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The ASSET High Level Policy Forum Insights on Relevant Science-in-Society Related Issues in Public Health Emergencies of International Concern

EXECUTIVE SUMMARY

The ASSET (Action plan in Science in Society in Epidemics and Total pandemics) program High-Level Policy Forum (HLPF) brings together European health policy/decision makers to discuss strategic priorities and challenges associated with response to pandemics and epidemics. After initial meetings in 2015 and 2016, the HLPF engaged in an online discussion of three key issues:

- *Participatory Governance in Public Health*
- *Ethical Issues in Pandemic Preparedness Planning*
- *Vaccination Hesitancy.*

The discussion of these issues continued at the third and final ASSET HLPF meeting in Brussels on 28 April 2017. This report summarizes these HLPF discussions and the insights gained from them, and the main findings are:

▪ **Citizens Voice and Participation**

Citizens believe that honesty and transparency can increase the public trust (no matter how bad the situation is), and that it is their right to know the facts and have an accurate understanding of the situation. Public health authorities should devote more resources to collecting citizen input on policies for epidemic preparedness and response.

▪ **Trust in Information**

General practitioners and health professionals need to be trained to adapt to changes in society, and decision makers should be urged to be visible and present on the web, as the the Internet is an increasingly important medium for all kinds of communication.

▪ **Risk Communication**

Authorities should communicate public health risks clearly and transparently, though information campaigns supported by experts and politicians, to restore trust between authorities and the public. These information campaigns need to be long term in nature, and communications should be segmented to target the many different audiences that exist in relation to epidemic and pandemic events.

▪ **Vaccination**

Low vaccination coverage is a significant public health problem, and the reasons for it are complex and vary across countries and population groups. Improving vaccination coverage requires a multifaceted strategy that provides updated, clarified, and standardized informational materials targeted to particular groups such as pregnant women and the elderly.

▪ **Ethics and Laws**

Public health interest should take priority over individual freedom in pandemic situations. Laws should reflect shared basic principles across the EU, be tailored to local history and culture, and be complemented by information campaigns and incentives.

Introduction to the ASSET HLPF

The objective of the [ASSET](#) EU program (Action plan in Science in Society in Epidemics and Total pandemics) is to create a blueprint for a better response to pandemics and Public Health Emergencies of International Concern (PHEIC). This is to be achieved through improved forms of dialogue and better cooperation between science and society at various stages of research, innovation, and implementation, according to a trans-disciplinary strategy to be implemented at local, national, and international levels.

The ASSET High Level Policy Forum ([ASSET-HLPF](#)) is one of several project outputs. It brings together selected European health policy/decision makers from 12 different countries (Bulgaria, Denmark, France, Greece, Ireland, Israel, Italy, Luxembourg, Norway, Romania, Sweden and United Kingdom) in a continuing dialogue to promote on-going reflection on European strategic priorities and challenges for tackling pandemics and PHEIC. The ASSET-HLPF works from a base of scientific assessment, followed by an appraisal phase, in which know-how and opinions of stakeholders are added to the discussion.

The Forum was charged to consider and revise specific issues related to EU strategic priorities in pandemic preparedness, including communication and other responses. It was envisioned that the Forum might produce recommendations; however, its primary role has been to create mutual trust, improve communication, and provide a “safe” environment to address questions, which are otherwise difficult to discuss.

The Forum aimed to strengthen the perception that further dialogue among the participants would be fruitful due to increased insights into each other’s perspectives, and the intrinsic value of conversation between parties concerned with multiple aspects of public health. Members of the Forum did not participate in any official position, but it was hoped that participation might influence policy decisions in a variety of ways.

The process of pandemic and PHEIC response necessitates effective interaction among several relevant actors. As this interaction must happen very quickly and under intense public scrutiny, preparedness is essential. The network of stakeholders can be well-prepared only through building trust and good working relationships prior to the occurrence of emergencies. In addition, identifying and discussing important policy issues and examining how they can be improved can best be done through the consideration of the multiple viewpoints of the main stakeholders.

The ASSET-HLPF is intended to provide such an opportunity, to allow productive interaction among decision makers in Europe. It is a place for stakeholders to meet, learn from each other, and come up with better policy proposals. The ASSET-HLPF has convened three physical meetings (click on the city to link to meeting reports):

1. [Brussels](#) 12th March 2015
2. [Copenhagen](#), 15th January 2016
3. [Brussels](#), 28th April 2017.

In addition to these physical meetings, a virtual discussion was carried out on the dedicated ASSET Community of Practice ([COP](#)) web-based platform. This discussion centered on three specific issues:

- ***Participatory Governance in Public Health***
- ***Ethical Issues in Pandemic Preparedness Planning***
- ***Vaccination Hesitancy.***

Details and findings of the discussions are explained in the next section of this report.

1. Selection of Three Issues for the ASSET HLPF Discussions

The focus of the ASSET-HLPF has been on significant challenges in epidemic/pandemic preparedness and response, including communication as well as several SiS related aspects. HLPF members were asked to identify the most relevant areas of concern affecting public health crisis management in Europe, and three main themes were selected:

- 1) *Participatory Governance in Public Health*
- 2) *Ethical Issues in Pandemic Preparedness Planning*
- 3) *Vaccination Hesitancy.*

A brief introduction to the three themes follows.

1.1 Participatory Governance in Public Health

ASSET convened eight [Citizens' Consultations](#) in as many European countries (Bulgaria, Denmark, France, Ireland, Italy, Norway, Romania, Switzerland), simultaneously carried out on 24th September 2016, asking 425 citizens questions, relevant to preparedness and response during epidemics, pandemics or in general PHEIC.

A comprehensive [report](#) of the results of the citizen consultations cited the following main conclusions:

- **Risk Communication**
Citizens believe that developing honest, clear and transparent communication can restore and further increase the public trust (no matter how bad the situation is). They think it is their right to know and understand occurrences.
- **Trustable Sources**
General practitioners and health professionals should be trained to adapt to changing society, and decision makers should be urged to be visible and present on the web, as the use of Internet is increasing.
- **Ethics**
In pandemic situations, public health interest should take precedence over individual freedom.
- **Vaccination**
Informational materials for vaccination needs to be updated, clarified and standardized, even considering particular target groups, such as pregnant women and the elderly.
- **Participation**
Public health authorities should devote more resources to collecting citizen input on policies for epidemic preparedness and response.

1.2 Ethical Issues in Pandemic Preparedness Planning

As influenza pandemics are unpredictable but recurring events that can greatly impact human health and socio-economic life on a global level, the World Health Organization (WHO) recommends all countries prepare a pandemic influenza plan following WHO's guidelines. The WHO guidance (2009 revision) highlights ethical principles such as equity, liberty, and solidarity, and states that any measure limiting individual rights and civil liberties (such as isolation and quarantine) must be necessary, reasonable, proportional, equitable, not discriminatory, and not in violation of national or international laws. WHO also developed a framework of detailed ethical considerations to ensure that certain fundamental concerns (such as

protecting human rights and the special needs of vulnerable and minority groups) are addressed in pandemic influenza planning and response.

Experts from the ASSET project conducted a [study](#) to assess the extent to which ethical issues are addressed in the national pandemic plans developed by ten European Union/European Economic Area (EU/EEA) countries and by Switzerland, member of the European Free Trade Association (EFTA). The study used a semantic analysis based on two keyword lists: (1) a generic list of keywords representing areas of possible ethical interest; and (2) a more specific list of keywords related to particular ethical issues that might be specifically addressed in each national pandemic plan.

The semantic analysis showed there was little mention of ethics, and a lack of discussion of ethical issues, in the pandemic plans developed by most European countries; the exceptions were Switzerland, United Kingdom, Czech Republic and France. The analysis also revealed multiple areas within the various plans where ethical considerations were relevant, but not addressed. Although this analysis was limited, it highlights ethics as an important area to consider for future drafters of pandemic plans. It also suggests the benefit of reviewing and updating all national pandemic plans to include ethical considerations, as well as other SiS issues, such as gender and participatory governance, which have proved to be of great relevance to pandemics and PHEIC.

1.3 Vaccination Hesitancy

The “[WHO Recommendations Regarding Vaccine Hesitancy](#)” is a collection of materials produced by a group formed by WHO and UNICEF in 2012 to study the issue. The definition of vaccine hesitancy used by this group is “*delay in the acceptance of, or the refusal of, vaccinations, despite the availability of vaccine services*”. Although skepticism regarding vaccinations is a phenomenon that has existed since the earliest vaccines, today this fear is supported and amplified by the fact that anybody can read about contradictory viewpoints on the Internet, even when such information is not scientifically based.

The WHO Strategic Advisory Group of Experts on Immunization (SAGE) emphasizes that it is urgent and necessary to develop institutional systems and organizational competencies on the local, national, and global levels to proactively identify, monitor, and address vaccine hesitancy, as well as to respond promptly to anti-vaccine movements that disseminate disinformation about possible adverse events following immunization. The final recommendations of SAGE concentrate on three main categories: (1) understanding the determiners of vaccine hesitancy; (2) highlighting the organizational aspects that ease the acceptance of vaccines; and (3) evaluating the instruments necessary for opposing this phenomenon.

In Italy, to address a [worrying trend](#) of decreasing immunization rates, some local and national authorities have suggested preventing unvaccinated children from entering childcare centres or nursery schools. This proposal ignited a public debate about whether this simple and quick measure is appropriate or effective. Some believe the situation is not serious enough to justify taking such action, and others fear the action would have little effect, or even backfire in the end. A [previous analysis](#) by the ASSET project, in fact, could not find any relationship between immunization rates in the EU/EEA countries, and whether vaccination was mandatory, for polio, pertussis and measles, suggesting that such measures will not by themselves guarantee good vaccination coverage. A new [feature](#) on the ASSET website suggests practical interventions as an alternative to mandatory vaccination, to improve dialogue with reluctant families, and with health professionals who do not support or openly discourage vaccination.

Donato Greco, former General Director of Health Prevention at the Italian Ministry of Health, WHO consultant, and currently participant in the ASSET project states: “*Low coverage in vaccinations is a complex issue, with several causes in different countries and in different population groups. It needs to be faced with a multifaceted strategy*”.

2. Summary of Perspectives Expressed during Discussion of the three Issues

2.1 Participatory Governance in Public Health

Where will a similar (to ASSET's Citizens Consultation) process be relevant in European public health politics?

Such a process is applicable almost everywhere because the current practice shows that when the communication between health authorities and the population is poor, there are always problems. The most recent example is the Ebola epidemic in West Africa, but the situation is similar in all other outbreaks and epidemics. The flu pandemic in 2010 showed that it is impossible to implement effective control measures without proper understanding by society. This is also relevant to all promotional activities related to the prevention of diseases, which should take into account the degree of health literacy for particular issues, such as antibiotic resistance and the proper use of antibiotics. Although it may seem questionable to consult the public on health issues for which they are ill-informed, it is actually more important to consult with the public when there is a low level of health literacy.

The case of antimicrobial resistance (AMR) is an issue that health care workers, decision makers and, consequently, lay public too, know little about. In this situation, Knowledge, Aptitude, Practices or Behaviours (KAP/B) studies could be a valuable way to guide consultation. On the other hand, sexually transmitted infections (STI) or Public Health Emergencies of International Concern (PHEIC) represent good examples of communicable diseases for which public consultation will be especially informative in designing effective interventions. Similar consultation processes can be relevant in any situation that involves the spreading of something dangerous. Some examples are: circulation of a radioactive cloud; dissemination of a new allergen that induces intense skin reactions; and dispersion of a phenomenon that impacts the public health whether visible or not. In developing interventions, public health authorities should be transparent with regard to levels of exposure. Citizens can improve the situation assessment by collecting local data and sending it to regional or national authorities. Public health authorities can then feed information back to the public. In the European context, the level of citizen engagement should be gauged to achieve the desired level of trust, and communication should be centrally coordinated.

In the end, the way people respond to public health campaigns and activities is influenced by how these actions satisfy their need for information and security. This is why it is important to know what people want and think regarding public health subjects, not only in the domain of communicable disease, but also subjects such as the impact of smoking on the general population, support offered to young mothers, and decisions regarding chemicals used in some steps of food production. In Romania as well as in other European countries for example, at present an important public health problem is the refusal of vaccination, which is influenced not only by vaccine shortages and people's mistrust of the health system, but also by public persons who promote ideas against vaccination.

What is the most relevant input from citizens to policy-makers?

As discussed above, authorities need to invest in reaching out and engaging citizens. This needs to be done not only when there is a pandemic event on the horizon, but continually in pre-event phases. There is a need for a strategic long-term approach to citizen-centric social policy delivery. This means authorities must modify their structures for implementing policy, and they must develop more expertise in market research and citizen engagement.

Citizens want to make vaccination mandatory for some health care professionals as well as for vulnerable population groups. The main issues that a decision maker should address are which members of the population groups must be vaccinated, and to what extent individual freedom is limited for the sake of community health protection. Making this choice and having it accepted requires that citizens understand the risks that health personnel are exposed to, and how health personnel represent an important link in the chain of transmission of communicable diseases. In order to have successful programmes, we must take into account what the citizens want and expect from authorities. Mandating vaccination raises ethical questions, which is the topic of the next issue discussed by the HLPF.

Any information available to the public can be important, whether or not it is from a reliable source. If civil society is concerned with something, that should be considered, whether their concern is justified or not. Sometimes even unconfirmed rumors can have very serious consequences. No information should be overlooked and go unanswered, especially information that affects the level of trust in public health institutions. If measures are to be effective, they must consider the wide diversity of values all over Europe.

Citizens have expectations of their politicians and policy makers in terms of priorities during a pandemic. It is important to find out what citizens feel are the most important parts of pandemic preparedness. Is it stockpiling antivirals? Is it vaccine delivery within three months? The World Bank notes that while citizens need to be a driving force in policy change, they can only do this if they have the language that will allow them to be a part of the discussion. It needs to be a two-way dialogue. In the past, policy makers and politicians decided the priorities; now we understand that we need a bottom-up approach. Citizens are telling us that they wish to be protected from the next pandemic, and they also insist our planet be protected from climate change, that we have measures in place to avoid a nuclear war, and so on. Steps must be taken to insure that citizens provide their input from an educated or a knowledgeable place, in order to guide authorities in selecting the best measures to protect them and their families from the next pandemic. The specifics of the best approach differ from country to country, because citizens of each European State have different expectations for their government, and there will also be different levels of interest in citizen engagement, dialogue and interaction.

It is difficult to proactively engage the spectrum of stakeholders that influence and are affected by pandemic response. While some stakeholder representatives are willing to attend meetings, they rarely have the time to provide substantial input. Stakeholder engagement needs to be done during “peace time”, but it can be difficult to create this engagement when a health emergency seems hypothetical.

Currently, surveillance data at local levels is provided primarily by physicians. However, citizens can provide complementary local data and increase the sensitivity of the surveillance system. This could be particularly useful for the detection and monitoring of an emerging epidemic.

People want transparency and they need accurate and complete information. Critical information for epidemics includes not only how the disease spreads and what measures should be taken to prevent it, but also truthful information about how serious the disease is, what resources of the country are being used to fight against it, and what outcomes people should expect. Of course, caution must be taken because there can be a fine line between establishing trust and creating a panic in the population. This emphasizes the importance of trusted, expert spokespeople from the appropriate domains of expertise in order to demonstrate credibility. Also, the way information is presented is particularly important, so that the message is accessible, correct, and complete. For example, media outlets may over-simplify or sensationalize the message, creating an undesirable impact on the general public. More transparency can lead to better response from citizens, based on a clearer understanding of the consequences of their actions,

resulting in better outcomes, for example reducing the spread of disease. Transparency is clearly demanded by citizens, and it will definitely improve the trust they have in the institutions responsible for public health.

What is the most interesting finding?

Looking at the results of the ASSET Citizens Consultations, stakeholders were most positively impressed by the following:

94% of people want the process to be repeated. This indicates a willingness of citizens to engage and provide input. Moreover, this provides evidence that citizens consider themselves competent to be part of the decision-making and policy process by providing data, concerns, etc., and by participating in the dissemination of information released by public health authorities.

The consultations showed people want health care worker (HCW) vaccination to be mandatory; there is no other evidence of this aspect in the literature. We know vaccination compliance among HCWs has been trending lower, even though vaccine uptake has been confirmed to be one of the most effective measures for public health protection.

Citizens trust most the people they communicate with most directly. These are often General Practitioners.

People also often believe what they read on the internet. The web is an attractive source because it provides quick access to multiple sources, from around the world, perhaps less censored and less subject to national politics. Unfortunately, these sources are often uninformed opinion or unverified and false information provided by people who are not experts. An example of this is the anti-vaccination movement, which has been a major problem for public health. Knowing that people often get their information from the internet, we could use websites to promote correct and updated information, which citizens would learn to trust.

Only after learning what they can from General Practitioners (GPs) and the Internet, people rely on international health authorities and finally the national health authorities. This is something public health authorities should take into consideration, and work to improve, perhaps in collaboration with GPs and through more effective use of the internet.

2.2 Ethical Issues in Pandemic Preparedness Planning

How have the following topics been addressed (or not addressed), in the pandemic plans associated with your nation or region?

a. Allocation of scarce resources, such as diagnostic laboratory testing, influenza vaccines, or antiviral drugs

In Bulgaria and in Italy ethical issues are not directly addressed in the National Pandemic Plan, but at the country level actions resulting from the plan comply with European practice. In case resources are insufficient for all needs, their allocation is predetermined in the plan and this allocation is to be done in a clear and transparent manner. Priority is given to essential public structures important for health and life, such as water supply, food supply, public services, and activities of healthcare facilities.

In France, diagnostic tests have not been an issue in past pandemics because sufficient quantity of influenza vaccines and antiviral drugs were available. A priority list of people to be vaccinated was set up. This included health care workers (HCWs), essential services (army, firemen, etc.), elderly, people with

underlying chronic diseases, and pregnant women. However, an order of priority within the list was not established.

In general, national Ministries of Health are involved in pandemic planning at the country level, and other relevant stakeholders, such as universities and researchers, are not much involved. The allocation of scarce resources is not explicitly dealt with in many of the pandemic plans across Europe; this issue is left open to decisions made on a case-by-case basis, depending on an assessment of factors such as the specific cause of the pandemic, associated risk factors, and the consequent high-risk groups.

Not surprisingly, many plans across Europe are similar in that they mention a priority to protect HCWs and essential staff. The allocation of scarce resources in these plans is fairly uniform, identifying high risk groups that will be prioritized, such as people with pre-existing lung conditions in the cases of influenza or asthma. These people would be prioritized for rapid diagnosis and for vaccines and antiviral drugs, but that would all depend on a risk assessment based upon initial epidemiological information, so most plans at the European level are quite flexible.

The plan approved by European Decision 826 in 2009 for the A/H1N1 virus outbreak is an illustrative example of the reaction in the case of a pandemic threat. (This plan is available on the European Centre for Disease Prevention and Control (ECDC) website.) The general strategy of the plan includes the rapid production of vaccine doses, and priority allocation of the vaccines to personnel working in high risk areas, to those susceptible to developing complications, and to those particularly likely to transmit the disease. A very important aspect is protecting HCWs. The plan also clearly identifies risk groups (according to WHO: pregnant women, children between 6 and 35 months old, people older than 65 years old), and the order in which they will receive the vaccine.

b. Compulsory vaccination

The issue of compulsory vaccination is an ethical issue that is debated across Europe. If this is to be imposed, it should be regulated by established law, and not by ad hoc rules. The laws should be accompanied by informative promotion campaigns, so they are accepted, if not by everybody, then at least by most of society. In Romania, for instance, there is not a compulsory vaccination law; however, a proposal for such a law is currently being debated. Although vaccination is not compulsory in Romania, their national pandemic plan states that both health care personnel and the general population must follow general measures of protection and hygiene.

c. Limiting personal freedom through isolation and quarantine

Given that limiting personal freedom cannot be done outside the law, isolation and quarantine are permissible only in special cases, under judicial control and court decisions. In Ireland, a number of legal instruments passed by the legislature deal with issues such as tuberculosis, so if someone has been diagnosed with a disease that poses a threat to public health, they can be isolated for a certain length of time until they are deemed to be non-infectious. The rules around quarantine are slightly more difficult to implement, and indeed it is a very specialised area. In France, when the H1N1 pandemic started (30 April 2009), hospitalization became compulsory for all subjects confirmed infected by laboratory test, regardless of clinical symptoms (severe or not). This compulsory hospitalization was maintained until mid-June. This decision was heavily contested by the population. School closures were also ordered in some regions.

The main evidence from the [ASSET study](#) of pandemic plans across the European Union, is that ethical issues are often not explicitly addressed, and that in the event of a pandemic, the legal backing and underpinning for measures such as isolation and quarantine are inadequate, and they could be easily challenged.

For example, if bird flu disease emerged in County Mayo in Ireland, and it could be contained by creating a cordon sanitaire around the area, that could very easily be challenged by a member of the public, preventing containment. In other countries such as the UK, authorities are given emergency powers, or the ability to enact emergency legislation, which would enable setting up a cordon sanitaire in emergencies.

European plans in fact identify criteria for deciding if isolation at home or in the hospital is appropriate. Limiting the spread of disease through quarantine or isolation also implies the limitation, if possible, of travelling in affected countries, or border controls. Other measures mentioned in European plans include temporary suspension of transport, schools or other institutions.

d. Use of human subjects in research

In general, the approach to this ethical issue is quite clear across Europe. Most countries have ethics committees that assess use of human subjects in scientific research, and such activities cannot be implemented without the consent of these committees. The use of human subjects in research on pandemics is generally not specifically addressed by pandemic plans, but as in other situations, the well-being of humans prevails, and generally human subjects are not used in pandemic studies.

In France where ethical issues are mentioned in pandemic plans but not addressed in detail, there are in fact very strict rules and ethical committees governing research in universities and research institutions, so this ethical issue is carefully monitored to a very high standard, ensuring this area is well covered. **In France**, when the pandemic occurred in 2009, the incorporation of human studies was poorly organized; for example, the follow-up of patients was not performed until the end of the pandemic. In the post-pandemic period, a validation process for clinical trials was implemented, allowing the quick activation of a clinical trial in the case of future pandemics. In the European Framework Programme for Research and Innovation Horizon 2020 there has been a major increase in the importance, recognition and profile given to ethical issues around the use of human subjects in research, including interviewing subjects as well as vaccinating and treating them. For people participating in research, there are extensive controls and protection mechanisms, particularly for more vulnerable subjects such as the elderly or young people. However, these rules are generally not specifically included in National Pandemic Plans.

Do you believe your current plans adequately address ethical issues? What changes do you believe should be made?

Freedom and human rights may be restrained during pandemics, and people may oppose the decisions taken regarding the prioritisation of scarce resources. However, if the principles by which they are administered are well explained and proper arguments offered, citizens will be more accepting and responsive.

In Bulgaria and in Italy, the current pandemic plan does not adequately consider ethical issues. Forthcoming updates to these plans are expected to add new items that will clarify and cover ethical issues more widely. **In Romania**, ethical issues in the current plan are addressed according to WHO and ECDC guidelines, so they can be considered quite adequate.

In France, the current plan mentions ethical issues but they have not been fully addressed and reviewed. For example, although the use of human subjects in research has been addressed in the plan, the appropriate

ethical committees have not been consulted. The overall pandemic plan should be reviewed by a committee concerned with general ethics, to find other potential concerns that could hamper the execution of the plan in case of future pandemics.

In general, to better address these relevant aspects it would be useful to include ethics guidelines which are shared at the international levels by Member States. In this way, each country's plan would include common mechanisms to put into practice, achieving a homogeneous approach across nations.

Would it be appropriate to incorporate international guidelines (e.g., the WHO Checklist) into national pandemic plans? What mechanism do you recommend to enable this?

It would be useful indeed to include international guidelines to insure best practices in each country, and to achieve interoperability among different countries, since epidemics affect not only one country. There are only a few international guidelines to consider - first within WHO; second in the International Health Regulations, where there are sufficient mechanisms for international cooperation; and third, for the European countries - Decision № 1082/2013/EC on serious cross-border health threats, which involves two institutions - the Health Security Committee (HSC) of the European Commission and the ECDC. It should be possible to rely on a set of international guidelines to be adopted by member states, and they would be obliged under the International Health Regulations (IHR) to ensure that they had ethical guidelines incorporated into their pandemic plans. **In Italy**, for instance, the pandemic plan has not been modified and further improved since 2011, fundamentally because of limited resources available for all public health prevention activities. If Member States had such a commonly agreed European document, procedure implementation would be easier. The public health sector must cope with evident limited availability of resources, so the activation of specific task forces to work on special issues is difficult. The mechanism that should be put into practice obviously depends on each member state, and the mechanism must ensure enough input from academics, policy makers, and people who are implementing pandemic plans on the frontline.

Thus, it is clearly essential that national plans incorporate international guidelines, ensuring that the heart of each pandemic plan is coherent around the globe. Plans should also take into consideration the specifics of each country. The WHO has the legitimacy to prepare a basic core for preparedness and response plans, and include a cross-checklist for country-specific plans. The specific mechanism put into practice should be tailored to each Member State, with input from academics, policy makers, and people who are actually implementing pandemic plans on the front line.

In Romania, international guidelines have already been incorporated into the national pandemic plan, and they work well. Some guidelines have not been fully incorporated because they imply the use of resources that are not currently available, so they need to be adapted. This reminds us that the mechanism for incorporating guidelines must insure the necessary resources are available, including adequately trained personnel.

Can you recommend other approaches to improve consideration of ethical issues in pandemic planning across the EU?

Greater input from citizens would be one; a more educated, aware and informed public will ensure that ethical issues are dealt with in advance of a pandemic. There is the need for a greater capacity to understand, implement, and improve public health law. It is recommended that a network of public health lawyers be set up across Europe, along with programs to foster greater knowledge and awareness about public health law among the public health community, including public health physicians, public health

nurses, and people working in policy. As stated above, ethical guidelines from WHO should be incorporated into national preparedness and response plans. However, a pandemic plan that outlines policy, which is not backed up by legislation, can fail in the event of a pandemic. Policy cannot be implemented without legal underpinning. Creating better plans requires better input from citizens, from public health lawyers, and from end users, the people who are at the front line.

Clearly one of the key elements in dealing with ethical issues is communication: if people could be better informed regarding disease and its transmission, they would probably have a better reaction to issues such as quarantine and the allocation of scarce resources.

2.3 Vaccination Hesitancy

Under what conditions should mandatory vaccination be considered? Can laws be passed in Europe to compel the population to agree to be vaccinated? What kind of laws are necessary?

How can these laws be enforced? What kind of sanctions can be imposed on people refusing to be vaccinated?

How will different countries in Europe respond to proposed legislation on mandatory vaccination?

The correlation between vaccine refusal and the incidence of certain diseases has already been established. Improving the level and quality of immunization at a populational level is the best method of protection against infectious disease (that are preventable through vaccination).

For instance in **Romania** in 2015, the DTaP vaccination rate was about 30% lower than the previous year. It is worrying that the proportion of the people who refuse vaccination (for themselves or for their children) increases year by year. This phenomenon is associated with a higher risk of developing vaccine-preventable diseases. The decrease in vaccination rates can lead to outbreaks. In this situation, vaccination should be mandatory, to avoid the spread of disease.

As examples, two years ago the identification of two cases of polio paralysis in Ukraine represented a threat for Romania, given the geographical proximity and the declining immunization rates. Moreover, the death of two children (one from Spain and another from Belgium), following infection by *Corynebacterium diphtheria*, produced an international "state of alert" about the importance of vaccination.

In the presence of highly transmissible pathogens, vaccination should be mandatory for HCWs everywhere. This will allow the health system to remain active, and avoid transmission between HCWs and patients. For security reasons, other essential groups such as army and firemen, should also be subject to mandatory vaccination. In **France**, the legal structure exists to make vaccination mandatory for HCWs, upon recommendation by public health authorities. Another national example is Finland where mandatory vaccination for HCWs is about to enter into force.

Mandatory vaccination should be avoided if possible, and practised only under a public health threat with high risk to the population. However, even in this circumstance, preliminary explanatory work is needed for public acceptance. People are less against mandatory immunization when they are convinced of the benefits. If vaccination is made mandatory for the entire population, public health authorities should insure the availability of sufficient vaccine doses. Entry to the work place or schools should be refused to people

who are not vaccinated. In the post-pandemic period, vaccination should remain mandatory if the pathogen continues to circulate.

A temporary law is an option for countries that do not have a mandatory vaccination plan. In the case of a pathogen with low transmission rate, mandatory vaccination is unnecessary.

Whether to immunize children should be the decision of Government, not parents. People should bear in mind that events in one European country can affect all of Europe, and we must stand together. The health of future generations depends on what is being done today. The immunization of children is key to preventing certain infectious diseases, epidemics, and pandemics and it is essential to convince, motivate, or compel parents to vaccinate their children. Besides preventing specific infectious diseases in individuals and throughout communities, vaccinations also reduce illness from complications. Effective information campaigns are the preferred way to gain compliance, however regulations should be developed to discourage parents' refusal to vaccinate their children by imposing constraints and curtailing privileges.

Pandemic response can require restriction of basic human rights, which raises questions that are the specialty of ethicists, questions of law and ethics that may be quite far from the focus and interests of public health officers and scientists. It should be kept in mind that from the public health viewpoint, the general aim is to protect public health, and that the key issues in this context are what laws are necessary, how can these laws be enforced, and what kind of sanctions would be most effective.

To better address the issue of vaccination, a complex strategy is needed for healthcare services; a strategy oriented towards prevention practices, health education, promotion and training. Law enforcement needs to consider socio-economics and how that affects the population's access to health services, including vaccine related services.

A key element of the strategy is an open dialogue with the population, through several channels. Given the importance of the doctor-patient relationship and the influence of medical personnel on the population's opinion of vaccination, there is a need for effective, reliable communication from physicians and HCWs. Physicians should focus their efforts on increasing parental compliance, especially when parents express uncertainty about the benefits of vaccines or misconceptions and fears. Of less influence but important nonetheless are other sources of information for the population, such as health insurance companies, vaccination campaigns, and internet advice. Actions related to these sources can include: expanding vaccination campaigns, creating online information platforms for vaccination, or offering mobile services for public health awareness. These channels can emphasize the importance of vaccination, or, for example, provide a free-of-charge medical guide with up-to-date, concrete and accessible information to parents, presenting pro-vaccination data to increase confidence in the medical procedure. These channels can also be used to counter scepticism about the benefits of vaccinations, fear of extremely severe adverse reactions, and anti-vaccination campaigns.

Another part of the strategy to be considered is sanctions. Although sanctions could be applied in a wide variety of ways, there is a critical need for debate about their use and associated penalties. When sanctions are required, they might include, for example, people losing the ability to use some public goods, funds, or payments, in recognition of their not making their contribution to the public health. Other sanctions might include a requirement to pay out of pocket, rather than using health insurance or free medical care, for an illness that would have been prevented through vaccination. People who refuse vaccination might also incur sanctions such as paying more taxes to the state, or losing welfare, health insurance benefits, or childcare.

An ASSET [report](#) on unsolved scientific questions concerning epidemics and pandemics outlines how, as we are living in the "post-trust" age, trust is a most important issue. If citizens trust government and public health institutions, and their community as a whole, citizens will believe vaccination will protect their own health, and mandatory vaccination will not be necessary.

The legal system is only one component of the solution to improve the current situation, and it is not always the most effective. Indeed, the law is a one-way communication tool; equally important to progress is two-way communication (and collaborative decision making) between decision-makers and civil society. Citizenship engagement must be a high priority. The Ministry of Health adopted a citizen consultation approach to vaccination in **Bulgaria and Romania** to foster vaccine compliance (and other important public health practices) among "Roma" people, using an effective system of health mediators. If these two states had simply decided to impose vaccination on these people by law, success would have been very unlikely.

It is noteworthy that countries in Europe differ in their social structure and therefore their vaccination practices. Differences in vaccination practice also apply between Eastern versus Western countries or Scandinavian versus Mediterranean Member States. For example, in Southeast Asia mandatory isolation and quarantine were applied when SARS, H5N1, and bird flu outbreaks occurred, and people complied. Whether that approach would work in other countries or in Europe is an open question. As another example, in Finland there is work in progress to make vaccination mandatory for HCWs.

The problem of vaccines is definitively far from a simple one, with many controversies on the subject, involving issues such as human rights, medical ethics, and conflicts of interest in the geopolitical sphere. Mass and social media have a strong effect on the population, sometimes exaggerating negative news and accidental "errors" resulting from vaccination, as well as presenting ill-founded accusations against the medical system. In spite of the fact that this is distorted and false information, in free society, this can compel people to deny immunization to their own children.

The success of an immunization program depends not only on technological advances in health care, but also on a compliant population that believes vaccination is beneficial, resulting in wide vaccination coverage. While technological advances have a similar impact across Europe, compliance of various populations differ. We can expect that the countries in Europe will respond differently to any legislation on mandatory vaccination, depending on history, culture, and influence of media in the region. The dominant political orientation (conservative, liberal or other ideology) will influence any proposed legislation. Until now, such factors have consistently blocked efforts that would prevent, control or even eradicate several potentially devastating infectious diseases.

In summary, vaccination is a critical public health practice that cannot be refused. It is freely available to all; it benefits the individual by preventing the target disease and associated complications; and it protects the community, especially vulnerable at-risk populations. Although immunization policies are decided at the national level, the importance of vaccination for all of Europe warrants the use of a European legal framework to compel compliance in Member States. An example of such a European legal framework is EU Decision № 1082/2013/EC on serious cross-border health threats, and two related international institutions, the Health Security Committee to the European Commission, and the European Centre for Disease Prevention and Control (ECDC).

3. General Insights and Lessons Learned from the ASSET HLPF Discussion

Citizens voice and Participation

Citizens believe that honesty and transparency can increase the public trust (no matter how bad the situation is), and that it is their right to know the facts and have an accurate understanding of the situation. Public health authorities should devote more resources to collecting citizen input on policies for epidemic preparedness and response.

The ASSET public consultations show a significant need and willingness of citizens to be engaged more actively in public health actions related to pandemic events. These exercises show that citizens want to be more engaged with all kinds of civic policy making and delivery. Agencies need to be more proactive and invest more time and financial resources to reach out to, inform, and engage citizens.

This represents quite a challenge because public health is an area where funding is cut on a regular basis. The recent financial crisis has been particularly hard on public health funding. Limited funding for even basic public health activities makes it difficult to start new initiatives in citizen consultation. However, investment in transparent and honest communication is fundamental to building trust, and building trust is a prerequisite to successful public health outcomes for pandemics. Citizen consultation activities need to be consistent and encourage active listening and response to citizens' concerns and worries during pandemics. Before and after pandemics, more investment should also be put into encouraging citizens to help with planning and implementation of programs, as well as evaluating their effectiveness, efficiency and acceptability.

Although it is clear that civil society wants to contribute and be engaged, experience shows that this engagement is difficult to implement. The challenge starts with selecting the contributors: who should represent the citizen? NGO's? Professional networks representing particular groups such as patients? Lobbies? Academic experts and associations? How to really involve the basic citizen? Forum discussions which can easily be biased? Through online consultations and questions from the authorities?

Experience shows very limited response to public surveys, often only from groups whose independence is questionable. So, the key question is: how to engage citizens in an inclusive and unbiased way?

Trust in information

General Practitioners should be trained to adapt to changing society, and decision makers should be urged to be visible and present on the internet, as its use is increasing.

The common theme for these two points is that further investments are needed to educate and train both GPs and decision makers. On the one hand GPs need to be better trained as facilitators, rather than just expert practitioners, and on the other hand decision makers need to learn to be proactive in the constant online conversation. This education and training will occur only if supported by adequate investments, otherwise it will certainly not happen. In pandemic scenarios, communication plans need to be established and expert staff needs to be available to advise decision makers. Too rarely do decision makers consider communication needs. They need to be trained for effective communication, and they need to also carefully consider advice coming from public health experts.

Risk Communication

Create transparent and clear risk communication to restore the trust of society.

Experience to date shows that this is something easy to say but hard to do. Effective risk communication requires that authorities, supported by experts and politicians, need to develop strategic communication

and marketing plans. These plans need to be long term in nature, and invest in brand building, develop citizen insight and understanding, and target segmented communications to the many different audiences that exist in relation to pandemic events.

An example of such a strategy is discussed in the summary report of the conference “Lessons Learned for Public Health from the Ebola Outbreak in West Africa - How to Improve Preparedness and Response in the EU for Future Outbreaks”, held in Luxembourg 12-14 October 2015. The report offers recommendations that have been endorsed by all communication experts attending the meeting, including the Health Security Committee communicators network members, WHO and ECDC. The report identifies difficulties experienced by the officials in charge of communication during the Ebola crisis, and recommends needs for priority attention by Member states and EU authorities. The report concludes that approaches have not evolved much since the 2009 pandemic, which reflects how difficult it is to implement change, even when it has been endorsed by Ministers at the highest level.

Pregnancy and vaccination

Update, clarify and standardize influenza vaccination advice materials for pregnant women.

Evidence from the literature as well as public health experience indicates that improving vaccine uptake among pregnant women has to be a key element in any strategy. Information materials should be subdivided, to target pregnant women in groups with similar attitudes, understanding, and behaviours. These materials should also focus on fathers-to-be, grandparents, and other supporters who can influence health related behaviours.

Ethics and laws

In emergency situations, public health interest should take priority over individual freedom. Laws should reflect shared basic principles across the EU, be tailored to local history and culture, and be complemented by information campaigns and incentives.

The consistency and acceptance of restrictions on personal freedoms to protect public health would be facilitated by establishing common criteria for such action. In this context, the [PANDEM](#) project carried out a review and analysis of ethical and human rights issues:

“Ethics... can make a significant contribution to debates such as what levels of harm the public are prepared to accept, how the burdens of negative outcomes should be distributed across the population and whether or not more resources should be invested in stockpiling antiviral medications”

(Thompson, A.K., et al., Pandemic influenza preparedness: an ethical framework to guide decision-making. BMC medical ethics, 2006).

- Pandemic management is not purely scientific, as it involves decisions which should reflect the moral values of the society
- Human rights need to be respected not just on moral grounds but also to comply with national and international obligations
- Pandemic response will often involve decisions which reduce individual rights for the common good. This may be justifiable but only if decisions are based on transparent principles which are clearly non-discriminatory and protect the vulnerable
- Effective pandemic management requires public trust and support. Ethical principles such as openness and collaboration are necessary to achieve this trust and support, as well as to reduce the likelihood of panic

- Resources may be scarce and rationing may be necessary, and this will draw upon implicit or explicit ethical principles.
- Several frameworks are in place on ethical issues in pandemic preparedness planning (WHO, Int. treaties, Siracusa, National etc etc)
- Greater prioritisation of ethics and human rights in pandemic planning is recommended (eg allocation of scarce resources)
- Greater alignment of national pandemic preparedness plans between EU Member States is recommended
- Increased research into ethics and human rights in pandemic planning is recommended (human rights has received almost no attention - duties of health care workers re risk to their life).

These conclusions support the importance of having predetermined, well-thought-out, transparent plans, and clearly understood laws. These elements create a solid foundation for ethical pandemic response. In planning and carrying out ethical pandemic response, the role of participatory governance is particularly important. Ethical principles, policies, and rules are to some degree fixed, however there are always judgements required to implement them. For example, at a 2006 workshop in Washington D.C., four principles were suggested as ethical guidelines for pandemic response:

- Utility - act so as to produce the greatest good
- Efficiency - minimize the resources needed to produce an objective or maximize the total benefit from a given level of resources
- Fairness - treat like cases alike and avoid unfair discrimination (that is, discrimination based on irrelevant or illegitimate characteristics of a person or group)
- Liberty - impose the least burden on personal self-determination necessary to achieve legitimate goals (or, broadly speaking, do not trade all freedom for security).

In applying principles such as these, we are faced with questions such as "which good is best?" or "how much benefit would be obtained?" or "what is fair?" or "what is the cost of giving up freedom?" In some situations, these questions have clear, objective answers, however in many cases it is often not so clear. It would seem that in these cases, public participation, i.e. participatory governance, is particularly important, to allow decisions that reflect local values, and decisions that the public may disagree with, but will see as having been fairly arrived at.

As in the discussion of vaccination hesitancy and whether vaccination should be mandated, we see again that public participation definitively represents an important complement to the foundation laid by plans and laws.

Appendices

- a. [Introduction](#) to the ASSET High Level Policy Forum
- b. [Terms of Reference](#) for the ASSET High Level Policy Forum
- c. *Participatory Governance in Public Health:* [Background information](#) [Topic Introduction with key questions to be answered](#)
- d. *Ethical Issues in Pandemic Preparedness Planning:* [Background information](#) [Topic Introduction with key questions to be answered](#)
- e. *Vaccination Hesitancy:* [Background information](#) [Topic Introduction with key questions to be answered](#)