

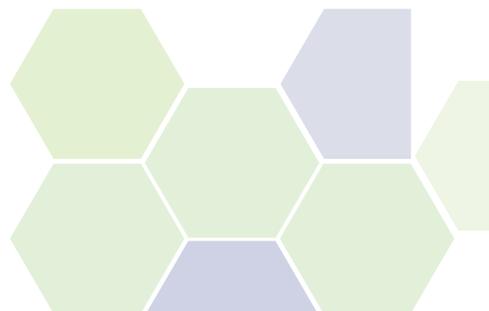


Pandemic Preparedness and Response Bulletin

Issue 6, July 2017



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share and move



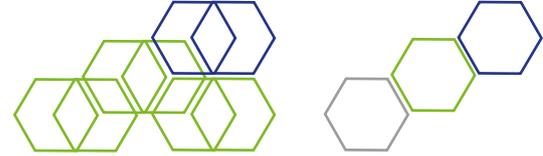
Action plan on Science in Society related issues in Epidemics and Total pandemics

ASSET on social networks



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“Share and Move” is the ASSET Bulletin that intends to highlight strategic priorities and policy-related initiatives on Pandemic Preparedness and Response, and to be essential to a wide-ranged target, from competent institutional actors and public health authorities to decision-makers and influencers, even on social networks.

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Editorial

THE SIXTH SHARE AND MOVE PANDEMIC PREPAREDNESS AND RESPONSE BULLETIN DEALS WITH ETHICS ACCORDING TO AN ASSET PERSPECTIVE

The European cooperative program ASSET aims to address effectively both scientific and societal challenges raised by public health emergencies of international concern (PHEIC), like pandemics, by combining multidisciplinary expertise. ASSET roots in the Science in Society (SiS) framework that was defined by the European Commission in 2001 to foster public engagement and a sustained two-way dialogue between science and civil society. Six are the fundamental pillars: governance, open access, science education, public engagement, ethics and gender equity.

In line with these general SiS key issues for a Responsible Research and Innovation (RRI), the editorial line of the ASSET Pandemic Preparedness and Response Bulletin, Share and move, has been set accordingly. Each issue is concentrated mainly on one specific topic: governance of pandemics and epidemics; unsolved scientific questions; intentionally caused outbreaks; crisis participatory governance; ethical, legal, and societal implications; gender pattern - vulnerability.

The second 'Share and move' focused in fact on governance of pandemics and epidemics, the third Bulletin concentrated on unsolved scientific questions, the fourth issue was associated to intentionally caused outbreaks, the fifth number dealt with crisis participatory governance. Here we come to highlight how ethical issues impact on preparedness and response toward public health emergencies. But in doing this, a pure ASSET perspective is developed: in other words, in the present Share and Move the ritual section called 'From the ASSET world' is missing because it is the basic and transversal approach followed overall.

In this way, we hope our readers would appreciate the editorial approach that offers a common structure but at the same time innovative elements are also entered. As already done in the previous issue (n.5), beside exploiting a specific matter, even 'unsolved scientific questions and open access to scientific outcome' or brief ethical reflections were presented even if the former were covered in the third publishing and the latter were instead programmed to be presented in the current Share and move. Furthermore, the bridging column that includes either pandemic or emergency (even called 'panepidemic') preparedness and response is run again.



Pandemic & Emergency Preparedness and Response

VIEWPOINTS AND PERSPECTIVES OF THE ASSET HIGH LEVEL POLICY FORUM ON ETHICAL ISSUES RELATED TO EPIDEMIC AND PANDEMIC OCCURRENCES

As stated in the last sentence of the Editorial, a column including either pandemic or emergency preparedness and response is here proposed. Given the outcomes from the ASSET research in the context of policy watch that are recalled above, the main perspectives from the High Level Policy Forum (HLPF) on ethical issues are here reported in addition to focusing on vaccination and vaccine hesitancy which are catalysing the attention at international level. The most attention paid by the third and last HLPF meeting in Brussels on 28th April 2017 was in fact on significant challenges in



epidemic/pandemic preparedness and response, including communication and other matters as well as several SiS related aspects. The HLPF members were indeed asked which are the most relevant scenarios affecting public health crisis management in Europe, and two out of the three themes selected were ethical issues in pandemic preparedness planning and vaccination hesitancy. Both topics are introduced by a brief text for background and then answers to the questions posed to the HLPF members are reported.

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 its own 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 European Free Trade Association (EFTA). The study used a semantic analysis based on two keyword lists: a generic list of keywords representing areas of possible ethical interest; and a more specific list of keywords related to particular ethical issues actually addressed in each national pandemic plan.

[The semantic analysis](#) showed there was little concern for ethical aspects and a lack of discussion of ethical issues in most pandemic plans developed by European countries, except for Switzerland, United Kingdom, Czech Republic and France. In addition, the analysis revealed multiple areas within the different plans where ethical considerations were important, but not addressed. Despite the limits of this analysis, it may represent a useful tool to guide future drafters of pandemic plans. It aims to encourage debate on the necessity to update all national pandemic plans to include ethical and other SiS issues, such as gender and participatory gov-



ernance, which have proved to be of great relevance in case of epidemics and pandemics.

Perspective from HLPF

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 the plan complies with European practice. In case resources are insufficient for all needs, their allocation is predetermined in the plan and this allocation should 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 (HCW), 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, the national Ministries of Health are called mainly to act on pandemic planning at the country level, and other relevant stakeholders, such as universities and researchers, are not much involved. If policies across Europe are analysed, the allocation of scarce resources is not explicitly dealt with in quite a number of pandemic plans; this issue is left open to decisions made on a case by case, depending on an assessment of several elements such as the specific cause of the pandemic, the associated risk factors, and the consequent high-risk groups.

Not surprisingly, a number of plans mentions a priority to protect HCWs and essential staff, so that is similar across the board. The allocation of scarce resources in most pandemic plans in across Europe is fairly general, 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 diagnostics and for vaccines and antiviral drugs, but that would all depend on a risk assessment based upon initial epidemiological information, so it is quite flexible and quite open in most plans at the European level.

The plan approved by European Decision 826 in 2009 for the A/H1N1 virus outbreak is an illustrative example of the way the reaction is put in place in 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 the healthcare workers. 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 so on), and the order in which they will receive the vaccine.

b. **Compulsory vaccination** Compulsory vaccination is an ethical issue that is debated across Europe: if it is to be imposed on people, it should be regulated by established law, and not just by ad hoc rules put in place. The laws should be accompanied by informative promotion campaigns so they are accepted, if not by everybody, then at least by a majority 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, the 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 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 decision for compulsory hospitalization was maintained until mid-June and was heavily contested by the population. School closures were also ordered in some regions. The main evidence from a 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 a bird flu disease emerged in Co. 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 by which the decision of isolation at home or in the hospital is appropriate. Limiting the spread of disease through quarantine or isolation also implies the limitation, as possible, of travelling in affected countries, or monitored control at the frontier. Other measures mentioned in European plans include temporary closing 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 wellbeing 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 definitively 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 a lot of controls and protection mechanisms, particularly for more vulnerable subjects such as the elderly or younger people. But 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. But 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 more widely cover ethical issues. 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, in order to find out 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 will include mechanisms to put into practice, and a homogeneous approach will be achieved among different nations.



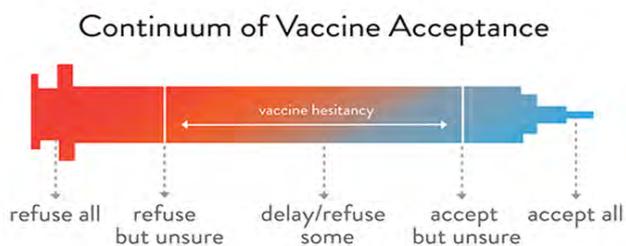


Would it be appropriate to incorporate international guidelines (e.g., the WHO Checklist) into national pandemic plans? What mechanism do you recommend to enable this? It would be useful indeed to include international guidelines to implement good practices in each country, and also for achieving interoperability with the plans of other countries, as the epidemic situation will affect not only one country but will have wider impact. 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; 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 has to cope with evident limited availability of resources, so the activation of specific task forces to work on particular issues is difficult. In Romania, international guidelines have already been incorporated into the national pandemic plan, and they work. Some guidelines have not been fully incorporated because they imply the use of resources that are not available at the moment, so they need to be adapted. This reminds that the mechanism for incorporating guidelines must insure the necessary resources are available, including adequately trained personnel. Thus, it is clearly essential to incorporate international guidelines, which should take into consideration the specifics of each country, but the heart of single pandemic plans should be coherent around the globe. WHO has the legitimacy to prepare a basic core for preparedness and response plans, and include a cross-checklist for country-specific plans. Then, the mechanism that should be put into practice obviously depends on each Member State, and the mechanism must be sure that there is enough input from academics, policy makers, and people who are actually implementing pandemic plans on the frontline.

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, so 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, that there would be a greater awareness of what public health law is and where deficiency exists. As stated above, ethical guidelines referenced by the WHO should be incorporated into national preparedness and response plans. However, a pandemic plan that outlines policy, but is not backed up by legislation, can fail in the event of a pandemic. Policy cannot be actually implemented without legal underpinning. Creating better plans requires better input from citizens, from public health lawyers, and from end users, people who are actually at the frontline. Definitely one of the key elements 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.

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 released by this partnership is “delay in the acceptance of or the refusal of vaccinations, despite the availability of vaccine services”. Although scepticism 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 has objectively nothing to do with science itself.





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.

Another fundamental aspect is the urgency to share as much as possible about the organization and availability of vaccination programs, involving all stakeholders in the decision-making process. It is essential to have a greater analytical capacity to establish the areas in which vaccine hesitancy originates. For this reason, the final recommendations of SAGE concentrate on three main categories: understanding the determiners of vaccine hesitancy; highlighting the organizational aspects that ease the acceptance of vaccines; and evaluating the instruments necessary for opposing this phenomenon.

In Italy, to face a [worrying trend](#) of decreasing immunization rates, a law decree has been approved in June 2017 after that some local and national authorities have suggested preventing unvaccinated children from entering childcare centres or nursery schools. The proposal ignited a public debate about whether this simple and quick measure can be effective: some call for taking such an action only for a more serious emergency and others fear little efficacy or even a backfire effect in the end. A [previous analysis](#) by the ASSET project, in fact, could not find any evidence of a relationship between mandatory vaccination and rates of childhood immunization in the EU/EEA countries for polio, pertussis and measles, suggesting that such measures are not able by themselves to guarantee a good coverage against preventable infectious diseases. [A new feature on ASSET website](#) provides some clues for other kinds of practical interventions, aimed both at improving dialogue with reluctant families and at targeting health professionals who do not support, while not openly discouraging, vaccination.

Donato Greco, former General Director of Health Prevention at Italian Ministry of Health, WHO consultant and currently working for ASSSET 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”.

Perspective from HLPF

[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 correspondence between vaccine refusal and the incidence of certain diseases has already been established: improving the level and quality of immunization at a population level is the best method of protection against infectious disease (that are preventable through vaccination).

For instance, in 2015, the DTaP vaccination rate was about 30% lower than the previous year in Romania. 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 for developing vaccine-preventable diseases. The decrease in vaccination rates can lead to outbreaks. When such things happen, vaccination should become mandatory, for avoiding the spread of the disease.

As an example, 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 the infection with *Corynebacterium diphtheriae* produced an international “state of alert” about the importance of vaccination.

In presence of highly transmissible pathogens, vaccination should be mandatory for HCWs everywhere: this allows 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, so upon recommendation by



public health authorities, mandatory vaccination can be made a law. 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 affecting most of the population. But even in this circumstance, preliminary explanatory work is needed for public acceptance. People are not so much against the mandatory nature of immunizations when they are convinced of the benefits of the measures. In the case vaccination should become mandatory for the overall population, public health authorities should insure the availability of the vaccine for the entire population. Refusing entry to the work place or school should be imposed on people who are not vaccinated. In the post-pandemic period, vaccination should remain mandatory if the pathogen continues to circulate. A temporary law for a limited period of time could be acceptable for countries that do not have a mandatory vaccination plan. And in the case of a pathogen with low transmission rate, the mandatory aspect is unnecessary.

Particularly concerning children immunization, it should be the decision of the Government, not the parents. People should bear in mind that events from each European country influence the whole Europe, as we stand together. Thus, we should act together. The health of future generations can be influenced by what is being done today. Vaccination is the most effective way to prevent some infectious diseases avoiding epidemics or pandemics at community level but also making people not becoming ill both for the disease itself and for related complications. The immunization of children is a key aspect of the problem, and to prove to parents that vaccines are beneficial is absolutely necessary. Besides making people abide by national laws, certain regulations should be developed to discourage parents' refusal to vaccinate their children (constraints, sanctions etc.). For this as well, explanation to the people should be done in the best manner.



Pandemic response can require restriction of basic human rights, which raises questions that are the specialty of ethicists, questions of law/ethics that may be quite far from the focus/interest of public health officers and scientists. It should be kept in mind that from the public health viewpoint, the general aim is to ensure that the population health is rightly protected, 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 again an open dialogue with the population, through several channels. Given the importance of the doctor-patient relationship and the influence of the medical personnel on the population's opinion on vaccination, there is a need for effective, reliable communication from physicians another HCWs. Physicians should focus their efforts on increasing parental compliance, especially when they 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 their confidence in the medical procedure. On the other hand, these channels can be used to counter scepticism about the benefits of vaccinations, fear of extremely severe adverse reactions, and even anti-vaccination campaigns. Another part of the strategy might be sanctions to be thought as a wide



ranging instrument even if there is a pretty critical need for debate before applying penalties. When sanctions are required, they might include, for example, people losing the ability to use some public goods, funds, or payments, in recognition that they are 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 illness that would have been prevented through vaccination. People who refuse vaccination might then incur in sanctions ranging from paying more taxes to the state, or losing welfare and/or some health insurance benefits till losing 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 one of the most outstanding issues. To the extent it is feasible maintain citizen’s trust in institutions and governmental and public health institutions, and with the community as a whole, citizens will believe vaccination will protect their own health, and mandatory vaccination will not be necessary. The solution to overcome the current “status quo” is complex but the legal approach is only a component and maybe not the most relevant. Indeed, the law is a typical one-way communication tool: “I inform you that if you kill the king then you will be beheaded”. Another issue to be overcome is the lack of two-way communication (and collaborative decision making) between decision-makers and civil society. Citizenship engagement must be a high priority. In France 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 the community of Roma people by law, success would have been very unlikely.

A noteworthy aspect is 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 countries 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.

To make mandatory vaccination effective, it will be necessary to take enforcement measures. Although enforcing laws is more a legal matter, it is better that compliance is not based primarily on punitive measures but rather motivation, providing more benefits to people who comply with the law, rather than penalties to those who do not comply. The need for enforcement can be reduced by measures such as building up broad public awareness using an integrated and coordinated communication plan, or encouraging mandatory vaccination through associated social benefits. 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. Also, mass and social media get 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, they 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 cover-



WP3 ACTION PLAN DEFINITION
TASK 3.2 ROADMAP TO OPEN AND RESPONSIBLE RESEARCH AND INNOVATION IN PANDEMICS

ASSET Project • Grant Agreement N°612236

ASSET

Action plan on SiS related issues in Epidemics And Total Pandemics

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SSET Action plan on Science in Society related issues in Epidemics and Total pandemics



age. 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. Also, the dominant political orientation (conservative, liberal or other ideology) would influence the proposed legislation. Until now, such factors have consistently blocked efforts that would prevent, control or even eradicate several potentially devastating infectious diseases. We hope for a better future for immunization in Europe.

In any event, then, broadly speaking about vaccination it has to be considered 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 as a whole, especially vulnerable at-risk populations. Although immunization policies are decided at national level, the importance of vaccination for all of Europe would warrant use of a European law frame to compel compliance of Member States. The recurring example of such a European law framework is the EU Decision № 1082/2013/EC on serious cross-border health threats, that is related to two international institutions, the Health Security Committee of the European Commission, and the ECDC.

General insights on ethics from HLPF

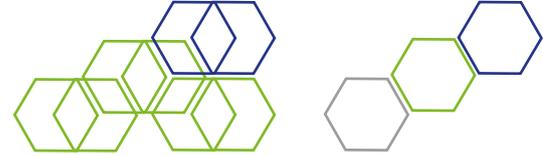
Ethics and laws In emergency situations, public health interest should take priority over individual freedom. Laws should reflect shared basic principles across the EU, be tailored to local history and culture, and be complemented by information campaigns and incentives.

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 (as from WHO or International treaties)
- Greater prioritisation of ethics and human rights in pandemic planning recommended (eg. allocation



of scarce resources)

- Greater alignment of national pandemic preparedness plans between EU Member States recommended
- Increased research into ethics and human rights in pandemic planning 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.



Pandemic Preparedness and Response

AN ANALYSIS CARRIED OUT IN ASSET ON TO WHAT EXTENT ETHICAL ISSUES ARE RECALLED IN NATIONAL PANDEMIC INFLUENZA PLANS

Influenza pandemics are unpredictable but recurring events that can have severe consequences on human health and socio-economic life to global level. For this reason, the World Health Organization (WHO) has recommended all countries to prepare a pandemic influenza plan following its own guidelines. The WHO guidance, revised in 2009, stresses the importance of ethical principles such as equity, liberty, solidarity and states that any measure limiting the individual rights and the civil liberties (such as isolation and quarantine) must be necessary, reasonable, proportional, equitable, not discriminatory, and not in violation of the national and international laws. For such purposes, WHO has developed a framework of detailed ethical considerations in order to ensure that overall concerns (such as protecting human rights and the special needs of vulnerable and minority groups) are addressed in pandemic influenza planning and response.

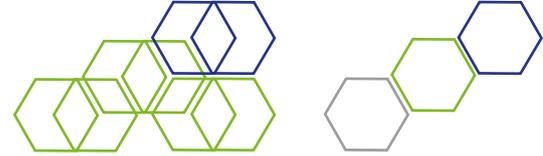
Experts from the ASSET project [conducted a study on this issue](#), performing a semantic analysis of national pandemic plans developed by ten European Union/European Economic Area (EU/EEA) countries and by Switzerland, member of European Free Trade Association (EFTA), including EU and WHO documents.

The analysis has been based on two keyword lists: in a first, generic, list, keywords represent areas of possible ethical interest; in a second, more specific, list, keywords are more precisely related to ethical issues actually addressed in each national pandemic plan. Aim of the research was to assess and compare the occurrence rates of each keyword within both lists, in order to evaluate the relevance of ethical issues and the application of ethical principles in the development of national preparedness and response plans. [The semantic analysis](#) showed little concern for ethical aspects and a lack of discussion on ethical issues in most pandemic plans developed from European countries, except for Switzerland, United Kingdom, Czech Republic and France. This is even more relevant since the analysis revealed multiple areas of possible ethical interest within the different plans.

Despite this work has some limits it may represent a useful tool to guide future drafters of pandemic plans. It aims at encouraging debate on the necessity to update all national pandemic plans including ethical and other SiS issues, such as gender and participatory governance, which have proved to be of great relevance in case of epidemics and pandemics.

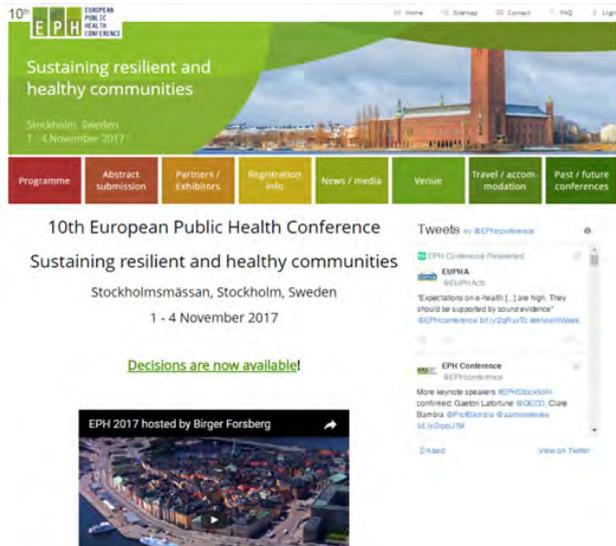
Two main messages can be deduced:

- Pandemic response national plan should include ethical issues
- Most of the actual plan from EU countries do not comply with WHO suggested ethical requirements



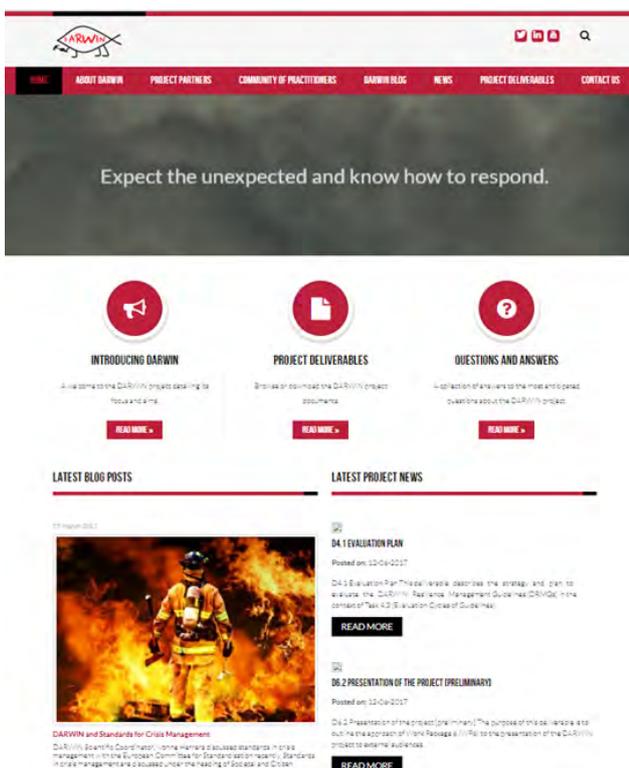
Public Health Initiatives

ONE OF THE TWO ASSET COMMUNICATIONS AT THE EUPHA CONFERENCE IS ON ETHICS



The 10th European Public Health Conference will be held in the Stockholm from the 1st to the 4th of November. The EPH Conference aims to contribute to the improvement of public health in Europe by offering a means for exchanging information and a platform for debate to researchers, policy makers, and practitioners in the field of public health and health services research as well as public health training and education in Europe. ASSET will be presenting two communications and one of them deals with the semantic analysis carried out starting from the national pandemic plans published on ECDC website that is reported in the previous column on 'Pandemic Preparedness and Response'.

ASSET AND DARWIN: TWO EUROPEAN PROJECTS TO TACKLE PUBLIC HEALTH EMERGENCY MANAGEMENT



DARWIN is a EU funded research project under the Horizon 2020 research programme and is focused on improving responses to expected and unexpected crises affecting critical societal structures during natural disasters (e.g. flooding, earthquakes) and man-made disasters (e.g. cyber-attacks). To achieve it, DARWIN is working on developing European resilience management guidelines aimed at critical infrastructure managers, crisis and emergency response managers, service providers, first responders and policy makers. Such these DARWIN resilience guidelines will serve to facilitate faster, more effective and highly adaptive responses to crises among European citizens in times of crisis and disaster as well as they will also be of significant benefit for governments of EU member states. The guidelines go under a process for test in two key sectors Healthcare and Air Traffic Management (ATM), and also ASSET partners have been involved in such this process. As done in ASSET, also DARWIN holds a Community of Practitioners (DCoP).



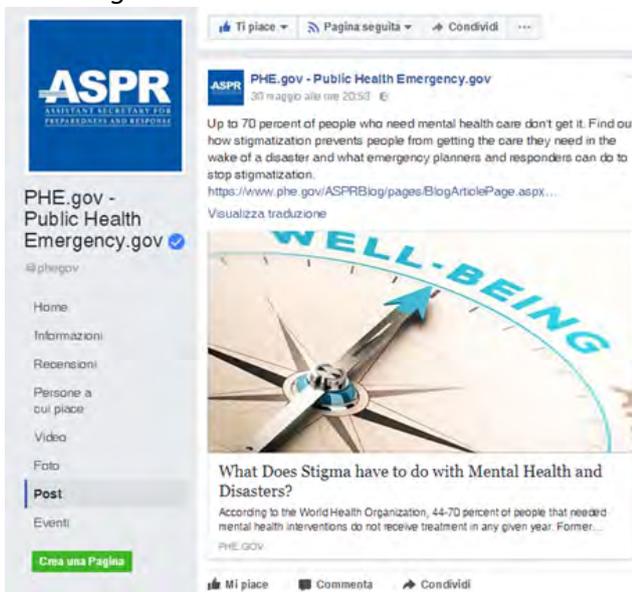
Social networks

ETHICS, EMERGENCY AND PANDEMIC PREPAREDNESS ON PUBLIC HEALTH EMERGENCY.GOV



The PHE.gov page on Facebook includes interactive information that is constantly updated in matter of public health emergency measures and tools to be used. The US Assistant Secretary for

Preparedness and Response uses social networks to address relevant issues in matter of emergency preparedness and response. First, an ethical issue such as stigmatization is here reported: *What Does Stigma have to do with Mental Health and Disasters?*



Up to 70 percent of people who need mental health care don't get it. Find out how stigmatization prevents people from getting the care they need in the wake of a disaster and what emergency planners and responders can do to stop stigmatization.

Zika Virus is a current emergency and CDC explains very clearly what kind of infection is, how the contagion occurs and what consequences are on health.

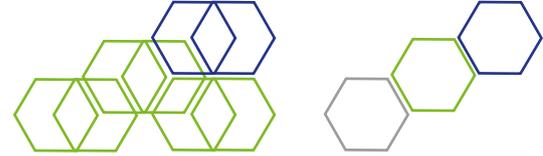
The post here shown gives advice in order to pre-



vent the infection by using condoms: *If you are infected with #Zika, you can transmit it to your partner – even if you don't have symptoms. Think you might be infected? Recently traveled to a location where Zika is present? Use a condom to prevent spreading the virus.* Since 2009, the U.S. Department of Health and Human Services (HHS) has established a domestic vaccine



manufacturing capacity, built stockpiles of medical countermeasures to protect people from pandemic influenza, and developed evidence-based guidance on the prevention, mitigation and treatment of pandemic influenza. They invite readers to check out the latest update to the Pandemic Influenza Plan to learn how they are working to meet next-generation challenges and better protect people in the face of the next pandemic.



On the web



Started in September 2015, Pandemic Risk and Emergency Management, [PANDEM](#), was a Coordination and Support action funded by the Horizon 2020 Secure Societies Programme (H2020-DRS-2014/2015) under the topic 'Crisis management 4: Feasibility study for strengthening capacity-building for health and security protection in case of large-scale pandemics'.



PANDEM matches the growing health security threat posed by pandemics that the European Union faces due to the convergence of risk factors driving disease emergence, amplification and dissemination of diseases with pandemic potential. As per ASSET, also in this H2020 project the core concept is that protecting the health and security of European citizens against pandemic threats requires a coherent response by all stakeholders.

PANDEM has then been contributing to the reduction in the health, socio-economic and security consequences of future pandemics so that society can be better prepared at regional, national, EU and global level.

PANDEM focused on the needs and requirements of users and first responders across the spectrum of pandemic risk management. Given the cross-border and multi-sectoral context of the health and security challenge for building pandemic risk management capacity, a systems-based methodology was applied in order to apply the final outcome for use in a pan-European setting. PANDEM has brought a highly skilled group of senior experts from the health, security, defense, microbiology, communications, legal, information technology and emergency management fields together to develop innovative concepts for pandemic management.

The consortium identified current best practice, user needs and research priorities in core areas of risk assessment, surveillance, communication and governance. As also done in ASSET, the PANDEM project also mapped stakeholders and end-users responsible for managing key functions in pandemic management. This includes policy-makers in national, EU and global public health agencies, security agencies, national laboratories, national communications offices, staff in civil defense units and first responders in health care facilities including paramedics, triage staff and health care workers.



In a SnapShot!



Donato Greco and Eva Benelli (ASSET project partners from Zadig) published an [article](#) commenting the Italian law decree that mandates 12 childhood vaccinations to allow children access state school.

First, they highlight to what extent the risk for a community to get a disease can be reduced or eliminated by a really effective protection that is vaccine, indeed.

What does school risk stand for?

Italy confirms to be one of the European countries with high vaccination coverages, up to 90%. However, even in a vaccinated population some people risk to be infected by those who are not vaccinated: about 25 thousand unvaccinated children per year, non-responders, immunodeficients or healthy carriers, migrants whose vaccination history is hard to reconstruct.

Diseases to be distinguished

Required vaccinations are justified because they are associated to state school attendance: the right for education and the right for health go together and are not conflicting. The Italian Constitution allows children to get educated and protected by vaccine preventable diseases. Vaccination is firstly a right.

The sense of the Italian law decree

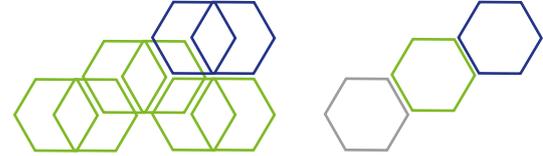
In Italy, despite vaccination refusal is around 2-3%, several studies estimate vaccination hesitancy among parents ranging from 20 to 30%. Then, an adequate counselling program could be planned to reduce people refusing vaccination to their children so that infective risk would be minimized.

Need for conviction and transparency

The decree foresees even penalties and suspension of parent responsibility: these elements indicate more obligation and coercion than affirming a fundamental right. A clear and transparent communication would always be the best choice: vaccination hesitancy is in fact generated by the mistrust of citizens in authorities. Three key aspects could have been communicated: why those 12 vaccinations have been selected, the little that vaccines cost to healthcare system yearly compared to drugs overall, how the vaccine surveillance works.

Limits of vaccination supply

It is finally important to look at the current vaccination supply and its own organization. In Italy there are one thousand active vaccination centres, six thousand pediatricians and forty thousand general practitioners to practice about two million vaccinations per year: eight vaccinations per working day are requested to the healthcare system but three of them are delivered by pediatricians and general practitioners. In the end, what can be achieved by imposing vaccinations in school children could be better reached by a better and more integrated vaccination supply. It is a crucial strategic objective: an obligation perspective suits better with healthcare services and professionals who are mandated to practice vaccinations actually



Disclaimer

The ASSET project was designed to accomplish a European Commission Call (DG Research and Innovation - HEALTH), for developing a Mobilization and Mutual Learning Action Plan in response to epidemics and pandemics with regard to Science in Society related issues.

The European grant agreement ensures scientific and editorial freedom to the ASSET consortium partners.

The views expressed in the ASSET Pandemic Preparedness and Response Bulletin “Share and move” are those of the authors and may not necessarily comply with European policy.

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In case of conflict of interests, it is declared.

Readers are advised to verify any information they choose to rely on.

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