Patient Summary Standards, building blocks, and Electronic Health Record Exchange Format: an IPS ecosystem emerges

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Secretary General

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“To support an innovative collaborative community of public- and private-sector entities working toward developing, deploying, and using eHealth science & technology:

✓ to empower individuals
✓ to support care
✓ to advance clinical outcomes
✓ to enhance patient safety, and
✓ to improve the health of populations.”

Critical Levers:
✓ International interoperability
✓ workforce development
✓ innovation ecosystems

Trillium Bridge Recommendation:

“Advance an International Patient Summary (IPS) standard to enable people to access and share their health information for emergency or unplanned care anywhere and as needed. At minimum the IPS should include immunizations, allergies, medications, clinical problems, past operations and implants.”
Trillium-II partnership: 14 countries – 7 health systems

**Standards Organizations:**
- HL7 International Foundation (Scientific Coordinator), BE
- NEN/CEN TC 251 Health Informatics, NL
- IHE EUROPE, BE
- CDISC EUROPE FOUNDATION, BE

**Health Systems & Associated Competence centers:**
- MedCom (Administrative Coordinator), DK
- LISPA - LOMBARDIA INFORMATICA, I
- THL - TERVEYDEN JA HYVINVOINNIN LAITOS, FI
- eSANTE - AGENCE eSANTE, LU
- TicSalut – Catalunia, ES
- SPMS, PT
- Reliant, Reliant Medical Group, Inc., US
- HSCP Healthcare Services Platform Consortium, US
- KAISER FOUNDATION HOSPITALS, US

**Dissemination and Networking:**
- ECHA - Connected Health Alliance CIC, UK
- ADI - Advanced Digital Innovation LTD UK
- I~HD - European Institute for Innovation through HealthData, BE

**Development and Evaluation:**
- Gnomon Informatics SA, Greece
- PHAST RESEAU Association, France
- SRDC, Turkey
- OFFIS EV, Germany
- EMPIRICA, Germany
- LANTANA Consulting Group, LLC, US
- PROSOCIAL Applications INC, US

**Other Parties**
- The Sequoia Project and eHealth Exchange, US
- AHIMA, US
Trillium II: Scaling up international patient summary (IPS) standards

- Highlight the **social value** of patient summaries and health data
- Contribute to their **Governance** of IPS specifications
- Develop, Collect, Assess **learning resources**
- Foster innovation & inform **health policy**
- Collaborate across **standardization bodies**
- Bridge **grassroot patient summary initiatives**
- Engage **mobile Health companies & app developers**
- Establish a **Global Community of Practice** for Digital Health Innovation using International Patient Summary Standards (IPS)

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Uses of the IPS through a personal lens

**Listening to the patient and the family**
- Quality assurance: medication reconciliation by the family
- Health goals: tracking progress and identifying health trends
- Early warnings: frailty in the elderly

**Navigating digital health data: portability, trust, and flow**
- Tracking hypertension: Chronic disease management
- Rare Disease Passport: patient summaries for patients with rare diseases
- European Vaccination Card: Vaccination of children in communities and refugee camps
- Survivor passport: Survivors of childhood cancer
- Mother / Child Summary: fertility, pregnancy, child birth, infant home records

**Tracking the health needs in communities**
- Disaster and emergency management
- My Healthy neighborhood
Advancing adoption of the IPS

Extending the scope of patient summaries beyond emergency/unplanned

Building FHIR IPS “library”

Refine the IPS components, with the knowledge gained from the project.

Disaster Management
Vaccinations
Vaccination Card
Survival Passport
Frailty
Child Health
Chronicity
RD-Passport

Vaccinations
Vaccination Card
Survival Passport
Frailty
Child Health
Chronicity
RD-Passport

FAIR research study

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International Patient Summary
Supporting the EHRxF

Current Intended Use
as a document
21 March 2019

1. The IPS document
2. The IPS data blocks

as a document and as a toolset for digital health systems
Trillium II International Patient Summary (IPS)
Use Cases and tools

➢ Come Learn about HL7 FHIR IPS and the available implementation tools!
➢ Help us Assess the efficiency and effectiveness of HL7 FHIR IPS

✓ Immunization List
  - HL7, SPMS, GNOMON, TicSalut, eSanté
  - In collaboration with MOCHA Project

✓ Assessing Frailty
  - SRDC, SIGLA, HL7
  - In collaboration with FrailSafe Project

✓ Chronic Patient Care
  - SRDC, HL7
  - In collaboration with C3Cloud Project

✓ Disaster Management
  - HL7, SPMS, GNOMON
  - In collaboration with EUMFH, EUMODEX Ro

➢ Learn how to win the Trillium II prize!

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New Use cases: Business Canvas for HL7 FHIR IPS

- Key partners & Suppliers
- Key activities and Revenues
- Value Proposition
- Customer Relationships and Channels
- Customer Segments
- Cost Structure
- Revenue Streams
Trust and Flow: the basis of well-functioning digital health systems

eStandards digital health Compass: Respect for perspectives of stakeholders

eStandards Roadmap Components: reusing eHealth artefacts

Co-Creation, Governance, Alignment: bringing them all together
### 0: Patient Summary Initiative Characteristics

<table>
<thead>
<tr>
<th>0.1</th>
<th>What is the name of the patient summary initiative?</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.2</td>
<td>What is the scope of the patient summary initiative?</td>
</tr>
<tr>
<td></td>
<td>Depth:</td>
</tr>
<tr>
<td></td>
<td>- What is the content of the patient summaries that are exchanged?</td>
</tr>
<tr>
<td></td>
<td>Width:</td>
</tr>
<tr>
<td></td>
<td>- Which use-cases are supported in the exchange of patient summaries?</td>
</tr>
<tr>
<td>0.3</td>
<td>What is the stated purpose of the patient summary initiative?</td>
</tr>
<tr>
<td>0.4</td>
<td>Which stakeholders are involved in the actual exchange of patient summary data?</td>
</tr>
<tr>
<td></td>
<td>Possible stakeholders</td>
</tr>
<tr>
<td></td>
<td>- Patients and relatives</td>
</tr>
<tr>
<td></td>
<td>- Healthcare professionals</td>
</tr>
<tr>
<td></td>
<td>- Healthcare provider organisations</td>
</tr>
<tr>
<td></td>
<td>- Payer organisations</td>
</tr>
<tr>
<td></td>
<td>- Patient data registries</td>
</tr>
<tr>
<td></td>
<td>- Research institutions</td>
</tr>
</tbody>
</table>
**1: Patient Summary Specification and Use of Standards**

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Is there a common specification for the Patient Summary?</td>
<td>Standards regarding:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Patient summary content</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Structure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Terminology</td>
</tr>
<tr>
<td>1.2</td>
<td>Are chosen standards in place for the use of patient summaries?</td>
<td>Possible forms of infrastructure:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Dedicated repository</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Dedicated registry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- IHE XDS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Secure e-mail</td>
</tr>
<tr>
<td>1.3</td>
<td>Are agreements made about a underlying infrastructure for the exchange of patients summaries?</td>
<td></td>
</tr>
</tbody>
</table>
## 2. Patient Summary Governance Scope and Objectives

<table>
<thead>
<tr>
<th>2.1</th>
<th>Which party (or parties) is (are) responsible for the patient summary specification?</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>2.2</th>
<th>Is patient summary governance part of a bigger governance process or is it dedicated?</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>2.3</th>
<th>Where is the patient summary governance aimed at currently?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Possible aims:</td>
</tr>
<tr>
<td></td>
<td>- Maintaining and updating specification of the patient summary</td>
</tr>
<tr>
<td></td>
<td>- The data, data quality and data protection regarding the parties exchanging patient summaries</td>
</tr>
<tr>
<td></td>
<td>- The involvement of the patient in the exchange of patient summaries</td>
</tr>
<tr>
<td></td>
<td>e.g. informing patients and asking permission</td>
</tr>
<tr>
<td></td>
<td>- The infrastructure of the patient summary exchange</td>
</tr>
<tr>
<td></td>
<td>- The implementation of a patient summary specification</td>
</tr>
<tr>
<td></td>
<td>- Testing existing implementations of a patient summary specification</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.4</th>
<th>What are the current objectives of patient summary governance?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Possible objectives</td>
</tr>
<tr>
<td></td>
<td>- Maintaining a stable specification of a fixed (minimal) dataset</td>
</tr>
<tr>
<td></td>
<td>- Enabling the growth of topics and applications of patient summary exchange</td>
</tr>
<tr>
<td></td>
<td>- Ensuring the data, data quality and data protection of the patient summary exchange.</td>
</tr>
<tr>
<td></td>
<td>- (improved) Alignment with international patient summary specifications</td>
</tr>
<tr>
<td></td>
<td>- Correct implementation of the patient summary specification at new affiliated parties</td>
</tr>
<tr>
<td></td>
<td>- Ensuring correct use of the patient summary specification at existing affiliated parties</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.5</th>
<th>What are the future aims and objectives of patient summary governance?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Possible aims and objectives- as described above - can be selected.</td>
</tr>
</tbody>
</table>
### 3: Stakeholders involved in the Patient Summary Governance

#### 3.1 Which stakeholders are currently involved in the patient summary governance?

<table>
<thead>
<tr>
<th>Two sorts of stakeholders:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stakeholders that are directly involved in the exchange of patient summaries (0.4)</td>
</tr>
<tr>
<td>Stakeholders which are not directly involved in the exchange of patient summaries but are involved in the patient summary governance:</td>
</tr>
<tr>
<td>The organisation managing the PS specifications</td>
</tr>
<tr>
<td>Health Authorities</td>
</tr>
<tr>
<td>Clinical Societies</td>
</tr>
<tr>
<td>Professional Societies</td>
</tr>
<tr>
<td>Patient Organisations</td>
</tr>
<tr>
<td>Vendor Associations</td>
</tr>
<tr>
<td>Payer Associations</td>
</tr>
<tr>
<td>Investment Partners</td>
</tr>
<tr>
<td>National eHealth Competency Centers</td>
</tr>
<tr>
<td>Standards Developing Organisations</td>
</tr>
<tr>
<td>Individual Experts</td>
</tr>
</tbody>
</table>

#### 3.2 What role does each stakeholder currently have in the patient summary governance process?

<table>
<thead>
<tr>
<th>Possible roles for stakeholders:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gathering requirements for draft specifications, including revisions</td>
</tr>
<tr>
<td>Providing stakeholder input on draft specifications</td>
</tr>
<tr>
<td>Deciding upon final specifications</td>
</tr>
<tr>
<td>Publication and dissemination of final specifications</td>
</tr>
<tr>
<td>Establishing and running incentive schemes for adoption of specifications</td>
</tr>
<tr>
<td>Monitoring the adoption of specifications (users/vendors/regions)</td>
</tr>
<tr>
<td>Monitoring the use of specifications (numbers of PS created or exchanged)</td>
</tr>
</tbody>
</table>

#### 3.3 To what extent are changes desired in stakeholders and their roles for the future?

| Possible stakeholders and roles as described above can be selected. |
# Questionnaire on governance of Patient Summary Specs

| 4.1 | Is updating of the patient summary specification part of the patient summary governance? | How are the adjustments brought to the attention?  
- Is there a process for capturing user feedback as input for adjustments to the specification?  
- How is decision-making carried out upon desired adjustments to the specification?  
- How are the adjustments implemented in the patient summary specification? |
| 4.2 | How frequent are adjustments made to the patient summary specification? | Dynamic adjusting the specification, on demand  
- Periodically adjusting the specification |
| 4.3 | Do adjustments of the patient summary specification require adjustments to be made in the used standards? | Do you wait for the adjustments to be addressed in a new publication of the corresponding standard or do you include the adjustment directly in the specification?  
- How are the required changes adopted by the standard developing organisation?  
- How are those changes of the standards adopted in the patient summary specifications? |
| 4.4 | Are there other (patient summary) specifications that need to be taken into account in the patient summary governance? | Which specifications are these?  
- How are those specifications addressed in the patient summary governance?  
- Is there a leading specification? |
| 4.5 | Is the implementation of the patient summary specification addressed in the governance process? | How is this implementation performed?  
- Knowledge exchange  
- Guidance of the implementation |
| 4.6 | Is there an audit process in place for testing existing implementations of the patient summary specification? | Who performs this audit process? |
| 4.7 | How is version management addressed when the patient summary specification is updated? | Are multiple versions of the same specification supported in parallel?  
- What flexibility/autonomy do stakeholders have in selecting a version?  
- Is backward compatibility required for new versions of the specification?  
- When to react to new versions of the underlying standards, profiles, etc.? |
Linkage of standards and interoperability

Global Standards Specification

National and/or Cross-border Standards Specification

Cross-border Implementation

National Implementation

Local Implementation
Elements of a governance framework for IPS

Initiative – aim of the patient summary initiative and stakeholders involved in exchange

Specification and Standards – patient summary specification developed or used in the initiative, extent that standards are referenced in the specification or exchange infrastructure

Governance Scope and Objectives – governance in place for the initiative, responsible parties, embedding of patient governance, current & future scope including sustainability

Stakeholder Involvement – stakeholders involved in patient summary exchange; responsible parties for patient summary governance, parties with particular purpose or indirect role;

Update and Version Management – for any specification to remain relevant in health care and health informatics, specification updates and version management need full alignment with the maintenance of the underlying standards.
Governance Framework for IPS projects: recommendations

- Identify clearly standards and specifications that are used, or referenced in the patient summary specification of the initiative

- Creating processes to be responsive to change
  - ✓ by engaging the user and stakeholder community from the inception of the initiative;
  - ✓ through active participation in and from the communities managing the standards and specifications as mentioned in the previous point;

- Engage in implementation, monitoring and auditing activities, to gather real-life experience and feedback. Build on best practices; address sustainability and continuity of the effort beyond the initial life cycle of the project or initiative;

- Refine governance structures, reflecting both a long-term and a short-term view, in flexible structures that facilitate alignment and incentivises feedback to standards bodies.
APPLY for the #TrilliumIIPrize

Deadline 1st May
• Giorgio will share a bit more about the IPS
• Marcello will let us know how the eHDSI treats these matters.
CEN-HL7-SNOMED Agreement: International Patient Summary Project Deliverables

EHN: Patient’s rights to cross-border care

EUMODEX2018
Disaster medicine and emergency Response, Oct 14-16, Romania

HL7 Int. & CEN/TC 251 agreement (April, 2017)
HL7 Int. & SNOMED agreement (February 2019)

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Four closely linked global IPS standards with EU Implementation Guidance

EU PS Guideline

CEN EN 17269

CEN TS 17288

EU Guidance

HL7 IPS FHIR IG

HL7 IPS CDA IG

EU eHDSI CDA IG

SNOMED CT IPS Free Set

US C-CDA IG

US MU Summary of Care

implement

refer

use

use
Extra slides
Business Canvas for HL7 FHIR IPS: Key Partners and Suppliers

Key partners:

✓ Healthcare Providers: need to incorporate IPS in their eHealth strategy for safer patient mobility
✓ health authorities: setting certification criteria for apps boosting demand for services & standards
✓ Telecomm companies: interested in incorporating health services in their digital offer
✓ Mobile health companies developing complementary apps
✓ Healthcare Software Providers: seeking new services to incorporate in the EHR or HIS they offer/manage
✓ Venture capitals/investors: seeking for innovative breakthrough services
✓ Insurances: seeking to benefit from IPS data collection for better risk assessment and new client services
✓ Healthcare professional associations: influencing offers and guiding demand for mHealth apps embedding specific services and standards by testing and validating apps

Key suppliers:

✓ SDOs
✓ Terminology organizations
Business Canvas for HL7 FHIR IPS: Key Activities and Resources

Key activities

✓ Integration of IPS in mHealth app
✓ Import/Export to EHRs and relevant information systems
✓ 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 datathons, connectathons, and similar.

Key Resources

✓ 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

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Business Canvas for HL7 FHIR IPS: Value Proposition

Value for citizens:
✓ Ease cross border health data mobility
✓ Increase safety in travelling
✓ Ease emergency and disaster response
✓ Ease chronic disease self-management

Value for mHealth app developers: By adopting IPS they
✓ get a set of resources to enhance their service offerings
✓ become part of a co-creation environment for building and expanding the IPS components
✓ can easily integrate with or be acquired by mainstream companies

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citizens are the final beneficiaries of the IPS integrated in the mHealth apps they use

types of customers and customer relationships:
✓ Citizen as direct clients of the mHealth app developing company (B2C relationship):
  ▪ search for apps they need in a marketplace, pay for subscription or use, review apps and contribute in iterative co-design processes by providing feedback
  ▪ Support by patient organizations
✓ Healthcare providers or mainstream telecomm providers (B2B approach)
  ▪ as clients (or even buyers of the whole mHealth company).
✓ Health authorities as direct interlocutors of the mHealth companies (B2G approach)
  ▪ as third party data suppliers setting minimum criteria for compliance.

Channels
✓ 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)
Business Canvas for HL7 FHIR IPS: Customer Segments

Citizens, in particular those benefiting of cross border healthcare services:

- 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
The Cost Structure is:

✓ **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;

✓ **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.

Main categories of costs are

✓ software development;

✓ integration costs;

✓ training;

✓ personal assistance and software maintenance;

✓ certification;

✓ standardisation training and

✓ membership fees.
Revenue Streams: Key types of revenues envisaged for mHealth companies are:

✓ 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 to outsource development of apps
✓ Acquisition by mainstream devices or OEM Revenue sharing on end to end services