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Review Article

5G IoT and HL7 FHIR for Mission Critical Healthcare Applications

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Abstract - *The Internet of Things (IoT) has brought a paradigm shift in how signals from devices can be reliably and continuously collected, enabling applications that have revolutionized many different technical and business domains. Medical applications like telehealth, at-home care, and personal health monitoring devices are changing how medical services are designed and delivered by increasing efficiency, lowering cost, and providing resources for patients and providers for better patient outcomes. The COVID-19 pandemic has accelerated the adoption of such services. Technology that enables Medical IoT has evolved over the years to meet requirements for new applications, as well as government and industry regulations. The success of smartphones and wearable devices has provided a large user base to launch applications. This paper discusses the technology, design, security, interoperability, and privacy aspects of mission-critical applications and applies them to elderly care and care of patients with chronic illnesses. The paper provides an overview of 5G Medical IoT devices, Ultra Reliable Low Latency Communication (URLLC), Geo-Fencing, and HL7 FHIR technologies and systems enabled by them. It presents how these technologies can help design an effective, reliable, affordable, and secure system for caring for elderly people. It can enhance the quality of life of people in care and caregivers' experience. These systems can be designed to be compliant with the Health Insurance Portability and Accountability Act (HIPAA), Trust Identity Privacy Protection Safety And Security (TIPPSS), or any other applicable government or industry regulations.*

Keywords - *5G IoT, HL7, FHIR, Network slicing, URLLC, Geofencing.*

1. Introduction

The capability of observing the state of distributed systems is fundamental to so many aspects, including designing, efficient running, and security. A multitude of properties can capture the state. The challenge is to get more samples, continuously and over a long period, to characterize the system under observation accurately. The Internet of Things (IoT) is a network of connected devices, including sensors, smartphones, wearables, etc. These are always connected mostly via wireless communication to the control center, where signals are continuously received and analyzed, and decisions can be made. 5G cellular technology is one of the most widely used means of connecting IoT devices.

Healthcare is a major application of 5G IoT, and adoption has grown exponentially over the past many years. The Healthcare Internet of Things (HIoT) brings many promises to providers and patients. There have been advancements in smart devices and wearables with sensors that can record different vital signs in the human body, including heart rate and temperature. These devices are small and have long battery life, enabling long observation periods. Along with other sensors, like a gyroscope and GPS, activity data can be correlated with the health data of the user. As a result, the applications of HIoT have grown in the number of users, conditions treated, and number of companies in the field. This paper discusses the use of HIoT for mission-critical applications, like elderly care and at-home care for patients suffering from chronic and life-threatening conditions. HIoT can reduce the overall cost and improve the lives of patients and caretakers. Trusted data regarding patients' health is recorded, converted to machine-readable format, and communicated continuously to the central system. Here, machine learning and pattern matching can be applied to analyze and make real-time decisions that can save lives. Interoperability and compatibility of data are major concerns as the HIoT and related industries grow. There are several industry and government-led standards to regulate the development, marketing, and operation of such devices. Companies have an incentive to follow these standards so that their products can interwork with others and reach a wider user base.

Due to the distributed systems, fragmented data, and regulations, HIoT products are very complex to develop. The solutions involved require specialized technology and know-how. This paper introduces the technologies and design choices behind them and provides the interconnections. Existing research covers individual aspects like HIoT devices [12] and security aspects [13]. This paper offers an end-to-end holistic view. Service Oriented Architecture is suited for designing these products so that the implementation can be broken down into logical blocks which can be implemented as microservices allowing for scalability, phased roll-out of features, and load sharing. Security and privacy are also paramount for these products, so a well-architected design is essential for the success of HIoT products.

2. Health Level 7

Health Level 7 (HL7) is an industry-led organization that sets standards for clinical data exchange. It is widely deployed in the USA and has been accredited by the American National Standards Institute (ANSI) since November 2000. A standard format for representing data provides a common language for different systems to exchange data between each other. This will provide a comprehensive view to any stakeholder in the healthcare system, making data-driven decisions leading to better patient outcomes, efficient management, and reduced cost.

Clinical data in HL7 is represented by messages in text form. Data to be exchanged is encoded into an HL7-compliant message and sent over the network. On the receiving side, the entity decodes the message to extract needed information. A message has segments, with each segment starting from a new line. Segment groups relevant fields of information together. HL7 defines these segments and specifies a 3-letter code for each. The message header (code: MSH) segment could tell what type of message it is and the version of the protocol that it conforms to. HL7 standard defines more than a hundred segment types along with details of what fields it can have and how to encode them. The segment has segment fields that can have levels of sub-fields with pre-defined data types. Fields are delimited by reserved characters.

For example, segment PID segment contains patient information and contains 30 different fields with values ranging from patient ID number to patient sex, to address, to marital status, to citizenship. The PID segment provides important identification information about the patient and is used as the primary means of communicating the identifying and demographic information about a patient between systems. HL7 has gone through many updates since inception and broadly can be divided into version 2 and version 3.

HL7 V2 provides the framework for the exchange of data between the majority of entities in the healthcare system. There are also interfaces defined to inter-work with lower-layer protocols or application protocols like Digital Imaging and Communications in Medicine (DICOM), which could be used to convert X-ray images to the digital domain.

HL7 V3 was created to address some shortcomings of V2 and make the data model more consistent. It was released in 2005. However, V3 is not backward compatible as it alters the message structure to incorporate some of the enhancements. An enterprise with existing systems on HL7 V2 will need to maintain them while implementing HL7 V3 compliant systems and implement an interface for V2 and V3 systems to inter-work and be able to exchange data.

HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of clinical documents for exchange. A CDA document is a defined and complete information object that can include text, images, sounds, and other multimedia content. CDA documents are encoded in XML using the HL7 Reference Information Model (RIM) and the HL7 V3 Data Types. CDA encompasses message formats, interfaces between Health Information Systems (HIS), and events concerning the patients and providers. Messages and events are used to capture a transaction between involved entities. HL7 specifies protocols that the entities adhering to the standards must follow. This ensures interoperability between different HIS systems. [2]

3. Fast Healthcare Interoperability Resources (FHIR)

Fast Healthcare Interoperability Resources is a standards framework created by HL7. FHIR combines the best features of HL7's v2, HL7 v3, and Clinical Document Architecture (CDA) product lines while leveraging the latest web standards and applying a tight focus on implementation ability. FHIR solutions are built from a set of modular components called "Resources." A resource is an entity that can be uniquely identified and addressed and is a type of resource identified in the specification. The resource contains a set of structured data according to the identified version that it complies with. A resource can be realized using Extensible Markup Language (XML), Resource Description Framework (RDF), or JavaScript Object Notation (JSON) format. These resources can easily be assembled into working systems that solve real-world clinical and administrative problems at a fraction of the price of existing alternatives. FHIR is suitable for use in a wide variety of contexts – mobile phone apps, cloud communications, EHR-based data sharing, server communication in large institutional healthcare providers, and much more. [3]

An example FHIR resource encoded in XML to represent a Patient is presented in the figure below. <*meta*> tag makes the resource easily searchable. Search algorithms can index documents using fields of this tag and can efficiently search relevant documents from millions. The description of the document for human readability is specified in <*text*> tag. <*extention*> tag allows extensibility to additional requirements. This can deliver specific information to applications that can process them, while the same documents will be accepted by other applications that may not have implemented the extensions. Standard data, in this case, is information relating to the patient.

There are several benefits of using FHIR as an underlying architecture to design Health Information Systems and products based on that. FHIR is the most widely accepted standard, so the product will be most compatible with other solutions so that it can be part of an end-to-end implementation. There is a big community providing opportunities to learn the framework, find reference implementations, and use test servers to test out the product under development. It is flexible and adaptable to any use case. It specifies a protocol for all products to follow for representing and exchanging resources so they are interoperable. However, it does not specify the design of the product, for example, how the resources should be stored, searched, and retrieved. This is where companies can build competitive advantage and differentiate their product offerings. There are a lot of open-source systems and component offerings that are compliant with FHIR and can help accelerate building solutions.

Google Open Health Stack is a suite of open-source components and developer resources designed to help accelerate the development of interoperable digital health solutions with a focus on standards, security, and advanced analytics.[5]

Samsung Health Stack is an open-source toolset that provides end-to-end solutions for various medical research and clinician service use cases on Android and Wear OS devices. It includes the App SDK, Web Portal, and a System to support backend services through API endpoints. [6]

4. End-to-End System View

An end-to-end system view of the HIoT application is presented. It can be used to implement solutions for elderly and chronic illness care using many of the off-the-shelf, standards-compliant, and industry-proven components. On the left of the figure is the source of medical data that could be emanated by sensors and wearables on patients, patient and clinical records from hospitals or universities, and information from other related sources like GPS location, etc.

```
<Patient xmlns="http://hl7.org/fhir">
  <id value="glossy"/>
  <meta>
    <lastUpdated value="2014-11-13T11:41:00+11:00"/>
  </meta>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml">
      <p>Henry Levin the 7th</p>
      <p>MRN: 123456. Male, 24-Sept 1932</p>
    </div>
  </text>
  <extension url="http://example.org/StructureDefinition/trials">
    <valueCode value="renal"/>
  </extension>
  <identifier>
    <use value="usual"/>
    <type>
      <coding>
        <system value="http://hl7.org/fhir/v2/0203"/>
        <code value="MR"/>
      </coding>
    </type>
    <system value="http://www.goodhealth.org/identifiers/mrn"/>
    <value value="123456"/>
  </identifier>
  <active value="true"/>
  <name>
    <family value="Levin"/>
    <given value="Henry"/>
    <suffix value="The 7th"/>
  </name>
  <gender value="male"/>
  <birthDate value="1932-09-24"/>
  <careProvider>
    <reference value="Organization/2"/>
    <display value="Good Health Clinic"/>
  </careProvider>
</Patient>
```

Fig. 1 Example of a resource (a patient) [3]

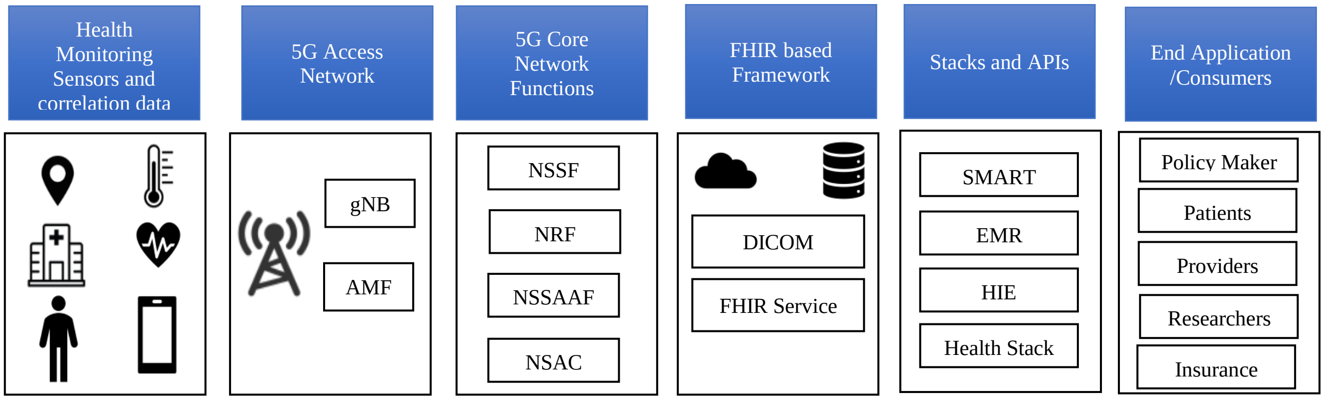

Fig. 2 End-to-end view of a HIoT solution

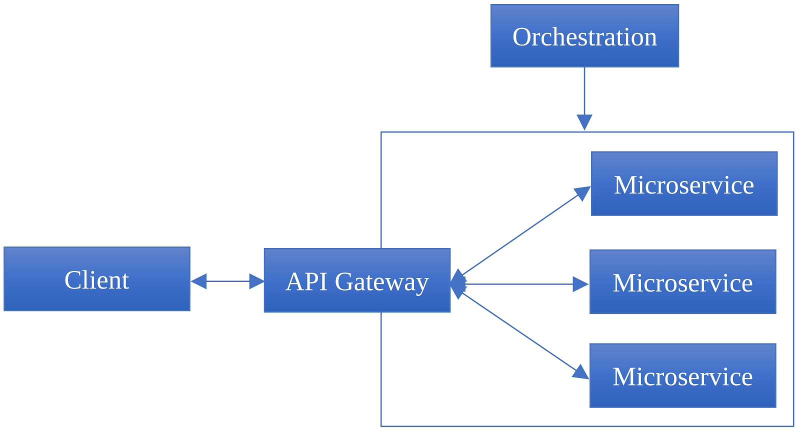

Fig. 3 Microservices design

Such devices will require a robust and reliable wireless access network to be always connected and reachable. 5G cellular networks incorporate many features that are built from the ground up to serve millions of IoT devices at the same time. 5G core the network provides infrastructure for cellular network providers to operate, maintain, and charge for services. 5G Network slicing provides Network As A Service (NAAS) [7]. An instance of a private network can be instantiated based on the specific needs of the application like the number of devices, battery life requirement, amount and frequency of data to be transferred, density of devices, and latency requirement. The next level is the FHIR-based frameworks that provide standards and other benefits, as discussed in the previous section. Applications can take advantage of existing services and platforms in this domain. Open-source health stacks are available that can help bring up products quickly, allowing application developers to focus on business requirements and user scenarios. These systems are flexible and scalable, suited for specialized applications for a particular use case or a nationwide system serving the population. World Health Organisation has specified Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable (SMART) guidelines. It is a comprehensive set of reusable digital health components (e.g., interoperability standards, code libraries, algorithms, technical and operational specifications) that transform the guideline adaptation and implementation process to preserve fidelity and accelerate uptake. SMART Guidelines provide a step-by-step pathway to advance the adoption of best clinical and data practices, even if a country is not yet fully digital [8]. The last box in the figure shows some of the end users of such an application, including policymakers, patients, healthcare providers, researchers, and insurance providers.

5. Microservices Based Design

Microservices is a service-oriented architecture style that divides an application into loosely coupled services that can perform independent tasks that together deliver a function or the whole application. Dividing application functions into services allows the use of pre-existing solutions and collaboration with multiple players. Each service can be deployed by a different company. Services can communicate via RESTful APIs.

The figure above shows the design of microservices. Clients with access can invoke an API to use the functionality offered by microservices. API Gateway directs the request to an instance of microservice and relays the response back to the client. The number of instances of microservices can be scaled up or down depending on the load.

Microservice Architecture is suited for developing distributed systems with diverse functions. HIoT products require solutions from different domains and collaboration with different entities. It will be very difficult and expensive to build an HIoT application as a monolith. Components of the solution can be implemented as independent microservices, and HL7 FHIR can provide the protocol to communicate between these microservices.

An application that provides an end-to-end solution will need to communicate with legacy systems using older versions of HL7 or proprietary protocols. This can be achieved by building a wrapper around such components that can meet the requirements of a microservice and implementing encoders and decoders so that it can communicate with other services using FHIR. In this way, components developed over microservices can be integrated with other components that are not FHIR compliant or do not have a RESTful API to integrate with. However, such an approach may require re-designing parts of the existing software, as it is not sufficient to put a wrapper that can make it communicate using FHIR over RESTful API. It will require flattening the design, software refactoring, and thorough testing. This can be done incrementally by delivering parts of the functionality through the microservice.

6. Geo-Fencing

Geo-fencing is a positioning technology that allows drawing a virtual boundary around a geographic area. A device entering or leaving the geo-fence will trigger signals to the central control system, which can take action based on that. It is enabled by positioning technologies such as GPS, WiFi, cellular, or RFID. Depending on the application and required accuracy, a suitable solution can be used. A 5G cellular mm-wave connection can allow the use of multiple radio frequency beams and compute the Angle of Arrival of these beams to pinpoint the device with an accuracy of a few centimeters. [11]

There can be several applications of geo-fencing and positioning technology in health devices, like efficient and accurate patient check-ins, tracking, and management of hazardous materials.

7. Ultra-Reliable Low Latency Communications (URLLC)

Wireless connections enable several use cases as devices can be free to move and place anywhere based on the need. URLLC has made the use of cellular communication more reliable and with low latency. 5G cellular standards have several provisions to make this happen. Data to be transferred is divided into blocks; each block is encoded, and radio waves are modulated based on the encoded sequence. Transmission time Interval is the period that one radio frame is sent over the air to carry this one block of data.

Due to the lossy nature of the wireless connection, each block of data has to be acknowledged by the receiving side, and in case it gets lost, retransmission has to happen. With URLLC, the radio frame is divided into mini-slots with signals going in both directions to carry the data and the acknowledgment within 1 ms. Other improvements, such as coding and gains from beamforming, have made cellular communication more spectrally efficient and reliable.

With 5G, the cellular core network is more aligned to deployment in the cloud and on general-purpose hardware. The nodes are logical functions that are implemented using a service-based architecture with a standard interface to communication within the nodes and to non-cellular nodes. This allows easier integration with applications that are also distributed over the cloud infrastructure. Multi-Access Edge Computing (MEC) is a technology that puts computing power closer to the device, reducing the round-trip time to critical components of infrastructure. It processes data coming from devices at the network's edge rather than in a distant data center. It is a cloud-based solution that enables real-time applications, supports ultra-low latency, and enhances the performance of 5G networks.

A healthcare application for which real-time and reliable communication links are important can utilize URLLC, which can connect medical devices over the air to the 5G core network through which it can reach the FHIR infrastructure. URLLC, combined with Multi-Access Edge computing, can provide powerful resources for use in a healthcare application. Critical health or clinical data can be transferred and decisions made in real time. A traceability matrix between requirements and features or between features and systems can be used to review different stages of product development.

8. Features, Technology, Systems aspects

There are various aspects to consider when developing products in the healthcare IoT domain. Features, technology, and systems are the primary sections that should be considered. This classification and planning process provides another perspective to think about the solutions. Requirements, design, and test plans can be analyzed using this framework. At each stage of product development, the traceability matrix between these sections can be used to review the completeness and interconnections. It can also be used to prioritize the development of more critical features.

8.1. Features

Successful HIoT products and services should solve real-world problems for patients, providers, policymakers, or whomever they are targeted for. To achieve value for the consumers, the product must provide features that add value for the consumer, like tracking vital health measurements, a dashboard to visualize all the EMRs for a patient, etc.

Features could also be the selling points for the products that companies will advertise. There are complementing features that together solve a problem.

8.2. Systems

The system is a conceptual grouping of functions implemented by hardware resources and software working together. Systems perform defined functions and implement a feature together. Interfaces between systems should be clearly defined, and the format and parameters to be exchanged at all the required events should be specified.

8.3. Technology

HIoT products leverage technologies from different domains like wireless communications, sensors and firmware, health records protocols, cloud storage and retrieval, machine learning, and AI. When designing a product or service, the role of each of these should be well understood, and the industry standards and best practices should be followed.

9. Impact of the Solutions Presented

The success of an application or service in this field depends on a lot of factors, including usability, demographic coverage, conformance to standards and regulations, flexibility, and scalability. Solutions provided in this paper address most of these factors. Service-oriented design will provide flexibility for adapting to changing industry views, customer needs, and government regulations. The microservices-based design will allow scalability. Network slicing will ensure proper integration with the transport and radio access layer that will provide connectivity to the devices and allow reliable, real-time, and bulk transfer of clinical records, user data, and associated data. HL7 FHIR will provide structure, semantics, and seamless exchange of data and allow for de-identification so that user privacy can be maintained and industry standards can be followed. Together, all the solutions provide an end-to-end view connecting the domains involved. Products and services designed with these best practices will be successful in transforming enterprises and resulting in better outcomes for patients and caregivers.

10. Research Gaps

HIoT encompasses so many different domains to provide an end-to-end solution that can change users' lives. Due to the different technologies and interfaces involved, it presents many challenges. One of them is the interoperability challenges. Standardization bodies like 3GPP address some of these for the device hardware and firmware, FHIR for clinical data exchange, and microservices for designing distributed systems. However, that still leaves a lot of interfaces where communication can break and requires more research and prototyping to solve the interconnectivity issues. Security and user privacy is another area where more research is needed. Although the standards have provisions for secure communications and respect user privacy, real-life solutions will depend on how these are used to implement commercial products and services.

More research is needed for Policymaking that will govern the entities involved. The government often follows the industry in setting regulations and guidelines in place. So, significant effort will need to be invested to ensure that commercial devices and services that they offer to the users are indeed designed to provide secure connections and that the user is duly informed about the data being collected and transmitted.

11. Conclusion

This paper provides an introduction to various technologies required to design a HIoT application that could be used for mission-critical applications, including care for elderly and critically ill patients. A well-designed application can result in better patient outcomes by providing stakeholders access to comprehensive information promptly. It can reduce patient costs and improve user experience while making the whole system more secure. It presents an end-to-end view of how such an application can be implemented, what interfaces and challenges are involved, and how some of them can be overcome. URLLC and Geo-fencing can enable compelling use cases in the healthcare field. Further, it specifies some research gaps where more investment is needed.

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