

TRILLIUM II

Reinforcing the Bridges and Scaling up EU/US Cooperation on Patient Summary

WP6

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Deliverable description

Number and name of deliverable:	D6.2 v2019-06-28 Establishing the value case for the international patient summary: indicators and results-WP6-empirica				
Publishable summary:	<p>The deliverable utilises a benefit matrix to frame the value case for an IPS, primarily, using the results of an evaluation of its added-value in the context of an Emergency and Disaster Management use case. The results of that evaluation show that the value for an International Patient Summary is very situational and requires up-to-date information. The different values cannot be realised in every disaster situation, at every disaster intervention team or for every (type of) patient. In a real disaster situation, the presence of an IPS significantly increases physicians' confidence to deliver better and safer care to patients, especially when a solid base for communication cannot be established. Improved quality of care and better care decisions through IPS use have been observed and verified through interviews in several situations where physicians lacked univocal patient information. An International Patient Summary helps allocating limited resources, such as vaccines and medications, more effectively.</p> <p>However, there certainly is a value case for the IPS beyond the context of Emergency and Disaster Management. As interviews with medical and non-medical disaster professionals showed, IPS-like solutions with patient identification information and emergency contact details would prove highly useful in unscheduled emergency care and also help in bridging an otherwise largely fragmented chronic patient care environment.</p> <p>What the evaluation could not bring forward were solid data on patient/victim satisfaction with and perceptions on the IPS. The "patients" in the disaster exercises were played by role-players and often had a medical background. However, interviews with both professionals and role-players indicated a high acceptance of the design of both IPS-like health apps which were used by Trillium-II during the exercises.</p>				
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Lead beneficiary:	empirica				
Contact:	Rainer Thiel, Rainer.Thiel@empirica.com				
Contributors:	Rainer Thiel, Lucas Deimel, Daniel Schmidtman, Veli Stroetmann				
Editors:	Marcello Melgara (Lispa), Dipak Kalra (i~HD)				

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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0.1	23.01.2018	Daniel Schmidtman	empirica	First outline and content of the document, including a first draft for a benefit matrix based on desk research and several new sections
0.2	02.06.2018	Daniel Schmidtman	empirica	Description of Patient Summary Use case scenarios
0.3	14.02.2019	Lucas Deimel	empirica	New sections on the disaster exercises and updated benefit matrix
0.4	16.05.2019	Lucas Deimel	empirica	Updated structure and Evaluation chapter
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Deliverable overview

Objectives

As stated in the DoA, this Deliverable establishes a qualitative value assessment framework for pilot demonstration that have been applied in several activities throughout the WP (i.e. IPS demonstration in Rennes, 2019). Indicators related to value realisation of patient-centered scenarios and selected use cases are specified in the shape of a Patient Summary benefit matrix which substantially builds upon previous efforts to assess the impact and added value of eHealth interoperability. It provides the framework to assess and quality assure progress in WP2 and WP3 in the context of the disaster exercises.

Content

The value assessment framework is provided in chapter 3.2 and reflects the structure and procedure of both evaluations in Romania and Estonia and also has been applied to other IPS demonstrations. The Patient Summary benefit matrix in chapter 1 forms the basis for the IPS value assessment and evaluation. Chapter 2 briefly sets out the use cases to be looked at and chapter 3 covers the actual evaluation and value assessment which is then summarised in chapter 4.

Deviations

The objectives of the task were realised and the report submitted on time.

Executive summary

This deliverable summarises and partly builds upon the work of preceding activities in T6.1 (to set up and run the Trillium II pilots) and T6.2 (to build the community of Practice), and the deliverables in WP4 and WP3. T4.3 has summarised examples of potential benefits for different stakeholders that would result from a large-scale implementation of an International Patient Summary (IPS). Based on these findings, a benefit matrix has been established which forms the framework for the main task of this deliverable: establishing the value case for an IPS and evaluating its added-value in the context of an Emergency and Disaster Management use case.

As already set out in the proposal, Trillium-II anticipated participation in an European Medical Disaster Exercise and successfully established links to the EU MODEX consortium, which conducts exercises for Civil Protection Modules and other Response Capacities throughout Europe bringing together hundreds of professionals and volunteers committed to strengthen the EU Civil Protection Capacities in the context of the European Civil Protection Mechanism.

The deliverable commences with an updated list of benefit indicators based on previous works and then presents the three use cases that were covered thematically by the evaluation undertaken during two Modular Exercises in Romania and Estonia or where knowledge could be transferred to.

It follows the main work of this deliverable: evaluation framework and methods and the evaluation itself, which comprises three parts: interview data & observations, IPS impact areas and transferable knowledge to other use cases.

The results show that the value for an International Patient Summary is very situational and requires up-to-date information. The different values cannot be realised in every disaster situation, at every disaster intervention team or for every (type of) patient. In a real disaster situation, the presence of an IPS significantly increases physicians' confidence to deliver better and safer care to patients, especially when a solid base for communication cannot be established. Improved quality of care and better care decisions through IPS use have been observed and verified through interviews in several situations where physicians lacked univocal patient information. An International Patient Summary helps allocating limited resources, such as vaccines and medications, more effectively.

However, there certainly is a value case for the IPS beyond the context of Emergency and Disaster Management. As interviews with medical and non-medical disaster professionals showed, IPS-like solutions with patient identification information and emergency contact details would prove highly useful in unscheduled emergency care and also help in bridging an otherwise largely fragmented chronic patient care environment.

What the evaluation could not bring forward were solid data on patient/victim satisfaction with and perceptions on the IPS. The "patients" in the disaster exercises were played by role-players and often had a medical background. However, interviews with both professionals and role-players indicated a high acceptance of the design of both IPS-like health apps which were used by Trillium-II during the exercises.

Introduction

Trillium-II aims at advancing global Electronic Health Record (EHR) interoperability. Activities surrounding the International Patient Summary (IPS) standards can nurture digital health innovation, lower trade barriers, and advance patient safety & trust, bridging the gap between strategic intent and capability for action by Standards Development Organization (SDOs) striving for interoperability, quality, and safety through standards adoption. In this context, WP6's objectives are to:

- Test patient summary use cases including profiles for patient identification, authentication & query
- Demonstrate patient summary use cases with import/export capabilities
- Address security and privacy policies for IPS sharing in demonstrators and pilots
- Support pilots in communities of innovation to confirm validity and utility of patient summaries
- Join a disaster readiness exercise to demonstrate the value of the patient summary
- Evaluate testing, demonstrations, and pilots using a scalable impact assessment framework

As part of WP6 – Making it Real: Engaging with the practice of Digital Health Innovation, Deliverable 6.2 establishes the value case for the international patient summary. This deliverable forms the final version and addresses the tasks set out in T6.3 of the Descriptions of Actions.

The underlying task T6.3 develops indicators related to value realisation of patient-centred scenarios and the selected use cases and provide a framework to assess and quality assure progress in WP2 and WP3. The task builds upon current and previous efforts to assess the impact and added value of eHealth interoperability as stated in D4.2.

This task builds on the use case selection and prioritisation in D3.1 by providing an additional value assessment framework and methodology. Since the use cases have finally been selected, D6.2 explores and applies the indicators to one use case and assesses the IPS benefits. Specifically, for this Deliverable, a qualitative evaluation framework was developed to guide the evaluations conducted during two disaster exercises in Romania 2018 and Estonia 2019. As is shown, two more use cases show close ties to the main use case Emergency and Disaster Management and value-added to these use cases will also be looked at.

1. Framework and Patient Summary Benefits Matrix

Based on a literature review of the use of national and regional patient summaries, T4.3 and T6.3 has summarised examples of potential benefits for different stakeholders that could be expected from the use of an IPS across domain boundaries / providers / borders. This matrix has served as the conceptual framework for the evaluations reported in this deliverable.

Category	Benefit indicators (examples)
Productivity / Efficiency	<ul style="list-style-type: none"> • Faster and more effective care decisions • Time savings • Faster and more accurate triage • Shorter emergency visits • Reduced number of admissions • Reduced redundant (double) testing • Reduced follow-up treatments¹ • Support for clinical decisions • Better targeted resources • Reduced costs for cross-border medical interventions
Access (to care; data; market, etc.)	<ul style="list-style-type: none"> • Improved access and service <ul style="list-style-type: none"> - Reduced wait-time • Improved quality and access to data for research • Equitable care <ul style="list-style-type: none"> - Better care for patients with low health literacy - Better care for international patients • New business cases, new opportunities for apps and decision support
Quality and safety	<ul style="list-style-type: none"> • Improved patient health outcomes • Improved safety <ul style="list-style-type: none"> - Reduced harm - Reduced Adverse (Drug) Events - Improved medication identification and reconciliation • Improved population health outcomes
Patient experience	<ul style="list-style-type: none"> • Increased patient empowerment • Patient satisfaction • Patient confidence • Freedom of care • Supporting communication and interaction with care providers
Health and care professional experience	<ul style="list-style-type: none"> • Professional satisfaction • Professional confidence

Table 1: Patient summary benefit indicators

Stakeholders involved in /potentially impacted by digital health solutions:

- Patients
- Healthcare provider(s) (organisations)

¹ Follow-up treatments are medical encounters following a major treatment intervention to monitor results of an intervention (e.g. surgery) over a longer period or examine post-intervention conditions or even malpractices.

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- Health professionals
- Health authorities
- Public health organisations
- Insurers (and travel insurers for travelling patients)
- Pharmacists
- Informal carers
- Research communities
- eHealth service providers (supplier community)
- ICT industry
- Clinical research sponsors (e.g. the pharmaceutical industry)
- etc.

Examples for expected value propositions

- Patients: safer, faster and more effective care decisions
- Clinicians: faster and safer decision making, better outcomes
- Healthcare provider organisations: reduced admissions, shorter emergency visits, better outcomes
- Medical crisis intervention teams: faster and more accurate triage, better targeted resources
- Healthcare funders, health insurers, travel insurers: reduced cost from cross-border medical interventions, more confident travellers
- Health ICT sector: new business cases for procurements, new opportunities for apps and decision support for clinicians and for patients, growth of personal health market
- Research: a new data source for studies, especially as condition specific data are added downstream

2. Description of Patient Summary Use Case Scenarios

For linking the use case selection approach in D3.1 with the use case benefit matrix, in the following, the proposed list of use case is here replicated again. This list, however, focuses on the main four items most relevant to developing benefit indicators, and, eventually assessing them: challenge, stakeholders involved, value proposition, and actual use case summary in form a of a user story. The list also only features the three use cases that could be linked to the IPS added-value evaluation in the context of the primary use case being assessed in this deliverable: Emergency and Disaster Management.

2.1 Emergency and Disaster Management – Evacuation camp and Field Hospital

This is the main use case assessed in this deliverable. Trillium-II participated in two disaster medical exercises with Emergency Medical Teams and Field Hospitals. Yet, the exercises revealed potential value of an IPS not solely in the context of Emergency and Disaster Management.

Challenge Statement	In Emergency and disaster management we are trying to capture the summary information of a disaster patient – carrying over context information that may be available in advance. This information is essential both in its primary as well as in aggregated form.
Communities of Interest/Stakeholders	We do this for people that are stressed and for humanitarian missions that put themselves in danger to help fellow people. Information technology

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	can improve the value chain in disaster management – capturing important information.
Value statement	With high quality information available promptly the needs of disaster and evacuated people will be served timely and effectively with safety.
User Story	Consider a large scale disaster – like an earthquake, a flood or a “Chemical-Biological-Radiological-Nuclear” (CBRN) disaster. People are injured, misplaced, confused and in pain. Among them vulnerable groups like children or elderly. Can we identify them accurately and promptly respond to their needs? What if they have an up-to-date patient summary? Important actors for patient summaries are the European Civil Protection modules of Field Hospitals, Emergency Medical Teams (EMTs) and evacuation camps.

2.2 Patient summaries Continuity of care per chronic patients

Initiative Challenge Statement	Accessing and presenting the Patient Summary of the patient to all care providers (GPs, specialists, social care givers) having an encounter with the patient for acute problems (which could be across borders as well) or management of his existing chronic condition.
Stakeholders/Sponsors	Chronic Disease Management programmes within countries.
Value statement; What is the value proposition	All of the healthcare and social care providers involved in the management of the chronic conditions of the patient have the same most recent medical context of the patient. This is also valid for the healthcare provider who needs to manage acute conditions of the patients suffering with chronic conditions. This is very valuable and essential to detect and avoid drug-drug, drug-disease, disease-drug interactions, polypharmacy problems, and also duplicate and clashing treatment options for chronic disease patients.
User Story	An elderly patient suffering from diabetes visits his GP and the specialists such as nephrologists, dietician, and ophthalmologist regularly for yearly control visits or upon referral by his GP as a part of his care plan. At these visits, all parties involved in the care of the patient will have the same view of patient summary. When the patient is being supported by social care workers visiting elderly, they will also have the chance to access his most recent treatment plan including his active medications and allergies via his patient summary. When the patient suffers from a severe cold during his visit to his son and grandchildren, he has to be hospitalized for risk of pneumonia. His existing treatments, including treatment goals and, medications are seen by the healthcare professionals treating his acute conditions, and his medications have been adjusted accordingly.

2.3 Medical Ids – Extending In Case of Emergency (ICE)²

Challenge Statement	Provide critical medical information to paramedics in case of emergency.
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² https://en.wikipedia.org/wiki/In_Case_of_Emergency

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Communities of Interest/Stakeholders	In Case of Emergency (ICE) enables first responders, such as paramedics, fire fighters, and police officers, and hospital personnel, to contact the next of kin based on information on the phone of the patient.
Value statement	The ICE campaign started in May 2005 by Bob Brotchie of the East Anglia Ambulance Service in the UK. After iOS8, iPhone comes with a health app, which stores medical contacts as well as key medical data, including indication of being an organ donor. The information content is an extension of the patient summary as provided in IPS, which is not planned to contain these types of information.
User Story	1) Jo has a rare disease and would like to be able to use her phone for support when away from home. She set with her GP and filled in the Medical ID on her phone, she also included information of her doctor and family phones. An accident occurred that left her unconscious. The paramedics could use the phone to find critical information about Jo and her next of kin. 2) Mary is an android phone user; she also likes ICE and downloaded an app that functions as screen saver to her phone. 3) Suzan is a rare disease patient; she wears a bracelet with a QR code. A paramedic reading the QR code can access her patient summary online.

Policy environment <i>What are the relevant policy and regulatory issues?</i>	This use of the patient summary is completely under citizen control. The patient may request to download their data or seek support from their GP to complete the data on the phone, but the information listed on the phone or online typically under the owner's control.
Information <i>How health data records are captured, retained and conveyed in this business context?</i>	Typically, data is entered by the owner of the phone, who is responsible for the provided information. In more advanced interoperability cases we may assume that the patient requests to receive their patient summary in a well-known format and then uploads and imports the information to the phone.
Patient summary components <i>What are the relevant patient summary components? How are they constrained or extended? What are the data set requirements?</i>	Medications Allergies & Reactions Date of birth Medical Notes Medical Conditions Photo Organ Donor Emergency contact Blood type Weight Height
Provenance and timeliness <i>Where does the information come from? Who is responsible for it? How recent is it? What are the functional requirements?</i>	Provenance and timeliness are relevant when the medical information comes from trusted sources, possibly without the patient intervention (e.g. a formal patient summary provided by the GP, uploaded into the App. The information on data, author, etc. needs to be included. Noted however, that this functionality is not available in any of the apps we have considered.
Quality assurance <i>What are the quality</i>	The quality of the information depends on the source and may vary. There are no well accepted standards for that.

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<i>standards components are subject to?</i>	
Governance <i>How is the information governed?</i>	In the ICE case and its various extensions, the patient governs the information.
Risks – Security & Privacy <i>What are the privacy and security requirements – what are the safeguards?</i>	Well known security and privacy risk apply here.
Pilot projects and/or services <i>Who has implemented patient summaries for this situation?</i>	The basic service is available in different forms, with varied functionality, in all well-known app stores. It is native to the Apple iOS since v8.
Anticipated impact <i>How many people or organizations will be impacted?</i>	Digitization of medicine and adoption of a data mentality will change the current status.
Open Issues	Terminology licensing – use of standard terms – translation – integration to medical systems.
Anticipated interoperability maturity level <i>What is the anticipated level of interoperability today?</i>	The maturity level on interoperability currently low. Lack of trust is one of the contributing factors.

3. IPS value demonstration in a disaster exercise

3.1 Introduction

Disasters resulting from natural phenomena, as well as man-made disasters, can have serious effects on communities and the areas they live in. It is therefore essential to ensure that civil protection systems are at all times ready to respond to crises in the most efficient manner, saving as many lives as possible. In the past decades, international volunteers and medical crisis intervention teams became an important factor for first-response in disaster-prone and vulnerable areas. When international teams are deployed into a disaster area, the first barrier to effectively help the local population and deliver first-response and trauma care is language, the second is information. Both are closely linked: without a common language obtaining the necessary information of a patient is not easy and the patient's medical background (chronic condition, pregnancy, allergic, etc.) immediately influences the treatment process. Thus, reliable patient information, especially in the chaos of a disaster, are imperative to safe and good care delivery.

The 2010 Haiti earthquake caused 316.000 casualties³ and left 310.000 injured⁴. International assistance was received in the early hours after the quake struck. The city of Port-au-Prince was severely devastated and only one hospital in an area with more than three million citizen remained partially operational. Immediate medical assistance was required for more than three weeks until the majority of disaster victims was cared for and local primary care infrastructure started to operate routinely again. In the light of such large-scale disasters and long-term missions, the question remains how care and treatment could have been improved through basic healthcare information for each victim.

EU MODEX⁵ simulation exercises in the framework of the EU Civil Protection Mechanism⁶ are designed to improve the operational cooperation in civil protection assistance. Contingency planning, decision-making procedures, communication to the public and the media in major emergencies can therefore be tested and it helps identifying further training needs and operational gaps.

The Civil Protection Mechanism facilitates cooperation in disaster response among 34 states (EU28, Iceland, Montenegro, Norway, Serbia, the former Yugoslav Republic of Macedonia and Turkey). The participating countries pool the resources that are available to disaster-stricken countries all over the world. When activated, the Mechanism coordinates the provision of assistance inside and outside the EU. The Commission manages the Mechanism through the Emergency Response Coordination Centre (ERCC).

The Mechanism was activated for some of the most devastating disasters the world has faced in recent years, such as the earthquake in Haiti (2010), the tsunami in Japan (2011), typhoon Haiyan that hit the Philippines (2013), the Ebola outbreak (2014), the conflict in Ukraine (2014), the earthquake in Nepal (2015), and numerous floods and forest fires in Europe.

3.2 Evaluation Framework

The two disaster exercises Trillium-II participated in had been different both in size and outline, hence slightly different evaluation approaches had to be applied. For instance, the team cooperated with different types of Emergency Medical Teams (EMTs); the number of employed role players and participating medical teams varied significantly between both exercises as well as the overall evaluation circumstances (local

³ <https://www.notimerica.com/sociedad/noticia-haiti-gobierno-haitiano-eleva-316000-numero-oficial-fallecidos-terremoto-20110112214237.html>

⁴ <https://earthquake-report.com/damaging-earthquakes-2010/>

⁵ <http://www.eu-modex.eu/Red/>

⁶ https://ec.europa.eu/echo/what/civil-protection/mechanism_en

infrastructure, number of interviews, exercise preparation). Apart from the mentioned variations, both evaluation protocols can be described as follows:

The Trillium-II team aimed to evaluate the societal benefits and use of an international patient summary (IPS) available on a victim’s mobile phone in the aftermath of a disaster. The main agitators the team cooperated with were role players and Emergency Medical Teams. During the EMT shift, a number of role play victims with mobile phones arrived in the search for treatment. Trillium-II team members shadowed some of the role players throughout most of their treatment process as background observers without interfering in the exercise. After their shift, selected EMT staff took part in interviews to share their experience and thoughts. A protocol supported the interview and is described later in this section. Role players’ views and thoughts on the IPS were reflected in informal interviews and talks. The hectic and chaotic nature of a disaster exercise with hundreds of participating role players, and the fact that Trillium-II had to make itself fit into the exercise without altering its course, did not allow for structured interviews under regular interview settings.

To ensure a realistic simulation, a medical professional from the Trillium-II consortium had complemented existing medical case descriptions provided by the exercise management with fitting medical information only the IPS would contain (for instance, allergies and medications that might impact the treatment of that case). Prior to the exercise, role players acquainted themselves with the use of the patient summary on a mobile phone provided to them by Trillium-II. EMTs received a briefing on the presence and overarching objectives of Trillium-II as well as on the notion of the IPS.

3.2.1 Interview protocol

The evaluation is mainly based on semi-structured interviews guided by questions derived from the patient summary benefit matrix (chapter 2).

Interviews were audio recorded. All EMTs expressed their will to collaborate with Trillium-II informally and interviewees signed a consent form (Annex A). There is a total of 9 interviews and 11 interviewees.

Category	Benefit indicators (examples)
Productivity / Efficiency	<ul style="list-style-type: none"> • Faster and more effective care decisions <ul style="list-style-type: none"> - <i>Do you think that using the IPS helps making more effective and/or faster decisions?</i> • Time savings <ul style="list-style-type: none"> - <i>Do you think that using the patient summary helps saving time?</i> • Faster and more accurate triage <ul style="list-style-type: none"> - <i>Does the IPS allow fast triage? How?</i> - <i>Does the IPS allow for more accurate triage?</i> • Shorter emergency visits <ul style="list-style-type: none"> - <i>Do you think that using the patient summary shortens emergency visits / speeds up emergency visits?</i> • Reduced admissions <ul style="list-style-type: none"> - <i>Do you think the IPS reduces the number of unnecessary admissions (instead of evacuation or direct local transfer)?</i> • Reduced redundant (double) testing <ul style="list-style-type: none"> - <i>Do you think that using the patient summary reduces redundant (double) testing?</i> • Reduced follow-up treatments <ul style="list-style-type: none"> - <i>Do you think that using the patient summary reduces the number of follow-up</i>

	<p><i>treatments?</i></p> <ul style="list-style-type: none"> • Support for clinical decisions <ul style="list-style-type: none"> - <i>Do you think that using the IPS can support clinical decisions?</i> - <i>Which of the following patient information did the IPS provide you (that you would not have had otherwise)?</i> - <i>Did you miss any other important information the IPS did not provide?</i> • Better targeted resources <ul style="list-style-type: none"> - <i>Do you think that using the patient summary can help better target resources?</i>
<p>Access (to care; data; market, etc.)</p>	<ul style="list-style-type: none"> • Improved access and service <ul style="list-style-type: none"> - <i>Reduced wait-time</i> • Improved quality and access to data for research • Equitable care <ul style="list-style-type: none"> - <i>Better care for patients with low health literacy</i> - <i>Better care for international patients</i> • New business cases, new opportunities for apps and decision support • Better care for international patients <ul style="list-style-type: none"> - <i>Do you think that using the patient summary helps with language barriers?</i> - <i>Do you think the IPS is easy to access?</i>
<p>Quality and safety</p>	<ul style="list-style-type: none"> • Improved patient health outcomes <ul style="list-style-type: none"> - <i>Do you think that using the patient summary can improve health outcomes?</i> • Information quality <ul style="list-style-type: none"> - <i>In general terms, do you trust the information in terms of accuracy and quality?</i> • Improved safety <ul style="list-style-type: none"> - <i>Do you think that using the patient summary can improve safety of care?</i> - <i>Do you think that using the patient summary can reduce harm to patients?</i>
<p>Patient experience</p>	<ul style="list-style-type: none"> • Increased patient empowerment <ul style="list-style-type: none"> - <i>Do you feel more empowered in emergency encounters with your IPS on your mobile phone?</i> - <i>Do you think the IPS improves patient empowerment in general?</i> - <i>Do you think the Evacuation Report attached to your IPS after treatment provides useful information?</i> • Patient satisfaction <ul style="list-style-type: none"> - <i>Do you think the IPS shortens time for diagnosis and treatment?</i> - <i>Do you think the IPS supports you as a patient in communicating with health professionals?</i> - <i>Do you feel satisfied with the modes of access to your IPS?</i> - <i>Do you think the information in your IPS is useful to you as a patient?</i> - <i>Did the IPS provide a positive intuitive user experience?</i> • Patient confidence <ul style="list-style-type: none"> - <i>Do you feel more confident and secure in an emergency situation with the IPS at hand?</i> - <i>Do you think the IPS improves the quality of diagnosis and health outcomes in the case of an emergency?</i> • Supporting communication and interaction with care providers <ul style="list-style-type: none"> - <i>Do you think the IPS improves the communication with health professionals at</i>

	<p><i>home?</i></p> <ul style="list-style-type: none"> - <i>Do you think the IPS contains valuable information for health professionals at home?</i>
Health and care professional experience	<ul style="list-style-type: none"> • Professional satisfaction <ul style="list-style-type: none"> - <i>Did the IPS provide a positive intuitive user experience?</i> - <i>Do you think that using the IPS has generally led to you delivering improved care?</i> - <i>Did the IPS detract you from clinical effectiveness?</i> - <i>Would you base a diagnosis exclusively on the information in the IPS?</i> - <i>Do you feel more confident with the IPS during an emergency encounter?</i> - <i>Do you think the IPS has greater benefits for patients with more severe conditions?</i>

Table 2: Overview of potential interview questions and topics to guide the evaluation

3.2.2 Participating observation

Participating observation originates from the social science field of ethnography, where the scientist passively observes the day-to-day life of the research object to understand the internal structures, values and institutions that are immanent to the research object⁷. This can be a societal group (e.g. elites or impoverished segments of society), an ethnic group (e.g. natives or African tribes) or other groups (e.g. criminals or groups of same sexual orientation). The main principles are as follows:

- The scientist remains passive and does not interfere
- The scientist observes and takes notes
- The scientist wants to understand the research object without "going native"⁸
- The scientist may have informal small talks with the research object to gain context information

These principles are applied to the IPS evaluation in both exercises. The observation focuses on the following aspects:

- Medical routine and how it varies when an IPS is available
- Verbal and non-verbal communication between the physician and the victim (e.g. language barriers, gestures, etc)
- Acceptance and usage of the IPS by physicians (e.g. physician has trouble to navigate the IPS on mobile phone)
- Interactions and communication between physicians in regard to the IPS (e.g. confidence in authenticity; do physicians ask for a second opinion or establish rules of thumb to estimate authenticity of IPS information?)

3.3 The evaluation

The audio-recordings were transcribed and qualitatively analysed. To this end, categories and indicators were established according to the benefit matrix to match single or several sentences of the interviews. For example, the first category "Productivity/Efficiency" consists of eight indicators ("Faster and more effective

⁷ Spradley, J. (1980). Participant Observation. New York: Holt, Rinehart and Winston.

⁸ The researcher "goes on a tightrope walk between closeness and distance, to which it belongs to be able to adopt the perspectives of the research subjects, but at the same time to keep distance as a "witness" of the situation. Without closeness one will understand the situation too little, without distance one will not be able to reflect on it sociologically". (Przyborski, A., & Wohlrab-Sahr, M. (2014). Qualitative Sozialforschung. Ein Arbeitsbuch (4. Ausg.). (A. Mohr, Hrsg.) München: Oldenbourg Verlag.)

care decisions”, “Time savings”, etc.). All interviews were carefully analysed and in a first step, every sentence was assigned to one or more indicators or categories. This produced an overview over which topics had actually been covered in the interviews and eventually formed the basis for the evaluation.

The information generated during both disaster exercises were grouped into three distinct areas:

- 1) value indicators; information that relates to the added value of an IPS in a major medical disaster situation (see Table 2)
- 2) Areas of high impact; information that relates to the degree of impact the IPS has on the different departments/units of Emergency Medical Teams deployed to disaster areas
- 3) other use cases; information that reveals in which other use cases the IPS is envisaged to add value

3.3.1 Value indicators

Interviews

During interviews, most physicians agreed that in an emergency they rate an additional source of information highly valuable and supportive in terms of increased confidence and improved care delivery: “[...] it was very helpful. You could check it quickly and you feel much safer already.” A mobile patient summary helps to create a “bigger picture” of a patient and his needs and allows for quick categorisation.

Current medication is frequently an indicator for specific disease patterns to which physicians can pay immediate attention by means of verbal communication either in a mutually understood language or through translators. *“This is also important because not every patient tells us in advance that he or she is haemodiluted. Usually they say this only in response to our question and do not actively do so. If we have the IPS immediately, then we investigate the matter further and certainly obtain relevant information for the treatment and the triage.”* While on the one side gaining confidence during the treatment, physicians tended to remain cautious and questioned the actuality of IPS information. For them, the application is not the ultimate source of truth and a verbal communication is always the best way to “scrutinize and compare” two sources of information (the IPS and the patient), for “[...] no matter how good the information in the IPS is, it can never replace communication with the patient - it would complement it, but never replace it.”

What concerns a potential design of an IPS, interviewees of both exercises preferred a condensed content presentation with a slide-and-push menu and a Hamburger-Icon⁹ (see also Figures 1-3). Role model and IPS-like test app was the TicSalut health app that is already available for download in the Google Play Store. This app is routinely used in the region of Barcelona. Interviewees fancied the concise design and easy-to-handle menu. The design of the app does not force physicians to read every piece of information; they simply select the information item they are interested in and receive a structured overview.

⁹ https://en.wikipedia.org/wiki/Hamburger_button



Figure 1: TicSalut health app with Hamburger-Icon in top left corner.

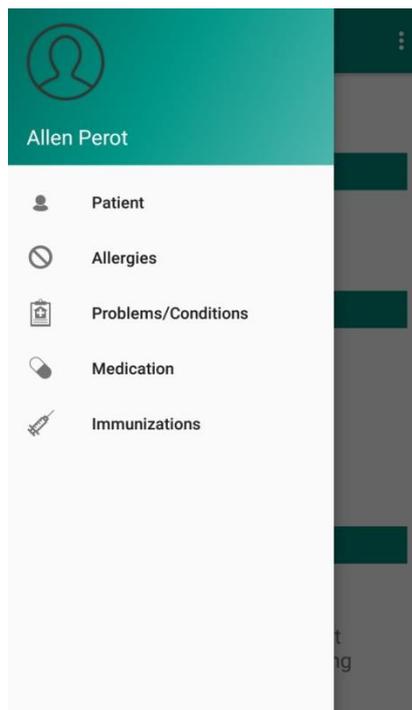


Figure 2: Slide-and-push menu opens and presents the information categories.

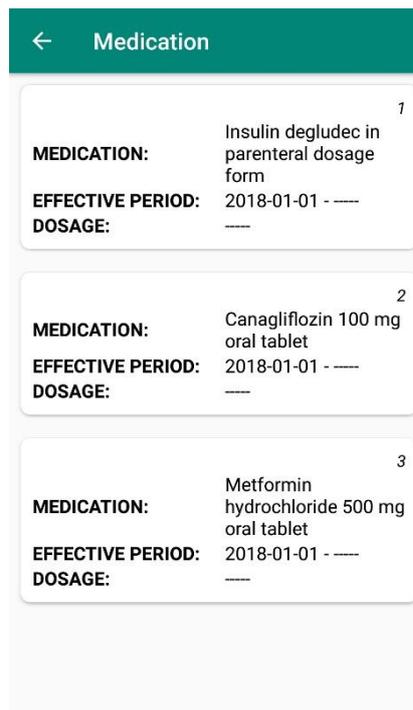


Figure 3: The medication item.

The patient summary is a new factor to consider within a long-established and experienced Triage system and adds an additional step to it, explicitly in cases where both sources of information (the patient and the IPS) do not match. Even though it ultimately requires additional time to solve an ambiguity, physicians regarded this as a valuable chance, “[...] because it also reveals whether the patient is confused or otherwise affected by the injury or the accident.” In such situations, only their medical experience and knowledge of human nature assists them to judge which information to trust in order to translate the new insights into a benefit for treatment.

Two other situations occurred at EMTs which are close to reality: language barriers and unknown immunization status. If held in an international language, for instance English, physicians regarded the IPS probably as most valuable when communication in a common language is not possible (or the patient is unconscious). Potential translators (i.e. relatives or friends) might not be available upon a patient’s arrival at the Emergency Medical Team. “Having an app with information in an international language helps me until we find a translator or a relative [...].” Physicians suggested the implementation of a translation mechanism based on international classification systems and GPS locations.

With regards to immunizations, the long-year experience of interviewed physicians showed that patients are usually not aware of their status. During disasters, patients’ vaccinations must always be replenished if the status is unknown. “[...] if one can detect an infection and a vaccination is missing or in the case of open injuries”, the wide use of patient summaries would enable Emergency Medical Teams to effectively allocate their resources. Patients with an active immunization status would not receive replenishment, thus saving limited resources. Another factor to consider is situations where a patient without active immunization

loses huge amounts of blood. For instance, during a birth, physicians need not only to protect arms and hands, but also their face. *“Once a patient will give birth [...] and she has Hepatitis or something like that [...]. How should I know that the patient has no protection against Hepatitis? In that case, I need to make sure no blood comes into my eyes.”* Not only do patient summary information provide reassurance in situation where understanding a patient is not possible, but also they inform physicians to improve their self-protection measures during the treatment and care process. Although, it has to be noted, that in general, instructions for medical teams are to treat all patients as infected, thus sufficient self-protection should always be in place.

Interviewees explained how they incorporated the IPS into their workflow at the Triage room. *“[...] especially the information about allergies or intolerances and the information about the current medication the patient is taking are very relevant. We include this in our protocol and pass it on to our colleagues in the relevant departments.”* However, physicians in the triage do not always enter every piece of information into the triage protocol and are selective as to which information to pass on. *“[...] for me in the triage it is only important whether the information is relevant in this situation. I have read the IPS briefly and if I have concluded that this is important for the doctor, then I have passed it on [...]”* That only applies to situations when there is time to consult the application, but generally, most interviewees stated that *“[...] [they] should find the time to enter the information in the [triage] protocol.”* Some even said, once it is evident that a patient has additional information on his phone but the time does not allow access to it, they would briefly make a remark in the protocol *“have a look at patient’s phone”*, enabling their colleagues in other departments to have a closer look on the patient summary.

On the contrary side, it has to be noted one physician disliked the idea of incorporating patient summaries into the triage workflow. He would not consult it during the triage and only during the actual treatment: *“To me the application is good to give you some information you could otherwise easily miss. But on the other hand, you also fall in the risk to follow some information you do not need in that very moment.”* In some cases, the information in his patients’ IPS was not useful to him in the triage. Instead, when the patient is stabilised and he *“[...] focus[es] on secondary care and treatment, this kind of information”* is important to know. Another physician that worked at the same EMT said she would definitely consult the mobile IPS at triage level. There is demand for consultations of patient summaries already at triage level, as she describes: *“We had a lady with a suspected pelvic fracture and [according to the IPS] she was taking hemodilators. Well, that did influence our triage here. We then classified her as unstable.”*

As a result, this patient was prioritised and received immediate treatment due to an increased risk of internal haemorrhage. Generally, interviewees said that elderly patients with pre-existing conditions would not tolerate such a situation or accident as well as a younger and otherwise healthy patient. A patient summary enables them to prioritise patients reliably, hence making effective use of the EMTs’ limited treatment capacities. Not that none of the patients are able to remember their active conditions or medication, but in stressful situations, explicitly in trauma patients and elderly people, doctors believe that memory is likely to be incomplete. Therefore, they hold the IPS to add multiple values to emergency medical disasters simultaneously: better and safer care delivery, more informed decision-making, more effective resource allocation and capacity management, professional confidence and satisfaction, faster care delivery and improved quality of care. As one interviewee phrased it, the IPS *“[...] helps [...] to focus or specify the tests [or treatment steps] and order them timelier, because reading the app, [one] can judge with higher certainty what the patient needs in the event of an emergency.”* and went on to say *“[y]ou need this information before taking actions to know what you can do and what you cannot do.”*

Observations

One case was observed where the physician was not able to identify the type and dosage of medication the patient was taking according to the information provided by the first responders. Half a minute passed until he was able to ask a nurse who confirmed that this drug was a spray. After confronting the physician with the corresponding patient summary for that case, he acknowledged it would have saved precious time in that situation. The patient suffered from a liver deficiency and required proper medication quickly. Generally he believes patient summaries are a useful tool as long as physicians have sufficient time to read it properly. The focus of interest typically lies on a specific piece of information that can be retrieved within seconds.

Except for this case, having a patient summary enables him to narrow the diagnosis and exclude other possibilities that do not match the information provided in the patient summary. If the use of patient summaries was common, this would lead into increased awareness of one's own conditions, medication, allergies ultimately empowering patients to inform physicians on their medical background in any care setting. *Identified value indicators: time savings, support for clinical decisions, information quality, patient empowerment, professional satisfaction.*

Two cases were observed where doctors would not have consulted a patient summary even if it was available and provided important information. Specifically, one patient was shot at and the other suffered from cardiac arrest. Interviews with the responsible physicians in the Emergency Unit revealed that when patients are critical, the primary aim in such situations is to treat the acute problems first to ensure the patient survives whatever the cost. Once stabilised and referred to the ward, the physicians there would be able to deal with any further issues.

Nevertheless, the patient summary informed the physician about information that affected the treatment. The physician gave penicillin to the first patient to reduce the pain but which the patient was allergic to. Another added-value in terms of resources was the immunity to Tetanus, so the physician did not need to vaccinate him. If the current immunization status is not known, all patients are routinely vaccinated. The second patient had asthma but was given Aspirin, provoking an allergic reaction to non-steroidal anti-rheumatics like Acetylsalicylic Acid (ASS, know as Aspirin) not uncommon for asthmatic patients. *Identified value indicators: support for clinical decisions, better targeted resources, improved safety and reduced harm, improved patient health outcomes.*

3.3.2 Areas of high impact

Definitions and EMT types

Areas of high impact are:

1. those physical spaces of an Emergency Medical Team where the IPS is expected to be accessed most often and
2. the type of injury/disease pattern where the presence of its additional information realise the highest value.

Interviews with different physicians in different departments of different types of EMTs revealed that the IPS is not equally relevant to all stages of care during emergency medical disasters. However, this does not exclusively depend on the stage of care, but also on personal experience, preferences and type of emergency.

For this to understand, one has to have a closer look at the different departments (services) and types of EMTs. The following minimum standards apply to the different EMT types¹⁰.

EMT type 1: Outpatient Emergency Care. It provides initial outpatient emergency care and other basic health care needs. This EMT must be capable of treating at least 100 outpatients per day and function during day-time for at least 12 hours. Key services are

- Triage, Examination, First Aid
- Stabilisation and referral of severe trauma and non-trauma emergencies
- Definitive care for minor trauma and non-trauma emergencies

EMT type 2: Inpatient Surgical Emergency Care. Provides inpatient acute care, general obstetric surgery for trauma and other major conditions. This EMT must be capable of performing at least seven major or 15 minor operations per day with at least 20 inpatient beds per operating table and be able to operate 24 hours, seven days a week if required. Key services are

- Advanced life support
- Definitive wound and basic fracture management
- Damage control surgery
- Emergency general and obstetric surgery
- Inpatient care for non-trauma emergencies
- Basic anaesthesia, X-ray, sterilisation, laboratory and blood transfusion
- Rehabilitation services and patient follow-up

EMT type 3: Inpatient Referral Care. It provides complex inpatient referral surgical care including intensive care capacity. This EMT must have at least two operating tables in two separate rooms, at least 40 inpatient beds (20 per table) and have the capability to treat 15 major and 30 minor surgical cases daily. Key services are

- Intake/Screening of referred and new patients, surgical triage and assessment, plus counter-referral
- Capacity to provide type 2 services when needed
- Complex reconstructive wound and orthopaedic care, when required
- Enhanced X-ray, sterilisation, laboratory and blood transfusion
- Rehabilitation services and patient follow-up
- High-level paediatric and adult anaesthesia
- Intensive care beds with 24/7 monitoring and ability to ventilate

The main medical departments (usually tents) for an EMT type 1 are the Triage room, the outpatient ward and a consultation room for minor non-trauma cases. At type 2 level, an additional Surgical Unit as well as an inpatient ward are involved and at type 3 level, two Surgical Units and more inpatient as well outpatient capacities as outpatient need to be provided. Non-medical departments, for instance storage or logistics, are outside the scope here.

During the MODEX exercises Trillium evaluated the IPS at several EMT type 1 and one EMT type 3 Field Hospital. Additional to the minimum standards, the Field Hospital owned an Emergency Department (ED)

¹⁰ Adopted from: Norton, I., von Schreeb, J., Aitken, P., Herard, P., Lajolo, C. (2013): Classification and Minimum Standards for Foreign Medical Teams in Sudden Onset Disasters. World Health Organization. Switzerland.

where critical patients received immediate treatment and a field pharmacy. Depending on the occupancy rate, non-critical patients were also treated at the ED and otherwise referred to the out- or inpatient ward.

Impact areas

Medical exercise simulations are always subject to limitations. Role-player proficiency, exercise planning, the type of injuries simulated and the local infrastructure are just a few of the decisive factors that influence the degree of reality of the exercise. A key element to consider in simulations is the shift from trauma patients to patients who need continuous basic healthcare within the disaster area. There is no precise indication of when this shift will occur, but 36-60 hours after a natural disaster strikes, an increasing amount of patients arrive who suffer from the consequences of partially or totally disabled primary care in the local area. The most severe trauma patients have already been treated or referred to other hospitals or EMTs.

This circumstance was reflected in both medical exercises in which Trillium-II participated. Especially the observations at EMT type 3 Field Hospital and interviews with the medical staff underlined the importance of primary care in the aftermath of natural disasters such as earthquakes or floods. At an EMT 3 that admits a large number of trauma patients, triage nurses quickly register and categorize each patient according to the severity of their trauma. The most severe cases receive priority; others have to wait for treatment. Once the number of trauma patients has significantly decreased, the emergency team is expected to be able to provide basic primary care, explicitly in situations where the regular primary care infrastructure is overloaded or incapacitated due to the destructive forces of natural disasters, hence indirectly affecting a large proportion of the local population.

Prescriptions have to be renewed and additional or lost medicines have to be dispensed not only to the local population, but also to displaced people who may have lost their homes to the disaster. Almost all interviewees mentioned long-term scenarios (e.g. the earthquake in Haiti in 2011) in which the affected population required international medical assistance for several weeks and established a link between widespread use of patient summaries and improved care delivery, quality of care and resource management.

After finishing the first exercise one key message from interviewed Field Hospital staff was hesitation to fully accept the IPS as part of their workflow. During the exercise, the interviewees were situated at the Emergency Department, which demanded quick decisions. In this environment, they said, full introduction of a patient summary document into their workflow would be cumbersome and happen at the cost of time-effectiveness. When asked in which department of their EMT type 3 they would expect the greatest impact on treatment, the inpatients and outpatients ward was frequently mentioned. The clear advantage for the IPS over the Emergency Room is time. In the ward, patients are more or less stable and out of mortal peril. This gives nurses and doctors sufficient time to carefully read a patient's medication list and vaccination status. Also, adverse drug reactions can be cared for (as described in observations in the previous chapter). This was generally confirmed by medical staff and validated through further observations at the second medical exercise, where several EMT type 1 showed huge motivation to integrate patient summaries in their triage and treatment workflow.

3.3.3. Other use cases

Trillium-II participated in two disaster medical exercises with Emergency Medical Teams and Field Hospitals. Yet, the exercises revealed potential value of an IPS not solely in the context of Emergency and Disaster Management, but also for chronic patients and in unscheduled emergency care.

Patient summaries – Continuity of care per chronic patients

There are two implications a patient summary has on patients suffering from chronic conditions. First, in the context of disasters, for EMT staff it is vital to know the medical history of highly vulnerable chronically-ill patients. However, of equal importance is that the patient's specialists and GP are informed on new medications or conditions that resulted from EMT treatment in a reliable way. So far, the state-of-the-art of EMT practice foresees a paper print-out with all details of the received treatment at an EMT which is given to the patient upon discharge. The paper print-out is the only reliable piece of information for other physicians to swiftly assess what happened during the disaster (apart from verbal communication). This also counts for non-disaster scenarios: either the patients carry the print-outs to their specialist or GP or they are being sent via post service. The print-outs might get lost and administrative effort is enormous in larger health systems. Both inside and outside disaster medical scenarios, the patient summary bridges different stages of care and creates a continuous digital care environment in otherwise fragmented care settings.

Medical Ids – Extending In Case of Emergency (ICE)

This use case foresees an app-like solution on patient's smartphones with which paramedics, first responders or police officers are able to contact the next of kin in the event of an emergency. Apple has already introduced the Emergency Pass which covers this functionality and also enables patients to add more medical information. An International Patient Summary must not only contain emergency contact details as set out in this use case, but go much further to keep-up with technological advancements and the needs of patients in order to be truly valuable.

Two interviewees mentioned that IPS-like solutions already exist and together suffer from three major problems.

1. Few solutions provide visual identification of a smartphone's owner;
2. Such solutions are held in local language and are not translated when crossing borders;
3. Access to the solutions usually requires unlocking the phone

There are multiple scenarios where a reliable identification of patients is not possible (e.g. large traffic accidents, burns, etc). Having a patient's picture and information on distinctive body characteristics helps physicians to reliably match smartphone and patient. There is no guarantee that the phone belongs to the person carrying the device, especially in mass incidents. Mismatching of health data can cause serious damage to patients' health.

When a patient requires care abroad, current IPS-like applications do not provide a translation service. This could be provided via GPS-based location or automatic translation via clinical terminologies like ICD 10. The simplest possible solution is to develop apps that are available in both native language and English.

When hospitalized, it is a challenge for physicians to access a patient's patient summary even when it is available on the phone without unlocking it. Unconscious patients are not able to give their consent, nor can they unlock the device by themselves. A Possible solution to this problem might be a closer look at the Apple Emergency Pass. By pressing "Emergency" on the locked phone, the emergency dial interface appears as well as the "Emergency Pass" button. Clicking this button opens a record with, among others, a

picture, the full name and information on allergies, medication, blood group and emergency contacts. According to an interviewed German health worker, the Emergency Pass is well known among emergency physicians in German hospitals and frequently used.

4. Summarising the value case

The value for an International Patient Summary is very situational and requires up-to-date information. The different values cannot be realised in every disaster situation, at every EMT (or other kinds of medical teams), for every patient, as has been pointed out in the previous chapter. However, there certainly is a value case for the IPS beyond the context of Emergency and Disaster Management. The distillate of what has been found out during both disaster medical exercises is presented below.

- The most important value identified is improved confidence for physicians and nurses during triage and treatment. There are many situations for EMTs in an international context where the IPS, if up-to-date, can prove a reliable instrument which mentally supports them in a somewhat chaotic environment
- A huge value is expected to be realised in long-term scenarios where not only disaster medical care needs to be delivered to people directly affected by the disaster, but where primary and secondary care infrastructure is not available in the affected area. International assistance and medical teams are required to compensate and replace local medical infrastructure at short notice until they fully recover from the disaster. Here, information on ongoing medication and active conditions are imperative to know.
- Improving a patient's health can be achieved through various aspects, but the most significant impact is achieved when the patient is unable to communicate effectively.
- The International Patient Summary is easy to integrate into established triage workflows during regular medical emergencies in the aftermath of a disaster. During mass incidents, there appears to be only little value for the triage and emergency treatment and an application of the IPS is rather more impactful in the inpatient or outpatient ward. Hence, it is, above all, limited by the time to access and read it.
- An International Patient Summary in English language will assist international medical teams in overcoming language barriers encountered in non-English speaking countries, especially rural areas or during holidays.
- In term of resource effectiveness, there is a big impact on the use of vaccines. In high-risk disaster areas (e.g. flood areas) all patients receive a vaccination as long as the immunization status cannot be reliably verified. The IPS supports medical staff in effectively allocation limited resources and medications.
- Although it takes a few seconds to briefly read the relevant (not all!) information provided by the IPS, this is outweighed by an increased time-effectiveness achieved through better coordination and execution of the necessary treatment procedures like blood tests, preparation of certain medication or advanced measures.
- Especially the information on vaccinations or permanent conditions is extremely valuable for medical staff in terms of self-protection. In cases where blood splatters around, it is extremely important to know if that patient carries blood-borne diseases or lacks immunization. Medical staff needs to take extra protection measures, i.e. to prevent blood from entering their eyes.
- All in all, the above aspects reflect a tendency of improved clinical decision making through the application of an IPS. More concrete, the IPS directly informs physicians and nurses about the most basic medical history which certainly do influence care decisions at specific stages of care. EMT type 1 and 2 are expected to fully benefit from additional IPS information. As for EMT type 3 and Field Hospitals, medical staff in the ward and the emergency department (given that no mass incidents occur) will largely benefit from an IPS.

Deliverable 6.2: Establishing the value case for the international patient summary: indicators and results

- As stated before, the patient summary also brings value to regular unscheduled care for patients suffering from chronic conditions bridging otherwise fragmented information silos and emergency care encounters. Having said this, the following actions are proposed in order to further improve the concept of an International Patient Summary:
 - Add the possibilities to name emergency contact details
 - Add a profile picture of the IPS/smartphone owner
 - Provide a translation mechanism or develop bilingual solutions (mother language + English)
 - Develop solutions that allow for accessing the IPS without having to unlock the phone

5. Ethics Considerations

Both method and content of this deliverable pose ethical requirements in regards to research ethics, privacy and data protection and, last but not least, legal issues if the IPS is used in the use cases in focus and in general (this has been addressed in detail in D4.1 and other deliverables and is not an immanent part of the deliverable). Also, the main part of this report is the evaluation of IPS added-values together with disaster health professionals and does not address ethical research questions.

The design and implementation of research projects must comply with legal requirements, scientific standards and ethical principles, and in practice there is an overlap between the rules on data protection, good scientific practice and research ethics. While legal requirements exist for data protection, ethical quality of research in scientific practice is generally only laid down in guidelines on good scientific practice; legal requirements such as data protection do not exist for the most part here. But even if data protection is respected and scientific standards are adhered to, the question often arises as to what is ethically required. Especially in social science research - which in most cases involves human interaction - the protection of participants plays an important role. However, this concern must be balanced with other values (e.g. to produce good research results).

5.1 Consent

Researchers who survey or process personal data are required to comply with relevant data protection regulations, especially the EU General Data Protection Regulation and its transposition into national law. Informed consent was the most appropriate legal basis for the collection of personal data in this context: study participants must give their consent to the collection, processing and use of their personal data. The consent must be based on the free decision of the participants and they must be fully informed about the reason for the data collection, data processing and data use. All interview participants had been informed about the purpose of the Trillium-II evaluation through information material (Annex A: Information Sheet) and consent forms (Annex A: Consent Form for Interviews).

In order to make an informed decision about participation in a research project, potential participants must be informed in advance, with all necessary information about the conditions and effects of participation in the research project, before participation. This was ensured through correspondence between the Trillium-II evaluators and the team leaders of each of the Emergency Medical Teams who cleared the ground for participation of their Teams in the interviews and discussed their voluntary participation verbally. Written consent was obtained from each participant at the exercise site.

It should be noted that all of the medical details presented within summaries was fictitious data, completely invented and not derived on or based on actual patient details. There were no ethical implications in respect of this data and its processing during the studies.

5.2 Documentation, anonymity and secondary use

The detailed documentation of the methodical procedure for data collection and evaluation is indispensable for the traceability of research results. Interviews had been transcribed electronically and analysed analogically with printouts. Only the raw interview records are stored on a server and will be deleted 12 months after this project ends. Transcripts are not anonymised. However, to ensure that no links between the evaluation and the personal opinions and beliefs of the study participants can be drawn, neither the names nor their affiliation to Emergency Medical Teams are specified in direct quotes of the evaluation chapter.

Secondary use of the transcripts is possible, since all participants agreed that "[...] extracts from the interviews, from which I would not be personally identified, may be used in any conference, report or journal article developed as a result of the research."

Annex A) Interview consent form

Trillium-II (2017-2019): Trillium-Bridge Reinforcing the Bridges and Scaling up EU/US Cooperation on Patient Summary



Trillium-II EMT Exercise Section at EUMODEX-Tallinn 11-14 April 2019 Information Sheet (08.04.2019)

Objective of the Trillium-II exercise section

Trillium II aims to evaluate use of the International Patient Summary (IPS) by the Emergency Medical Team Level (EMT-1) and solicit feedback from EMT members and role players after the exercise. The IPS will be available in a victim's smartphone in the aftermath of a disaster. The IPS comprises key elements of a person's health profile as critical problems and conditions, allergies, medication, vaccinations, aiming to serve as a window to a person's health prior to the disaster.

Evaluation of the exercise

After the shifts or during breaks, Trillium-II evaluators will interview EMT members or role players about the benefits and how the IPS affected their medical decision-making, care management, and patient safety and about their patient experience of carrying the IPS on their smartphone or tablet. Disaster incident medical cases are evaluated both with and without IPS information. In this way, Trillium-II will assess the advantage of having an IPS or its parts e.g. medications, allergies, etc., in real emergency situations:

- EMT experience: feasibility / acceptance / usability
- Quality and safety: added value/effectiveness
- EMT Care management and productivity: Increase/decrease of efficiency

Interviews

Participation is voluntary at all times. Individuals will be anonymised and no names will be linked to any materials or reports whatsoever. In the interest of both the EMT members and the evaluators interviews will not exceed 25-30 minutes length and a tape recorder will record the interview. To be able to give their consent, interviewees must read this information sheet and sign a consent form prior to each interview. If consented, interview recordings will be (a) used only for evaluations purposes (e.g. transcriptions) related to the Trillium-II project, (b) stored in a safe environment or on request deleted once the project ends, (c) not used for secondary research purposes.

1

Trillium-II (2017-2019): Trillium-Bridge Reinforcing the Bridges and Scaling up EU/US Cooperation on Patient



Summary

Trillium-II EMT Exercise Section at EUMODEX-Tallinn 11-14 April 2019
Consent Form for Interviews

Thank you for participating in the Trillium-II evaluation session during the EUMODEX exercise on Saaremaa island. If you are happy to participate and agree to be interviewed then please complete and sign the form below. Please initial the boxes below to confirm that you agree with each statement:

Please Initial box:

I confirm that I have read and understood the information sheet dated [08/04/2019] and have had the opportunity to ask questions.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without there being any negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline.

I understand that my responses will be kept strictly confidential. I understand that my name will not be linked with the research materials, and will not be identified or identifiable in the report or reports that result from the evaluation.

I agree for this interview to be tape-recorded. I understand that the audio recording made of this interview will be used only for analysis and that extracts from the interview, from which I would not be personally identified, may be used in any conference presentation, report or journal article developed as a result of the research. I understand that no other use will be made of the recording without my written permission, and that no one outside the evaluation team will be allowed access to the original recording.

I agree to take part in this interview.

Name of participant

Date

Signature

Principal Investigator

Date

Signature

