Interoperability standards in digital health

A White Paper from the medical technology industry

COCIR
Advancing Healthcare

MedTech Europe
from diagnosis to cure

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1. Introduction

Lack of interoperability is widely acknowledged to be a critical barrier for the adoption and deployment of digital health technologies, as well as the broader digital transformation of healthcare.[1] Addressing and overcoming this barrier requires awareness and cooperation among all stakeholders. This should start with a shared understanding of the relevant standards in digital health. Advancing such a shared understanding is the purpose of this paper.

There is not one single digital health interoperability standard. Instead, there is a diversity of standards, specifications and profiles coming from various organisations and initiatives, many of which have organically emerged and grown to meet interoperability needs around specific uses. This has resulted in a fragmented environment and a sometimes bewildering variety of voices, leading to uncertainty that has held back the adoption of information and communication technologies (ICT) in healthcare. While other industries – mobile communications, consumer electronics, banking, and commerce – have delivered tangible examples of interoperable data flows while preserving competition, healthcare appears to lag behind.

MedTech Europe and COCIR are partnering to present a medical technology industry perspective on the standards, profiles, and specifications relevant to digital health, and to provide insight into how they relate to interoperability needs. This paper is intended for companies in the medical technology industry, policymakers at all levels (European and international, national, regional, and municipal), decision makers in provider organisations, and all other interested stakeholders.

Section 2 describes the current state of play, sheds light on the most relevant players in the landscape of standards development organisations (SDOs), explores layers and aspects of interoperability, and discusses the policy context in Europe. Section 3 offers a more detailed look at specific healthcare domains and the state of standards development, including personal/patient health devices, cardiac implants, imaging devices in hospitals, and the world of medical laboratories. A brief conclusion offers insight into upcoming developments.

The paper presents an overview of existing standards in digital health to the best of our knowledge. It should not be considered as a recommendation to mandate these standards. MedTech Europe and COCIR will aim to periodically review and update the paper to reflect new technical, political, and market developments.

MedTech Europe and COCIR hope this paper contributes to an increased awareness about the international nature of interoperability standards and specifications, and to advancing an interoperable ecosystem for digital health in Europe.

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[1] OECD (2019), "*Health in the 21st Century: Putting Data to Work for Stronger Health Systems*", *OECD Health Policy Studies*, Éditions, Paris, https://doi.org/10.1787/e3b23f8e-en (Accessed 21 Sep 2021).

2. Digital Health Interoperability – the State of Play

This chapter outlines the state of play in the field of health interoperability. It includes a definition of the term "interoperability", a reflection on the importance of interoperability, the policy environment, a framework on how to think about the interplay of the different SDOs and types of standards, the SDO landscape, and a discussion about some myths around interoperability.

Definition of interoperability

There is no generally agreed-upon definition for interoperability in digital health. The European Medical Device Regulation 2017/745 and the In Vitro Diagnostic Regulation 2017/746, which regulate all medical devices on the market in Europe, define interoperability as follows:[2]

> "'interoperability' is the ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to:
> > (a) exchange information and use the information that has been exchanged for the correct execution of a specified function without changing the content of the data, and/or
> > (b) communicate with each other, and/or
> > (c) work together as intended."

The medical technology industry agrees with this definition but believes that, by its brevity, some relevant domains and aspects are left uncovered. The Health Information and Management Systems Society (HIMSS), a global health IT (HIT) membership association, offers a more detailed definition: [3]

> "[Interoperability] is the ability of different information systems, devices and applications (systems) to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organisational, regional and national boundaries, to provide timely and seamless portability of information and optimise the health of individuals and populations globally.
>
> Health data exchange architectures, application interfaces and standards enable data to be accessed and shared appropriately and securely across the complete spectrum of care, within all applicable settings and with relevant stakeholders, including the individual."

HIMSS distinguishes four levels of health information technology interoperability: (1) foundational; (2) structural; (3) semantic; and (4) organisational. These levels are further discussed below.

We believe that, while this may not be the perfect definition of interoperability (for example, there may be additional dimensions of interoperability), it offers a good working definition to serve as the basis for this paper.

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[2] *Regulation 2017/745/EU* and *2017/746/EU* of the European Parliament and of the Council, 2017.
[3] HIMSS (Healthcare Information and Management Systems Society), *Interoperability in Healthcare,* https://www.himss.org/resources/interoperability-healthcare (Accessed 21 Sep 2021).

Why Interoperability

Lack of interoperability is a critical barrier to the digital transformation of healthcare. There is broad agreement that digitalisation in the healthcare sector has enormous potential if data is freed from its silos and data flows, data sharing, and advanced use of data are enabled. Some tangible examples of this potential include:

- Ready-to-use patient-centric information can enable advanced clinical decision support in diagnostics and treatment.
- Care coordination can greatly benefit from sharing data in uniform formats that all players can interpret.
- Patients' access to their own health data can empower them to actively pursue a healthy life and manage their condition.
- Operational data can help smoothen workflow and enable outcomes-driven improvement cycles.

Thus, interoperability will help deliver better care at a lower cost, leading to higher quality patient outcomes and the support of carers. Achieving these goals requires all relevant data to be accessible without barriers and uniformly interpretable. A recent example from the pandemic was the need to share all information of COVID-19 patients who were moved between hospitals in the Netherlands to balance the capacity of intensive care units (ICUs). A portal was set up using digital health standards to assist these efforts, which provided invaluable support to doctors and healthcare workers during the peak time of hospitalisations.

Some fear that sharing interoperable and readily interpretable data makes this data more vulnerable to cybersecurity threats and privacy breaches. However, standards and technical specifications are capable of both ensuring data safety and security, and of delivering audit and control measures for access and control. They can also provide consent management solutions where needed.

Similarly, there are concerns that standards inhibit innovation. We believe instead that interoperability is an enabler of innovation: it can create an ecosystem where different players compete based on the strength of their products and features. Such an ecosystem lowers the barrier to entry, especially for innovators and small and medium-sized companies.[4]

The SDO Landscape

Where do international standards come from? The standards organisations based on the country representation model (International Organization for Standardization [ISO], International Electrotechnical Commission [IEC], and International Telecommunication Union [ITU]) have not always delivered standards at the required speed and granularity to benefit healthcare systems. As a result, a landscape has emerged of semi-official and private organisations and initiatives, with complementary and sometimes overlapping objectives, often driven by coalitions of industry, academia and users. Below is a discussion of the initiatives that are most relevant to the purposes of this paper: DICOM, HL7, IICC, IHE, LOINC, SNOMED CT, UCUM,

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[4] Compare MedTech Europe (July 2019),, *Call to action for an interoperable data ecosystem for digital health.* https://www.medtecheurope.org/wp-content/uploads/2019/07/2019_MTE_DH_Interoperability_position_paper_ws.pdf (Accessed 21 Sep 2021).

Continua, and IEEE. These organisations emerged in specific contexts, and today exist not to compete, but to cooperate and coordinate on setting international standards.

The order of discussion below follows roughly chronological lines and illustrates two aspects: (1) most (if not all) interoperability initiatives are launched in the United States, which appears logical given the predominance of the US market; and (2) the discussion of interoperability started in the radiology and imaging departments of America's hospitals.

- **Digital Imaging and Communications in Medicine (DICOM)** is the international standard for medical images and related information. This is the use case that first started the interest in standardised transfer of health information (in this case, radiology images). The first version of the standard was developed and released in 1985 by a joint committee of the American College of Radiology (ACR) and the [US] National Electrical Manufacturers Association (NEMA). DICOM did not evolve into an organisation; the standard is currently managed by a secretariat of NEMA and the Medical Imaging & Technology Alliance (MITA).
  The standard, also published by ISO as ISO 12052, defines formats, workflow support and exchange mechanisms for medical images with the data and quality necessary for clinical use. DICOM is implemented in virtually all devices creating medical images, picture archive and communications systems (PACS), processing/reporting workstations, radiation dose reporting systems, as well as oncology, electrocardiography, laboratory, and endoscope systems. DICOM is deployed in hospitals and healthcare institutions worldwide.

- **Health Level Seven International (HL7)** develops international standards for the transfer of clinical and administrative data. The organisation was founded in 1987 in the United States as a non-profit organisation to provide a framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information. Today the organisation counts more than 1,600 members from over 50 countries, including corporate members representing healthcare providers, governments, payers, medical technology, and pharmaceutical companies. Since 2010, there has been a European Office to drive forward its international ambitions, to support many national HL7 groups, and to engage in EU-funded projects.
  HL7 standards define how information is packaged and communicated from one party to another, setting the language, structure, and data types required for seamless integration between systems. HL7 standards support clinical practice and the management, delivery, and evaluation of health services, and are recognised as the most implemented in the world. HL7 is present globally in practically all hospitals and healthcare institutions for enterprise and cross-enterprise integration of health IT systems. HL7 standards were referenced in the European Electronic Health Record Exchange Format (EHRxF).
  The most widely deployed set of HL7 standards is the so-called version 2, primarily a messaging standard and widely seen as a legacy technology today. HL7 version 3 was a comprehensive but complex meta-standard that only found its way to practical use through Clinical Document Architecture (CDA).

In 2013, HL7 introduced *Fast Healthcare Interoperability Resources (FHIR)*, an interoperability standard that provides a standardised interface to individual EHR systems for healthcare-related data intended to facilitate the exchange of healthcare information between healthcare providers, patients, caregivers, payers, researchers, and anyone else involved in the healthcare ecosystem. Fast Healthcare Interoperability Resources (FHIR) builds on previous HL7 data format standards but uses a modern web-based suite of Application Programming Interface (API) technology, including an HTTP-based Representational State Transfer (RESTful) protocol, and several choices for data representation.[5]

- **The IVD Industry Connectivity Consortium (IICC)** was established in 2009. IICC "is a global, non-profit organization dedicated to creating and encouraging the adoption of a unified connectivity standard to reduce the cost and variability of data exchange between IVD (*in vitro* diagnostic) devices and healthcare informatics. This will improve healthcare efficiency and patient care. Member organisations include Abbott Diagnostics, Beckman Coulter, Becton Dickinson, bioMérieux, Data Innovations, Orchard Software, Ortho Clinical Diagnostics, Roche Diagnostics, Siemens Healthcare Diagnostics, and Systelab Technologies, S.A."[6]
  - IICC collaborated with several government bodies and industry organisations for the specification of the IHE Laboratory Analytical Workflow (LAW) profile and for LOINC for IVD (LIVD), a digital format for publication of LOINC codes mapping by IVD manufacturers.

- **Integrating the Healthcare Enterprise (IHE) International** was established in 1998 by a consortium of radiologists, information technology (IT) experts, and manufacturers to address DICOM's limitations: where DICOM addressed technical interoperability issues in medical imaging, a framework was needed to advance the clinical workflow. IHE initially established the coordinated implementation of DICOM and HL7 to address radiology scheduled workflow by selecting specific features from DICOM and HL7 to standardise transactions for specific medical imaging interoperability use cases. These definitions are openly published as "Profiles" on these standards in the IHE Technical Frameworks.
  Today, IHE International remains a non-profit organisation based in the US state of Illinois and governed by healthcare professionals and industry, with national deployment committees in 17 countries around the globe (including in ten EU Member States). IHE has created and operates a process through which interoperability of all aspects of health care IT systems can be improved. IHE Profiles are created not only for Radiology but in 14 domains, including Pathology and Laboratory Medicine, Pharmacy, Laboratory, and IT Infrastructure. IHE builds on specific use cases, gathers requirements, identifies available standards, and develops technical guidelines which manufacturers can implement. IHE also stages "IHE Connectathons", "Projectathons", and "interoperability showcases" for vendors to demonstrate the interoperability of their products based on IHE Profiles.
  IHE Europe, the regional deployment committee for Europe, has been running annual IHE Europe Connectathons and has participated in numerous European projects to advance

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[5] HL7, *Fast Healthcare Interoperability Resources Specification*, https://www.hl7.org/fhir/overview.html (Accessed 21 Sep 2021).
[6] The IVD Industry Connectivity Consortium (IICC), https://ivdconnectivity.org/ (Accessed 21 Sep 2021).

interoperability, including the European Patient Smart Open Services (EPSOS), Antilope, and The eHealth Interoperability Conformity Assessment Scheme for Europe (EURO-CAS). The Commission listed IHE Profiles for referencing in public procurement in 2015 and referenced them in the 2019 EHRxF Recommendation.

- **Logical Observation Identifiers Names and Codes (LOINC)** is the international standard for identifying medical laboratory health measurements, observations, and documents that enable semantic understanding and interoperability. First developed in 1994, it was created and is maintained by the Regenstrief Institute, a US non-profit medical research organisation. LOINC was created in response to the demand for an electronic database for clinical care and management and is publicly available at no cost. The standard is maintained and developed in the form of a database that has expanded to include not just medical laboratory code names but also nursing diagnosis, nursing interventions, outcomes classification, and patient care data sets. A detailed discussion of the LOINC database is in the chapter "Medical laboratories" in section 3.

- **SNOMED CT** is a systematic, computer-processable collection of medical terms that presently represents the world's most comprehensive clinical terminology. Formed originally as a "systematized nomenclature of medicine" in the United States, it was merged in 2002 with a UK effort on clinical terms, hence "SMOMED-CT". Today, SNOMED-CT is a multinational and multilingual terminology and is managed by SNOMED International. SNOMED-CT licenses the use of SNOMED through membership for national governments: a membership allows all healthcare stakeholders to access and use SNOMED free of charge. As of this writing, 19 EU Member States are members of SNOMED.[7] Annual affiliate licenses are open to individual providers or projects, but their benefits are limited and a fee applies.

- **The Unified Code for Units of Measure (UCUM)**[8] was created as a grammar/syntax for describing units of measure across scientific, business, and engineering disciplines, and is thus broader than health-related measurements. UCUM provides a computable representation of units of measurement. UCUM codes are intended for use in electronic communication (such as messages or documents in formats defined by HL7). UCUM is under the control of the Regenstrief Institute at the University of Indiana in Indianapolis (which also manages LOINC).

- **Continua Design Guidelines (CDGs)** were first released in 2008 to advance the interoperability of personal health devices – both medical devices and consumer ("mHealth") devices – with clinical health IT systems. The CDGs were initially developed by the Continua Health Alliance, which was founded in 2006 following the model of IHE, both in terms of governance (convening industry and providers) and with the aspiration to choose from existing standards and describe how to combine and use them for the purpose. In contrast to IHE, the membership included both medical technology and consumer IT companies (including Nokia, Panasonic, and Sony). In 2013 the CDGs became an

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[7] SNOMED International, *Members*, http://www.snomedhttp://www.snomed (Accessed 21 Sep 2021).
[8] The Unified Code for Units of Measure, https://unitsofmeasure.org (Accessed 21 Sep 2021).

ITU standard (ITU-T H.810). In 2014 the Alliance merged with HIMSS to form the PCHAlliance. Today the technical management and testing regime of the CDGs sits with IHE.

- **The Institute of Electrical and Electronics Engineers (IEEE)** is a professional association for electronic engineering and electrical engineering. It includes a standards-setting arm that has delivered the IEEE 11073 series of standards, which have become the leading standards for vital signs measurement and communication for in-hospital patient monitoring and personal health devices. They define data models and communication protocols for this domain, distinguishing between Point of Care (PoC) devices for in-hospital use and Personal Health Devices (PHDs) for out-of-hospital settings. ISO also publishes the series as the ISO/IEEE Standard 11073.

Such diversity across the SDO landscape brings the risk of conflicting guidance and confusion among external actors and non-experts. To address this risk, in 2015 some SDOs founded the "Joint Initiative Council"[9] (JIC) to bring together relevant organisations listed above "to align and collaborate, as well as connect with other expert organisations, in the delivery of coordinated—not competitive—standards and implementation guides".[10] The JIC also produced a graphic illustration of the interplay of various health IT standards, which is reproduced in Figure 1.

Lastly, this chapter should acknowledge the role of HIMSS, the professional/industry association for health IT headquartered in the US, with offices in Europe, the Middle East, and Asia Pacific. In 2018, together with IHE International and HL7 International, HIMSS founded the Global Consortium for eHealth Interoperability, which works to amplify and align the work of SDOs to increase adoption of emerging and mature health IT standards. The consortium's goal is to coordinate work with governments and national ministries of health to further align existing and emerging standards and implementation guidance.[11] Recently, IHE and HL7 embarked on closer cooperation and alignment to advance FHIR in the so-called Gemini project.[12]

Figure 1: Schema of clinical and laboratory domain standards
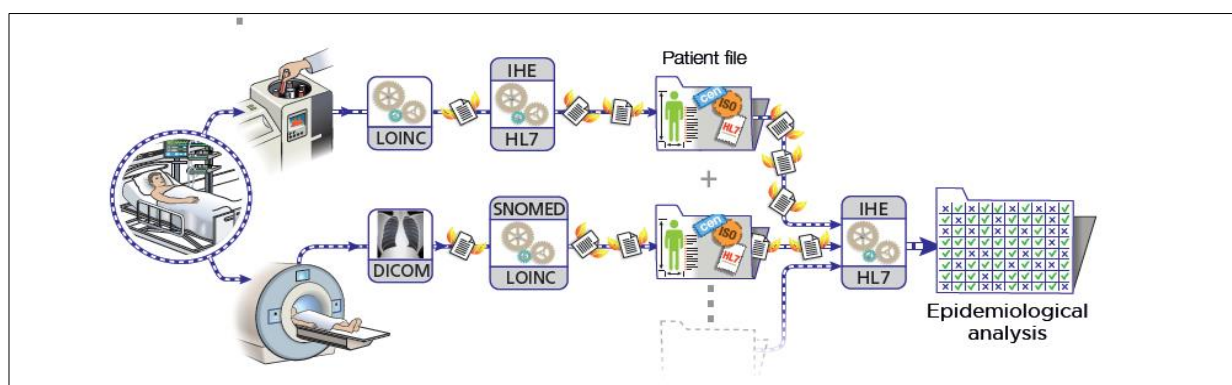
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[9] Joint Initiative Council, *Joint Initiative Council for Global Health Informatics Standardization*, http://jointinitiativecouncil.org/ (Accessed 21 Sep 2021).

[10] Joint Initiative Council (June 2020), *Setting the stage for the future: , Enabling the digital transformation of healthcare*, http://jointinitiativecouncil.org/images/pdf/jic.setting.the.stage.for.the.future.pdf (Accessed 21 Sep 2021).

[11] HIMSS, *Interoperability in Healthcare.*

[12] Confluence, *Project Gemini: A Joint Venture of HL7 and IHE to Advance Use of FHIR for Interoperability*, https://confluence.hl7.org/display/GP/Project+Gemini (Accessed 21 Sep 2021).

Levels of Interoperability and Types of Interoperability Standards

To understand how different health IT interoperability standards complement each other and can jointly cover the needs of care providers, it helps to position different interoperability needs in a model. Two existing models can be used: (1) the eHealth Network model; and (2) the HIMSS model. Figure 2 provides a rough mapping of both:

Figure 2: Levels of interoperability (comparison eHealth Network and HIMSS)
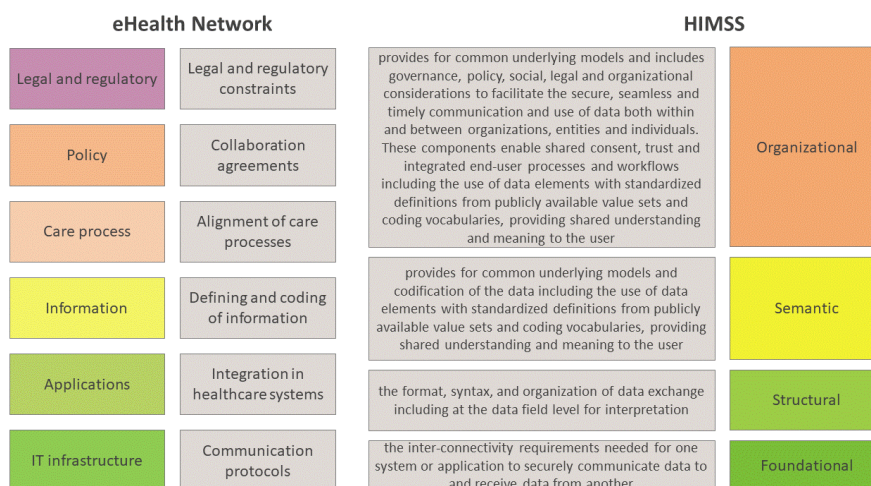
When analysing the models from the bottom up and focusing on technical health IT interoperability standards, the main elements include:

- Standards that concern moving data between system elements agnostically or managing generic functional aspects such as security. The information and communication technology (ICT) industry develops such standards to cover the needs of many sectors; the health IT industry applies what is suitable. Sometimes specific requirements inspire adjustments or application guidance. ICT standards move with the pace of technology and consumer markets. This drives an on-going cycle of adjustments to vertical Healthcare IT standards to benefit from ICT innovations.

- Standards that technically manage care-specific functional aspects, such as patient consent as a condition for data usage. These are typically much like ICT standards but address a more specific need and therefore require better understanding of the care sector to develop.

- Standards that define the format, syntax, and organisation of data exchange. This includes data models to represent different pieces of information and their interrelationships. In healthcare IT, these models are complex because the underlying reality of care provision is involved. Development of these standards requires an understanding of this reality and deep data modelling expertise.

- Standards that provide uniform interpretation of meaning by codifying clinical concepts. Data models are also very important here, but the emphasis is on semantics. Development of these standards requires deep knowledge of clinical science and practice, and an understanding of data modelling.

- Standards that support clinical workflows involving different actors and health IT tools by specifying the interactions between them. The development of these standards requires an understanding of clinical workflows and the typical setup of medical devices and health IT systems to support them.

Care providers also use operational (non-clinical) workflows, for which they can apply horizontal workflow standards.

So-called *base standards* focus on the details for any of these elements for a given domain. They include DICOM and many HL7 standards, or the IEEE 11073 series, or LOINC and SNOMED. In practice, many base standards combine aspects for several of these elements, as the lines of separation are not clear-cut. In addition, several base standards may apply to more than one domain. There is a trend of increasing overlaps, which complicates the selection of the right standards.

To realise interoperability for solutions to truly support care provision, one must apply different types of base standards in a broader system context, which need to be agreed upon as well. So-called *interoperability guidelines* or *profiles* address this need. They typically provide some sort of *reference architecture* as technical context for a given domain. They prescribe how to cover all interoperability needs of selected *use cases* within this domain and context by referencing base standards and specifying how exactly to combine and apply them. While there are differing views on this, this paper considers these standards as well. Many organisations develop profiles, often tuned to regional or domain-specific needs. Their abundance complicates the selection of the right standards, and regional differences hinder true interoperability.

Health IT (HIT) standards keep evolving for several reasons:

- **Medical science** keeps expanding, and new technologies for diagnosis and treatment emerge. Existing notions typically remain valid alongside the development of new ones. This moves relatively slowly and mainly leads to ongoing expansion of semantic code sets and evolution of format / syntax standards, addressing new domains where necessary.

- At the same time, the **delivery and organisation of care** keep evolving as well. The roles, responsibilities, decision authorities, liabilities, and mutual dependencies between and among different players such as healthcare organisations, public authorities, insurers, citizens, and patients develop and affect how they optimise their organisations, resources, and processes. As a result, clinical practice evolves next to scientific progress. In this process, new care provision methods and processes emerge, which call for new domain or workflow standards. An example is the growing role of telemonitoring services that enable patients to be monitored remotely.

- **New or changing legislation** creates new organisational and technical requirements for the provision of healthcare, which often lead to new interoperability needs. Changes may happen quickly and introduce new domains in need of standards or call for new standards to manage care-specific functional aspects, such as patent consent and data privacy. Interoperability itself is increasingly the subject of top-down stimuli and direction setting by public authorities in a rightful pursuit to foster better interoperability.

- **ICT technology and standards** keep evolving and move relatively fast. To benefit from these innovations and keep pace with the supply of engineering skills and equipment, health IT standards must adjust. Often the "payload" data remains essentially similar, however, in terms of data models, syntax, and semantics. Likewise for the interactions between system elements.

- Learning by **trial and error**. The market does not embrace every standard. Non-adoption may have many reasons but is hard to counter. Adjusting the standard or creating a new one that takes lessons learned into account may remedy the issue.

The ongoing expansion and evolution of HIT standards is, therefore, both unavoidable and valuable. This makes it a challenge to choose and deploy a set of standards that truly achieves interoperability in support of better provision of care.

Tiers of Interoperability Needs and Solutions in Care Provision

Different interoperability needs and solutions are needed for different care provision contexts. Goals may, for instance, include providing patient care, optimising the efficiency of care provision, enabling automated clinical decision support, strengthening alert mechanisms for infectious disease outbreaks, or supporting national scale infectious disease surveillance.

Figure 3: Interoperability in the Health Ecosystem
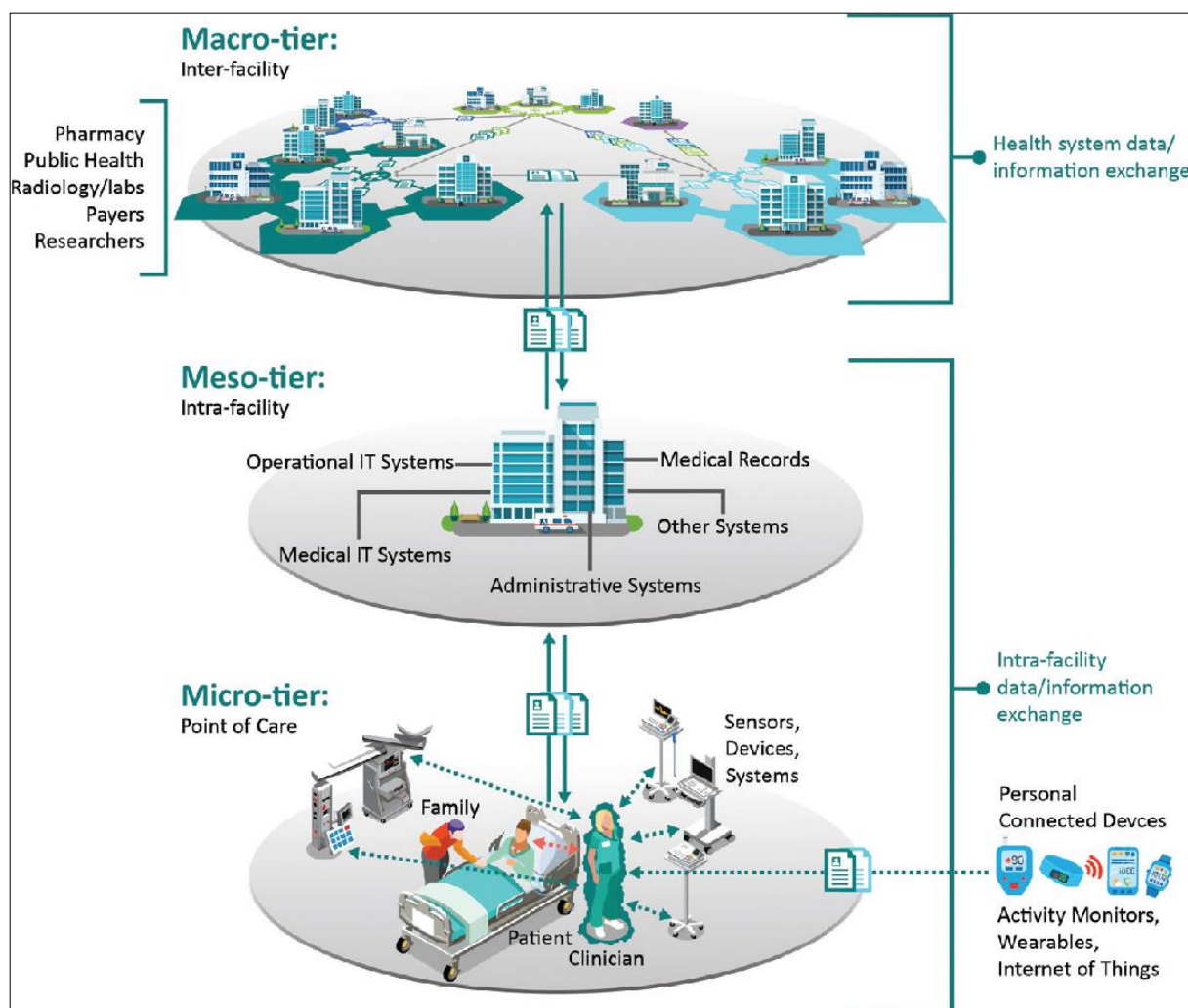
One useful way of structuring the different roles and areas of deployment of interoperability standards has recently been put forward by the US National Academy of Medicine. In its 2018 publication "Procuring Interoperability", the Academy divides the healthcare ecosystem into three tiers: inter-facility (macro-tier), intra-facility (meso-tier), and point of care (micro-tier).[13] A graphic illustration (figure 3) is shown above.

Whereas patient data typically originates at the micro-tier, the meso- and macro-tiers leverage the accumulated data for a diversity of purposes, many of which do not immediately relate to providing care to an individual patient, but support research and innovation leading to new treatments and better care outcomes.

The Policy Environment

The preceding chapters offered a discussion of the world of SDOs and their standards and specifications that cover many aspects of digital health. However, the presence of standards does not mean that they are universally recognised and adopted. Lack of interoperability is often considered a failure of the market that may require the intervention of governments to redress.

In the European Union (EU), governance is dispersed: the competence for health and social policy lies with the Member States, with the European Commission taking on a supporting role in health and care.[14] Advancing interoperability in healthcare has been high on the EU agenda for about a decade. The first European Interoperability Framework, published in 2010 (and renewed in 2017), set up a framework for interoperable public services.[15] The Cross-Border Healthcare Directive of 2011 established an EU competence on healthcare and eHealth matters and delivered a rationale for EU action to support the Member States on interoperability.[16] Two years later the Commission published the *eHealth Interoperability Framework* study, which recognised the role of private profiling organisations like IHE and Continua in advancing digital health interoperability and complementing the work of the official standards development organisations (SDOs).[17] The Commission also supported several EU research initiatives to advance interoperability.[18] In 2015, the European Commission identified a list of 27 IHE profiles for referencing in public procurement.[19]

The 2011 cross border healthcare directive also created a collaborative governance structure for eHealth that respects the national competence over health and social care while allowing for collaboration where it

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[13] Pronovost, P. et al. (2018), *Procuring Interoperability: Achieving High-Quality, Connected, and Person-Centered Care* (eds. Samitt, C. et al.)*,* Washington, DC: National Academy of Medicine, 2018, https://nam.edu/wp-content/uploads/2019/08/Interop_508.pdf (Accessed 21 Sep 2021).

[14] The role of the EU to support Member States in health and care matters was established by the 2007 Treaty of Lisbon, which that went into effect in 2009.

[15] European Commission, *ISA - Interoperability solutions for public administrations, businesses and citizens,* https://ec.europa.eu/isa2/eif_en (Accessed 21 Sep 2021).

[16] *Directive 2011/24/EU* of the European Parliament and of the Council, art 56, 2011.

[17] European Commission (July 2013), *Shaping Europe's digital health future: , eHealth Interoperability Framework Study*, https://ec.europa.eu/digital-single-market/en/news/ehealth-interoperability-framework-study-0 (Accessed 21 Sep 2021).

[18] Milestone projects include epSOS (2008-2014); Antilope (2013-2015); EURO-CAS (2016-2018); and X-eHealth (2020-2022).

[19] *Commission Decision (EU) 2015/1302 of 28 July 2015 on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement,* 2015, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015D1302 (Accessed 21 Sep 2021).

makes sense: the eHealth Network bringing together the Member States' national health authorities on the political level, with technical support from a funded project ("Joint Action") convening the subject matter experts from the national eHealth competence centres. In the following years, the eHealth Network defined issues to collaborate on, but it took time for a critical mass of national governments to reach a consensus that more European coordination was needed.

A first turning point may have been the December 2017 Council Conclusions which invited Member States and the European Commission to work together "with the aim of achieving interoperable and user-friendly health information systems which allow connectivity of personal health devices and better interaction and information exchange between health and care providers and patients."[20] This invitation and collaboration led, in February 2019, to the publication of the EHRxF, formally as a European Commission Recommendation (C(2019)800). For the first time, and with the support of the Member States, the Commission recommended specific standards for the following health information domains:

(i)   Patient Summaries
(ii)   ePrescriptions/eDispensations
(iii)   Laboratory reports
(iv)   Medical images and reports
(v)   Hospital discharge reports

The recommendation referred to HL7 and DICOM specifications, and IHE profiles, and expressed interest for future work in HL7 FHIR among other specifications. MedTech Europe and COCIR have both expressed support for the European Electronic Health Record Exchange Format and called on further development, which is now being advanced in the X-eHealth project.[21]

In fact, the project of the European Health Data Space prioritises interoperability of health data systems. The European Commission and the Member States' efforts seek to advance "FAIR" data principles which stipulate that data should be: Findable, Accessible, Interoperable, and Reusable.[22] Several Member States have already made interoperability and adherence to international data standards a component in their processes for reimbursement of digital health applications, such as the DiGA fast track process in Germany and the

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[20] *Document 14078/17* (2017), Employment, Social Policy, Health and Consumer Affairs Council meeting, Draft Council conclusions on Health in the Digital Society.

[21] MedTech Europe (July 2019), *MedTech industry calls on all stakeholders to support digital health interoperability standards specified by the European Commission.* https://www.medtecheurope.org/news-and-events/press/medtech-industry-calls-on-all-stakeholders-to-support-digital-health-interoperability-standards-specified-by-the-european-commission/ (Accessed 21 Sep 2021); MedTech Europe (May 2020), *MedTech Europe Statement on the European Strategy for Data.* https://www.medtecheurope.org/news-and-events/news/medtech-europe-statement-on-the-european-strategy-for-data/ (Accessed 21 Sep 2021); COCIR Press Release (February 2019), "European Commission's adoption of the recommendation on a European EHR exchange format is welcome", https://www.cocir.org/media-centre/press-releases/article/european-commission-s-adoption-of-the-recommendation-on-a-european-ehr-exchange-format-is-welcome.html (Accessed 21 Sep 2021); COCIR Position Paper (May 2020), "COCIR input on the European Strategy for Data", https://www.cocir.org/fileadmin/Position_Papers_2020/COCIR_input_European_Strategy_for_Data.pdf (Accessed 21 Sep 2021).

[22] FAIR data principles are cited in the February 2020 European Data strategy (COM(2020) 66 final) and the Data Governance Act (COM(2020) 767 final), and will be further specified in the forthcoming European Health Data Space legislation expected in early 2022.

mHealth Belgium platform. Achieving interoperability is essential for the success of the European Health Data Space initiative.[23]

Looking at the international context, it is instructive to see that the United States federal government has also taken a more active role in advancing interoperability by requiring specific standards to improve patient access, foster portability, and promote safety and transparency. Empowered by the 2016 21st Century Cures Act, the Office of the National Coordinator for Health Information Technology (ONC) has enacted several rules that address information blocking and calls on medical providers and device developers to promote patient data access through the adoption of a common set of data elements and Application Programming Interfaces (APIs). As part of this work, ONC requires the implementation of HL7 FHIR, related implementation guides and associated standards as a condition for health IT certification in 2022.[24]

Additionally, the Global Digital Health Partnership that works to advance digital health and consists of around 30 countries, including five EU members and an observer status for the WHO, published its white paper *Advancing Interoperability Together Globally* in July 2020. This white paper documents the members' embrace of international specifications including IHE and HL7: of 22 countries surveyed, 19 used at least HL7 version 2, and 17 employed IHE profiles.[25]

These are encouraging signs of convergence around key international standards.

3. Standards, Specifications by Domain and Care Provision

Having established the current state of play on digital health interoperability, this section offers a detailed look at specific healthcare domains and the state of standards development in each of these domains. We will look at (1) personal health devices, including wearables, which help people manage their health and chronic conditions; (2) cardiac implanted devices that enable remote monitoring of patients with heart conditions; (3) imaging devices in hospitals which, as noted earlier, may have started the need for interoperable data transfers; and (4) the world of medical laboratories that deliver critical health information from in vitro diagnostic devices. Through this analysis we aim to provide a detailed overview of the standards present in these domains and how these standards interact, showcasing current changes and opportunities for improvement.

Personal Health Devices

The domain of personal health devices (PHDs) is broad, and there are many definitions for PHDs. We define PHDs as health devices that primarily relate to an individual user for an extended period, as opposed to

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[23] The German government's conditions for reimbursement are found in the "Guide for Manufacturers, Service Providers and Users", https://www.bfarm.de/SharedDocs/Downloads/EN/MedicalDevices/DiGA_Guide.pdf (Accessed 21 Sep 2021); Information on mHealth Belgium and its interoperability specs can be found at https://mhealthbelgium.be/validation-pyramid (Accessed 21 Sep 2021).

[24] EHR Intelligence (March 2020), *ONC Interoperability Rule to Standardize APIs via FHIR Release* 4.https://ehrintelligence.com/news/onc-interoperability-rule-to-standardize-apis-via-fhir-release-4 (Accessed 21 Sep 2021).

[25] Global Digital Health Partnership, *Advancing Interoperability Together Globally*, Table 3, p. 49, https://www.healthit.gov/sites/default/files/page/2021-01/GDHP-Advancing%20Interoperability%20Together%20Globally.pdf. (Accessed 21 Sep 2021).

devices that caregivers dynamically allocate to patients. The intended use setting of PHDs is thus predominantly outside hospitals. People may use PHDs in a non-clinical context, such as fitness or curiosity; or in a clinical one, such as managing a chronic condition. As such, they include both medical devices and consumer/lifestyle devices without intended use claims that would make them a medical device in a regulatory sense. Typical examples are a weight scale, blood pressure meter, thermometer, and glucose meter devices, all designed for personal use, as illustrated by the "home/on the move" scale in Figure 4.[26]

Figure 4: The Patient Monitoring Continuum
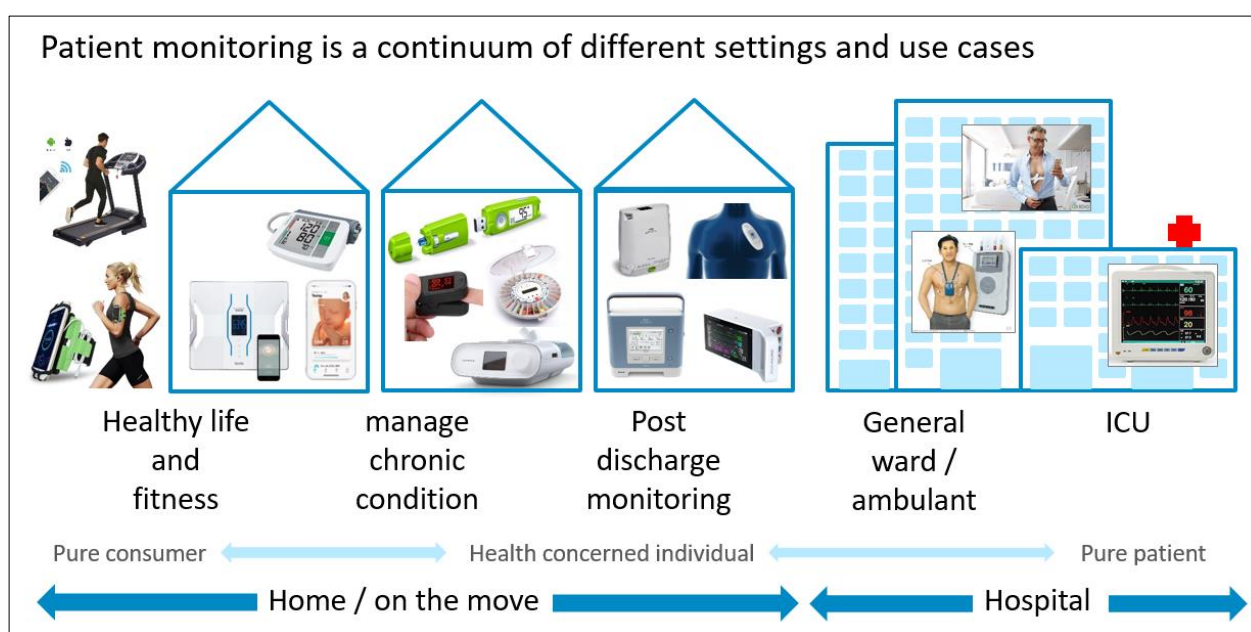
Regardless of the context, PHDs may need interoperability to communicate captured vital signs or device status data, to give therapeutic guidance (such as targeted instruction), for tele-meetings, and/or for device control. As generic ICT means can support therapeutic guidance and tele-meetings, we will focus on the collection, transmission, and exchange of data, where capturing data can comprise vital signs monitoring, reporting therapy compliance, capturing patient-reported outcomes, and more. This paper will not include the remote control of medical devices as this is a more complex use case that creates regulatory challenges and is therefore rare.

As Figure 4 illustrates, vital signs monitoring devices feature in many different contexts of use. On one end of the spectrum, there are purely consumer-oriented devices and applications, such as those supporting healthy lifestyle and fitness by measuring parameters. On the other end, patient monitors support critical care in a clinical setting. PHDs span the *home / on the move* part of the scale.

Across all uses, there are many similarities regarding the nature of data and interoperability needs, with quite comparable sorts of data being moved into systems that support their collection, aggregation, and analysis. Despite this similarity in data input, the needs and preferences of consumers differ substantially from those

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[26] Figure 4 reproduced with kind permission of one of MedTech Europe's member companies.

of professional caregivers. This is partially because medical devices must meet regulations. Clinical applications are more demanding than consumer applications in many respects, while consumers weigh cost, robustness, and functionality differently than healthcare organisations do. Therefore, requirements for the comprehensiveness and semantic interpretability of data, processing capacity, safety, and data integrity increase in complexity when moving from catering to consumers to catering to healthcare professionals. Such differences have implications for many aspects of standards and, as a result, a variety of standards exist to cover the needs across the scale. There is significant coherence in the structural and semantics layers across the continuum, while the clinical side simply has richer, more complex data models. The differences are most prominent in the *foundational* layer (see Figure 2 on page 9), where technology innovations keep driving the development of new standards most dynamically.

This complexity explains much of the current interoperability standards landscape for PHDs:
- For the structural and semantics layers, the IEEE 11073 series is the leading set of base standards. Originally developed for in-hospital patient monitors – called PoC devices in these standardisation circles – the series expanded into a derived set of specifications for PHDs.
- HL7 standards complement the IEEE 11073 series, mainly for episodes of care reporting from central monitoring systems that collect vital signs for many outpatients into EHRs (to contribute to comprehensive longitudinal patient records), using HL7 V2, V3 and CDA based families of standards. This is currently also evolving into the HL7 FHIR family of standards.
- For the foundational layer, several standards are in use that are subject to ongoing evolution:
    - Consumers prefer Bluetooth-based communication to a phone or tablet and, if needed, connection with a cloud service. Bluetooth defines dedicated profiles for measurement devices to cover the structural and semantics layers in a way that low footprint devices can handle, while supporting easy, high-fidelity transcoding to IEEE 11073.
    - Wi-Fi dominates in hospitals, but Bluetooth is gaining ground. This is likely to evolve into 5G-based direct-to-cloud solutions.
- To place base standards in context, Continua guidelines govern the out-of-hospital needs, referring to IHE profiles for communication to EHRs, and IHE profiles support the intra- and inter-hospital needs. All Continua standards development work moved into IHE in 2019-2020. IHE has PoC devices and PHDs programs in the Devices domain (a similar structure to IEEE 11073).

In addition to monitoring, these standards cover adjacent needs such as patient-reported outcomes and means to manage functional aspects, including time stamping of data (essential but complex when users move between time zones) as well as authenticity, security, and privacy concerns.

The recent move of the Continua work into IHE is a welcome simplification in the complex standards-setting landscape improving transparency. The market has not yet taken up Continua at scale for various reasons, including perceived over-design and complexity, and being too far ahead of the real demand (absent large-scale remote monitoring deployments). Nevertheless, the Continua Interoperability Guidelines continue to evolve:

- A recent extension is a FHIR-based alternative for the original way to upload data from the gateway to the health service (called Observation Upload).
- Work is in progress in IEEE, Bluetooth SIG, IHE and HL7 to simplify the IEEE 11073 PHD data models further without real loss of generality (*Unified Simple Device Information Model*) and supporting its communication via Bluetooth. This will provide continuity by connecting successfully to the leading existing standards while eliminating a number of hurdles. In addition to Bluetooth, a suitable 5G profile will be able to carry the data directly into the cloud. This is the most significant development at present in the standards space for PHDs.[27]
- Work is in process to define a direct-to-cloud profile for the somewhat longer future.

Following the increasing trend towards patient empowerment and self-management of chronic conditions, the world of PHDs is set to gain more prominence.

Cardiac Implantable Devices

The prevalence of cardiac implantable devices (CIEDs) with remote monitoring capabilities continues to grow, resulting in increased volume and complexity of biomedical data. Data coming from CIEDs can provide diagnostic information for timely intervention and maintenance of implanted devices, improving the quality of care. Current remote monitoring procedures do not utilise device diagnostics to their full potential due to the lack of interoperability and data integration among proprietary systems and electronic medical record platforms. At the same time, the development of a technical framework that standardises the data and improves interoperability shows promise for improving remote monitoring while preserving the proprietary features of the devices.

In May 2019, the American Heart Rhythm Society published a White Paper summarising the current state of play on interoperability of medical devices, calling for more data standardisation and interoperability to build technologies that can support easier and better interpretation of implantable device data by patients and providers.[28] Indeed, remote monitoring of CIEDs includes proprietary data formats from multiple device manufacturers, creating challenges for data integration and interoperability. In response to this issue, a collaboration between Integrating the Healthcare Enterprise (IHE) and the Heart Rhythm Society resulted in the development of a technical framework for CIED data integration into diverse platforms.

The development of this framework has been an ongoing collaboration of clinical research scientists and industry biomedical engineers to develop an IEEE data standard to allow structured data to flow into the EHR environment with consistency between industry vendors. These stakeholders developed the Implantable Device Cardiac Observation (IDCO) profile, a standard for device data incorporating IEEE 11073-10103 nomenclature, HL7 messaging, and a technical framework. The IDCO profile addresses the need for standardised observations that can be seamlessly integrated into various electronic platforms from all device vendors without human intervention. One goal of the IEEE nomenclature and IDCO profile is to allow

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[27] Bluetooth, *Specifications*, https://www.bluetooth.com/specifications/ (Accessed 21 Sep 2021).

[28] Slotwiner, D. J. et al. (May 2019), "*HRS White Paper on interoperability of data from cardiac implantable electronic devices (CIEDs)*", Heart Rhythm, 16:9. https://www.heartrhythmjournal.com/article/S1547-5271(19)30433-3/fulltext (Accessed 21 Sep 2021).

[28] Heart Rhythm Society (March 2019), *RE: RFI Response: Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care,* (Accessed 21 Sep 2021).

clinicians to review and manage their CIED patient data on a single EHR or remote monitoring data management platform. Indeed, over the past several years, research using the IDCO profile has demonstrated the potential for integrating data from at least one device manufacturer.[29]

Imaging

The domain of medical imaging is about the creation, processing, and management of images that support clinicians in effective decision-making during their diagnostic, therapeutic and interventional processes. Traditionally, medical images are depictions of the anatomy or physiology (the function of some organ or tissue) of a human body. In general, these medical images are created noninvasively, meaning that no instrument is introduced into the body, or the insertion is without physical damage (e.g., when a probe is inserted into the oesophagus). There are many ways of creating medical images, such as by x-ray radiography, ultrasound, and magnetic resonance. Nowadays, medical imaging also includes: a) images that depict the outside of the human body, for example of the skin (for dermatology); b) microscopic tissue images as used in pathology, which requires some invasiveness; and c) measurement and recording procedures, like the electrocardiogram (ECG).

Commonly, professionals like radiologists and cardiologists perform medical imaging in a professional setting like a hospital or a medical institution. This is because most medical imaging systems are large, quite expensive, and require very specific knowledge and capabilities to be used safely and effectively. This secures the quality of the images and recordings and makes them fit for use, supporting sound diagnostic decision-making and the ability to perform an interventional procedure safely and correctly.

An example of a typical scheduled workflow in medical imaging is as follows:
1. A person with complaints, for instance in the knee, visits a hospital to see a physician and is identified (or registered) in the hospital information system (HIS). After an examination, the physician sees the need to perform a medical imaging procedure as the physical exam indicates a tendon tear, and more information is needed for diagnosis.
2. The physician orders a knee imaging procedure – in this case a knee MRI – through the HIS. The order information is forwarded to the applicable planning system (in this case a radiology information system – RIS), where the procedure is planned based on patient and equipment availability.
3. The acquisition modality – the system that will generate the medical images, in this case an MRI scanner – retrieves information on what kind of procedure to do and for whom from the RIS. In this case, it is an MRI knee scan of the applicable knee (what) of the person with complaints (for whom).
4. The scan is performed by a technologist. The resulting images are sent to the PACS, together with metadata including what procedure was performed, on which patient and by whom.
5. On a medical workstation, a radiologist interprets the images and associated metadata in context of the ordered procedure and may decide to perform specific (computer-aided) analysis on the images, adding new information to the scan in the PACS. Eventually, a radiologist creates a diagnostic report on what is concluded from the images and associated analyses; this report is stored in the HIS.

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[29] The (US) Heart Rhythm Society commented on these learnings in a March 2019 letter to the US government, see https://www.hrsonline.org/documents/rfi-interoperability-hrs-comments-final/download (Accessed 21 Sep 2021).

6. The referring physician will have a look at the report, and will decide on treatment (e.g., do nothing, operate, or physiotherapy, having also possibly looked at the imaging information in the PACS.) Finally, the person with complaints is informed about the decision by the referring physician.

Naturally, there are many different workflows in real clinical settings, such as in emergency cases, where the patient demographics may not be known, or in encounter-based imaging, where dermatologists make pictures by themselves (no ordering, no planning, etc), or for tracking therapy effects. Many of these workflows are covered by additional IHE Radiology Profiles. The HIT systems involved will, however, be similar: HISs, RISs, acquisition modalities, PACSs, and clinical processing and/or reporting workstations.

The landscape of interoperability standards for healthcare imaging is comprised of the following:[30]

- **DICOM** is the standard for the communication and management of medical imaging information and related data. DICOM is most used for storing and transmitting medical images enabling the integration of medical imaging devices such as scanners, servers, workstations, printers, network hardware, and PACSs from multiple manufacturers. DICOM has been globally adopted by hospitals and is making inroads into smaller applications like dentists' and doctors' offices.
- **HL7** is a set of international standards for the transfer of clinical and administrative data. In the scope of medical imaging, HL7 is used for patient registration, ordering and scheduling of imaging procedures and reporting. HL7 is present worldwide in practically all hospitals and healthcare institutions for enterprise and cross-enterprise integration of HIT systems.
- **IHE** plays an important role in medical imaging, as it defines integration profiles for typical use cases/workflows, in which the coordination of the base standards DICOM and HL7 is specified. In the scope of medical imaging, the relevant IHE domains are Radiology and Cardiology, on top of IT Infrastructure (which supplies generic infrastructure for sharing healthcare information). IHE is well-established in hospitals and healthcare institutions.

In the workflow outlined above, DICOM specifies the information exchange formats and protocols between systems in steps 3-6, while HL7 does so in steps 1-2 and 5-6. Exact orchestration of the systems involved in the workflow is described in IHE integration profiles; in this case, in the IHE Scheduled Workflow Profile.

DICOM and HL7 address the foundational, structural, and semantic levels of interoperability as described in the section "Levels of interoperability and types of interoperability standards". To this end, they reference other standards like internet communication protocols (TCP/IP, HTTPS) on the foundational level, JPEG and MPEG at the structural level, and UCUM, SNOMED CT and LOINC at the semantic level. Together, they provide a healthcare imaging integration of standards where IHE adds typical interaction patterns on top.

While the standards are well accepted in the field, the deployment of these standards in practice is not comprehensive in scope. It is not necessary to implement the entire DICOM or HL7 standard in every healthcare imaging integration. For instance, the MRI scanner in the workflow above applies only the DICOM

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[30] ISO 21860:2020 (2020) "Health Informatics — Reference Standards Portfolio (RSP) — Clinical imaging" lists and describes global standards for clinical imaging in more detail.

parts pertaining to MRI and workflow management. Within those parts, options will be selected based on features available on the particular MRI scanner, which is often attributed to, and limited by, clinical demand and compatibility with peer systems in the marketplace.

Regulations by public authorities increasingly mention healthcare imaging standards. Yet a similar limitation to adoption in the field is observed: hospitals and healthcare institutions are only guided regarding specific parts of these standards. Obligatory deployment of, or conformance to, (specific aspects of) the standards is quite rare, even though that would improve interoperability and the use of the healthcare imaging standards, including more advanced aspects.

Broad deployment of healthcare imaging standards has led to the ability to mix and match systems of different vendors reasonably easily, with basic interoperability functionality being supported quite well. However, issues can arise in areas beyond basic functionality. For instance, there may be limitations in case metadata containing patient names cannot be transferred or interpreted due to the mismatch in support of applied character sets. Additionally, not taking up new developments in the standard in products or regulations, and therefore deployments, limits potential. For example, multi-energy CT DICOM modules, which address state-of-the-art spectral CT acquisitions are not yet adopted widely. Regulations can boost the uptake of more advanced features, demonstrated by the X-ray dose registration in the United States. Once this was mandated, broad deployment went quickly, as the standard was already prepared and only required hospitals and healthcare institutions to address this aspect asking for implementation by the vendors.

Medical laboratories

A substantial share of patient data in the EHR is created in the medical laboratory,[31] which is one of the key sources of medical data. Interoperability in the laboratory domain is key in allowing data to flow seamlessly across the healthcare ecosystem. The objectives are inter alia to improve patient care, reduce redundant laboratory testing, enable automated clinical decision support, aid in alerting about infectious disease outbreaks, and support national scale infectious disease surveillance. This situation can be easily explained in context of the three "tiers" mentioned earlier (macro, meso, and micro-tier – see Figure 3), where the medical biology laboratory pertains to the micro-tier.

Interactions between instruments or systems in the Customer Laboratory can be represented through the simplified picture in **Error! Reference source not found.**[32] below. It shows a schematic view of the four main data flows and involved systems and may be seen as a lab centric simplified version of **Error! Reference source not found.**.

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[31] Ngo, A., Gandhi, P. and Miller, W. G. (2017), "Frequency that Laboratory Tests Influence Medical Decisions", *The Journal of Applied Laboratory Medicine*, 1:4, p.p. 410–414.
[32] Figure 5 is reproduced with kind permission of one of MedTech Europe's member companies.

Figure 5: Software interoperability with laboratory related standards
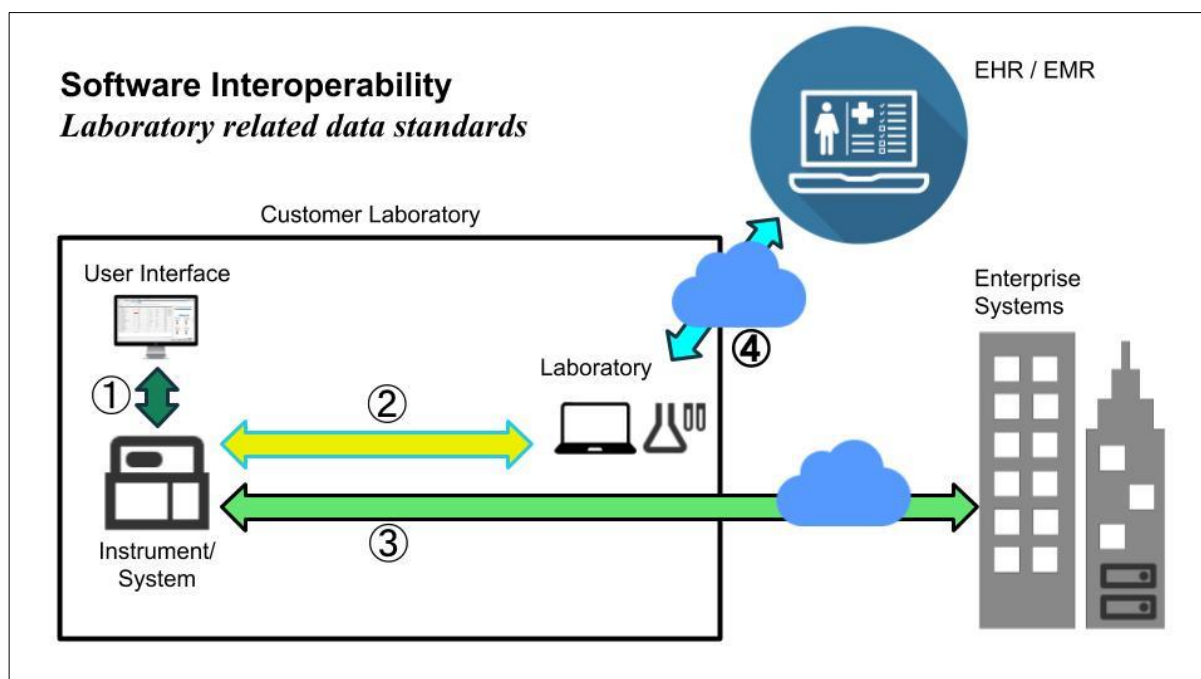
1. The dark green arrow shows the data flow to/from the user and the user interface. The yellow arrow shows data flow between the instruments/systems and the laboratory.
2. The light green arrow shows the data flow between instruments/systems and the Enterprise systems (for example data used by service, analytics, statistics, etc. but also Calibration data and Software Updates).
3. The light blue arrow includes governance, policy, social, legal, and organisational considerations to facilitate the secure, seamless (keyword "plug and play") and timely use of data within and between organisations[33].

In the US laboratory domain, under a public-private partnership, two public workshops were organized on "Promoting Semantic Interoperability of Laboratory Data" in 2015 [34] and 2016. [35] Those preceded the formation under the Medical Device Innovation Consortium of the SHIELD[36] project (Systemic Harmonization and Interoperability Enhancement for Laboratory Data) with representations from US governmental agencies, IVD manufacturers, EHR vendors, laboratories, SDOs, and others. SHIELD aims "to improve the quality,

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[33] LiberEurope, *Implementing FAIR Data Principles: The Role of Libraries*, https://libereurope.eu/wp-content/uploads/2017/12/LIBER-FAIR-Data.pdf.

[34] US Food & Drug Administration (September 2015), *Public Workshop FDA/CDC/NLM Workshop on Promoting Semantic Interoperability of Laboratory Data*. https://wayback.archive-it.org/7993/20170722213550/https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm453897.htm (Accessed 21 Sep 2021).

[35] US Food & Drug Administration (November 2016), *Public Workshop FDA/CDC/NLM Workshop on Promoting Semantic Interoperability of Laboratory Data.*, https://wayback.archive-it.org/7993/20170404181837/https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm523316.htm (Accessed 21 Sep 2021).

[36] Medical Device Innovation Consortium, *Systemic Harmonization and Interoperability Enhancement for Lab Data (SHIELD)*, https://mdic.org/program/systemic-harmonization-and-interoperability-enhancement-for-lab-data-shield/#toggle-id-2 (Accessed 21 Sep 2021).

utility and portability of electronic laboratory data (i.e., *in vitro* diagnostic data) through the harmonized implementation of semantic data standards that have been appropriately qualified by a sole authoritative source."[37] In line with the SHIELD activities and to enable a consistent implementation of LOINC for *in vitro* diagnostic tests in the USA, the US-FDA published a dedicated guidance on using the LOINC standard.[38]

Standards supporting this lab data liquidity are presented below according to three of the four dimensions of Interoperability as defined earlier in this paper. We do not consider here the "Foundational level" as it is not HIT specific.

- At the Organisational level, intra lab workflow will be mainly based on the IHE profiles "Lab Analytic Workflow" (LAW) for lab information system (LIS) to device communications. It may also employ "Lab technical workflow" (LTW) when a middleware sits between the LIS and the devices. When seen from the LIS to the different elements of the hospital information system, we may find different IHE or FHIR profiles. Specific IHE profiles also exist for lab-to-lab communications and digital pathology image acquisition. The LAW profile standardizes the message definitions and workflow definitions necessary to achieve plug-and-play connectivity among instruments, middleware, and LISs in the laboratory. The profile's message definitions are based on the messaging standard developed by HL7.

- LAW was developed in a collaboration between the IICC and the IHE pathology and laboratory medicine (PALM). The LAW profile also provides the basis for the Clinical Laboratory Standard Institute (aka CLSI[39]) AUTO16[40] "Next-Generation *In Vitro Diagnostic* Instrument Interface". CLSI Auto 16 / IHE LAW is currently being implemented by some major IVD companies and can help the lab & IVD manufacturers improve interoperability, reduce connectivity installation cost and time, and further improve integrity of patient data.

- At the Structural (aka syntax) level, HL7 is the power horse of intra and inter lab communications, replacing pre-existing communication standards, as well as from lab to other information systems. As described above, HL7 syntax is the basis for the 'organisational' workflows. HL7 FHIR is now foreseen (not inside the lab, but from lab to other information systems) as the next interoperability standard intended to facilitate the exchange of healthcare information between healthcare providers, patients, caregivers, payers, researchers, and anyone else involved in the healthcare ecosystem. It consists of 2 main parts – a content model in the form of 'resources', and a specification for the exchange of these resources in the form of real-time RESTful interfaces as well as messaging and Documents.

- At the Semantic level, the list of standards is driven by the data elements used or generated in the laboratory. Those data elements are the IVD assays (tests or observations) being ordered and the ones being implemented and reported; the IVD results obtained from the assay; and the biological

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[37] Medical Device Innovation Consortium, *Systemic Harmonization and Interoperability Enhancement.* Ibid.
[38] US Food & Drug Administration (June 2018), *Guidance document, Logical Observation Identifiers Names and Codes for In Vitro Diagnostic Tests.*, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/logical-observation-identifiers-names-and-codes-vitro-diagnostic-tests (Accessed 21 Sep 2021).
[39] CLSI, *Global Laboratory Standards for a Healthier World*, https://clsi.org/ (Accessed 21 Sep 2021).
[40] CLSI (April 2019), *AUTO16 Next-Generation In Vitro Diagnostic Instrument Interface*, 1st Edition https://clsi.org/standards/products/automation-and-informatics/documents/auto16/ (Accessed 21 Sep 2021).

specimens from which results are drawn. A unique identification of the device used is a potential future element to consider.

- The main standard used worldwide to describe IVD assays is LOINC. It should be noted that LOINC is not the only available standard. The UK uses SNOMED CT (formerly Read Codes), Nordic countries use NPU[41]; and Japan uses JLAC10.[42]

- It is generally acknowledged that for IVD assay results, SNOMED CT should be used for qualitative data, whereas UCUM should be used to describe the unit associated to quantitative results (i.e., numerical values).

- While using SNOMED CT requires a license, one exception lies in the Global Patient Set (GPS) that is free for use internationally. The GPS is "a managed collection of existing SNOMED CT reference sets released by SNOMED International" and "is comprised of unique identifiers, fully specified names (FSN), preferred terms in international English, and active/inactive status flags."[43] The intention of the GPS is to support the encoding of the international patient summary report mentioned in section "The Policy Environment".

4. Closing

The world of interoperability standards and specifications is moving fast. As a result, this White Paper can only provide a snapshot. The SDO landscape will continue to evolve, and so will the policy environment in Europe and the Member States, particularly with the European Health Data Space triggering more legislative and administrative actions in the coming years. Member States and regions are accelerating mandating or incentivise adherence to interoperability specifications. Additionally, the COVID-19 pandemic has intensified the collaboration between the European Commission and Member States on interoperability issues, notably on the the European Federation Gateway Service for contact tracing apps and the EU Digital COVID Certificate. This current momentum may influence deployment of interoperability in the European Health Data Space going forward.

MedTech Europe and COCIR will continue to observe, accompany, and participate in these developments, and may update this White Paper as appropriate. We hope this will become a helpful resource for industry, policymakers, providers, and stakeholders, and will contribute to ensuring adherence to international standards and specifications.

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[41] *NNPU Terminology: An IUPAC-IFCC success in Health Care*, June 2019, https://iupac.org/wp-content/uploads/2020/03/NPUterminologi2019_Leaflet.pdf (Accessed 21 Sep 2021).
[42] Japanese Society of Laboratory Medicine, *Laboratory test item classification code,* https://www.jslm.org/committees/code/ (Accessed 21 Sep 2021).
[43] SNOMED International, *Global Patient Set*, https://www.snomed.org/snomed-international/learn-more/global-patient-set (Accessed 21 Sep 2021).

5. List of acronyms

CDA	Clinical Document Architecture
CDGs	Continua Design Guidelines
CIED	Cardiac Implantable Device
CLSI	Clinical & Laboratory Standards Institute, https://clsi.org/
DICOM	Digital Imaging and Communications in Medicine, www.dicomstandard.org
EHRxF	European Electronic Health Record Exchange Format (EC recommendation)
EHR	Electronic Health Record
EPSOS	European Patient Smart Open Services
FAIR	Findable, Accessible, Interoperable and Reusable
FHIR	Fast Healthcare Interoperable Resources, from HL7 www.hl7.org/fhir/
FSN	Fully Specified Names
GPS	Global Patient Set
HIMSS	Health Information and Management Systems Society, www.himss.org
HIT	Healthcare IT
HL7	Health Level Seven, www.hl7.org
IDCO	Implantable Device Cardiac Observation
IEC	International Electrotechnical Commission
IICC	The IVD Industry Connectivity Consortium, https://ivdconnectivity.org/
ICT	Information & Communication Technology
ICU	Intensive Care Unit
IEEE	Institute of Electrical and Electronics Engineers, www.ieee.org
IHE	Integrating the Healthcare Enterprise, www.ihe.net
ISO	International Organization for Standardization
ITU	International Telecommunication Union
HIS	Hospital information system
IVD	In vitro diagnostic
LAW	Laboratory Analytical Workflow, IHE profile
LIS	Laboratory information system
LTW	Laboratory Testing Workflow, IHE profile
LOINC	Logical Observation Identifiers Names and Codes, https://loinc.org/
MITA	Medical Imaging & Technology Alliance
NEMA	National Electrical Manufacturers Association (US)
ONC	Office of the National Coordinator for Health Information Technology
PACS	Picture archive and communications system
PALM	Pathology and Laboratory Medicine, domain of IHE
PHD	Personal health device
PoC	Point of care
REST	Representational State Transfer
RIS	Radiology Information System
SDO	Standards Developing Organisations
SNOMED	"Systematized Nomenclature of Medicine", www.snomed.org
UCUM	Unified Code for Units of Measure

Bluetooth, *Specifications*, https://www.bluetooth.com/specifications/. For Mesh Interoperability: https://www.bluetooth.com/blog/models-for-bluetoothmesh-interoperability/. For Health Device Profile: https://www.bluetooth.com/specifications/assigned-numbers/health-device-profile/ (Accessed 21 Sep 2021).

CLSI (April 2019), *AUTO16 Next-Generation In Vitro Diagnostic Instrument Interface*, 1st Edition https://clsi.org/standards/products/automation-and-informatics/documents/auto16/ (Accessed 21 Sep 2021).

CLSI, *Global Laboratory Standards for a Healthier World*, https://clsi.org/ (Accessed 21 Sep 2021).

COCIR Press Release (February 2019), *European Commission's adoption of the recommendation on a European EHR exchange format is welcome,* https://www.cocir.org/media-centre/press-releases/article/european-commission-s-adoption-of-the-recommendation-on-a-european-ehr-exchange-format-is-welcome.html (Accessed 21 Sep 2021).

COCIR Position Paper (May 2020), *COCIR input on the European Strategy for Data*, https://www.cocir.org/fileadmin/Position_Papers_2020/COCIR_input_European_Strategy_for_Data.pdf (Accessed 21 Sep 2021).

Decision (EU) 2015/1302 on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement, 2015, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015D1302 (Accessed 21 Sep 2021).

Confluence, *Project Gemini: A Joint Venture of HL7 and IHE to Advance Use of FHIR for Interoperability*, https://confluence.hl7.org/display/GP/Project+Gemini (Accessed 21 Sep 2021).

Directive (EU) 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, art 56, 2011, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0024&from=EN (Accessed 21 Sep 2021).

Document (EU) 14078/17, Employment, Social Policy, Health and Consumer Affairs Council meeting of 8 December 2017 on *Draft Council conclusions on Health in the Digital Society - making progress in data-driven innovation in the field of health* – Adoption (2017], http://data.consilium.europa.eu/doc/document/ST-14078-2017-INIT/en/pdf (Accessed 21 Sep 2021).

EHR Intelligence (March 2020), *ONC Interoperability Rule to Standardize APIs via FHIR Release* 4, https://ehrintelligence.com/news/onc-interoperability-rule-to-standardize-apis-via-fhir-release-4 (Accessed 21 Sep 2021).

European Commission, *ANTILOPE project* (2013-2015), https://cordis.europa.eu/project/id/325077 (Accessed 21 Sep 2021).

European Commission, *epSOS project*, 2008-2014, https://cordis.europa.eu/project/id/224991 (Accessed 21 Sep 2021).

European Commission, *EURO-CASE project*, 2016-2018, https://cordis.europa.eu/project/id/727028 (Accessed 21 Sep 2021).

European Commission, *European Data Strategy*, https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-data-strategy_en (Accessed 21 Sep 2021).

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About

MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries. Our focus is to open markets for COCIR members in Europe and beyond. We provide a wide range of services on regulatory, technical, market intelligence, environmental, standardisation, international and legal affairs. COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (www.globalditta.org). For more information, visit www.cocir.org or contact Danny van Roijen, Digital Health Director at vanroijen@cocir.org.