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

WP7 – Overcoming implementation challenges

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Acronyms and Abbreviations

Acronym	Description
CEO	Chief Executive Officer
CIO	Chief Information Officer
eHAction	eHAction – 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 Health Care Enterprise
PCP	Pre- Commercial Procurement
ReEIF	Refined European eHealth Interoperability Framework
WP	Work Package

Abstract

During its 15th meeting, the eHealth Network (eHN) adopted the 'Recommendations and guidelines for IT Management on implementing interoperability actions in healthcare organisations' presented as an Information Note by the eHAction Work Package 7 – Overcoming Implementation Challenges.

This document complements the D7.1 document submitted to the eHealth Network in spring 2020; it describes the content of the Interoperability Guide which will be made available through the eHAction website by WP2. This deliverable presents the Interoperability Guide for Hospital CEOs and CIOs. The Guide is intended to be an aid for healthcare providers for planning and procuring standards-based interoperable solutions. This in turn will enable meaningful data sharing within and across organisations, national and professional boundaries, and for harvesting the significant potential of knowledge out of health data.

1. ABOUT THE INTEROPERABILITY GUIDE

The Guide has been elaborated based on the conceptual design, which was submitted for information to the eHN in spring 2020, in terms of its target audience; its breadth and depth of content and key design characteristics; the participation of the community of the informal network of European hospitals established in WP7; and the collaboration with Integrating the Healthcare Enterprise (IHE) and the European Institute for Innovation through Health Data (I~HD) for the updating of the content that will be maintained by these organisations. More specifically:

The eHAction interoperability Guide targets the senior executive level in health care providing organisations. Its strength lies in that it pitches – in a few pages – what a hospital manager should know and appreciate about the value of interoperability.

The guide, *by design*, is not meant to be a "complete" eHealth interoperability guide; this would be neither feasible nor sustainable. It is not the objective to re-iterate the content produced by European and international organizations, such as IHE, IHD, HL7 and others that are devoted to this challenge and they create and maintain content for a range of user profiles. This material is too overwhelming to address the needs of the management of any health care organization.

However, the guide does not stop at merely providing basic information to its target audience. It further provides links to where the information is, in a guided and specific way; hence it can help a hospital senior level officer (a) to obtain an understanding of key interoperability benefits, challenges and means of achieving it and (b) become aware that of what specific EU level guidance and re-usable assets exist for the organizational and the technical level that can help maximize the benefit for own projects.

In this sense, the Guide may be also seen also a "meta-guide" for the operational level and as such it can be continually enriched as links to "information providers" such as IHE, I~HD, HL7 and other relevant organisations are added and become operational. For this reason, the guide is made accessible as a web page on the eHAction website[1]. Developing the lower information layers fully, is however outside the scope of the eHAction deliverable, which is limited to exposing this opportunity, should this guide be adopted and maintained by an entity or a scheme, beyond the JA.

[1] http://ehaction.eu/interoperability-guide/

The sustainability of this guide beyond the end of the project is therefore the most important challenge that needs be addressed over the remaining lifetime of deHAction.

Sustainability has been considered already at the design of the Guide. There are two significant elements that are central to the stewardship of the Guide and can guarantee its continuing fitness for purpose and currency:

- 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 information itself is maintained by the competent organisations that generate and take stewardship of it.

The main design principle has been that

(a) the top layer of information in the eHAction guide, which is less dynamic, can be sustained in the future by either one organisation or a collaborative community or group (as for example a subgroup of eHMSEG and/or a Community of Practice),

(b) its full layered content will need to be sustained by key EU level organisations that develop and maintain such content that will commit to creating and maintaining such content either for their own purposes or will in the future create it for the needs of the guide in terms of audience and needs addressed.

The current implementation of the Guide is also a proof of concept of this co-creation principle which has been tested with two such EU/international organisations, namely IHE Integrating the Health Care Enterprise) and I~HD (the institute of Innovation through Health Data). The eHAction team has collaborated with these two organisations mentioned above and together they have: (a) identified areas on their websites with existing information suitable for the Guide; (b) agreed the content of landing pages where the readers of the Guide will arrive at when seeking more detailed information; (c) ensured timely delivery of this content.

WP 7 has also kicked off discussions on the potential interest to establish one such community of practice around the topics of the Guide, leveraging on the informal network of hospitals that have contributed to its inception. A webinar focusing on the creation of communities of practice was organised on 21st April 2020 and five testimonials have been received. Some further considerations on the potential role of Communities of Practice as well as a proposed process towards sustainability are provided in the following paragraphs.

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. WP7 has in parallel launched an activity for collecting such testimonials and good practices. A template (see Annex 1) for the collection of good practices and experiences has been distributed to the network of hospitals for collection of good practices. Collection of good practices is however an ongoing process and it is also to be facilitated through the functionality of the webpage.

There has been however limited progress till now in terms of launching a sustainable community, as some further clarity would be needed on the aspects of post project potential of its sustainability.

Over the next period, WP7 will further explore the potential of the seed community of practice to provide for the necessary organisation of contributions and in particular, differentiating between

submissions and selected good practices and considering the assessment of submissions prior to publication.

As part of future work, WP7 will review these contributions and will make proposals as to the potential to enrich the present Guide by their inclusion. The outcome of this activity will feed into the sustainablity discussion, described in the next paragraph.

Sustainability and Future Governance of the eHAction Interoperability Guide

For the Guide to remain current, it is important that it is reviewed at planned intervals or if significant technological or legal changes occur, to ensure its continuing suitability, adequacy, and effectiveness. eHAction explorations have resulted in an initial proposal which has been brought to consultation within the project within the project groups and the EC. This consultation has pointed to a number of steps involving a broader consultation with the eHealth Stakeholders and the Member States in order to arrive timely to a meaningful and sustainable hand-over of the Guide at the end of the Action. In particular:

RECOMMENDATIONS

1. It is recommended that the Interoperability Guide
    a. is handed over, at the end of the eHAction, to an entity that can maintain its content, in collaboration – where necessary – with organisations contributing detailed guidance on specific aspects;
    b. a conducive environment for the creation of a self-sustained community of practice, actively contributing knowledge and exchanging on good practice experiences is also supported, within the general post project environment of the Interoperability Guide;
    c. a practical, supportive and facilitating organisational governance is elaborated in collaboration with the current informal community of hospitals and in consultation with the stakeholder community.
2. It is recommended that over the next few months to the end of the Action,
    a. The European Commission facilitates a consultation on the Guide and its sustainability principles and potential with its Advisory eHealth Stakeholder Group
        i. this consultation will aim at both validating these principles and, at the same time, seeking concrete stakeholder collaboration commitments on sustaining the Guide beyond the eHAction;
    b. Leveraging on the eHAction network, a further engagement of the user community is pursued in validating the current Guide and in elaborating the organisational framework for collecting and publishing user experiences and sharing good practices.
3. Based on the evidence collected through these activities, it is recommended that
    a. the eHAction prepares and presents sustainability proposals for the Interoperability Guide and effectively prepare for a hand over to a successor;
    b. the eHealth Network is requested to assess and decide on the most appropriate proposal for hand-over of the Interoperability Guide after the end of the Action.

2. INTRODUCTION TO THE INTEROPERABILITY GUIDE

2.1 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.

2.2 Frequently asked Questions

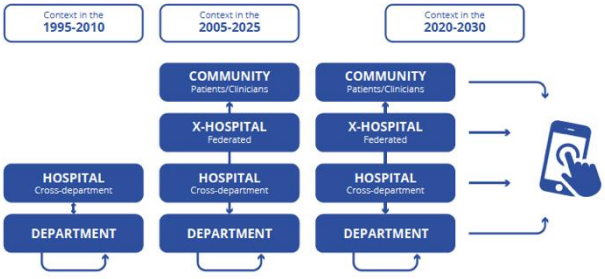
Who is this Guide for?

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 executives in the health care organizations 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 Services 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 on 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[2]. 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 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

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

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.

3. 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[3], which targets pan-European interoperability of health records for care purposes and at the same time supports the European strategy for data[4], underpinning the creation of the common European Health Data Space for scaling up secondary use of this data for research, innovation and regulatory compliance.[5]

3.1. 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 e-Prescription kernels in your Electronic Health Record systems:

- you can select and reference, in your procurement, one or more of the 27 interoperability specifications[6] published by the European Commission, in the framework of the Standardisation Regulation[7];

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

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

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

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

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

- You can draw upon the general implementation framework provided through the eHealth Network Guidelines[8]. 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[9], 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.

3.2. 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[10] (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.

3.3. 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 5 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

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

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

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

within the organisation and across organisations, and will further support continuity of care for mobile citizens.

3.4. 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[11] (MVC) is a collection of terms, used in the context of exchanging data on patient summaries and e-prescriptions (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[12] 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.

4. 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.

4.1 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 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

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

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

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 Category 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.

5. 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 European eHealth Interoperability Framework (ReEIF) has transposed the European Interoperability Framework[13] (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 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 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

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

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.

6. 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[14].

7. 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.

[14] 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 has made public procurement more efficient in using public funds. New tools have been introduced and guidance has been issued by DG COMMERCE on procurement models supporting innovation. Pre-commercial procurement 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. Pre-Commercial Procurement (PCP), on the other hand, 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.

8. Annex 1: Template for the Collection of Testimonials

Good Practices	**TITLE of Good Practice/Experience** **Under "Good Practices", please report proven approaches to solving interoperability challenges for healthcare providers. You may wish to consult the two provided in the Ann** • **Responses required**	
Organization*	Briefly describe the organization	
Name of expert& Position in the Organization		
What was the interoperability challenge for health care providers that you have addressed? (What & Why, Scope of interoperability project)*		
How was this challenge addressed?*	For example: You may describe the workflow or the design of solution, the resources that have been used (e.g. Budget, work plan, infrastructure, SW, etc)	
	duration of the project	Year completed
What were the major enablers and pre-conditions?	For example: national interoperability FW, availability of interoperability specifications and assets, previous experience etc)	
What type of tender did you use ?*	Direct Award of Contracts	
	Prior Consultation	
	Public Call	✓
	Invitation by Grant Agreement	
	Other:	
Cross Border Relevance (if any)*	Information exchange for cross border patient care	✓
	Information exchange for public health and secondary use	✓
	Information exchange for the patient	
Which interoperability use cases have you addressed?*	Laboratory orders/results	✓
	Imaging orders/results	
	Medication Prescription/dispensation	
	Discharge letters	
	Patient summaries	✓
	Patient referrals	
	Teleconsultation (patient/doctor)	
	Telecollaboration (doctor/doctor)	

	Public health reporting(reportable diagnosis & key interventions)		✓
	Other:***e.g. Hospital Admissions/Bed Management at the regional level***		✓
	Other: ***e.g. enter your UC name***		
	Other: ***e.g. enter your UC name***		
What interoperability standards and profiles have you used for each of the above use cases?*	Laboratory orders/results	e.g. HL7 CDA, IHE-XD-Lab	
	Imaging orders/results		
	Medication Prescription/dispensation		
	Discharge letters		
	Patients summaries	e.g. HL7 CDA, IHE-XDS	
	Patient referrals		
	Teleconsultation (patient/doctor)		
	Telecollaboration (doctor/doctor)		
	Public health reporting	e.g. National standard	
	Other: ***e.g. Hospital Admissions/Bed Management at the regional level***	e.g. HL7 V2	
	Other: ***e.g. enter your UC name***		
	Other: ***e.g. enter your UC name***		
How did your project define its interoperability specifications?*	They were created by the project based on our own selection of standards and profiles		✓
	We referenced/reused the national interoperability framework		
	We ask the main vendor to set these specifications		
	Other:		
What interoperability testing strategy have you employed?*	Used a project mandated specific set of interoperability test tools before systems where interconnected?		
	Reused an existing set of interoperability test tools that were customized before systems were interconnected?		✓
	Tested the point of care systems by connecting them to a lab version of central systems		
	Other:		
What were the main implementation challenges you encountered	Spent a lot of time to connect each point of care systems		
	When interoperability issues occured, it was complex to decide which system is at fault		

	We had long discussions on which standards to select	
	Other: ***e.g. enter your UC name***	
	Other: ***e.g. enter your UC name***	
Who were the perceived beneficiaries of your interoperability initiative?	Citizens/patients (e.g. improved care outcomes, improved citizen experience)	**Directly Indirectly**
	Health Professionals(e.g. improved workflow, access to information, re-use of data in research)	**Directly Indirectly**
	Hospital administration (e.g. reduction of wast, cost savings, improved monitoring)	
	Financial and social factors (e.g. eHealth Mmarket competitiveness, more jobs)	**Directly Indirectly**
	Health System (improved efficiency, quality and effectiveness, supporting learning systems)	**Directly Indirectly**
Did your project used the ReEIF5 layer model to analyse its interoperability?		
Based on your experience, what can you recommend to others?	Small healthcare organizations (doctors, pharmacies, etc.	
	Large healthcare organizations	
	Policy makers at EU level	
	Policy makers at Member State Level	