is a cross-European institution which takes responsibility for helping out individual states in relation to public health responses to disease. But also explaining to them what the limits are to what they can do. They can't just arrest people or throw them out of the country. There are legal limitations to what they can do. So they start to understand what they can and can't do and what they should do."

"A website could deal with a lot of the problems. So you wouldn't need to spend a lot of money and people would pass information around. And a place where people could ask questions and get help."

5.1.4 ANALYSIS: CAPACITY PYRAMID

Tools: Database and evaluation of existing domestic legislation in EU Member States
Skills: Knowledge in negotiation and drafting of public health law legislation
Staff and Infrastructure: Training to increase capacity in public health law
Structures, Systems and Roles: Forum for debate by knowledgeable public health lawyers and public health practitioners familiar with relevant law, from 28 Member States with authority to represent their nations and contribute to design of a model act.

5.1.5 SUMMARY

Creating a model act, and the steps required to achieve its creation, would provide a number of important and long-term benefits:

- Capacity building in public health law
- Data collection
- Better cooperation and understanding between Member State representatives
- Leadership and support from the EC
- Potential for future development, e.g. a Legal/Ethical Committee to sit at the heart of Europe and give advice to Member States, an advisory website.

Above all, a model law approach could provide a thoughtful, well considered template for reform of antiquated and inconsistent rules in European countries and achieve an appropriate balance between security and civil liberties. This is a pressing need as there are likely to be future outbreaks, epidemics, biosafety breaches, and bioterrorism.

5.2 INCREASING TRUST IN PUBLIC HEALTH INSTITUTIONS

A recognised loss of trust in public institutions was a key concern amongst experts at the first Brussels workshop, held 17-18 February 2016. This theme also arose during research into the case study on the *E. coli* outbreak in Germany 2011 [Section 14, D4.1].

5.2.1 THE IMPORTANCE OF TRUST IN PUBLIC HEALTH INSTITUTIONS

Ensuring the trust and support of the population in its national and regional public health institutions is critical to effective and efficient pandemic management. Potentially controversial, but necessary, measures such as enforced quarantine or isolation, or rationing of scarce medical resources, vaccination policy implementation, etc. will not be easily achieved without the support and understanding of the public. The population is unlikely to provide this support unless they trust public health authorities and key stakeholders. The communication environment has changed radically in recent years with many more voices being heard through a multitude of different media often in real-time. A lack of trust and support – perhaps even leading to population panic – can obstruct or damage the effectiveness of pandemic preparedness and response. A critically important area that needs further understanding is the issue of trust in the face of uncertainty and where knowledge is accumulating daily, and where authoritative voices may change their position as new knowledge becomes available.

Several interviewees noted that loss of trust in government institutions is an increasing phenomenon. They pointed to recent developments in Europe and the United States, where political groups have harnessed and even encouraged institutional distrust. Such developments are dangerous and threaten to undermine other measures.

"Well of course it's an issue. And there's a whole series of issues that arise around it. Who is the most trusted? Who is best able to gather the evidence and assimilate it? Who will have the best ways of communicating it? The problem is that if you look in a country like the UK…the vast majority of the population has no idea about the difference between the European Parliament, the Council and the Commission."

"I don't think the public trusts anybody in positions of power at the moment. And they don't trust our systems. So it's also fascinating that the politicians talk about bringing back sovereignty. That's not going to make any difference because the public doesn't trust any of the systems we've got: the EU ones or, don't think that our ones here are any better. We just don't trust."

"In all the EU countries, how connected are the different individual members from countries to what the EU does, and process…We don't understand how these groups link up. All we see is this massive bureaucracy in Brussels… But there's no understanding of how transparent those processes are."

"*There's a lack of trust in authority generally. That's why people are voting for Donald Trump and extreme parties. It's not just this, it's a more general problem in society.*"

5.2.2 HOW CAN TRUST IN PUBLIC HEALTH AUTHORITIES BE INCREASED?

At present, it is unclear why exactly there has been such a loss of trust in public institutions and authoritative figures/experts. It is likely to be multi-factorial and further research is required. Research would include developing an understanding of levels of trust in public health institutions, where challenges exist, and what their implications are in relation to pandemic preparedness and response. It would also include analyses of trust between individuals, and trust in experts, as well as how trust develops and how it can be destroyed, and the role of communication tools and strategies in notions of trust. Until the reasons for this loss of trust are understood, it will be difficult to take effective measures to improve the situation and inform effectively communication strategies.

5.2.3 POTENTIALLY RELEVANT FACTORS FOR INVESTIGATION

Research conducted for D4.1 and subsequent interviews suggested a number of factors which may be relevant to trust:

- Communication
- Trust and uncertainty
- Working with the media
- Managing population apathy or panic
- Community education
- Ethics and transparency in public health planning and response.

Communication

Several commentators identified the ECDC as a key source of information for Member States. It would be a trusted and reliable European body, although it should remain a matter for individual countries to communicate and pass on that information to their populations. The role and mandate of the ECDC also arose in considering the role of the EU as a whole in global health governance (5.3).

The role of the ECDC as a source of technical information

"We need a central body where you can go for information. That is trusted, and that people understand, and that the process is fairly simple. Every country has its own system, but if you go to, say, the ECDC then it's there and we can see all the different bits it does and it has a group that work on outbreaks, and this is what it's reporting, and these are its recommendations. If you know that those are the European ones, then every country will still have its own, but at least there will be something still identified as European. "

"I would be leaving that up to each individual country. The ECDC has a responsibility of overarching all that, but holding the information from different states. Then you could go to them, and they would be fantastic because they would have information about: well this is what they do in Italy, and in Spain they do this, and in Denmark they do this. …Yes maybe just the Danes but perhaps you could try it in Northern Ireland."

"There will always be mavericks. There will always be people who want to make their mark in publicity. But I think ECDC has a role to identify the important things to be communicated, to suggest how they should be communicated, and I think Member States should listen to that."

"There needs to be a technical agency such as ECDC which provides the evidence and the messages. And countries can take those, and adapt them to use in their own communications. I believe that's what happened in influenza and swine flu and in other areas. But I think there needs to be a constant source of valid technical information. And countries then take this information and present it to their populations as best they see fit. Understanding that countries may nuance these in different ways depending on their own strategies."

"I think the level of confidence in what ECDC says is quite high, because they're highly respected people at ECDC… So the trust issue is a matter of the European Commission

maybe not trusting its own institutions, whereas the countries maybe do trust those institutions, I don't know."

Member States as national communicators

"It's clear that Member States want their public health institutes to communicate with their public. They are happy to take the groundwork from ECDC, but they want to be the ones who inform the public. And there may be some reason for that. You probably communicate differently in Malta than you do in Norway."

"I think the countries consider themselves sovereign and don't want to be nannied by the European Commission. What they want is the information. I think that's what has to be portrayed to Europe. That they should stop trying to coordinate communication if they have been. But rather, to provide the right messages so those people can use them."

"Europe is a bunch of individual countries that have their own context….. I think to try to rigidly control that would be impossible. Countries do know to go to ECDC and CDC and WHO for current information. They then can package that at ECDC. And countries can unpack it and use it as they wish."

Trust and uncertainty

The case study of the *E. coli* outbreak in Germany of 2011 illustrated the challenges for public health authorities to give messages which protect the population from potential hazards when information is still uncertain. In that case the authorities had to achieve a balance between alerting the public to a health risk, while exercising caution to prevent panic, and while information was still being received on an ongoing basis. Official spokespeople were subsequently criticised for health warnings given in good faith which proved to be inaccurate. It is unclear whether this has resulted in a long term loss of trust.

"There was clearly a difficulty between the state and the federal government in Germany. As a result the state was blaming cucumbers and the federal government said we don't have the information yet. But then going to ECDC who sorted all this out, could tell you there's not enough evidence for this right now. "

"Timeliness, accuracy, uncertainty are all challenging for authorities to deal with."

Working with the media

"There's always the sensationalists, but I have found…that if I spent time with the key journalists in the world, that others emulate, that could get the message through on SARS for example, and on Ebola… We could get those messages to the reputable journalists, and that in itself was a major accomplishment. That's why I'm still very conscious about the importance of having a good group of press people from countries around the world who you can speak with. Maybe that's what the European Commission needs to do. To have a list of those journalists who they want to inform on a regular basis. Not necessarily during outbreaks, but just to keep them up-to-date with issues, and have a virtual briefing session with them every 6 months to tell them what's going on in public health. If you do that kind of thing then you get the right press."

"Of course the media does what they want to do... they would trust ECDC if they were given updates on what's going on in outbreaks around the world every 6 months."

"People are looking for the catastrophic events rather than the positive events. It's a phenomenon that's in the world today and it's one that it's very difficult to deal with. It often can't be dealt with. But through constant information to the press, helping them understand the issues you can sometimes overcome that. Though most people hate to spend time with press, if you can get the technical people to do that, and they can understand it, then they can understand how they can help, I think it's much better."

Managing population apathy or panic

Experts disagreed on the extent of potential public panic. They also disagreed on whether public apathy was a good or bad thing, with the argument being that the alternative might be hypersensitization of the public, such as the disproportionate fear of Ebola amongst the US population during 2014-2015. An acknowledged difficulty in assessing this is that contemporary Europe has never been tested by a major pandemic with the virulence of historic examples such as the Black Death and Spanish Flu. These clearly occurred in non-comparable contexts.

"The public doesn't panic. That's a myth. Everyone says that…But the public doesn't panic. They're very rational. The Public Health Institute says "we had a thousand people call into our switchboard yesterday about this or that". But what about the other X million people who didn't call?... It's a myth. People are quite rational… They may change their daily activities if there's an infectious disease for a week. Then they go back to normal. It's too cumbersome to take the car instead of the tube."

"Was there panic in the UK when this nurse came in? I don't think so. I don't think there was any panic in the UK…I think the response in Europe was much more sane, because the public is less informed maybe! Less informed on disaster, on potential issues. Modelling is probably the worst enemy in all of this. Because modelling is sometimes not perceived properly by governments."

"That was an issue that came up with SARS. There was an incredible amount of panic. But I'm not sure that it can be regulated by laws so much, as by the approach of the government. How it deals with people who are panicking, or people who become very frightened by the existence of a disease, and making clear what is safe and what is not safe. So it's clear to the ordinary reader what they can and can't do, where they can go and where they can't go. With SARS there was a lot of very good advice about wearing face masks when you go out. In Hong Kong all the different masks became like a fashion item, but people did wear them. And people changed their customs of spitting in the street."

"Maybe apathy is the right approach to it. Apathy among the public, but alertness among the governments… I get tired of going to airports in the US and hearing we're now on Alert Red or whatever. That stuff is not necessary to me and it causes panic. So I'm not so sure that we want the public involved at all in these discussions. We want the government to be able to understand the issues and deal with it. I think apathy is helpful in the population, but not helpful in the government…The European public is less hyper-sensitive and more agnostic, if you would, than the US public...I don't like a hyper-sensitised public to be all the time worrying about the next outbreak or the next security crisis. I think that's wrong. I think governments should be ready and should be able to kick into action and get people mobilised when they need to."

"There's a problem of apathy until it becomes a serious threat. Then suddenly everyone goes into panic mode. There probably is a problem of apathy in that people are not prepared to take precautions if they don't see themselves at risk."

Community Education

"I think there is a problem that many people, even in public health in the UK, don't understand the role of international cooperation. So I think we need to do much more in public health in our training curricula. But one of the biggest problems is that the mass media don't understand anything of Europe at all."

[Would community education help?] "I do think that. Especially starting young, going into schools, letting kids know that if they have a disease like a flu bug or anything else, that they could be a danger to other people. And that it would be nice and helpful of them if they were to wear a mask or stay home etc, not spread the disease to others."

[On the benefit of community education] "Yes, but not with the objective of hyper-sensitising the population. With the objective of helping them understand many different issues in health, including the need for washing hands. It's a whole series of educational events that we'll talk about this within. But it won't be specifically targeted for pandemics."

Ethics and transparency in public health planning and response

The limited role of ethical consideration in EU national planning was identified in report D4.2. This illustrated that few Member States had ethical frameworks which were either referenced in national plans or publicly accessible. This is of concern because so many response measures can involve controversial issues balancing individual rights against the public good. Such measures need to be justifiable for public acceptance and trust. Yet there is only brief reference to ethics in the ECDC website and there is no European-wide Ethical Framework. This was raised with interviewees, who also pointed out the relevance of ethics to communication and reporting.

[On having an Ethical Framework] *"That would be doing something around values within communication organisations…Getting some way to get them to take responsibility ultimately for the effects of what they're putting out there. Journalist ethics at the end of the day… The whole thing around how fear is driven in the media. It's just so shocking and so obvious. Maybe they think it's normal and OK. But it's not... There's this norm now, soundbites. 24-hour news. There's this very particular way of getting things across. And if you look at the values in it. What are the values in it? They're not good values, they're not balanced values."*

"It would be important to have some general ethics considerations. The basic one is if you're talking about control, what is the other side of control? It's around generosity and openness and protection of rights and so on, of individuals. So if you're wanting to do stuff where you're going to be controlling the population, then the danger is that you're going to be on the other side, discriminating against individuals. So even highlighting that as the start: you're doing this but you're considering the other side of the story as well. Which is what the balance in ethics is about. In all the things that you're doing.

And don't just assume that "control" is the only aspect that you need to be considering. For example, maybe at the time you're dealing with controlling Ebola, but after it's over you then need to be considering why did it happen? Why are there no health systems here? How are we supporting this population to prevent them getting Ebola, and so on? So social determinants, structural interventions, that kind of thing. That's to me what the ethics should be. Kind of like a reminder that if you're doing this, you need to be thinking about the other side of things as well…"

"I think a bit of training in ethics and human rights would go down well with the people who are making policy. You'd be surprised how few people know what human rights do and don't exist, what is being put into legislation etc. They just don't really know much about human rights laws or constitutions."

"Having the people who have the surveillance data understanding completely what can be done and what shouldn't be done with it, proper training. You can't bring in laws that are going to do anything about it. It's really a question of people having a full understanding of medical ethics. There's a lot less ethics teaching than there used to be. People don't seem to be that interested any more."

5.2.4 ANALYSIS: CAPACITY PYRAMID

Tools: Ethical framework
Skills: Communication, Community Education
Staff and Infrastructure: Official Spokespersons
Structures, Systems and Roles: Information structures and systems.

5.2.5 SUMMARY

The number of potentially relevant themes and differing views illustrate that trust is both critical and also little understood. More research is needed into this issue.

Further factors identified at the Brussels workshop held 21-22 September 2016 were that trust involves an understanding of behavioural responses, as well as institutional consistency. Health literacy is important both among journalists and with the general public. It is not a binary choice between appealing to emotions, or focusing on scientific evidence. A public health message requires both to gain the trust of the public.

Some factors which were agreed were that trust in institutions seems to be correlated to overall trust in government and that an ethical, transparent approach should lie at the heart of pandemic planning.

5.3 SUPPORTING THE EU'S ROLE IN INTERNATIONAL PANDEMIC GOVERNANCE

The role of the European Union in global public health governance was discussed during the Brussels workshop 21-22 February 2016. It was explored further in the case study "European Union response to Ebola outbreak 2014-2015" at section 13 of report D4.1. The EU was generous with financial support to the Ebola response and by July 2015 the total contribution stood at €1.8 billion. This included funding from individual Member States and over €869 million from the European Commission. While the deployment of the Dutch naval ship and deployment of European mobile laboratories were significant contributions to the response, the EU Ebola Coordinator acknowledged that there were organizational challenges in deploying medical and multidisciplinary response teams to the field. The mandate of two key agencies DG SANTE and ECDC are primarily to support coordination of health activities in the EU. However when an epidemic or pandemic threatens the EU from outside its borders, this requires support to affected States external to the EU. While progress has been made including the launch of the European Medical Corps, further work is needed to ensure the EU is better prepared for the next major global health emergency.

Further defining the European Union's international governance role during pandemics is important for the following reasons:

- Early detection and control of emerging diseases with pandemic potential as close to the point of origin as possible is the best protection for EU citizens
- The EU is a major contributor of international aid in terms of finance, supplies, human resources and technical services
- Coordinating all aspects of the EU's response would provide the best opportunity for mitigation and control and would ensure the most effective use of EU resources.

Further strengthening of the EU's activities aimed at contributing more effectively to international efforts to contain and mitigate epidemic and pandemic threats outside EU borders might include an EU Global Health Strategy consistent with current ongoing EU collaboration in the area of global health (http://ec.europa.eu/health/strategy/principles/eu_actions_principle4/index_en.htm) and which could consider the following areas:

- Coordination and cooperation between the EC and Member States with regard to support and assistance to affected States outside the EU
- Coordination and cooperation between EC agencies.

Governance experts at the February 2016 workshop agreed that the scope of PANDEM's research should be:
"*The European Union as an actor at national, regional and global levels in the sense of protection of EU Member States and of the EU in general. European interests are interlinked with global interests, including those of low and middle income countries.*" [Section 12, D4.1].

Subsequent interviewees supported this view:

"For infectious diseases there's clearly a remit to work outside Europe, to protect Europe. I think there's no question of that."

"They're politically sensitive issues… protecting yourselves means strengthening capacity of others so that their diseases don't come this way."

"They need to really consider how they can best add value to the global environment, while not forgetting that the most important thing is strengthening country capacity. It's not a boy scout activity, or a girl scout activity, it's an activity of goodwill, of strengthening capacity so that countries can do it on their own."

"I think what's important is for them to understand that this is the way they're working within their development funding. And also that the bilateral donors in Europe can't run the same thing. It's not a matter of waiting till these things happen and responding. It's a matter of helping countries prevent them from occurring."

5.3.1 HOW MIGHT THE EUROPEAN UNION DEFINE ITS ROLE IN INTERNATIONAL PANDEMIC GOVERNANCE?

This is clearly a political decision, to be decided following political debate among representatives of all Member States.

A strategy proposed by interviewees is to create a global health strategy for the EU, perhaps following the model of the UK's "Health is Global" Plan[3]. The content and summary of the 2014-2019 plan[4] are set out at Annex 4, but key features are:

- Strategy scope

- Strategic priorities
- Achieving the strategic priorities
- Addressing practicalities (including appropriate use of resources and prioritisation)
- Monitoring activity and accountability.

5.3.2 A GLOBAL HEALTH STRATEGY FOR THE EU CONSISTENT WITH DECISION 1082/13

Apart from clarifying the EU's global role in international governance, possible themes for a global health strategy consistent with Decision 1082/13 could include those suggested in other proposals, such as model legal or ethical frameworks. Other key issues which arose during research were how to achieve better coordination and cooperation between agencies and the role and mandate of the ECDC. These are all difficult and complex issues, which would benefit from substantive review by all agencies of the European Commission with the aim of achieving a long term vision and strategy.

"Getting the sectors together to understand that they all need to participate in protecting Europe by going broader than they are, then their reasoning might be the way to move ahead."

"Get all the different agencies together in Brussels and Luxembourg and have them make some sort of "Health is Global" plan based on the model that the UK successfully developed. Second, once that's in place and responsibilities are understood, of who would be doing what, then develop some Europe-wide exercises. It would include not only the European agencies involved in response, but also WHO. Because WHO can guide what the Europeans should be doing… Exercising within Europe would do a great deal to show where the weak points are, and what needs to be done."

"Individual states work separately without getting together [in relation to global responsibilities beyond EU borders]. *And individual states take different perspectives about their role. I don't know of any actual EU policy. It may be that there is one now. But there never used to be one EU policy that would take on the whole issue of global responsibility by the EU. It was just left to each individual state to take its own view. I think getting some sort of agreement across all the states in the EU is going to be quite difficult. It's the same with the refugee crisis. What Germany thinks you should do is not the same as the UK will do."*

[During the Ebola crisis] *"All health specialists in the commission were much more focussed on Europe. So there was a mismatch, and not only at policy levels but also at very practical operational levels. So that was definitely an issue and no one had really thought through what to do when we'd have to assist a country in such a way and needing that expertise there rather than in Europe… There was quite a big Cuban mission that went to West Africa. One of the doctors got infected and needed evacuation. So we evacuated one of them but because he wasn't an EU citizen it took us quite a while to find a country that was willing to accept this patient. Because all Member States see it as a threat coming into your country."*

5.3.3 SUMMARY

A Global Health Strategy consistent with Decision 1082/13 could be a key tool for improving coordination and cooperation both within the European Union and its Member States, and in relation to the international community. It would set priorities and targets, and ensure accountability. It could help to resolve some of the problems experienced in the past, and help support the EU's role in future international pandemic governance.

5.4 RESOURCE ALLOCATION MODEL FOR PREPAREDNESS AND RESPONSE (BASED ON PRINCIPLES OF GOOD GOVERNANCE)

This proposal was identified by consortium members in August 2016. Health care planning for pandemic influenza is a challenging task which requires predictive models by which the impact of different response strategies can be evaluated. However, current preparedness plans and simulation exercises, as well as freely available simulation models previously made for policy makers, do not explicitly address the availability of health care resources or determine the impact of shortages on public health. Nevertheless, the feasibility of health systems to implement response measures or interventions described in plans and training exercises depends on the available resource capacity. As part of an earlier EU-funded project, AsiaFluCap, a simple, flexible resource modelling tool to support public health officials in understanding and preparing for surges in resource demand during future pandemics was developed. Yet this tool was limited in several important aspects including the impact of allocation on non-pandemic disease, the constraints of differing governance arrangements, and a graphic interface accessible to policy makers. A resource allocation model would answer the questions of what resources are needed to minimise morbidity and mortality in the event of a pandemic, where should they be deployed to be

most effective, efficient and equitable, and how can the impact of a pandemic on other areas of public health be ameliorated?

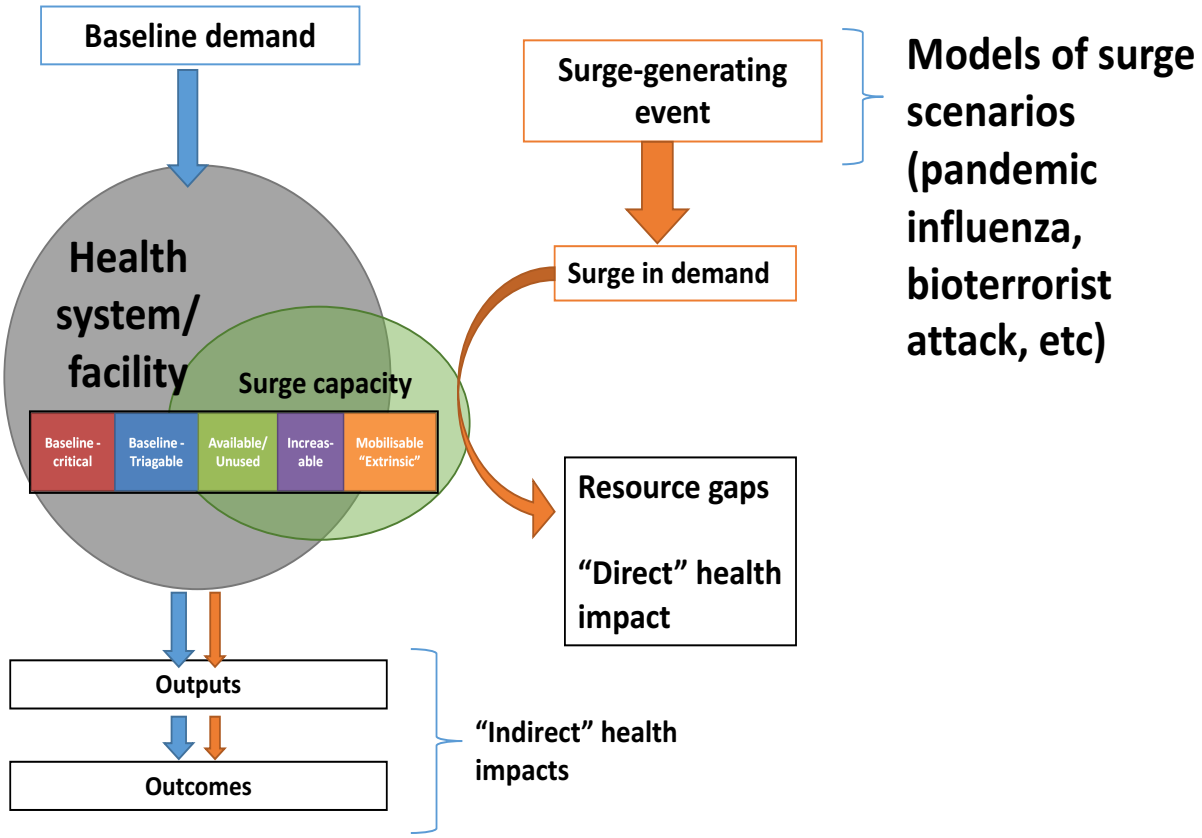
Related questions were identified at the first expert workshop in Brussels, 21-22 February 2016 [Section 12, D4.1]:

- How and where do you allocate scarce resources in an effective, efficient and equitable manner to gain the optimal public health benefit?
- How can we create a standard reporting system (whether at EU or country level) for what resources are mobilised and where they are mobilised?
- How can we monitor the implementation of pandemic response in a standardised way so that we can see what works and start to learn best practice?
- How can we evaluate and "stress-test" institutional pandemic preparation and response capability?
- Can we develop a 'war room' tool with an accessible graphic interface to inform policy making and operational implementation in real time?

5.4.1 HOW TO ACHIEVE A RESOURCE ALLOCATION MODEL

Developing a resource allocation model, or perhaps several models for different threats, would need to link epidemiological transmission models to resources and frame resource allocation scenarios based on existing and potential governance arrangements. This would build upon the EU-funded earlier work on AsiaFluCap, extend it to the European context, and take it to another stage to include a more sophisticated understanding of surge capacity, governance arrangements, and 'war room' needs.

As a late proposal, there is less research input and this did not form part of the questionnaire. Therefore, a limited literature review was conducted to obtain an indication of current research on this subject.



Coker *et al*: Graphic conceptualisation of analytical framework informing determinations of surge capacity (AsiaFluCap)

5.4.2 LITERATURE REVIEW

A limited purposive and systematic literature review was conducted using Google Scholar and PubMed: "investment" AND "model" AND "pandemic" (all words in title or abstract). This produced 15 papers, of which 12 were both relevant and available in full text, see references 5-16, Section 7.

These papers were read in full and indicated that investment models have been created and used both in pandemic preparedness and response. They can be valuable for modelling risk, cost-benefit and resource allocation.

5.4.3 ANALYSIS: CAPACITY PYRAMID

Tools: The development of a graphic interface to support real-time decision making at policy and operational levels

Skills: IT and graphics, epidemiology, transmission dynamics modelling, economics, economic modelling

Staff and Infrastructure: Staff skilled in the above

Structures, Systems and Roles: Needs assessment of users to define how such a tool will be best harnessed, close cooperation in development with users.

5.4.4 SUMMARY

A readily useable policy-friendly graphic interface that aids real-time decision-making in the distribution and allocation of health service resources given unfolding knowledge of the transmission dynamics of a given threat (or healthcare consequences of other events such as earthquakes) offers substantial benefits to improving the effectiveness, efficiency and equitableness of responses at national and regional level. The development of a template would also build upon EU-funded earlier projects coherently.

6 CONCLUSION/RECOMMENDATIONS

All four of the identified proposals are supported and justified by research conducted to date. Each one would provide multiple, long-term benefits to improve pandemic governance in Europe and beyond.

It is apparent that there are many structural weaknesses in current pandemic governance. Some of these have clear solutions, such as collecting data for evaluation or increasing skills capacity with training. Other weaknesses, equally as important, such as the loss of public trust, need further research in order to understand and take effective measures to improve the situation.

Specific recommendations are:

1. Increase capacity in public health law:

    1.1 Training courses accessible to lawyers and/or public health policy makers in all Member States

    1.2 Data collection. Mapping of relevant national legislation and policy documentation for pandemic management in all Member States

    1.3 Creation of a Legal Committee with representatives from all Member States to discuss and draft a model legal framework for Member States.

2. An extensive research plan to investigate trust in public health institutions, including issues such as communication, community education, managing trust and uncertainty.

3. Supporting the EU's role in international pandemic governance and potential input to an EU Global Health Strategy consistent with Decision 1082/13 which could consider the following areas:

    - Coordination and cooperation between the EC and Member States with regard to support and assistance to affected States outside the EU

    - Coordination and cooperation between EC agencies.

4. Design of a resource allocation model (or models) as an investment tool for the countries of the European Union to enable more effective and efficient allocation of

scarce resources in the future (and to further inform the Joint procurement Initiative under Decision 1082).

As explained at the beginning of this report, a limited, 18 month project can only provide a preliminary assessment of gaps and priorities for further research. Some of the most pressing priorities have been identified, more extensive and properly resourced research is needed to tackle these priorities. The project will now move forward with input from an expert workshop to review the research priorities identified. The research areas with the greatest potential to protect EU citizens from the health, security and economic consequences of the next pandemic will be taken forward in a roadmap for a phase II demonstration project.

7 REFERENCES

1. PHLawFlu: Public Health Law to Support Pandemic Influenza Preparedness. Technical Implementation Report, December 2010.
2. Martin R, Conseil A, Longstaff A, et al. Pandemic influenza control in Europe and the constraints resulting from incoherent public health laws. *BMC Public Health* 2010; **10**(1): 1.
3. UK, Government. Health is Global: An outcomes framework for global health 2011-2015.
4. England PH. Global Health Strategy 2014 to 2019. 2014.
5. Attema AE, Lugnér AK, Feenstra TL. Investment in antiviral drugs: a real options approach. *Health economics* 2010; **19**(10): 1240-54.
6. Drake JM, Chew SK, Ma S. Societal learning in epidemics: intervention effectiveness during the 2003 SARS outbreak in Singapore. *PloS one* 2006; **1**(1): e20.
7. Drake T, Chalabi Z, Coker R. Buy now, saved later? The critical impact of time-to-pandemic uncertainty on pandemic cost-effectiveness analyses. *Health Policy and Planning* 2015; **30**(1): 100-10.
8. Hanvoravongchai P, Chavez I, Rudge JW, et al. An analysis of health system resources in relation to pandemic response capacity in the Greater Mekong Subregion. *International journal of health geographics* 2012; **11**(1): 1.
9. Krumkamp R, Kretzschmar M, Rudge J, et al. Health service resource needs for pandemic influenza in developing countries: a linked transmission dynamics, interventions and resource demand model. *Epidemiology and infection* 2011; **139**(01): 59-67.
10. Lugnér AK, Postma MJ. Investment decisions in influenza pandemic contingency planning: cost-effectiveness of stockpiling antiviral drugs. *The European Journal of Public Health* 2009: ckp119.
11. Maro JC, Fryback DG, Lieu TA, Lee GM, Martin DB. Responding to Vaccine Safety Signals during Pandemic Influenza: A Modeling Study. *PloS one* 2014; **9**(12): e115553.
12. Rudge JW, Hanvoravongchai P, Krumkamp R, et al. Health system resource gaps and associated mortality from pandemic influenza across six Asian territories. *PLoS One* 2012; **7**(2): e31800.
13. Khilji SUS, Rudge JW, Drake T, et al. Distribution of selected healthcare resources for influenza pandemic response in Cambodia. *International journal for equity in health* 2013; **12**(1): 1.

14. Stein ML, Rudge JW, Coker R, et al. Development of a resource modelling tool to support decision makers in pandemic influenza preparedness: The AsiaFluCap Simulator. *BMC public health* 2012; **12**(1): 1.
15. Watson SK, Rudge JW, Coker R. Health systems'"surge capacity": state of the art and priorities for future research. *Milbank Quarterly* 2013; **91**(1): 78-122.
16. Yaylali E, Ivy JS, Taheri J. Systems engineering methods for enhancing the value stream in public health preparedness: the role of Markov models, simulation, and optimization. *Public Health Reports* 2014; **129**(Suppl 4): 145.

ANNEX 1: PANDEM INTERVIEWS CONDUCTED: MARCH-OCTOBER 2016

ID	AFFILIATION	DATE
1	PH England	18.03.16
2	Chatham House	18.03.16
3	DG ECHO	30.03.16 & 13.05.16
4	LSHTM	07.04.16
5	PHLawFlu (retired)	11.04.16
6	LSHTM	12.04.16 & 18.07.16
7	HPSC, Ireland (retired)	13.04.16
8	Toulouse University	14.04.16
9	Zadig, Rome	18.04.16
10	ISS, Rome	05.05.16
11	Chatham House	08.09.16
12	ECDC (retired)	29.09.16
13	Temple University, US	03.10.16

ANNEX 2: Personal View: Can the US Model State Emergency Health Powers Act be a guide for Europe?

Elizabeth M Speakman[1] Lawrence O. Gostin[2], Richard Coker [1,3]

[1] London School of Hygiene and Tropical Medicine, Faculty of Public Health and Policy, London, UK.

[2] O'Neill Institute for National and Global Health Law, Georgetown University Law Center, Washington DC, USA

[3] Faculty of Public Health, Mahidol University, 420/1 Rajwithi Road, Bangkok, Thailand

Corresponding author: Elizabeth.Speakman@lshtm.ac.uk

ABSTRACT

Following the events of late 2001 and the recognised national security threat, academics in the United States drafted the Model State Emergency Health Powers Act (MSEHPA). This was model legislation to provide legal authority to adopt measures necessary to respond effectively to a major public health emergency, such as an infectious disease outbreak or bioterrorism. The MSEHPA also aimed to modernise and standardise existing state public health legislation across the US. The measures included coercive powers over individuals and property, without liability, but subject to safeguards to protect civil liberties. Although initially controversial, measures in the MSEHPA have now been adopted in 34 states. Europe faces similar security risks and we consider whether model legislation for public health emergencies in the European region would be helpful, or feasible, and the extent to which it might be adopted by individual European countries. Europe would likely face greater challenges to acceptance than the US, but as in the US, a major benefit of the drafting process would be to encourage greater discussion and cooperation. Even more important, a model law could be a carefully considered template to reform antiquated and inconsistent rules in European countries and achieve an appropriate balance between security and civil liberties. Given the current crises in Europe, and with the constant risk of future outbreaks, epidemics, biosafety breaches, and bioterrorism, this would be a timely and much-needed reform.

Key words

Model; legislation; public health; emergency; US; Europe

INTRODUCTION

For the United States, the catastrophic events of 11th September 2001, followed by bioterrorism in the form of anthrax attacks, were an unprecedented incentive to strengthen national security. A key security need was for legislation to support an effective response to a major public health emergency. Such state legislation could not be mandated, but a model act could define and frame appropriate measures. This was the basis of the Model State Emergency Health Powers Act (MSEHPA), published in December 2001, which later became incorporated in the broader Turning Point Model State Public Health Act 2003. The Turning Point Act was a foundational tool for modernising and strengthening public health legislation throughout the US.

The MSEPHA was controversial as it involves temporary curtailment of civil liberties in specified circumstances, but many of the provisions were subsequently adopted and enacted into state laws. This paper reviews the MSEHPA as an example of emergency public health legislation and considers whether a similar model would be appropriate within the European context.

BACKGROUND

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

While 9/11 brought urgency to the debate, deliberations had already begun years earlier. A CIA report in 2000 noted that infectious diseases could have significant implications for US national security, and that "emerging and re-emerging infectious diseases…will continue to kill at least 170,000 Americans annually" [1].

There was recognition that many state public health laws were outdated, inconsistent or inadequate. Some appeared to be unconstitutional and to conflict with laws in neighbouring states, for example in disclosure of health information. Others did not "reflect contemporary scientific understandings of disease (e.g. surveillance, prevention and response) or legal norms for protection of individual rights..." [2]

The U.S. Centers for Disease Control and Prevention (CDC) commissioned a joint team from Georgetown and Johns Hopkins Universities to draft model state legislation to support a more effective response to future emergency public health threats. Following a rapid collaborative effort, the result was the Model State Emergency Health Powers Act (MSEHPA) 2001 [3].

MSEHPA Content

The basic premise of the MSEHPA is that each state is responsible for safeguarding the health and security of its population – a situation similar to that which holds for the European Union (EU). In the US, state and local governments must be able to respond quickly and effectively to public health emergencies. The MSEHPA grants specific emergency powers to state governors and public health authorities to enable them to do so, while also safeguarding personal interests. In the United States, federal powers are

limited to those specified in the constitution. Most public health powers are constitutionally reserved to the 50 states under what is known as the "police powers." Therefore the MSEHPA was a "model" act, for the guidance of state legislators who it was hoped would adopt its proposed measures.

The MSEHPA first requires the state to have a comprehensive plan to respond to a public health emergency. The emergency can be investigated immediately by granting access to individuals' health information in specified circumstances. The act sets out a procedure for declaring a public health emergency and stresses the importance of communication and coordination. Public health, law enforcement and emergency agencies are given defined roles and are expected to collaborate in planning and sharing information (Articles II and III).

Article IV sets out the circumstances in which a state governor can declare a public health emergency. These are intended to be "demanding threshold conditions" where there is an existing or imminent threat to health, whether from bioterrorism or other infectious agent, which poses "a high probability of a large number of deaths, a large number of serious or long-term disabilities" or where there is "a significant risk of substantial future harm to a large number of persons" [2]. The clause is intended to be flexible so states may for example adopt an all-hazards approach, beyond just biological threats.

During the period of the public health emergency, state and local officials are authorised to use and appropriate property as necessary for the treatment of patients, and to destroy contaminated facilities or materials. Officials are also empowered to provide care, testing, treatment and vaccination to people who are ill or who have been exposed to infectious disease, and to isolate infected people from the rest of the population to contain further infection transmission (Articles V and VI). The majority of people may comply willingly with these measures, but for those who will not, the MSEHPA provides the necessary powers to enforce them.

The MSEHPA emphasises that in exercising these emergency powers the state must respect the dignity and rights of individuals and groups. Actions must be based on scientific evidence and promote the common good. Civil rights and liberties must be "protected to the fullest extent possible consistent with the primary goal of controlling serious health threats" [3]. The MSEHPA aims to strike a balance. It "seeks to ensure a strong, effective and timely response to public health emergencies, while fostering respect for individuals from all groups and backgrounds" [3].

The act's authors argued that these are powers which health agencies have always had, but that the safeguards contained within the MSEHPA mean that it "affords explicit protections…that go beyond most existing state laws" [2].

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

While these may seem extreme measures, they are intended only for extreme situations. The MSEHPA stresses repeatedly the importance of individual rights, but where there is a severe threat to public health, the rights of the public must prevail.

Enactment

The MSEHPA opened up a vigorous debate about the extent to which state powers to "promote the common good" [2] should be permitted to outweigh individual rights to liberty and property. Some commentators criticised it for insufficient protection of civil liberties and that "what constitutes a real or possible 'emergency' is left subject to wide interpretation, leaving the governors little or no accountability" [4]. Reich argued that in an open democratic society the ideal and most effective response is strong leadership supported by civil cooperation. However, "the MSEHPA presents the necessary tools for dealing with situations in which the ideal response does not take effect" [5].

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

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

Declaration of Public Health Emergency

The authors of the MSEHPA envisaged that a public health emergency declaration (and the powers such a declaration would enable) would only be made in extreme and rare circumstances where there was a severe risk to population health.

In fact since 2001 declarations of public health emergency have been made by federal, state, local and tribal representatives in many and varied circumstances. These include disasters such as Hurricane Katrina, the H1N1 outbreak and many cases of local

environmental contamination. In 2016, for example, the Zika outbreak was declared a public health emergency. Also, less obvious scenarios, such as "prescription drug abuse related deaths" (Florida 2011), "food insecurity" (Hawaii 2012) and "opioid addiction epidemic" (Massachusetts 2014) [6].

A MODEL FOR EUROPE?

We do not here give a view on whether the MSEHPA achieved the correct balance between individual rights and the "common good". It was drafted for the US context and to standardise and modernise US state laws and traditions. It is likely to need further review and refinement to resolve challenges such as "interjurisdictional coordination, duplicative legal declaration of emergency, disaster, and public health emergency; real-time legal decision making; and liability protections for emergency responders and entities" [7]. However, even one of its critics, Reich, admits that the MSEHPA is "a great step forward in laying the groundwork for debate on reconsideration and improvement of state quarantine laws" [5].

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

Justification

At a time when Europe and the European Union are struggling with political and economic challenges, model legislation for a public health emergency may seem inopportune. Yet such emergencies are a permanent threat and bioterrorism may be more likely because of existing political unrest. An outbreak of infectious disease caused by a high risk pathogen is one of the most serious events a country or region can face. Apart from the human cost, an epidemic which is out of control can become a security threat, damaging national institutions, the economy and international relations. The current disarray in Europe may be a reason precisely why efforts towards greater cooperation would be beneficial at this time.

Preparedness

A key aspect of preparedness is having good governance in place well before a public health emergency arises. This "good governance" being policy underpinned by laws which have been carefully considered and debated with relevant stakeholders, and which is legal, ethical and flexible enough to respond to a range of circumstances. Policy or law

created in the midst of a public health emergency is at much greater risk of being unethical and/or ineffective. A full and transparent debate on emergency powers in the pre-pandemic stage is also more likely to gain public trust and support.

In addition to providing a more coherent legal response across Europe, a model law should incorporate ethical principles and safeguards to ensure respect for human rights. This is essential in an open democratic society where potentially coercive measures will need public understanding and cooperation.

Public health threats, outdated planning and laws

It is unclear what, if any, national legislation is currently in place to underpin emergency planning in European countries, whether members of the EU or not. No complete mapping and gap analysis of national laws exists, although an EU funded research project of 2007-10: PHLawFlu, achieved a partial assessment. This found that "few states have an adequate legal framework to support the measures they intend to implement during a pandemic [8]." Where legislation does exist, the project identified many of the same problems as with the US states: "…many [European] states have public health laws that originate in the nineteenth century. In some cases attempts have been made to amend laws in recognition of IHR obligations and pandemic planning, without addressing the outdated science and jurisprudence that underlay old legislation, resulting in an inaccessible collection of uncoordinated and unconsolidated laws [9]."

Another similarity was that just as some US state laws were possibly unconstitutional, in Europe a number of national pandemic influenza plans seemed to have given little consideration to human rights and might not meet the obligations of the European Convention of Human Rights (ECHR) [10].

Challenges

Principle of subsidiarity

Model legislation would need to be in the context of European Union commitments as the EU is the biggest and most powerful regional grouping. Despite some similarities between a federal US and the EU, gaining acceptance of a model emergency powers act is likely to be more difficult in the European context.

Under Article 168 of the Treaty on the functioning of the European Union, human health protection must be privileged in the definition and implementation of all EU policies and activities [8]. The EU also has a particular obligation to encourage cooperation between

Member States "to improve the complementarity of their health services" [11]. However these measures explicitly exclude "any harmonisation of the laws and regulations of the Member States." Any model law would need to be very carefully framed as advisory only, maintaining the subsidiarity principle.

Different legal systems

Apart from the challenge of different languages, cultures, politics and capacities, a fundamental hurdle to drafting model legislation would be that the countries of Europe incorporate a range of different legal systems. The majority follow different versions of codified civil law, while others, including the UK and the Republic of Ireland are founded on common law. Some countries combine the two systems. Any model law would need to be flexible enough to be adopted by either. Model legislation would need to take as a starting point, compliance with Decision 1082/13/EU, the key EU instrument on serious cross-border threats to health. At present the extent of compliance with Decision 1082/13/EU in the national laws of EU Member States is not known. Furthermore, drafting a model act would require the collaboration of public health lawyers from a majority of European countries when there is a dearth of public health law expertise across the continent [10].

Political will

Adoption of a model act by Member States would require high level political support from both within the European Commission and from national governments. The response of US states to the model Turning Point Act (which incorporated the MSEHPA) was found to depend on multistate partnerships and participation in the drafting process, the conducting of formal gap analyses and recognition of legislative need. "Assuming that the mere presence of model legislation is sufficient to stimulate change is erroneous."[12]

Hitherto, the European Centre for Disease Prevention and Control (ECDC) and the WHO Regional Office for Europe have collaborated to guide and support European countries in matters of public health security and compliance with commitments to the International Health Regulations 2005. These commitments include provision of national pandemic preparedness plans, yet many European plans are outdated or inaccessible despite this support, a WHO model and a clear obligation. Plans are frequently published only in the local language and there are many inconsistencies of content and approach [13]. It is unclear whether this is due to limited capacity or low prioritisation or both. Achieving regionally coherent legislation is likely to be an even greater challenge and lack of political will may prove to be one of the greatest obstacles.

The United States was galvanized by the catastrophic events of 9/11 to draft a model act, while European countries have not experienced a provocation on this scale. However, the current crises of terrorism and mass migration in Europe could well change this calculation.

CONCLUSION

The most immediate benefit of the MSEHPA was that it prompted a debate on many difficult legal and ethical issues which arise in a public health emergency. Similarly, a model emergency powers act for Europe would be a means to spur debate, bringing together legislators from across Europe, and at a time of uncertainty and division amongst many European countries, encourage greater cooperation for a common benefit.

Above all, a model law approach could provide a thoughtful, well considered template for reform of antiquated and inconsistent rules in European countries and achieve an appropriate balance between security and civil liberties. This is a pressing need as there are likely to be future outbreaks, epidemics, biosafety breaches, and bioterrorism. With ongoing crises in Europe, the time is ripe for reform.

Author contributions

EMS wrote the manuscript, LOG and RC contributed to interpretation and critical review. All authors approved the version for submission.

Conflict of interest

None declared.

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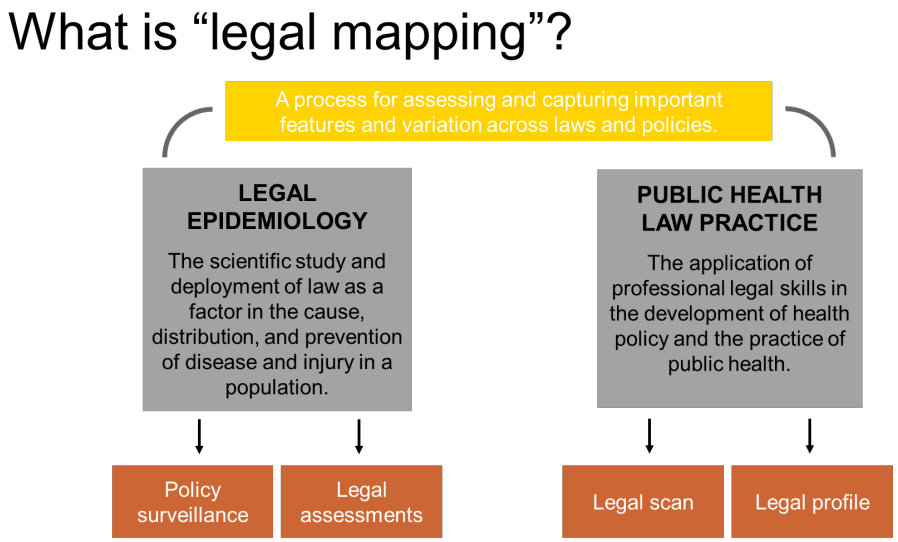
REFERENCES

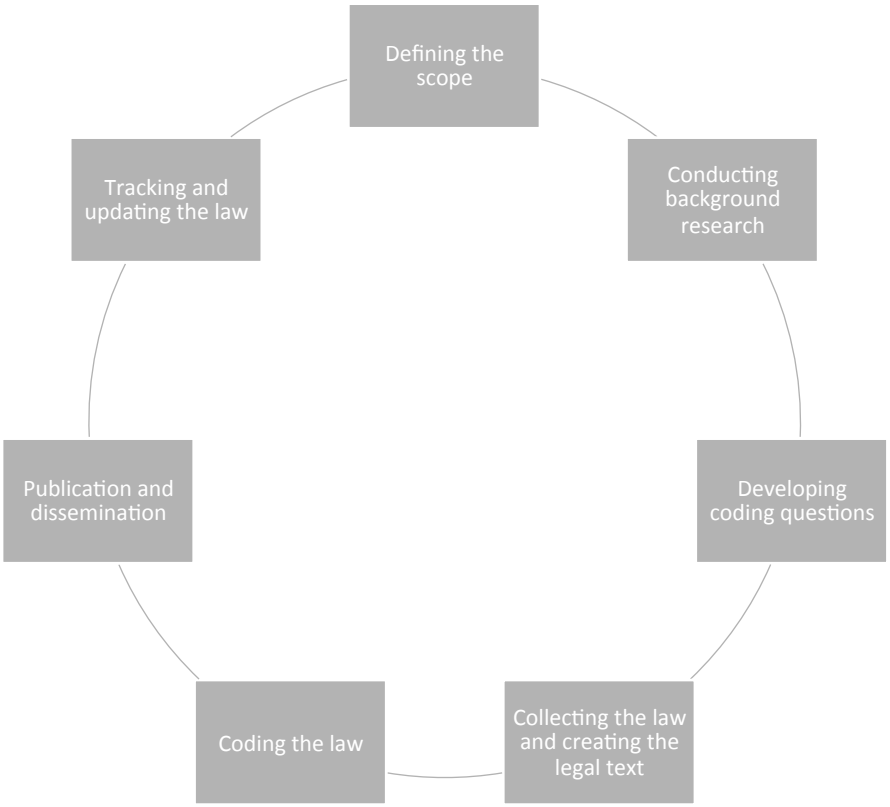
1. Noah, D. and G. Fidas, *The global infectious disease threat and its implications for the United States*. 2000, DTIC Document.
2. Gostin, L.O., et al., *The Model State Emergency Health Powers Act: planning for and response to bioterrorism and naturally occurring infectious diseases.* JAMA, 2002. **288**(5): p. 622-628.
3. *Georgetown University ; Johns Hopkins University;The Model State Emergency Health Powers Act*. 2001.
4. AAPS. Association of American Physicians and Surgeons, I., *Model State Emergency Health Powers Act Petition*.
5. Reich, D.S., *Modernizing local responses to public health emergencies: bioterrorism, epidemics, and the model state emergency health powers act*. J. Contemp. Health L. & Pol'y, 2002. **19**: p. 379.
6. *The Network for Public Health Law. Public Health Emergency Declarations - Select Examples* January 20, 2016.
7. Hodge Jr, J.G., *The evolution of law in biopreparedness*. Biosecurity and bioterrorism: biodefense strategy, practice, and science, 2012. **10**(1): p. 38-48.
8. Martin, R. and A. Conseil, *Public health policy and law for pandemic influenza: a case for European harmonization?* Journal of health politics, policy and law, 2012: p. 1813854.
9. Martin, R., et al., *Pandemic influenza control in Europe and the constraints resulting from incoherent public health laws*. BMC Public Health, 2010. **10**(1): p. 1.
10. *PHLawFlu: Public Health Law to Support Pandemic Influenza Preparedness. Technical Implementation Report DRAFT*. December 2010.
11. *Article 168, Treaty on the Functioning of the European Union*.
12. Meier, B.M., K.M. Gebbie, and J.G. Hodge Jr, *Contrasting experiences of state public health law reform pursuant to the Turning Point Model State Public Health Act*. Public health reports (Washington, DC: 1974), 2006. **122**(4): p. 559-563.
13. Holmberg, M. and B. Lundgren, *Framing post-pandemic preparedness: Comparing eight European plans*. Global public health, 2016: p. 1-16.

ANNEX 3: MAPPING PROCEDURE



Policy surveillance:

1. Uses a systematic approach
2. Emphasizes transparency
3. The process is replicable
4. There is a focus on producing a highly accurate product through quality control



Define the Scope

- Clearly identify the topic and parameters for what you will study
- Refine your topic to include or exclude sub-topics.

Conduct background research

- Identify secondary sources
- Draft a background memorandum to identify key elements of the law and explore the legal landscape on your project's topic
- Draft a five state memorandum to identify variation in the law across a sample of five states (or other jurisdictions depending on the project's scope)
- Develop a search strategy
- Compile a sample of laws relevant to your project
- Generate a list of preliminary variables that should be explored to meet the goals of your project.

Question development

- Set standard variables
- Identify variables in the law
- Develop your responses from identified variables

- Convert variables into questions
- Capture unexpected responses through coding.

Collect and Build the Law

- Refine citations and search strategy based on scope
- Record the search strategy
- Record refined citations on a Master Sheet document
- Collect relevant laws
- Organize the law into folders
- Organize laws by jurisdiction and hierarchy, and chronologically for longitudinal projects
- Create legal text.

Code the law for each jurisdiction.

Quality Control.

ANNEX 4: PUBLIC HEALTH ENGLAND. GLOBAL HEALTH STRATEGY 2014 TO 2019

Contents

About Public Health England - Summary: PHE's global health strategic priorities

Introduction

- What PHE means by "global health" and "international activity"
- Rationale and mandate for PHE involvement in global health
- Wider UK context for global health work
- International context for global health work
- Strategy scope
- Behaviours and principles that guide global health work.

Strategic priorities

- Improving global health security
- Responding to outbreaks and incidents of international concern, and supporting the public health response to humanitarian disasters
- Public health capacity building
- Strengthening the approach to international aspects of health and wellbeing, and non-communicable diseases
- Strengthening UK partnerships for global health activity.

Achieving the strategic priorities

- Building on PHE's strengths
- Sharing excellence, expertise and assets
- Working in partnership
- Learning
- Supporting staff.

Addressing practicalities

- Using resources appropriately
- Prioritising what PHE does.

Monitoring activity and accountability

- Monitoring and evaluating activity
- Delivering the strategy
- Accountability.

What PHE will deliver over five years

Appendix 1: Development of the strategy

Summary: PHE's global health strategic priorities

PHE's global health work will protect and improve health in England, contribute to improving health globally, reduce global health inequalities and help PHE become a stronger organisation.

PHE's global health strategic priorities for the next five years are:

1. Improving global health security and meeting responsibilities under the International Health Regulations – focusing on antimicrobial resistance, mass gatherings, extreme events, climate change, bioterrorism, emergency response, new and emerging infections, cross-border threats, and migrant and travel health
2. Responding to outbreaks and incidents of international concern, and supporting the public health response to humanitarian disasters
3. Building public health capacity, particularly in low and middle income countries, through, for example, a programme of staff secondments and global health initiatives
4. Developing our focus on, and capacity for, engagement on international aspects of health and wellbeing, and non-communicable diseases
5. Strengthening UK partnerships for global health activity.

These will be achieved through:

1. Building on our strengths–public health delivery, public health leadership, public health systems and public health training
2. Sharing excellence, expertise and assets – people, evidence, guidance and data
3. Working in partnership–collaborating, influencing, facilitating and leading around matters of global health
4. Learning – from others and from our own experiences
5. Supporting PHE staff and the wider public health community to engage on global health issues.