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**ASSET**

share and move to face nasty bugs

## Reflection on Ethics at the ASSET High Level Policy Forum

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THE INTERNATIONAL EMERGENCY MANAGEMENT SOCIETY  
(TIEMS)

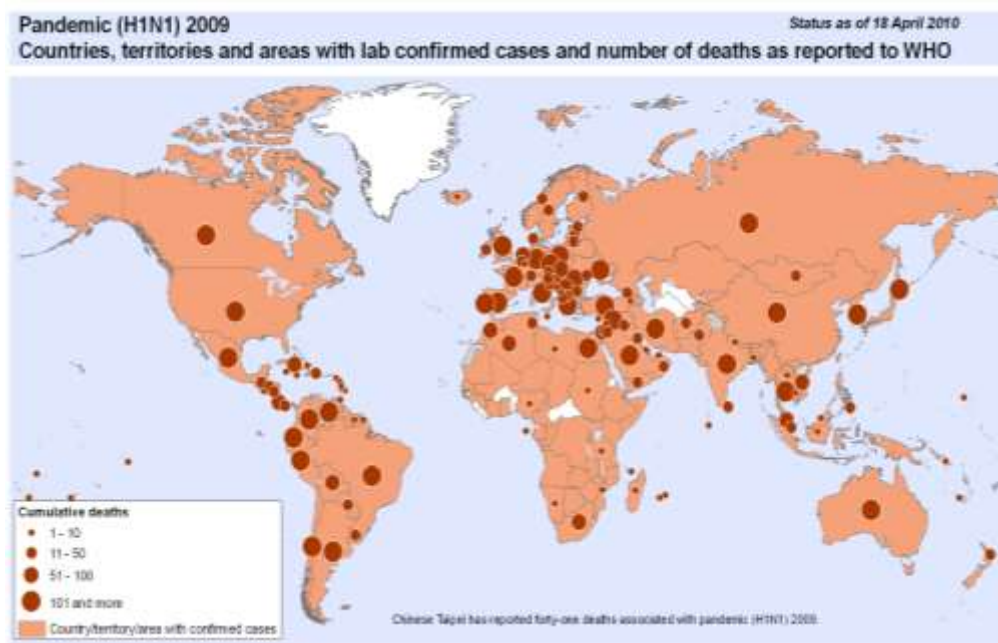
Rome, 30 October 2017



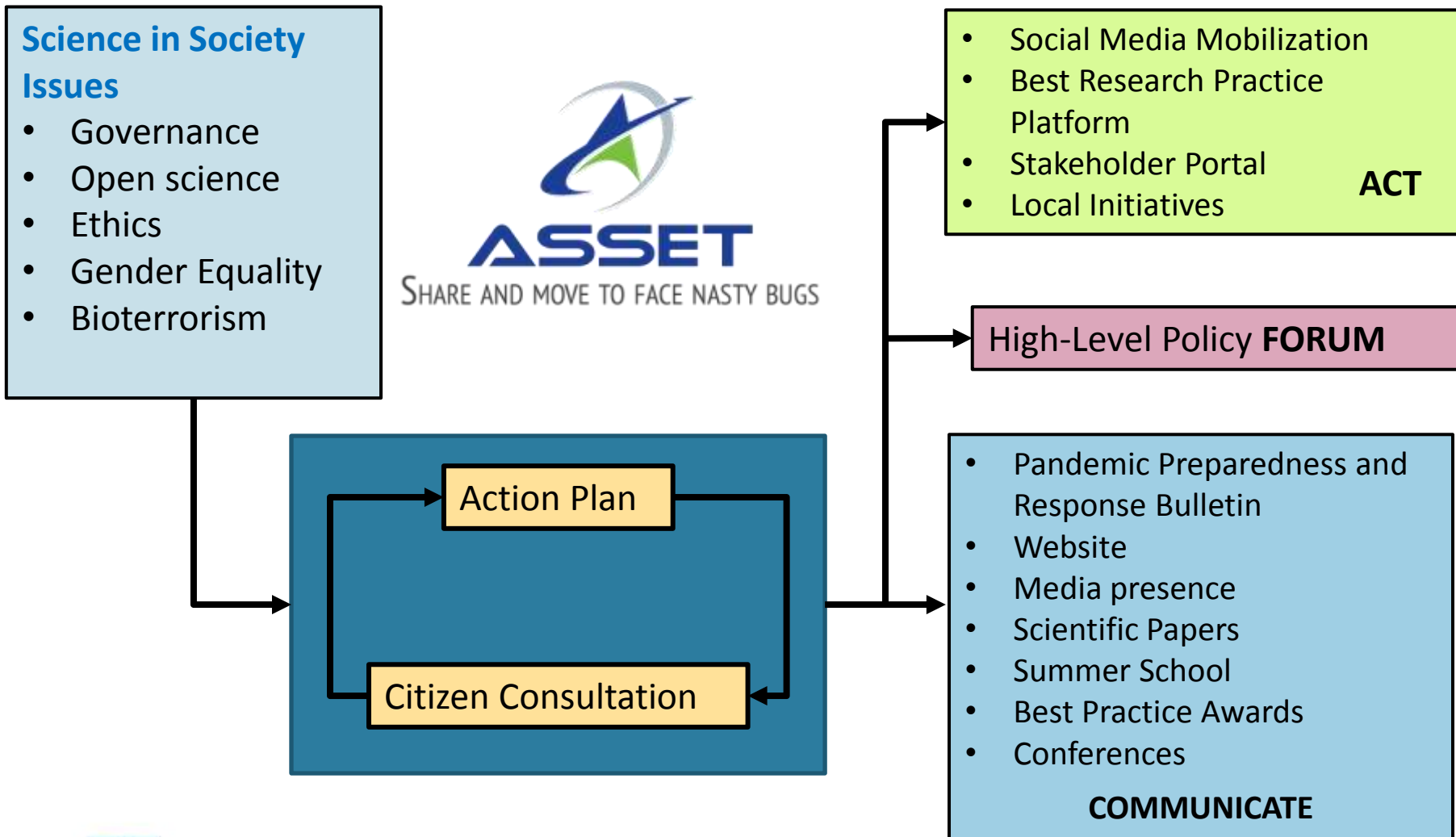
co-funded by the EU. GA: 612236

# The 2009 H1N1 Pandemic

- Alarming outbreak in Mexico;
- soon in 73 countries
- Authorities predict many deaths;
- actual deaths like mild flu
- 78 million vaccine doses delivered, too late
- Confidence in health authorities eroded; low public compliance
- Influence of pharmaceutical companies questioned
- Mistrust fed by news coverage and social media



# ASSET Activities



# ASSET Project

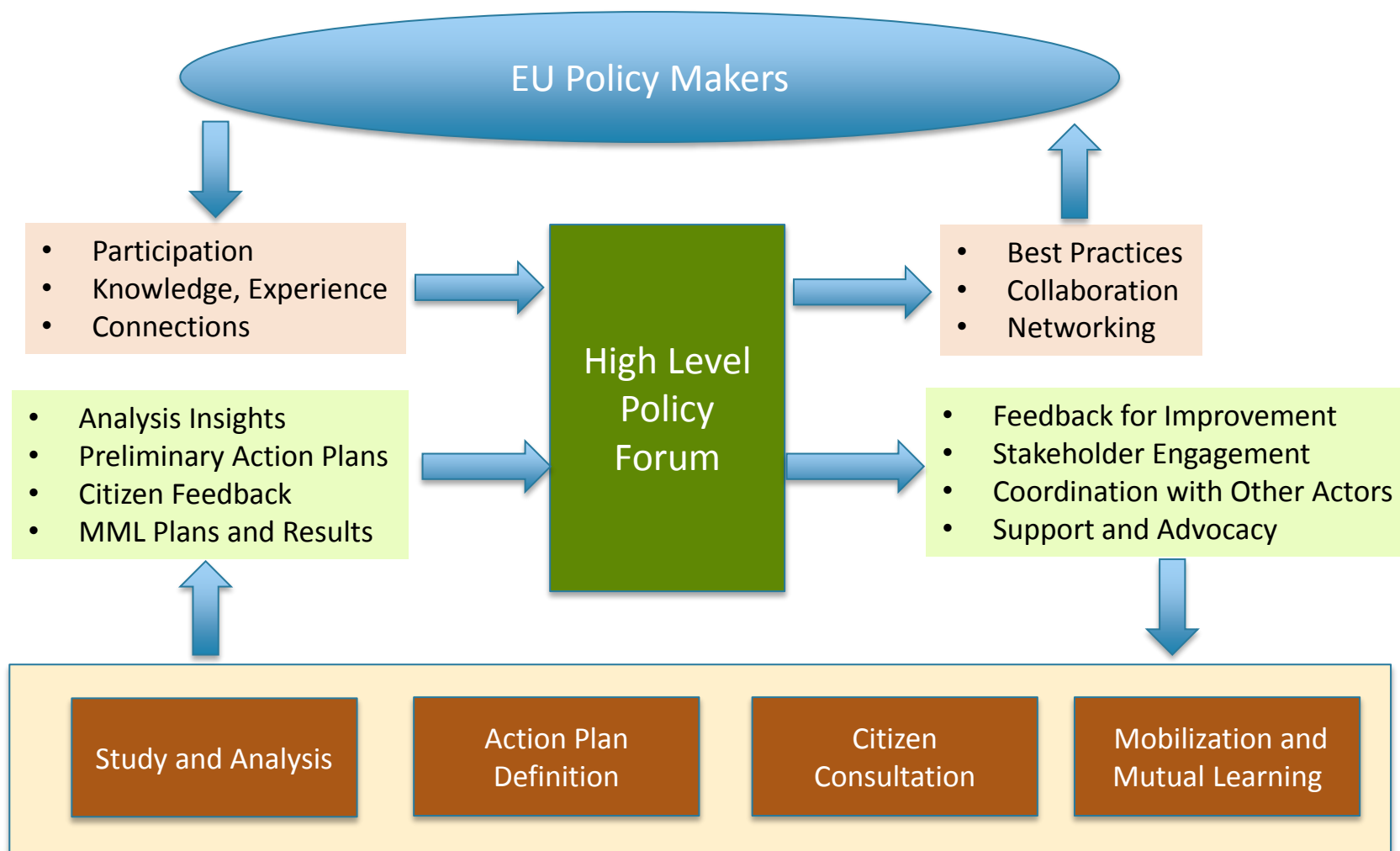


# HLPF Objectives

1. **Bring together** selected European policy-makers at regional, national and EU levels, key decision makers in health agencies and pharmaceutical industry, and civil society organizations, in a **unique and interactive dialogue** to promote on-going reflections on EU strategic priorities about pandemics
2. **Create mutual trust**, improve communication, and provide a “safe” environment to **address questions which are otherwise difficult** to discuss
3. **Establish the value** of this type of dialogue among participants due to increased insights into each others perspectives



# The ASSET High Level Policy Forum (HLPF)



# HLPF Activities

- 14 members, from Bulgaria, Denmark, France, Greece, Ireland, Israel, Italy, Luxembourg, Norway, Romania, Sweden, UK
- Meetings in Brussels (Mar 2015) and Copenhagen (Jan 2016)
- HLPF discussions of three key issues on the ASSET Community of Practice (CoP) online forum
  - **Participatory governance in public health**
  - **Ethical issues in pandemic preparedness planning**
  - **Vaccination hesitancy**
- Third HLPF meeting in Brussels April 28, 2017
  - Continued discussion of three key issues
  - Developed recommendations





## Discussion Issues

- Participatory Governance in Public Health
  - Reflection on findings of ASSET Citizen Consultation
- Ethical Issues in Pandemic Preparedness Planning
  - Consideration of core issues and regional differences
- Vaccine Hesitancy
  - Role of laws, incentives, and effective communication



**Menu principale**

- Community news

**Navigazione**

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# ASSET Community of Practice

## Welcome to the ASSET Community of Practice web platform!

ASSET (Action plan in Science in Society in Epidemics and Total pandemics) is a 48 month Mobilisation and Mutual Learning Action Plan, started in January 2014 aimed to

- forge a partnership with complementary perspectives, knowledge and experiences to address effectively scientific and societal challenges raised by pandemics and associated crisis management
- explore and map Science in Society related issues in global pandemics
- define and test a participatory and inclusive strategy to succeed
- identify necessary resources to make sustainable the action after the project completion

## This is a work area accessible only to the ASSET Community of Practice members!

If you are already logged in, please, press a button to get into the area of your interest

<b>General Forum</b>	<b>Events</b>	<b>Glossary</b>	<b>Resources Database</b>
<b>WP1</b> Dialogue and participation	<b>WP2</b> Study and analysis	<b>WP3</b> Action plan definition	<b>WP4</b> Citizen Consultation
<b>WP5</b> Mobilization and Mutual Learning	<b>WP6</b> Policy Watch	<b>WP7</b> Communication	<b>WP8</b> Evaluation
<b>WP9</b> Legacy	<b>WP10</b> Management	<b>WP Leaders Forum</b>	<b>MMLAP Area</b>

**Help**

For any information or request, please send a email to  
eva.appelgren@iss.it

**Calendario**

dicembre 2015

Lun	Mar	Mer	Gio	Ven	Sab	Dom
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

**Utenti online**

(ultimi 5 minuti)

Eva Benelli

## Discussion Highlights:

### *Participatory Governance in Public Health*

- The value of engaging the public is clear
  - Agencies need to prioritize and **allocate resources** toward a strategic communication plan
  - Engagement is needed for **preparation** as well as response
  - **Training GPs and policy makers** in communication (e.g. Social media) is needed
  - Select participants and **design process** to avoid biases (difficult)
  - Public can help **monitor** situations
- Sophisticated communications is needed to build trust and combat misinformation
  - Situation
  - Expectations
  - Differences across countries
- ASSET found 94% of citizen participants wanted process to be repeated, and felt competent to participate

# Discussion Highlights:

## *Vaccination Hesitancy*

- Vaccine hesitancy, including vaccine refusal, is becoming an **increasing problem** - responsible for a number of infectious disease outbreaks polio, measles, pertussis, and diphtheria
- People refuse vaccines for **various reasons**:
  - Religious objections
  - Fear of side-effects
  - Lack of confidence in efficacy
  - Lack of trust in selected vaccines
  - Misinformation (anti-vaccine organizations, conspiracy theorists)
- **European countries differ** in occurrence of and response to vaccine hesitancy - particularly the dividing line between East and West Europe
- Society can accept mandatory immunizations when it is convinced of the **benefits** of the measures
- Enforcement must **balance** basic human rights, lawful mandates, and practical effectiveness

## Discussion Highlights:

### *Ethical Issues in Pandemic Preparedness Planning*

- Public health laws, policies and plans **differ widely across Europe**, in how they deal with tensions inherent in pandemic response
  - Individual rights versus common good
  - Allocation of limited resources
  - Uncertainties in risk and intervention effectiveness
  - Protection of minorities
  - Compensation for compliance
- These differences reflect **regional historical and cultural differences**; ethical considerations are rarely explicitly addressed in plans and policies
- Bringing ethics (with science) to the forefront in state and international pandemic planning will improve both local preparedness and global collaboration
  - **Global ethical and science-based framework**
  - Local adaptation to social, political, and economic considerations
- Effective non-coercive information and compliance campaigns and **two-way communication** can reduce the need for infringement on personal liberty



# Topics Addressed

- Allocation of scarce resources, such as diagnostic laboratory testing, influenza vaccines, or antiviral drugs
- Compulsory vaccination
- Limiting personal freedom through isolation and quarantine
- Use of human subjects in research

## Questions Asked

- Do you believe your current plans adequately address ethical issues? What changes do you believe should be made?
- 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?
- Can you recommend other approaches to improve consideration of ethical issues in pandemic planning across the EU?



# Topics Addressed

## 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



## Topics Addressed

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

- In general, national Ministries of Health are involved in pandemic planning at the country level, but 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





# Topics Addressed

## 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



# Topics Addressed

## 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



# Questions Asked

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

- **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



# Questions Asked

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



# Questions Asked

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

- **In Italy** 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
- **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



# Questions Asked

## 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
- 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



# 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*



# General Insights and Lessons Learned from the ASSET HLPF Discussion

## 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*

# General Insights and Lessons Learned from the ASSET HLPF Discussion

## Risk Communication

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

# General Insights and Lessons Learned from the ASSET HLPF Discussion

## Pregnancy and vaccination

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

# General Insights and Lessons Learned from the ASSET HLPF Discussion

## 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*

# General Insights and Lessons Learned from the ASSET HLPF Discussion

## Ethics and laws

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)

# General Insights and Lessons Learned from the ASSET HLPF Discussion

## Ethics and laws

In applying above principles, 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*