

What is Needed to Create an Eco-System for Digital Health in Europe!

Interoperability Framework and Public Investment

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What is it all about? What constitutes the public interest?

- Exchanging / sharing health data of **ALL** patients within a (public) health systems
- Patient data is generated by **ALL** Health Care / Nursing Providers, which should always be
 - Exchangeable with other HCP nationally and cross-border for the **continuity of care**;
 - Exchangeable with registries or data bases to enable **research / Artificial Intelligence**.
- It is in the **public interest** that the use of health data leads to **improved and faster availability of medical information**, which in turn contributes to **higher quality in diagnostic and therapeutic decision-making** and treatment as well as to an **increase in the process and performance quality** of health services.

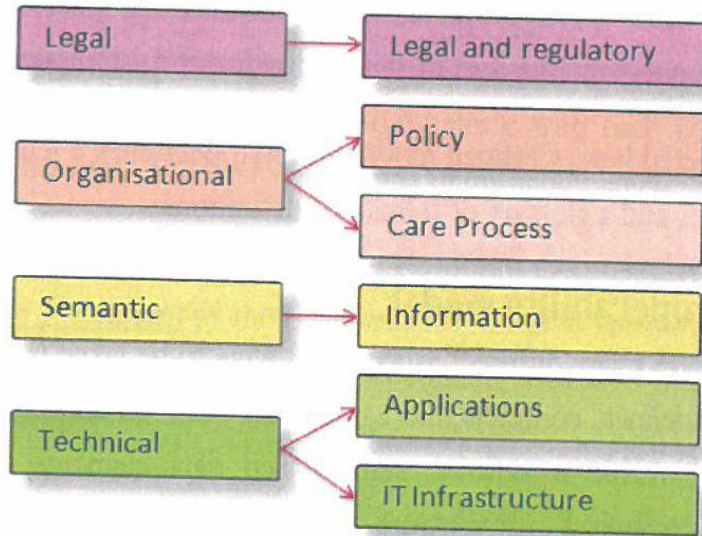
What is this „Eco-System for Digital Health“?

- It is a **fragmented system** of patients, HCPs (GPs, specialists, hospitals, laboratories, radiologists, pharmacists ...), nursing homes, registries, data bases, public health institutes ...
- **Each participant generates, shares, exchanges, accesses health data ...**
- **Each participant needs an electronic identification**, a role, an authentication and authorization to generate, share, access the patients / health data ...
- **Each participant uses (different!) IT-Infrastructure** which is capable of generating, sharing, accessing the patients data ...
- **And is it working?** The glass is half full. There are many hurdles to take.

The Magic Word: „Interoperability“

- By its very nature, a **Digital Health Eco-System is a fragmented system** involving many different participants, with a large variety of needs, uses cases and IT-Infrastructure.
- **Without a commonly shared** strategic and political understanding about what defines „Interoperability“ in digital health, there is **no way to create a widely shared Eco-System for Digital Health**; not on the regional, national, European or even global level.
- Since sharing health data is in the public interest it is a **public obligation to come up with an „Interoperability Framework for Digital Health“**.
- Since the **specifications of interoperability don't stop at regional or national borders** (limits of subsidiarity), this is truly a multilateral task.

Refined eHealth European Interoperability Framework



- Adopted by EU eHealth Network
- Clearly defined policy areas for the regional, national or cross-border setting
- Reduced complexity
- Holistic approach
- True for ALL use cases

Prerequisites for Sharing Health Data



Figure 4: refined eEIF (ReEIF)

An Interoperability Framework Is Not Rocket Science

- Sound legal regulations : eID, roles, data protection, patient autonomy, liability ...
- Collaborative planning and implementation in the overall health system: define use cases, processes, needs and priorities
- Agreement on semantics, codes, mapping systems
- Agreement on technical standards, formats and protocols which have proofed effective
- Agreement on the further development of standards and formats for new use cases ...
- Everyone has a clear orientation: stakeholders on the market, (public) procurers, health professionals ...

Technical Standards, Formats, Protocols etc.

ABSTRACT FROM THE NON-PAPER ON EHR EXCHANGE FORMAT – BACKGROUND FOR DISCUSSION – eHEALTH NETWORK MEETING – 13.11.2018

Specifications of the European EHR Exchange Format

The European EHR Exchange Format comprises specifications for:

1. information categories to be exchanged;
2. exchange protocols;

Information categories

The set of healthcare information categories and associated data reference models should be as follows:

No	Information categories	Data Reference Models
1	Patient's Summary Structured according to the provisions in Chapter 4 of the "GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Release 2 – Patient Summary for unscheduled care" adopted by the eHealth Network on 21 November 2016 ⁴	HL7 Clinical Document Architecture (CDA) Release 2 ³¹ (Level 3 and Level 1)
2	ePrescriptions and eDispensations Structured according to the provisions in Chapter 4 of the "GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Release 2 – ePrescriptions and eDispensations" adopted by the eHealth Network on 21 November 2016 ⁴	HL7 Clinical Document Architecture (CDA) Release 2 ³¹ (Level 3 and Level 1)
3	Laboratory results reports <u>As currently structured within Member States, until common specification are agreed at EU level.</u>	HL7 Clinical Document Architecture (CDA) Release 2 ³¹ (Level 3 otherwise Level 1 PDF/A)
4	Medical imaging reports and images <u>As currently structured within Member States, until common specification are agreed at EU level.</u>	Reports: HL7 Clinical Document Architecture (CDA) Release 2 ³¹ Level 3 otherwise Level 1 (PDF/A) Imaging: DICOM [®] (Digital Imaging and Communications in Medicine) ³²

5	Medical Summaries - Episode Summary - Discharge Summary - Transfer Summary <u>As currently structured within Member States, until common specification are agreed at EU level.</u>	HL7 Clinical Document Architecture (CDA) Release 2 ³¹ (Level 3 otherwise Level 1 PDF/A)
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Exchange protocols

In order to be able to fulfil requests for the exchange of healthcare information categories across borders, the following specifications should be considered (based on the Commission Decision (EU) 2015/1302 of 28 July 2015 on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement)³³:

No	Purpose	Specifications
1	To use patient identifiers for locating communities which hold patient relevant health data.	IHE XCPD - Cross-Community Patient Discovery ³⁴
2	To retrieve patient relevant health data held by other communities.	IHE XCA - Cross-Community Access ³⁵
3	For document interchange using a reliable messaging system and permit direct messaging interchange between EHRs, PHRs, and other healthcare IT systems in the absence of a document sharing infrastructure such as XDS Registry and Repositories.	IHE XDR - Cross-enterprise Document Reliable Interchange ³⁶
4	To facilitate the registration, distribution and access, across health enterprises of patient electronic health records.	IHE XDS - Cross-Enterprise Document Sharing ³⁷
5	For the establishment of relevant security measures and together with the Security Policy and Procedures, provide patient information confidentiality, data integrity and user accountability.	IHE ATNA - Audit Trail and Node Authentication ³⁸
6	To support authentication in cross-enterprise transactions.	IHE XUA - Cross-Enterprise User Assertion ³⁹
7	For the sharing of laboratory reports among a community of healthcare settings and care providers.	IHE XD-LAB - Sharing Laboratory Reports ⁴⁰

8	To provide a mechanism to record the patient privacy consent(s) and a method for Content Consumers to use for enforcing the privacy consent appropriate to the use. This profile complements XDS by describing a mechanism whereby an XDS Affinity Domain can develop and implement multiple privacy policies, and describes how that mechanism can be integrated with the access control mechanisms supported by the XDS Actors (e.g. EHR systems).	IHE BPPC - Basic Patient Privacy Consents ⁴¹
9	To query and retrieve patient relevant medical imaging data held by other communities. The XCA-I Profile extends the XCA Profile by providing access to the images referenced in the imaging manifests.	IHE XCA-I - Cross-Community Access for Imaging ⁴²
10	For publishing, finding and retrieving imaging documents across a group of affiliated enterprises. This profile extends XDS in order to share images, diagnostic reports and related information across a group of care sites.	IHE XDS-Ib - Cross-enterprise Document Sharing for Imaging ⁴³

No	Technical Frameworks
1	IHE Technical frameworks ⁴⁴

Public Interest and Public Investment

- There is a **clear public interest** in sharing health data
- There is a **clear need to invest in a new generation of interoperable IT-infrastructure** at the level of HCP and interconnecting platforms
- All **public investment** (national or multilateral funding) **has to support interoperability.**
- There should be **no public investment or public procurement that does not reference the widely agreed „Interoperability Framework for Digital Health“**

Thank you for your kind attention!

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