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Platform for European Medical Support During Major Emergencies

D7.1 Trials Definition

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PULSE

Platform for European Medical Support during major emergencies

WP7 Trials and Validation

Deliverable D7.1-Trials Definition

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Abstract:

The purpose of the trials is to evaluate the PULSE Tools in the context of two realistic emergency management situations.

The document provides the complete definition of all aspects of the two trials for the PULSE project:

- Emerging Viral Desease (EVD)-SARS-like outbreak(in Italy, Rome))
- Mass Casualty Incident (MCI)-crowd crush in a stadium (Ireland, Cork

The document also outlines dates, locations, sequence of the simulated events (explicitly related to the Scenarios' Use Cases), timing/agenda, participants, infrastructure/equipment, data, evaluation mechanism.

Partipants will be very experienced emergency managers. They will be asked to compare the "with" vs the "without" PULSE decision making process.

Evaluation will be based on the feedback provided by the participants along three dimensions: Effctiveness, Performance, EELPS (Ethical, Economic, Legal-Political, Societal) impacts. Related metrics are provided.

Keywords:

Major medical emergency, health services, SARS and STADIUM scenario, trials design, system evaluation, measures of effectiveness, measures of performance, measurers of Ethical, Economic, Legal-Political, Societal impact

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0.9_rev TRI	04.05	Amendments to 2.4 Legal and Ethical Considerations and Implications of the Trial Exercises	RR (TRI)
0.10	08.05	Insertion of • 2.3 Trials' key contents and locations according to feedback from S. Bourke (SKY) 4.9 Summary of Trial (SARS)	PM (UCSC)
0.11	29.05	• EVD Amendments following the ERC feedback • UC8 Script links with MoP scheme • Cancellation of UC2 from MCI Trial	PM (UCSC), PD (HSE), RR (TRI), HK (CESS), FM (SES), PK (SKY)
1.0	29.05	• Glossary • MCI locations • MCI Amendments following the ERC feedback	PM (UCSC), PD (HSE), PK (SKY)

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1 Introduction

1.1 Purpose of the Document

This document provides the complete **definition of all aspects of the two trials** for the PULSE project:

- Mass Casualty Incident (MCI)-crowd crush in a stadium (Ireland)
- Emerging Viral Disease (EVD)-SARS-like outbreak (in Italy)

Note: in this document the terms "MCI" and "Stadium crush" will be used as interchangeable; also the terms "EVD" and "SARS-like" will be used as interchangeable.

1.2 Scope of the Document

The purpose of the trials is to evaluate the PULSE Tools in the context of two realistic emergency management situations.

Therefore, the Document provides

- the high level script of each trial, in terms of sequence of events
- the related key evaluation methodology
- definition of remaining aspects, in coherence with script and evaluation methodology:

The level of detail has been set in order to check overall coherence and to provide sufficient input to the trial implementation phase, of which we will define every aspect in deeper detail. The final version of these aspects will be provided in Deliverable D7.2-Report on trials implementation, as shown in following table:

Table 1: Documentation of Trial Design and Implementation

Aspect	In D7.1-Trials Definition	In D7.2-Report on trials implementation
Script (trial scenes)	Concept + key elements of the script	Detailed script
Evaluation methodology	Evaluation mechanism and aspects to be evaluated	Detailed questionnaires and tools
Timing	High level timing	Detailed timing
Participants	Categories, profiles, roles in the trial	Actual roles and organizations
Infrastructure/Equipment	Categories	Actual Lists
Data	Data types per scene	Actual Data
Legal and ethical aspects	Aspects to be considered in the trial design and execution Concepts for evaluating the tools from the legal and ethical perspective	Finalised EELPS evaluation methodology

1.3 Sources and links PULSE project deliverables

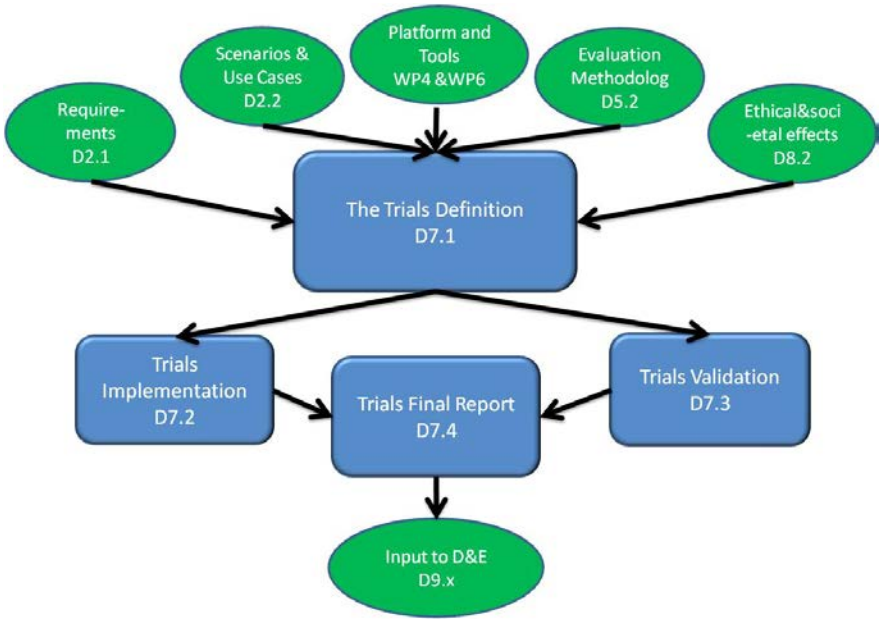
Both trials are based on two backbones:

- Use Cases, as defined in D2.2
- PULSE tools, as described in WP4 and WP6

Anyway, other inputs from previous PULSE documents have been taken into account. D7.1 is the basis for remaining WP7 Deliverables.

Links between previous and future PULSE documents are shown in following figure.

Figure 1: D7.1 in the overall PULSE Context



1.4 Structure of the Document

The document includes:

- Chapter 2, clarifies Trials Goals and Objectives for both trials
- Chapters 3 and 4, define all the SARS-like trial-specific aspects at a concept (3) and more detailed (4) level
- Chapters 5 and 6, define all the STADIUM trial-specific aspects at a concept (5) and more detailed (6) level
- Chapter 7, defines the evaluation methodology for both trials
- Chapter 8, conclusions

1.5 Terms and Definitions

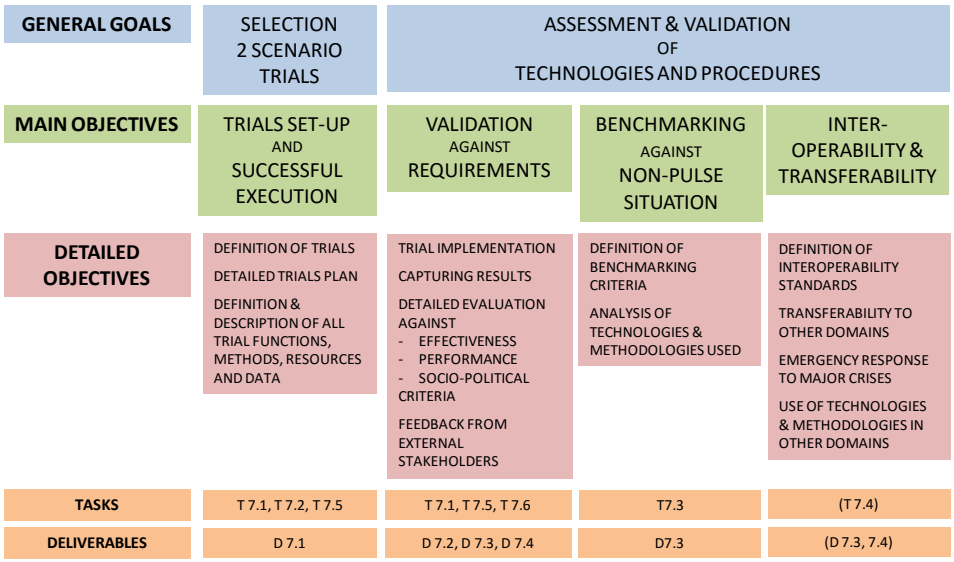
Terms and acronyms are defined in chapter 9

2 Trials Goals and Objectives

PULSE technologies and scientific concepts developed aim to span a whole range of scenarios and requirements for medical support during major emergencies in a national and European context.

Substituting for this potential scale of extremities, the two application scenarios chosen for the purpose of this project follow a similar concept determined by the goals and objectives depicted in below Figure 2.

Figure 2: PULSE Trials Objectives Hierarchy



2.1 General Goals

The overall approach of PULSE will be validated via the use of the system in these two simulated application scenarios, however the conditions are realistic.

Results and conclusions will not be restricted to these validation scenarios but will be transferable to other application areas. Consequently, the general goal of this work package is twofold:

- On the one hand to create and prepare for the trials prototypes of
  - An EVD SARS-like scenario and
  - a mass casualty incident/major STADIUM CRUSH scenario at a large concert.
- They will show proof of concept of the technologies and scientific methodologies developed in WP2, WP3, WP4, and WP5.
- The scenarios serve as the framework for assessing and validating the technologies and procedures developed by the project.

Within these trials, we will not exercise full-scope scenario games. In order to follow the main goal of evaluating the PULSE platform and its tools, a number of key situations and processes within the scenarios- the **Use Cases**- have been selected

and specified in great detail in D2.2 and D5.2.

The PULSE system will be exposed to and will perform within these (simulated) use cases.

2.2 Main and Detailed Objectives

In demonstrating the fulfilment of requirements, displaying operational capabilities, proving the technological and scientific concept, and receiving feedback from stakeholders, the objectives are:

- Definition and set-up of the two trials and their successful execution. This objective directly relates to the tasks mentioned in Figure 2 and in this deliverable D7.1 'Trials Definition'.

However, D7.1 also creates the basis for the detailed objectives related to the tasks and follow-on deliverables D7.2, D7.3, and D7.4, including for

- PULSE technology validation against requirements,
- PULSE technology assessment through the benchmarking developed in WP2 (before and after PULSE), and
- Studying the interoperability, and transferability and other characteristics of PULSE.

2.3 Trials' key contents and locations

Two Trials will be performed:

- in Rome (Italy), a table-top exercise that will evaluate PULSE tools in a SARS-like scenario (EVD Trial)
- in Cork (Ireland), a live exercise that will evaluate PULSE tools in a STADIUM crush scenario (MCI Trial)

Each trial will be based on the relevant Use Cases defined in D2.2-Use Case Specification and described in more detail in D5.2-PULSE SOPs, as per following table:

Use Case ID	Use Case content	Trial
UC-SARS LIKE-01	Weak signal detection and surveillance	Rome (Italy)
UC-SARS LIKE-02	An airplane is landing in Italy. A probable case is now identified	Rome (Italy)
UC-SARS LIKE-03	A ship is arriving in Italy. A passenger has been identified as probable case	(*)
UC-SARS LIKE-04	Identification of a new probable case in a community	Rome (Italy)
UC-SARS LIKE-05	Assessment of the available medical resources during the pandemic phase	Rome (Italy)
UC-SARS LIKE-06	ECDC recommendations	Rome (Italy)
UC-SARS LIKE-07	National Authority periodic assessment	Rome (Italy)
UC-SARS LIKE-08	Post emergency learning at national level	Rome (Italy)
UC-SARS LIKE-09	Post emergency learning at WHO level	(*)
UC-STADIUM CRUSH-01	Scoring System in the Event Medical and Other Plan Preparation Phase	Cork (ireland)
UC-STADIUM CRUSH-03	User wishes to mobilise additional resources from Public, Private, Voluntary and Response Assets from other member states. Via surge capacity tool.	Cork (ireland)
UC-STADIUM CRUSH-04	Hospital Surge Capacity and Bed Management	Cork (ireland)
UC-STADIUM CRUSH-05	Triage in Casualty Clearing Station [CCS] and links to PULSE proposals on electronic patient care records [ePCR].	Cork (ireland)
UC-STADIUM CRUSH-06	Input critical data for the RCS on Site and from other relevant off-site sources	Cork (ireland)
UC-STADIUM CRUSH-07	Post-Event, Post Exercise Evaluation Tool to identify lessons to be learned.	Cork (ireland)
UC-STADIUM CRUSH-08	Casualty Bureau Operation searchable data base created for specific multi casualty incident.	Cork (ireland)

(*) SARS UC 03 and 09 are similar to UC 02 and 08; therefore, Trial focuses on UC 02 and 08

2.4 Restrictions and Limitations

The two trials shall be performed first in Italy and then in Ireland within work package 7.

For the purpose of evaluation and validation, both scenarios chosen are quite different with regard to hazards involved, geographic distributions, target audiences affected, inherent scenario dynamics, and trial artificialities, as described in detail in D2.2.

Moreover, executing the trials in Italy and Ireland under realistic conditions means PULSE encounters nationally shaped emergency routines and differently designed or interpreted international connections, these all have their own specific impact on the planning and execution of the trials.

The trials' setup and evaluation will need to generalize as far as possible and avoid conclusions that are limited to national or local specificities.

Observers from other Countries will be invited to attend the Trials and will be asked to provide feedback on PULSE, in relation to their own national systems

2.5 Legal and Ethical Considerations and Implications of the Trial Exercises

Tabletop exercise for SARS scenario (EVD Trial)

A tabletop exercise is a meeting to discuss a simulated emergency. Members of the

team review and discuss the actions they would take in a particular emergency. Tabletop exercises are also used to clarify roles and responsibilities and to identify additional mitigation and preparedness needs. Tabletop exercises have the advantage of being low cost, low stress environment, and facilitate a group discussion of problem areas. However, there are also disadvantages to the process, including a lack of realism, and a lack of a true test of operational capability.

There are ethical issues that need to be taken into consideration when undertaking tabletop exercises. These may include: the manner in which research is undertaken and the issue of fairness; how participants are recruited, ensuring that those who participate in the tabletop exercise provide informed consent and are aware of the recording and/or reporting of the workshop; and ensuring that researchers leading the tabletop exercise operate within clearly defined constraints to ensure that when sensitive issues are touched upon (such as national security or commercial confidentiality) that neither individuals nor organisations are put at risk.

Live – or semi-live - trial for stadium crush (MCI Trial)

A live exercise is set up to test the emergency response to a given situation. It should be realistic, plausible and challenging. A live exercise is designed to test and validate plans, policies, agreements and procedures, to clarify roles and responsibilities, and to identify resource gaps in an operational environment. Live exercises have the advantage of being very realistic, and ensure that all services and communications operate effectively. However, there are also disadvantages to live exercises as they are very expensive, labour intensive, and can cause disruption to the areas they are held.

In terms of ethical considerations, designers of the live exercise need to ensure that participants are aware that the exercise is not a real emergency. The scenario should not be so challenging that it overwhelms participants. Prior information should be given to members of the public in the surrounding areas of the exercise, to ensure that the public do not think it is a real emergency situation. Other ethical issues include those related to research ethics: how participants are recruited, safety and well-being of participants, informed consent of participants, recording of information, consideration of sensitive issues and/or sensitive personal data.

Ethical Research Framework

A framework for ensuring ethical research processes in relation to tabletop exercises and live trials should be designed prior to carrying out the exercises.

As an example, a framework for ensuring an ethical research process may include the following:

- Ethical issues examined and highlighted at the start of the live trial process
- Procedures established to monitor the research
- Complaints, appeals and conflict of interest procedures devised
- Legal and data protection requirements met
- Risk assessment of the live trials undertaken
- Consent procedures put in place

Principles and expectations for ethical research[1]:

[1] Adapted from: http://www.esrc.ac.uk/files/funding/guidance-for-applicants/esrc-framework-for-research-ethics-2015/

- Research participants should take part freely, free from any coercion or undue influence, and their rights, dignity and autonomy should be respected and appropriately protected.
- Research should be worthwhile and provide value that outweighs any risk or harm. Researchers should aim to maximise the benefit of the research and minimise potential risk of harm to participants and researchers.
- Research staff and participants should be given appropriate information about the purpose, methods and intended uses of the research, what their participation in the research entails and what risks and benefits, if any, are involved.
- Individual research participant and group preferences regarding anonymity should be respected and participant requirements concerning the confidential nature of information and personal data should be respected.
- Research should be designed, reviewed and undertaken to ensure recognised
- Standards of integrity are met, and quality and transparency are assured.
- The independence of research should be clear, and any conflicts of interest or partiality should be explicit.

Alongside the above research framework, the tabletop exercise and live trial need to take the following into account:

- Roles and responsibilities of leaders and participants need to be assigned prior to the commencement of the trials and during the planning stage.

  For example:

  Responsibilities of researchers: all researchers involved in the PULSE tabletop and live exercises are responsible for knowing and following the law and the principles of good practice relating to ethics, science, information, health and safety. They will give priority to the dignity, rights, safety and well being of participants. Researchers will also protect the integrity and confidentiality of records and other data generated by the research.

  Responsibility of exercise leaders: The exercise leaders will be directly responsible for ensuring that the exercises take place in accordance with the processes and protocols set out. The lead will take on the responsibility for the design, management and reporting of the exercise, and co-ordinating the investigators who take the lead at each site.

- The timeline needs to be established as soon as possible, to ensure efficient and effective communication between the project team, and the project team and participants.
- Communication plans and rules (such as an information sheet and consent form) need to be developed prior to commencement of the trials, to ensure that all participants (including external end users, media, voluntary agencies etc.) are informed and aware of the nature of the trials (in particular, that everyone involved understands that they are ‘tests’). Plans should also be put in place in the case of a real emergency or incident occurring during the trial and/or exercise (e.g. a keyword repeated three times to highlight that the trial has changed to a real emergency).
- Although participants are expected to be ‘experienced’ (highlighted in trials documents), clear communication about the nature of the exercise needs to be ensured and explicit (not taken for granted).
- Informed consent therefore needs to be sought from all participants prior to commencement of the trials. The form should be filled in, saved and documented by task leaders.

- The Stadium Crush scenario mentions the possibility of 'alternative futures'. However, these need to be mapped out prior to the exercise taking place. Trials should not encounter unforeseen/unplanned scenarios.

Instructions must be given to participants on the fairness and non-bias principles of the evaluation process and tools: Participants will operate in previously assigned roles. They should be sufficiently briefed on the goals and contents of the trials which is the evaluation of the PULSE platform and tools. This may be different from e.g. training exercises participants are used to. They should be advised to act in the assigned role and give feedback for evaluation independent of their personal preferences and possible bias.

Each participant must be provided the PULSE Information Sheet and Informed Consent Form (see Annex 1).

Some specific measures will be taken to ensure the both Trials comply with ethical and legal requirements (see Annex 2)

3 The Basic EVD Trial Concept

3.1 Key concepts

The main goal of the trial is to demonstrate and validate the effectiveness and performance of the PULSE tools and platform.

The validation and demonstration will be based on the simulation of situations that are normally managed without PULSE and the subsequent use of PULSE is the key difference with respect to the normal way of operating.

Therefore, the SARS-like trial is based on following key concepts:

- Make reference to a recurrent epidemic management situation → **Pandemic Influenza**
- Develop the trial making reference to a proven operational scheme → **Italian Pandemic Plan, based WHO pandemic phase** (it is coherent with WHO guidelines, which are also adopted by other European countries)
- Involve actors, that have already managed similar situations in the proven scheme → **actors with current or past roles in managing Pandemic Influenza applying WHO phase scheme**
- Make reference to the decision making situations that are expected to be supported by PULSE tools → **the trial runs along the Use Cases** defined in Deliverable *D2.2- Use case specification* and whose relationship with PULSE tools has been clearly stated in Deliverable *D5.2- Pulse SOP.*

3.2 Scenario

Chinese researchers in December 2015 detected a new potential pandemic Influenza virus, highly contagious and potentially lethal. It could affect large numbers of people. An alert about was notified to the National Health Competent Authorities. Afterwards, the scenario describes the likely spread of the new pandemic virus in Italy and Germany

The trial action starts on the 2016 May 3rd, when an airplane lands at Frankfurt airport. On board there are a group of 50 Italian farmers returning from the fair of breeders in Guandong. The same plane after the Frankfurt airport continues for the Fiumicino Airport, in Rome, Italy.

Key actors are the Italian institutions, but they interact with German authorities, ECDC and WHO.

WHO declares the end of the Pandemic emergency on the 01/08/2017. The last trial scene happens just after that date: The Italian Ministry of Health converge a meeting to evaluate the downgrade of the response, to discuss the lesson learned and to revise and reactivate the preparedness actions

3.3 The Italian Pandemic Plan: phases and key actions

The Trial assumes that the actors should comply with the actions stated by the Current Italian Plan, both “without” and “with” PULSE tools.

The Current Italian Plan adopts the epidemic phases issued by WHO in April 2005 as updated in 2009, and shares the aims for the public health authorities recommended by WHO for each phase. (see Table 2).

Table 2: Pandemic phases[2]

[2] according to WHO 2005/2009 and respective public health objectives for each phase, as described in the Italian plan

PANDEMIC PHASES	LEVELS	PUBLIC HEALTH OBJECTIVES
Interpandemic period		
Phase 1. No new influenza virus subtypes have been detected in humans. An influenza virus subtype which has caused human infection may be present in animals. If present in animals, the risk[a] of human infection or disease is considered to be low.		Strengthen pandemic preparedness at global, country and local level
Phase 2. No new influenza virus subtypes have been detected in humans. However, a circulating animal influenza virus subtype poses a substantial risk[a] of human disease.	**Level 0**: no risk in Italy **Level 1**: risk in Italy or presence of extensive travel/trade links with countries at risk	Minimise the risk of transmission to humans; identify and rapidly report such transmission if it occurs
Period of Pandemic alert		
Phase 3. Human infection(s) with a new subtype, but no human-to-human spread, or at most rare instances of spread to a close contact.	**Level 0**: no infection in Italy **Level 1**: presence of infections in Italy or presence of extensive travel/trade links with affected countries	Ensure the rapid characterisation and rapid identification of the new viral subtype, reporting and response to further cases
Phase 4. Small cluster(s) with limited human-to-human spread but spread is highly localised, suggesting that the virus is not well adapted to humans[b]	**Level 0**: no small clusters in Italy **Level 1**: presence of small clusters in Italy or presence of extensive travel/trade links with countries where clusters of disease have been identified	Contain the spread of the new virus inside the circumscribed outbreaks or delay the spread to gain time, with an aim to implement preparedness measures, including the development of a vaccine
Phase 5. Larger cluster(s) but human-to-human spread still localised, suggesting that the virus is becoming increasingly better adaptive to humans, but may not be fully transmissible (substantial pandemic risk [b]).	**Level 0**: no large clusters in Italy country **Level 1**: presence of large clusters in Italy or presence of extensive travel/trade links with countries where large clusters of disease have been identified	Maximise efforts to contain or delay the spread of the virus, to avoid the pandemic as far as possible and to gain time with an aim to implement response measures
Pandemic Period		
Phase 6. Increased and sustained transmission in general population [b].	**Level 0**: no cases in Italy's population **Level 1**: presence of cases in Italy or presence of extensive travel/trade links with countries with a pandemic in act **Level 2**: decreasing phase **Level 3**: new wave	Minimise the impact of the pandemic
Post-pandemic period Return to interpandemic period	Return to interpandemic period	Work towards ensuring the country's recovery

[a] The distinction between *phase 1* and *phase 2* is based on the risk of infection in humans or disease resulting from strains circulating in animals. The distinction must be based on different factors and on their relative importance in accord with current scientific knowledge. These factors can include: pathogenity in animals and humans; the presence in domestic animals and farm-reared animals or solely wild animals. If the virus is enzootic or epizootic, geographically limited or widespread; other information from the viral genome; and/or scientific knowledge.

[b] The distinction between *phase 3*, *phase 4* and *phase 5* is based on the assessment of a pandemic risk. A number of factors and their relative importance can be considered, in accord with current scientific knowledge. These factors can include: transmission rate; geographic localisation and spread; severity of the disease; the presence of genes coming from human strains (if derived from an animal strain); other information from the viral genome; and/or other scientific information.

Each phase includes one or more of the following **key actions**:

A. Improve epidemiological and virologic surveillance
B. Bring out measures for the prevention and control of infection (public health measures, anti-viral prophylaxis, vaccinations)
C. Guarantee treatment and assistance for the sick
D. Prepare emergency plans to maintain health services and other essential services
E. Prepare a training programme
F. Prepare suitable communication strategies
G. Monitor the implementation of the actions planned for risk phases, existing resources for the response, necessary extra resources, effectiveness of interventions already begun. This monitoring must take place in a continuous and interconnecting manner, integrating and analysing the data coming from different information systems.

Each of the key actions involves the implementation of a group of specific interventions for each phase; actors and their responsibilities are identified for each intervention.

NOTE: relationship with WHO directions

The 2005 WHO global pandemic plan introduced the concept of pandemic phases. In 2009 it published Pandemic influenza preparedness and response: a WHO guidance document. Six phases were used to describe the evolving risk of efficient human-to-human transmission as a basis for defining a pandemic.

In 2013, WHO released interim guidance for pandemic influenza risk management, which included restructured WHO global phases (interpandemic, alert, pandemic and transition).

The revised WHO phases are based on virologic, epidemiologic, and clinical data. WHO uses the phases to describe evolving situations pertaining to the circulation of novel influenza viruses.

The WHO global phases are distinct from declarations of either a public health emergency of international concern or a pandemic and are not specifically aligned with national risk management decisions. Therefore, in this interim guidance, WHO strongly advises countries to use local circumstances and information provided by the WHO global assessments to develop their own national risk assessment.

According to WHO recommendation, single States perform pandemic plans. They are based on the assumption that global emergencies call for co-ordinated and global responses, where the decision-makers must share planning times. The timing of interventions must be made known before the event takes place so that all concerned decision makers can properly carry out their roles and responsibilities.

3.4 Trial scenes: Pandemic Phases, Use Cases, Tools and Key actions

The trial will run through seven "scenes". Each scene is based on one of the Use Cases defined in D2.1 for the SARS-like scenario.

The sequence of the scenes and the relationship between Pandemic Phases and Use Cases is show in following Figure (1-UC2 is the first scene, 7-UC8 is he last one):

Figure 3: Sequence of the EVD Trial Scenes

USE CASE		PANDEMIC PHASE					
		3	4	5	6	1	2
1	Weak Signal detection and surveillance			4-UC1			
2	An airplane is landing in Italy. A probable case is now identified	1-UC2					
4	Identification of a new probable case in a community		3-UC4				
5	Assessment of the available medical resources during the pandemic phase			5-UC5			
6	ECDC recommendations	2-UC6					
7	National Authority periodic assessment				6-UC7		
8	Post emergency learning at national level					7-UC8	

Scenes have been designed in order to cover, as a whole,

- all Pandemic phases
- all key Use Cases (note: Use Case n.3 is not included because is very similar to Use Case 2; Use Case n. 9 is not included because is very similar to Use Case n.

8)

- all PULSE Tools
- all key actions of the Italian Pandemic Plan

This is shown in table below

Table 3: EVD Trial-Key elements of each scene

Scene	Pandemic phase	Use Case	PULSE TOOLS							KEY ACTIONS						
			DSVT	ENSIR	IAT	Smartphone app.	Logistic tool	SCGT	PCET	A	B	C	D	E	F	G
1	3	UC2	x			x	x			x	x					
2	3	UC6	x	x			x				x				x	x
3	4	UC4	x				x			x			x	x		
4	5	UC1	x		x					x						
5	5	UC5	x				x	x		x	x	x				
6	6	UC7	x				x			x		x				x
7	6,1,2	UC8	x						x	x			x	x	x	x

3.5 Participants' typologies

There will be following roles:

- **Actors**, who will be asked to describe actions, try PULSE, provide feedback on PULSE, comparing the "without" and "with" PULSE operating model
- **External Observers (in the following: Observers)**, who will be asked evaluate PULSE without taking part to the simulation
- **White room,** which will simulate actors not present at the simulation table
- **Director**, who coordinates the smooth running of the trial from a logistic point of view
- **Facilitator**, who will interact with the Actors to introduce the situations, formulate questions, facilitate discussion (including the final discussion with the Observers)
- **PULSE tutors,** who will explain PULSE functions and will support Actors and Observers in using PULSE
- **Internal Observers,** who are the Consortium members; they will also be present, to elicit feedback relevant for the production of future PULSE deliverables and to interact during the final discussion; they will also answer the questionnaires.

3.6 Trial nature and dynamics

The trial will be an Extended Table-Top Exercise (TTX[2]), meaning that it will be a classical Table-Top (TTX), enriched with the direct interaction with the PULSE Platform and tools. Interaction will happen in each scene.

The trial will last one day and a half. Each scene will last 60-90 minutes. Actors will all stay in the same room. Observers will all stay in a separate room, from which they can see and hear what happens in the Actors' room.

For each scene, Actors will be provided with a short description of the situation and will be asked how they would operate (without PULSE). A discussion will be facilitated. Answers and discussion will be recorded.

Then they will immediately receive a description (and demo) of how PULSE may support in the situation and will be invited to try to use it. They will then be asked, with an on-line questionnaire, to evaluate PULSE comparing the two situations (without

and with PULSE). Answers will be immediately elaborated and results will be discussed.

In the meantime,

Observers will be given the possibility to use PULSE. They will fill the on-line Questionnaire after each scene (but answers will not be provided to the Actors).

At the end of the trial, a two-hour discussion will involve Actors and Observers all together, for a summary evaluation of the PULSE support and for evaluating, via a questionnaire, the system performance and socio-political impacts

All discussions will be recorded.

Questionnaires and facilitated discussions will be structured in order to scan all the evaluation criteria applicable to the scene and elicit relevant information.

4 Plan of the EVD Trial

4.1 Trial dates and location

SARS Trial will be run on the June 30th and July 1st 2016 in Rome, in a meeting room located at “Istituto Nazionale per le Malattie Infettive Lazzaro Spallanzani”,

4.2 Trial agenda

The draft agenda for the trial, to be fine-tuned during the implementation phase, is as follows

Table 4: EVD Trial timetable

Day	Time	Content
1	14:00-15:00	Introduction: PULSE, PULSE purpose, Trial logic, roles and dynamics
	15:00-18:00	Scenes 1, 2, 3; Questionnaire filling (Actors and Observers) and discussion after each scene (Actors)
2	09:00-12:30	Scenes 4, 5; Questionnaire filling (Actors and Observers) and discussion after each scene (Actors)
	14:00-17:00	Scenes 6,7; Questionnaire filling (Actors and Observers) and discussion after each scene (Actors)
	17:00-19:00	Questionnaire filling, to evaluate system performance and socio-political impacts **End user Workshop**: plenary discussion, involving Actors and Observers

4.3 Actors and language

Actors to be involved should be able to cover in a credible way all the roles required by the scenes. Following table lists all the required roles:

Table 5: EVD Trial Actors and Roles

Level	Required role	Type of role
EU/W	WHO	T

EU/W	ECDC	T
N	Federal Ministry of Health Germany	T
N	Italian Ministry of Health-CCM	T
N	Italian Civil Protection (National level)	M
N	Istituto Zooprofilattico-IZP (Veterinary system)	T
N	USMAF	T
N	Head of Referral Microbiology Laboratory Hospital- Spallanzani Rome	Clin
N	Medical Director Unit of Emerging and Re-emerging Infectious Disease of Hospital Spallanzani	T
N	Head of Clinical Unit of Referral Hospital- Sacco Milan task force	Clin
R	Regional HC Director	M
R	Emergency Management (118)	T
R	Civil Protection (Regional level)	M
L	Head of Prevention Department	T
L	Head of Clinical Unit of Referral Hospital – Spallanzani Rome task force	Clin
L	Head of Emergency Dept of Major Hospital	Clin

Legend: N=National, R=Regional, L=Local, T=Technical, M=Managerial, Clin=Clinical

Actors will be (possibly) ECDC and WHO, all members of Italian institutions. They will be asked to speak in **English**.

This will allow Observers (External and Internal) to understand what Actors say.

4.4 Script

A high-level script has been designed (see Annex 3).

For each scene, the script indicates:

- Brief scenario description
- Scenario details
- Actors involved
- Pulse tools involved
- Data needed and data sources
- Steps in the scene; for each step
    - Actions/Interventions required by the Pandemic Plan
    - Activities required by the Use Case
    - Actors involved in the step
    - Output
    - Role played by PULSE
    - Link with the evaluation criteria (see next paragraph on evaluation)

4.5 Scene workflow

Each scene will be run following the same sequence.

Following table shows the steps of the sequence and the participants that will be involved:

Table 6: EVD Trial-Step by step actors' involvement

Step		Participants				
		Facilitator	Actor	Observer	White room	Pulse tutors
1.	Describes the situation	X				

2.	Asks questions: What would you do How would you do it	X				
3.	Answers the questions		X			
	Provides “injects” (additional messages/information), also considering the answers				X	
4.	Describes and demonstrates PULSE functionalities					X
5.	Asks Actors and Observers to try some of the functionalities					X
	Actors and Observers try some of the functionalities		X	X		
	Support					X
6.	Submits questionnaire	X				
7.	Fills questionnaire		X	X		
8.	Facilitates discussion	X				
	Discuss		X			

4.6 Evaluation criteria

Evaluation will be performed according to the methodology defined inchapter 7. Trial is structured in order to allow evaluation along three aspects: effectiveness, performance and socio-political impact.

For each scene (and, as a consequence, for each Use Case) PULSE evaluation will focus on effectiveness.

Performance and socio-political impact will be evaluated at the end, when all the scenes will have been run.

See Annexes 5, 6 and 7 for more details on evaluation criteria.

4.7 Infrastructure and equipment

Actors will operate in a big meeting room (see photo below)..

Figure 4: Trial Operating Room

Each Actor and Observer will be provided with a tablet.

Wifi will be available, in order to access the web for real time data capturing (for the Trial), tablet connection, Questionnaire data capture.

4.8 Data

Two macro.types of data will be used during the trial:

- Data (real or realistic) that will be prepared before the trial
- Data that will be captured in real time from the web during the trial (at least two sources have been already identified: PROMED and HEALTHMAP, which geo-localize info on number of cases)

Table below shows the relationship between the two macro types and the Use Cases:

Table 7: EVD Trial-Data types per Use Case

USE CASE		To be prepared before the trial			Acquired on-line in real time	
					PROMED	HEALTHMP
		Procedures/Recommendations	Genal overview of patient geographic distribution in Italy	Resources (vsaccines, hosiptals, Beds, staff, Medical eqipment)	Genal overview of patient geographic distribution worldwide	Genal overview of patient geographic distribution worldwide
1	Weak Signal detection and surveillance	X			X	X
2	An airplane is landing in Italy. A probable case is now identified	X	X		X	X
4	Identification of a new probable case in a community	X	X		X	X
5	Assessment of the available medical resources during the	X	X	X	X	X
6	ECDC recommendations	X	X	X	X	X
7	National Authority periodic assessment	X	X	X	X	X
8	Post emergency learning at national level	X		X	X	X

4.9 Summary of Trial

Summary of SARS Scenario	
General Description	This scenario is based upon a Pandemic flue in Italy which includes an element of cross-border collaboration (due to flying passengers) and European collaboration.
Actors Involved	• WHO and ECDC • Italian Healthcare and Civil Protection insitutions at National, Regional and Local levels • Italian Lead Hospitals • Federal Ministry of Health Germany
Activities Performed	**Pandemic Phase 3** • An airplane is landing in Italy. A probable case is now identified • ECDC recommendations **Pandemic Phase 4** • Identification of a new probable case in a community **Pandemic Phase 5** • Weak signal detection and surveillance • Assessment of the available medical resources during the pandemic phase **Pandemic Phase 6** • National Authority periodic assessment **Pandemic Phase 6-1-2** • Transition and Post emergency learning at national level
Resource Used	The trial will be an Extended Table-Top Exercise (TTX^2), meaning that it will be a classical Table-Top (TTX), enriched with the direct interaction with the PULSE Platform and tools. Interaction will happen in each scene. Actors and observers will have the opportunity to use PULSE tools. To this purpose, each one of them will be equiped with a tablet.

5 The Basic MCI Trial Concept

5.1 Key concepts

The **aim** of Work Package 7 is to demonstrate, test and evaluate the PULSE toolset in the context of the scenario outline in the proposal.

Since PULSE targets the central challenges in risk management by developing a holistic framed approach, it will be necessary to demonstrate that the tools are applicable in all of kinds large scale disasters – be they natural, deliberate or

accidental.

The key to understanding the proposed test and demonstration process is that participants are aware that it is the tools that have been developed that are being tested and not the players nor existing plans and protocols.

To meet the EU requirements, PULSE has developed a set of tools for inclusion in the toolkit

The PULSE tools were created by adapting available technologies and by developing security specific technology and knowledge aimed at tangible results.

It would be impractical to devise a series of demonstrations aimed at testing each tool in the toolset at each and every phase of an exercise.

At the same time it is necessary to demonstrate that the tools can function and are applicable during various disasters (Stadium crush and a public health outbreak).What is being proposed is to only use the scenario for the purpose for which scenarios were intended. Scenarios are used to enliven or focus an exercise.

The scenario should not take over the demonstration and test – the scenario is just a means to an end.

Scenarios which fit with local geography and which could reasonably happen **have been developed to add a degree of realism which, in turn, should add to the interest in, and credibility of, the demonstration and test**.

The PULSE crowd –crush scenario has been based on a combination of three actual events:

- The history of the Garth Bookes Concert http://www.thejournal.ie/garth-brooks-ireland-timeline-1560327-Jul2014/
- The Swedish House Mafia concert http://entertainment.ie/music/news/One-dead-nine-stabbed-at-Swedish-House-Mafia-Phoenix-Park-concert/129830.htm.
- Reports on the Hillsborough Inquest http://www.bbc.com/news/uk-england-merseyside-35383110

Those three real events have been combined into one incident. This approach has certain advantages:

1) A comparison can be made with what occurred at the real events.
2) We can draw on the implicit data from the real events.
3) We have a degree of credibility at the dissemination stage.

Those who will participate in the demonstration and test are very familiar in the traditional exercises used to test and train for major emergencies. End-uses at every level of responsibility are familiar with exercises both within individual organisations or on an inter-agency basis or at member-state level.

Such experienced participants will expect well stated objectives:

- That will be clear, concise and focus on the participant's performance of tasks
- That will describe actions that can be observed
- That will state the conditions under which the actions are to be performed by the participants
- That will state to what standard or level the actions will be performed

Experienced participants will expect an *"exercise"* and will see it as an integral part of major emergency management.

They will expect that

- in participating in the demonstration and test they will be doing so in the same context as planning and staging regular exercises.
- such an *"exercise"* is to validate plans, systems, procedures and training, to enable practice of lessons identified and capabilities developed and to test and enhance the overall capability of their organisation to respond.

To reduce the impact of the demonstration and test on the end-user participants it will be necessary to provide them with a familiar exercise experience while at the same time focusing on the specifics of the tools in the PULSE toolset.

5.2 Scenario

Crowds, or large concentration of people, occur frequently in modern society. A major sporting or entertainment event can attract upwards of 80,000 avid fans.

International literature suggests that large transportation terminals can accommodate hundreds of thousands of passengers each day. In addition to transportation services, large scale office buildings and retail complexes can have thousands of employees and visitors.

Occasionally the combination of inadequate facilities and deficient crowd management results in injury and death. The lethal potential of crowds is illustrated by description of major crowd incidents. This sampling shows that crowd incidents occur in a wide variety of venues and different circumstances. Minor incidents resulting in crowd induced falls and other incidents occur more frequently.

The scenario is 'set' in Dublin and executed in Cork, Ireland. Ireland like all EU Members States has very specific regulations in regard to crowd events but regulations alone will not prevent a crowd event. There is no guarantee that such regulations will be obeyed and that is particularly true in the type of event where crowd behaviour is erratic. Alcohol and drug taking , counterfeited tickets, training of private stewards and crowd behaviour profiling are all governed by regulation but that is not to say that everything will always be perfect.

For the purpose of testing the PULSE platform, it is essential to note that for the purpose of this trial the creation of a simulated stadium *crowd crush is required*.

The stadium crush scenario has been chosen as one of two test scenarios under the PULSE project to be delivered and tested by using all partners and resources allocated in WP7 as planned in the work plan.

It is essential to note, that the scenario will be adapted to focus on various stages of a crowd crush incident – pre-incident phase, incident phase and post-incident phase.

Accordingly, stakeholders are expected to begin working collaboratively to monitor and establish preventive measures, and be ready for emergency response if an incident happens in a stadium.

Two of the crowd crush use cases will be tested before the incident during the '*pre-event phase'*, UC 01 and UC 02, UC03 – UC06 will be tested during the incident at the '*incident phase'*, while UC07 and UC 08 will be test during the '*post-incident phase'.* Only a minority of the PULSE platform is aimed at *prevention* with the majority of the tools being aimed towards the response and post incident analysis.

Overview

This scenario is provided by the Inter-Agency Emergency Management Office in the

context of the PULSE programme, which will be further developed towards a virtual scenario whereby the PULSE technical solution can be tested.

The scenario is based upon a 'stadium crush' in the island of Ireland.

Such an incident could impact on both the Republic of Ireland (ROI) and Northern Ireland, due to health service capacity to deal with a large volume of seriously injured patients. Such an event could potentially demand high levels of collaboration throughout the lifespan of the incident.

Stadium Crush Scenario General Timeline: the scenario, as currently defined, includes a range of actors who will be become active and make contributions at different stages as the impending stadium crowd crush develops.

- The Local Government Authorities have given permission for a three day sell-out concert in a football stadium by a well-known pop group. The concerts are planned to run over three consecutive nights. The concert promoters originally requested five days but the request was denied by the local government authorities due to planning regulations. Evidently there have been a large number of disappointed fans. This concert is an outdoor event and the concerts promoters have indicated that it will take place irrespective of the weather. The stage is built in the centre of the pitch with runways, ramps and raised podiums to bring the group every closer to the fans. The number of tickets per concert is 82,000.
- In the pre-event planning phase the police service have conducted an assessment of the potential crowd at the concert and have indicated to the event promoters that the majority of fans will be in the 18 to 25 age group category. Before the group UC42 became very popular it did have a reputation for a negative attitude towards authority. Recent intelligence information from local police and security forces, information the event organisers that a very small number of original fans travel from country to country following the band.
- It is an older design of stadium due to be closed and refurbished but has had many such concerts before without any serious problem. The new layout of the stage set up in the stadium is a new design not tried before and unsuited to this type of pop-group and this type of crowd.
- In the lead up to the event, all planning arrangements go well and everything is in place, as per the guidance documents, for the concert which is due to commence begin at 20:00.
- A support group is due to play for about an hour and UC 42 is expected to come on stage at 21:00 and play for two hours. The local authorities have placed a curfew on the group playing beyond 23:15, which must be strictly adhered to.
- Shortly before the gates open disputes with the ticket control staff begin to happen with stadium security staff and stadium patrons in relation to counterfeit tickets or tickets for the wrong night – it emerges that some tickets were sold very early on for what they thought would be a five day series of concerts and which is now only three days.
- The concert gets underway on time at 19:30 with a support group but not all fans (including those with the correct tickets) are in the venue.
- The pop-group recognises a group of their older fans from their heavy metal days and decides to play some of the *old numbers* and turn up the sound.
- Due to the confusion over the tickets and because the stadium is 30 minutes walk from the city centre and fans gather outside to listen to the music.
- Some spectator-related problems are occurring directly outside the stadium and as a result of this begin to engage in swarming which in turn is rushing the gates and trying to crash the gates to gain entry and there are some injuries from

trampling.

- Inside the stadium, the promoters initially ignore the instruction to turn down the level of the sound. The fans inside and outside the stadium are communicating via social media. Some fans inside try to rush the stage and a 'progressive crowd collapse' occurs which causes and constrictive/restrictive asphyxia.
- The disaster develops quickly (in minutes) and the event emergency medical plan is activated.
- The police order the concert to be stopped. The music is halted but in the confusion of the urgent instruction to stop the concert power is cut off to a large section of the stadium.
- Many fans start to leave the stadium to encounter other fans trying to get in.
- It soon becomes obvious that this event is beyond the ability of those in the stadium to manage appropriately and a major emergency is declared by the senior police commander who is an authorised officer to make such a decision.

5.3 Trial Scenes

The Stadium crush trial will run though numerous focus points, that have been designed in order to cover:

- All key use cases
- All PULSE tools
- All actions of the Stadium Event Medical Plan

Each focus point will be based on one of the use-cases as defined in D2.1 for the Stadium crush scenario. The sequence of the focus points and the relationship between the pre-incident phase, incident phase and post incident phase, and all assocaited use cases are detailed in the below table.

Use Case		Stadium Crush		
		Pre-Incident Phase	**Incident Phase**	**Post Incident Phase**
1.	Scoring System in the Event Medical and Other Plan Preparation Phase	**X**	5.3.1	5.3.2
3.	User wishes to mobilise additional resources from Public, Private, Voluntary and Response Assets from other member states	5.3.3	**X**	5.3.4
4.	Hospital Surge Capacity and Bed Management	5.3.5	**X**	5.3.6
5.	Triage in Casualty Clearing Station	5.3.7	**X**	5.3.8
6.	Input critical data for the RCS on Site and from other relevant off-site sources	5.3.9	**X**	5.3.10
7.	Post-Event, Post Exercise	5.3.11	5.3.12	**X**

	Evaluation Tool to identify lessons to be learned.			
8.	Casualty Bureau Operation	5.3.13	5.3.14	**X**

MPORG MCI UC 2 will be validated in a separate session, before the MCI Trial day, with end-users who will also participate to the MCI Trial. Feedback will be provided in accordance with the criteria contained in the UC2 MoE evaluation scheme, for the functions "Simulation" and "Training" (see Annex 5).

Cross-border element will be inserted in the pre-incident phase, simulating arrangements on healthcare facilities wtih Northern Ireland authorities

Key Activities in the Stadium Crush Scenario

Prevention

- Scoring of an event medical plan
- Training of event organisers

Rescue Operations

- Implementation of a system to mobilise additional medical resources (public, private, voluntary and other member states)
- Utilisation of a hospital Surge Capacity/Bed Management system
- Mass Casualty Triage in a Casualty Clearing Station
- Input of critical data for the Recognised Current Situation as the incident evolves
- Implementation of the Casualty Bureau
- Post event (exercise) evaluation

The following table represents in a matrix the different key activities and the involved organisations.

Stadium Crush	Health Service Executive	National Ambulance Service	An Garda Síochána	Fire & Rescue Service	Voluntary Emergency Services
Scoring of an event medical plan	X	X	5.4	5.5	X
Training of event organisers	X	X			X
Implementation of a system to mobilise additional medical resources	X	X	X	X	X
Surge Capacity/Bed Management	X	X			
Recognised Current Situation	X	X	X	X	X
Casualty	X		X		

Bureau					
Post event evaluation	X	X	X	X	X

Aims of these Activities are as follows:

- To improve the method of scoring events to establish parameters for an event medical plan.
- To create a training platform for event organisers in order that they become proficient in event medical planning.
- To improve the management and co-ordination of mobilising additional resources (public, private, voluntary and other member states)
- To improve the management of hospital surge capacity and bed management during major emergencies
- To assist in the collection of triage data in a casualty clearing station
- To improve and assist with the collection of data that is required in order to give an overview of the recognised current situation
- To improve the method of lessons learned during an incident/exercise
- To improve and assist the creation of the Casualty Bureau operation

5.6 Participant Typologies

There will be following roles during the stadium crush:

- Exercise participants, who will test the PULSE tolos and provide feedback
- External observers, who will be asked to evaluate the PULSE platform without taking part in the trial, they may also be asked to evaluate the system.
- Exercise Director, who will coordinate the running of the trial
- Trial Facilator, who will interact with the exercise participants to introduce the trial, pose questions, faciliate discussion (including the final discussion with the exercise particiapnts)
- PULSE tutors, who will explain the PULSE platform functionalities and will support the actors and oversivers when using the PULSE system and tools.
- Internal Observers, which are the consortium members, they will also be present

5.7 Trial Nature and Dynamics

The stadium crush trial will be a live trial.

Exercise participants actually perform all of the activities that they are expected to during an event (within the confines of the exercise environment) and all exercise injects are delivered by a simulation team member of an audio-visual tool.

The trial will last one day and will be approximately 4-6 hours in duration. Exercise participants will be gathered at their various locations and observers may also be present. Prior to the exercise, exercise participants will receive a tutorial on the PULSE tools and platform from the PULSE tutors. Following on from the exercise, feedback will be gathered from the exercise participants, in addition to the exercise participants, all observers of the PULSE live trial will be asked to give their feedback.

Process for Scenario Enactment

Since the purpose of this scenario is to provide a context for testing the PULSE platform, the exercise participants must be provided with some level of tuition in using the PULSE platform prior to the trial. They should also be provided with clear role descriptions and expectations (clear boundary conditions for tasks). The tasks which participants are expected to conduct should be outlines (objectives and general actions) but no specific timeline should be provided. If a detailed timeline is provided then exercise participants will follow the script exactly which in turn is not a 'true' reflection. In order to fully test the PULSE platform, is it essential to realistically attempt to deal with an impending emergency and with that exercise participants will be knowledgeable of the entire exercise outline (from pre-incident, incident and post incident phase).

Benefits of this scenario

The stadium crush scenario has numerous benefits. The proposed scenario meets the needs of the project in that it:

- Is complex
- Is prolonged
- Has an international cross border aspect (Republic of Ireland and Northern Ireland)
- Involves two EU member states (Republic of Ireland and Northern Ireland)
- Is multi-agency (Health, Local & Regional Authorities, Police Fire and Rescue Services)
- Demands high levels of co-ordination and collaboration
- Involves all levels of Command, Control and Co-ordination from Operational, tactical and strategic
- Demands timely and accurate sharing of information

Risks of this scenario

The risks associated with this scenario are internal to both the end users and mainly ensuring appropriate 'buy-in' from the respective stakeholders. These potential risks can be appropriately migrated through close liaison with interested stakeholders and highlighting the benefits of such an exercise.

6 Plan of the MCI Trial

6.1 Trial Dates and Location

The Stadium Crush trial will be conducted in 1st week of September 2016, in Cork Ireland,in four separate locations

Stadium

Páirc Uí Rinn is located on the Boreenmanna Road, just off the South Link Road, in the Ballinlough parish. It is just ten minutes walk from Páirc Uí Chaoimh.

Regional Control Center

This will be locatied in the Central Fire Station

Hospital Emergency Control Team

Cork University Hospital

EMS Dispatch Centre

South/South East Hospila Group HQ Erinville

6.2 Trial Agenda

The name of the exercise will be: "Distant Rock"

Real Time: 13:30 – 20:00

Exercise Time: 24 hours – the scenario will unfold in a series of vignettes corresponding to stages along a defined timeline.

The draft agenda for the stadium crush trial will be as follows:

Day	Time	Content
1	13:30-14:00	Introduction: PULSE, PULSE purpose, Trial logic, roles and dynamics, overall contents and methodology of the evaluation taking place
	14:00-15:00	Scoring of an event medical plan & Training of event organisers
1	15:00-19:00	Mass Casualty Triage in a Casualty Clearing Station, Input of critical data for the Recognised Current Situation, Utilisation of a hospital Surge Capacity/Bed Management system, Implementation of the Casualty Bureau & Post event (exercise) evaluation
1	19:00 – 20:30	**End user Workshop**: plenary discussion, involving Actors and Observers, to evaluate PULSE Platform

6.3 Actors and Language

Exercise participants involved with the stadium crush trial will be required to take part in the trial as if it were real life. Language: English.

Key Actors

- Health Service Executive – Irish National Health Service
- Irish National Ambulance Service
- An Garda Síochána (Irish Police)
- Irish Fire & Rescue Service
- Voluntary Emergency Services (St John Ambulance, Irish Red Cross, Order of Malta, Civil Defence)

In addition to the key actors, below is a list of agencies that would typically be involved with an incident of such nature and that will be simulated as injects generators:

- **Emergency Coordination Centre** – Formally organised co-ordination centres (eg: regional police and responder, ambulance)
- **River Agency** – Authorities in river management working together with harbours and facilities
- **Public Authority** – Primarily regional and local authorities formally involved through legal responsibilities in relation to emergency management
- **First Responders** – Fire and Rescue Services including Civil Defence
- **Police** – Local and Regional authorities
- **Environment Agency** – Environment protection and arrangement of response
- **Transport Authorities/Operator** – Regional and local transport authorities plus a spectrum of road, rail and water transport operators.
- **Army** – Army staff acting as emergency support on ground
- **Medical Services** – Providing medical care at the incident, care and transport and casualties – including Red Cross, Order of Malta, St John Ambulance

6.4 Script

A high-level script has been designed. For each scene (Use Case) the exercise script includes:

- Brief scenario description
- Scenario details
- Actors involved
- PULSE tools involved
- Data needed and associated resources required
- Anticipated Steps in the focus points;
    - Actions/Interventions required by the Event Medical Plan
    - Activities required by the Use Cases
    - Exercises participants involved in each focus point
    - Output
    - Role played by the PULSE platform
    - Link with the evaluation criteria

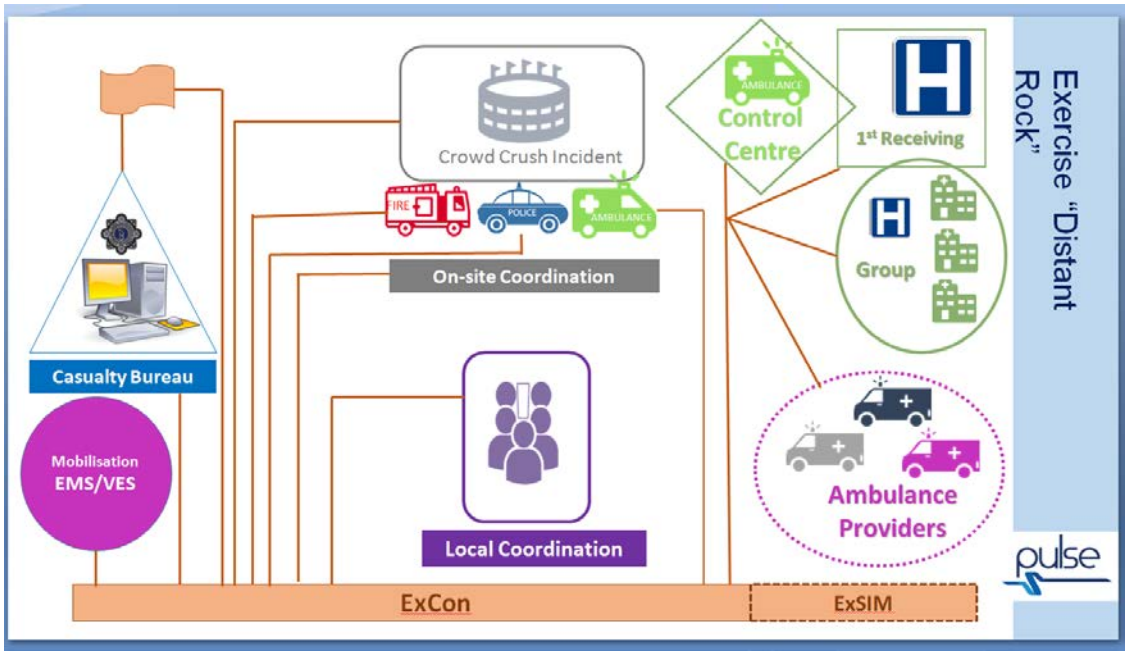
6.5 Scene Workflow

EXercise CONtrol (ExCon) will be a group under the direction of the exercise director who have the responsibility for conducting the exercise.

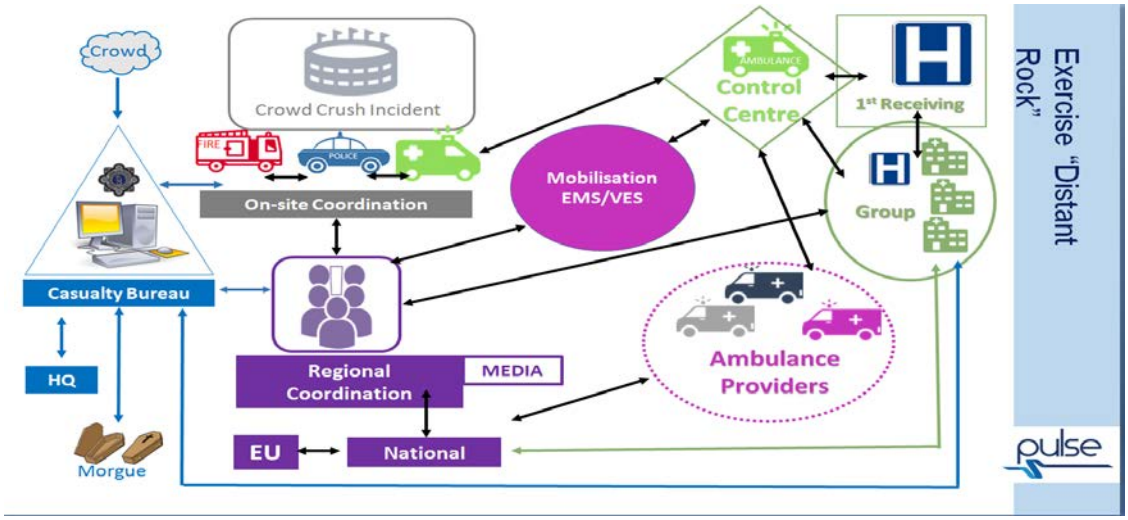
Exercise Simulation (ExSim) has the potential role of simulating an element that is not present or not available during the exercise. ExSim is NOT an exercise player and is part of the assets available to ExCon. Some of the key actors of Exercise ‘Distant Rock’ are:

- HECT Hospital Emergency Control Team
- HGECT Hospital Group Emergency Control Team
- RCC Regional Coordination Centre
- OSC On-site Coordination Centre
- NEOC National Emergency Operations Centre

The role of ExCon and ExSim can be seen in the below figure.



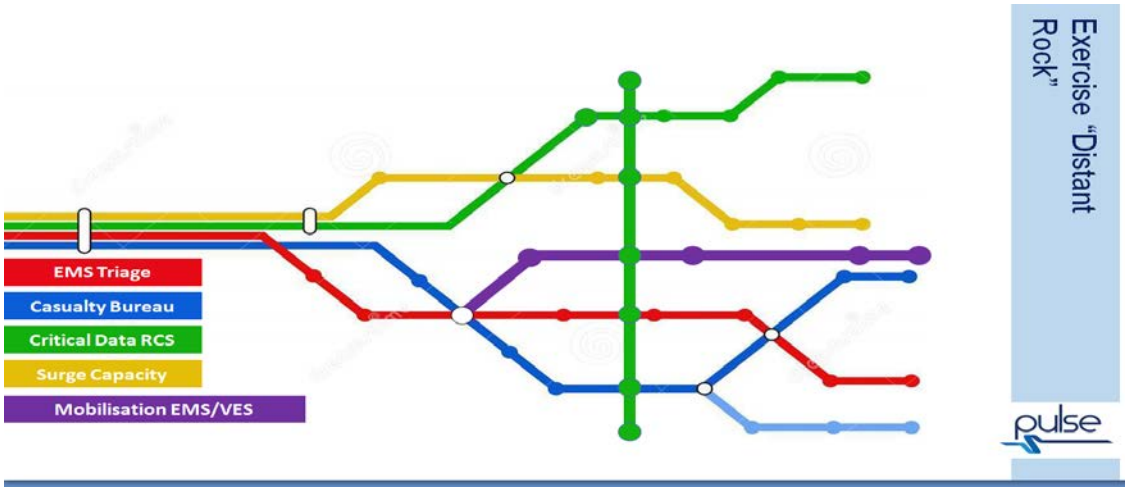
An overview of the exercise can be seen in the below figure, which displays the linkages between various 'actors'.



Multiple PULSE tools will be tested at various focus points throughout the exercise, it is important to note that several tools can be tested at a single point.

Due to the nature of a stadium crush, which has the ability to be a prolonged incident, the exercise will be accelerated to test various elements of toolset which can be considered as key focus points or layers.

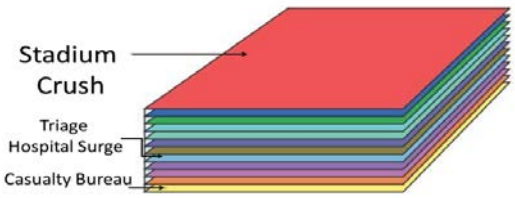
There is a base layer which is the underlying stadium crush scenario. There are additional layers which have a specific focus and which have the clear aim of demonstration and testing of a PULSE tool, all within the context of the underlying scenario. This technique will allow both a cross section of a series of layers or an individual layer to be identified, illustrated and then tested as an event.



This close focus on a specific tool within the time line of the scenario is just a device to ensure that each tool will be demonstrated and tested.

Additional detail in the form of inject material will be prepared for each scenario. It is important to note that these injects may or may not be used, which will be dictated by the demand of the demonstration and test. This is quite normal and it is regarded a sign of a well-planned exercise that extra and/or unused exercise material is available at the end of an exercise. It may even be possible to provide for a number of alternative futures depending on the complexity of the exercise material or the demands of the demonstration and testing regime.

The same tool can be used for different events in different scenarios and different points on the exercise timeline. Different combinations of tools can be also be demonstrated for similar or differing events, depending on the requirements or the demands of the scenario or the demonstration and testing regime. Using this focus layer technique it will even be possible to jump between events, if that was required during the exercise.



Multi-layer scenario with key focus points

The intention is to provide a full "exercise-style" environment based on a stadium crush scenario. This will allow all exercise participants, the PULSE team, and the observers to be in a familiar situation and in a conventional exercise participation stance or viewpoint. The agreed scenario will run through the exercise from Exercise Start to Exercise End.

Ex End

Ex Start

Each circle represents a specific event in the overall scenario selected to demonstrate one or more of the tools in the PULSE toolkit.

By ensuring that the participants are very familiar with the details of the scenario it will be possible to focus on the specific individual tool demonstrations while retaining overall situational awareness of the unfolding scenario.

In reality, all incidents of the sort described in these types of scenarios have extended time-lines. This is the case in most exercises, especially table-top exercises. We can also use the technique of an exercise “time-jump”. In this, the participants are asked to note that for exercise purposes that time has now moved forward (or backwards) by a defined period. This technique can be used where for the purpose of the exercise has moved on by a number or hours or days.

As is explained elsewhere the key to this being a successful technique is that all participants are thoroughly familiar with the detail of the scenario. Normally, this degree of familiarity is only available to the exercise directing staff but given that it is the “tool-set” that is being exercised and not the players then it will have no effect on the conduct of the underlying exercise.

The fact that participants are permitted to know a significant proportion of the scenario will make the moves from event to event within the scenario more effective.

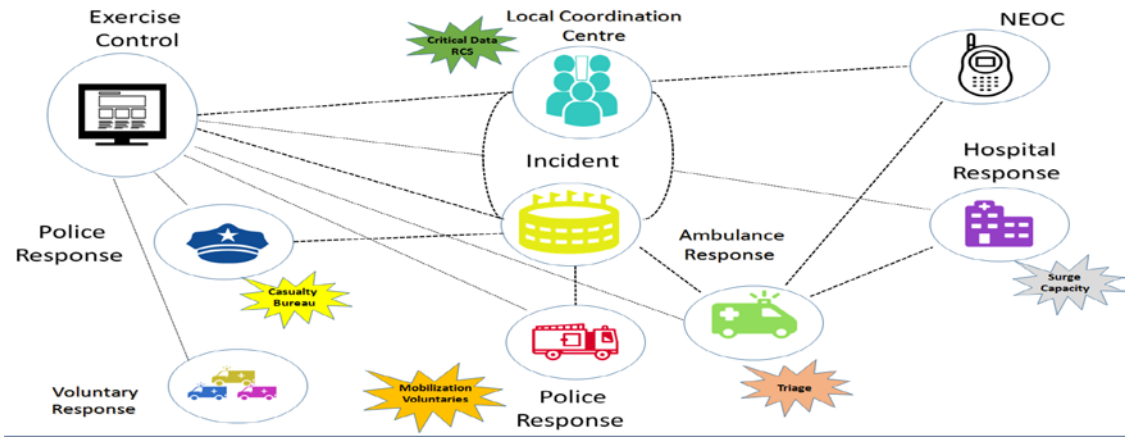
6.6 Evaluation Criteria

Evaluation will be performed according to the methodology defined in chapter 7. Trial is structured in order to allow evaluation along three aspects: effectiveness, performance and socio-political impact

For each scene (and, as a consequence, for each Use Case) PULSE evaluation will focus on effectiveness (see Annex 5 for evaluation forms).

6.7 Infrastructure and Equipment

It is envisaged that the stadium crush trial will be spread over 3-4 locations. The location of these can be seen in the below image. The main location will be the incident site, the Local Co-ordination centre, and will further be supplemented by the police station of the hospital group centre.



The below images displays the setup of the casualty clearing station and the on-site co-ordinators centre at the incident, respectively.

The below images display the typical setup of members at the Local co-ordination Centre

Suggested injects that might be used during the activity

The following list is a brief list of potential exercise injects that may be used during the scenario (to be confirmed during the trial impplementation phase):

- Crisis escalation in the context of the stadium crush
- Energy supply disruption
- Lack of communication infrastructure
- Complete or partial obstruction of access and egress routes
- Aggressive and/or panicked crowd
- Multiple presentation casualties at the incident

Resources Used

During the stadium crush scenario the following list of resources will be utilised, throughout the life span of such an incident, a wide range of state and non-state resources would be brought into play. The following list contains a number of high level resources from both the Republic of Ireland and Northern Ireland, which would be used:

- Department of Health staff
- Local authority staff and equipment
- Police staff and equipment
- Fire service and equipment
- Civilian contractor staff and equipment
- Stadium event organisers and equipment
- Staff of the Voluntary Emergency services

Scenario Operation

The storyline will be provided to the exercise participants after the necessary training/demonstration and then they will execute an exercise in the management of a stadium crowd crushing.

The scenario operation will be partly open-ended.

During the implementation phase, specific goals will be set in consultation with the PULSE platform developers but also in conjunction with past historical events. Specific changes to the exercise will be defined as part of the final storyline and selected to ensure coverage of target activities and system functionalities. A schedule/master list of information feeds will be devised to ensure that the participants are faced with realistic and developing landscapes of risks and probabilities so that they will be pressed to deal *realistically* with the exercise via the PULSE platform.

6.8 Data

Two types of data will be utilised during the stadium crush trial:

- Simulated data which will be prepared by the exercise director in order to progress the trial
- Data that will be captured in real time from the incident site.

6.9 Summary of Trial

Summary of Stadium Crush Scenario	
General Description	This scenario is based upon a stadium crush in Ireland which requires due to the number of casualties an element of cross-border collaboration in order to achieve an effective response.
Actors Involved	• Health Service Executive – Irish National Health Service • Irish National Ambulance Service

	• An Garda Síochána (Irish Police) • Irish Fire & Rescue Service • Voluntary Emergency Services
Activities Performed	**<u>Pre-Incident Phase</u>** • Scoring of an event medical plan • Training of event organisers **<u>Incident Phase</u>** • Implementation of a system to mobilise additional medical resources (public, private, voluntary and other member states) • Utilisation of a hospital Surge Capacity/Bed Management system • Mass Casualty Triage in a Casualty Clearing Station • Input of critical data for the Recognised Current Situation as the incident evolves **<u>Post Incident Phase</u>** • Implementation of the Casualty Bureau • Post event (exercise) evaluation
Resource Used	▪ Department of Health staff ▪ Local authority staff and equipment ▪ Police staff and equipment ▪ Fire service and equipment ▪ Civilian contractor staff and equipment ▪ Stadium event organisers and equipment
Comments	This scenario deals with complex issues and demands a high level of co-ordination and collaboration. Specifically, it requires the timely and accurate sharing of information between multipleagencies in a situation with the potential to have a major health impact.

7 Evaluation Methodology

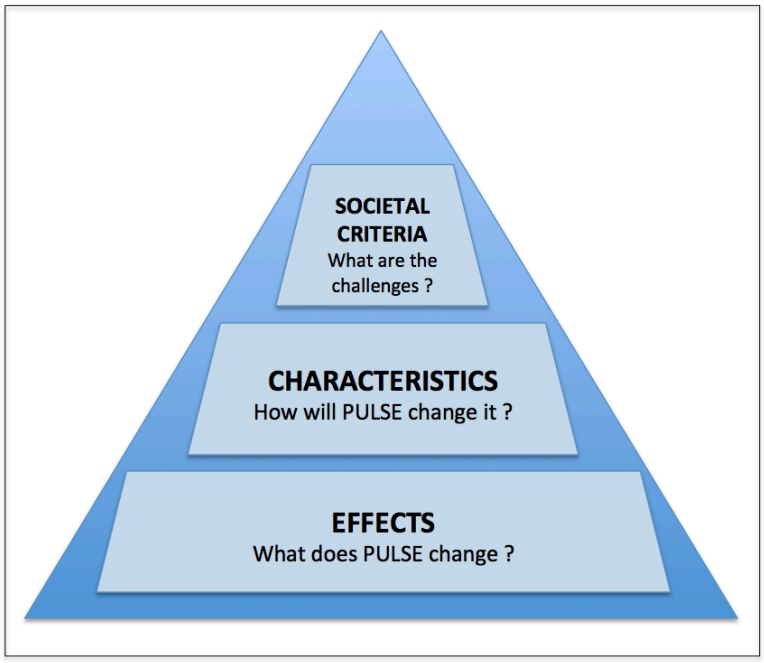
7.1 General Approach

Drafting this chapter, a number of "international" handbooks have been consulted [7], [8], [9], [9].

The PULSE platform and its individual tools will be demonstrated in two realistic scenarios, which have been described in D2.2. These scenarios are further detailed in a total of 17 use cases in each of which selected scenario events and their processes are described. The processes are depicted in this D5.2 in detailed workflow diagrams using the "Swim Lane Diagram" (SLD) methodology. Each diagram is further detailed by a table showing the application of the PULSE tools and describing the functions to be performed in the respective use cases. For both trials, as detailed in this document, this constitutes the basis for the integrated evaluation of effects, characteristics and societal impact, which will prove the power of the PULSE platform and its tools leading to the validation process eventually.

In consequence, trial design and evaluation had to be planned at the same time, influencing and determining each other. Evaluation is the essential final component of the PULSE trials cycle. In PULSE it measures the extent to which pre-determined objectives have been achieved and is exclusively concerned with the projected PULSE platform functionality and resulting benefits. The evaluation will not cover the behaviour of the exercise participants nor the impact of applied response standards or crisis management plans.

Figure 5: The Basic Elements of Evaluation



The subsequent validation and its respective methodology is the inherent part of D7.3. It will be based on a benchmarking approach, where the benchmarking reference system are the requirements contained in D2.1, covering the general requirements, PULSE tools and SOPs key innovative features. “The assumption underlying this

approach is that if these requirements were satisfied, end-users would count on systems and procedures that would allow better decision making. As a consequence it is expected that emergencies will produce lower negative impacts on health and lives."[3]

This D7.1, chapter 7 contains in its main part the basic concept of evaluation in these three pillars. Further elaborated methodological details have been documented in the Annexes 5 (MOE measures), 6 (MOP measures), 7 (EELPS measures)

7.2 Measures of Effectiveness and Benchmarking

7.2.1 MoEs derived from expected benefits

Measures of Effectiveness (MoE) are parameters by which the effects and benefits of the PULSE platform and its components can be described and validated. Typically, MoEs can be:

- Quantitative (e.g. reduced reaction time in a given situation, better utilization of resources, saved lives, reduced numbers of injuries etc.) or
- Qualitative (e.g. quality of decisions, quality of information etc.).

The two PULSE scenarios were deliberately designed to be different. Consequently, the effects generated will vary depending on how the PULSE tools interact in the scenarios chosen and in the individual use cases applied. Working in the background and remaining more or less invisible and not directly perceptible to the users and beneficiaries of the PULSE system, the individual tools are not prime evaluation targets for the user community. Thus, the evaluation focuses on the use cases and how and to what extent the PULSE system as a whole better supports decision-making and operational functions compared to situations ante-PULSE. In short, this is the raison d'être of the PULSE project.

7.2.2 Benchmarking and the Reference Case

Describing the applied benchmarking philosophy amounts to below statements:

- The reference case is the "world as is": The world before/without PULSE.
- The PULSE case: The world after introducing PULSE.
- The PULSE "effectiveness" needs to be compared to the Reference Case.

For both trials the solution chosen isto involve professional trial participants and to expose their respective ante-PULSE expertise to routine situations supported by PULSE.

7.2.3 Data Collection and Analysis

Capturing information and data for measuring effectiveness will address the following evaluation audiences for different purposes in different ways as follows:

- Active trial participants:
  - During the trials by structured questionnaires,
  - Post-trial through hot-wash up briefs,

[3] See: PULSE D2.1 Requirements Specification, Chapter 9.7

- Independent observers:
  - During and post-trial in interviews,

- Consortium members:
  - Pre- and post trial by special questionnaires and interviews,

Captured data and information are reference points for the subsequent analysis aimed at the main product of this part of the evaluation, the After Action Report feeding into the final validation results of the PULSE system covered by D7.3. A set of evaluation templates for the SARS and the STADIUM CRUSH trials are included under Annexe 5.

7.3 The Characteristics of the PULSE System

7.3.1 Definition of Performance Categories

The second part of the evaluation will focus on the **inherent qualities of the PULSE platform**. This comprises a set of characteristics called **Measures of Performance (MoP)**.

While the MoE questionnaires are different for the two Trials because they reflect the specific trial scenarios and their associated use cases, the MoP questionnaires are identical because the characteristics they scrutinize are common to both trials and scenarios.

Detailed testing of the system and its modules against the requirements and specifications will be done in Task 6.3 and documented in D6.3.For the evaluation and validation of how PULSE perform the tasks it has been designed for, below primary collective performance categories have been identified.

- **Efficiency**

Regarding the human-computer interaction in PULSE, in a complex and complete system set-up, efficiency includes: the optimization of speed and transparency and ease of access for end users while using the system.

- **Flexibility**

Characterized by the capabilities of the present system to adapt to new, different, or changing situations and requirements, e.g. various scenario types, different frameworks of health organizations etc.

- **Dependability**

Addresses the attributes of the system's maturity,its readiness and continuity of service.It also addresses the absence of malfunctions and ability to undergo modifications identified to be necessary to improve dependability.

- **Scalability**

Ability for diverse end-users, agencies, organizations to

- To share and use PULSE
- to enhance it by adding new functionalities or address hazards in scenarios other than the demonstrated ones
- to maintain performance regardless of expansion from a local area to a larger geographic pattern

- to easily manage and expand the resource pool (number and categories of enrolled ambulances, hospitals etc), and to scale up to comply with new generations of hard- and software components.

- **Inter-operability**

System interfaces working with other products or systems, present or future; depending on common definitions, common information exchange models, and cross-domain capability (e.g. to police systems).

- **Extensibility**[4]

Understood as a system design based on broad generalized features and inter-operability, which facilitates transfer and adaption to other crisis management domains and different national or international organizational and technical frameworks.

- **Usability**

Ease of learning, understanding and application of the system for exploiting its potential. This could be measured in terms of required skills, time and effort to get familiar to the system and to adapt to new situations, from a user perspective.

7.3.2 MoP Information Collection and Analysis

Ultimately aimed at an innovative operational and technical framework, PULSE wants to support an enhanced European health system and provide the scientific and technological backbone of this framework. In assessing and evaluating the above performance criteria, they need to validate against the operational guidelines described in D5.2 Chapter 4.

Table 1

PULSE Performance Categories vs. PULSE Operational Guidelines

Operational Guidelines / Performance Categories	Intelligence & Information Gathering	Threat & Risk Analysis Alert & Warning	Operational Picture Generation & Situation Assessment	Task & Resource Planning	Training & Exercising Capability	Knowledge Management
Efficiency						
Flexibility						
Dependability						
Scalability						
Interoperability						
Extensibility						
Usability						

Above operational guideline areas describe the basic functionalities relevant for the PULSE platform. They constitute a plausible and realistic flow of actions and functions

[4] The term transferability also used sometimes

embedded in a recurring process cycle, contingent on each other. They have the character of basic processes, which have the potential to contribute to a common European framework that will ease harmonization of systems, cross-border coordination and knowledge sharing.

Each operational guideline area will be checked and validated in view of the more general performance categories.

Predominantly qualitative in its character, the scoring of the MoPs will be done by external stakeholder and by PULSE consortium members in pre-structured questionnaires.

This questionnaire will also ask for a summary evaluation of the overall quality of the PULSE project and of the experiments' setup and execution. Structured in accordance with the performance categories as outlined above, the questionnaires will be finally included in D7.3. A set of draft examples is enclosed here under Annex 6.

In combination with the MoE data collected, MoP information captured is another reference point for the subsequent analysis aimed at the production of the main product of this second part of the evaluation, the After Action Report, which feedsinto the final validation results of the PULSE system covered by D7.3.

7.4 Societal Impact Assessment (EELPS[5])

7.4.1 Societal Criteria Evaluation - Rationale

The field of security measures is extremely manifold and the need to improve security views changing scenarios and vulnerabilities, threats, political and diverse societal frameworks, and societal perception of security. Measures to improve security may comprise legislation, strengthening of law enforcement and for first responders: international agreements, improving preparedness by training and exercising, adapting organizations, and improving underlying disaster and crisis management processes, introducing new surveillance, hardening of recovery technologies, or alerting people and use of social media.

A system such as the PULSE platform is also considered a complex security measure, with possible huge "societal" implications. They may range from positive effects of societal perception of improved security and healthcare to negative effects as the increased risk of abuse of personal data, from generating a competitive advantage for industries to inappropriate manipulation of the distribution and allocation of health resources.

These kinds of "qualitative criteria" are often neglected when it comes to investing in and implementing of new security measures such as PULSE. Treating such qualitative factors can lead to endless discussions and frustrating unsolved contradictions. This can drastically be mitigated if Qualitative Criteria Assessment (QCA) methods and tools were available and became common and accepted in security planning, procurement, operation and administration. Differences in objectives and agendas can be overcome by agreeing on and jointly applying a methodology known as MCDA[6]. Such a methodology has been particularly developed

[5] EELPS: Ethical, Economic, Legal-Political, Societal

[6] Multi-Criteria Decision Analysis. *Belton & Tewart: Multi Criteria Decision Analysis – an Integrated Approach,* Kluwer Academic Publschers, 2002: https://books.google.de/books?hl=de&lr=&id=mxNsRnNkL1AC&oi=fnd&pg=PR11&dq=mcda+multi+criteria+decisi

in the FP7 project ValueSec[7]. It contains a two-level hierarchy of 98 qualitative Criteria grouped into 9 categories.

7.4.2 Criteria Selection and Benchmarking

The purpose of the ValueSec method was to offer an exhaustive catalogue of criteria applicable to all types of security measures. For PULSE a selection and re-definition of criteria is being performed which probably will result in 4 categories

- **E**thical - e.g. freedom of personal decision,
- **E**conomical (those which are not directly quantifiable in monetary terms) – e.g. reputation on applying leading technologies),
- **L**egal and **P**olitical – e.g. compliance with national and/or international regulations,
- **S**ocietal – e.g. general acceptance or aversion.

The PULSE version of this QCA will therefore be called **EELPS**. Each category will be broken down into about 10 criteria each.

Ethical criteria
Societal values
Privacy
Equality, non-discrimination
Freedom
Confidentiality
Trust
Openness/Transparency
Relationships
Integrity of the decision maker
Stewarding of resources
Fairness

Economic criteria
Economic stability
Compensation for side effects
Cost-benefit
Validation
Cooperation
Market
"Outside" sectors
Dependence on foreign technology

Legal and Political criteria
Data protection
Legal conformity/compliance
Human rights
International compliance
Responsibility and accountability
Strategy & political relevance
Partnerships (PPP)
Reputation
Political acceptance
Relation to Standards
Opportunism
Media acceptance
Acceptance by civil society
Political risks

Societal criteria
Fundamental rights and values
Technology intrusiveness or surveilance
Culture of control
Empowerment
Confidence or trust in institutions
Needs of society
Direct benefits to society
Perceived security
Impact on health
Attitude towards technology
Preparedness
Public awareness
Additional impacts on society
Impacts on vulnerable groups
Environment

The evaluation based on these criteria is an implicit benchmarking process, as people doing the evaluation will always compare possible improvement or potential risks or drawbacks for society to the present situation he/she is used to.

Methodological background is provided in Annex 7.

on+analysis&ots=DKJoKSAzJE&sig=nE1Q9odQ1tihrjLiiEkVlQkbokc#v=onepage&q=mcda%20multi%20criteria%20decision%20analysis&f=false or full copy: http://bookzz.org/s/?q=multiple+criteria+decision+analysis+belton&t=0

[7] http://www.valuesec.eu/

7.4.3 The Evaluation process

The basic logic of the EELPS method is the transfer of qualitative descriptions of a criterion into a numerical value and calculation of the hierarchical weighted sum[8] of the evaluated criteria. The input process and evaluation runs are supported by the EELPS tool. The verbal scale of a criterion description may range from "high risk of no acceptance" up to "full support and appreciation by society". These verbal scales will be transferred into a scale between -10 to +10 via the so-called utility functions.

Input on the verbal judgements on criteria by the trial participants will be gathered during the trials, probably via a questionnaire. They will be transferred to the tool and evaluation calculations will be done after the trials. This can only produce a sample evaluation, which can be extended by parametric variations, by using alternative sets of criteria, and by sensitivity analyses. Based on this sample, recommendations will be described and discussed in D7.3 on how future "customers" of a system like PULSE should evaluate its introduction from a socio-political point of view. A full-scale evaluation would then have to regard further scenarios, different objectives of different stakeholders or changing framework conditions such as national regulations or limited budgets. A more detailed application guide is given will be elaborated for the trials.

It should be noted that similar evaluations are being prepared in other current projects, both dealing with scenarios of critical Infrastructures. Therefore, in this field of socio-political evaluation, PULSE contributes to and benefits from substantial synergies and dissemination and exploitation effects with other projects[9] .

7.5 Integrated Summary Validation Procedure

The results of the 3 "evaluation pillars" will be summarized in Table 8 for the two scenario trials. These summarizing results will be verbally interpreted and aggregated in SWOT analysis tables (Table 9 andTable 10).

Table 8: Summary Evaluations

May be further detailed depending on the type of results

	Effectiveness Evaluation Summary	Performance Evaluation Summary	Socio-Political Criteria Evaluation Summary
SARS Trial			
STADIUM Trial			

[8] Weighted products are sometimes also possible but not suggested here.
[9] http://ecossian.eu and http://www.cirasproject.eu/

Table 9: SWOT Analysis Summary EVD trial

Strengths 7.5.1 7.5.2 7.5.3 7.5.4	Opportunities
Weaknesses 7.5.5 7.5.6 7.5.7 7.5.8	Threats

Table 10: SWOT Analysis Summary MCI trial

Strengths 7.5.9 7.5.10 7.5.11 7.5.12	Opportunities
Weaknesses 7.5.13 7.5.14 7.5.15 7.5.16	Threats

8 Conclusions

This document D7.1 “Trials definition” sets the stage for the PULSE Trials.

It provides guidelines for

- task T7.2 “Implementation of trials with the integration of PULSE tools and technologies” and the relevant deiverable D7.2 “Trials final report”
- task T7.3 “Benchmarking and evaluation and assess public acceptance” and the relevant deliverable D7.3 “Validation results”

8.1

9 Terms and definitions

Term	Definition	Notes (examples from PULSE, explanations. ...)
CB	Cost-Benefit	
CBA	Cost-Benfit-Assessment	
CCM	Centro nazionale per la prevenzione ed il Controllo delle Malattie	Italian National Center for disease prevention and control
DoW	Document of Work	The official document, version 2013-10-11, that states PULSE project scope and content
DSVT	Decision Support and Validation Tool	
ECDC	European Center of Desease Prevention and Control	
EELPS	Ethical, Economic, Legal-Political, Societal	
ENSIR	Event Evolution model for Biological Events	
ERC	Ethical Review Committee	
EU	European Community	
EVD	Emerging Viral Disease	
ExCon	EXercise CONtrol	
ExSim	Exercise Simulation	
HC	Healthcare	
HEALTHMAP	HealthMap, a team of researchers, epidemiologists and software developers at Boston Children's Hospital founded in 2006, is an established global leader in utilizing online informal sources for disease outbreak monitoring and real-time surveillance of emerging public health threats.	
HECT	Hospital Emergency Control Team	
HGECT	Hospital Group Emergency Control Team	

IAT	Intelligence and Analysis Tool	
IHR	International Health Regulations The International Health Regulations (2005) are legally binding regulations (forming international law) that aim to a) assist countries to work together to save lives and livelihoods endangered by the spread of diseases and other health risks, and b) avoid unnecessary interference with international trade and travel	
IZP	Istituto Zooprofilattico	Italian public institutions of the Italian Veterinary system
LT	Logistic Tool	
MCI	Mass Casualty Incident	
MoE	Measures of Effectiveness	
MoP	Measures of Performance	
MPORG	MultiPlayer Online Role Playing Game are popular for both training and recreational gaming. People typically use an avatar to represent themselves in a virtual world where they can perform tasks in predefined scenarios. Multiple people participate and interact in the same virtual world in parallel. MPORG system are typically accessed via the internet and used by end users in disparate locations.	Within PULSE an MPORG system and environment will be used to train personnel within the stadium crush scenario where individuals will assume the roles of different resource personnel involved in such a scenario.
NEOC	National Emergency Operations Centre	
OSC	On-site Coordination Centre	
PCET	Post Crisis Evaluation Tool	
PROMED	A global electronic reporting system for outbreaks of emerging infectious diseases and toxins	
PULSE	Platform for European Medical Support during major emergencies	
PULSE	Platform for European Medical Support during major emergencies	
QC	Quality Criteria	
QCA	Qualitative Criteria Assessment (QCA)	
RCC	Regional Coordination Centre	
RCS	Recognised Current Situation	
RRA	Risk Reduction Assessment	
SARS	Severe Acute Respiratory Syndrome	
SARS-like	Infectious respiratory desease	
Scenario	Description of an incident in terms of background, occurrence and the course of a incident, including response and other related processes of relevance	In PULSE we consider two Scenarios: SARS-like epidemics and Stadium crush-like incident
SCGT	Surge Capacity Generation support Tool	
SLD	Swim Lane Diagram	

SOP	Standard Operational Procedures	SOPs may have different levels of detail: e.g. Policy, Actor/Activity tables, Procedures
SWOT	Strenght, Weakness, Opportunity Threat	
Tool	Any helping software instrument, including input/output interfaces with users or other Tools or Systems (mostly software). A Tool may use PULSE Models. A software Tool may also be identified with a set of functionalities.	PULSE Platform includes 8 Tools.
TTX^2	Extended Table-Top Exercise	
TTX2	Table-Top Exercise	
UC	Use Case	A sample materialization of a scenario quantitatively described, including hazardous event or attack event lines, organizations involved, response procedures, numbers and classes of victims, responder and health resources etc.
UC42	The name of the band in the MCI Trial	
USMAF	USMAF (Uffici di Sanità Marittima, Aerea e di frontiera), reporting to Ministry of Health in Italy	
WHO	World Health Organization	
WP	Work Package of the PULSE Project	

10 References

[1]. COPE Project, http://cope.vtt.fi , D6.1 Evaluation Methodology,
[2]. ValueSec project http://www.valuesec.eu
[3]. CIRAS project, http://www.cirasproject.eu
[4]. ECOSSIAN project, http://ecossian.eu
[5]. http://www.victoria.ac.nz/som/researchprojects/publications/Mulit-Criteria_Decision_Analysis.pdf
[6]. http://www.valuesec.eu/content/d53-description-developed-tools-and-data
[7]. ECDC Handbook on Simulation Exercises in EU Public Health Settings
[8]. WHO Exercise Development Guide for Validating Influenza Pandemic Preparedness Plans,
[9]. US Department of Homeland Security, Exercise and Evaluation Program (HSEEP) Vol. III,
[10]. Swedish Civil Contingencies Agency Handbook Evaluation of Exercises.

ANNEX 1 - PULSE TRIALS INFORMATION SHEET AND CONSENT FORM FOR PARTICIPANTS FOR EVD AND MCI

EVD-Emerging Viral Disease

PULSE TRIALS INFORMATION SHEET – TRIAL EXERCISE - Emerging Viral Disease - SARS-like outbreak

We invite you to participate in this trial of PULSE (Platform for European Medical Support during Major Emergencies (PULSE) project, funded by the European Commission. The project aims to develop tools to substantially improve the preparedness and response capabilities of the health services in major emergency situations, to mitigate the loss of life and raise the survival rates among mass casualties. Further details about the project and this trial exercise are available in your invitation letter, and will also be provided to you in the trial exercise briefing. Please read it and the following information carefully and discuss it with others if you wish. Do ask us if there is anything that is not clear or if you would like more information.

This exercise aims to perform an evaluation of the PULSE Toolset. The trial will last one day and a half and will develop through all the WHO pandemic phases, in 7 scenes. Each scene will last 60-90 minutes. At the end of the trial, a two-hour discussion will involve *actors* and *observers* all together, for a summary evaluation of the PULSE support and for evaluating, via a questionnaire about the system performance and socio-political impacts.

Your participation is entirely voluntary. You are entitled to ask questions and receive answers from the PULSE project partners before you make your decision about whether to participate. You are free to withdraw at any time and without giving a reason. In addition to withdrawing yourself from the trial, you may also withdraw any data or information that you might already have provided. In any case, your input and feedback will be handled anonymised. In case you withdraw consent after the information has already been transcribed in the related report, the consortium will ensure an irreversible (link destruction) of the provided input and/or feedback.

You will participate in the trial according to the role assigned to you. Participants will operate in previously assigned roles. While this exercise may be different to what you are used to, we kindly advise you to act in the assigned role and give your feedback for the evaluation independent of your personal preferences, and any possible bias.

If you do decide to take part, please sign the consent form and return it to the project team.

PARTICIPANT INFORMED CONSENT FORM

We thank you for your participation in research conducted for the PULSE project.

The data collected during the trial exercises will be recorded. Any information that might identify you will be removed. Only the research team undertaking the research project will be able to access them. When the information you provide is used for the

writing of the report, we will remove your name and all identifying features of that information so that your identity and experiences remain confidential.

The information that we collect from you is considered as non-sensitive personal data under the current European data protection legal framework, i.e., the Data Protection Directive 95/46/EC. Under that Directive, we have obligations to inform you of the purpose of our collection, use, storage and retention of that information you provide to us. We will collect from you information that is relevant to our research, and we inform you that your information will be stored by us on our internal server, and accessible to only those involved in the research process. We will not transfer your personal information to third parties.

By signing this form, you consent to this collection of information (including personal data) from you so that we may meet our commitments for the research project and its associated reports. You also acknowledge that you are aware of the reasons for our collection, the manner in which the information you provide will be used, processed and stored. You acknowledge that you are aware of who to contact in order to ask questions about the research process and/or assert your rights under the Data Protection Directive. If you have any further questions, concerns or complaints, please contact the PULSE project co-ordinator, Sarah Bourke: sarah.bourke@skytek.com or tel.: +353 6787660.

Consent terms	**Please tick to confirm that you have read and accepted the terms listed.**
I confirm that I have read the information sheet explaining the purpose of the research project and I have had the opportunity to ask questions.	
I understand that my participation is voluntary; I am free to withdraw at any time without giving any reason and without any negative consequences. In addition, should I not wish to answer any particular question or questions, or take part in any aspect of the trial exercises, I am free to decline.	
I confirm that I agree to the recording of the research in which I am participating and that any recorded data will only be used for the purpose of the preparation of the report of the trials.	
I understand that any information that I provide will be kept confidential and anonymised for the purpose of the report.	
I agree I may be contacted by the PULSE project consortium in the event of its requiring further information as a follow-up to the initial research.	
I agree that any information I provide can be used in the report of the trial produced by the PULSE consortium.	

Name (please print):

Signed: Date:

PULSE TRIALS INFORMATION SHEET – Trial Exercise: Mass Casualty Incident – crowd crush in a stadium

We invite you to participate in this trial of PULSE (Platform for European Medical Support during Major Emergencies (PULSE) project, funded by the European Commission. The project aims to develop tools to substantially improve the preparedness and response capabilities of the health services in major emergency situations, to mitigate the loss of life and raise the survival rates among mass casualties. Further details about the project and the trial exercise are available in your Exercise Pack, and will be provided to you in the trial exercise briefing. Please read it and the following information carefully and discuss it with others if you wish. Do ask us if there is anything that is not clear, or if you would like more information.

This trial exercise aims to perform an evaluation of the PULSE Toolset and meet the training objectives of participants' organizations in relation to Interagency MCI preparation. The exercise will last one day. The trial details are set out in the on-line multimedia instructional and informational inject, which explains the nature of the PULSE Project, describes the PULSE platform and the MCI "crowd crush" scenario, and sets out the timetable for the exercise, the nature and mechanism of the validation and the methods that will be used to gather their feed-back by way of on-line or paper based targeted questionnaires.

Your participation is entirely voluntary. You are entitled to ask questions and receive answers from the PULSE project partners before you make your decision about whether to participate. You are free to withdraw at any time and without giving a reason. In addition to withdrawing yourself from the trial, you may also withdraw any data or information that you might already have provided. In any case, your input and feedback will be handled anonymised. In case you withdraw consent after the information has already been transcribed in the related report, the consortium will ensure an irreversible (link destruction) of the provided input and/or feedback.

You will participate in the trial according to the role assigned to you. While this exercise may be different to what you are used to, we kindly advise you to act per your assigned role and give your feedback for the evaluation independent of your personal preferences, and any possible bias.

If you do decide to take part, please sign the consent form and return it to the project team.

PARTICIPANT INFORMED CONSENT FORM

We thank you for your participation in research conducted for the PULSE project.

The data collected during the trial exercises will be recorded. Any information that might identify you will be removed. Only the research team undertaking the research project will be able to access them. When the information you provide is used for the writing of the report, we will remove your name and all identifying features of that information so that your identity and experiences remain confidential.

The information that we collect from you is considered as non-sensitive personal data under the current European data protection legal framework, i.e., the Data Protection Directive 95/46/EC. Under that Directive, we have obligations to inform you of the purpose of our collection, use, storage and retention of that information you provide to us. We will collect from you information that is relevant to our research, and we inform you that your information will be stored by us on our internal server, and accessible to only those involved in the research process. We will not transfer your personal information to third parties.

By signing this form, you consent to this collection of information (including personal data) from you so that we may meet our commitments for the research project and its associated reports. You also acknowledge that you are aware of the reasons for our collection, the manner in which the information you provide will be used, processed and stored. You acknowledge that you are aware of who to contact in order to ask questions about the research process and/or assert your rights under the Data Protection Directive. If you have any further questions, concerns or complaints, please contact the PULSE project co-ordinator, Sarah Bourke: sarah.bourke@skytek.com or tel.: +353 6787660.

Consent terms	**Please tick to confirm that you have read and accepted the terms listed.**
I confirm that I have read the information sheet explaining the purpose of the research project and I have had the opportunity to ask questions.	
I understand that my participation is voluntary; I am free to withdraw at any time without giving any reason and without any negative consequences. In addition, should I not wish to answer any particular question or questions, or take part in any aspect of the trial exercises, I am free to decline.	
I confirm that I agree to the recording of the research in which I am participating and that any recorded data will only be used for the purpose of the preparation of the report of the trials.	
I understand that any information that I provide will be kept confidential and anonymised for the purpose of the report.	
I agree I may be contacted by the PULSE project consortium in the event of its requiring further information as a follow-up to the initial research.	

I agree that any information I provide can be used in the report of the trial produced by the PULSE consortium.	

Name (please print):

Signed: Date:

ANNEX 2 - SPECIFIC MEAURES TO ENSURE ETHICAL AND LEGAL TRIAL COMPLIANCE

- Information sheet will be attached to the invitation letter and will be collected by the exercise support team before the start of the exercises in Rome (for EVD Trial) and in Cork (for MCI Trial).
- Participants (actors and observers) will be identified by the Consortium Partners among people with strong direct experience in managing the emergency situations simulated during the Trials.
- They will be provided with information about PULSE and the trial in three steps, during the first informal contact (aimed at verifying their interest and their availbility), when they are formally invited (written invitation+Information Sheet and Informed Consent Form), the day of the trial, before starting the exercise (via an illustrative briefing).
- For MCI Trial, due to its higher complexity, there will be an additional step, some days before the Trial
- With reference to MCI Trial, all participants will be provided with appropriate “joining” instructions (ie“exercise pack”) a number of days prior to participation in the MCI Exercise. They will also be directed by SMS messaging, a number of days prior to an on-line multimedia instructional and informational inject. This will explain to all participants, observers, support staff and visitors the nature of the Pulse Project, and give a description of the Pulse platform and the MCI “crowd crush” scenario. It will also set out in some detail the timetable for the exercise, the nature and mechanism of the validation and the methods that will be used to gather their feed-back by way of on-line or paper based targeted questionnaires.
- For MCI trial, the same information that is included in multimedia inject will also be contained in the “exercise pack”. Specific information on the parts they will play and the procedure that will be followed in relation to their participation will be included in their pack. It is intended that the initial multimedia inject will be shown to all participants on the day of the exercise irrespective of whether they have viewed it already or not.
- Consortium aims at contacting prospective participants at least one month before the Trial takes place. They may ask questions on the trial purpose and structure and on their expected role whenever they feel necessary.
- No voice recording will take place.
- A video, for dissemination purposes, may be produced. Participants will be informed when the relevant video recordings will take place.
  Event organisers will place visual signs when recordings are being made.
- In the briefing before the exercise, the Exercise leader will give instructions to participants on the fairness and non-bias principles of the evaluation process and tools.

ANNEX 3 - EVD TRIAL HIGH-LEVEL SCRIPT

Scenario Background

The new threat

In December 2015, Chinese researchers identified a new swine flu virus H1N1 (EAH1N1).The virus which has been circulating among pigs since 1979, has obtained the ability to infect humans and may "pose the highest pandemic threat" among the flu viruses currently circulating in animals.

Based on scientific analysis and comprehensive comparison of the main animal flu viruses, H1N1, H3N2, H5N1, H7N9, H9N2 and EAH1N1, Chinese researchers found that the EAH1N1is most likely the one to cause human flu pandemic.

Two lineages of H1N1 swine influenza viruses (SIVs), classical H1N1 SIVs and EAH1N1 SIVs, have been circulating among pigs since 1918 and 1979, respectively. The classical H1N1 SIVs emerged in humans as a reassortant and caused the 2009 H1N1 pandemic flu.

The EAH1N1 SIVs have been detected in pigs in many Eurasian countries and have caused several human infections in European countries and also in China, where a fatal case was reported.

Chen's team performed extensive flu surveillance among pigs in China and isolated 228 flu viruses from 36,417 pigs in slaughter-houses and farms of 24 provinces from August 2010 to March 2013. The researchers found that 139 of the 228 strains from pigs in 10 provinces in China belong to the EAH1N1 lineage. It indicates that "the EAH1N1 is the predominant swine flu virus circulating among pigs in China".

Simulations exercise

Scenario elements occurring a new pandemic threat

Phase 3

Brief scenario description

A new potential pandemic Influenza virus has been detected, and an alert about it has been notified to the National Health Competent Authorities. Afterwards, the scenario describes the likely spread of the new pandemic virus in Italy and Germany

Scenario details

In December 2015, researchers from China identified a new swine flu virus H1N1 (EAH1N1). In February 2016, veterinary surveillance activities in China reported the presence of EAH1N1 swine influenza in several livestock farms. An extensive influenza surveillance of pigs in 10 province has identified 2280 influenza cases due the new virus from 36,417 pigs. Influenza-related clinical signs and symptoms among

the pig farms employees are not reported. However, according Chinese researchers, the virus has obtained the ability to infect humans, and they believe that the EAH1N1 is the one most likely to cause next human pandemic flu.

Researchers form WHO and European CDC have confirmed this date and recommended to the member States to take appropriate actions according to their National Pandemic Preparedness Plan.

At the end of April 2016 the Chinese health authorities reported the onset of 65 flu cases in humans by EAH1N1 swine influenza viruses, most of them (45 cases) in pig farms employees who have been exposed to pigs affected by swine flu, but also 10 cases were among close contacts of the employees. Most cases were clinically severe, and twenty were dead (among whom 5 children). WHO warned the Member States of a new pandemic threat, and raised the level of influenza pandemic alert phase to 3.

Use Case 2
Use Case 2 Scenario Details: From April 25th to 30th in Guangzhou (Canton) there was a trade fair of breeders from different countries of the world (two hundred thousand visitors). In this context, on May 3rd, an airplane is landing at Frankfurt airport. On board there are a group of 50 Italian farmers returning from the fair of breeders in Guandong. The same plane after the Frankfurt airport continues for the Fiumicino Airport, in Rome, Italy. When the plane is landing at Frankfurt airport, the Commander shall notify to the health authority of airport that among Italian passengers ten passengers have high fever, two with dyspnea. The commander also notify to Fiumicino airport where the plane is directed after the scale in Frankfurt. The health facilities of both airports are alerted.
Actors to be involved For Italy: Italian Government, Italian Ministry of Health and its Health officers at boarders (Uffici di Sanità Marittima, Aerea e di Frontiera, USMAF), Regional authorities, National Reference Hospitals (Spallanzani in Rome, Sacco in Milan), Italian Ministry of Foreign Affair. For Germany: Federal Ministry of Health, RKI (as consultant), Local Health Authorities in Germany.
Data source *A set of epidemiological parameters should be taken into account:* • Route of transmission (droplet transmission is efficacious, airborne transmission cannot be ruled out, other routes of transmission to be determined. In the simulation we should consider to use high-level isolation measures for the management of these patients); • Existence of high-risk group (in the simulation children seem to be an high-risk group, it is rational to consider persons with co-morbidities and older people as high-risk group); • Morbidity and mortality (in the simulation we can consider an high morbidity –

20% of acute respiratory failure -, and an high mortality – 5-10%);

- Attack rate, Reproductive number, and other epidemiological parameters are usually not known at this stage of an epidemic/pandemic.

Framework of the exercice – Use case 2					
Selected actions for UC2	**Activities**	**Actors**	**Output**	**Pulse Role**	**Link with evaluation**
Evaluation and confirmation of the event	Reporting and first assessment of the event by the crew; On-board assessment of cases by health authorities: confirmation of symptoms, evaluation of severity (through MEWS Score), decision about the capability to continue the travel (in Germany), and decision about the need for hospitalization (in Italy)	Airplane Captain and crew; Italian and German MoH, RKI in Germany and Spallanzani in Italy (as consultant), Local Health Authorities in Germany and USMAF (Medical Border Control Office) in Italy	Medical decisions, situation reports	Direct links to all documents needed (MEWS Score, Passenger Locator Card; Medical and epidemiological Forms); Creating of a "Suspected Case Record with all information"; Real-time availability of procedures and regulations; Reminder about key actions; Direct link with National Preparedness Plans	Confirmation of cases
Notification of cases	Once confirmed as suspected, cases should be immediately notified to Regional/National authorities, through appropriate communication chain	From local Health Authorities in Germany and USMAF in Italy to Ministry of Health	Clear and concise communication	Direct link with command and communication chain procedures; Real-time availability of procedures and regulations; Reminder about key actions	Immediate communication with appropriate medical authorities and national actors (NA)
Contact tracing	Achieve???? of passengers' list, identification of passengers at risk (because seated in proximity, or exposed in other way), identification of other "social" contacts of cases	Italian and German MoH, RKI in Germany and Spallanzani in Italy (as consultant), Local Health Authorities in Germany	List of passengers and other contacts	Support to reduce error rate in filling and handling documents, Direct link between suspected case and contacts Direct link with	Electronic filling of diagnosis forms, passenger lists, passenger contact lists Identification of passenger social

	(e.g. fellow travelers who travel on other planes)	and USMAF in Italy International travel?		Operative Procedures	contacts, own-ward itineraries and final destinations Addressing individuals having had contacts with patients
Allocation of patients	Decision about appropriate allocation of patients (which hospital); Decision about modalities of transport (risk assessment); Decision about infection control procedure to implement	Italian and German MoH, RKI in Germany and Spallanzani in Italy (as consultant), Local Health Authorities in Germany and USMAF in Italy	Practical decision, SOPs	Direct link with SOPs; Immediate availability of Infection Control Guidelines	Immediate identification & selection of the optimal medical facility
Isolation and treatment of patients	Transport of patients to reference hospitals (in bio-containment or not, depending on risk assessment); admittance, diagnostic confirmation and appropriate treatment of patients	Italian MoH, Spallanzani, Regional authorities, Local prefecture	Protocols, guidelines.	Direct link with available SOPs and National Guidelines; Update of the "Case record"	Allocation of patients to optimal hospitals with disease and treatment specific capabilities
Further actions triggered by this event	Alert International Public Health bodies according to IHRs	Italian MoH	Report about the event	Support in correct Communication chain; Direct link with GLs, procedures and regulations; Reminder of key actions; Direct links with available SOPs and National guidelines.	Easy access to IHR communication procedure Continuous update of the operational picture on all levels concerned
	Evaluate antivirals for limiting the cluster	MoH, Reference hospitals	Decision		
	Increase, if possible, the production and the approval of pandemic vaccine	WHO, ECDC, AIFA (in Italy)	Decision		
	Prevent hospital- and laboratory-based transmission	Reference hospitals	SOPs, GLs		
	Rapidly implement training for HCWs in other hospitals, including	Regional authorities	Training materials and events		

	Emergency Departments				
	Communicate the event in a clear way to general public	MoH	Communication document		

Use Case 6 – ECDC recommendations
Brief scenario description Assessment of the epidemic evolution during ECDC periodic meetings and creation of recommendations.
Scenario details In December 2015, researchers from China identified a new swine flu virus H1N1 (EAH1N1). In February 2016, veterinary surveillance activities in China reported the presence of EAH1N1 swine influenza in several livestock farms Researchers form WHO and European CDC have confirmed this date and recommended to the member States to take appropriate actions according to their National Pandemic Preparedness Plan. At the end of April 2016 the Chinese health authorities reported the onset of 65 flu cases in humans by EAH1N1 swine influenza viruses. WHO warned the Member States of a new pandemic threat, and raised the level of influenza pandemic alert phase to 3. April 25th to 30th in Guangzhou (Canton) there was a trade fair of breeders from different countries of the world (two hundred thousand visitors). On May 3rd, the WHO reports two cases of new swine influenza virus in USA. The index case is a returning traveler from China (Guandong). The second case is the traveler's wife with no history of recent travel in affected area. No cases have been reported in Europe up to now. Do to the involvement of a new continent and to the frequent travel between Europe and USA, the ECDC converge an international meeting of Public Health Experts in order to revise the epidemiological situation and the available evidence and provide recommendation to the Member States. The Meeting is held in Stockholm with possibility to participate by Teleconferencing**.**
Actors to be involved ECDC, Robert Koch Institute, INMI "L.Spallanzani", Norwegian Institute of Public Health, Public Health England and other similar agencies
PULSE tools of potential use Decision Support and Validation Tool (DSVT)

ENSIR

PULSE tools may support Public Health Officials in risk assessment, appropriate decision chain, geo-localization of clusters, evaluation of surge capacity of Public Health resources

Data source (As Use Case 1)

Human influenza Italian websites

- http://www.epicentro.iss.it/problemi/influenza/FluNews.asp
- InfluNet: http://www.iss.it/flue/
- Monitoring system for severe influenza (restricted website): https://www.iss.it/Site/FLUFF100/Login.aspx?ReturnUrl=%2fsite%2ffluff100%2fAdmin%2fManageUser.aspx
- InfluWeb, a population-based site: https://www.influweb.it/

Human influenza International websites

- ECDC, FluNews Europe: https://flunewseurope.org/
- US-CDC, FluView: http://www.cdc.gov/flu/weekly/fluactivitysurv.htm
- Influenzanet is a system to monitor the activity of influenza-like-illness (ILI) with the aid of volunteers via the internet: https://www.influweb.it/
- PROMED-Mail is an Internet-based reporting system dedicated to rapid global dissemination of information on outbreaks of infectious diseases, including Influenza: http://www.promedmail.org/

Framework of the exercice

Selected actions for UC6 (From the phase 3 action of the PP)	**Activities**	**Actors**	**Output**	**Pulse Role**	**Link with evaluation**
Improving co-ordination and control	The MoH will request main technical partners to be briefed on the main evidence of the pandemic prior to meeting	MoH, Reference Hospitals, Research Institutes	Report by on the global epidemiological and virological evidene	Pulse will report the global epidemiological situation showing: a map of distribution of cases epidemic curve virological strain and with any association with dead cases	Graphical overview of disease cases in Europe & potential epidemiological spread Provision of particular virological data
Implement and verify systems in place for the rapid identification and management of clusters; Verify the systems in place for the safe and appropriate clinical management of cases; Promptly share all available data with International Public	Prior to the meeting: The MoH to send to reference hospitals request for information about isolation beds The MoH to	MoH, Reference Hospitals, Regional Health Authorities	Reports from Regions and from Reference Hospitals	Pulse will give automatically a report on the resource situation	Overview of resources available to be shared at ECDC

Health bodies.	Regional Authorities request for information about the surveillance systems in place and data from the past years				
Evaluate the extension and efficacy of human-to-human transmission	At the ECDC Meeting a model on the possible evolution of the epidemic will be showed based on the risk of human to human trasmission	ECDC	Technical Report	Pulse will give automatically a report on the possible spread of the disease	Graphical overview of disease cases in Europe & potential epidemiological spread
Revise the Case Definition Revise clinical protocols for isolation and care, if additional scientific evidence are available; Implement the rational distribution and use of anti-virals for prophylaxis and care, including their use for the containment of clusters; Consider the use of vaccine, if available, for the containment of clusters;	Recommendation will be issued by the ECDC based on the evidence provided during the meeting The communication of new recommendation from ECDC "to be soon released" is sent to the Regional Authorities The ECDC declare Phase 4 of the Epidemic The MoH shares recommendation to the Regional Authorities regarding: - New case definition - Suspect case management (referral to INMI AND Sacco)	ECDC, European Public Health Agencies, Public Health Isntitutes	Technical Document	Pulse to collect all the available evidence Pulse will upload the document and share with all actors at national level Pulse to disseminate the declaration of phase 4	Creation & suggestions of disease-specific recommendations & guidelines Electronically supported distribution of the ECDC communication protocol Ease of access of national authorities to ECDC guidelines & recommendations

Phase 4

Brief scenario description

The scenario describes probable cases of the new potential pandemic influenza virus identified in the community, within Italy. Immediate response is required to Health Competent Authorities.

Scenario details

At the end of April 2016 the Chinese health authorities reported the onset of 65 flu cases in humans by EAH1N1 swine influenza viruses, most of them (45 cases) in pig farms employees who has been exposed to pig affected by swine flu, but also 10 cases were among close contacts of the employees. Most cases were clinically severe, and twenty were dead (among which 5 children). WHO warned the Member

States of a new pandemic threat, and raised the level of influenza pandemic alert phase to 3.

At the beginning of May, Chinese Health Authorities referred the onset of 10 severe EAH1N1 flu cases hospitalized in Canton Hospital, with no epidemiological links to pigs or to other cases. Quickly it became clear that the new virus was circulating among humans. From May 12th to May 20th several human flu cases are notified in Hong Kong, Macao. Bangkok is notified of a new flu virus.

Based primarily on epidemiological data demonstrating human-to-human transmission and the ability of the virus to cause community-level outbreaks, on May 27th the WHO Director-General raised the level of influenza pandemic alert from phase 3 to phase 4.

On May 25th, humans cases referred to new flu swine virus are reported from Japan, Phlippines, Australia, New Zealand, and United States.

Use Case 4
Use Case 4 Scenario Details: In this context, new cases in travelers returning from aboard are expected in Italy. For this reason, a set of actions are required by MoH in order to improve rapid detection of potential cases, including the development and dissemination of a Case Definition. According to National Procedures, suspected patients (or specimens from suspected patients) should be sent to Reference hospitals/laboratories. On May 28, a 68-year-old-man refers to “Gemelli” Hospital Emergency Department in Rome with fever and dyspnea. He refers that, in the last days, he is in close contact with the 9-year-old nephew, who had a mild respiratory illness just after a one-week visit to Disneyland, Florida, USA. The nephew was in USA from May 15 to 23, together with his father and mother. The father was always fine, while the mother had a mild respiratory disease, with low-grade fever, cough and general malaise. The 9-year-old boy had fever and cough from May 23 to 26, and during these days he slept together with the grandfather. The 68-year-old man, who has diabetes and hypertension, is identified as a patient suspected to have the new EAH1N1 and he is sent to Spallanzani, where diagnostic specimen are collected and confirmed positive.
Actors to be involved Italian Govern, Italian Ministry of Health, Italian Ministry of Interior, Regional authorities, Local Health Authorities, Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA), National Reference Hospitals (Spallanzani in Rome, Sacco in Milan).
A set of epidemiological parameters should be taken into account: • Route of transmission (droplet transmission is efficacious, airborne transmission cannot be ruled out, other routes of transmission to be determined. In the simulation we should consider to use, at this stage of pandemic, droplet isolation only for the management of these patients); • Existence of high-risk group (in the simulation children seem to be an high-risk group, it is rational to consider persons with co-morbidities and older people as high-risk group); • Morbidity and mortality (in the simulation we can consider an high morbidity – 20% of acute respiratory failure -, and an high mortality – 5-10%); • Attack rate, Reproductive number, and other epidemiological parameters are usually not known at this stage of an epidemic/pandemic.

Framework of the exercice – Use case 4					
Selected actions for UC4	**Activities**	**Actors**	**Output**	**Pulse Role**	**Link with evaluation**
Evaluation and confirmation of the event	Application of the case definition to the case, and identification of the case as a suspect; Collection of the specimen and confirmation of diagnosis	Regional and local health authorities, Community hospital, Reference hospital clinical and laboratory Departments	Medical decision, SOPs, Guidelines	Creating of a "Suspected Case Record with all information"; Real-time availability of procedures; Direct link with National Preparedness Plans	Electronic filling of alert form creating probable new case Electronic filling of diagnosis form confirming a new case
Notification of cases	Once confirmed, the case should be immediately notified to Regional/National authorities, through appropriate communication chain	From reference hospital to Regional Authorities and MoH	Clear and concise communication	Direct link with command and communication chain procedures	Electronic sending of forms to national authorities
Contact tracing	Identification and immediate testing to symptomatic and asymptomatic contacts, including not only family memebers	MoH, Local Public Health Authorities	List of contacts and surveillance form	Support to reduce error rate in filling and handling documents, Generation of electronic surveillance forms, Direct link with Operative Procedures	Electronic filling of alert form creating suspected/probable new case Electronic filling of diagnosis form confirming a new case
Allocation and management of patients	Decision about appropriate allocation of patients (e.g. level of isolation); Decision about modalities of transport, if needed; Decision about infection control procedure to implement	MoH, Reference hospital	Practical decision, SOPs	Direct link with SOPs, IImmediate availability of Infection Control Guidelines, Direct link with International guidelines for treatment and medical management	Immediate identification & selection of the optimal medical facility Fast allocation of patients to hospitals with disease and treatment specific capabilities
Further actions triggered by	See Use Case 6	Italian MoH, Regional Authorities,	SOPs, Protocols, Guidelines,	Support in correct communicatio	Easy access to IHR communication

this event		Reference hospitals, AIFA, Healthcare settings at all level	Assessment documents, Training materials and events, Communication document.	n chain, Decision support (e.g. about antiviral cost-effectiveness), Support in case-definition generation, Direct links with available SOPs and National guidelines	procedure Continuous update of the operational picture on all levels concerned

Phase 5

Brief scenario description

Scenario described is like to pandemic flu Phase 5, Level 1: "Presence of large cluster in the country or presence of extensive travel/trade links with countries where clusters of the disease have been identified".

Scenario details

On May 25th, humans cases referred to new flu swine virus are reported from Japan, Phlippines, Australia, New Zealand, and United States.

Based primarily on epidemiological data demonstrating human-to-human transmission, on May 27th the WHO Director-General raised the level of influenza pandemic alert from phase 3 to phase 4.

On May 29th 2016,WHO raises the influenza pandemic alert from phase 4 to phase 5, reporting that a pandemic was imminent, and requestes that all countries immediately activate their pandemic preparedness plans and be on high alert for unusual outbreaks of influenza-like illness and severe pneumonia. The CDC and European CDC adopt case definition and give recommendations.

Use Case 1 Weak signals
Scenario Details: In the meanwhile, in Italy a number of imported cases occurred, with local secondary transmission. In this context, the MoH asks for the improvement of surveillance systems for the detection and geo-localization of cases and clusters, in order to promptly isolate cases and recognize chains of contact.
Actors to be involved Italian Govern, Italian Ministry of Health, Italian Ministry of Interior, Regional authorities, Local Health Authorities, Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA), National Reference Hospitals (Spallanzani in Rome, Sacco in Milan).
Data source *Human influenza Italian websites* • http://www.epicentro.iss.it/problemi/influenza/FluNews.asp • InfluNet: http://www.iss.it/flue/

- Monitoring system for severe influenza (restricted website): https://www.iss.it/Site/FLUFF100/Login.aspx?ReturnUrl=%2fsite%2ffluff100%2fAdmin%2fManageUser.aspx
- InfluWeb, a population-based site: https://www.influweb.it/

Human influenza International websites

- ECDC, FluNews Europe: https://flunewseurope.org/
- US-CDC, FluView: http://www.cdc.gov/flu/weekly/fluactivitysurv.htm
- Influenzanet is a system to monitor the activity of influenza-like-illness (ILI) with the aid of volunteers via the internet: https://www.influweb.it/
- PROMED-Mail is an Internet-based reporting system dedicated to rapid global dissemination of information on outbreaks of infectious diseases, including Influenza: http://www.promedmail.org/

Virological surveillance

- European Influenza Surveillance Network (EISN): http://ecdc.europa.eu/en/healthtopics/influenza/EISN/Pages/index.aspx
- WHO, Flu-net: http://www.who.int/influenza/gisrs_laboratory/flunet/en/
- WHO, Global Influenza Surveillance Network (GISN) Surveillance and Vaccine Development: http://www.influenzacentre.org/centre_GISN.htm
- NCBI Influenza Virus Resource: http://www.ncbi.nlm.nih.gov/genomes/FLU/FLU.html

Framework of the exercice – Use case 1					
Selected actions for UC1	**Activities**	**Actors**	**Output**	**Pulse Role**	**Link with evaluation**
Detection of Warning signals	Increase/reinforce of institutional activities for the surveillance of ILI and Influenza Severe Forms (Sentinel networks, specific national and international websites, virologic surveillance and characterization	MoH, Regional Authorities	Periodical (weekly) surveillance Reports	Real-time monitoring of data from GISPE and textual analysis of Twitter, in order to detect weak concordant signals about Influenza activity	Information quality on weak signals; relevance & categorization List of zone-specific signals exceeding thresholds List of zone-specific signals exceeding thresholds
Evaluation of Epidemic Spread	Analysis of weekly data for the localization of cases, at Regional/Provincial level	MoH, Regional authorities	Analysis of weekly reports	Real-time and detailed geolocalization of the signal	Expected time evolution & geographical spread Particular attention to

					social, logistic & geographic characteristics
Decision about appropriate actions	Epidemiological investigations, if appropriate; Revision of decisions and procedures at local/regional level; Implementation of training programme; Evaluation and improvement of the response at regional/local level	MoH, Regional authorities, Local Health authorities	Reports of epidemiological investigations, SOPs, Training materials and events	Real-time alert about the signal Support in analysis of Data that generate the signal Direct link with protocols and SOPs Immediate visualization of hospital resources in the affected area	Visualization of epidemic information & screen sharing Depiction of hospital resources Automatic personalized suggestions to decision makers & laboratories

Use Case 5 – Assessment of the available resources during the pandemic phase
Brief scenario description National Authority declares SARS as a pandemic disease and requires information on the availability of medical resources from health facilities.
Scenario details In the mean time, in Italy a few number of imported cases occurred, and all cases were promptly isolated and managed in the two Italian referral hospitals for Highly Infectious Diseases (Spallanzani in Rome, Sacco in Milan), with apparently no secondary transmission. To June 15 2016, the contact tracing and surveillance of contacts of the case in Rome have brought the number of confirmed cases to 15. Of these, 5 people were household members of the first case. The case was also in contact with a Veteran Meeting held in Milan during the infectious period. The tracing of the workshop participants has showed symptoms of infection in 10 colleagues. Five residing in Milan and five residing in Naples (the Company has a branch in Naples and Milan). One case from Naples and one from Milan have been admitted to ICU due to acute respiratory distress syndrome (ARDS). One case among the household members has been admitted for a severe rabdomyolisis. All admitted cases have been treated with Oseltamivir with no improvement of clinical conditions. All contacts have been vaccinated**.**
Actors to be involved Italian Govern, Italian Ministry of Health, Italian Ministry of Interior, Italian Center for Disease Control (Centro controllo Malattie, CCM), Regional authorities, Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA), National Institute of Health (Istituto Superiore di Sanità, ISS), National Reference Hospitals (Spallanzani in Rome, Sacco in Milan),

PULSE tools of potential use

Decision Support and Validation Tool (DSVT)

Surge Capacity Generation Tool (SCGT)

LT

PULSE tools may support Public Health Officials in risk assessment, appropriate decision chain, geo-localization of clusters, evaluation of surge capacity of Public Health resources

Data source

- Data sources already reported for Use Case 1 – Exercise 1
- Data sources for estimating the impact at population-level:
  - Data from Emergency Departments (overall visits, distribution of colour-code);
  - Clinical data from selected hospitals (detailed data from suspected/confirmed patients);
  - Data from General Practioners and Family Pediatricians Networks;
- Mapping of the hospitals, clinics, haealthcare residential structures, primary healthcare workers, general practitioners, general pediatricians – Regional Authorities and Ministry of Health; http://dati.istat.it/
- Data will be requested to the single hospitals (priority will be given to the hospitals located in the areas of transmission/clusters) and loaded to the DSTV
- The following data will be requested: number of beds, number of respiratory isolation beds, number of ICU beds, number of isolation ICU beds, number of ER with isolation rooms, number of mechanical ventilation equipments available, number of trained personnel (nurses, attendants, MDs), presence and quantity of antiviral stockage

Framework of the exercice Use case 5

Selected actions for UC5 (From the phase 6 action of the PP)	**Activities**	**Actors**	**Output**	**Pulse Role**	**Link with evaluation**
Coordinate timely and effective interventions for facing the event; Coordinate actions for reducing the risk of spreading Prevent hospital- and laboratory-based transmission; Verify the systems in place for the safe and appropriate clinical management of cases; Verify the availability of resources for the correct application of infection control procedures; Identify additional resources if needed;	MoH to provide a list of resources to be assessed The MoH to send to all hospital request for information about isolation beds (including ICU), personnel, trained personnel, respirators The MoH to send to all hospital request for information about stockpile of antivirals and vaccines Hospitals and Regional Authorities to send back the requested reports	MoH, Regional Authorities, Hospitals	Reports received and collected from all hospitals and reference centers	Authomatically send a request to all the hospitals PULSE to provide census of health facilities and utilization rates Pulse to provide data from ER (Gipse on line) Pulse to update on the status	Immediate access to resources data & information of medical facilities concerned Continuous up-dating on hospital resources status Instant & direct communication with national authorities on the status of resources and stocks

	MoH issues a notice to Regional Authorities to increase surge capacity				
Rapidly implement training for HCWs in other hospitals, including Emergency Departments	MoH issues a training curriculum to increase trained personnel MoH requests Regional Health Authorities to set up a Traning Implementatiojn Plan	MoH, Reference Hospitals, Regional Health Authorities	Reports from Regions and from Reference Hospitals	Pulse to select key resources to be reinforced based on data from hospitals Pulse to disseminate the notice on surge capacity Pulse to send to each hospitals the list of resource needed	Suggestions for best distribution or re-distribution of medical resources/stocks Suggestions for acquisition or otherwise obtainment of medical resources

Phase 6

Brief scenario description

National Authority declares the outbreak as a pandemic disease and requires information on the availability of medical resources from health facilities.

Scenario details

On June 21st, the WHO declared the outbreak a pandemic

The virus has started spreading in Europe with a Cluster of autochtonous transmission in Germany with index case being a returning traveller from Australia.

In Italy, the cases continue to rise with signs of autochtonous transmission in two different clusters, one in Tuscany Region and one in Campania Region.

By November 2016, 48 states had reported cases of H1N1, mostly in young people. That same month, over 61 million vaccine doses were ready. Reports of flu activity began to decline in parts of the country, which gave the medical community a chance to vaccinate more people. 80 million people were vaccinated against H1N1, which minimized the impact of the illness.

The CDC estimates that 43 million to 89 million people had H1N1 between November 2016 and April 2017. They estimate between 8,870 and 18,300 H1N1 related deaths.

The new virus has also led to patterns of death and illness not normally seen in influenza infections. Most of the deaths caused by the pandemic influenza have occurred among younger people, including those who were otherwise healthy. Pregnant women, younger children and people of any age with certain chronic lung diseases or other medical conditions appear to be at higher risk of more complicated or severe illness. Many of the severe cases have been due to viral pneumonia, which is harder to treat than bacterial pneumonias usually associated with seasonal influenza. Many of these patients have required intensive care.

Even in the case of previously very healthy people, a small percentage will develop pneumonia or acute respiratory distress syndrome (ARDS). This manifests itself as increased breathing difficulty and typically occurs 3–6 days after initial onset of flu symptoms. The pneumonia caused by flu can be either direct viral pneumonia or a secondary bacterial pneumonia.

A meeting amongst the National steering group is organized during the crisis evolution in order to assess the epidemic evolution.

Use Case 7 – National Authority periodic assessment
Brief scenario description Assessment of the epidemic evolution during national meetings and communications to the media
Scenario details The CDC estimates that 43 million to 89 million people had H1N1 between November 2016 and April 2017. They estimate between 8,870 and 18,300 H1N1 related deaths. On September 2016, Italy have already reported more than 1500 cases distributed in 6 regions. In early October 2016, a report from the Regional Authorities in Campania and Lombardia, inform the Ministry of Health of a lack or antivirals and vaccine doses. The AIFA has issued a notice on the efficacy of a new vaccine Due to new data on the prolonged and intensified spread of the Epidemic, data showing increased mortality and severity of the infection in risk groups and new cases in Italy the National steering group calls for a meeting in order to assess the epidemic evolution and the need for new resourses. The Meeting is held at the Ministry of Health
Actors to be involved Italian Government, Italian Ministry of Health, Italian Ministry of Interior, Italian Center for Disease Control (Centro controllo Malattie, CCM), Regional authorities, Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA), National Institute of Health (Istituto Superiore di Sanità, ISS), National Reference Hospitals (Spallanzani in Rome, Sacco in Milan),
PULSE tools of potential use Decision Support and Validation Tool (DSVT) LT

PULSE tools may support Public Health Officials in risk assessment, appropriate decision chain, geo-localization of clusters, evaluation of surge capacity of Public Health resources

Data source (As Use Case 1)

Human influenza Italian websites

- http://www.epicentro.iss.it/problemi/influenza/FluNews.asp
- InfluNet: http://www.iss.it/flue/
- Monitoring system for severe influenza (restricted website): https://www.iss.it/Site/FLUFF100/Login.aspx?ReturnUrl=%2fsite%2ffluff100%2fAdmin%2fManageUser.aspx
- InfluWeb, a population-based site: https://www.influweb.it/

Human influenza International websites

- ECDC, FluNews Europe: https://flunewseurope.org/
- US-CDC, FluView: http://www.cdc.gov/flu/weekly/fluactivitysurv.htm
- Influenzanet is a system to monitor the activity of influenza-like-illness (ILI) with the aid of volunteers via the internet: https://www.influweb.it/
- PROMED-Mail is an Internet-based reporting system dedicated to rapid global dissemination of information on outbreaks of infectious diseases, including Influenza: http://www.promedmail.org/

Data source (As Use Case 5)

- Data sources for estimating the impact at population-level:
  - Data from Emergency Departments (overall visits, distribution of colour-code);
  - Clinical data from selected hospitals (detailed data from suspected/confirmed patients);
  - Data from General Practioners and Family Pediatricians Networks;
- Mapping of the hospitals, clinics, healthcare residential structures, primary healthcare workers, general practitioners, general pediatricians – Regional Authorities and Ministry of Health; http://dati.istat.it/
- Data will be requested to the single hospitals (priority will be given to the hospitals located in the areas of transmission/clusters) and loaded to the DSTV
  The following data will be requested: number of beds, number of respiratory isolation beds, number of ICU beds, number of isolation ICU beds, number of ER with isolation rooms, number of mechanical ventilation equipments available, number of trained personnel (nurses, attendants, MDs), presence and quantity of anti-viral stockage

Framework of the exerciceuse case 7

Selected actions for UC7 (From the phase 6 action of the PP)	**Activities**	**Actors**	**Output**	**Pulse Role**	**Link with evaluation**
Determine the need for additional resources and powers Monitor the geographical spread	The MoH will request main technical partners to be briefed on the main evidence of the pandemic prior	MoH, Reference Hospitals, Research Institutes	Report by on the epidemiological situation Reports received and collected from	Pulse will report on the epidemiological situation in Italy showing: epidemic curve	Continuously up-dated trend on the epidemic evolution & review of

from the point of initial identification through the use of the system already in place in stage 5 and the intake database aimed to case management , in order to identify initial cases and contacts and track the spread Monitor possible changes epidemiology , clinical presentation and virological features Monitor and evaluate the impact of the pandemic at the national level (morbidity, mortality, work absenteeism, regions affected , risk groups affected , the availability of health workers , availability of workers in essential services , availability of health facilities , pressure on hospitals , use of alternative treatments , of cemeteries capacity etc .)	to meeting The MoH will request main technical partners to be briefed on epidemiological situation in Italy The MoH to send to all hospital request for information about isolation beds (including ICU), personnel, trained personnel, respirators The MoH to send to all hospital request for information about stockpile of antivirals and vaccines		all hospitals and reference centers	Data from different epidemiological surveillance system Data from GIPSE online Pulse will give automatically a report on the resource situation Pulse will give automatically a map of the global situation	hospital's resources
Evaluate the necessary emergency measures , eg emergency burial procedures , use of legal powers to maintain essential services and so on. employ additional strength and voluntary work; provide medical support staff and not for the sick , psychological and social support for caregivers , victims and the community	Based on the epidemiological data the MoH issue new plan for resource enforcement MoH issues a training curriculum to increase trained personnel MoH issues a notice to Regional Authorities to increase surge capacity	MoH, Reference Hospitals, Regional Health Authorities	Reports from Regions and from Reference Hospitals	Pulse to select key resources to be reinforced based on data from hospitals Pulse to disseminate the notice on surge capacity Pulse to send to each hospitals the list of resource needed	Instant suggestions for major procurements & delivery in specific risk zones Quick & seamless contact to AIFA for procurement & delivery in risk zones Immediate alert to hospitals regarding delivery of medical resources
Assess and update the impact of treatments and countermeasures , The emergence of non-pharmacological interventions resistance etc . When disease activity is intense and begins a greater spread , adapt the surveillance system Revise the case definition; Maintain sufficient virological surveillance to detect antigenic drift	MoH request Regional Authorities to reduce virological surveillance MoH request referral hospitals and Public Health Institute to convey a meeting for revision of case definition case definition will be based on clinical symptoms (ILI) MoH to issue guidelines for the use of the novel vaccine MoH and Regional	MoH, Referral Hospitals, Public Health Authorities, AIFA	Technical Reports	Pulse to reccoment and disseminate recommendation	Focused reconsideratio n of plans & decisions taken according to epidemic evolution spread

	Health Authorities to deploy new vaccines dose to the referral hospitals				
Collect data on the efficacy and safety of clinical interventions and transmitting information in countries not yet affected and WHO	Daily Data collection from Regions (aggregate case counts). Stop single case report. Set up of a dedicated database	MoH Public Health Agencies, Research Institute, Referral Hospitals	Database Collection forms Study protocols	Pulse to provie recommendations	Focused reconsideration of plans & decisions taken according to epidemic evolution
Maintain the ability to answer to the question of national and international information Activate all elements of communications plan	MoH to select messages for the public (including twitter) and to disseminate MoH to slect list of networks and media to disseminate informations	MoH, Communication agencies	IC Material	Pulse to provide recommendation and list of target media	Suggestion of templates for information & communication purposes Direct access to a list of confirmed spokes persons and authorized talking points

Transistion phase- Interpandemic phase

Transition phase- issued by WHO Interim Guidance 2013 ***(****de-escalation of global actions and reduction in response activities or movement towards recovery actions by countries, according to their own risk assessments.)*

Inter-pandemic phase- issued by WHO Interim Guidance 2013 **Phase 1-2 -** National pandemic flu plan

Brief scenario description

The National Authority evaluates how the country responded to the epidemic

Scenario details

Cases started to decline worldwide for one month. The WHO has declared the end of the Pandemic emergency on the 1st of August 2017. There are no more reported cases in Italy since one month when the last confirmed case was reported.

The Ministry of Health converge a meeting to evaluate the response, to discuss the lesson learned and to revise and reactivate the preparedness actions

Use Case 8 – Post emergency learning at national level
Brief scenario description The National Authority evaluates the downgrading of the response and how the country responded to the epidemic
Scenario details Cases started to decline worldwide for one month. The last reported cases were two weeks before. The WHO has declared the end of the Pandemic emergency on the 1st of August 2017. There are no more reported cases in Italy from one month when the last confirmed case was reported. The Ministry of Health converge a meeting to evaluate the downgrade of the response, to discuss the lesson learned and to revise and reactivate the preparedness actions
Actors to be involved Italian Government, Italian Ministry of Health, Italian Ministry of Interior, Italian Center for Disease Control (Centro controllo Malattie, CCM), Regional authorities, Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA), National Institute of Health (Istituto Superiore di Sanità, ISS), National Reference Hospitals (Spallanzani in Rome, Sacco in Milan),
PULSE tools of potential use Decision Support and Validation Tool (DSVT) LT PULSE tools may support Public Health Officials in risk assessment, appropriate decision chain, geo-localization of clusters, evaluation of surge capacity of Public Health resources

Data source (As Use Case 1)

Human influenza Italian websites

- http://www.epicentro.iss.it/problemi/influenza/FluNews.asp
- InfluNet: http://www.iss.it/flue/
- InfluWeb, a population-based site: https://www.influweb.it/

Human influenza International websites

- ECDC, FluNews Europe: https://flunewseurope.org/
- US-CDC, FluView: http://www.cdc.gov/flu/weekly/fluactivitysurv.htm
- Influenzanet is a system to monitor the activity of influenza-like-illness (ILI) with the aid of volunteers via the internet: https://www.influweb.it/
- PROMED-Mail is an Internet-based reporting system dedicated to rapid global dissemination of information on outbreaks of infectious diseases, including Influenza: http://www.promedmail.org/
- Data will be requested to the single hospitals on the resource utilized and available and loaded to the DSTV

Data source (FOR PAST PANDEMIC)

- Integrated epidemiological surveuillance of the pandemic influenza A/H1N1v in 2009-2010 (Attached)
- Pandemic 2009 evaluations: http://ecdc.europa.eu/en/healthtopics/pandemic_preparedness/pandemic_2009_evaluations/Pages/pandemic_2009_evaluations.aspx

Framework of the exercice Use case 8					
Selected actions for UC8 (From the phase 6 action of the PP)	**Activities**	**Actors**	**Output**	**Pulse Role**	**Link with evaluation**
Scale response as indicated by the epidemiological situation Communicate to the general public on the dow	MoH to restore the referral of suspect patients to referral hospital MoH to restore the usual surveillance requesting only laboratory confirmed cases to be notified. Restoring the virological surveillance Request to the Regional Health Authorities to have information about the stockpile of vaccine and antivirals Revised case definition to be disseminated	MoH, Regional Health Authorities, Referral Hospital, Hospitals	Reports and Notices	Pulse to remind recommended actions Pulse to disseminate notice to Regional Authorities to restore surveillance and clinical management pathways Pulse to update MoH on the status of the resources	Immediate communication with appropriate medical authorities and national actors (NA) (from UC2) Immediate access to resources data & information of medical facilities concerned (from UC5)
Revise the national response	MoH to produce a document on lesson learned	All Actors		Pulse to show all data related to the epidemic response	Access to the documentation of experts &

					individuals having managed the pandemic Ease of access to & retrieval of data & information stored during the crisis User-friendly data-mining application for quantitative and qualitative evaluation support Provides the basis of a common pandemic evaluation framework across Europe

ANNEX 4 - MCI TRIAL HIGH-LEVEL SCRIPT

Scenario Background

- The Regional Government Authorities have given permission for a three day sell-out concert in a football stadium by a well-known pop group called UC42. The concerts are planned to run over three consecutive nights. The concert promoters originally requested five days but the request was denied by the regional government authorities due to planning regulations. Inevitably there has been a large number of disappointed fans. This concert is an outdoor event and the concerts promoters have indicated that it will take place irrespective of the weather. The stage is built in the centre of the football pitch with runways, ramps and raised podiums to bring the pop-group ever closer to the fans. The number of tickets per concert is 82,000.
- In the pre-event planning phase the police service have conducted an assessment of the potential crowd at the concert and have indicated to the event promoters and the regional government that the majority of fans will be in the 18 to 25 age group category. Before the pop-group UC42 became very popular they did have a reputation for a negative attitude towards authority. Recent intelligence information from regional police indicates that a very small number of original fans travel from country to country following the pop-group UC42.
- It is an older design of stadium, due to be closed and refurbished next year but has had many such concerts before without any serious problem. The new layout of the stage set up in the stadium is a new design not tried before and is unsuited to this type of pop-group and this type of crowd.
- In the lead up to the event, all planning arrangements go well and everything is in place, as per the guidance documents, for the concert which is due to commence begin at 20:00 hrs.
- A support group is due to play for about an hour and UC 42 is expected to come on stage at 21:00 hrs and play for two hours. The regional authorities have placed a curfew on the group playing beyond 23:15 hrs , which must be strictly adhered to.
- Shortly before the gates open disputes with the ticket control staff begin to happen between stadium security staff and stadium patrons in relation to counterfeit tickets or tickets for the wrong night – it emerges that some tickets were sold very early on for what they thought would be a five day series of concerts and which is now only three days.
- The concert gets underway on time at 19:30 with a support group but not all fans (including those with the correct tickets) have been able to get into the venue.
- The pop-group recognises a group of their older fans from their heavy metal days and decides to play some of the *old numbers* and turn up the sound beyond the agreed decibel lelel sed down in the regulations.
- Due to the confusion over the tickets and because the stadium is 30 minutes walk from the city centre and fans gather outside to listen to the music.
- Some spectator-related problems are occurring directly outside the stadium and as a result of this begin to engage in ‘swarming’ this is rushing the gates and trying to crash the gates to gain entry and there are some injuries from trampling.
- The mainly private security event personnel have not been trained to handle such a severe situation.
- Inside the stadium, the promoters initially ignore the instruction to turn down the level of the sound. The fans inside and outside the stadium are communicating

via social media. Some fans inside try to rush the stage and a 'progressive crowd collapse' occurs which causes and constrictive/restrictive asphyxia.

- The disaster develops quickly (in minutes) and the event emergency medical plan is activated.
- The police order the concert to be stopped. The music is halted but in the confusion of the urgent instruction to stop the concert electrical power is cut off to a large section of the stadium.
- Many fans start to leave the stadium to encounter other fans trying to get in.
- It soon becomes obvious that this event is beyond the ability of those in the stadium to manage appropriately and a major emergency is declared by the senior police commander who is an authorised officer to make such a decision.

Framework of the exercise – Stadium Crush Use case-01

"Scoring of an event to establish parameters for an event medical plan"

Selected actions	Activities	Actors	Output	Pulse Role	Link with evaluation
Identify the relevant actors	Relevant actors input critical data that govern the creation of an event medical plan.	Event Medical Co-ordinator & Regional Authority	Current Score *Scoring systems includes historical event data	Providing the data capture form for the definition of the event medical plan. Automated system for generating a medical plan assessment based on the event medical coordinators definitions	Completeness of scoring categories including historical data User review of running score
Decisions on permissions	The PULSE platform governs the ability of the actor to modify the event medical cover based on the current score.	Event Medical Co-ordinator & Regional Authority	A recommended level of event medical cover	Assigning role based access. Only relevant personnel can edit and review the plan.	Continuous up-dating of scores Visualisation & distribution of cascading alert levels
Planning of medical cover required.	The event medical coordinator analyses the event score	Event Medical Co-ordinator & Regional Authority	Agreed level of event medical cover	Automated assistance in generating recommended level of event medical cover based on the current score. Immediate real time access to the event medical	Depiction of medical resources & responder status on current summary score Automated system for the efficient handling and constant review of medical

				plan which is consistently updated, which reflects the real time threat level.	resources
Confirm the medical cover is adequate & planning of additional medical cover (if necessary)	By re-running the tool with revised data, this will generate the current score	Event Medical Co-ordinator & Regional Authority	Current updated score, which confirms if the allocated medical cover is adequate based on the score. Alert and/or confirmation is generated and sent by SMS. System will generate a cascade or alerts.	Event medical coordinator can consistently update the event medical plan. Automatic distribution of the current and any updated threat.	Automated system for the efficient handling and constant review of medical resources

Stadium Crush **Use Case – 03** **"User wishes to mobilise and coordinate resources"**
Scenario Details: In response to the stadium crush, and as a result of the 200 mass casualty/missing person incident, the onsite co-ordinators have declared a Major Emergency. Due to the vast numbers of injured patients and missing persons, the response agencies have indicated that they require the resources of the ***voluntary emergency services*** to assist with the incident.
Actors to be involved **Regional Authority** official agencies dealing with response at *strategic* level. **Managers or commanders or units or members** of potential response organisations **On-site Co-ordinators or on-site commanders** who will have responsibility to respond to an emergency.
PULSE Tools to be applied: • Smartphone app

- DSVT

Data

On-site coordinators
Police Commander
Ambulance Commander
Fire and Rescue Commander

A Framework for Major Emergency Management

- http://mem.ie/wp-content/uploads/2015/05/A-Guide-to-Working-with-the-VES_Jan-2011.pdf

Framework of the exercise – Use case 03

User wishes to mobilise and coordinate resources

Selected actions for UC4	Activities	Actors	Output	Pulse Role	Link with evaluation
Fills in registration form	Smartphone app	Resource Provider	Capture data that is then stored in the DSVT	The Smartphone app records the entered data that the resource provider has submitted	Capturing data & ease of access to data base
Review data	Data submitted by resource provider	National authority	Confirmation/rejection of the responders skill level claim	The database reviews the data and cross matches against national and international registration systems in near real time	Ability for on-line registration of additional and volunteer resources Cross-matching of actual resources against original response data base entries
Alerts & instruction via Smartphone or social medial/broadcast	Data from DSVT	National authority	An alert request distributed	The Smartphone app instructs registered responders based on the previous data input and location an current	Initiation of general requests by broadcast and/or social media

				status	
Confirms availability of responder for tasking an acknowledges instructions	Availability status via Smartphone app	Resource provider	An graphic and tabular representation of current responding resources	Confirmation of availability and information of status and location details.	Matching assignment of resources to specific tasks
Monitors responders location and availability status	Smartphone app	National authority	Common picture of resources availability	Graphical and tabular review of the recognised current situation. .	Status of committed and available resources Tracking of individual smartphone locations Issuance of instructions via the smartphone app and feeding back status reports
New registrations of not previously responders	Web/ Smartphone app	Resource provider	Capture data that is then stored in the DSVT (invalidated)	The Smartphone app records the entered data that the resource provider has submitted	Cross-matching of actual resources against original response data base entries
?	?	?	?	?	Graphic & tabular display Drop-down menu functionality & selection of options Handling of smartphone app under response conditions

Stadium Crush

Use Case -04

“Hospital Surge Capacity Bed Management”

Scenario Details:

Due to the fact that there are reports of 200+ casualties, the Ambulance Onsite Co-ordinator has indicated to the National Ambulance Operations Centre, that the vast majority of the patients will require admission to the Emergency Department for further treatment. The representatives from the local hospitals indicate to ambulance control that they are already running at 97% capacity.

Actors to be involved

On-site Coordinator controls or co-ordinates resources at the site of an incident.

Hospital controllers and bed managers who have responsibility for co-ordination hospital resources.

Regional Authority is the official organisation who are required to make preparations for the events or which will be responsible for co-ordination of the response.

Crisis Management Teams (CMT) at Hospital, Regional, National and International Levels. These can be either pre-existing CMTs or one set up as a result of the incident to create additional hospital capacity either in the region or nationally or in the hospital of adjacent or other MS.

PULSE Tools

- Smart phone app
- Web app
- DSVT
- LT

Data source

- Admission avoidance strategies
- Closed bed status
- Entire Census data
- Availability of step down facilities
- Number of possible expedited discharges
- Number of day case beds for emergency admissions
- Availability of beds on 5 day wards for emergency admissions

Framework of the exercise – Use case 04 Hospital Surge Capacity Bed Management					
Selected actions	**Activities**	**Actors**	**Output**	**Pulse Role**	**Link with evaluation**
Senior triage officer triage information	Triage status photographic evidence, bar-coding information	Triage officer	Real time picture of triage information	Capturing on site triage information	Photographic evidence & bar-code display
Request current bed status from local hospital level	Hospital defined bed availability	Local hospital	Current resource defined by hospital stored by DSVT system	Online capturing of current resources at local level	Matching patient condition with bed type availability Capturing & storage of current resources
Current report completed from local hospital	Local hospital bed definitions	Local Hospital	Resource definitions submitted to DSVT, LT tools	Current resource Details submitted and stored on server	Capturing & storage of current resources
Request current bed status from national hospital level	National Hospital defined bed availability	National hospital groups	Current national resource availability information stored by DSVT system	Online capturing of current resources at national level	Display of resources at different levels
Current report completed from national hospital	National hospital bed definitions	National Hospital	Resource definitions submitted to DSVT, LT tools	Current resource Details submitted and stored on server	Capturing & storage of current resources
Current Bed availability report national	Summary of bed availability	National hospital groups	Report of current resource availability	Simultaneous access to the current resource information at national hospital level	Simultaneous access to current resource information levels
Current Bed availability local	Summary of bed availability	Local Hospital	Report of current resource availability	Simultaneous access to the current resource information at onsite hospital	Simultaneous access to current resource information levels

Capacity Requirements	Definition of surge capacity resources required	National & Local	Reports on the level of discontinuity of the requirements and availability	Generation of at scene surge requirements of response	Definition of surge capacity resources Common capacity picture at different levels
Activates surge capacity generation procedures nationally	National summary of needs vs. availability of national bed capacity	National Coordinator	Capacity picture at national level	Using the generated output will facilitate relevant surge capacity requirements	Report on the level of discontinuity of requirements and availability
Activates surge capacity generation procedures local	Local summary of needs vs. availability of national bed capacity	Local Coordinator	Capacity picture at local level.	Using the generated output will facilitate relevant surge capacity requirements	Report on the level of discontinuity of requirements and availability

Stadium Crush

Use Case 05

"Triage in CCS and links to ePCR"

Scenario Details:

200+ patients are injured at the incident, as per the Pre-Hospital Emergency Care Council Guidelines, the responders will triage all their patients on site into triage categories (Red, Yellow, Green, White) and then a further re-triage of patients in the casualty clearing station.

Actors to be involved

The **Casualty Clearing Officer** is an Officer of the Medical Response Service who is in charge of the casualty clearing station.

The **Triage Officer** is a medical professional who triages the casualties into priorities and 'sieves and sorts' the casualties. There may be more than one triage officer and these additional triage officers work under the direction of the principal Triage Officer.

On-site Coordinator controls or co-ordinates resources at the site of an incident.

PULSE tools to be applied

- **Smartphone app**
- **DSVT**

Data source

- PHECC Patient Care Records
- Triage tag & associated bar code
- Aggregated total of patients on site
- Aggregated total of patients in the casualty clearing station

Framework of the exercise Use case 5 Triage in CCS and links to ePCR

Selected actions for UC5	Activities	Actors	Output	Pulse Role	Link with evaluation
Record triage data for each patient	Current individual casualty triage status	First Responder	Current patient triage status	Triage data entry	Real-time mobile capture of triage data Transmission to central storage repository Data entry into smartphone application
Report of consolidated triage	Consolidated triage status of identified patients	CCS Triage Officer	Graphical and tabular report on current casualty status	Presentation of consolidated triage data from first responder	Automated presentation of consolidated triage data Automatically available for distribution
CCS Triage Report	Current consolidated triage list	CCS Officer	Revised Graphical and tabular report on current casualty status	Revision and review of the consolidated triage data	See above
Current Casualty board data	Description of the casualty	On-Site Coordinator	Revised Graphical and	Presentation of verified	Presentation of consolidated

	data definition		tabular report on current casualty status	information	data a appropriate levels Availability of data & summary in graphical & tabular format in near real-time
Input critical data RCS	Updated casualty data board	On-Site Coordinator	Graphical and tabular summary of the current casualty status	Presentation of consolidated data at appropriate response levels	See above

Stadium Crush

Use Case 06

"Input Critical Data for the RCS"

Scenario details

1. The event organisers prepare their event management plan and event medical plan.
2. Prior to the event taking place, the event organisers will populate the RCS with their 'up-to-date' status of the event. Closer to the date the organisers will document any findings and update the RCS. As the event progresses the RCS will indicate that an incident in 'imminent'. As the crowd crush becomes the RCS will indicate

Actors to be involved

Regional Authority is the official organisation responsible for co-ordination of the response to an incident or for commissioning the exercise.

The **On-site Co-ordinators** and Commanders are those who either command, control or co-ordination resources at the site of an incident.

PULSE tools to be applied

Web app

LT

DSVT

Data source

On-site coordinators
Police Commander
Ambulance Commander
Fire and Rescue Commander

Information Management Boards http://mem.ie/wp-content/uploads/2015/05/A-Framework-For-Major-Emergency-Management.pdf page 64

Framework of the exercise Use Case 06 – Input Critical Data for the RCS

Selected actions for UC7	Activities	Actors	Output	Pulse Role	Link with evaluation
Input critical data from the on-site coordinator	The onsite coordinator feeds in information from the incident to the DSVT, which is previously populated by the Web App and LT	On-site coordinator	Provides a common framework for identifying critical data from the on-site coordinator	Data is collated from the web app, LT and DSVT from the on-site coordinator	Collation & display of current critical data Application of geo-referenced information
Input critical data from ambulance mobilisation and dispatch services	The ambulance mobilisation and dispatch team input data into the DSVT	Ambulance mobilisation and dispatch centre	Provides a common framework for identifying critical data from the ambulance mobilisation and dispatch services	Data is collated from the DSVT from the ambulance mobilisation and dispatch services	See above
Input critical data from regional authority	The regional authority feeds in information into the DSVT	Regional authority	Provides a common framework for identifying critical data from the regional authorities	Data is collated from the DSVT from the regional authorities	See above
Grade appropriate RCS picture view and update on-site coordinator	The DSVT systematizes, classifies and stores the RCS from the on-	On-site coordinator	A current RCS from the on-site coordinator	The DSVT automatically generates the RCS in relation to the on-site	Continuously up-dated status Decision support to on-site co-

	site coordinator			coordinator	ordinators & commanders
Grade appropriate RCS picture view and update ambulance mobilisation and dispatch services	The DSVT systematizes, classifies and stores the RCS from ambulance mobilisation and dispatch services	Ambulance mobilisation and dispatch centre	A current RCS from the ambulance mobilisation and dispatch services	The DSVT automatically generates the RCS in relation to the ambulance mobilisation and dispatch services	See above
Grade appropriate RCS picture view and update regional authority	The DSVT systematizes, classifies and stores the RCS from regional authority	Regional authority	A current RCS from the regional authority	The DSVT automatically generates the RCS in relation to the regional authority	See above

Stadium Crush **Use Case 07** **"Post Event Evaluation Tool to identify lessons learned"**
Scenario Details:
Actors to be involved **Regional Authority** is the official organisation responsible for co-ordination of the response to an incident or for commissioning the exercise. The part of **each participating organisation** whose role it is to deliver the major emergency planning function **Exercise Players or Incident Officials** are those who were actively involved **Official Umpires or Observers** are those appoint to observe or validate an exercise
PULSE tools to be applied • **PCET** • **Mobile app** • **LMS** • **MPORG**

Data source (As Use Case 1)

Framework of the exercise Use case 07 Post Event Evaluation Tool to identify lessons learned					
Selected actions	**Activities**	**Actors**	**Output**	**Pulse Role**	**Link with evaluation**
Identify actors	KO search in PCET all the actors that had been involved in the event/exercise with decision making roles	Knowledge Officer	Actors to be activated	Provides names of the actors recorded during the event/exercise	Complete list of actors Rapid access to actor's data
Activate actors	KO sends an invitation to all the actors via Mobile App	Knowledge Officer	Request to Provide evaluation	Automatic invitation to all the relevant actors	Automated invitation to actors identified
Fill questionnaire	Each operator fills the questionnaire directly in the mobile App	Operators	Filled questionnaire	The questionnaire may be filled on line via Mobile App.	On-line filling and usefulness of smartphone application
Elaborate Report	KO elaborates a report containing the lesson learned	Knowledge Officer	Report on lesson learned	PCET allows to store and analyse the responses to the questionnaire LMS allows to store the report MPORG may be updated to take into account the new lessons leaned	Analysis & storage of information Constant access to stored information Diffusion of knowledge of lessons learned for future events

Stadium Crush Use Case 08 "Casualty Bureau Operation"

Scenario details: With some 200+ patients injured and many more missing, the local police force have requested to establish the Casualty Bureau to aid with the recording of missing and injured people. This will also help to deal with the flood of inquiries from the relatives and friends of both the injured and non-injured.
Actors to be involved The **police asset** responsible for Casualty Identification Role and **Civil Protection asset** responsible for Casualty Identification Role **Regional Authority officials** responsible for Casualty Identification Role
PULSE tools to be applied • Decision Support Validation Tool (DSVT)
Data source (As Use Case 1) An Garda Síochána Member of the public Hospital Morgue Call centres (taking missing person information)

Framework of the exercise Use Case 08 – Casualty Bureau Operation

Selected actions	Activities	Actors	Output	Pulse Role	Link with evaluation
Data capture from the general public	A member of the general public inputs data into the DSVT in relation to a specific casualty	General public	Creation of a unique casualty/missing person in the system	The DSVT captures the data from the member of the general public creating a unique entry	On-line single point entry Collation of data of single point entries
Data capture from the police at	A member of the police force	Police at incident	Creation of a unique	The DSVT captures the	See above

incident level	at incident level puts data into the DSVT in relation to a specific casualty/missing person	level	casualty/missing person in the system	data from the member of police force at the incident in turn creating a unique entry	
Data capture from the police at regional level	A member of the police force at regional level puts data into the DSVT in relation to a specific casualty/missing person	Police at regional level	Creation of a unique casualty/missing person in the system	The DSVT captures the data from the member of the police force at regional level creating a unique entry	See above
Data capture from the police at national and international level	A member of the police force at national and international level puts data into the DSVT in relation to a specific casualty/missing person	Police at national and international level	Creation of a unique casualty/missing person in the system	The DSVT captures the data from the member of the police force at national and international level creating a unique entry	See above
DVI Data display in a tabular format from international and national level	A current real time picture of data from international and national input	Police at national and international level	DVI Data display in a tabular format from international and national level	The DSVT creates a current near real time view of casualty bureau	Automatic generation of current overview Identification of matching entries and suggestions Display & detail of current overview
DVI Data display in a tabular format from police at a regional level.	A current real time picture of data from regional input	Police at a regional level	DVI Data display in a tabular format from police at a regional level.	The DSVT creates a current near real time view of casualty bureau	See above
Consolidated DVI Data display in a graphical format from police at regional level	A current real time picture of data from regional input	Police at regional level	Consolidated DVI Data display in a graphical format from police at regional level	The DSVT creates a current near real time view of casualty bureau	See above

ANNEX 5 - PULSE TRIALS EFFECTIVENESS MEASURES

The description of the use cases provided by the deliverables D2.2 and D5.2 are the starting points for the evaluation and validation process. In doing so, the templates captured in this Annex filter out the various benefits of the PULSE system in order to formulate questions, which aim at the evaluation and validation of the PULSE system.

Methodically, the following templates for the SARS and the STADIUM CRUSH use cases are an intermediate step in the final deduction of respective questionnaires. By navigating towards the evaluation aspects as given in the templates, 'function', 'aim', and 'objective' not only allow the following of the logical progression but also help to trace back individual evaluation aspects to the source in case multiple use cases are mixed in s single trial event or snapshot.

To make sure that the evaluation aspects, and the final questionnaires by the same token, actually match the screenplay of the trials, these templates included have been closely co-ordinated by the developers of the PULSE platform and its tools.

EVD Trial

PULSE System Effects

Participant Category: Player/Actor | Observer | Consortium

SARS Trial – UC1: Weak Signal Detection

FUNCTION	AIM	OBJECTIVE	EVALUATION	Poor	Average	Good	Excellent	Final Comment
Warning	Prompt public health intervention	Alert decision makers to unusual biological events occurring	Information quality on weak signals; relevance & categorization					Most missing or criticisable:
			List of zone-specific signals exceeding thresholds					
			Timely notification to cognizant national & international authorities					Most advantageous finding:
Epidemic spread	Focused evolution of the geographical spread	Surveillance & evaluation of - susceptible - exposed - infectious - recovered population members	Expected time evolution & geographical spread					
			Particular attention to social, logistic & geographic characteristics					General Summary:
Decision support	Efficient management of major health crises	- Enhanced operational picture - Decision making suggestions - Resource management	Visualization of epidemic information & screen sharing					
			Depiction of hospital resources, responder status probable & confirmed cases					
			Automatic personalized suggestions to decision makers & laboratories					

PULSE System Effects

Participant Category: Player/Actor | Observer | Consortium

SARS Trial – UC2: Airplane Landing Identification of Probable Case

FUNCTION	AIM	OBJECTIVE	EVALUATION	Poor	Average	Good	Excellent	Final Comment
Confirmation of cases	Instant determination and verification of the epidemic situation	- Reduction of time and error rate in filling and handling documents - Limiting the spread of the disease	Electronic filling of diagnosis forms, passenger lists, passenger contact lists					Most missing or criticisable: Most advantageous finding : General Summary:
			Identification of passenger social contacts, own-ward itineraries and final destinations					
			Addressing individuals having had contacts with patients					
Notification of medical authorities	Immediate alerting & action	Providing reliable information and visibility to the appropriate responder entities & medical facilities	Immediate identification & selection of the optimal medical facility					
			Immediate communication with appropriate medical authorities and national actors (NA)					
			Allocation of patients to optimal hospitals with disease and treatment specific capabilities					
Operational picture	Efficient management of major health crises	Assessment of events that may constitute a public health emergency	Continuous update of the operational picture on all levels concerned					
			Easy access to IHR communication procedure					
			Questionnaire electronically handled and visible to IHR contact point & ECDC					

PULSE System Effects

Participant Category: Player/Actor | Observer | Consortium

SARS Trial – UC4: Community New Probable Case

FUNCTION	AIM	OBJECTIVE	EVALUATION	Poor	Average	Good	Excellent	Final Comment
Confirmation of new cases	Instant determination and verification of the epidemic situation	Reduction of time and error rate in filling and handling forms & documents	Electronic filling of alert form creating probable new case					Most missing or criticisable:
			Electronic filling of diagnosis form confirming a new case					
			Electronic sending of forms to national authorities					
Notification of medical authorities	Continued alerting & action	Providing reliable information and visibility to the appropriate responder entities and medical facilities	Immediate identification & selection of the optimal medical facility					Most advantageous finding :
			Fast allocation of patients to hospitals with disease and treatment specific capabilities					
Operational picture	Efficient management of major health crises	Assessment of events that may constitute a public health emergency	Continuous update of the operational picture on all levels concerned					General Summary:
			Easy access to IHR communication procedure					
			Questionnaire electronically handled and visible to IHR contact point & ECDC					

PULSE System Effects

Participant Category: Player/Actor | Observer | Consortium

SARS Trial – UC5: Medical Resources Assessment

FUNCTION	AIM	OBJECTIVE	EVALUATION	Poor	Average	Good	Excellent	Final Comment
Medical resources assessment	National level assessment on disease related medical resources	Description of current status and identification of shortages and deficiencies	Immediate access to resources data & information of medical facilities concerned					Most missing or criticisable:
			Continuous up-dating on hospital resources status					
Medical resources management	Availability of adequate medical resources & stocks	Collection of data for the calculation and forecasting of medical treatment against the most probable epidemic evolution and provision of suggestions to overcome potential deficiencies and shortages	Consideration of the epidemic evolution vs. re-assessment solutions of hospital resources					Most advantagdous fini rg :
			Effective & reliable forecasting of medical resources requirements					
			Suggestions for best distribution or re-distribution of medical resources/stocks					General Summary:
			Suggestions for acquisition or otherwise obtainment of medical resources					
Operational picture	Efficient management of major health crises	Continuous information on logistic status & measures taken to effectively control the epidemic	Continuous update of the operational picture on all levels concerned					
			Instant & direct communication with national authorities on the status of resources and stocks					

PULSE System Effects

Participant Category: Player/Actor | Observer | Consortium

SARS Trial – UC6: ECDC Recommendations

FUNCTION	AIM	OBJECTIVE	EVALUATION	Poor	Average	Good	Excellent	Final Comment
European rapid risk assessment	Up-to-date epidemic overview	Support of nations potentially affected in the course of the pandemic	Graphical overview of disease cases in Europe & potential epidemiological spread					Most missing or criticisable:
			Provision of particular virological data					Most advantagdous fini ng :
European counter measures	Collective European approach	Issuance of focused guidelines & recommendations	Creation & suggestions of disease-specific recommendations & guidelines					
			Electronically supported distribution of the ECDC communication protocol					General Summary:
			Ease of access of national authorities to ECDC guidelines & recommendations					

PULSE System Effects

Participant Category: Player/Actor | Observer | Consortium

SARS Trial – UC7: National Authority Periodic Assessment

FUNCTION	AIM	OBJECTIVE	EVALUATION	Poor	Average	Good	Excellent	Final Comment
Actual epidemic evolution	National level periodic assessment	Better govern the epidemic and more effectively control its course	Continuously up-dated trend on the epidemic evolution & review of hospital's resources					Most missing or criticisable:
			Instant suggestions for major procurements & delivery in specific risk zones					
			Quick & seamless contact to AIFA for procurement & delivery in risk zones					Most advantageous finding:
			Immediate alert to hospitals regarding delivery of medical resources					
			Focused reconsideration of plans & decisions taken according to epidemic evolution					General Summary:
Public awareness	Public support	Pro-active information of the public and communication for the media & social networks	Suggestion of templates for information & communication purposes					
			Direct access to a list of confirmed spokes persons and authorized talking points					

PULSE System Effects

Participant Category: Player/Actor | Observer | Consortium

SARS Trial – UC8: National Level Post Emergency Learning

FUNCTION	AIM	OBJECTIVE	EVALUATION	Poor	Average	Good	Excellent	Final Comment
Post pandemic actions	Orchestration of the national level learning process	Identification of experts and actors involved and collection of lessons identified	Access to the documentation of experts & individuals having managed the pandemic					Most missing or criticisable:
			Allocation of experts having dealt with certain specific aspects of the pandemic					Most advantageous findings:
			Allocation of experts associated to specific pandemic phases, problems or decisions					
Post pandemic evaluation	Execution of the national level learning process	Coordination and conduct of joint analysis forums and mutual exchange of expert knowledge	Ease of access to & retrieval of data & information stored during the crisis					General Summary:
			User-friendly data-mining application for quantitative and qualitative evaluation support					
			Provides the basis of a common pandemic evaluation framework across Europe					

MCI Trial

PULSE System Effects

Participant Category: Player/Actor | Observer | Consortium

STADIUM Trial – UC1: Scoring System in the Event Medical Preparation Phase

FUNCTION	AIM	OBJECTIVE	EVALUATION	Poor	Average	Good	Excellent	Final Comment
Event characteristics & risks	Definition & monitoring of risk categories	Constant scoring of: - geographic area - urban characteristics - medical response facilities - event characteristics & dynamics - audience profiles & characteristics - additional hazards	Completeness of scoring categories					Most missing or criticisable: Most advantageous finding: General Summary:
			Weighing factors of individual scores					
			Handling of check boxes and outline tool					
			User review of the running score					
Threshold definition	Identification of changing summary scores	Automatically crossing a pre-set tripwire triggers alert and/or notification routines	Continuous up-dating of scores					
Alerting	Adequate response to escalating risks & hazards	Tuning of crisis management and medical response to changed conditions and activation of surge capacity generation procedures	Visualization & distribution of cascading alert levels					
			Depiction of medical resources & responder status based on current summary score					
Event medical plans	Coordination of event-related preparations	Development & confirmation of the site-specific medical cover allocated	Automated system for the efficient handling and constant review of the medical resources					

PULSE System Effects

Participant Category: Player/Actor | Observer | Consortium

STADIUM Trial – UC2: Use of MPORG Simulation

FUNCTION	AIM	OBJECTIVE	EVALUATION	Poor	Average	Good	Excellent	Final Comment
Simulation	Creation of an emergency simulation & training platform	Integration of: - Roles - Health impacts - Medical responses - Multiple response levels - Scenario evolutions - Feedbacks and re-runs	Choice of roles & creation of avatars					Most missing or criticisable: Most advantageous finding: General Summary:
			Simulation of injuries & health impacts					
			Selection of medical responses & therapy applicable					
			Selection of medical facilities to be transported to					
			Simulation of media / TV programs					
			Range of decision makers applicable					
Training	Training for decision makers and professional experts and access to a training learning management system	Enhancement of skills & processes in emergency management environments and health services Management of triage, single victims and health care resources	Real-time updates on scenario & resource evolvement					
			Multiple training options and tracking of training elements and units					
			Assignment of training courses					
			Multiple victim categories and evolution of patient health status'					
			Feedback to improve decision making capability					
Decision Making	Management of health care resources	Training of decision makers to respond appropriately under pressure	Real-time updates and tracking of decisions taken					
			Automated comparison of decisions taken with optimised solutions					

PULSE System Effects

Participant Category: Player/Actor | Observer | Consortium

STADIUM Trial – UC3: Mobilization of additional resources

FUNCTION	AIM	OBJECTIVE	EVALUATION	Poor	Average	Good	Excellent	Final Comment
Smartphone application	Real-time management of response resources	On- and off-site management of pre-arranged as well as additionally mobilised resources and unsolicited response offers	Graphic & tabular display					Most missing or criticisable: Most advantageous finding: General Summary:
			Drop-down menu functionality & selection of options					
			Handling of the smartphone app under response conditions					
Data base	Continuous on-line & on-site processing of the response data base	Effective and efficient population and modification of the data base, and ease of application of data base information for managing resources	Capturing data & access to data base					
			Ability for on-line registration of additional resources					
			Cross-matching of actual resources against original response data base entries					
Tracking & Up-dating	Real-time management of response resources	Establishment & maintenance of a common picture on resource allocation and the requirements process	Tracking of individual smartphone locations/positions					
			Initiation of general requests by broadcast & social media					
Tasking & status reporting	Real-time management of response resources	Maintenance of a common picture on resource allocation and tasking	Status of available and committed resources					
			Assignment of resources to specific tasks					
			Issuance of instructions via the smartphone app and feeding back status reports					

PULSE System Effects

STADIUM Trial – UC4:
Hospital Surge Capacity & Bed Management

Participant Category: Player/Actor | Observer | Consortium

FUNCTION	AIM	OBJECTIVE	EVALUATION	Poor	Average	Good	Excellent	Final Comment
Triage status	Capturing of on-site triage information	Real-time picture of triage information and advanced warning of potential bed capacity	Photographic evidence & bar-coding information					Most missing or criticisable:
			Matching patient condition with bed type availability					
			Use of instruction matrix application on the smartphone					Most advantagdous fini rg :
Bed status	Real-time management of medical resources	Status of current resource availability by bed definition leading to informed decisions on patient transport	Capturing & storage of current resources at different levels					
			Simultaneous access to current resource information levels					General Summary:
			Display of resources at different levels					
Surge capacity generation	Real-time improvement of patient care	Reliable & expeditious estimate of requirements and immediate generation of additional capacities	Definition of surge capacity resources					
			Common capacity picture at different levels					
			Report on the level of discontinuity of requirements and availability					

PULSE System Effects

STADIUM Trial – UC5:
Triage in CCS and links to ePCR

Participant Category: Player/Actor | Observer | Consortium

FUNCTION	AIM	OBJECTIVE	EVALUATION	Poor	Average	Good	Excellent	Final Comment
Triage data	Management of patients	Current individual patient triage status	Real-time mobile capture of triage data					Most missing or criticisable:
			Transmission of triage data to a central storage repository					
			Triage data entry into the smartphone application					Most advantagdous finiᵲg :
Triage report	Real-time management of patients	Graphical and tabular report on current casualty status of identified patients	Automated presentation of consolidated triage data					
			Automatically available for distribution					General Summary:
Casualty board data	Real-time management of patients	Graphical and tabular summary of the current casualty status	Presentation of consolidated data at appropriate levels					
			Availability of data & summary in graphical & tabular format in near real time					

PULSE System Effects

STADIUM Trial – UC6:
Input critical data for the RCS

Participant Category: Player/Actor | Observer | Consortium

FUNCTION	AIM	OBJECTIVE	EVALUATION	Poor	Average	Good	Excellent	Final Comment
Critical data input	Common framework for identifying critical data	Identifying critical data from - On-site co-ordinators - Ambulance mobilisation and dispatch services - Regional authorities	Collation and display of current critical data from on-site co-ordinator					Most missing or criticisable: Most advantageous finding :
			Collation and display of current critical data from ambulance mobilisation & dispatch services					
			Collation and display of current critical data from regional authorities					
			Use of geo-referenced information					
RCS grading & up-dating	Systemisation, classification & storage of information	Provision & maintenance of a current RCS from - On-site co-ordinators - Ambulance mobilisation and dispatch services - Regional authorities	Continuously up-dated status of the on-site RCS					General Summary:
			Continuously up-dated status of the RCS to the ambulance mobilisation & dispatch services					
			Continuously up-dated status of the RCS to the regional authorities					
			Decision support to on-site co-ordinators and commanders					

PULSE System Effects

STADIUM Trial – UC7: Post-event Evaluation

Participant Category: Player/Actor | Observer | Consortium

FUNCTION	AIM	OBJECTIVE	EVALUATION	Poor	Average	Good	Excellent	Final Comment
Actors	Collation of evaluation information	Actors involved with decision making roles identified and invited to take part in the evaluation	Complete list of names of actors involved					Most missing or criticisable:
			Rapid access to actors' data					
			Automated invitation to actors identified					Most advantagdous fini rg :
Questionnaire	Collation of evaluation information	On-line provision of file d-in questionnaires	On-line filling of the questionnaire					
			Usefulness of the smartphone application					General Summary:
Report	Lessons-Learned report	Elaboration & prompt completion of the lessons-learned report	Analysis & storage of questionnaire information					
			Storage of the report and constant access to information stored					
			Diffusion of knowledge to take into account lessons learned for future events					

PULSE System Effects

Participant Category: Player/Actor | Observer | Consortium

STADIUM Trial – UC8: Casualty Bureau Operation

FUNCTION	AIM	OBJECTIVE	EVALUATION	Poor	Average	Good	Excellent	Final Comment
Data capture	Capturing data for the creation of unique entries	Creation of a unique casualty or missing individual entry from: - The general public - The police at local, regional, national or international level	On-line single point entry during major emergencies					Most missing or criticisable: Most advantagdous fini ng : General Summary:
			Collation of data of single point entries					
Data display	Real-time management of police information	Real-time picture of data provided from police authorities at local, regional, national, and international level	Automatic generation of a current overview in the casualty bureau					
			Identification of matching entries and offering suggestions					
			Display and detail of the current overview					

ANNEX 6 - PULSE TRIALS PERFORMANCE MEASURES

Measures of performance summary

Table 11: MoP and Evaluators

	Category	Description	Question		Criteria	PULSE tool developer	Player/Actor	Observer
1	**Efficiency**	Regarding the human-computer interaction in PULSE, in a complex and complete system set-up, efficiency includes: the optimization of speed, and transparency and ease of access for end users while using the system.	**How do you asses the following characteristics of human-computer interaction in PULSE?**	1,1	timeliness and effects caused by the system operation		x	x
				1,2	transparency and ease of access to system's resources (user friendly)		x	x
2	**Flexibility**	Characterized by the capabilities of the present system to adapt to new, different, or changing situations and requirements, e.g. various scenario types, different frameworks of health organizations etc.	**How do you evaluate the PULSE system's capability to adapt to new, different or changing situations and requirements?**	2,1	PULSE system's adaptability to new or changing situations and requirements	x	x	x
3	**Dependability**	Addresses the attributes of system maturity, readiness and continuity of service, absence of malfunctions and ability to undergo modifications identified to be necessary to improve dependability.	**How do you asses PULSE system's maturity and fiability ?**	3,1	the PULSE system maturity and its readiness for operation	x	x	x
				3,2	continuity of the service without malfunctions/ blocking errors	x	x	x
				3,3	ability to undergo modifications for dependability improvements	x		
4	**Scalability**	Ability for diverse end-users, agencies, organizations to share and use PULSE, to enhance it by adding new functionalities or address hazards in scenarios other than the demonstrated ones, to maintain performance regardless of expansion from a local area to a larger geographic pattern, to easily manage and expand the resource pool (number, type, location and categories of enroled ambulances, hospitals etc), and to scale up to comply with new generations of hard- and software components.	**How do you evaluate the PULSE system's scalability ?**	4,1	ability to fit to different organizations/ agencies requirements		x	x
				4,2	ability to be enhanced by adding new functionalities or to address new hazards	x	x	x
				4,3	maintain performance regardless of expansion from a local area to a larger geographic area	x	x	x
				4,4	easily manage and expand the system's resource pool (number and categories of enroled ambulances, hospitals etc)		x	x
				4,5	scale up to comply with new generations of hard- and software components	x		
5	**Interoperability**	System interfaces working with other products or systems, present or future; depending on common definitions, common information exchange models, and cross-domain capability (e.g. to police systems).	**How do you evaluate the PULSE capability to be interfaced with other products or systems?**	5,1	the PULSE's definitions are similar or same compared to other known systems (which are those systems?)	x	x	x
				5,2	the PULSE's information exchange model is suitable for interconnection with similar systems		x	x
				5,3	overall PULSE cross-domain interfacing capability		x	x
6	**Extensibility**	Understood as a system design based on broad generalized features and interoperability, which facilitates transfer and adaption to other crisis management domains and different national or international organizational and technical frameworks.	**How do you evaluate PULSE capability to be extended?**	6,1	transferability and adaptability to other crisis management domains		x	x
				6,2	transferability and adaptability to different national or international organizational and technical frameworks		x	x
7	**Usability**	Ease of learning, understanding and applying/ using the system for exploiting its potential. This could be measured in terms of required skills, time and effort to get familiar to the system and to adapt to new situations, from a user perspective.	**How do you asses the PULSE's ease of learning, understanding and usability?**	7,1	estimated time and effort necessary to learn and understand PULSE system		x	x
				7,2	Ergonomy and ease of handling the system	x	x	
				7,3	ability to addopt and use PULSE system in new operational end-user situations		x	x

PULSE System Characteristics Evaluation Templates

The Pulse System characteristics evaluation will be done by external stakeholders and by PULSE consortium members in pre-structured questionnaires. The questionnaires will be the same for both scenarios.

The questionnaire will allow the evaluation of each performance category (as presented into D7.1 Chapter 7.3) against the operational guidelines as described in D5.2 Chapter 4.

Each performance category will be assigned at least one evaluation criteria; the respondents will answer to each criteria on a scale from 1 to 4: Poor(1), Average (2), Good(3), Excellent(4). Furthermore, the respondent will have the possibility to add comments and recommendations to each evaluated performance category.

The performance categories (and their associated criteria) will be assigned to relevant type of respondent: external stakeholder (observer or actor/player) and/or PULSE tool developer.

The external stakeholder questionnaire will cover also the summary evaluation of the overall quality of the PULSE project and of the experiments' setup and execution.

ANNEX 7 - PULSE TRIALS EELPS IMPACT (Ethical, Economic, Legal-Political, Societal) MEASURES[10]

Introduction

This document proposes a qualitative criteria assessment methodology (herein referred to as the EELPS methodology), based on learning from other EU security research projects and work in WP5 (Methodology) of PULSE. This is designed to support the work in the WP8 of the PULSE project – i.e. to facilitate and explore the impact of the overall PULSE system on and in society. This document will also be useful for analysing the societal impacts of other existing and future systems that are similar to PULSE (and particularly those related to public health emergency preparedness and response. This work is supported by CESS via its contributions from WP5 (Methodology) and to WP7 (Trials Validation) of PULSE.

Aim of the EELPS methodology

The aims of the EELPS methodology are to assist in determining the ethical, economic, legal-political and societal impacts of the PULSE system. This assessment methodology is intended to be used at two levels (a) with participants at the PULSE trial exercises (b) as a guidance for future commissioners or end users of the PULSE or of PULSE-like systems.

Development of the methodology and the criteria

The EELPS methodology developed and outlined here is based on a similar, useful methodology developed in the ECOSSIAN[11] and the CIRAS[12] project which aim to develop a complex ICT system for the improvement of CIP13 across EUROPE, and Risk Analysis tools, respectively. Although those projects address a security sector (CIP) that is different from PULSE, they are critical infrastructure security projects that have ethical, economic, legal-political, and societal effects that need to be adequately examined. This is essential to maximise the positive social benefits of security research and development and minimise negative effects. The ECOSSIAN methdology has its roots in the FP7 projects ValueSec (http://www.valuesec.eu).

While the PULSE requirements concerning privacy, data protection, legal framework etc.might be different from those in classical infrastructures such as transportation or energy, the metholdogy and criteria proposed here provide a good means to help evaluate the ethical, economic, legal-political and societal effects of PULSE (or PULSE-like systems and projects). The EELPS methdology in PULSE will comprise:

- A criteria catalogue specifically relevant to PULSE (based on the results and discussions of PULSE work packages 5, 7 and 8, and our discussions with PULSE stakeholders)
- A digital tool supporting such assessmenr in EXCEL and in more sophisticated, in Java, running on a partner's server

[10] a Collaborative venture between PULSE WP5/WP7 and WP8
[11] http://ecossian.eu
[12] http://www.cirasproject.eu
[13] Critical Infrastructure Protection

- A guidance on how to set up and execute quality EELPS evaluations

Value of the methodology for PULSE as a security measure

The PULSE project is an FP7 security research project and the PULSE system is designed under that mandate. The PULSE system may considered to be a rather complex and sophisticated "Security Measure" (SM).

The field of security measures is extremely diverse. Measures to improve security include: legislation, security policies, strengthening of law enforcement and of first responders, international agreements, improving preparedness by training and exercising, adapting organizations, and improving underlying disaster and crisis management processes, introducing new surveillance, hardening or recovery technologies, security alerts, surveillance of people and assets etc.

The need to improve security presents challenging possibilities in terms of vulnerabilities, threats, risks and impacts. The impacts of security measures may be: ethical, economic, legal, political or societal. The impacts could be positive or negative. The perception and acceptability of these measures are also relevant.

Drivers for security measures

The project ValueSec, in the years 2012 to 2014 [2] developed a general methodology for the assessment of security measures which was thought to become a certain standard or at least a guideline for the EU.

Although the spectrum of scenarios of planning and implementing possible security measures (SM)[14] is highly versatile, the ValueSec project assumed one underlying model which describes the three main drivers of planning and deciding on security measures:

- The need to improve security, mainly by avoiding or reducing risks of damages and consequences,
- The cost involved, both, investments for implementation and operation as well as possible savings.
- A huge number of societal and political factors which are widely intangible in the sense that we cannot directly translate them into monetary or physical terms.

These drivers apply principally to all major security measures, including those of improving healthcare.

The following figure summarises the factors influencing security decisions.

[14] This term is used here for measures planned and implemented for improving preparedness and response capabilities. I does not include operational decisions in a "real" or simulated scenario

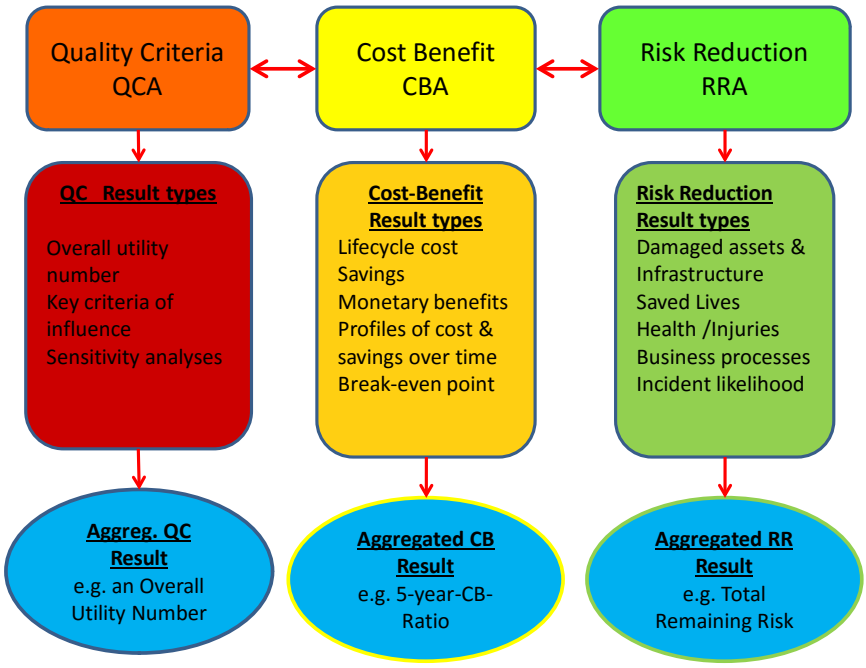


Figure 6: Decision Analysis of security measures[15]

Risk reduction is the reduction of damages and/or the reduction of the probability of an adverse event from happening. **Cost** relates to the cost for planning, preparation and procurement plus the operational, maintenance and consequential cost. Often also cost of measures for system enhancement and disposal during the life cycle of the system need to be regarded. Risk Reduction Assessment (RRA) and Cost-Benfit-Assessment (CBA) have since long been addressed by sound research and covered by known analytical methodologies and supporting econometric tools. The EELPS for PULSE is based on the first pillar, the so called QCA[16].

The role and importance of QCA methods for impact assessment

Qualitative Criteria Assessment (QCA) methods for impact assessment have been around since long [5] (pg.7 "... ever since its origins in the late 1960's...) . But they are often neglected by planners, policy makers, researchers, or treated divergently (and even unprofessionally) by users. Some factors that account for this include: lack of willingness to use these methods and to open up to such assessments, lack of training to opitmise the use of such knowledge, hidden political and organisational agendas, complexity of legal restrictions, ignorance of the vulnerabilities, threats, risks and impacts, costs of such assessments, availability of easy techniques to facilitate the systematic application of such assessments.

Though the public discussion about security measures often shows that ethical, economic, legal and political impacts (often of intangible nature) of security measures are important, they are not adequately considered via systematic assessment in the decision making process during the design, development and implementation of security measures. This leads to security decisions which are suboptimal to say the least. Often they turn out to be obsolete after a short time and the real drivers of the

[15] From ValueSec; modified for PULSE
[16] The version for PULSE is named EELPS

decisions made remain unclear and are not made transparent.

In the EU, there is, however, growing support for holistically assessing the impacts of security research. This has been evident in the case of FP7 projects such as PULSE, ECOSSIAN, and CIRAS, all containing work packages on methods and tools for assessing the societal, ethical, legal etc. factors of security measures. “Societal impact” is included as a category to be to addressed in Horizon 2020 research proposals. H2020[17] also explicitly and generally emphasises stronger inclusion of **societal actors and factors** in its projects.

In the domain of CIP and Healthcare, a QCA could help assess e.g.

- The type of societal reactions a new measure could provoke (e.g. outright rejection, protests, acceptance)
- Whether the measure would fit into, or fall foul of an existing legal framework (e.g. a country's constitution, or human rights legislation)
- Whether the measure complies with, or supports national and the EU strategies in security, technology leadership, market exploitation
- Whether the measure would promote the technological and/or scientific ambitions in the country and the EU
- Whether the measure would support or hamper the establishment of public-private partnerships (PPP) and other cooperation concepts?

The above are only a few examples and in practice, there are a number of relevant questions that could be broken down into a number of driving qualitative criteria.

The benefits of using QCA methods

As stated before, the systematic treatment of the "intangible" effects of security measures is complex and varies per use case. Treating qualitative factors can lead to endless discussions and frustrating unsolved contradictions. This can drastically be mitigated if QCA methods and tools were available and became common and accepted in security planning, procurement, operation and administration.

When it comes to supporting tools, the qualitative assessment process needs to translate qualitative factors into pseudo-quantities such as rankings, weightings, scorings, relative importance between criteria etc. Although these processes to some extent can be arbitrary and subjectively biased, they inherently offer a number of benefits:

- The methodology facilitates a systematic structuring of the problem, by individuals or within a group.
- The methodology facilitates consensus building on the problem, its structure, and the basic questions to be answered, within a group, particularly when members have different objectives and preferences.

[17] http://ec.europa.eu/programmes/horizon2020/en/h2020-section/ethics

- The evaluation process and related discussions create awareness of how important societal, political etc. factors really are.
- Once consensus is reached on the methodology and problem structure, e.g. in a group of diverging interests or opinions, the chances of reaching agreement on the assessment results, and on the security measure itself substantially increase.
- The consensus is based on a tedious, but transparent selection of, finally agreed and jointly assessed criteria. After that, there is, in principle no further need for debating the final outcome
- The outcome of the process is transparent[18] and the process can be repeated if needed for justification or if doubts later arise (similar as with brainstorming results)

These benefits have been proven and appreciated in a large variety of management processes and decisions, in social science and psychology. In the field of security, however, we are at infancy in exploiting QCA methods – and this proposal goes some way in supporting that process.

Challenges and obstacles in using QCA methods

By definition, qualitative factors are, firstly, not directly expressible in numbers. They don't have quantifiable physical or economical dimensions or attributes such as loss numbers, fatalities, saved property or reliability of business processes. Qualitative factors relate to human perception, ethical impact, political correctness or adequacy, human rights impacts (e.g. on civil liberties, data protection) etc. Qualitative factors of influence have some characteristics which complicate or sometimes do not lend themselves well to systematic evaluation. Examples include criteria as subjective security feeling of people, or hidden agendas of politicians. E.g they are often badly defined, vaguely understood and give room for interpretations and bias.

A successful QCA approach, therefore, requires a number of thorough analyses and preparatory steps and agreement within the community that will perform the assessments. The following is essential:

- Clear definition of the hierarchy of criteria
- Clear definition of the terms and criteria to be used
- Understanding of inter-dependencies between criteria
- Clear description and wherever possible, avoidance of overlaps and redundancies in the criteria to be applied
- Agreement on the weighting schemes
- Understanding of, and agreement on the utility functions (see e.g. [5], capter 4.3 ff.)

If a decision is supposed to be supported and carried by different individuals or organizations, it requires a common understanding of the methodology, the evaluation process and agreement on the role and importance of the decision support. Otherwise, separate independent evaluation rounds may help.

[18] There are, however, decision processes and decision makers who prefer confidentiality and concealment over transparency.

Developing the QCA for PULSE, and its proposed use

The development and finalisation of the criteria have undergone many iterations based on discussions with consortium partners of WP5 and WP8 within PULSE itself, and has been based and cross checked with a number of sources:

(a) VALUESEC, ECCOSIAN, SURPRISE
(b) ASSERT criteria
(c) Deliverable 8.1 of PULSE
(d) Heuristic table of ethical principles, risks, and impacts developed for Deliverable 8.2 of PULSE.
(e) Horizon 2020 Societal Impact Table

The QCA criteria catalogue will form the basis of a questionnaire that will be circulated to the participants at the two PULSE trial exercises in Cork (Ireland) and Rome (Italy). The results will feed into Deliverable D7.3 and D8.2. Trial participants will be provided a questionnaire based on the criteria catalogue and will be asked to complete and return it to the consortium (trial organisers). The LEPPI[19] team will collate the responses and analyse them to support the work in WP8.

Innovation and future relevance

The evaluation of the PULSE platform and technologies will elaborate the effects and benefits produced in two simulated sample scenarios, a SARS-type pandemic originating in Italy and a major stadium crush event occurring in Ireland. The effects will be measured in terms of specified measures of effectiveness and performance, and will be "benchmarked" against the situation as-is, without PULSE. Evaluating the PULSE platform against ethical, economic, societal, legal etc. criteria implies that evaluatior always compare to the existing situation..

Applying the EELPS approach and methodology in security is rather innovative as it offers a systematic identification, definition, review and evaluation of the numerous socio-political criteria relevant for planning of and deciding upon security measures, particularly in systems such as or similar to PULSE. The underlying methodology is basically state of the art. The innovation also lies in the fact that methods and criteria have been specifically developed for the security domain and adapted to the evaluation of a complex system, the PULSE platform. They form a baseline for different types of security decisions and can be adapted to various different domain types such as new legislation, public surveillance, healthcare, critical infrastructure protection and more.

The EELPS criteria

The criteria presented here may have varying meanings and importance depending on the subject of evaluation. For example, the protection of personal data in a system for improving healthcare in cases of pandemics, has characteristics which are different from that of personal data protection evidenced in domestic smart energy systems.

This section discusses the tentative qualitative criteria with respect to their characteristics and features they might show in PULSE.

Societal criteria have two dimensions. They may (a) describe how a system (such as the PULSE platform) may impact society and individuals, and (b) show how society,

[19] Legal Ethical, Privacy and Policy Issues

societal groups or individuals will perceive and evaluate such a system. The scales may vary from positive (welcome, appreciation,) to negative (fear, rejection, protests) reactions. The need, relevance and expected effects related to the criteria discussed, may in certain cases (e.g. for ethical or legal issues) be perceived differently by different stakeholders, by individuals, by social groups, by IT systems providers and operators or by politicians.

98 criteria developed in the ValueSec project were taken as a starting point [6][20] for selecting those that might be relevant for systems like PULSE. However, we have also used other relevant projects and societal impact sources (as outlined below). These sources were analysed and reviewed for applicable criteria. The criteria developed in this document for PULSE also underwent several rounds of discussion as part of WP8.

The grouping of the criteria into the EELPS categories and the individual criteria are tentative and can be adapted, if changes are required and in further iterations, or during the final evaluation. The categories and criteria descriptions listed in the table below are those which have been collaboratively determined as relevant for systems like PULSE. However, they could also be adapted to other types of systems. There could also be other criteria that might need to be included depending on the context.

The interpretation of the criteria below and of their possible benefits and shortfalls assumes a future situation when the PULSE System would be implemented in Europe. Models of how many health organisations and nations would participate, and the role of the EU in implementation and operation of such a system will be exemplified in PULSE work package 7 trial scenarios.

The Criteria are grouped into the following categories:

1. Ethical Criteria
2. Economic Criteria
3. Legal and Political Criteria
4. Societal Criteria

The questions are framed using the term “measure” for the PULSE platform, rather than “security measure” as PULSE might not be viewed by all external stakeholders as exclusively a “security measure”.

[20] VS D5.3. The detailed catalogue is not in a public deliverable. However, it has been made available to the PULSE project.