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Chapter 9: Standardization and interoperability of devices across healthcare ecosystems

9.1. Introduction

Interoperability plays a key role in the future of digital health. It allows seamless workflows by connecting patients, technologies and stakeholders into a unified healthcare ecosystem. Standardized data transactions allow millions of interconnected devices, applications, machines, people and stakeholders to reliably exchange and interpret health data, while preserving data privacy and uniqueness. Interoperability connects devices, applications, stakeholders and services to the healthcare ecosystem. It also refers to the seamless and reliable exchange of data between devices, applications, back-end integrations and big data infrastructures, while providing and preserving the unique data privacy of individual patients. A unique digital health ecosystem enables a unified data flow around the patient, where points of care, stakeholders and devices come together and securely connect, allowing data to flow to and from individual patients and their physical and digital health. Seamless workflows of connected devices allow stakeholders to increase healthcare system performance and transparency, while reducing costs, effort, errors, fraud and delays. Digital and data-driven patient engagement solutions connected to point of care, patient generated health data, social determinants and back-end infrastructure drive seamless and meaningful patient participation into a digital health ecosystem. From a digital health ecosystem perspective, relevant focus areas of medical device interoperability include remote and point-of-care diagnostic solutions, sensor-based and digital treatments delivered from wearables, implanted devices, connected pharmaceuticals, bio-responsive digital therapies, advanced telehealth solutions and patient-centered care connectivity during the perioperative period. A unique digital health ecosystem enables a unified data flow around the patient through connected point-of-care diagnostic devices, sensors, data analytics infrastructure and digital health solutions, while allowing secure access to

individual patient's unique digital health data from their back-end infrastructure and big data banks (Kumar & Silambarasan, 2019; Khan & Rehman, 2020; Ganaie & Kim, 2021).

There is a growing smorgasbord of sensors and devices from emerging technology companies. However, the lack of clear guidance and standards from the healthcare ecosystem is exposing patients and consumers to risks of development and validation of these devices. Significant gaps in nursing and physician education and limited research and evidence-based funding are inhibiting the incorporation of connected devices into practice. Devices are becoming less uni-functional like their forebears, e.g., ECG Holter monitor, digital thermometer, and hCG blood analyzer; and increasingly capable of multi-functionality, e.g. the smartphone, and wearable patches. Healthcare devices are becoming multifunction with embedded actuators rather than monofunctional tools that take measurements using passive transducers (Wang & Cai, 2020; Salem, 2021).

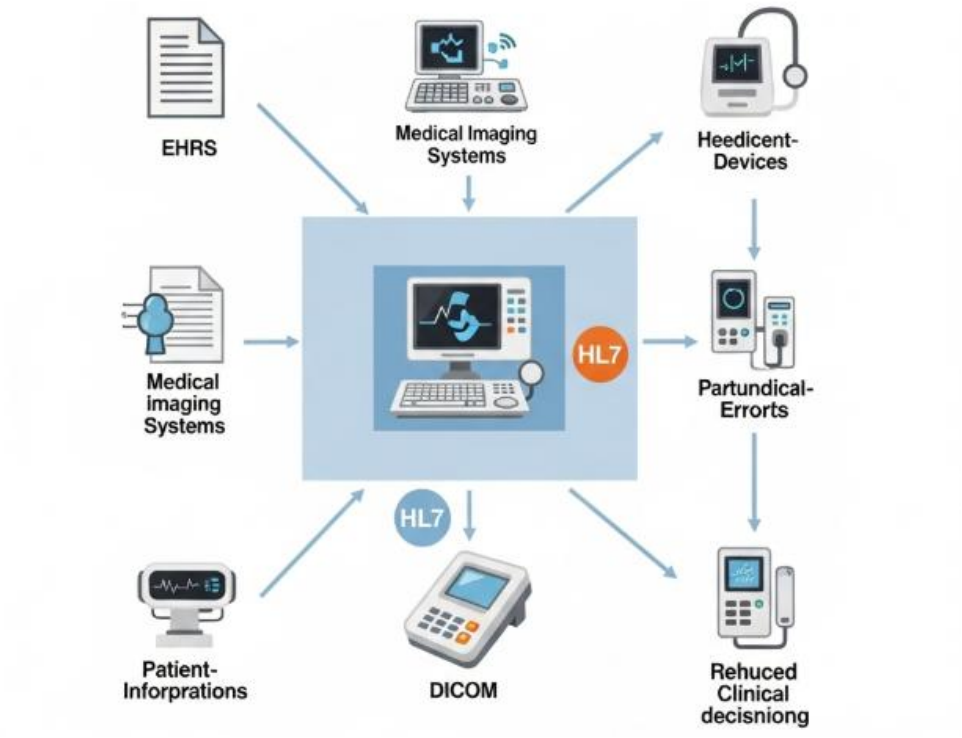

Fig 9.1: Standardization and Interoperability

9.2. Importance of Standardization

The ubiquitous adoption of information and communication technologies across healthcare ecosystems has brought a fundamental change, making healthcare more proactive, personalized, and convenient. There is a pressing need for the standardization of protocols and interfaces between devices, and between devices and product-centered applications. The pace at which new devices are produced and adopted far outstrips the pace of standardization. Industry efforts to push for some standards have been met with little support from the healthcare community. Followed in the long run only by those who can afford to add functionality without regard to costs, product-centered applications are becoming locked-in to particular device types, violating end-to-end functionality. It is most critical to address healthcare standards now, while we are forming a global networked ecosystem of connected devices.

The past decade has seen a rapid uptake of portable, wireless, and low-cost mobile health devices, such as wearables, smartphone-connected, and mobile phone embedded sensors. Heterogeneous and dispersed distributed healthcare ecosystems are emerging that provide radical new opportunities for improving both preventive and diagnostic medicine; as well as managing chronic diseases and enabling population health.

9.2.1. Benefits of Standardization

Historically, standardization has assumed a crucial role in various industries, becoming a common aspect in everyday life. Devices and services aligned with formalized specifications can work together more easily and independently from proprietary benchmarks and requirements, fostering a more extensive array of components, augmenting device features, providing integration, vendor independence and reducing costs. These advantages have been widely used in the telecommunications, computer, automotive and aeronautical domains. Standardization has also brought advantages in sectors in earlier stages of development and where strong economic interests have traditionally resisted any standard effort, like the banking and payment sector. These sectors increased their offered services after adopting international standardization processes, enhancing the interoperability of their devices. Horizontal overview, rather than the traditional vertical system provider strategy, characteristic of the origin of these sectors lies with their rapid growth.

Similar advantages can be foreseen with respect to healthcare ecosystems. These systems are developing and expanding at a fast pace, attempting to provide accessible and personalized healthcare. They are becoming innovative using traditional methods and new services obsessed with customers, citizens and patients and willing to present extended and distinct paths of personalized and integrated services. These distinct paths,

usually presenting different sets of devices and services, are relying on device ecosystems exploring specific requirements and aspects of their domains. Ecosystems are strongly attached to their formed infrastructures, heavily loaded with devices from different vendors, all using non or only partially interoperable proprietary software modules and protocols. Limited standardization across these existing ecosystems is likely to put at risk the fast development and small cost advantages.

9.2.2. Challenges in Achieving Standardization

Standards are necessary to enable digital interoperability, but some key challenges slow progress. Healthcare is a conservative sector and adopting new technologies takes time, partly because of the impact on patient safety. Besides, the government has influence on standardization initiatives, directly or indirectly through funding agencies, as well as on the whole system architecture. All these factors militate towards a low capability of adaptation by the healthcare system.

There is a wide variety of service-enabling devices. The number of tools and services is increasing rapidly, and the tools have different degrees of maturity. Therefore, it is not easy to come up with a standard that would be appropriate for the entire ecosystem or for different functionalities of the tools. Further, for standardization to be efficient, the standard would have to be open to new categories of solutions coming from new vendors. The device implementations can be simple or very complex, and sophisticated devices can comprise many small devices and functionalities. Moreover, when it gets into the terms of image processing, the methods and filters used keep changing over time depending on computational capability and evolution of the standards for the file formats. It is important to have these modules updated and having a versioning mechanism so they can have maximum reusability across different customer products and solutions.

Some of these challenges compound as the number of vendors, devices, services, and capabilities increases. Users become overwhelmed and confused about value propositions as similar solutions appear as service offerings with different capabilities from different vendors. Users develop brand loyalty, but the brand usually reflects the vendor’s regional presence rather than their offerings’ technical capabilities. Standardization serves to counteract this problem of market fragmentation by establishing criteria for quality, safety, and reuse.

9.3. Current Standards in Healthcare Technology

Interoperability of devices is currently achieved through the use of a limited set of standards. Healthcare digitization has focused on healthcare data, its exchange between institutions, and its maintenance integrity through several evolutionary steps. Standardization has played a fundamental role in solving issues across time. The result is a set of several standards that are widely used in different areas of healthcare technology. The most well-known standards are those created by an organization that allows standards for an efficient exchange of healthcare semantic data, even in very different institutional scenarios, from different vendors, and with a possibly very asynchronous approach. The Fast Healthcare Interoperability Resources (FHIR) was released as a draft standard in 2011 and then as a standard in 2014. The FHIR standard has gained significant attention because the specifications are based on widely known format standards, as well as known web standards, but extended to provide a low-data loss healthcare-oriented exchange process. FHIR allows a semantic mapping between different semantic domains and resources thanks to the use of terminology services.

Fig 9.2: Current Standards in Healthcare Technology

The Digital Imaging and Communications in Medicine (DICOM) standard is the most used standard for the exchange of diagnostic imaging data. The DICOM provides

services that allow the path of an imaging exam to be followed, from the images acquisition through the communication with the acquisition equipment to the communication with any post-processing, storage, or display application. DICOM is implemented by imaging acquisition devices, image processing devices, image storage servers, and image visualization devices. Since image processing requires access to the image data, compression, and transmission time, it is important to take into account that both image acquisition and post-processing devices use DICOM standard services.

9.3.1. HL7 and FHIR

The Health Level Seven organization is a not-for-profit organization involved with the development of standards for the exchange, management, and integration of electronic healthcare information. HL7 is accredited by the American National Standards Institute, and is involved with joint activities with several international standards development organizations. As a voluntary standards organization, HL7 relies on collaboration and consensus building among its members to develop the required standards, and then on the marketplace to implement the standards, and thereby realize the planned benefits. HL7 standards develop a framework for information exchange and sharing that allows for the free movement of all healthcare data regardless of the technical structures and languages used to create those data components. These frameworks support electronic transactions, and facilitate interoperability, thereby supporting the meaningful use of vast amounts of data available to clinicians and researchers.

HL7 Version 2 is the most widely used health standards in the world, and has allowed hospitals and health systems to share data better for the last 30 years. However, as the technology and healthcare landscapes changed, so did the needs and demands of the customer base. These factors contributed to the development of HL7 FHIR, which is becoming a technology foundation, enabling the digital health ecosystem. FHIR combines the features of HL7 Version 2, HL7 Version 3, and CDA, but with a focus on simplicity, web standards, and implementation support. The FHIR standard, and the resources it defines, support a wide variety of exchange patterns. It is not the intention of the standard to dictate the methods of access to health data, only to define the health resources that are to be exchanged. FHIR simplifies development and speeds up implementation time by providing an easier learning curve that increases productivity for both developers and implementers.

9.3.2. DICOM Standards

Founded in 1983, the Digital Imaging and Communication in Medicine (DICOM) standard enables data interoperability of images and related information in medical

imaging. It is a standard that allows for the communication, transfer, and storage of medical imaging objects, primarily images but also structured reports and presentation states. DICOM defines the format of the file that is used to store the image data and the header that contains information about the patient, the data embedded in the file and much more. This standard has its roots in the ACR-NEMA standard.

The DICOM standard is not only a file format standard; it also defines a network communication protocol by which images can be stored or transmitted. The DICOM protocol itself is built on other existing base protocols such as Transport Control Protocol, the File Transfer Protocol and the Hypertext Transfer Protocol. DICOM has a broad impact on the healthcare ecosystem because it not only covers image acquisition devices but also sets the standards to which Picture Archiving and Communication Systems and other third-party vendors' products interact. Because of the broad impact of DICOM, interaction between medical devices and PACS work quite well. However, the clear limitation of DICOM is its design for the area of medical imaging alone. Other than imaging, DICOM does not address other modalities such as genomics or lab tests, which are fast evolving, and healthcare is moving from a traditional model of focusing on treatment to a model of prevention.

9.3.3. ISO and IEC Standards

Apart from the aforementioned specific standards, a number of general standards were developed at the International Organization for Standardization and International Electronic Commission. These organizations are both known for generic standards facilitation in multiple areas for products, services, and systems to ensure quality, safety, and efficiency. The general standards which have some impact on the healthcare ecosystem technologies are discussed shortly.

International Standard on Information Security Management System is the foundation of information security assurance and deals with the requirements and standardization and certification of the information security management systems. Another important standard in this domain is the standard on Security and Privacy. This expands the previous standard and is the standard for data protection and privacy in the healthcare ecosystem, especially when dealing with patient information, related to security and privacy.

Information Security Risk Management and Risk Management - Guidelines deal with aspects of risk management related to the overall healthcare ecosystem. It is important to mention here that the risk and security of the different technologies deployed should take into account the interactions and interdependencies of each technology in the overall ecosystem. The risk in one technology can affect others in the same ecosystem.

Guidelines for adoption of formalized IT ecosystem services are useful in managing the healthcare ecosystem services based on IT.

9.4. Interoperability Frameworks

The integration of disparate devices into a unified infrastructure of standards, policies, specifications, and structured data is often called interoperability. The adoption of such an interoperable infrastructure yields many benefits, such as lower costs and development time, increased service delivery speed and quality, improved information access, sharing and management, and so on. Since the healthcare ecosystem is characterized by a lack of effective interoperable infrastructures, it is currently fragmented along multiple business units with the established vertical integration of the past decades displacing patients along the wave of such fragmentation.

Interoperability is a multi-leveled phenomenon and is neither binary nor intrinsic. It can be seen as a set of qualitative levels that applications, services, and systems can attain. Certain types of interoperability relate to other types of interoperability. At its lowest level is technical interoperability, which does not add any value to integrated services, and refers to the ability of disparate systems to interpret and transceive signals appropriately. At its intermediary stage is syntactic interoperability, which allows for the exchange of data and information that are based on agreed and consistent language and data representation. At its next stage is semantic interoperability, which involves agreed meaning and conceptualization of data and information exchanged by both parties of the exchange.

9.4.1. Interoperability Levels

Interoperability is a multifaceted concept, encompassing a variety of technical challenges and solutions. In the various and diverse systems found across the healthcare sector, successful data communication and sharing occurs only when the system, device, or service recognizes and accepts the information it receives. As a result, a variety of details lay the groundwork for device interoperability across these diverse ecosystems. Unique data formatting is one of the main boundaries that must be overcome. In most cases, the sending system has developed a unique way of capturing and storing data, making it difficult for other devices to read and use needed data. Data formatting is a substantial barrier, as the information shared must use the same library to identify the specific codes for any clinical variable.

In addition to the formatting of data shared across devices, other factors help to define meaningful interoperability. These additional details have also been defined as levels of

interoperability and include transport, syntactic, semantic, workflow, and policy. These specifics are also relevant for devices, services, or systems that individually do not interact. As devices gain more interoperability, closing sensor-to-sensor loops becomes conceivable, and device capabilities such as caring for the sensor system while another does not are also perceived. However, in the end, data is shared with little to no human interference, allowing for seamless use and interpretation of various data streams.

9.4.2. Frameworks for Device Integration

Over the past years, different standardization efforts attempted to bridge silos across the healthcare ecosystem through interoperability frameworks, defined as common architectures, models, standards, and infrastructures enabling interoperability across devices, applications, and actors for exchanging and interpreting shared data. Based on a general structure of the concept of interoperability, different frameworks exist for bridging specific interoperability levels targeted at particular use cases for decentralized cities or services across computer science, social science, and information systems. Among them, the eHealth Architecture Framework has been identified as one of the many levels pertaining to the exchange of data and information across eHealth services regarding devices and applications enabled for this purpose. Similarly, other frameworks have been cultivated from the digital heritage and preservation domain ontology for translating organization models across multiple domain services into software application, and security interoperability.

However, only a few frameworks apply the principle of interoperability on distributed device platforms. One of the first initiatives was Continua, establishing a framework focused on health and wellness applications for aging and chronic diseases by providing a reference architectural model with guidelines for compliant devices. More recently, the Fast Health Interoperability Resources, by defining a specific set of semantic and syntactic rules for devices and mobile applications based on the generic RESTful Web Services, attempts to bridge resource-oriented proxies to electronic health records.

9.5. Regulatory Environment

The regulatory oversight of medical devices has become increasingly complex as device capabilities expand. Regulatory bodies were not designed to address interoperability issues across regulated manufacturers and devices. Manufacturers are working within a broad legislative environment that does not mandate a standards approach, yet standards are required by some regulators to clear devices. These competing pressures make the space quite challenging for both manufacturers and regulatory agencies, specifically in the areas of standardization and interoperability. Manufacturers are often hesitant to

engage in shared risk spaces, such as interoperability, because of the potential for increased regulatory burden and liability. If manufacturers can use standards to meet regulatory requirements, are regulators then mandated to require standards or voluntary guidance documents for these requirements?

While a risk-based assessment of device regulatory approaches is used and devices are cleared using a pathway, it is rare that review of a submission will consider or ask for details on interoperability.

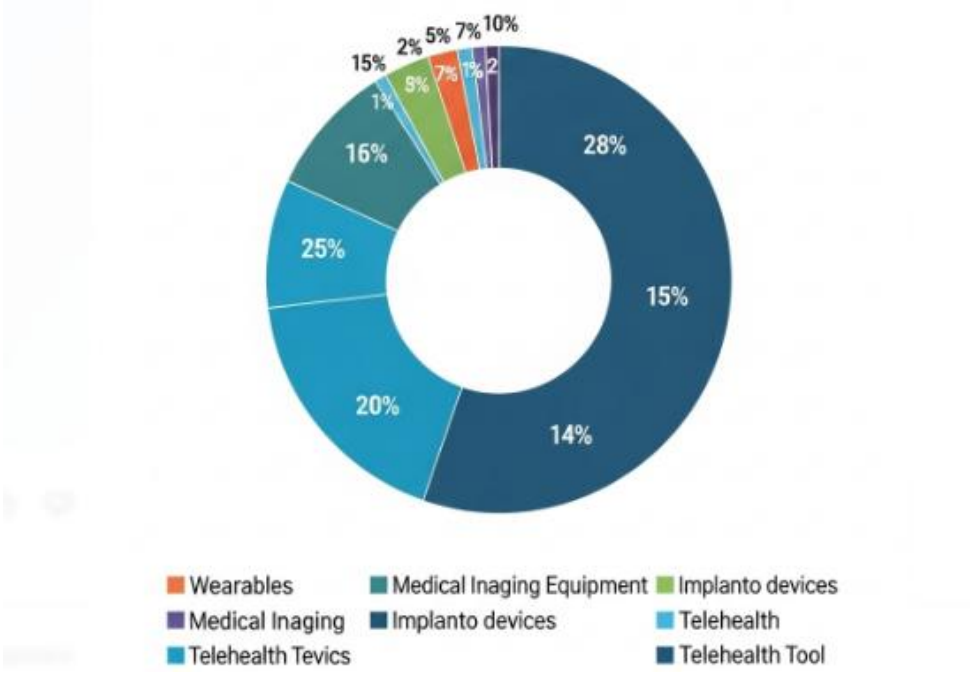

Fig 9.3: Devices Across Healthcare Ecosystems

9.5.1. FDA Regulations

The FDA defines devices per the Federal Food, Drug and Cosmetic Act, Section 201(h): "The term 'device' means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or similar or related article, including any component, part or accessory, which is recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, and is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals, or to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purpose through chemical action within or on the body of man or other animals and which is not

dependent upon being metabolized for the achievement of its primary intended purposes." Many healthcare-related products are defined by the FDA as medical devices, including products that are used in the prevention of disease, products that affect the structure of man or animals, or products that are used to affect a man's or animal's bodily functions.

The FDA has classified medical devices into three classes (Class I, Class II, and Class III), with Class I posing the least risk and Class III the greatest. Classes II and III devices are typically required to follow the Premarket Approval or 510(k) processes. The PMA process serves as the source of FDA risk and safety product evaluation for Class III devices. In the case where the PMA process is applicable, the FDA cannot approve a device unless the sponsor has established that the device is safe and effective for its intended use. If submitted via the 510(k) notification premarket review process, the sponsor must show that the device is "substantially equivalent" to a device that is already legally marketed and at least one of the predicates is not subject to PMA. The FDA does not formally classify or clear devices that are classified as Class I under the FD&C Act.

9.5.2. EU Medical Device Regulations

The EU Medical Device Regulation and In Vitro Diagnostic Regulation lay down a comprehensive and uniform regulation addressing the safety and performance of medical devices. These regulations define medical devices broadly and include a wide variety of products throughout the therapeutic continuum, ranging from low-risk items that have been traditionally regulated by the EU Member States, to the latest innovative high-risk products. These regulations reinforce the requirement of a clinical assessment for all Classes of medical devices and ensure that devices are safe and perform as intended throughout their lifecycle. This includes appropriate clinical evaluation, post-market surveillance and vigilance, as well as the use of appropriate technical documentation. These regulations also enhance transparency requirements for the public.

Transparency is mainly provided by the European Database on Medical Devices, which is established and maintained by the Commission. Market surveillance is also strengthened, particularly with regard to products imported into the EU from third countries. A series of guidelines on the application of the MDR and IVDR have been issued, but most will need further specifications: to supplement a few of their provisions, and to ensure their practical application. This report is focused on the MDR. The MDR was published on 5 May 2017 and regulates the implementation and configuration of Medical Devices on Humans.

9.5.3. Impact of Regulations on Interoperability

Regulations have been and remain one of the major reasons why many interfaces between medical devices are proprietary and unique. As different regulators for different countries or regions give clarity to more specific aspects of device development, the result is often that different device designs are accepted, thus creating non-uniform interfaces. A universal and specific set of regulations for a wide margin of devices would reduce the situation of many unique designs for similar devices created for different applications, thus leading to advantages in efficiency of designing as well as entirely new and sometimes even better technologies that come available for many applications. Regulations should enhance and not restrict the ability of devices to communicate and should also focus on ergonomics and patient comfort when entering any information into an application. Currently, different regulatory organizations employ quite different routes for clearing interoperability. A universal roadmap for device connectivity is thus a long-term vision that should be followed and universally accepted by all regulatory organizations. The standardization organizations should also be working with relevant stakeholder organizations for collaboration between companies and health authorities on the one hand and global health organizations on the other. These stakeholders should work continuously on evolving low-hanging proposals, which will enhance connectivity and interoperability while improving patient outcomes. The motivation should be that further eradicating the current lack of device communicability and interoperability is a priority for all parties concerned. Further, a lesser degree of emphasis should be placed on the impact and extent of consequences from a regulatory point of view with respect to the established risk classification for devices, specifically the lower classes of devices for which less stringent rules currently exist.

9.6. Conclusion

Standard medical device interoperability standards can solve problems of patient care safety and efficiency that arise from the fact that patient connected wellness devices – ECGs, pulse oximeters, instantaneous blood glucose meters, wearables, or any other patient device that takes readings in real-time, non-invasively, and transfers patients' physiological data wirelessly to a remote monitor, a mobile app, or the cloud – are not interoperable. Around-the-body wearable devices that continuously monitor parameters like ECG, temperature, heart rate, blood pressure, oxygen saturation, and blood glucose level – the "Big 5" parameters of patient states associated with COVID-19 – and upload this data to the cloud to facilitate telehealth-based remote monitoring could provide inexpensive early warning systems to detect the onset of pathological signs and symptoms without an adversarial interaction that could expose both the doctor and the

patient to COVID-19 but would not be able to help to do so if such monitoring is not built on a standard architecture with implementations defined from the ground up.

Future advances in wireless technologies will increase the scalability of these monitoring systems and facilitate level 1 telemedicine and expanded-focused virtual and community care. With such scaling, the healthcare industry will start a paradigm shift away from expensive acute and long-term therapy in hospital settings toward inexpensive and effective point-of-care diagnostics and chronic disease management, in-home therapy, and post-acute care at home. These advances will affect every subsystem of healthcare – connectivity, power efficiency, and fabrication technology, and consequently the electrical and mechanical design, manufacturability, operating characteristics, and cost of telemonitoring for wellness or the management of some chronic disease among specific classes of patients aging at home.

9.6.1. Future Trends

This section focuses on what may be some of the short to medium term trends in interoperable devices or systems within healthcare ecosystems. Following this are reflections on why these areas are of interest, with a more detailed discussion of key areas such as Digital Twins and Virtual Testing and Simulation presented in separate sections at the end of the chapter. Other specialists in medicine, standardization, interoperability, security, regulatory, will also be adding their perspectives to future research and activities in these areas.

A device ecosystem strategy will arise where interoperability is assessed at a system rather than device level.

Concerns around privacy and security will increase and require greater focus on addressing these. This has association with Trusted Exchange Frameworks.

Post-market device risk management development will increase. The area may play a growing role in this area.

Healthcare systems, and activities within them such as surgery, will likely become increasingly optimized and efficient. Over-design for flexibility of device systems may give way to improved efficiency, where security, Byzantine fault tolerance issues are still respected.

The clinical cost, risks, need for availability, safety, efficacy of specific devices during use is becoming subject to research. At some point, this will functionally constrain which device may best be used for a specific procedure, within a situation where device eutaxy

is operating (or not). The virtual twin of the device ecosystem, using enhanced models may become regularly used, at specific scales.

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