eHAction

Joint Action supporting the eHealth Network

D7.1 - Recommendations and guidelines for IT Management on implementing interoperability actions in healthcare organisations

WP7 – Overcoming implementation challenges

Version 1.0

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1.0	27.03.2021	Hugo Agius Muscat	MFH	QM review of version 0.13

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Acronyms and Abbreviations

Acronym	Description
CEO	Chief Executive Officer
CIO	Chief Information Officer
eHAction	eHealth Action – 3rd Joint Action supporting the eHealth Network
eHDSI	eHealth Digital Service Infrastructure
eHN	eHealth Network
EHR	Electronic Health Record
EHRxF	Electronic Health Record Exchange Format
EU	European Union
GDPR	General Data Protection Regulation
HA	Health Authority
i~HD	The European Institute for Innovation through Health Data
ICT	Information and Communication Technology
IHE	Integrating the Healthcare Enterprise
IT	Information Technology
NDHN	National Digital Health Network
PCP	Pre-Commercial Procurement
ReEIF	Refined eHealth European Interoperability Framework
WP	Work Package

Abstract

This deliverable presents recommendations and guidelines for IT management on implementing interoperability actions in healthcare organisations.. The first two chapters of the deliverable focus on the journey of co-creation of guidance, primarily for healthcare providers, in planning and procuring standards-based interoperable solutions. Implementing interoperable solutions will enable meaningful data sharing within and across organisations, national and professional boundaries, and create a potential for harvesting knowledge out of health data. This guidance, has taken the form of a web-based eHealth Interoperability Guide for Hospital CEOs and CIOs which is also included here as an Annex,. It is available online at http://ehaction.eu/interoperability-guide/. As the eHAction is coming to its conclusion, it is important that we consider the sustainability of this co-creation process which could maintain the Guide and provide for its evolution. The document proposes a number of options for rendering this process sustainable after the end of eHAction, including principles for continued collaboration.

Executive Summary

This deliverable presents the final 'Recommendations and guidelines for IT Management on implementing interoperability actions in healthcare organisations', in line with the scope of the work in T7.1. and T7.3. adopted by the eHealth Network (eHN) during its 15th meeting.

The first part of the deliverable focuses on the journey of co-creation of guidance, primarily for healthcare providers, in planning and procuring standards-based interoperable solutions. Implementing interoperable solutions will enable meaningful data sharing within and across organisations, national and professional boundaries, and create a potential for harvesting knowledge out of health data. The guidelines that have been produced through this process, have taken the form of a web-based eHealth Interoperability Guide for Hospital CEOs and CIOs which is also included in the second part of the document. The Guide is available online at http://ehaction.eu/interoperability-guide/; its web version incorporates the second guidance document produced under D7.3. i.e. a Cybersecurity Guide.

The guide itself has been elaborated based on the conceptual design of the Interoperability Guide, which was submitted for information to the eHN in spring 2020, in terms of its target audience and its breadth and depth of content and key design characteristics. It has been collaboratively created with the participation of the community of the informal network of European hospitals established in eHAction and the collaboration with three international, not-for-profit organisations, namely, Integrating the Healthcare Enterprise (IHE), the European Institute for Innovation through Health Data (I~HD) and HL7 Europe.

As the eHAction is coming to its conclusion, it is important that we consider the sustainability of this co-creation process which could maintain the Guide and provide for the its evolution. The document proposes a number of options for rendering this process sustainable after the end of eHAction, including principles for the continued collaboration. This requires a co-ordinated approach and collaborative processes to be agreed upon; the current implementation of the Guide is therefore also a proof of concept of this co-creation principle which has been tested with the above organisations.

The guidance has been targeted primarily towards healthcare provider organisations such as hospitals, procurement decision-makers and people responsible for the quality and governance of health data in such organisations; it is intended to be a low-jargon resource to help them to understand the value of interoperability and better health data management. It points to some of the bodies that could be valuable resources to help them in that mission, who are themselves creating landing pages on their sites which are intended to be introductory and low-jargon for that audience.

WP7 has in parallel kicked off discussions on the potential interest to establish one or communities of practice around the topics of the Guide, which have reinforced the need for further and deeper discussions and maturation before launching such communities.[1]. At this stage, the web-based version of the Guide provides links to existing communities of practice.

Since its inception, it was considered that the Guide could usefully also leverage testimonials in the form of experiences and good practices primarily from healthcare providers but also from other members of the community. Several such testimonials were collected and used in the process of elaboration of the guidance. In the future, the environment of communities of practice could further provide for the selection amongst submissions of good practices to be also published, in supplement of the guidance.

[1] Such discussions are now taking place under the X-eHealth project

1. INTRODUCTION

During its 15th meeting, the eHealth Network adopted the 'Recommendations and guidelines for IT Management on implementing interoperability actions in healthcare organisations' submitted by means of an Information Note by WP7 – Overcoming Implementation Challenges of eHAction.

The main elements of the conceptual design of the co-creation process and the design and content of the guidance emerged largely from the first consultation, held in Thessaloniki, 10-11 July 2019, with a representative group of the Guide's intended audience.[2] The participant organisations, which were recommended by the members of eHAction, formed a seed informal network of healthcare providers which contributed to thinking out the process during and in between subsequent consultations and also expanded over time.

The relevant aspects that need to be most urgently addressed and practices that have proven efficient in practice and enable a co-creation approach for the elaboration of guidance were presented to the eHN in November 2019 and covered a number of aspects, summarised below:

Target Audience	The decision-making level, where the main enablers for effective data management – interoperability, data quality and data security – are operationalised.
Design	The guidance should observe the specific needs and tolerances of its special target group. It should be brief and at the same time rich in conveying the most important messages that will compose a bird's eye view for the management level.
Content	The guidance should provide answers to key questions: • *Why should I deal with interoperability issues?* • *What is the level of legal certainty for taking action in the area of interoperability?* • *How can I maximise standards-based ICT solutions in my organisation?* • *What should I know for operationalising procurement for innovation?* • *How can I capture and exchange with other organisations high-quality clinical and administrative data?*
Structure and Format	Guidance will be a layered information paper and web document, providing an overview of the most burning issues and pointers to solutions and more detailed information. Supplementing with exchange of experiences and good practices would greatly enhance value.
Co-creation	Guidance should be created as a walk through our best, consolidated knowledge and experience on tackling data interoperability and quality challenges in healthcare providing organisations. It should be a live document, regularly updated by its generating community and within its collaborative governance.

The first report also examined principles of governance of the process and of sustainability of the guidance. Concerning the former, there are three significant elements that are central to the provision of this Guide and can guarantee its continuing fitness for purpose and currency:

[2] Nine representatives of hospital CEOs and CIOs; 11 eHealth competence centres and health authorities and 3 academic institutions in 10 EU Member States; representatives of the European Commission and 3 European organisations in the area of eHealth interoperability.

- The Guide focuses on the 'what' and the 'what for', leaving the 'how' to a highly selective set of pointers to where the information is;
- The detailed 'how' information itself is maintained by the competent organisations that generate and take stewardship of it and the European Commission providing sources of information and liaison with the most appropriate projects and project outcomes of relevance.
- The Guide should leverage testimonials in the form of experiences and good practices from primarily healthcare providers but also other members of the community: successful projects, incidences at the lack of proper and timely action, measures that proved effective and efficient. Therefore, healthcare provider organisations and local health authorities act both as 'customers' and 'providers' of content of this Guide.

Each one of the above participants have their internal governance, procedures, priorities and planning for creating and uploading content which serves their own mission and objectives; there is however a sufficient area of overlap to warrant a continuing collaboration and co-creation process and through this a sustainable process for the maintenance of the content.

Updates about the work on the Interoperability Guide were presented in every subsequent eHN meeting. The completed first edition of the document was submitted to a written process last spring. The Interoperability Guide was also presented to the eHealth Stakeholder Group last autumn. Feedback received focused mainly on the need to secure the sustainability of this content. Indeed, this has been the main focus of work in over the last months, in addition to completing content and links, which has been performed in close co-operation with information-providing organisations and has resulted in the recommendations to the eHN presented in this document.

In parallel, in order to assess the Guide's value for the community it addresses a survey[3] has been launched with the objective to capture opinions as to the usefulness and usability of the interoperability of the Guide as well as suggestions for additional areas to be covered. The survey is still in process at the time of issuing this version of the document and the results will be reported as soon as sufficient replies for drawing meaningful conclusions have been collected.

[3] https://docs.google.com/forms/d/e/1FAIpQLScCq13o-Xcdz4JDuLnjUaasRHU8XVUm7SyAf4tD2WBzsIAxiA/viewform

2. RECOMMENDATIONS

SUSTAINABILITY AND FUTURE GOVERNANCE OF THE EHACTION INTEROPERABILITY GUIDE

2.1. Relevance to the National Digital Health Networks initiative

National Digital Health Networks (NDHNs) are envisioned to support the alignment of those entities at national level that are likely to drive use and reuse of health data within the European Health Data Space, with a focus on interoperability and security of national health systems and support the secure exchange of health data across borders. National Digital Health Networks should: i) Achieve 'Development and promotion of usage of the EEHRxF and other outcomes of European governance (e.g. Common Semantic Strategy (CSS), Joint Coordination Process, etc.), as a way to mature an interoperable eHealth ecosystem'; ii) 'Encourage sharing of best practices towards improving access, quality and sustainable health and care services'.

The eHAction Interoperability Guide presents a potential to support the goals of NDHNs, both in terms of providing implementation guidance but also in terms of supporting the creation of connected national communities of practice.

2.2. Sustainability Options

While the Guide aims to support implementation at local level, its continuing development will be through EU-level co-operation and with an EU-level (light) governance for maintaining the content and making it available through proper technical infrastructure. The principles of collaboration are be specified in paragraph 2.3.

The three options presented below represent three alternative approaches, each reflecting different commitments and adoption strategies. It should be noted however, that whatever the chosen option, the principles of co-operation, co-creation, transparency and safeguarding of independence of the Guide will apply as such and will be only tailored to the specific situation. A combination of the above three options can therefore also be a potential way forward.

Option 1. The Guide is maintained as an eHealth Network co-ordinated activity

The eHealth Network is facing an increasing challenge related to lack of visibility of its policy outcomes. This Guide can be instrumental for the eHealth Network to establish a consistent and highly accessible channel to make its interoperability outcomes (e.g. guidelines, frameworks, policies, strategies) widely available for EU and international stakeholders. The increased accessibility and visibility can become a multiplier effect towards national stakeholders, especially when used by the National Digital Health Networks to increase awareness and promote alignment with the eHealth Network vision.

In that line of thinking, the eHealth Network, through its subgroups on semantic and technical interoperability, could take ownership of this tool for supporting the dissemination and implementation of eHealth Network interoperability outcomes.

The eHAction can start working on the handover to the subgroups that should be completed by the end of the project (June 2021). Candidate organisations (option 3) or projects (option 2) could support and operationalise its maintenance and further development through a collaborative approach under the ownership of the two eHN subgroups. 'Ownership' should be understood in the meaning of the term under eHealth Network governance, i.e. the eHN subgroups should provide the directions for its further extension and updating, and approve proposals made by its stewards and its stakeholders. The Guide would be hosted on the eHealth Network web presence.

Option 2. The Guide is inherited to the X-eHealth Coordination and Support Action, the Joint Action Towards the European Health Data Space (TEHDAS) or another relevant project. The Guide is hosted at the project's website.

Decisions on its definitive handover would be postponed. The Guide will continue to exist as a work item under different projects and according to its workplan and foreseen activities, provided however, that the scope and target audience points are upheld and that the takeover organisation aligns with the awareness and knowledge gap that this Guide is seeking to close. This would require agreement of the consortium and the funding agency. Project resources would be mobilised for this purpose.

Option 3. The Guide is hosted by an organisation with a suitable profile, under a standalone (non-organisation-specific) web domain name and is collaboratively maintained under the agreed governance.

Such an organisation could be, for example, any of the partner organisations, a user organisation such as HOPE,[4] a network of hospitals such as the European University Hospital Alliance or a national competence centre. The organisation's resources would be mobilised for this purpose and could be supplemented by additional funding streams or in kind, e.g. through mutualising activities with other initiatives.

[4] https://hope.be/

	Sponsor/policy owner	Network	Provider	Host	Target Groups	Funding
OPTION 1	eHN /subgroups	eHN, eHDSI communities , ERNs, …	mandated project or eHDSI entity	(eHN web page with links to , eHDSI, EHRxF, EHDS, web pages	as specified in the Guide through national Digital Health Networks	eHN relevant financial support
OPTION 2	As specified in the project	project specific network	Project WP	project, project website	as specified in the Guide -through targeted project dissemination activities	project budget
OPTION 3	non-for-profit EU organisation/ association	membership	orgnaisation	organisation, organisation's website under a non organisation specific domain name	as specified in the Guide through members and associated stakeholders	organisation budget

2.3. Principles of collaboration and governance

Irrespective of the option chosen above, the same principles of collaboration and decision-making governance should apply, modified only in so far as necessary to accommodate the specificities of the option.

(i) **Long-term action:** The Guide and its maintenance should be a long-term action, focused on targeted guidance, involving local actors in existing and new communities of users and exchange of experiences and good practices and providing the necessary infrastructure across several projects;

(ii) **Collaboration:** The collaborative approach should appropriately engage the stakeholders that the Guide addresses at all levels, ensuring alignment around common priorities and ensuring openness, neutrality and inclusiveness throughout the process;

(iii) **Co-creation:** Avoidance of duplication and maximise quality and currency of content through co-creation with organisations that share commonality of purpose in making interoperability happen at the most appropriate level of project implementation and in promoting a quality and safety culture in data capture.

(iv) **Implementation Approach:** The maintenance and further development of the Guide should cater for high quality of content, presentation and fitness for purpose. The following governance and description of roles are not meant to be prescriptive, beyond merely exposing the various elements of implementation for supporting decisions on sustainability commitments.

Policy Owner/ Sponsor

- Provides priorities **and direction**; approves implementation **principles** and oversees adherence of the provider to them:
  - supporting implementation of **common EU-prioritised use cases**
  - based on identified needs and common challenges of its relevant network
  - according to principles for **quality, openness, neutrality and inclusiveness** in the process of elaboration of content.

Network

- Expresses evolving **requirements** and needs to be supported through the Guide:
  - driven by a broad array of **common implementation challenges**
  - focused on organisational, technical and semantic **interoperability and data quality** and reusability.

Provider (of the Guide as a service)

- Operates a high-performance **editorial group and process within a stable working environment.**
- The editorial group is the operating group that coordinates the support and content evolution of the Interoperability Guide:
  - driven by needs of the target audience, the rapidly evolving implementation challenges and the development of new knowledge and potential
  - defines the scope and topical areas that need to be covered to address emerging implementation challenges; allocates authoring tasks; reviews content for consistency, currency and integrity
  - regularly reviews the existing links to external sources, not directly under its supervision (such as linked communities of practice) for their continuing fitness and relevance to the Guide.
- Secures **partnerships** with 'approved' content providers and agrees a collaborative editorial approach:
  - in order to build the necessary breadth, depth, currency and quality of guidance; provided at varying depth and meeting diversified implementation needs and maintained through shared responsibility amongst the partner organisations
  - secures **selective participation of content providers** according to their core expertise to address specific needs and to the right information layer.
- submits to the policy owner/sponsor **proposals and reports** relevant to implementation in order to ensure:
  - continuous **policy alignment and trust** of the target audience
  - systematic bidirectional communication with the sponsor/policy owner.

  Note: The last two bullets may alternatively come also directly under the responsibility of the editorial board.

Host

- Hosts the website/page of the Guide to an agreed performance level
- Provides the necessary infrastructure, and media and communications expertise.

Annex I: eHACTION INTEROPERABILITY GUIDE

Editorial Team

3rd RHA	Zoi Kolitsi, lead editor, Stergiani Spyrou WP7 leader
SPMS	Diogo Martins eHAction Co-ordinator, Jose Dias, Vanessa Viana, Website editor
IHE	Karima Bourquard, Charles Parisot, Alex Berler
I~HD	Dipak Kalra
HL7	Christoff Gessner, Catherine Chronaki

Acknowledgements

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INTRODUCTION TO THE INTEROPERABILITY GUIDE

Supporting healthcare providers in tackling interoperability challenges

> *Enabling data exchange within and across healthcare organisations will require a paradigm shift towards the establishment within the environment of the healthcare provider of a vendor-neutral interoperability architecture that is modular, scalable, service-based, and secure. This in turn requires a reframing of purchasers, vendors relationships, promoting a culture of partnership with the vendors and supported appropriately by health policy.*

It is important for health systems to work collaboratively in order to develop shared technical requirements for procuring industry solutions, as well as in moving toward an agreed-upon open architecture layer for seamless end-to-end interoperability and data exchange in the long run.

Frequently asked Questions

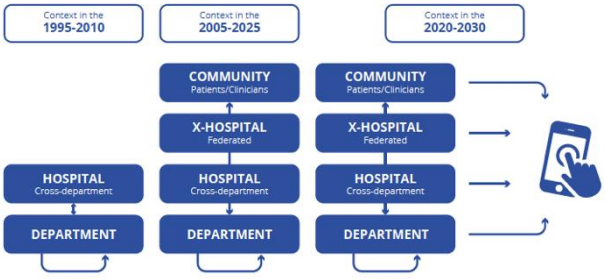
Who is this Guide for?

The Interoperability Guide is intended to support healthcare providers in planning and procuring standards-based interoperable solutions. Such decisions are typically shared within the higher management executive level in the healthcare organisations responsible for procurement of equipment, ICT systems and related services. Thus, the Guide addresses Chief Executive and Information Officers. However, more management functions may be relevant in European hospitals and as such may be addressed by this Guide.

Several actors must be engaged and align efforts under national eHealth interoperability frameworks, in order to achieve meaningful sharing of health data across borders. The Guide assumes that such national frameworks exist and provide the necessary direction in terms of common standards to be deployed in the healthcare providers' projects. However, even where such clear national guidance does not exist, there is still great potential for leveraging international standards and interoperability specifications and European legal enablers for interoperability.

Context of interoperability in the hospital

The focus of interoperability within hospitals has evolved over the past 30 years. Starting from the research type projects in the early 1990s until recently, where – depending on the hospital IT maturity and budget – the focus was mainly on digitising the key departments (laboratory, radiology, pharmacy, etc.), both internally and connecting them with the hospital-wide information system (HIS). It has then slowly shifted to the integration of different hospitals within a geographical area or an organisational structure (e.g. hospital networks), while a first generation of regional/national information exchange communities were established, with hospitals broadly connected to their referral base of primary care providers and other specialised hospitals, in the current period that we can approximatively position around 2005-2025.



Some early deployment across borders has also successfully materialised, such as the European eHealth Digital Service Infrastructure (eHDSI). Most recently, there is a new wave where the role of mobile phone and personal health devices is emerging and likely to grow over the next 10 years. However, the hospital is increasingly faced with interoperability challenges that come from the external environment.

The challenges of interoperability for healthcare providers may be also differentiated by means of the level of information exchange involved:

- The meso level: this relates to the ability of the systems within the hospital to seamlessly exchange data, e.g. with patient medical records or for reporting and internal monitoring purposes.
- The micro level: here, the challenge becomes to further integrate IoT and personal connected-devices information into personal health records. In these two tiers, significant portions of data exchange today depend on manual entry by clinical staff or the patients and carers, which in turn impacts data quality.
- The macro level: this relates to the organisation's role in the broader ecosystem and its ability to exchange information with other care providers. It will typically rely on national interoperability frameworks, specifying common standards and formats, which may in turn relay to European common specifications.

The business case of interoperability

It is time to inject some positivity back into interoperability. Often, it has been perceived as complex, messy and a source of frustration for CEOs and CIOs, but the smooth exchange of health information is a must and a critical business priority for healthcare organisations. Now is the moment to seize a fresh and strategic rethink and work towards change.

Healthcare providers can leverage EU standardisation to meet their local needs in a global environment and use their buying power to stimulate competition within their local health ICT markets based on interoperability requirements. They should, furthermore, take legal advice to ensure that they are complying with the right legal basis, and ICT security advice on how to safeguard the data being used for care purposes and for research.

Capturing and exchanging health data

Learning Health Systems are systems where science, ICT, incentives, and culture are aligned for continuous improvement and innovation.[5] High-quality EHR data is vital to the delivery of safe and effective patient care, enables the reuse of your data across your Learning Health System, strengthens your strategic and medical decision-making insights and improves your opportunities to scale up your participation in clinical research. You can stimulate and promote an interoperability culture amongst clinicians and other hospital staff engaged in data capture; develop competences for assessing data quality and maximising its reusability for other purposes such as reporting, learning and improving own practices and exchanging data with other organisations for care purposes or for clinical and public health research.

Setting up and running internal systems, capable of capturing and securely exchanging health data within the hospital and with other organisations, do not need to start from scratch. There are available assets in the form of common technical and semantic interoperability specifications, interoperability

[5] Roundtable on Value and Science-Driven Health Care: The Learning Health System and its Innovation Collaboratives: Update Report. Washington, DC: IOM; 2011

testing tools and platforms, guidelines, integrated frameworks, and semantic resources that can be exploited. The Guide provides a compass to finding relevant information.

Procurement for Innovation

The eHealth Network has adopted Guidelines on 'an interoperable ecosystem for digital health and investment programmes for a new/updated generation of digital infrastructure in Europe'. On their journey to interoperability, healthcare organisations should consider ICT procurement strategies and models that cater to interoperability and create an organisation-wide capacity.

HEALTH DATA EXCHANGE

European Commission action in this area focuses on policy support through facilitating voluntary coordination of authorities and other stakeholders to share data, fostering the further use of standards and the development of technical specifications for secure access and cross-border exchange of health datasets in the EU. The vision is that, by implementing such common standards and specifications, healthcare providers may address interoperability challenges both at national and international levels. It should however be understood that European interoperability assets will need a certain amount of localisation in the national contexts, an activity that is commonly taken forward by national health authorities working together with national stakeholders.

European co-operation on interoperability is exemplified through the common Electronic Health Record Exchange Format,[6] which targets pan-European interoperability of health records for care purposes and at the same time supports the European strategy for data,[7] underpinning the creation of the common European Health Data Space for scaling up secondary use of this data for research, innovation and regulatory compliance.[8]

1.1. Electronic Health Record Exchange Format (EHRxF)

In an effort to support Member State efforts to overcome interoperability challenges, the European Commission is promoting a stepwise approach for creating EU-level interoperability of EHRs, building on the European Patient Summary and ePrescription information domains and creating a roadmap for extending to additional three domains:

- Patient Summary
- ePrescription/eDispensation
- Laboratory Results
- Medical Imaging and Reports
- Hospital Discharge reports

When implementing the European Patient Summary and ePrescription kernels in your Electronic Health Record systems:

[6]https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format

[7] https://ec.europa.eu/info/sites/info/files/communication-european-strategy-data-19feb2020_en.pdf

[8] https://ec.europa.eu/info/sites/info/files/communication-european-strategy-data-19feb2020_en.pdf

- you can select and reference, in your procurement, one or more of the 27 interoperability specifications[9] published by the European Commission, in the framework of the Standardisation Regulation;[10]
- You can draw upon the general implementation framework provided through the eHealth Network Guidelines.[11] This ensures standards-based implementation and your project will deliver a solid pan-European interoperability baseline for your health records;
- If your country joins the European cross-border community, your organisation will be able to share health data of foreign EU patients;
- If your country has agreements with countries outside the EU, your organisation will be to leverage the International Patient Summary,[12] in order to share health data of non-EU patients;
- Given that other coding systems are gradually linked to terminologies and classifications used in the European Patient Summary and ePrescriptions (such as unique identification of medicines and of medical devices), these basic kernels support integrated management within your organisation;
- Your data will be reusable for research. You may become an active node in the common European Health Data Space and develop win-win business models as a data provider with your data reuse network.

1.2. Secure access to Electronic Health Records

Hospitals are organisations that process health data, which is a special category of sensitive data requiring greater protection, and as such they will have to review their compliance to the GDPR. Hospital managers should take legal advice to ensure that they are adopting and complying with the most appropriate legal basis, and ICT security advice on how to safeguard the data being used for care purposes and for research.

Healthcare providers (HCPs) – hospitals and private clinics – are, in the meaning of the Directive on Security of Network and Information Systems[13] (NIS Directive), 'Operators of Essential Services (OES)', i.e. operators considered 'essential for the maintenance of critical societal and/or economic activities'.

These operators should comply with several binding provisions defined nationally in accordance to measures defined in the Directive for a high common level of security for networks and information systems across the EU. Healthcare providers and other organisations managing healthcare data should take appropriate and proportionate technical and organisational security measures to manage risks posed to the security of their networks and information systems, that are proportionate to the identified risks. In this way, the compliance of OES with such measures will significantly contribute to raising the level of security across the EU.

[9] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015D1302

[10] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF

[11] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20190611_co922_en.pdf

[12] http://www.ehealth-standards.eu/en/projects/international-patient-summary-ips-project/

[13] https://ec.europa.eu/digital-single-market/en/network-and-information-security-nis-directive

1.3. Common Technical Specifications

The European Patient Summary and ePrescription cross-border information services have been made possible through Member State level implementations leveraging common European technical specifications. Furthermore, the five priority information domains in the EHRxF are largely supported by the 27 IHE profiles published by the European Commission. Data exchange at this level, when based on European technical specifications, will allow effective cross-border exchange of health data within the organisation and across organisations, and will further support continuity of care for mobile citizens.

1.4. Common Semantic Specifications

Meaningful sharing of health information across healthcare providers, both internally within a country and across borders, can be achieved when information can travel though common standardised messages, using standardised formats. Modelling and coding standards are the pillars on which technical, syntactic and semantic interoperability rests. Thus, health information should flow for European citizens along their healthcare pathway, with minimal loss of meaning, or no loss at all.
At the European level, the Master Value Sets Catalogue[14] (MVC) is a collection of terms, used in the context of exchanging data on patient summaries and ePrescriptions (parts describing the patient demographics or the clinical problems, for example), based on standardised code systems such as ICD-10, SNOMED CT, ATC Classification, EDQM Standard Terms, or UCUM. This catalogue was created collaboratively by multinational teams under the epSOS large scale pilot and is now maintained by the eHDSI community of semantic experts. New information domains will need to be covered. A five-year strategy[15] and a common semantic approach towards standardised exchange of health information in the EU has been adopted by the Member States. This strategy contains the shared view about semantic interoperability among EU Member States; it was elaborated by Member State and Commission semantic specialists and includes a structured governance scheme and a solid roadmap for implementation.

LEGAL AND POLICY ENABLERS

European legislation has increasingly become a facilitator to innovation by supporting the dynamics of change while providing full protection and legal and ethical certainty. This is achieved in synergy with other enablers including standardisation and clinical governance, and through fostering security and quality cultures under an integrated framework of trust that is enforced and protected by law.

When an eHealth solution is the primary vehicle for delivery of care, then the legal and ethical issues are wide and will arise not only in terms of privacy and data protection, but also in terms of complying with competition rules and meeting safety and quality requirements, to mention but a few.

1.5. The use of interoperability specifications in public procurement

ICT technical specifications are not developed by European or international standardisation organisations, or by national standardisation bodies. They do not fall under any of the categories of standards and approvals laid down in the EU's public procurement legislation. To provide for the possibility that tenders for public procurement could refer to such ICT technical specifications, the Regulation lays down a procedure for the identification of selected ICT technical specifications

[14] https://ec.europa.eu/cefdigital/wiki/pages/viewpage.action?pageId=35208905

[15] EU Common Semantic Strategy in eHealth.
https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_201811135_co0494_en.pdf

eligible for referencing. These specifications are produced openly, meeting specific requirements on both the ICT specifications and the process of their development, set by the Regulation.

Public authorities can therefore make use of the full range of specifications when buying IT hardware, software and services. This, in turn, creates more competition in the field, reducing the risk of lock-in to proprietary systems. Through an Implementing Decision, the European Commission has identified 27 IHE profile as such suitable ICT interoperability specifications that healthcare providers can reference in public procurement, hence operationalising a major legal enabler for standards-based procurement by healthcare providers.

a. Safeguarding Health Data

The GDPR requires that all processing of data has a legal basis and that appropriate safeguards are in place. The high financial and reputational cost of being in breach of the GDPR is a worry to hospitals. The use of health data (for example, in EHRs) for direct patient care and internal quality monitoring is less of a problem to most healthcare providers. Cross-border care transfers are sometimes seen as a cause for concern, but if the transfer is within the EU and the purpose is to support safe continuity to a hospital's patient receiving care whilst abroad, the legal basis should be the same as for a hospital's internal data use for direct care.

Beyond using data for the provision of care, healthcare providers within the EU are concerned about how the GDPR will impact on population-based uses they make of their data, especially for research and for participating in regional or national quality improvement programmes. The lack of national or local guidance about the interpretation of how to comply with the GDPR for making data available for research adds to uncertainty in many countries today, which will hopefully lessen as countries update their national data protection laws.

As a starting point, every hospital within the EU will have appointed a Data Protection Officer who should be able to develop a suitable GDPR compliance strategy. The incorporation of a Data Protection Officer is obligatory as of May 2018 for organisations that have, among their main activities, to process a large amount of sensitive data. Data Protection Officers should have autonomy in carrying out their duties.

b. Lawful uses of data for research and for quality improvement programmes

It is important to recognise that there are legal bases that are applicable to scientific research conducted on personal data. These also cover special categories of data, under which most health data falls. Safeguards such as pseudonymisation can be used, provided that one remembers that pseudonymised data are still personal and have to be kept securely and only used for legally acceptable purposes (such as research). Although it is not always easily to anonymise clinical data whilst retaining its research usefulness, this method can render the data non-personal and not within scope of the GDPR. Good anonymisation practices can be applied to data before it is used for research.

Hospitals should therefore not see the GDPR as an obstruction to making better use of their health data, for learning and for research. However, they should take legal advice to ensure that are adopting and complying with the right legal basis, and ICT security advice on how to safeguard the data being used for research.

STANDARDS-BASED IMPLEMENTATION

Standards-based implementation reduces technical complexity when it comes to integration projects, enables easier roll-out of emerging technologies, lowers

IT deployment costs and reinvestment fatigue, and supports standardisation of processes and transaction mechanisms.

While procurement of interoperable solutions is a necessary prerequisite for establishing an effective digital environment in a hospital, it alone will not automatically deliver the value-added services for the health professionals and the patients, which will entail specific additional activities to establish the needed coherent framework within which interoperable solutions will be introduced and operated. Any investment in health ICT and digital technology in a hospital should be viewed as a project that involves much more than acquisition of digital equipment or an ICT system.

Specific guidance on how to set up interoperable digital services may be found in several sources, two of which are quoted here. The Refined eHealth European Interoperability Framework (ReEIF) has transposed the European Interoperability Framework[16] (last revision in 2017) for public authorities and organisations on how to improve governance of their interoperability activities, establish cross-organisational relationships, streamline processes supporting end-to-end digital services and ensure that both existing and new legislation do not compromise interoperability efforts.

As a starting point, every European hospital should appoint an Interoperability Officer who should be able to develop a suitable Interoperability Strategy.

Implementing an interoperability project usually involves several steps and phases. More information on the following may be found at the IHE website[17] and in particular on the following topics, which are further linked to more detailed information on the IHE website.

c. Using IHE for interoperability in your eHealth Project

The Refined eHealth European Interoperability Framework defines the different interoperability layers to be considered, demonstrating that within an eHealth project, it is crucial to define a sub-project dedicated exclusively to solve and to manage all aspects of interoperability or health information exchange: legal, care process and organisation, health information, technical interfaces and networking infrastructure.

Interoperability in digital health is one of the key challenges for a successful deployment of an eHealth or health IT project. Robust interoperability allows interactions between systems in a standardised way to ensure that the systems understand each other and foster the quality of exchanges. It is not so obvious to understand why interoperability in an eHealth project needs to receive special attention to achieve success. This is why IHE has been developing a structured and now proven methodology that leads to support the implementation of IHE profiles and underlying standards in your eHealth or health IT project.
IHE, with its 20 years of experience in interoperability and successful support to various eHealth projects across Europe and beyond, offers expertise in interoperability. It enables the diversity of eHealth projects operating at different levels from local, such as hospitals, to regional, national and cross-border.
These resources are presented in the following pages as accelerators and guidance for realising interoperability in your project. They are organised along the various phases of eHealth projects, where information exchange between IT systems and devices needs to be achieved as follows:

Interoperability Requirements
The objectives for interoperability in your project need to be documented in the form of one or more business/clinical use case(s) where the information to be exchanged between systems and

[16] https://ec.europa.eu/isa2/eif_en

[17] https://www.ihe.net/

devices, if necessary, is described in a few pages. Each of these business cases supports the eHealth strategy of the hospital/country/region;

Methodology
IHE has been developing a methodology that allows you to document, in the form of a use case, the interoperability needs for any eHealth project;

Policy alignment
Various policies impact an eHealth project, such as the collaboration agreement between health professionals that support the care processes, the patient identification policy, the consent policy, the security policy, etc;

Interoperability Specifications
These specifications express how the interoperability between the systems and devices involved in the project will be realised. Such specifications are typically based on standards. Many projects are taking advantage of standards-based profiles that support their use cases. Leveraging profiles such as those developed by IHE, reduces the specification effort, increases quality and broadens vendor support.

Testing strategy
IHE has developed a widely accepted testing continuum, that starts with vendors submitting their products to the IHE Connectathon, where they are tested against other products. IHE also provides an array of testing tools for its profiles and test management software to ensure quality of implementation in the various testing phases of a project (projectathon, pre-production, production);

Procurement of Interoperability
The content of a tender is crucial for successfully deploying an eHealth project. If it is based on the above Interoperability Specifications, suppliers will benefit from clear requirements that can be tested per the above strategy to provide evidence of their implementation of interoperability and ability to integrate;

Deployment
The deployment of an eHealth project introduces the support of new care workflows for which information exchange is critical. When diverse systems are interconnected, retesting them in pre-production accelerates deployment and reduces risks of delays. To support health professionals as well as engineers and managers, communication and training on information exchanged is beneficial.

Governance of Interoperability
IHE stresses the importance of developing an interoperability framework (requirements, specifications, testing) along the phases of your eHealth project. Such a framework needs maintenance, with changes governed alongside the addition of new use cases and systems evolution to preserve interoperability.

VALIDATING DATA QUALITY IN YOUR HEALTHCARE ORGANISATION

The quality of hospital EHR data is vital for the delivery of safe and effective patient care and further enables the reuse of your data across your Learning Health

System, strengthens your strategic and medical decision-making insights, and improves your opportunities to scale up your participation in clinical research.

As we increasingly capture, rely upon, and communicate electronic health record information, we have become heavily dependent on the quality of the data for decision-making and analysis. Within your organisation, clinicians have to know if they can trust information that they read on a screen that has been captured by other colleagues, and it is even more important to be confident about information that has been imported from a different healthcare organisation in an ever-increasing cross-organisational medical landscape.

This is not just a matter of human reading, but for the accurate performance of decision support and alerting systems. If any one of a patient's drugs has been wrongly coded, or if one of them is in free text and not coded at all, prescribing decision support will be inaccurate and place the patient at risk. An alert for a drug contraindication will similarly fail if one of the conditions is not correctly coded.

If your hospital has systematically-poor data quality in certain areas, perhaps due to an ill-designed electronic health record screen or template, or if there is a weak organisational culture of using the EHR, then population-based analytics will also be misleading. That makes it very difficult to track clinical outcomes, to ensure patient safety and to examine care pathways to optimise their efficiency. There is also a reputational risk to your hospital if your data are widely known outside the organisation to be of poor quality and therefore not reliable for shared care.

Furthermore, you want to give your patients access to the newest medical advances and have your clinicians stay at the top of their game by taking part in clinical trials. Reliable health data analyses will allow pharmaceutical companies to easily select your hospital if your patient population fits their needs.

Healthcare will be increasingly reliant upon accurate, computable health data, as care coordination and planning become more and more complex and reminders, alerts, decision support and artificial intelligence become more critical to supporting health professionals and patients. Investing in your data is investing in high-quality and cost-effective services, not only for your patients but for clinicians, healthcare managers, public health agencies, healthcare funders, pharma, regulators and health technology assessment agencies alike. For more information see Data Quality is a win-win for all stakeholders.[18]

PROCUREMENT FOR DIGITAL INNOVATION

On their journey to interoperability, healthcare organisations should consider ICT procurement strategies and models that cater for interoperability and create an organisation-wide capacity, such as a Steering Group to guide health ICT purchasing decisions and champion the acquisition strategy across the organisation.

In contrast to other ICT application domains, where consumer demand has driven a convergence on standardised interfaces and platforms, healthcare providers have not – so far – collectively demanded a consistent means of interoperability. As a result, hospitals often experience vendor lock-in when purchasing proprietary and closed communication systems and medical devices and equipment.

[18] https://www.i-hd.eu/health-data-quality/

As a starting point healthcare organisations should

- *identify the set of organisational priorities and patient outcome goals and define priority use cases to be supported through the most appropriate procurement process*
- *partner with other stakeholders in their ecosystem within which data is shared and exchanged, to align on common contracting requirements*
- *Leverage common and/or collaboratively developed specifications to articulate clear functional interoperability requirements in existing and future proposals, purchases, and contracts*
- *Gauge progress and formally assess contributions of interoperability to system-wide learning and improvement of health outcomes.*

Leveraging open procurement specifications in healthcare remains an important yet underused approach to drive healthcare integration, quality improvement, and cost containment. Over the last few years, public procurement for innovation in health has revealed major and significant transformations. Building on intelligent, sustainable and inclusive growth, the European 2020 strategy made public procurement more efficient in using public funds. New tools were introduced and guidance were issued by DG COMMERCE on procurement models supporting innovation. Pre-commercial procurement (PCP is a recommended approach for buying R&D services in a way that shares both the risk (cost) and the benefit (results). It enables public authorities to pay less for R&D services while leaving industry with sufficient rights to reuse the successful results in other projects. PCP challenges industry from the demand side to develop innovative solutions for public sector needs and it provides a first customer reference that enables companies to create competitive advantage on the market. PCP enables public procurers to compare alternative potential solution approaches and filter out the best possible solutions that the market can deliver to address the public need.