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Business Model Canvas Insights for the Adoption of International Patient Summary Standards in the Mhealth Industry

Valentina Tageo¹, Carina Dantas^{1*}, Catherine Chronaki², Charles Lowe³, Alexander Berler⁴, and Federica Porcu¹

Abstract

Purpose: This article intends to present and discuss two promising business models for deploying IPS (international patient summary) standards in mobile health (mHealth) apps, enhancing the value brought by standards, in particular by HL7 (Health Level Seven International) of the FHIR (Fast Healthcare Interoperability Resources) for IPS. More specifically, it will explain how these standards may be understood as the strategic and financial incentives for organisations - and nations - to adopt the IPS.

Approach: A thorough analysis of concepts will be followed by the presentation of a business canvas for mHealth applications, that aggregates basic information on a common framework for the adoption of IPS standards.

Findings: To better understand this framework, two illustrative use cases (Disaster management and MOCHA - Models of Child Health Appraised/Vaccination) are presented and the benefits of IPS standard adoption in these situations are specifically highlighted as they may translate better quality care and well-being and, at the same time, represent reduction of costs on health-related expenditure.

Originality: This article is a summary of work developed specifically as part of the Trillium II project, primarily by collaboration by the organisations represented by the authors. Logically, it uses concepts previously developed, and referenced in the text as appropriate, however the authors maintain that the business models presented represent an original synthesis of these concepts specifically appropriate to the task of encouraging widespread adoption of the HL7 FHIR IPS.

Keywords: Patient Summary; Standards; mHealth apps; Electronic Health Records; Business models

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¹ ECHAlliance - European Connected Health Alliance (Community Interest Company)
NISP Innovation Centre, Queen's Road, Queen's Island, Belfast, United Kingdom, BT3 9DT

² HL7 Foundation

³ DHACA

⁴ Gnomon Informatics SA

*Corresponding author - Carina Dantas | +351 936498277 | carina@echalliance.com

Introduction

This paper identifies and discusses two possible business models to be used in deploying patient summary standards in mobile health (mHealth), thereby enhancing the value brought by standards, in particular Health Level 7 International (HL7) of the Fast Healthcare Interoperability Resources (FHIR) for the International Patient Summary (IPS),² More specifically, it explains how these standards may be understood as the strategic and financial incentives for organisations – and nations – to adopt the IPS.

The Trillium-II project³ responded to the EU-US interoperability roadmap call (SCI-HCO-14-2016) of the European Union Research and Innovation Horizon 2020 Programme to realize as its key recommendation: to advance IPS standards to enable people to access and share their health information for emergency or unplanned care anywhere and as needed. Connecting regional or national eHealth projects to standardization to highlight best practices and share resources where possible was another aspiration for Trillium II, towards the creation of a global IPS community of practice for digital health innovation. To this end, Trillium partners aimed to identify relevant projects and use cases of interest that help validate and promote the use of IPS standards in demonstrations, readiness exercises, and other pilot projects. This project activity responsible for this task was “Explore business models for patient summary standards adoption in mHealth apps” and its main outputs and conclusions are presented in the following pages.

Concepts and background

In order to better understand the content of the paper, some basic concepts are briefly outlined.

¹ HL7 (2020 last update), International Patient Summary Implementation Guide, available at: hl7.org/fhir/uv/ips/index.html;

² Hausam R., Cangoli G. (2020 last update), International Patient Summary (IPS) FHIR Repository, available at: <https://github.com/HL7/fhir-ips>.

³ The Trillium II project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 727745 (<https://trillium2.eu/>).

1. *The International Patient Summary (IPS)* is a concise document or set of information components that can inform clinicians at the point of care about relevant personal health information such as conditions, allergies, medication. IPS information is useful in planned care but is critical to the safety of the patient when an unscheduled or unplanned health care event occurs, and the patient's clinical history is unknown to the attending clinician(s). In such cases it may be the only source of information available to support the clinical process and decision making, and its absence may have life changing or life-threatening consequences for the patient. An IPS provides information needed for healthcare coordination and for the continuity of care.

There are considerable benefits to the patient if an accurate and up to date IPS is available at the point of care and conversely there are the associated high risks and costs for that person if it is unavailable. In addition to the patient safety aspects, for an organization, the absence of IPS information can be costly and wasteful of both clinical and administrative resources. IPS is not the same as a patient's full electronic health record; it is often an extract of the full record, so it does not include the detailed previous history, e.g. detailed history of medication or a comprehensive account of each health condition and contact with the health system that a person may have had. The objective of the IPS is to provide sufficient, relevant and usable information, fit for purpose at the point of care⁴ optionally with links to further information:

“A Patient Summary is an identifiable ‘dataset of essential and understandable health information’ that is made available “at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in unscheduled care”; it can also be defined at a high level

⁴ Joint Initiative Council (2018), Patient Summary Standards Set. Guidance Document v1.0, January 2018, available at: http://www.jointinitiativecouncil.org/registry/Patient_Summary_Standards_JIC_Jan_2018.pdf.

as: 'the minimum set of information needed to assure healthcare coordination and the continuity of care'.⁵

"IPS is a minimal and non-exhaustive Patient Summary, specialty-agnostic, condition-independent, but readily usable by all clinicians for the unscheduled (cross-border) care of a patient"⁶.

"A Patient Summary provides background information on important aspects such as allergies, current medication, previous illnesses and surgeries, etc. These are necessary for the proper treatment of a patient abroad, especially when there is a language barrier between the healthcare professional (HP) and the patient."⁷

2. *Mobile Healthcare (mHealth)* is a second relevant concept. It refers to the use of apps to allow users to monitor, evaluate and improve their health using data recorded by their smartphones and other mobile devices. While apps of this type clearly provide a vastly useful service to their users, the data the apps record – e.g. heart rate, blood-sugar levels, general fitness, behavioural data etc. – is highly sensitive. Therefore, mobile health apps must be designed in such a way that the privacy of the end users is optimally protected. Similarly, these apps have the potential to empower users, provided that the users receive sufficient insight into the functioning of the app and are able to assess more easily which of the many apps on the market meet their privacy and safety

concerns. In addition, these apps can increase patient satisfaction and understanding, while empowering them to take charge of their own health. mHealth apps have the potential to make healthcare professionals' work more efficiently and reduce the cost of healthcare, resulting in the current availability of more than 325,000 mHealth. A stream of new, exciting products and services are being launched every day.⁸ When creating an app for the mHealth space, there is a plethora of rules and regulations that determine how they should handle data privacy and security, as well as efficacy and safety. All these rules and regulations can have a chilling effect on innovation in the mHealth space. Certifications may be the future of mHealth apps, but this is still a very new space that may be explored also as an opportunity for new business models.

3. *Standards.* Most importantly to Trillium II's purposes, compliance with relevant standards may be a differentiating factor for apps to sell their potential to the consumer and build their trust. Therefore, analysing how standardization is enforced is a cornerstone to evaluate future business models for IPS standards in this sector.
4. In this paper a *Business Model* is understood to describe the rationale of how an organization creates, delivers and captures value, in economic, social, cultural or other contexts. The process of business model construction and modification is widely referred to as business model innovation, and forms a part of business strategy⁹.

Finally, the term B2B stands for *business to business* and refers to businesses who sell products and services to other businesses instead of to consumers¹⁰. This can include everything from invoicing software

⁵ eHealth Network (2013), Guidelines on minimum/nonexhaustive Patient Summary dataset for electronic exchange in accordance with the Cross-Border Directive 2011/24/EU. Release 1, adopted on 19 Nov 2013, available at: https://ec.europa.eu/health/sites/health/files/ehealth/docs/guidelines_patient_summary_en.pdf.

⁶ The Implementation Guide for the International Patient Summary is hosted in an ad hoc wiki identifying the required clinical data, vocabulary and value sets, available at: http://international-patient-summary.net/mediawiki/index.php?title=Main_Page

⁷ eHealth Network (2016), Guideline on the electronic exchange of health data under CrossBorder Directive 2011/24/EU. Patient Summary for unscheduled care, Release 2, adopted on 21 Nov 2016, available at: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co10_en.pdf.

⁸ Pohl M (2017), 325,000 mobile health apps available in 2017 – Android now the leading mHealth platform, articles based on Research2Guidance mHealth App Developer Economics Study 2017, available at: <https://research2guidance.com/325000-mobile-health-apps-available-in-2017/>.

⁹ Geissdoerfer M., Savaget P., Evans S. (2017), The Cambridge Business Model Innovation Process. *Procedia Manufacturing*. 8: 262-269. doi:10.1016/j.promfg.2017.02.033.

¹⁰ Market Business News, What is B2B or business-to-business? Definition and examples, accessed in 2020-10-06, <https://marketbusinessnews.com/financial-glossary/b2b>.

to office furniture to security services for office buildings. Digital goods, physical products, and services can all be included here. B2B's counterpart is B2C, which stands for business to consumer. The focus here is selling products, goods, and services to customers for personal use. *Business to government* (B2G) is a business model that refers to businesses selling products, services or information to governments or government agencies. B2G networks or models provide a way for businesses to bid on projects or products that governments might purchase or need for their organizations. This can encompass public sector organizations that propose the tenders or offers. B2G activities are increasingly being conducted via the Internet through real-time bidding. The B2G acronym is widely referred to in public sector marketing¹¹.

Stakeholder identification

As one component of the broader Trillium II project¹² a stakeholder identification exercise was pursued, resulting in the identification of a wide range of potential stakeholders, most of whom are expected to be positive and supportive to Trillium II's objectives:

- Patients and their carers;
- Health and care professionals, including organisations and professionals in Europe, China, Australia, Japan and the United States of America (USA), international emergency agencies (Doctors without Borders, Red Cross, IMC ...) and other country-based organisations;
- Early organisational users including Foreign Affairs Ministries, University educational exchange departments, Military staff serving abroad, North Atlantic Treaty Organization (NATO), tour operators and cruise ships, travel organisers, tourism offices;

¹¹ Market Business News, What is B2G or business-to-government? Definition and examples, accessed in 2020-10-06, <https://marketbusinessnews.com/financial-glossary/b2g/>.

¹² Lowe C. et al. (2018), Deliverable D7.1 Stakeholder analysis and dissemination plan, published in the frame of Trillium II project, available at: <https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5bb4ff7dc&appId=PPGMS>.

- Indirect beneficiaries including travel insurance organisations, Healthcare provider organisations (public and private), Community care organisations (including civil protection, social care, and integrated care), National health ministries and their agencies, 112/911/999 service providers, Patient associations, e.g. European Patient Forum and disease specific organisations such as the European Heart Association;
- Health and Care Information Technology/Service vendors and national eHealth agencies i.e. patient summary providers;
- Transnational organisations including the European Commission (DGs CNECT, Sante, Grow, Competition, Research and Innovation, ECHO), World Health Organisation (WHO), other United Nations (UN) Agencies, such as UNHCR, IOM, UNICEF, IMO; and
- Project team members, including members of the steering committee of the IPS Community of Practice for digital health innovation.

From this comprehensive list of stakeholders, the following were found to be the most crucial for analysis in regard to the development of the business strategy and models:

- developers
- governments
- healthcare providers
- insurance providers
- health and care professionals
- citizens

Empirical insights

The Business Model Canvas (BMC), developed by Osterwalder and Pigneur (2010), is the most widely recognised strategic management and lean start-up template used for developing new or documenting existing business models. It is a visual chart ('canvas') incorporating elements describing the value proposition, products, infrastructure, customers and finances of a firm, designed to assist businesses in aligning their activities by identifying potential

trade-offs. The BMC was recognised to be of potential utility to participants in the Trillium-II project in realising their objective promoting the adoption of IPS standards within the evolving mHealth industry.

Two potential BMCs were developed based on experiences consequent on involvement in two very different case settings. The first case relates to the benefits derived from IPS standards adoption in the context of disaster management. By contrast the second case relates to how IPS standards can be utilised to enhance child health appraisal and child vaccination activity.

Case 1: Disaster management experience from EU Modex Patient with IPS on their mobile

This case highlighted the cost savings that could accrue to national emergency services from improved management of teams and more effective emergency response, as a result of embedding IPS standards on individuals' mobile phones. These savings are potentially large; for example, in the UK, in 2003 the Fire Service reckoned that every person lost in a house fire costs the nation £1m¹³. In Portugal, in 2017, the fire losses implied over 523 million euros¹⁴ and in the US the average fire injury is estimated at \$128,800 (2013 US\$)¹⁵.

The Trillium-II project participated in the 5th European Union Module Exercise (EU MODEX-Ro) to evaluate the utility of the International Patient Summary (IPS) in the context of a disaster management and emergency response civil protection exercise with

participation of 28 countries. EU MODEX-Ro was the largest medical exercise in the history of the European Union with more than 3500 participants and by number of teams and participants it was the largest Medical Module Exercise within the framework of the Union Civil Protection Mechanism with participants from all member states, 600 role players and 2000 medical injects. The EU MODEX-Ro exercise scenario involved a devastating earthquake of 7.5 Richter in Bucharest. At the request of the Romanian government, the EU responded by, amongst others, sending a large and highly skilled Emergency Medical Team (EMT), merging on the spot with an Israeli IDF, an EMT-3 (level 3 means fully operational field hospital).

The value of the IPS available in the smartphone of a victim in the aftermath of a disaster was assessed at different levels of disaster management. 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 data prior to the disaster. During the EMT-3 shifts on October 16, 2018, 20 earthquake victims (role players) arrived in groups with other medical cases to the mobile field hospital for treatment. The victims had the IPS on their mobile phones and showed it to the EMT team.

The visual presentation of specific medical case injects was assessed on three different apps developed by GNOMON (eHealthPass), SPMS (MySNS), and SRDC (Care Planner of the C3Cloud project), as well as in free text in discussions with the Italian, Austrian, and Israeli medical teams:

1. *eHealthPass* enables patients to carry their medical information (medical record, vaccination list, prescriptions calendar, appointments with doctors, etc) on their smartphone and empowers them to gain control of their own data by determining who will have access to which piece of information. In the context of the Bucharest exercise, *eHealthPass* facilitated the demonstration of the IPS on the victims' smartphones and additionally it incorporated the produced encounter report on the victims' medical record. European Mobile Field Hospital information

¹³ Office of the Deputy Prime Minister (2005), *The Economic Cost of Fire: estimates for 2003*, March 2005, London, available at: <https://webarchive.nationalarchives.gov.uk/20120919224305/http://www.communities.gov.uk/documents/corporate/pdf/145111.pdf>

¹⁴ Pedro A. (2017), *Incêndios custaram cerca de 613 milhões de euros*, published on *S//Portugal* on 12 Oct 2017, available at: <https://www.sabado.pt/portugal/detalhe/os-custos-associados-ao-incendio-de-pedrogao-grande>.

¹⁵ Yellman, M. A., Peterson, C., McCoy, M. A., Stephens-Stidham, S., Caton, E., Barnard, J. J., Padgett, T. O., Jr, Florence, C., & Istre, G. R. (2018). Preventing deaths and injuries from house fires: a cost-benefit analysis of a community-based smoke alarm installation programme. *Injury prevention: journal of the International Society for Child and Adolescent Injury Prevention*, 24(1), 12-18. <https://doi.org/10.1136/injuryprev-2016-042247>.

system developed by Leipzig University accessed and retrieved IPS and subsequently produced the encounter report retrieved by eHealthPass.

2. MySNS was developed by SPMS in Portugal, and allows presentation of IPS related information in different cards information on vaccinations, allergies, etc. and is available to all Portuguese citizens.
3. The SRDC adaptive care planner accesses the IPS and can assist health professionals to formulate a care plan based on the most recent professional guidelines covering the care of patients already suffering from chronic diseases including diabetes, heart failure and renal failure. It is a technology tested in the C3Cloud project, which could appeal to social workers dealing with earthquake victims in the period following the disaster, while still in the hospital or evacuation camp. The adaptive Care Planner also allows medical professionals to quickly review the medical summary of a patient by processing and visualizing the IPS.

The HL7 FHIR IPS format used has been the result of collaboration between CEN and HL7 and provides a refined representation of the IPS used in the Connecting Europe Facility (CEF) eHealth Digital Services Infrastructure (eHDSI).

In the exercise earthquake incident medical cases were evaluated both with and without IPS information. In this way, Trillium-II assessed the advantage of having an IPS as a document or as set of information blocks or parts e.g. medications, allergies, etc., in real emergency situations, by developing several in depth interviews (9 interviews and 11 interviewees)¹⁶. They reflected the importance of keeping a photo in the IPS as a means of confirming identification and supporting the language of the country where the disaster occurs. They also illustrated the importance of the user interface design. Depending on the setting where information is used

¹⁶ Thiel R. et al. (2019), D6.2 Establishing the value case for the international patient summary: indicators and results, published in the frame of Trillium II project, available at: <https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5c54d8e9b&appId=PPGMS>.

and the specific medical case, different elements of the IPS were considered of higher importance. Whereas, in the Emergency Room, physicians stated the medical background is of lesser importance, physicians at the field hospital's Ward believed their work could benefit the most from the IPS. Additionally, as part of the integration with the EUMFH Electronic Health Record system (EHR), which can provide long-term medical relief to the earthquake victims, the relevant information (procedures, medication, other medical actions, etc.) is available to the team accompanying the patient as an encounter report, which can also be imported to GNOMON's eHealthPass mHealth app.

It became evident, from the experience gained in EU Modex-RO, that the integration of IPS in disaster management scenarios results in low cost-benefit ratios, which makes it an attractive scenario for a business model that could be government-lead with national authorities being the leading costumers of the supported IPS services.

Based on the experiences of the exercise, the BMC presented in table 1 was developed. It incorporates the various components valuable for this use case and displays the value proposition it brings to citizens and mHealth app user organisations, that were identified as the most direct users/buyers of the model. As noted at the beginning of this section, this canvas represents the more generic portrait of this business model and not only the disaster management one, but incorporates all the relevant information for this specific situation as well.

Case 2: Child health - MOCHA home-based records and the European Vaccination Card

The second case relates to the European project MOCHA: "Models of Child Health Appraisal"¹⁷, which aims to define optimal models of primary child health care that have potential of transferability to other EU countries. After productive discussion with the World Health Organisation Child and Adolescent Health and Development Division¹⁸, MOCHA has undertaken an

¹⁷ The MOCHA project is funded by the European Commission through the Horizon 2020 Framework under the grant agreement number: 634201. <http://www.childhealthservicemodels.eu/>.

¹⁸ <http://www.euro.who.int/en/health-topics/Life-stages/child-and-adolescent-health>

Table 1.

Key Partners & Suppliers	Key Activities	Value Proposition	Customer Relationships	Customer Segments
<p>Key partners:</p> <ul style="list-style-type: none"> • Healthcare Providers: need to incorporate IPS in their eHealth strategy to cover safer patient mobility needs • Health authorities: they set the certification criteria for the apps, thus enhancing the demand for specific services and standards • Emergency services and civil protection: need to use IPS in eHealth apps to access valuable information for accidents and emergency response • Telecomm companies: they are increasingly interested in incorporating health services in their digital offer • Mobile health companies developing complementary apps • Healthcare Software Providers: seeking for new services to incorporate in the EHR or HIS they offer/manage • Venture capitals/investors: seeking for innovative breakthrough services • Insurances: they seek for IPS as additional service to offer to clients and benefit data collection from IPS to better assess health related risk • Healthcare professional associations: they influence the offer and guide the demand for mHealth apps embedding specific services and standards by testing and validating apps <p>Key suppliers:</p> <ul style="list-style-type: none"> • SDOs • Terminology organizations 	<ul style="list-style-type: none"> • Integration of IPS in mHealth app • Promotion and marketing actions to create awareness of the added value of having mHealth apps complying with IPS standards • Participation in standardization groups • Participation in data-thons, connectathons, and similar. <p>Key Resources</p> <ul style="list-style-type: none"> • HL7 FHIR Foundation • Trillium II digital health innovation community • eHDSI Resources and Governance • Agreements with terminology organizations (SNOMED) • Standardization groups • Resources such as datasets, servers and tools provided by the SDOs 	<p>We may distinguish different types of values generated by the adoption of the IPS in mHealth apps:</p> <p>Value for citizens:</p> <ul style="list-style-type: none"> • Ease cross border health data mobility • Increase safety in travelling • Ease emergency and disaster response • Ease chronic disease self-management <p>Value for mHealth app user organizations:</p> <ul style="list-style-type: none"> • By adopting the IPS they are provided with a set of resources to enhance the services they are offering • Be part of a co-creation environment for building and expanding the IPS components • More easily integrate with or be acquired by mainstream companies 	<p>Although citizens and patients and, more in general, citizens are the final beneficiaries of the IPS integrated in the mHealth apps they use, different types of customers and, thus, customer relationship may be envisaged:</p> <ul style="list-style-type: none"> • Citizen as direct clients of the mHealth app developing company (B2C relationship): the citizens themselves search for the product addressing their needs in a marketplace, pay for subscription or use, review the apps and contribute in iterative co-design processes by providing their feedbacks. Such processes are encouraged or led by patient organizations. • Healthcare providers or mainstream telecom providers as clients (or even buyers of the whole mHealth company) in a B2B approach. • Health authorities as direct interlocutors of the mHealth companies as data third party suppliers setting minimum criteria to be complying with (B2G approach). <p>Channels</p> <ul style="list-style-type: none"> • Online marketplaces for apps • Apps prescribed as clinical services by health professionals • Apps tested/validated/recommended by patients' associations or healthcare professional societies • Apps integrated in mainstream devices • Cross sector collaboration (e.g. services offered by work insurances to expat workers) 	<ul style="list-style-type: none"> • Citizens In particular those benefiting of cross border healthcare services: <ul style="list-style-type: none"> - Tourists - Chronic patients - Expat workers • Healthcare professional associations (e.g. EU Society of Hypertension, etc.) • Healthcare provider organisations (e.g. hospital, primary care provider) • Insurers • Patient advocacy organizations • Medical tourism / hospitality organizations • Other digital health companies and EHR/PHR/HIS software providers

Table 1: Business model canvas for IPS standards adoption in mHealth

Cost Structure	Revenue Streams
<p>The Cost Structure is:</p> <ul style="list-style-type: none"> • value driven, thus less concerned on cost minimization and more focused on value creation by enhancing the services offered by the app incorporating the IPS; • characterized by "economies of learning" meaning here that incorporating the IPS gives them the opportunity to know in advance the key information to be searched for and its format and may access to a set of resources such as training, servers, and tools provided by the SDOs which reduce considerably their R&D and integration costs. <p>Main categories of costs are software development; integration costs; training; personal assistance and software maintenance; certification; standardisation training and membership fees.</p>	<p>Key types of revenues envisaged for mHealth companies are:</p> <ul style="list-style-type: none"> • Subscription/download fees following e.g. medical prescription of the mHealth app, recommendations formulated by patients' associations or healthcare professionals' societies • Usage fees • Agreements with healthcare providers, insurers which outsource the development of their own apps • Acquisition by mainstream devices or OEM Revenue sharing on end to end services

Table 1: Business model canvas for IPS standards adoption in mHealth (Continued)

in-depth investigation to find out more about the existence and use of home-based records in the EU and EEA countries. A home-based record (also known as a 'parent held record') is a record of a child's growth, development and utilisation of public health/preventive health services. It is normally issued at birth and held by the parents. Traditionally the record was a paper booklet but some countries now use digital platforms, including Citizen Patient Portals. In a home-based record, a health professional adds key information about the child, but in some cases the parent(s) and other professionals also make entries. The MOCHA Home Based Records report¹⁹ investigates the extent of use of such records, and how they fit into the delivery of primary care services to children in the digital age.

There is considerable heterogeneity between primary care systems that have evolved in individual national cultural environments. MOCHA studied how the transfer of models or their individual components can be achieved across nations, using examples of combinations of settings, functions, target groups and tracer conditions. There are many factors that determine the feasibility of successful transfer of these from one setting to another, which must be recognised and considered. These include the environment of the care system, national policy

¹⁹ Deshpande S. et Al. (2018), Home Based Records, published in the frame of MOCHA project in dialogue with Dr. Martin Weber, WHO Regional Office for Europe, Sep 2018, available at: <https://www.childhealthservicesmodels.eu/wp-content/uploads/R15-Home-Based-Records-Report.pdf>.

making and contextual means of directing population behaviour – in the form of penalties and incentives, which cannot be assessed or expected to work by means of rational actions alone.

One positive finding evident in the MOCHA report is shown by the design elements present in a home-based record across EU/EEA countries (page 23). From the list below, almost all the countries collect the first 6 items as part of their home-based records and when referring to immunisation, apart from Ireland which only has information on some service areas, all countries include this feature in their regular data collection:

1. Birth and postnatal data
2. Allergies and other alerts
3. Height and weight measurements
4. Immunisation
5. Developmental checks
6. Long-term conditions
7. Prescribed medication
8. Urgent referral plans for long-term conditions
9. Plan of care and services
10. Other

In order to assess transferability, the MOCHA project developed a list of criteria, summarised in a PIET-T process, that identifies key Population

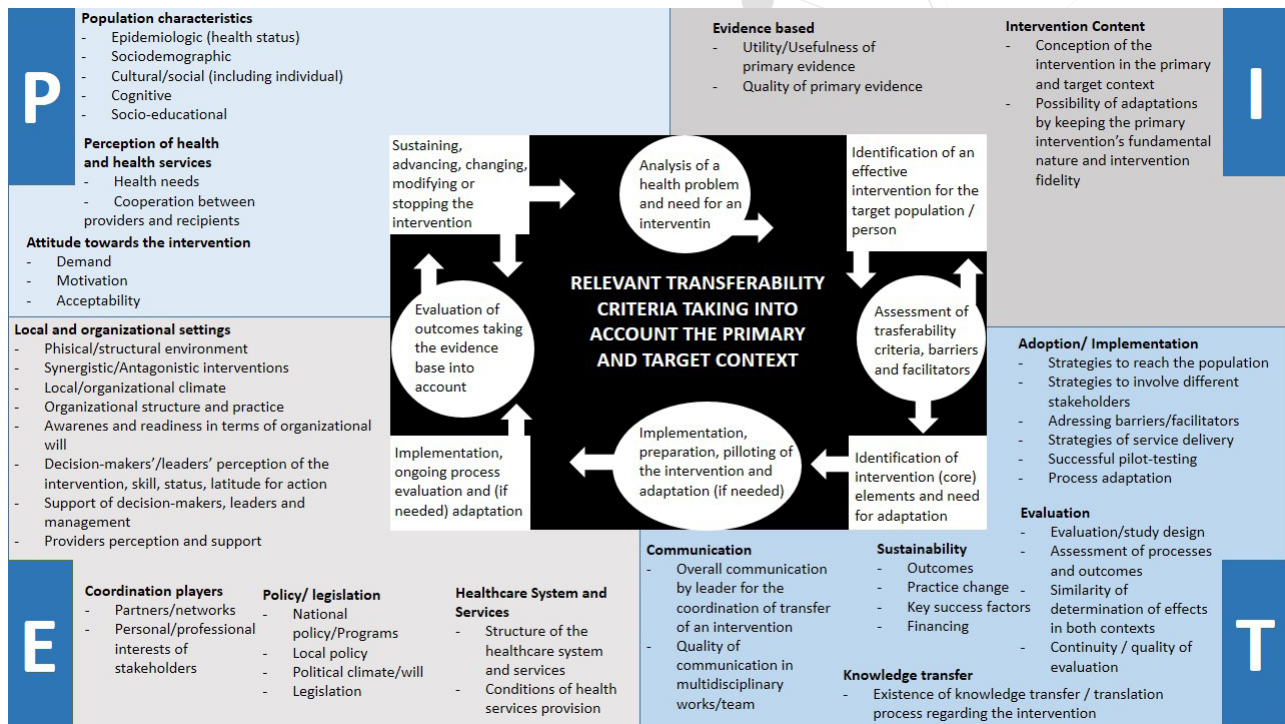


Figure 1: The PIET-T model with systematized criteria to determine transferability

characteristics, Intervention content, Environment and Transfer.

To explore the process and means of transferability, the project obtained consensus statements from the researchers on optimum model scenarios, and conducted a survey of stakeholders, professionals and users of children’s primary care services that involved three specific health topics: vaccination coverage in infants, monitoring of a chronic or complex condition and early recognition of mental health problems.

The results²⁰ provide insight into features of transferability – such as the availability and use of guidelines and formal procedures; the barriers and facilitators of implementation and similarities and differences between model practices and the existing model of child primary care in the country. Stakeholders expressed a need for improvements to the child

primary care system and valued the importance of system components in the field of public access to information about vaccination, coordination and continuity of care, and open access to services for adolescents and confidentiality until treatment is in place. Heterogeneity was found between countries with regard to the presence of these components and their demand for change.

In this context, MOCHA and Trillium-II partners proposed to improve the availability of up-to-date immunisation information on children when they are seen by a health or care professional. These efforts aim to strengthen children’s immunization in Europe through health data standards, by connecting Patient summaries to EU vaccination cards and immunization registries. This may lead to a national, and even international, measure that prevents epidemic outbreaks with relevant financial and health-related outcomes. This information may be vital in emergency situations, to determine the level of immunity of a child who has been exposed to an infection risk, such as tetanus or meningitis. It can also be useful for the care professional to advise a child or parent if the child is due for a vaccine or booster or has fallen behind schedule. It also fits within the context of

²⁰ Blair M. et Al. (2018), Issues and Opportunities in Primary Health Care for Children in Europe: The final summarised results of the Models of Child Health Appraised (MOCHA) Project, published in the frame of the MOCHA project, Nov 2018, available at: <http://www.childhealthservicemodels.eu/wp-content/uploads/MOCHA-Issues-and-Opportunities-in-Primary-Health-Care-for-Children-in-Europe.pdf>.

Table 2.

Key Partners & Suppliers	Key Activities	Value Proposition	Customer Relationships	Customer Segments
<p>Key partners:</p> <ul style="list-style-type: none"> • Healthcare Providers: there is a need to organize, digitize and make accessible also cross-border immunization info (in many countries still paper-based only) • Health authorities: <ol style="list-style-type: none"> 1. they set the app certification criteria 2. they seek to include digital vaccination records in their national/regional eHealth strategies for child health 3. they can benefit from larger datasets of vaccination information (including info from families using private paediatric services) for population health studies, risk detection and prevention • Telecomm companies: they are increasingly interested in incorporating health services in their digital offer and paediatric health is one of the most consulted and pressing topic • Mobile health companies developing complementary apps such apps for parental guidance, child health and wellness trackers, etc. • Healthcare Software Providers: seeking for new services to incorporate in the EHR or HIS they offer/manage • Venture capitals/investors: seeking for innovative breakthrough services • Insurances: additional service to offer to clients and data collection from IPS to better assess risk • Paediatric societies • Parents associations • Educational center <p>Key suppliers:</p> <ul style="list-style-type: none"> • SDOs • Terminology organizations • ECDC and National Center for Disease Control 	<ul style="list-style-type: none"> • Integration of IPS in paediatric mHealth app including vaccination validated info • Promotion of actions to create awareness about the benefits of having a paediatric IPS with the vaccination component • Establish agreements with health authorities to retrieve data from vaccination registries • Establish agreements with associations of paediatric doctors to make their vaccination activity traceable through the app <p>Key Resources</p> <ul style="list-style-type: none"> • HL7 FHIR Foundation • eHDSI Resources and Governance • Agreement with terminology organizations (SNOMED) • Standardization groups • Resources such as datasets, servers and tools provided by the SDOs Data agreements with health authorities • Consent from parents • WHO vaccination strategies • Access to home care records • Access to vaccination cards 	<p>The mHealth companies offer paediatric health management app including IPS</p> <p><i>Value for citizens:</i></p> <ul style="list-style-type: none"> • Ease cross border children health data mobility • Increase safety in travelling • Ease decision-making from the doctors in situations of emergency • Provide public health authorities with reliable datasets including wider coverage of the population (also those using private services) <p><i>Value for mHealth app user organizations:</i></p> <ul style="list-style-type: none"> • Have a set of resources to enhance the services they are offering (e.g. mHealth companies which are already offering paediatric health apps to foster healthy habits, provide guidance to parents, etc.) • Be part of a co-creation environment for building and expanding the IPS components • More easily integrate with or be acquired by mainstream companies 	<p>Different types of customers and thus customer relationship may be envisaged:</p> <ul style="list-style-type: none"> • <i>Parents of minors as direct clients of the mHealth app developing company</i> (B2C relationship): the parents themselves search for the product addressing their needs in a marketplace, pay for subscription or use, review the apps and participate in iterative co-design processes that are frequently encouraged or led by parents' networks or paediatric societies. • <i>Healthcare providers subcontracting a MHealth company to design and operate an app for paediatric care record access</i> (B2B). • <i>Mainstream telecom providers</i> as potential buyers of the apps (B2B). • <i>Health authorities</i> as direct interlocutors of the mHealth companies as third-party suppliers (B2G approach). <p>Channels</p> <ul style="list-style-type: none"> • Online marketplaces for apps • Apps prescribed as clinical services by paediatric doctors • Apps suggested, reviewed or released by paediatric doctor associations (e.g. child health tracker apps) • Apps integrated in mainstream devices 	<ul style="list-style-type: none"> • Citizens, in particular parents • Paediatric doctors and their associations • Healthcare provider organisations (e.g. hospital, primary care provider) • Public health agencies for population studies • Educational centers • Parents associations

Table 2. Business model canvas for child vaccination use case

Cost Structure	Revenue Streams
<p>The Cost Structure is:</p> <ul style="list-style-type: none"> • value driven, thus less concerned on cost minimization and more focused on value creation by enhancing the services offered by the app incorporating the IPS; • characterized by “economies of learning” meaning here that incorporating the IPS gives them the opportunity to know in advance the key information to be searched for and its format and may access to a set of resources such as training, servers, and tools provided by the SDOs which reduce considerably R&D and integration costs. <p>Main categories of costs are software development; integration costs; training; personal assistance and software maintenance; certification; standardisation training and membership fees.</p>	<p>Key types of revenues envisaged for mHealth companies are:</p> <ul style="list-style-type: none"> • Subscription/download fees following e.g. medical prescription of the mHealth app, recommendations formulated by patients’ associations or healthcare professionals’ societies • Usage fees • Agreements with healthcare providers, insurers which outsource the development of their own apps • Acquisition by mainstream devices or OEM Revenue sharing on end to end services

Table 2. Business model canvas for child vaccination use case (Continued)

both the EU and WHO seeking to drive higher child immunisation uptake, and effective holistic child health care.

To this end, it is necessary to examine the data flows that would be needed to enable care professionals to be informed of immunisation status when they consult a child, the feasibility of harmonising the core information at a European level, the data protection and ethical issues that would need to be catered for, how better supply of immunisation status could facilitate improved uptake, and what practical steps might be recommended for action in the near future.

The insights collected in the course of the MOCHA project on home-based medical records can be incorporated into a Business Model Canvas as illustrated in table 2, the principal objective of which is to enhance the value created, delivered and captured for a range of stakeholders.

Synthesis

Although these are two very different cases, they exhibit many common beneficial elements attendant on the use of IPS standards. The following are particularly important:

Cost-saving: the disaster management exercise clearly demonstrated significant cost saving from

the use of the IPS; the child-immunisation example less so, though avoidance of epidemics is clearly a potentially huge benefit;

Improved decision-making by clinicians: both examples highlighted this benefit in a clear manner; *Better patient outcomes:* again, both examples bring this improvement, in the short-term for the disaster management and in the longer term from improved immunisation protecting growing children, especially those moving cross-border;

Peace of mind, especially when travelling: improved safety is clear in both examples.

The above benefits indicate that there is clearly a good business case for all the major stakeholders identified by the project: patients and clinicians obviously benefit hugely; health providers save money and improve the statistics of their patient populations; suppliers access a larger market. This therefore raises the question of why it hasn't already happened. Or, phrasing it as a challenge towards societal development, who needs to initiate the change? In the EU, the temptation is to say that there is only one organisation with the power to enforce implementation; if enforcement is still not the initial solution, adoption may be encouraged by promoting the business case at every opportunity, particularly through standards organisations, to encourage *worldwide* acceptance.

This highlights the crucial question of what the trigger might be to promote international acceptance of this common standard. This is certainly a complex question with multiple pathways, although it is logical that the answer almost certainly involves mHealth app developers as key stakeholders.

Conclusion

As recognized by the WHO²¹, the spread of digital technologies and global interconnectedness has significant potential to accelerate member states' progress towards achieving universal health coverage, including ensuring access to quality health services. Increasing the capacity of member states to implement digital health, and in particular mHealth, could play a major role in realizing that potential, particularly by increasing the safety and quality of care. Mobile phones are now a globally available communications tool, providing telephonic and internet access. Due to smart phones' capacity to deliver computer and communication capabilities, third-party software apps are proliferating as a means to improve diagnosis and personalize health care. Using a wide array of instruments, sensors and other technologies, patient data can be transmitted to clinical and/or research teams, enabling data analysis and facilitating response time.

On the issue of regulation, the healthcare sector is, and has been, subject to a very intense scrutiny. Digital as well as non-digital health solutions that could pose a risk to patient safety must be cleared by an approved regulatory body, such as the FDA in the USA. However, there are signs of big future changes in regulating digital health and thus mHealth too. In

²¹ WHO (2018), "mHealth. Use of appropriate digital technologies for public health", Report by the Director-General, A71/20, 26 March 2018, available at: http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_20-en.pdf.

July 2017, the Food and Drug Administration (FDA) announced a very new approach to approving digital health solutions (called Digital Health Innovation Plan). Instead of approving individual digital products, entire companies could be approved, and digital products released by those pre-selected companies would not have to go through a regulatory process for each of their product releases. This development is still very fresh but the FDA seems to initiate a paradigm change in regulating digital health solutions. This could act as a blueprint for more countries to follow and represents a key opportunity for IPS standards' adoption to position it as a core requirement for approval and/or certification.

The concept of making IPS data available through mobile technologies, and specifically an individual's mobile phone, looks set to increase the safety and quality of care by providing secure access to the information needed by the attending physicians at the time of care. A critical step towards making effective use of health data will be taken. This is particularly important in the event of disasters, emergencies and other unplanned care. Mobile technologies allow individuals to have access to their own summary health records and give physicians timely access to these records, which is particularly important when patients seek care outside of their normal care settings.

To this purpose, it is crucial to build a business case for mHealth app developers to adopt IPS standards and develop tools that will simplify and accelerate adoption. The commercial and competitive advantages of such adoption, together with relevant business models, are presented in this paper with the aim of fostering adoption and further refinement, in addition to serving as the basis of continue innovation.

References

- Aitken M, Clancy B, Nass D (2017). The Growing Value of Digital Health. Evidence and Impact on Human Health and the Healthcare System. Iqvia Institute. Retrieved in 2019-07-22 from <https://www.iqvia.com/institute/reports/the-growing-value-of-digital-health>
- Betts D, Korenda L (2018). Findings from the Deloitte 2018 Health Care Consumer Survey. Inside the Patient Journey: Three key touch points for consumer engagement strategies". Deloitte Center for Health Solutions. Retrieved in 2019-07-22 from https://www2.deloitte.com/content/dam/insights/us/articles/4632_CHS-Consumer-survey/DI_CHS-consumer-survey.pdf
- Blair M, Rigby M, Alexander D (2018). Issues and Opportunities in Primary Health Care for Children in Europe: The final summarised results of the Models of Child Health Appraised (MOCHA) Project. Retrieved in 2019-07-22 in <http://www.childhealthservicemodels.eu/wp-content/uploads/MOCHA-Issues-and-Opportunities-in-Primary-Health-Care-for-Children-in-Europe.pdf>
- Cvrkel T, The ethics of mHealth: Moving forward, Journal of Dentistry, Volume 74, Supplement 1, 2018, Pages S15-S20, ISSN 0300-5712, Retrieved in 2019-07-22 in <https://doi.org/10.1016/j.jdent.2018.04.024>
- eHealth Network (2013). Guidelines on minimum/non-exhaustive patient summary dataset for electronic exchange in accordance with the cross-border directive 2011/24/EU. Retrieved in 2019-07-22 in https://ec.europa.eu/health/sites/health/files/ehealth/docs/guidelines_patient_summary_en.pdf
- European Commission (2017). Public consultation on Transformation of Health and Care in the Digital Single Market. Retrieved in 2019-07-22 from https://ec.europa.eu/info/consultations/public-consultation-transformation-health-and-care-digital-single-market_en
- Joint Initiative Council (2018) Patient Summary Standards Set. Retrieved in 2019-07-22 in http://www.jointinitiativecouncil.org/registry/Patient_Summary_Standards_JIC_Jan_2018.pdf
- Lewis TL, Wyatt JC (2014), mHealth and mobile medical Apps: a framework to assess risk and promote safer use. J Med Internet Res. 2014;16(9): 210. DOI:10.2196/jmir.3133. Retrieved in 2019-07-22 in <https://www.ncbi.nlm.nih.gov/pubmed/25223398>
- Monteiro M, Stichele R, Kalra D, Chronaki C, Cangilioli G, et al (2017). Patient Summary Moving clinical data from country to country in Europe. Accessed in 2019-07-22 in [http://www.eStandards-project.eu/eSTANDARDS/assets/File/27062017_%20Patient%20Summary_brochure_V9_eStandards\(1\).pdf](http://www.eStandards-project.eu/eSTANDARDS/assets/File/27062017_%20Patient%20Summary_brochure_V9_eStandards(1).pdf)
- Osterwalder, A, Pigneur, Y (2010), *Business Model Generation: A Handbook for Visionaries, Game Changers and Challengers*, Wiley
- Research2Guidance (2017), mHealth App Economics 2017/2018. Current Status and Future Trends in Mobile Health. Retrieved from <https://research2guidance.com/product/mhealth-economics-2017-current-status-and-future-trends-in-mobile-health/>
- Trillium II, Deliverable D6.2 - Establishing the value case for the international patient summary: indicators and results. Retrieved in 2019-09-02 in <https://trillium2.eu/deliverables/>

Trillium II, Deliverable D7.1 - Stakeholder analysis and dissemination plan. Retrieved in 2019-09-02 in <https://trillium2.files.wordpress.com/2018/08/d7-1-v2018-06-05-stakeholder-analysis-and-dissemination-plan-wp7-adi.pdf>

Trillium II, Deliverable D7.4 - Business models for Patient Summary standards in mHealth apps. Retrieved in 2019-09-02 in <https://trillium2.eu/deliverables/>

World Health Organisation (2018). mHealth, Use of appropriate digital technologies for public health. Report by the Director-General, A71/20, 26 March 2018. Retrieved in 2019-07-22 from http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_20-en.pdf.

About the Authors

Valentina Tageo graduated in Economics at the Catholic University of Milan, obtained a Master in European Project Management and she is currently a MSc candidate in Population Health Sciences at the University of Glasgow. Valentina has multiannual experience in international project management and proposal writing under several funding programmes (e.g. FP7, H2020, URBACT, INTERREG, among others). She has been working as Research Project Manager at different healthcare, research and industry organizations. For 11 years she provides consultancy services to public administrations like Barcelona City Council and the Catalan Agency for Health Information, Assessment and Quality (AQuAS) and non-profit entities such as the Italian Multiple Sclerosis Society. Currently, she is the project manager of the RRI MULTI-ACT project and Lead Expert for the Urban Innovation Actions (UIA) project GAVIUS. At ECHAlliance she is the Director of the International Projects Unit. In 2018 Valentina founded the research and consultancy company Wise Angle which has been recently awarded two contracts by the European Economic and Social Committee.



Carina Dantas has 20 years of experience in the social and health care sector. She is Senior International Project Manager at the ECHAlliance and CEO of SHINE 2Europe, Vice-President of the European Covenant on Demographic Change, Main Coordinator of group D4 - *Age-friendly Building, Cities and Environments* of the EIP-AHA, Coordinator of the Stakeholders Network SHAFE - Smart Healthy Age-friendly Environments and a Member of the Standing Committee of Policy and Advocacy in the International Health Literacy Association. She is also a member of the Expert Team developing the EU Ethics framework for the ICT Profession, as external expert for CEN/CENELEC, Team Leader of the group of experts designing the AAL Reference Guidelines in the Field of Ethics, Data Privacy and Security, contracted by the AAL Programme and evaluator/reviewer for the European Commission, Eureka, AAL and EIT Digital.



Catherine Chronaki is the President of the European Federation for Medical Informatics (2020-2022). In her role as Secretary General of HL7 Europe, she is active in Digital Health Policy and Standards. She led the Trillium project on International Patient Summary standards under the EU-US MoU on eHealth. Now, in x-eHealth, she co-leads work on innovative communities of practice for the European EHR exchange format. She serves on the eHealth Stakeholders group since 2013.



About the Authors

Charles Lowe has an extensive background in digital health, working in both public & private sectors. His recent work has centred on the regulation & assessment of mHealth apps. He is CEO of the Digital Health & Care Alliance (DHACA), a Contributing Editor to www.telecareaware.com, a Special Adviser to NICE, organiser of the London Health Technology Forum, and a Past President of the Royal Society of Medicine's Telemedicine & eHealth Section. He consults for Humetrix Inc on app-related matters and is an advisor to Testcard and Yourmeds. He chairs Citizens Online, the digital inclusion charity.



Dr. Alexander Berler has an MSc in Biomedical Engineering and a PhD in Medical Informatics. He was affiliated with the Electrical Engineering Department, National Technical University of Athens, Greece, as a Postgraduate Student and Research Associate in the areas of healthcare information systems interoperability, medical informatics and telemedicine until 1999. He has worked at Information Society SA, the Greek official governmental information technology project office, as a project director responsible for the large healthcare informatics projects of the Greek government until 2006. He is currently employed as the Director of consulting services department at Gnomon Informatics with an expertise in international projects related to e-health, e-procurement and e-government. He is an active member of the eHDSI community on the adoption of tools for cross border healthcare across Europe and beyond. He is also acting as the IHE services director on behalf of IHE Europe, promoting the use of international standards via the IHE Technical frameworks and Integration profiles. He is a member of several societies, institutes and organizations (IEEE, ACM, etc), a member of several IHE Europe Committees and the Chair of HL7 Hellas, the Greek HL7 International Affiliate. More information available at: <http://gr.linkedin.com/in/aberler/>



Federica Porcu is an International Project Manager with a strong background in European projects covering the socio-economic impact of ICT, innovation policies, and stakeholder engagement. Federica has worked with several European bodies (DG CONNECT, DG RTD DG JUSTICE, JRC, EACEA and EIGE) on various studies and projects. She has a strong expertise in understanding of European institutions and processes. Prior to joining ECHAlliance, Federica worked for Open Evidence SL, a spin-off from the Open University of Catalunya, as a researcher and communication officer, and she conducted several studies for the European Commission and its agencies. She has a track record of stakeholders' engagement strategies and to plan and coordinate conferences, workshops and seminars. At ECHAlliance Federica is the Communication Manager of several projects funded by EU Research and Innovation Programmes, such as H2020, Erasmus+, Interreg Europe and IMI, and member of the Management Team of the Digital Health Society initiative. She holds a MSc in Governance and Global Systems and a BSc in Political Science and International Relations from University of Cagliari, as well as a Master in Innovation Management from the Regional Government of Sardinia.

