Non-paper on EHR Exchange Format

Background for discussion

eHealth Network meeting - 13.11.2018

Introduction

This document presents for discussion a set of technical specifications for the interoperability of Electronic Health Records across borders, as well as some principles for the exchange of digital health data and core elements of an Open Governance Framework to further define the core elements of the exchange format.

Benefits for Member States and Citizens

The benefits to interoperable electronic healthcare records at national level are being increasingly understood in two fundamental ways: *firstly* to support a service to citizens whereby they can access their own records, and give their consent to share them with trusted third parties; and *secondly* to support the linkage of healthcare records in order to identify system efficiencies and innovations. Both benefits, at the individual and societal levels, aim to improve healthcare outcomes and reduce costs that may together contribute to making healthcare systems more effective, and more sustainable, in the long run.

The Council's Conclusions from December 2018 also highlighted an ambition to develop the interoperability of healthcare record systems across the EU with further benefits to ensure the continuity of care for citizens across borders, and to create a common digital single market for information technologies (IT). The Mid-Term Review of the Commission's Digital Single Market strategy highlighted a lack of standardisation and interoperability in several fields. Notably, it identified health and care as one of the pre-eminent areas where the creation of a digital single market will be beneficial for citizens, society as a whole and European businesses.

In an open public consultation conducted in 2017 in preparation of the Commission Communication on Health and Care in the Digital Single Market the vast majority of respondents (93%) either agreed (29%) or strongly agreed (64%) with the statement that "Citizens should be able to manage their own health data." More than 80% of respondents believed that sharing data could improve treatment, diagnosis and prevention of diseases across the EU. A large majority of respondents (almost 60%) identified the heterogeneity of electronic health records as one of the main barriers for exchange of health data in Europe.

Overcoming the lack of interoperability which this heterogeneity causes, and the free movement of data across the EU, are foreseen to boost the application of innovative data-driven technology (Artificial technology, high performance computing, etc.) to improve health outcomes, and identify health system efficiencies, for example through enabling the development of new therapies, or disease prevention approaches.

The General Data Protection Regulation considerably changes the landscape with regard to data portability rights for citizens, who have the right to access their data not only when at home, but also in another Member State.

The development of interoperability of EHR across the EU will require a number of barriers to be overcome, among them the lack of a common IT infrastructure and standards; fundamental differences in the way that healthcare records are created and stored; and differences in legal interoperability that have an impact on what health data can be shared.

The exercise can take advantage of a series of European wide digital solutions and common approaches for government and institutions. This includes the eHealth Digital Services Infrastructure; the eIDAS Regulation, that allows for the enforcement of citizens right of access to health data online, and its underpinning electronic identification interoperable infrastructure; the identification of common measures for the security of network and information systems (NIS); the European Interoperability Framework (EIF)[1] and the Refined eHealth European Interoperability framework (ReEIF)[2], and the Commission Decision identifying 27 "Integrating the Healthcare Enterprise" (IHE) profiles for public procurement.

General Principles

The following principles for the functioning of an interoperable EU system for the exchange of electronic health records should be envisaged:

Comprehensiveness and machine-readability: EHRs should be comprehensive in order to ensure the availability of longitudinal health data for every citizen in an automatically exploitable format in order to support seamless, evidence-based and personalised provisioning of health and care services throughout the European Union. Health data introduced in EHRs should be machine-readable. Consideration should be given to structuring and codifying information with a view to making health data interoperable across borders.

Data protection and confidentiality: The fundamental right to protection of personal data should be fully and effectively protected, in conformity with the General Data Protection Regulation (GDPR). In particular, citizens should be able to access and share their health data in line with the right of access and the right to data portability as provided for in Articles 15 and 20 of the GDPR. The European EHR exchange format and the systems that adopt and make use of the format should guarantee the confidentiality of personal health data and electronic communications containing health data, and protect the integrity of a citizen's personal device, on which health data are stored.

Consent: EHR systems should include specific provisions for seeking explicit consent from the citizens. In case of modification of the scope of use, citizens' explicit consent should be requested.

Auditability: Any access, exchange, modification or transformation of health data should be subject to information or, where applicable, consent by the citizen, in accordance with data protection rules.

[1] ANNEX to the COM(2017) 134 final - European Interoperability Framework - Implementation Strategy. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2017:134:FIN

[2] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf

Any data exchange should be registered and verified, using appropriate techniques, such as time stamping, to maintain accurate time of electronic records' access and exchange. Transactions should be logged for auditing purposes, for example to demonstrate compliance with the GDPR.

Technological development such as on secure, distributed, resilient and certified ledger technologies could help build trust among multiple actors accessing and processing health data, ensure integrity assurance, traceability of health records.

Security: Members States should to take all necessary measures, including legislative and regulatory measures, to ensure that EHR systems operating under their jurisdiction meet the highest standards of data security. Health data disclosure and use may increase the risk of data loss or misuse that can harm citizens. Health data should therefore be processed (disclosed and used) in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures. EHRs should be appropriately protected during exchange, processing and storage by various security processes, such as defining and applying security policies, security training and awareness.

Appropriate mechanisms should be put in place with regards to personal data security and security breaches, in conformity with the GDPR and the Directive on the Security of Network and Information Systems. In line with the security by design approach, appropriate security measures should be embedded in EHR systems, meaning that both at the time of determination of the means for processing and during the processing itself, appropriate measures are implemented to ensure security.

Identification and authentication:

Strong and reliable identification and authentication of all users is key to guaranteeing trust in exchanges of data between EHR systems.

The use of national electronic identifications (eIDs) could support citizen's cross-border authentication to access their health data in full security and convenience and for the principle of "non-repudiation" as related to the origin and integrity of such data. Through the mutual recognition of national eID schemes (including smartcards, mobile and log-in), as foreseen in the eIDAS Regulation[3], citizens of one Member State could use their national eIDs to securely access online services provided to them in another Member State. Pursuant Article 6 of the eIDAS Regulation, online public services requiring eID assurance corresponding to a certain level ('substantial' or 'high') shall be able to accept the notified eID schemes of other EU Member States.

Continuity of service: Continuity and availability of the EHR exchange service is essential to guarantee continuity of care. Any issues or interruptions that may arise in the course of the use of the service should be promptly solved.

[3] Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC

Open Governance Framework

The purpose of the Open Governance Framework is to regularly revise and enrich the specifications of the European EHR Exchange Format, with a view to improving the interoperability of health data across the EU. It defines a joint, voluntary cooperation process involving Member States, the Commission and other relevant stakeholders to analyse current and emerging requirements, establish new specifications and policies, and share best practice.

The specifications of the European EHR Exchange Format are to be revised periodically in order to ensure that, as a system to exchange health data, they remain up-to-date, sustainable and become more comprehensive in line with the needs of citizens, health systems and society more widely.

Further progressive and incremental improvements to interoperability can be foreseen through:

1. the improvement of the quality of health information exchanged within the proposed healthcare information categories, in particular as semantic interoperability is developed;
2. a gradual widening of the range of information categories;
3. a regular upgrading of technologies and infrastructures in line with new generations of IT.

The process to further develop the European EHR Exchange Format should be steered on the basis of a shared roadmap that identifies agreed priorities, tasks deliverables and milestones.

The eHealth Network could provide the forum to facilitate adoption, share experiences, and further elaborate common requirements and the specifications for the European EHR Exchange Format. The coordination process should be inclusive with the participation of experts, including those from competent authorities responsible for digital health, and providing opportunities to capture contributions from a wider group of stakeholders notably representing the ICT sector, service providers, standardisation bodies, regional and local authorities and civil society.

The Open Governance Framework should also monitor and assess progress and allow for horizon scanning with regard to technological and methodological innovation.

Supporting investments

The expansion of cross-border exchange of health data beyond e-prescriptions and Patient Summaries to a full health records will require considerable work and targeted investment in interoperability. Several programmes of the next Multiannual Financial Framework could support these efforts alongside Member States' own contribution to the development and uptake of the exchange format.

For example, the new Digital Europe Programme (DEP) could invest in capacity building and the roll-out of high-performance computing, artificial intelligence, cybersecurity and digital transformation, as well as adequate security, authentication guidelines and solutions across all levels of governance, and further development of the national eHealth platform and relevant business continuity solutions.

The Connecting Europe Facility could support fundamental infrastructures for connectivity in healthcare providers across the EU. The objectives of HorizonEurope in the health cluster, related missions and partnerships, could be designed to ensure that the new research and innovation framework supports further advancement of digital health in Europe. Putting in place common standards and a strong infrastructure would support research, personalised and precision medicine.

EU funds could also be deployed to support Member States to build national digital health portals accessible to citizens that will serve as both single gateways for cross-border exchange with other countries and as an aggregation system for health data deriving from various sources at national level (national and regional administrations, hospitals, clinics, healthcare providers, laboratories, citizens).

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[5] (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 [6]	HL7 Clinical Document Architecture (CDA) Release 2[7] (Level 3 and Level 1)
3	Laboratory results reports As currently structured within Member States, until common	HL7 Clinical Document Architecture (CDA) Release 2[8]

[4] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co10_en.pdf
[5] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[6] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co091_en.pdf
[7] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

	specification are agreed at EU level.	(Level 3 otherwise Level 1 PDF/A)
4	Medical imaging reports and images As currently structured within Member States, until common specification are agreed at EU level.	*Reports:* HL7 Clinical Document Architecture (CDA) Release 2[9] Level 3 otherwise Level 1 (PDF/A) *Imaging:* DICOM© (Digital Imaging and Communications in Medicine)[10]
5	Medical Summaries - *Episode Summary* - *Discharge Summary* - *Transfer Summary* As currently structured within Member States, until common specification are agreed at EU level	HL7 Clinical Document Architecture (CDA) Release 2[11] (Level 3 otherwise Level 1 PDF/A)

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)[12]:

No	Purpose	Specifications
1	To use patient identifiers for locating communities which hold patient relevant health data.	IHE XCPD - Cross-Community Patient Discovery[13]
2	To retrieve patient relevant health data held by other communities.	IHE XCA - Cross-Community Access[14]
3	For document interchange using a reliable messaging system and permit	IHE XDR - Cross-enterprise Document Reliable Interchange[15]

[8] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[9] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[10] https://www.dicomstandard.org/
[11] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[12] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2015_199_R_0011
[13] https://wiki.ihe.net/index.php/Cross-Community_Patient_Discovery
[14] https://wiki.ihe.net/index.php/Cross-Community_Access

	direct document interchange between EHRs, PHRs, and other healthcare IT systems in the absence of a document sharing infrastructure such as XDS Registry and Repositories.	
4	To facilitate the registration, distribution and access, across health enterprises of patient electronic health records.	IHE XDS - Cross-Enterprise Document Sharing[16]
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[17]
6	To support authentication in cross-enterprise transactions.	IHE XUA - Cross-Enterprise User Assertion[18]
7	For the sharing of laboratory reports among a community of healthcare settings and care providers.	IHE XD-LAB - Sharing Laboratory Reports[19]
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[20]
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[21]
10	For publishing, finding and retrieving imaging documents across a group of	IHE XDS-I.b -Cross-enterprise Document Sharing for Imaging[22]

[15] https://wiki.ihe.net/index.php/Cross-enterprise_Document_Reliable_Interchange
[16] https://wiki.ihe.net/index.php/Cross-Enterprise_Document_Sharing
[17] https://wiki.ihe.net/index.php/Audit_Trail_and_Node_Authentication
[18] https://wiki.ihe.net/index.php/Cross-Enterprise_User_Assertion_(XUA)
[19] https://wiki.ihe.net/index.php/Sharing_Laboratory_Reports
[20] https://wiki.ihe.net/index.php/Basic_Patient_Privacy_Consents
[21] https://wiki.ihe.net/index.php/Cross-Community_Access_for_Imaging

	affiliated enterprises. This profile extends XDS in order to share images, diagnostic reports and related information across a group of care sites.	

No	Technical Frameworks
1	IHE Technical frameworks[23]

[22] https://wiki.ihe.net/index.php/Cross-enterprise_Document_Sharing_for_Imaging
[23] https://wiki.ihe.net/index.php/Frameworks