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A COMPARISON OF MODERN FRAMEWORKS FOR THE DEVELOPMENT OF INTEROPERABLE HEALTHCARE INFORMATION SYSTEMS

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ABSTRACT

Despite the strong consensus behind the need for an interoperable Healthcare Information System (HIS), the universal acceptance of a standard HIS framework has advanced very little and is yet to become a market reality. In an effort to advance this endeavor, this work provides a systematic comparison regarding two of the most relevant HIS frameworks recently proposed: The Integrated Clinical Environment (ICE) and the Healthcare Industry 4.0 Framework. The paper analyzes their differences and similarities and proposes a minimum set of requirements for prospective interoperable HIS architectures compliant with the Industry 4.0 design principles, goal-setting pillars, as well as support for closed-loop physiological systems. Finally, the paper discusses future works in the field.

Keywords: Interoperability; Healthcare Framework; Closed-Loop; Physiological System; Cyber-Physical System

1. INTRODUCTION

According to the Food and Drug Administration (FDA), there are frequent annually reported events directly concerning medical devices (MD) which may lead to severe injury of the patient, and sometimes even resulting in fatal incidents. Existing Healthcare Information Systems (HIS) do not fully provide the comprehensive capabilities necessary to monitor or detect these harmful events due to their limited ability to integrate cross-manufacturer MDs and also coordinate their activities, such as to automate clinical workflows with real-time integrated data and closed-loop physiological control for the rapid diagnosis and safe treatment of high-acuity patients, for example, patient transfers from the operating room to the Intensive Care Unit (ICU) and Patient-Controlled Analgesia (PCA) systems [1].

In the last decade, several academic healthcare researchers, physicians, and industry professionals have all promoted the adoption of intelligent HIS capable of seamless interoperability as a model to significantly improve treatment safety while simultaneously reducing cost and enabling at-home healthcare. Despite the strong consensus behind this proposal, interoperable HIS is yet to become a market reality [2] [3]. The Integrated Clinical Environment (ICE) interoperable framework standard was initiated in 2006 by American Society for Testing and Materials (ASTM), committee F29, based on work performed by the Medical Device Plug-and-Play Interoperability Program. ICE was developed and standardized in 2009 as ASTM F2761 [2]. It has since then become a foundational standard for new initiatives in the development of interoperable HIS. Standard IEEE 11073, Service-oriented Device Connectivity (SDC), has recently gained traction among leading market vendors who are considering its adoption. Despite its relevance to the field, it will not be discussed in this work as it has already been studied in detail [4] [12]. Health 4.0 is an extension of the Industry 4.0 Framework towards healthcare [3]. Industry 4.0 is a smart manufacturing plant concept which was recently introduced as a strategic technology used to strengthen the industry for catering future needs [5] [6]. In recent years, there has been a growing interest within healthcare-related communities to further explore disruptive solutions to existing healthcare problems.

This work provides a systematic comparison regarding ICE and Health 4.0, two of the most relevant HIS frameworks recently proposed. Few select works have compared IEEE 11073 SDC and ICE and studied how their combined use can be helpful towards a more robust solution [4]. Several other previous works have focused on the discussion of ICE, as well as the Health 4.0 HIS frameworks, independently. However, to the best of the authors' knowledge, no attempt has been made to either identify their differences and similarities, or to better understand their relative weaknesses and strengths. In this work, ICE and Health 4.0 are compared through a systematic review. The insight obtained from this analysis allowed us to identify several user-based needs which were then used to propose a set of requirements pertaining to the development of interoperable

HIS. If these contributions are hence able to provide a significant improvement to the development of HIS architectures capable of interoperability, interconnecting devices to patients, nurses, doctors, and other stakeholders, then it may contribute to the development of a more reliable and flexible HIS for prompt diagnosis, safer and cost-effective treatment of acute and non-acute patients.

2. APPROACH

2.1 Problem Definition

A smart HIS architecture compliant with the objectives laid out in section 1 should leverage key technologies such as Cyber-Physical Systems (CPS), Internet-of-Everything (IoE), and real-time communication to enable systems capable of context-aware healthcare delivery in order to better assist people with medical equipment to execute complex tasks. In this section, we start with a discussion of two enabling technologies. Afterwards, we analyze two HIS frameworks recently proposed in literature: ICE [2] and Health 4.0 [3]. Initially, their similarities and differences are identified and compared, followed by a detailed discussion over their respective strengths and weaknesses. This knowledge is then used to both identify user-based needs and define the architecture-level requirements in section 3.2, which should thus be met by smart and interoperable HIS architectures. The conclusions of this analysis are summarized in section 3.3.

2.2 Internet-of-Everything (IoE)

TABLE 1: THE INTERNET-OF-EVERYTHING

Technology	Segment	Group	Examples
Internet-of-Everything (IoE)	Internet-of-Things (IoT)	Sensors	Monitor heart-rate, body temperature, pressure, oxygen levels, wearable, etc.
		Actuators	Infusion pumps, PCAs, ventilators.
	Internet-of-Services (IoS)	People	Patients, doctors, nurses, and other healthcare staff.
		Process	Diagnostics, treatments, health-related scheduling, health insurance, medications, etc.
		Data	Patient profile, electronic health records (EHR), monitoring data, lab results and imaging data, etc.

In the context of HIS, IoE aims to facilitate intelligent connectivity among people, processes, data, and things. The notion is based on the ability of interconnected machines to transfer data over a network without requiring human-to-human or human-to-computer interactions. As shown in Table 1, IoT serves as a method to enable the connection of different physical medical devices such as medical sensors and actuators. IoS, on the other hand, is intended to enable the providing of services for different health-related systems and organizations via the Internet. These services would then be used by their respective owners or any other associated health systems and organizations

that may utilize or require them accordingly. The purpose of the IoE concept, encompassing IoT and IoS, is hence to address the framework design principles of interoperability, real-time capability, service-oriented, and to further facilitate modularity, as defined in the Industry 4.0 framework [7] [8].

2.3 Cyber-Physical Systems (CPS)

ICE and Health 4.0 frameworks require machines (devices and apparatuses) capable of integration between cyber and physical processes. This key technology is referred to as cyber-physical systems (CPS). In a healthcare setting, there are also specific CPSs known as medical cyber-physical systems (MCPS). CPSs are mechanism-related systems controlled or monitored by sets of computer-based algorithms. Within the framework, both CPSs and MCPSs serve to facilitate useful interactions between the cyber and physical worlds, the patients, and offer continuous health monitoring and treatment services. As the principal gateway of carrying out the actual treatments supported by the HIS architecture, CPSs directly address several design principles linked to the framework. This results in CPSs playing a significant role in the effective clinical workflow of healthcare delivery.
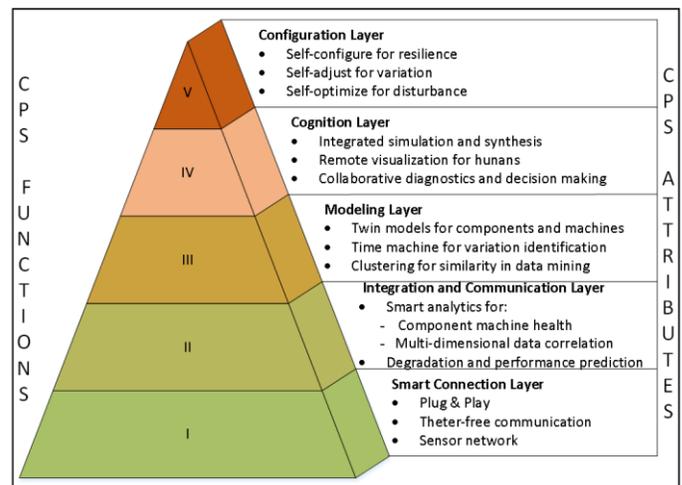

FIGURE 1: CPS 5 LAYERS (5C) ARCHITECTURE [10]

The CPS structure shown in Figure 1 consists of five layers including smart connection, integration and communication, modeling, cognition, and configuration. Their functionalities are summarized in Table 2. This 5C architecture allows for a CPS to be context-aware and plug-and-play. The term context-aware, within a HIS framework, means the system can use context (e.g. QR code, location, and status of an item) as well as real world and virtual data to autonomously realize their virtual and real life tasks. Existing flaws in current healthcare facilities and clinical workflows are frequently related to the limited transfer and monitoring of medical information in real-time or simply accidental operation errors. Clinics and distributed healthcare facilities providing arrangements such as General Practice networks, public nurses, pharmacies, etc., while being similar to factories, would also greatly benefit from context-aware people

assistance as well as the most optimal use of medical devices throughout their duties. The smart connection layer of CPS refers to the direct interconnection of multiple smart devices within the architecture. This includes wearable sensor technologies such as biosensors (electrocardiogram (ECG), heart-rate monitoring, body temperature, blood pressure, pulse oximeter (SpO2), etc.), location tracking (GPS, altimeters, accelerometers, etc.), and other sensors such as multispectral cameras. It also allows for the integration of drug administering devices such as smart infusion pump systems (IPS) and medication delivery systems (MDS) [9].

TABLE 2: CPS LAYERS & FUNCTIONALITIES [10]

CPS Layers	Design Principle	Functionality
Smart Connection	Interoperability & real-time communication	Promotes interoperability between simultaneously interconnected devices.
Integration and Comm.	Decentralization and modularity	Satisfies the requirement for cloud & edge computing-based device compatibility.
Modeling **Cognition**	Virtualization, service oriented and modularity	Incorporates AI and NCA to propagate virtualization services and decentralization within HIS.
Configuration	Decentralization and modularity	Integrate self-capabilities enabling corrective and preventive decisions such as reconfiguration.

The integration and communication layer is meant to bridge the interconnected MDs to the system, either through a mobile device or computer. This layer then filters and assigns semantics to the raw data obtained from the previous layer (IoT, etc.), generating meaningful information, which can be achieved using algorithms for prognostics and health management, and then uploads it to a storage system for further analysis by the upper layers. The term digital twin relates to the cybernetic representation of the real entity. Following the creation of a digital twin, the modeling layer (also known as the cyber layer) runs a set of potential simulation configurations based on specific patient data (from the Cloud or IoT). Complex modeling and simulation algorithms, AI, and Numerical Computing Algorithms (NCA), are prominent throughout this layer as they extract non-obvious information relevant to patients undergoing treatment and use it to create new insights into how the treatment is progressing, predict the likelihood of the expected outcome, and scan for deviations due to treatment side-effects, product malfunctions or unintended operating errors. Based on the knowledge extracted in the modeling layer, the cognition layer provides a comprehensive list of prospective/potential medical recommendations to continually improve the treatment plan. Analytical conclusions are thus adequately presented to healthcare personnel, depicting preventative measures intended to facilitate superior quality of care. The alerts, advice, and orders are then delivered to the system stakeholders to help them conduct corresponding actions to any adverse medical issue relating to the patient. Finally, the configuration layer acts as a

supervisor since it can attribute self-capabilities (predict, compare, configure) to the system, such as corrective functions.
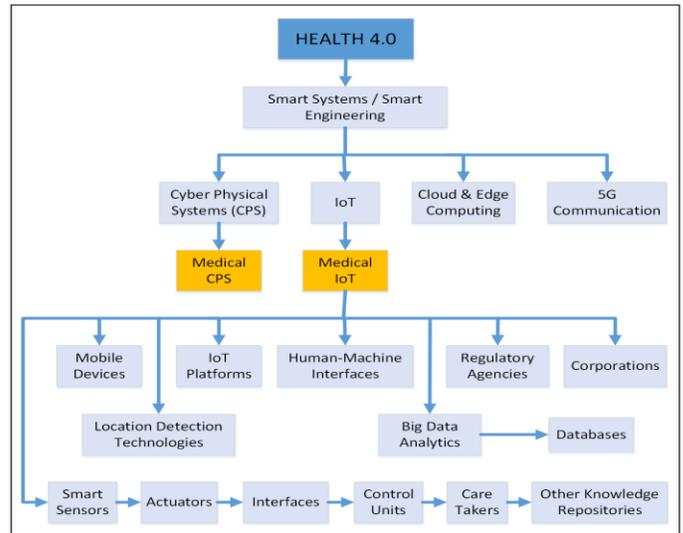
2.4 Health 4.0 Framework

FIGURE 2: HEALTH 4.0 FRAMEWORK [1]

The Health 4.0 Framework, shown in Figure 2, is an extension of the Industry 4.0 framework translated into a healthcare delivery setting. Industry 4.0 is a recent industrial shift encompassing novel concepts based on disruptive technologies such as smart manufacturing, IoT, CPS, and real-time communication [7] [3]. This allows for improved connectivity between devices (medical and others) as well as promoted context-awareness throughout the healthcare delivery system, thus further facilitating the effective monitoring of patients and the delivery of safer treatments. It essentially aims to optimize the dynamic workflow of treatment and care delivery by thoroughly interconnecting devices to patients, nurses, doctors, etc., consequently establishing a more reliable and self-learning computer-integrated healthcare environment. Health 4.0 is based on the following design principles [7] [8]:

- **Interoperability:** The ability of computer systems and related medical devices within the framework to interrelate and communicate through a secure network connection.
- **Virtualization:** The ability to monitor different healthcare processes such that virtual copies (digital twin) can be created for these individual treatment processes.
- **Decentralization:** The ability of different CPS and other medical systems to function autonomously within the framework and make decisions on their own to increase productivity such as tacit task delegation.
- **Real-time Capability:** The ability to seamlessly collect and analyze both incoming patient health data and system status reports, effectively decreasing the adverse medical reaction and/or faulty system operation response times.
- **Service-oriented:** The ability to design and present the functions, features, and devices as healthcare services which

are inherently scalable and can be modified to integrate into any patient's current treatment protocol.

- **Modularity:** The ability of the framework's components to be separated and variably combined, propagating flexibility and scalability used to improve individual modules to meet requirements in both new and existing healthcare processes.

These principles provide the basis for Health 4.0 to further develop its prospective architectures and integrate relevant technologies to enable the desired and ideal implementation of the framework. Health 4.0 also seeks to actively define and accomplish its goal-setting pillars when putting in place a viable system architecture for standardized clinical use. The framework philosophy is based on the following three pillars [3]:

- **People:** The active transition from a product-selling to service-providing framework capable of patient-centered integrated service intended to provide patients with the most optimal treatment plans without delivery workflow delay caused by human and computer operations.
- **Technology:** The enabling technologies intended to fulfill the predetermined framework requirements such as providing an interconnected method of healthcare delivery.
- **Design:** The adaptive methods of intended framework implementation based on a human-centered design which enables the system to understand and attend to patient needs.

Health 4.0 Framework inherently seeks to enable healthcare collaborations between stakeholders (patients, hospitals, medical insurance providers, etc.) and provide effective apparatuses for healthcare monitoring and virtualization to serve as both a powerful and open-data healthcare platform for in-hospital and remote patients. As shown in Figure 2, the Health 4.0 framework leverages CPS, IoE and low-latency real-time communication (i.e. 5G networks) to enable systems capable of limited context-aware operation and autonomously executing tasks. The term context-aware signifies that the system can proactively use context (position and status of a particular device) including real world and virtual data to perform cyber-level and physical tasks.

2.5 Integrated Clinical Environment (ICE) Framework

ICE is a platform designed to propagate medical device interoperability through medical IoE services such as data logging, physiologic closed-loop control, data visualization, clinical research applications, and compatibility with other related healthcare systems. As shown in Figure 3, it is precisely structured through a streamlined workflow centralized at the Network Controller (NC). Its functional model requires several components which are responsible for predefined system roles:

- **Supervisor:** Hosting and managing the applications offered within the framework, as well as providing an effective operator interface for the system.
- **Network Controller (NC):** Providing communication and mediating the incoming data traffic from interconnected devices and external systems while acting as the "plug-and-play" for the architecture and only access to the Supervisor.

- **Equipment Interface (device adapter):** Connecting ICE-compatible and other devices to the NC.
- **Data logger:** Forensic analysis and storage of incoming data from the connected devices.
- **External Interface:** Connecting one or several external healthcare systems (e.g. EHR, ADT, or pharmacy system) and processes to the NC, serving as the bridge between ICE and clinical environments outside the framework.
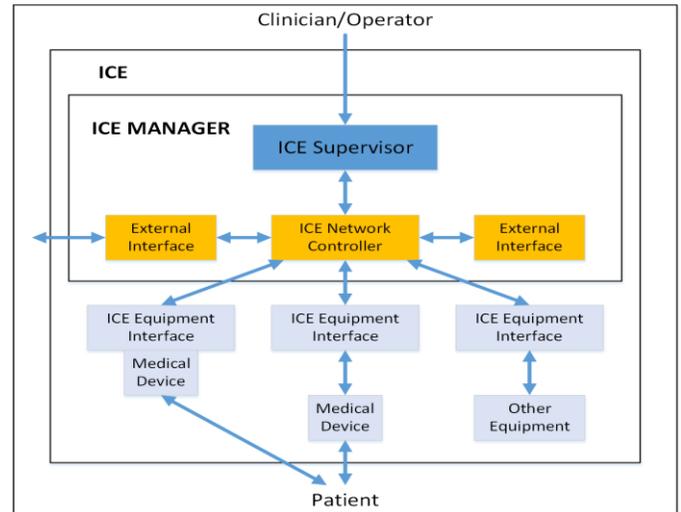

FIGURE 3: ICE FRAMEWORK (ASTM F2671) [2]

This results in an open framework capable of seamless external interface integration. Although the architecture might not natively be able to provide certain healthcare delivery services such as system configuration/reconfiguration due to its pre-defined structure, it allows for users to equip the framework with additional external functionalities capable of addressing these interoperability and plug-and-play limitations. ICE provides a high-level architecture containing functional blocks in need of specified task proposals through realistic technological options. A crucial aspect to this proposal includes the adoption of a middleware software acting as a basic network communication backbone connecting the different MDs with both basic services, as well as other enhanced logic. The topology connecting the Supervisor, NC, and the MDs is pre-defined in the framework. ICE is intended to enable and assist in both the creation and instantiation of prospective system architectures outlined to efficiently deliver services relating to patient safety, treatment efficacy, and workflow efficiency, and serves as a platform for autonomously interconnected MD tasks.

Various middleware algorithms are used to integrate other technologies into the framework. The potential for ICE lies in its innate capability to adopt relevant technologies, map them within the architecture, and address complex healthcare delivery issues. For example, ICE could integrate an external system which enables the use of virtual medical devices (VMD) to replicate virtualization and treatment simulation services. The architecture would define the device by type, specify the integrated device's offered applications, and then relay its

operability to the clinician/operator interface. This would provide an effective method of treatment plan customization for acute and non-acute patients alike. Albeit the framework's flexible design permits device scalability and facilitates system implementation, it also results in certain limitations. Firstly, the open-ended communication backbone propagates security concerns as it allows for impersonating or harmful middleware to access the system and its interconnected devices, potentially resulting in harm to the patient. Researchers and developers are currently working to mitigate this problem by establishing a middleware-independent authentication scheme for ICE systems. Furthermore, due to its inherently more centralized framework, ICE requires external systems and processes to perform complex healthcare monitoring and treatment delivery tasks such as reconfiguration, digital twin, and device clock synchronization; functions which are innate within Health 4.0.

3. RESULTS AND DISCUSSION

3.1 Analysis

TABLE 3: ICE VS HEALTH 4.0 HIS FRAMEWORKS

Health 4.0 Framework		ICE Framework
Similarities		
CPS-enabled Modularity	Real-time capability Support virtualization	Support interoperable Flexible & scalable architectures
Differences		
Decentralized architecture		Centralized architecture
Pre-defined digital twin		Undefined digital twin
Scalable model		User-based model

The Health 4.0 and ICE frameworks are intrinsically similar in nature, however, they both possess critical differences in their philosophies and respective system architecture approaches. Their major differences and similarities are summarized in Table 3. In likeness, both frameworks are CPS-enabled, promote interoperability and virtualization, offer real-time capability, and drive modularity through their flexible and scalable model designs. On the other hand, Health 4.0 is an inherently decentralized framework. It operates on the basis of autonomous interoperability, meaning that its interconnected CPSs should have the ability to make context-aware and self-analyzing decisions. In the case of ICE, albeit some decentralization is possible through the integration of external HIS and treating MDs as CPSs, the framework is naturally standardized throughout its pre-defined equipment interfaces and the NC. It is thus incumbent on the user to identify a specific system limitation, develop a compatible technology platform, and equip it onto the established ICE architecture as an external HIS. For example, with the iLand Project, configuration/re-configuration services were extended to an ICE-based architecture [11].

Additional examples of this include communication interfaces in Health 4.0 not being standardized. The prospective

system architecture either chooses or develops an ideal method of communication intended for effective system interoperability, while in ICE, this is also defined in the equipment interface. Lastly, although the ICE Framework is capable of virtualization, it is not inherent to the framework itself, as opposed to Health 4.0. In ICE, there is no specific medical device defined with the role of digital twin capability, meaning that the location and method to integrate the capacity to generate relevant simulations, given a stream of patient data for analysis, must be defined by the architecture designer. In contrast, Health 4.0 model has a pre-defined, AI-enabled cloud model providing digital twin services.

From a high-level structural comparison, both frameworks address the design principles proposed in Industry 4.0. However, Health 4.0 details the pre-defined roles of it select enabling technologies for decentralized healthcare delivery, as opposed to ICE, which allows integration and compatibility of these technologies within its system architecture, but not under a pre-defined role. This results in Health 4.0 being a more flexible and scalable, but also more computationally demanding framework. The abundance of disruptive technologies operating with interoperability might lead to inefficient services and slower response times. ICE serves as a more standardized and plug-and-play incentivizing framework. It balances compatibility with technologies able to provide effective services based on the shared design principles, however, it is upon the discretion of the proposed system architecture. In conclusion, both frameworks have the potential to develop disruptive HIS architectures, however, Health 4.0 is depicted as a more facilitative model, while ICE details a more user-based model. All in all, they are both able to meet the design principles defined by Industry 4.0, leading to disruptive healthcare delivery and treatment services.

3.2 User Needs and Architecture-Level Requirements

Healthcare interoperability is very difficult to achieve, let alone maintain, ensuring high quality performance and constant reliability. Following the in-depth analysis of both frameworks, Health 4.0 is depicted as an overarching framework which aims to facilitate the automated delivery of healthcare treatments through various enabling technologies, while ICE is depicted as a platform-based framework intended to provide medical device interoperability within a more controlled clinical environment. Nevertheless, prospective system architectures deriving from either framework must adhere to certain user-based needs in order to fulfill the desired objectives as defined in section 1:

- Ability to monitor, capture, and seamlessly access patient clinical data in real-time through interconnected devices.
- Ability to provide customizable templates intended for varying treatment specialties so as to further ensure both personalization and virtualization capabilities.
- Ability to construct ideal and tailored medical solutions for each patient suitable to their specific needs.
- Ability to both, simultaneously and in real-time, update and alert various systems such as clinical records (i.e. EHRs), administration, inventory, pharmacy, and accounting so as to eliminate fraud, waste, and other needless operations.

- Ability to synchronize data for cloud based solutions, so that the system can be used in remote (at-home) settings with limited or no infrastructure, as well as in structured and developed in-hospital sites.
- Must adhere to the fundamental goal-setting philosophy of human-centered design, meaning to provide healthcare delivery as a service rather than a product.

To properly address and effectively satisfy the above-listed user needs, a derivative system architecture stemming from either the Health 4.0 or ICE interoperable frameworks, should therefore adequately adhere to a set of functional requirements defined to provide the means for:

- MCPS modeling and simulation methods algorithms should be capable of achieving high level accuracy, stability, and computational complexity to be implemented in embedded hardware or software.
- AI algorithms to be implemented in the MCPS should be available for embedded as well as cloud implementation.
- Effective data collection and processing methodologies.
- Secure and reliable distributed architecture.
- An architecture that is flexible, scalable, and capable of functional composition.
- Support easy configuration and automatic reconfiguration of MCPS on a patient workflow.
- Interoperable device and equipment capabilities.
- Non-proprietary standardized interface and protocols.

3.3 Analysis Conclusion and Future Work

The Health 4.0 model is highly scalable and decentralized, does not require a standard network communication interface, and defines a vast plethora of features and services while also defining how they are interconnected. ICE, on the other hand, requires a pre-defined backbone for communication among medical devices and other equipment. Moreover, some key functionalities and services are not defined in the standard and left up to the designer to define them and see how they fit into the framework. In summary, Health 4.0 depicts a more flexible and decentralized model while ICE adopts a more pragmatic approach, one that favors higher performance. To properly continue the work presented in this paper, we will be focusing our scope and efforts on the development of a prospective HIS architecture based on the listed design principles of interoperable frameworks such as Health 4.0 and ICE. This entails addressing the weaknesses discussed in section 2, while maintaining the strengths of both frameworks and simultaneously meeting the design requirements detailed in section 3. The ultimate goal is to develop safer and more effective HIS capable of providing interoperability and unmet healthcare delivery services while maintaining a decentralized approach to system functionality.

4. CONCLUSION

In this paper, we reviewed two enabling technologies, CPS and IoE, which facilitate the adoption and implementation of prospective HIS architectures. This creates a platform for developing ingenious healthcare services as well as novel, smart treatment workflows capable of seamless interoperability and closed-loop control to detect and prevent harm to patients. The work subsequently analyzed both the Health 4.0 and ICE frameworks, their differences, and similarities, along with their relative weaknesses and strengths. It was concluded that, although the frameworks possess some key similarities, most notably device interoperability, patient-centered design, systems scalability, and integration to heterogeneous MDs, there are also differences in structural approach, being that Health 4.0 mainly acts as a more decentralized model, as opposed to the heavily centralized ICE.

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