



## **WP8 LEGAL, ETHICAL AND SOCIETAL IMPACT**

*Findings of stakeholder interviews*

*David Wright, Rowena Rodrigues, Inga Kroener,*

**Trilateral Research Ltd.**

**Trilateral  
Research**



[www.pulse-fp7.eu](http://www.pulse-fp7.eu)

# WP8 – April stakeholder consultations

- ▶ **Aim of consultations:** to seek external stakeholder views on ethical, legal and social issues related to the PULSE platform in order to inform the project.
- ▶ **Period of consultation:** April 2016
- ▶ **Mode of consultation:** Interviews via phone, Skype.
- ▶ **Invitations issued** (personalised): 50 across variety of EU countries (particularly outside consortium).
- ▶ **Responses:** 6 declines, 12 positives.
- ▶ **Results:** will be documented in Deliverable 8.2.

# Interviewees

- ▶ **Interviews conducted:** 7 + 1 written response = 8
- ▶ **Countries covered:** Belgium, Italy, Ireland, UK, Sweden.
- ▶ **Types of stakeholders:**
  - ▶ Academic – ethical and/or legal
  - ▶ Hospital, emergency medicine
  - ▶ Ethics committee member
  - ▶ Representative organisation of the national Associations of Medical Specialists in the European Union.
  - ▶ Related EU projects: EDEN, ECOSSIAN, TACTIC.

# INTERVIEW RESULTS



# Ethical issues raised by the PULSE platform

- ▶ Privacy and consent.
- ▶ Dignity.
- ▶ Issues in relation to storage and use of data, sharing of data.
- ▶ Issues relating to the effectiveness of the platform.
- ▶ Does the system represent an improvement on existing structures and systems?
- ▶ Research across Europe handles identical clinical scenarios differently in different jurisdictions; difficulties in harmonisation.

# EU or national policy PHE initiatives that might impact the use and/or implementation of PULSE platform

- ▶ Any EU developments would have to **integrate with existing national policies**.
- ▶ There are **many other platforms in different areas**: Similar programmes such as the Early Warning and Response System (EWRS) at the EU level!
- ▶ **EU-level initiatives highlighted**: General Data Protection Regulation, NIS Directive, telecoms policies.
- ▶ All countries have **national policies for emergency care** (and emergencies ranging from political emergencies to disasters (e.g. chemical disasters)).
- ▶ National health systems are **complex structures**; responsibilities of people and departments vary between countries.
- ▶ Politico-legal frameworks in different countries especially **devolved** ones are something to watch out for.

# Burdens of implementing PULSE at EU-level

- ▶ If super-imposed = **practical problems and additional burdens for participants** e.g. issues related to excess paperwork, re-input of data in different systems.
- ▶ **Financial and resource burdens:** cost of maintenance, funding, infrastructure to make those developments and to apply the PULSE platform.
- ▶ The platform **needs to work well during an emergency** – needs to be well oiled and well-funded.
- ▶ There is also the issue of **who is responsible for doing what** – which government body, who has the responsibility – this has impacts for the system long term.
- ▶ **Need to harmonise outputs of similar EU projects.**

## EU or national-level policy initiatives related to emergency management that might limit PULSE's effectiveness

### ▶ Several issues highlighted:

- ▶ **Who will use PULSE system?** There are different implications: regional level is different from the national level.
- ▶ **Confidentiality of information:** treated differently at the regional level, and in different areas of the same country.
- ▶ PULSE structure is detailed and good, but the major concern is that it **seems to do things that are already being done**. How is PULSE adding value?
- ▶ **Greater need to co-ordinate with what already exists.** The threat is two or more regulatory bodies asking you to do the same thing.

## EU or national-level policy initiatives related to emergency management might limit PULSE's effectiveness

- ▶ May be a **LIMIT** or an **OPPORTUNITY**.
- ▶ May be **useful to look at instruments already developed and being used at the national level** for information sharing, surveillance, risk assessment, national epidemiological surveillance.
- ▶ PULSE should be **open and try to engage with people in various countries** to try and push this forward – i.e., to harmonise across Europe and how we deal with different disasters.

# Potential societal impacts - positive

- ▶ **Beneficial** particularly to know if there is an emergency in one country, there was an EU policy to deal with it.
- ▶ **Enhance efficiency of emergency preparedness and response** - added value and advantage (as long as it's a true co-ordination and not duplication of efforts).
- ▶ **Improve** first responders' reactions.
- ▶ **Helpful for emergency training**, sharing information across the EU more broadly.
- ▶ **Might improve the efficiency in use of resources** – e.g. ambulances and local resources.

# Potential societal impacts - negative

- ▶ Impact on **autonomy** of individuals.
- ▶ Increase in surveillance via tracking **conflicts with individual integrity**.
- ▶ **Feeding into privacy anxieties**: about how data is obtained, how people are tracked.
- ▶ **Potential to infringe privacy**, impact personal data via sharing of information.
- ▶ **Function creep** – data collected for one purpose may be used by another agency for another purpose (Snowden type anxieties)
- ▶ **Impact on decision-making**: tools should support operators in making the right decision but cannot be a substitute for the operator.
- ▶ **Compatibility challenges**: depending on how cumbersome local level systems are for managing patient data or sharing patient data with healthcare providers.

# Potential economic impacts

- ▶ Who is going to pay for it?
- ▶ Would it be that the country that had the disaster would have to reimburse the country dealing with its patients?
  - ▶ **BUT, this can be worked out.**
- ▶ Human and financial resources will need to be in place for planning etc. This is **essential**.
- ▶ Might have an economic impact at the local level because of the requirements of the PULSE platform.

# Some impacts specific to the EU-level

- ▶ Impact related to **harmonisation** with other countries.
- ▶ **Mutual learning** between countries in dealing with public health emergencies – could be a positive experience for all.
- ▶ Issue of **duplication of systems**, e.g. communications system for the regions of the WHO is already duplicated by the Early Warning Response System (EWRS) in the EU
- ▶ **Additional burden** on economically challenged countries.

## How medical resources are allocated in PHE might affect PULSE

- ▶ Depends on who would be doing the allocation.
- ▶ Challenges in terms of health care budgets
- ▶ Depends on who will pay for the use of PULSE.
- ▶ Depends on cost evaluations and decisions at regional, national and local levels, and the cost of integration, interconnection between systems.

# Legal or other factors might affect the cross-border implementation of PULSE

- ▶ Europe is not homogenous, countries have **different laws and regulations related to health care.**
- ▶ **Diverse data protection laws** (will be alleviated with the General Data Protection Regulation).
- ▶ **Issues surrounding protection of confidentiality** and treatment of sensitive data (depends on final use of PULSE)
- ▶ **Legal differences between countries related to which healthcare professionals are allowed to do what** – roles differ from jurisdiction to jurisdiction.
- ▶ **Ethics are contextual** – e.g. prioritisation of care; this differs across countries.

# Regulatory barriers might hinder cross-border operation of PULSE services

- ▶ PULSE might challenge or conflict with some plans and practices for dealing with national emergencies within countries.
- ▶ To have effect on cross-border operation, PULSE will need acceptance by Member States and approval by competent authorities.
- ▶ National level clearance for sharing sensitive information.
- ▶ Divergence in recognition of medical credentials.
- ▶ Deploying the PULSE system in countries outside the EU might be a problem; e.g., Safe Harbor.

# Measures to boost the societal acceptability of the PULSE platform

- ▶ A **good understanding** of the differences in healthcare practice and priorities.
- ▶ **Buy-in** from senior people, national leaders, healthcare delivery leaders at the government and ministerial level (including different DGs of the EC)
- ▶ **Implementing PULSE in a co-ordinated way.**
- ▶ **Knowledge sharing** with users and **proper training.**

# Measures to boost the societal acceptability of the PULSE platform

- ▶ Greater consideration of the **security aspects** of the platform to protect against deliberate hacking attempts.
- ▶ Use of **high levels of security** and anonymisation.
- ▶ **Transparency** of system and purpose limitation (use of system only for designated purpose)
- ▶ Respect for people's rights even in emergencies.
- ▶ Connect with people and create media and **public awareness** about the usefulness of the platform.

# Discussion and feedback

[david.wright@trilateralresearch.com](mailto:david.wright@trilateralresearch.com)  
[rowena.rodriques@trilateralresearch.com](mailto:rowena.rodriques@trilateralresearch.com)  
[inga.kroener@trilateralresearch.com](mailto:inga.kroener@trilateralresearch.com)

Twitter: @Trilateral\_UK  
[www.trilateralresearch.com](http://www.trilateralresearch.com)

