

Why is medical interoperability important, and how is patient data protected?



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Key Points

- Medical interoperability is the ability of different computerised devices (e.g. personal care wearables, imaging devices, cardiac-implanted devices) to connect and exchange information seamlessly
- Facilitates remote patient monitoring, optimises healthcare practitioners' access to vital information, improves the quality of patient care, makes medical records easier to locate and share with other healthcare providers, and improves organisational efficiency
- Regulatory requirements and a lack of standardisation make interoperability challenging
- Medical interoperability is essential for digital healthcare adoption to succeed. However, the more interoperable healthcare systems are, the more vulnerable they are to cyber-attacks
- Studies show that telemedicine – facilitated by the interoperability of connected devices – results in improved clinical outcomes, better follow-up by health professionals, and an overall benefit for patients and health workers
- G7 nations have agreed to address interoperability challenges at a local, regional, and international level to collaborate on Open Standards and Interoperability

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The digital healthcare market is expanding at a rapid pace. It's being fueled by a need to reduce healthcare costs, manage a rising prevalence of chronic illnesses, and increase the accessibility to virtual care (e.g. telemedicine and remote patient monitoring) ^[1]. This has resulted in significant amounts of continuous data generation – how this patient data is accessed, managed, and protected is an ongoing concern. [Interoperability](#) refers to the essential ability of different computerised devices to connect and exchange information without restriction. In a healthcare context, medical interoperability is important as it ^{[2] [3]}:

1. Allows for the seamless transmission and communication of patient information and makes their records easier to locate
2. Increases productivity by optimising healthcare practitioners' access to vital information so they can spend more time taking care of patients
3. Reduces the need for paperwork, and mitigates physician administrative burnout, thus improving organisational efficiency and reducing costs
4. Improves the quality of patient care by providing information in real-time and improving decision making which results in better outcomes for the patient
5. Improves public health data by reducing the chance of disparity as interoperability is standardised across the healthcare system
6. Reduces the chance of errors by automating data entry processes, which results in better patient outcomes and improved reliability for healthcare institutions
7. Reduces exposure to cyber security threats by ensuring that data is shared safely and securely

While medical interoperability has many benefits, one of the biggest challenges is in how the data generated is regulated. Legal regulations and compliance requirements stipulated by the [UK General Data Protection Regulation](#) (UK GDPR) can complicate the integration process. For example, 'vulnerable devices' such as IoT (internet of things) that share personal information across a network must be secured against cyber threats. At the same time, these devices often have to exchange information with third-party software (e.g. a hospital patient's health records), which can affect compliance.

Can different elements of the [health IT](#) (HIT) network be integrated seamlessly? What safeguards are put in place to enable information sharing without compromising security? What role does this play in

both the manufacturer's and healthcare system's [Governance, Risk-management, and Compliance](#) (GRC) strategy?

Seamless data transmission on Health IT networks

Medical interoperability not only has to support various interests (i.e. regulatory, manufacturing, healthcare), but it also has to support various levels of complexity. Firstly, the software and medical devices that use them need to be able to exchange sensitive data. Secondly, technical interfaces must be able to understand and process the data (sometimes across operating systems which may not be compatible). In addition, a legal and organisational framework must be enabled to allow different systems to collaborate ^[4].

Implementing successive levels of interoperability across the entire HIT network helps to provide the different support elements needed and enhance the GRC strategy by providing a high-level, big-picture view of compliance ^[5]. These levels are:

1. **Structural:** The foundational level that provides the basic standards necessary for one system or application to communicate with another. This level doesn't enable the data that is received to be interpreted but instead establishes the connections to facilitate secure exchanges between authorised partners
2. **Syntactic:** This level ensures that health data such as x-rays, doctor's letters, or diagnoses are recorded in a format and with syntax that allows various software services to understand it. For example, [HL7® FHIR®](#) (Health Level 7 Fast Healthcare Interoperability Resources) defines about 140 common healthcare concepts and is an emerging standard for communicating healthcare data. Another widely used international standard, [Digital Imaging and Communications in Medicine](#) (DICOM), defines formats, workflow support and exchange mechanisms for medical images with the data and quality necessary for clinical use
3. **Semantic:** A shared set of terms to describe illnesses, symptoms, diagnoses etc., is vital to delivering the correct treatment. With more than 340,000 medical concepts in use across HIT networks, SNOMED CT ([standardised nomenclature of medicines clinician terms](#)) ensures that the terminology is common across different countries and specialists. These standards and the collaborative efforts to develop them also form the basis for using Machine Learning to further the automatic processing of data
4. **Organisational:** This relates to the GRC, social, legal, and organisational requirements that facilitate seamless data transmission between healthcare organisations,

manufacturing entities, and individuals. Establishing secure, efficient and effective cross-system processes and clarifying permissions is the ultimate goal of medical interoperability.

Implementing these different levels of medical interoperability will ultimately help to ensure that the entire HIT network – from device engineers and medical software developers to healthcare delivery organisations and medical industry regulators – can achieve a common goal: improve patient care and ensure that important information is transmitted efficiently and securely.

Medical interoperability and the Internet of Medical Things

Over the past few months, we at Ignitec have been looking at how the Internet of Medical Things (IoMT) has the potential to transform the healthcare industry ^[6]. Not only does this give patients more autonomy and agency over their healthcare practices, but it also enables healthcare practitioners to monitor, diagnose, and treat illnesses more efficiently. [Healthcare domains](#) where IoMT devices have the most significant impact include:

- Personal health devices, e.g. wearables, which help people manage their health and chronic conditions
- Cardiac-implanted devices that enable remote monitoring of patients with heart conditions
- Imaging devices in hospitals that support physicians in effective decision-making
- Medical laboratories that deliver critical health information from in vitro diagnostic devices

In a study conducted by Charité University Hospital in Berlin, they showed the advantages of having connected devices that record patient data that can transfer it across a cooperating network ^[7]:

- More than 1500 patients with chronic heart failure participated in the study for one year
- Participants received four easy-to-use IoMT devices: an electrocardiograph, a blood pressure monitor, a scale, and a tablet computer for self-assessment
- Data was recorded and sent automatically to the university clinic for evaluation
- Patients were advised on what to do (e.g. change medication or the dosage, or schedule a doctor's visit)
- Patients who received telemedical care spent fewer unplanned hospital days than those who did not

- The mortality rate of chronically ill patients who received telemedical care decreased

The COVID-19 pandemic highlighted the benefits of IoMT and telemedicine even further. The World Health Organisation conducted a study to give an overview of the telemedicine status in Europe and Asia ^[8]. They looked at data from over 20,000 studies across 53 countries and found improved clinical outcomes, better follow-up by health professionals, and an overall benefit for patients and health workers. At the same time, the study also found barriers related to users, technology, and infrastructure.

The WHO study highlighted another challenge that digital healthcare needs to overcome: if the data generated by a digital device is incompatible or not easily integrated with the system that needs to access it (e.g. a hospital's [electronic health records](#)), this potential becomes diluted. Medical interoperability could help to overcome these challenges.

Interoperability opportunities and challenges

Medical interoperability is a mixed bag of opportunities and challenges.

An opportunity for medical device engineers and software developers is to consider medical interoperability from the early stages of a device's design and development. This could improve the overall big-picture viability of their product. In addition, interoperable medical devices and software have a better competitive edge over those that aren't.

However, even though a device might be interoperable, that doesn't mean that the healthcare system using it is. An overall lack of standardisation creates an inconsistency in how healthcare systems receive, send, and manage information between them. For example, the electronic health record (EHR) system of one provider should be able to transfer patient data to another provider's system. Many healthcare providers use customised EHR systems making this process harder to convert to a shareable standard format.

Another interoperability challenge is that [big data equals big business](#). There is an organisational resistance to sharing information with other organisations – especially when they are in direct competition for the same customers: patients.

More importantly, there are the issues of security and consent. The more interoperable healthcare systems are, the more vulnerable they are to cyber-attacks. In addition, by building healthcare systems where information flows freely from one provider to the next, it's not always clear when consent is needed and the level to which it's required. This makes healthcare providers understandably hesitant to share information and more likely to err on the side of caution by not doing so.

That being said, this presents opportunities for all the entities involved to engage a trusted party to facilitate communication and verify that data requests are appropriate and secure. A [data management platform](#) designed for interoperability that leverages automation with human inspection to verify data requests and accuracy could be an ideal solution.

Digital healthcare transcends borders: Can interoperability be achieved internationally?

That medical interoperability is essential for digital healthcare adoption to succeed is undeniable. However, the implementation of standards across borders varies widely from one country to the next. Some countries have local protocols, and others might use a different standardisation system altogether.

For example, there are commonly used standards (e.g. SNOMED CT) that most HIT systems implement, but semantic interoperability doesn't need to use that specific standard. Other systems might use a different lexicon, such as the [Medical Dictionary for Regulatory Activities](#) (MedDRA), which obstructs interoperability with another system that doesn't. For example, abdominal spasm and incision site pain (MedDRA names) vs abdominal colic and postoperative pain (SNOMED CT names).

Efforts are being made to address these concerns at a country, continental, and international level. The [G7 Open standards and Interoperability](#) (final report published in Dec 2021) agreed to the following principles:

- Conformity to open and international standards whenever possible
- Standards should be largely free of charge
- Standards should be compatible with open-source development and permissive licensing
- Standards should support easy patient access and clinical safety
- These standards should refer to data, data exchange, security and user interfaces

The UK continues to demonstrate its commitment to the digital transformation of health and social care, as well as promoting innovation while prioritising patient care. [NHS Digital](#) provides an [interoperability toolkit](#) (ITK) and advises developers and innovators on which open standards to use to ensure data quality and facilitate adoption.

It remains to be seen whether medical interoperability – even if secured at a national level – will be possible internationally. Time will also tell whether integration to this extent will be possible without compromising patient privacy and data protection.

Are you a device engineer or software developer, and is medical interoperability part of your design process? Do you think interoperability is possible at a national and international level? Share your thoughts in the comments section below, and let's see if we can co-create solutions!

Comments

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