

## How to develop and implement pandemic preparedness plans? The need for a coherent European policy

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### Abstract

How should public health authorities confront the threat of pandemic influenza? Is massive stockpiling the answer? If so, the costs could be overwhelming. Or is vaccination of pre-selected segments of the population the best approach? If so, then what about the tough ethical question that must be addressed: for whom—and by whose decision? Are local and national health authorities operating on the same wavelength? Just how all-encompassing should a national preparedness plan be? Finally, can we count on one national government to shuttle vaccines across Europe's internal borders where they are needed to deal with an outbreak—or will hoarding and panic ensue?

These issues and more were the focus of debate during the conference's session on preparedness plans, chaired by Dr. D. Fedson, former professor of medicine at the University of Virginia. As participants observed, Europe faces an alarming diversity of approaches and states of readiness from one country to the next, which cries out for a coherent European policy.

Report on the conference session *How to develop and implement pandemic preparedness plans?*

*Chair:*

- Prof. D.S. Fedson, Sergy-Haut, France

*Speakers*

- Dr. M. Esveld, Ministry of Public Health, The Hague, The Netherlands
- Dr. J. Löwer, Paul-Ehrlich-Institut, Langen, Germany
- Dr. T. Melillo, Disease Surveillance Unit, Malta

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Marja Esveld, Ministry of Health, Welfare and Sport, The Netherlands

"Our policy is to share vaccines and not close our borders. Whether this would hold during a bad pandemic remains to be seen."

Johannes Lower, Paul-Ehrlich-Institut, German Federal Agency for Biological Medicinal Products

"Every Maltese who coughs and sneezes will expect a GP visit. And our GPs will not be able to cope."

Tanya Melillo, Disease Surveillance Unit, Malta

An influenza pandemic will inevitably wreak a certain degree of havoc in any population it hits, but the level of casualties can be mitigated according to the kind of preparations a country takes and the amount of resources it possesses to confront the threat. The best-laid preparations mean little without the wherewithal to implement them. But just as important are the right kinds of planning—and a sensible skepticism about the efficacy of over-planning, as Session 12's first speaker made crystal clear.

“Pandemic preparations can be a huge waste of resource unless the main goal is to boost general epidemic preparedness,” said M. Esveld of The Netherlands’ Ministry of Health, Welfare and Sport.

“An influenza plan must lay down clear responsibilities and ensure that they can be carried out. This demands financial resources, a thorough training of personnel and common sense, which means you don’t disregard the basics such as hygiene and food safety. These can be easily overlooked in an emergency situation.”

Esveld said her government has learned from experience in dealing with previous flu epidemics and other diseases that public health officials *must manage expectations before a pandemic arises*.

“It is easy to describe all the options in a plan, with shopping lists of choices. But to decide on an option in advance is more difficult. You have to adjust policy as events unfold. That is what we in the Netherlands are trying to do: a description in our operational action plans of the choices that everyone should follow. Everyone must understand what the flow chart of actions is. Doing this in advance helps you focus your measures and funding,” she said.

“A 500-page preparedness action plan is not useful. It must be concise and action-oriented, with summaries offering basic lines of action and flow-charts that are easy to read,” she declared, adding that “it must be circulated to all institutes that will be involved. If there’s a pandemic, you can’t start carving up responsibilities between hospitals; they must have plans ahead of time. And there must be a central authority that monitors and directs health care demand and capacity during a pandemic.”

Esveld said the Netherlands has a long history of developing health action plans and has tailored a generic plan to fit three different flu scenarios: avian flu, pandemic flu and sporadic cases of a new flu virus. Each involves other ministries and public services such as fire departments and the police to protect immunisation sites.

The Netherlands’ pandemic readiness blueprint is divided into 24 local security regions, each with its own plan for maintaining primary and secondary health care. Their viability is proven via sporadic testing rather than scenario-oriented exercises, according to Esveld.

## 1. The Dutch way: testing is better than exercises

“Testing is very different than an exercise. Give too much advance notice to an exercise and you don’t learn anything new. It is too easy to make agreements with hospitals and police organisations and then have them go out of date a year later,” she said. “Testing comes out of the blue. We drop in on doctors to see what they know, examine their list of contact persons and so on. This shows whether preparedness will work or not. And you learn a lot at the local level, which is useful for the central government and national institutes.”

The 24 local plans are regularly reviewed and revised, shifting responsibilities from local to national level – or vice versa – as deemed necessary. For instance, Esveld said the creation of a clear ‘policy of risk communication’ to the public and press was a key element of the pandemic plan.

“When we discussed what this would mean for our infectious disease law, we had to change things. Currently, responsibility for communicating a crisis lies with municipal authorities. We have now changed the law to give our minister of health a mandate to over-rule city authorities when necessary in dealing with communications to the public,” she said. Similarly, she said the Dutch government has empowered its health authorities to impose quarantines.

Meanwhile, she said the 24 local plans have recently been evaluated by the country’s health inspectorate to integrate them with the national plan to ensure harmonisation of response across the Netherlands to an outbreak.

Somewhat surprisingly for its thorough approach to pandemic planning, the Netherlands has not opted for massive stockpiling of either antivirals or vaccines, though it has a tender for a priority contract covering the advance purchase of pandemic vaccines.

Esveld said the government plans to have 5 million antiviral courses on hand for therapeutic use – enough for about 35% of the population – but “does not consider stockpiling of the H5N1 vaccine to be the best solution.”

Asked why, she said the government based its decision on risk-assessment and cost-benefits analysis. “We think it is far more cost-effective to look at the benefits of preparedness for your health care infrastructure. H5N1 production is a good exercise and that is one reason to stockpile. But if you look at it from public health perspective, we’re not sure if this is a sure bet. It may not be the right response to next pandemic, and it is expensive. We’re not convinced that it is the right way forward.”

Stockpiling is seen somewhat differently across the border in Germany, where national public officials aim to vaccinate the whole population in case of a pandemic.

## 2. Germany: preparing producers to ramp-up

“Our main goal is to immunise the entire German population in 4–6 weeks,” said the next speaker, Dr. J. Löwer of the Paul-Ehrlich-Institut—Germany’s Federal Agency for Biological Medicinal Products in Langen. “This means administering 80 million doses in 6 weeks and another 80 million in the following 6 weeks. These are huge quantities in a short period of time. Can we do this in Germany as things stand right now? No, we can’t.”

At current rates of production in Germany – which, unlike other countries in Europe, has benefit of two major vaccine manufacturers within its borders instead of just one – it would take 2 years to produce 80 million doses. “Even if the pharmaceutical companies increased their weekly output by a factor

of three, it would still take 12–20 weeks to ramp up to the dose levels required,” said Löwer.

“So should we stockpile for the whole population? Stocking two doses each for 80 million people would cost € 1.6 billion. I do not need to go to my minister to ask for this amount. I already know the answer: no way,” he observed.

Were a pandemic to hit today, Löwer said the stockpile shortfall would have huge political implications in Germany.

“How to explain that some will get a second booster shot and others won’t?” he said, adding that a pandemic would also test the limits of Germany’s humanitarian intentions. “Our policy also is to share vaccines and not close our borders. Whether this would hold during a bad pandemic remains to be seen.”

Raising vaccine production to meet Germany’s goal involves either building new plants to increase capacity or rapidly increasing yield with existing production. Given the time and cost of the former, Löwer said his institute is researching how to achieve the latter by ensuring that production can be increased to quickly to the volumes required. However, this means balancing a number of pharmacological variables.

“We cannot drastically decrease the antigen content of vaccines because that would reduce their effectiveness and possibly their safety. But to increase antigen content would reduce the number of vaccines available,” he said, noting that other questions his institute has addressed are whether to use whole viruses and whether these should adjuvanted or non-adjuvanted ones. Roughly analogous with chemical catalysts, adjuvants are agents that modify the effect of other agents while having few, if any, direct effects when administered by themselves.

To enable Germany’s vaccine manufacturers to quickly step up production, Löwer said his institute opted in the end for a vaccine that comprises:

- some reduced antigen content;
- an aluminum-based adjuvant;
- a whole virus;
- eggs as the substrate for production.

“There are many advantages in using cells for production. But it will take a couple of years to get them vetted and on the market. If someone can assure me that the next pandemic won’t come before 2–3 years, then that is okay. But failing that, we recommend the use of eggs (as the substrate),” he said.

As for the preparation of antigen sparing vaccines, Löwer said his government is ready to spend up to 20 million euros for research in this field.

“As a second priority, it could make sense to stockpile a limited amount for two reasons,” he said. “First, it helps prepare production processes, meaning that companies can

train to ramp up for rapid production volumes. And second, we need the stocks to protect first-line health care workers. That is our goal.”

Different as the German and Dutch approaches are from one another, the two countries’ wealth at least offers their decision-makers a wide range of preparatory options. This contrasts sharply with the EU’s poorer or more isolated members where limited resources or restricted access to vaccines severely limits health policy choices.

Few other countries better illustrate the problem than Malta, whose dense population, low GDP, limited health care resources, isolation from vaccine manufacturers and lack of self-sufficiency in food and water could result in major problems should a pandemic hit the Mediterranean island nation.

### 3. Malta: struggling against a nightmare scenario

“Unlike Germany, we would not get vaccines until at least 6 months after a pandemic is declared. If the pandemic virus reached our shores, timely containment measures need to be taken to try and stop the spread of disease like closing down all our schools, churches and isolating any passengers arriving to our country suffering from influenza,” said Dr. T. Melillo of Malta’s Disease Surveillance Unit.

Noting that Malta is a non-vaccine producing country and that 38% of all vaccines produced in world were used by non-producing countries, she said: “We can only imagine what the global demand would be once the pandemic starts. Those countries who would not have yet procured the pandemic vaccine will have great difficulty procuring them and even those who have put in orders have no guarantee that the vaccine will arrive.”

Melillo outlined a long and sobering list of factors that her country must overcome if it is to avoid a plague of biblical proportions.

“We have no available health experts in the field, and there are limits on both our clinical influenza surveillance capacity and virological surveillance,” she observed. “There is only one state hospital for the whole population and it is burdened with constant overcrowding. And with only 120 full time private GPs catering for half the population, it will be impossible to provide adequate primary health care.”

As daunting as Malta’s situation is, however, Melillo said mitigation of a possible pandemic influenza has been given priority by the Ministry of Health (see accompanying box).

But even with the best planning, Melillo said Malta’s overwhelming dependence on imported resources means “we will need guaranteed supplies of food, fuel, expertise advice and vaccines supplies if we are to survive.”

Indeed, if her concluding remarks do not convince Europe’s policymakers of the need for a collective and coordinated approach to influenza preparedness, nothing will.

**Malta: straining against the worst case**

Make no bones about it: Malta faces a very difficult set of logistical and resource-based challenges as it prepares for a future pandemic.

As Europe's most densely populated nation, its 400,000 citizens are squeezed into 1261 people per km<sup>2</sup> – 10 times the EU average – and 90% of them live in an urban setting, the worst for disease transmission.

Producing only 20% of its population's food needs and possessing no natural resources other than building stone, the island is overwhelming dependent on imports of everything for its survival. Moreover, it has only one national hospital and no local capability to produce pharmaceuticals or protective clothing for its health care workers (HCWs).

"If our island's supplies were cut during a pandemic, there may be food shortages," said Melillo. "And the disease itself would hit our HCWs hard."

Malta's indigenous health problems do not make things any easier. Approximately 18% of the population is over 65 years of age; asthma is prevalent among 11% of the population; 10% have diabetes, causing one out of every four deaths before the age of 65; and cardiovascular disease is main cause of death, accounting for over a fifth of the mortality rate. According to Melillo, the predicted 1–1.8 transmission rate is likely to be greater here due to overcrowding.

The government has moved quickly since early 2005 to prepare the island for the next pandemic. Recent actions include:

- *a National Influenza Pandemic Standing Committee created in February 2005;*
- *massive campaign to increase seasonal vaccine coverage;*
- *an educational campaign has started to educate HCWs and the general public about vaccines and preventative measures;*
- *procurement of pandemic vaccines for 90% of the population and protective clothing for HCWs;*
- *antivirals ordered to cover a quarter of the population;*
- *a plan to block part of the state hospital for flu patients.*

Despite these measures, Malta will remain vulnerable. "We are in a unique situation, surrounded by sea with very little possibilities for support of neighbouring countries, unlike other small European nations. We will need help. Without it, we won't cope," said Melillo.