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ASSESSING BARRIERS AND ENABLERS FOR WEARABLE HEALTH TECHNOLOGIES TO IMPROVE DATA QUALITY IN EHR USING HL7 FHIR

Master's Thesis

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TALLINNA TEHNIKAÜLIKOOL
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TAKISTUSTE JA VÕIMALUSTE HINDAMINE PARANDAMAKS ANDMETE KVALITEETI ELEKTROONILISTES TERVISEANDMETES KASUTADES HL7 FHIR STANDARDIT

Magistritöö

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BSc. Pharm. MSc.

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Author's declaration of originality

I hereby certify that I am the sole author of this thesis. All the used materials, references to the literature and the work of others have been referred to. This thesis has not been presented for examination anywhere else.

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Abstract

Data generated by wearable devices can play a very crucial role in improving the quality and quantity of data to be available in Electronic Health Records. This depends if seamless data transfer mechanism can exist between Wearables and EHR systems. Data captured by various wearable technologies including tracking and monitoring devices can provide health professionals with various data to empower making the best clinical and care decision. However, the direct health information exchange from wearables to Electronic Health Records is yet limited due to lack of interoperability as well as data quality issues such as inaccuracy, unstructured representation, and missing values.

Fast Healthcare Interoperability Resources is a standard developed by HL7 which has many potentials for health information exchange from wearable devices to EHR and anticipated to be the next generation standard but the suitability and practicality of using FHIR standard has not assessed fully yet. Currently, there are over 90 resources published by HL7 which cover medication, diagnostics and other clinical factors but none of these resources are especially designed for wearables data.

The first phase of this thesis work is to investigate the challenges and barriers towards the transferring of health data directly from the wearables to the EHR. In this section, an analysis shall be performed based on the existing literature and scientific research. That would be followed by assessing the suitability of FHIR for various wearables to be the next generation for healthcare information exchange. This will address also all known for successful use of FHIR in Wearables and supported by use-cases.

At last, a simplistic implementation guide based on use case shall be put together to summarize the effort of the first two items with the assistance of industrial experts and professionals to leverage the full potentials of the wearable-generated data when put together with other data stored in EHR for better informed care decisions and establish a continuous data feed into EHR.

This thesis is written in English and is 76 pages long, including 6 chapters, 19 figures and 4 tables.

Annotatsioon

Kantavate seadmete genereeritud andmed võivad olla väga olulised elektroonilistest tervisekaartidest kättesaadavate andmete kvaliteedi ja kvantiteedi parandamisel. See sõltub sellest, kas kantavate ja EHR-süsteemide vahel võib olla sujuv andmeedastus mehhanism. Erinevate kantavate tehnoloogiate, sealhulgas jälgimisseadmete abil kogutud andmed võivad anda tervishoiutöötajatele mitmesuguseid andmeid, et anda parim kliiniline ja hoiualane otsus. Otsene tervisealase teabe vahetamine kantavast tehnoloogiast elektroonilistesse tervisekaartidesse on siiski piiratud koostalitlusvõime puudumise ning andmete kvaliteedi probleemide, näiteks ebatäpsuse, struktureerimata esindatuse ja puuduva teabe tõttu.

Kiirete tervishoiuteenuste koostalitlusvõimaluste vahendid on standard, mille on välja töötanud HL7 ning, millel on palju võimalusi tervisealase teabe vahetamiseks kantavatest seadmetest EHR-sse ja, peaksid olema järgmise põlvkonna standardid, kuid FHIR-standardi kasutamise sobivust ja otstarbekust pole veel täielikult hinnatud. Praegu on HL7 avaldanud üle 90 vahendi, mis käsitlevad ravimeid, diagnostikat ja muid kliinilisi tegureid, kuid ükski neist vahenditest pole spetsiaalselt kantavate andmete jaoks mõeldud.

Selle lõputöö esimene etapp on uurida väljakutseid ja tõrkeid terviseandmete ülekandmise kohta otse kantavatelt seadmetelt EHR-le. Selles osas tehakse analüüs olemasoleva kirjanduse ja teadusuuringute põhjal. Sellele järgneb FHIR-i sobivuse hindamine erinevatele kantavatele tehnoloogiatele järgmise põlvkonna tervishoiualase teabevahetuse jaoks. See käsitleb ka kõike teadaolevat FHIR-i edukaks rakendamiseks kantavates tehnoloogiates, mida toetavad kasutusjuhtumid.

Lõpuks koostatakse kasutusjuhtumil põhinev lihtsustatud kasutusjuhend, et kokku võtta kahe esimese elemendi jõupingutused tööstusekspertide ja spetsialistide abiga, et kasutada ära kogu kantavate andmete potentsiaal, kui need koos teiste salvestatud andmetega teadlikumaid hooldusotsuseid ja luua pidev andmevoog EHR-i.

See lõputöö on kirjutatud inglise keeles ja on 76 lehekülge pikk, sealhulgas 6 peatükki, 19 joonist ja 4 tabelit.

List of abbreviations and terms

ECG	Electrocardiogram
EHR	Electronic Health Records
FHIR	Fast Healthcare Interoperability Resources
HL7	Health Level 7
HIE	Health Information Exchange
REST	Representational state transfer
API	Application Programming Interface
EAI	Enterprise Application Integration
OS	Operating System
ICD 10	International Classification of Diseases
LONIC	Logical Observation Identifiers Names and Codes
HITSP	Healthcare Information Technology Standards Panel
CDA	Clinical Document Architecture
EMR	Electronic Medical Records
RQDA	R-based Qualitative Data Analysis
HIPAA	Health Insurance Portability and Accountability Act
GDPR	General Data Protection Regulation
FDA	Food and Drug Administration
UI	User Interface
OMH	Open Mobile Health
SNOMED	Systematized Nomenclature of Medicine Clinical Terms
ENTREQ	Enhancing transparency in reporting the synthesis of qualitative research

Table of contents

List of figures

List of tables

1 Introduction

1.1 Background

In the 21st century, the world has experienced incredible developments, innovations, and adoptions especially in the arena of digital health. The emergence of technology brought valuable innovative products such as wearable devices and connected the gaps in order to resolve outstanding health challenges through information and communication technology intelligence. In the last few decades, there has been immense developments observed in the healthcare industry including robust wearable devices that meticulously track and monitor the day to day healthcare activities substantially. Furthermore, the chief idea behind the technological transformation is to empower the health of individuals.

It has been researched that there are more than 325 million people who have wearable connected devices in the world [1]. In the recent past, the adoption of wearable devices became widely popular and experienced a global trend. Bove (2019) stated that adoption of wearables doubled from 2014 to 2016 and has been continuously growing rapidly [2]. Distinct groups of society use wearable gadgets for various purposes such as monitoring weight loss, tracking daily steps, setting targets to burn daily consumable calories, impact of physical exercise on health, heart rate monitoring and alter diet plan in order to become more healthy and physically fit respectively. The wearable activity tracker technologies are extremely beneficial for those patients or individuals who want to track their physical activities in order to maintain their health and monitor their overall movements. Moreover, mental health applications in wearables monitor mental health behaviour [1].

It was found that 9 out of 10 (87%) of physicians have already adopted Electronic Health Records (EHRs) in US [3] and 96% of the GPs across Europe use EHR as a part of their daily routine. This is in order to capture better patients' data and enhance effectiveness, patients' satisfaction, care coordination, decision outcomes [4]. However, currently wearable health technologies data is not a part of EHR but can facilitate instantaneous data tracking which envisage rapid recovery procedures, reduce time and cost for hospitals and enable medical practitioners to monitor patient's health status in more effective manner if integrated with EHR.

1.2 Statement of Problem

Data from wearable health technologies into EHR can play a vital role in proper diagnosis and improvement of patient's health. This is because such valuable data can help healthcare providers make better decisions about patient's health, provides better services and improve care coordination. It has been studied that nowadays, many patients also expect healthcare providers to use this wearables data during treatment [2]. At present, this data cannot be integrated to EHR due to lack of interoperability and only patients can visualize and track their activities and quantify its output. The healthcare professionals depending on EHRs are unable to view patient's health data with other health records and provide more effective treatment and health outcomes [5]. Integration of health data from wearables to EHR is relatively new and healthcare systems are lacking technologies to extract this data from patients' wearable devices and integrate to EHR. There are closed communication methods used by few EHR vendors but not so effective in terms of communication and data exchange due to lack of interoperability [6].

FHIR, HL7 is one of the latest interoperability standards in today's world and widely known for health information exchange but it's suitability to exchange wearables data has not been assessed and fully demonstrated yet. There are 93 FHIR resources published by HL7 but none of these resources was specifically designed for wearables data. It has been analysed that there is numerous potentials to send this wearable-generated data to EHR via HL7 FHIR [7].

1.3 Aim of the Study

In this section, the main aims of this research have been identified which can help to conduct this study. Following are the main objectives and aim of this research study:

- Assessing the barriers and enablers towards transferring of health data from wearable devices to EHR

- To evaluate the suitability of FHIR for integrating wearables data to EHR

1.4 Research Questions

In this section, the research questions have been stated which will help to achieve the main aim of this study:

Q1: What are the existing barriers and enablers in terms of interoperability and quality of data that is being exchanged from wearables to EHR?

Q2: What is the suitability of Fast Healthcare Interoperability Resources (FHIR) to enabling exchange wearable-generated data to EHRs?

2 Literature Review

2.1 FAIR Principles

FAIR is a set of guiding principles which can be used for the management and handling of scientific data and published in 2016. FAIR aims to define good practices of data sharing and improve findability, accessibility, interoperability, and reusability of data. The FAIR technique is based on machine actionability which means that the information system will find the data, access, exchange, and re-use it without any major human support. Furthermore, human tending to rely on computational ability to handle data which subsequently surpass the volume and incur complexity respectively [8]. In this thesis, the fair principles will be considered as a set of principles while evaluating the suitability of FHIR standard for sharing the data from health wearable technologies with EHRs.

The first step of FAIR principles is to ensure findability which means that both data and metadata should be easily findable for both humans and information systems. Metadata is essential component in FAIR process because it facilitates to discover datasets and services. Both data and meta data should have unique and consistent identifier to make it easier to find required data. The second principle is related to accessibility which makes data retrievable for the users only with proper authentication and authorization by using standardized communication protocols. If the data is no longer available, then meta data is still accessible. Interoperable is the third principle of FAIR because the data is required to be integrated with other applications and systems. To make data interoperable, formal, universal, shared and broader applicable language or standard is used for the representation of knowledge. The last principle of FAIR is optimizing the reusability of data which is also the main purpose of FAIR guiding principles. In order to acquire this principle, the data must be described richly with relevant and accurate attributes [8].

2.2 Application of Wearables Health Data in EHR

Electronic Health Records are basically a digital version of patients' health records which captures and stores the health data electronically and has been widely adopted worldwide. The EHR is a software application that comprises of patient documentation, billing, clinical decision support and Electronic Health Records include data of patients' demographics, medical history, symptoms, laboratory data, radiology reports, diagnosis etc. This data is usually created, modified, and used by healthcare professionals in clinics and hospitals. HL7 is a data transfer protocol technology standard that is being used by healthcare providers to communicate and share patient's data in EHR with other health organizations via HIE [9]. There are several benefits of adopting EHRs in healthcare organizations such as better access to health records and medical history, avoid medical errors, prevent loss of documents, improve quality services, facilitates better informed clinical decisions, enhance patient safety and reduce administrative and management cost [10], [9].

Health Wearable Technologies are widely available and designed to collect and analyse data in real time. These technologies include fitness trackers, smart watches, ECG monitors, blood pressure monitors, glucose monitors, sleep trackers, cardiovascular defibrillator, and many other devices. Some of the measurable health parameters which could play a vital role in EHR are blood pressure, pulse rate, glucose level, body temperature, heart rate and sleeping hours. Furthermore, the prevailing health data from these wearables to EHR is robust and valuable which can be useful in clinical diagnosis and research. Additionally, these health wearable technologies can support as healthcare preventative tool as well as telemedicine [11]. According to a research conducted in 2019, it is predicted that 61 million people will use wearable devices in order to track their health data [12]. Moreover, a survey was conducted in April 2019 by Lisa Hedges for a wearable medical devices report and it can be seen in the image below that 97% of participants were quite interested in sharing the health data gathered by wearable medical devices with health providers [13]:

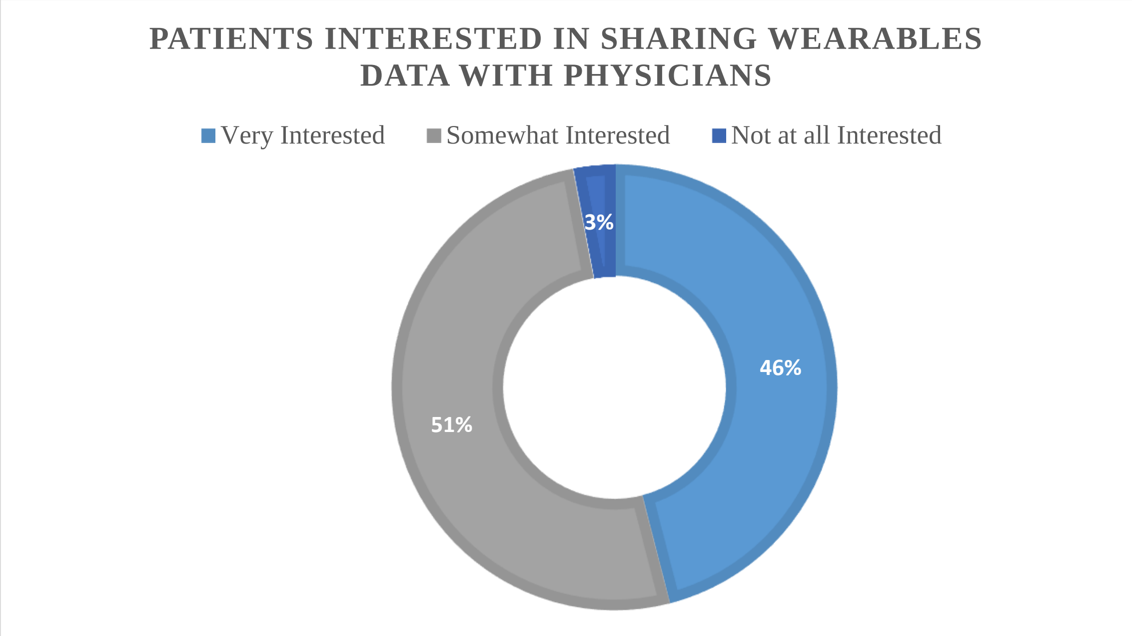

Figure 1: Patients interested in sharing wearables data with physicians [13]

The same survey was concerned about patients' likelihood of choosing doctors who use wearables over those who don't. It can be seen in the below figure that 92% of the respondents prefer doctors who use wearable health technologies to view patients' health and include these devices in their care plans:

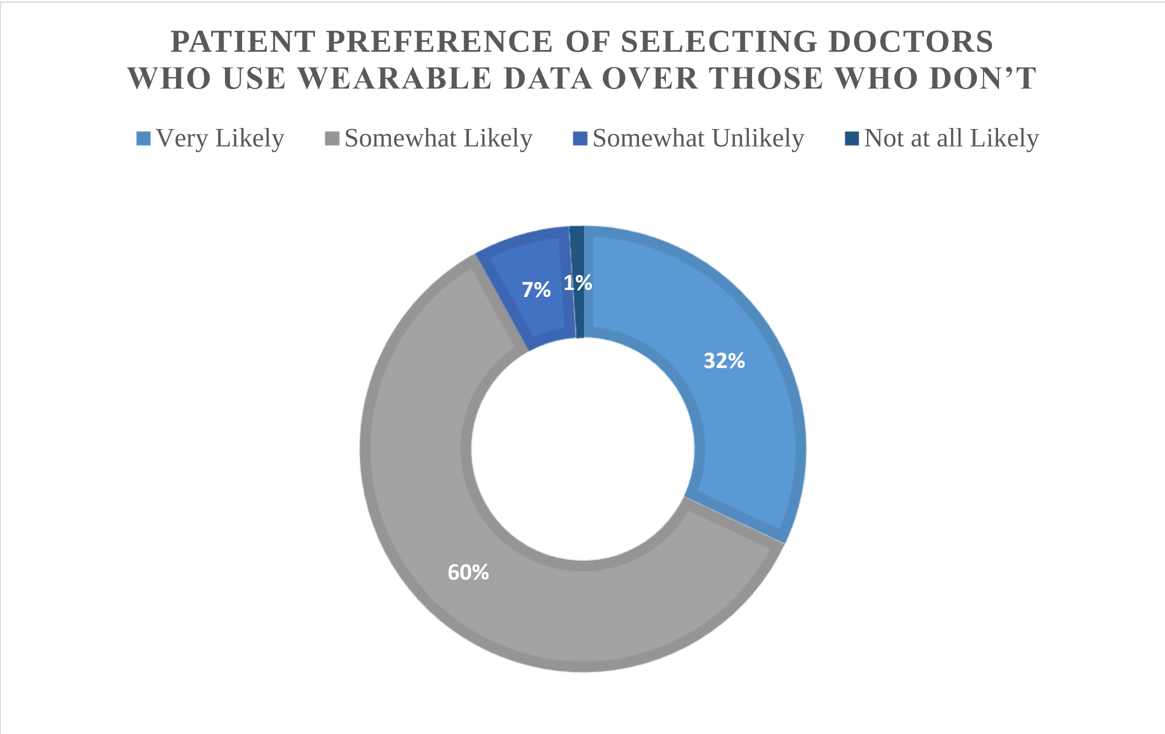

Figure 2: Patient Likelihood of Selecting Doctors Who Use Wearable Data [13]

In the traditional patient encounter with healthcare professionals, patients must visit the health care institution to provide and record health readings so doctors and physicians can observe patient's condition and provide care plans, however, it's not possible to capture or analyse real time health data of patients. The essence of using health technology wearables is to provide enormous amount of data at minimal effort, time and visits. In addition to that, the ability to capture, analyze and integrate data into EHR can provide more accurate and comprehensive assessment of health situation of patient. Undoubtedly, these wearables can support healthcare providers to have a better insight of patients' health outside examining centres, hospitals and clinics and can also assist in remote patient monitoring and preventions against chronic illness [14].

The impact of rehabilitation and health maintenance via data from these wearable gadgets has enormous benefits. For instance, during rehabilitation the patients will be under exclusive monitoring with the support of wearable devices and it will enhance the process efficiently. A study conducted in Cedars-Senai hospital where post-operative healthcare professionals used wearable health technologies with patients to track and monitor recovery times of patients after having their major surgery. This technology not only helped to monitor patients' steps and foster engagement but also motivated them during recovery process [14].

Data from wearable health technologies is accurate, systematic, collected electronically and analyzed directly which means that it is not prone to mistakes like manual reporting. It has been also identified that if this data is integrated to EHR, it may reduce number of appointments as patients will avoid unhealthy behaviours, adopt healthy lifestyle and take prescribed medications regularly because they believe that their behaviours are continuously monitored [14]. Moreover, this data can help in chronic diseases management such as hypertension, diabetes and obesity where the behaviours of patients should be regularly monitored and require significant changes in lifestyle and behaviour. For example, it can be analyzed from activity tracker wearable if the patient is following exercise routine to achieve healthy outcomes such as weight loss and lower sugar levels. Here, the role of healthcare professionals can be to motivate the patient to maintain their healthy activities and improve their heath by choosing healthy lifestyles.

In the below figure, the results of the survey can be analyzed where the patient were asked how the wearables data could impact their lives if the doctors start incorporating wearables data in their treatment and care plans:

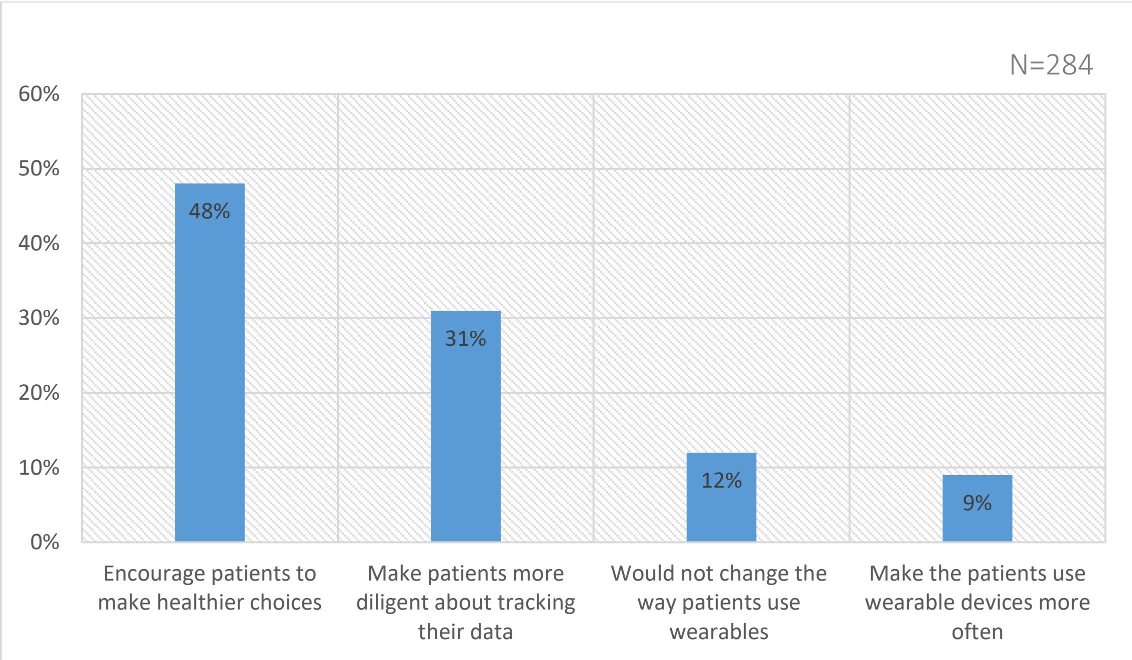

Figure 3: Impact on Patients of Providers using Wearables Data [12]

2.3 Integration of Wearable Technologies into EHR

In this section, distinct integration solutions and possibilities will be discussed to integrate wearable health technologies data into EHR:

2.3.1 Health Information Exchange

Electronic Health Records are the main source of patients' data and used by healthcare professionals to make care decisions. The data captured by EHRs such as medical history, medications, images, diagnosis can be shared with distinct healthcare systems across organizations. Interoperability can be achieved by leveraging standards which allow different organizations to share, communicate and integrate health data. HL7 V2 and V3 are very well-known messaging standard which are being used for the communication of EHRs and FHIR is the latest adopted HL7 framework being adopted by EHR providers (e.g. EPIC, Cerner, etc.). Many of EHR vendors ensure their software products are interoperable but there are several interoperability challenges in sending health data from wearables to EHR [15].

It’s not possible to directly record quantified activity data from wearables such as heart rate, blood pressure, calories, steps etc. into EHR due to lack of standards or provision in the current healthcare standards being used in the organizations. Moreover, data generated from wearable health technologies can be synchronized to health organization’s data repository via mobile apps such as Fitbit. It is possible for standalone or customized systems to access this data from repository using REST API but this data might be stored in unstructured or incompatible format to integrate with EHRs. In this case, the data from the wearables will be stored in non-digitalized format using logbooks and cannot be used for evidence-based practice and decision making [15].

Nowadays, there are several analysis and decision support tools used in the healthcare organizations integrated to EHR. At present, the physicians and doctors can analyze patients’ data and statistics, but the implementation of these tools is different in distinct organizations and healthcare systems. As wearables are the source of large amount of heterogenous data, it is a demand of current times to develop analytical, decision support and additional tools which are compatible with existing healthcare systems and fulfil the needs of healthcare professionals. This change and development in healthcare systems can also create another concern of security and privacy as this will open a way to capture and analyze data from distinct sources. Moreover, it is quite challenging to develop such tool which is adoptable and open to different healthcare systems containing different databases. Similarly, standardization is not developed specifically for wearables data and many standards are being used in different healthcare systems [16].

In the below figure, it illustrates how data are captured in wearables or other paper-based logs cannot be consumed by EHRs when interoperability is neglected:

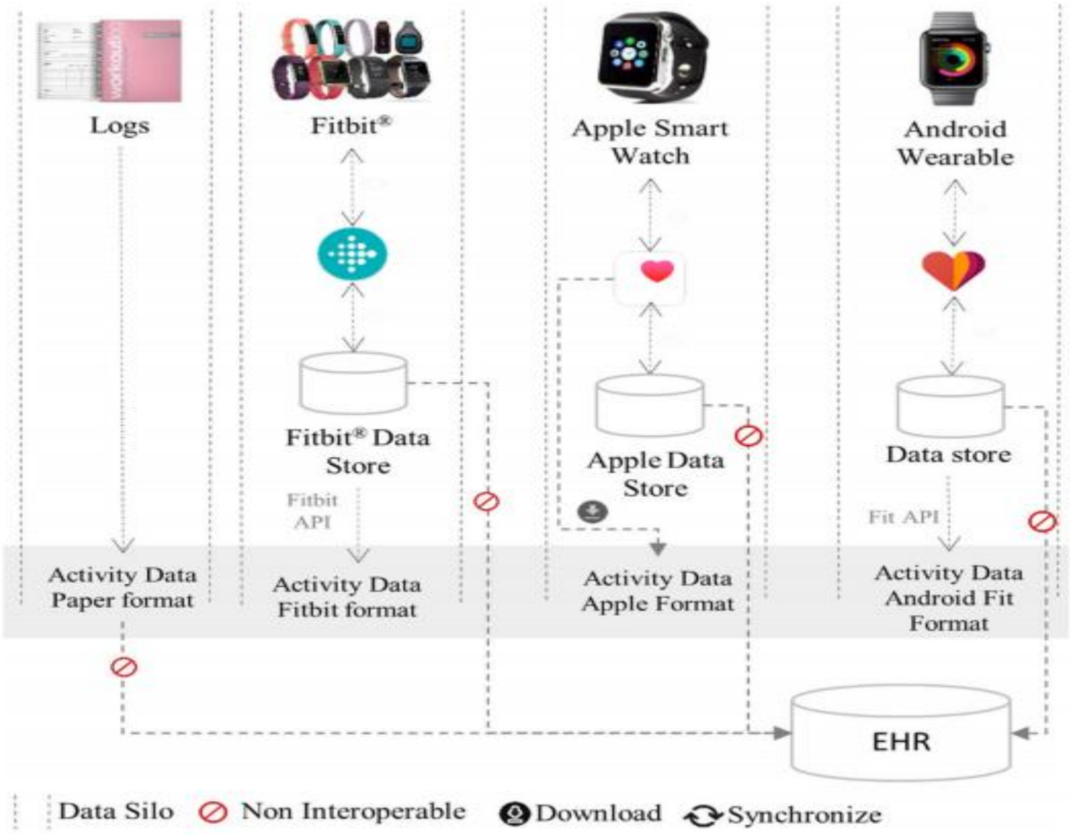

Figure 4: Interoperability Issues to Integrate Wearables Data into EHR [15]

2.3.2 Middleware

In the previous section, few challenges were discussed related to directly transferring data from wearables to EHR. In this section, Middleware or Aggregators will be discussed as a possible communication to transfer wearables data to EHR.

Middleware is an intermediary software that enables interaction between distinct applications in healthcare and essential in enterprise application integration (EAI) so different healthcare application can share and communicate data with each other simultaneously. Middleware also solves one of the interoperability problems by developing a platform to connect various EHRs with other health systems and developing a single interface to view all of the patient's data in an effective way [17].

It was seen in previous research that few health monitoring wearable devices connected to mobile application support middleware or aggregator such as Shimmer, Glooko and Tidepool. The main aim of these middleware is to provide standardized format which can be readable for EHRs and transfer of data from wearables to EHR. Google Fit and Apple Health are known as main health tracking and monitoring platforms associated with mobile OS i.e. Android and iOS. Health platforms basically store health data from wearables which is received via smartphone application or 3rd party applications. These third-party applications such as myFitness Companion, MyFitness Pal and many others basically collect and combine activity data from multiple wearable devices cloud services and send them to health platforms and middleware. Besides these health platforms, server-based solutions are available ande known as middleware are used to collect, analyze and process health data from health platforms and third-party API providers. In the below diagram, data flow between these systems can be seen thoroughly:

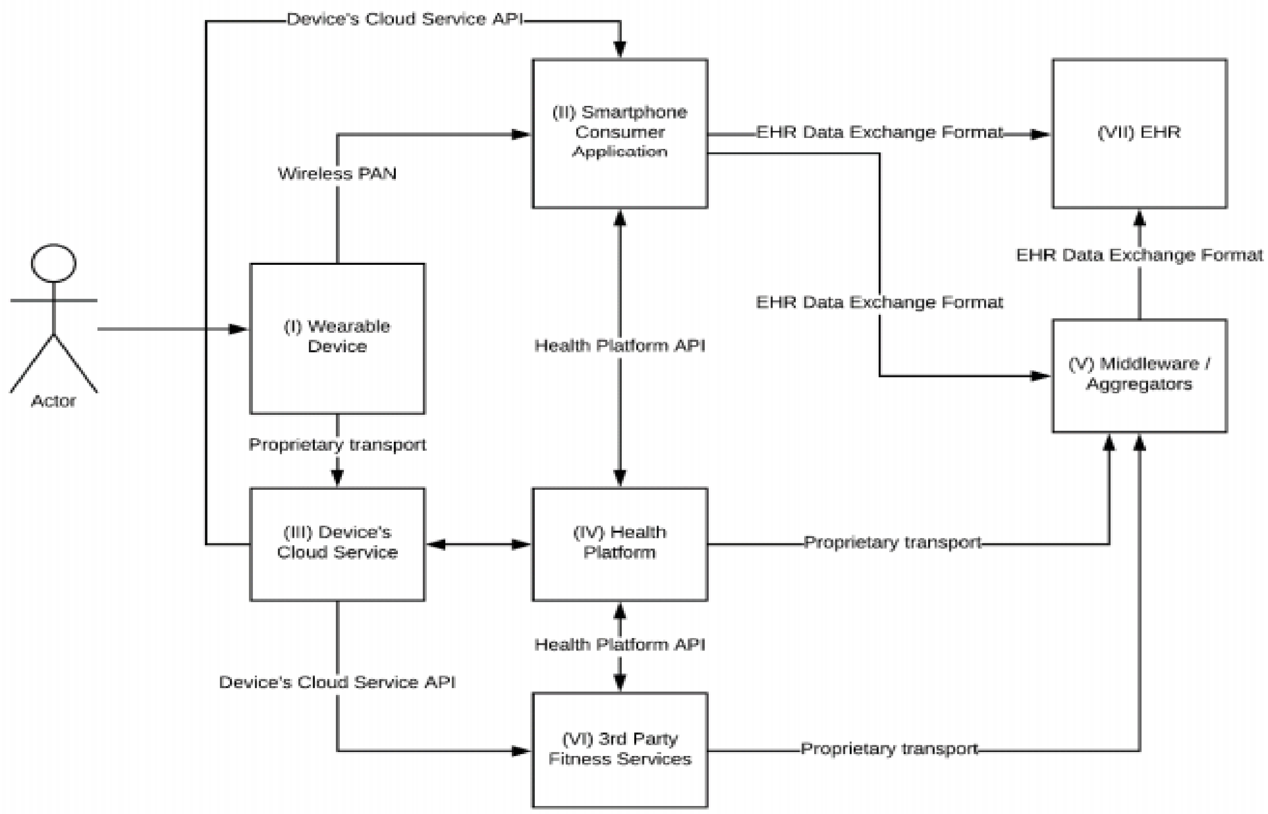

Figure 5: Data flow between different components in wearable devices [18]

It was identified that those middleware do not support all the wearable devices and the main cause of this problem is limited access to user data that might be available on these wearables and hinders the further use. Shimmer is supported by only 37% of wearable devices and this data can be integrated to EHR. Another middleware, Tidepool is supported by only 3% of wearable device family and provide centralized health data from wearables in a cloud-managed solution but unfortunately this solution doesn't integrate wearable data to EHR. Moreover, Tidepool must set up individually per user and requires specific technical knowledge. Both middleware, Shimmer and Tidepool are open source projects and continuously being developed and improved by developers. Similarly, another middleware named as Glooko is supported by only 19 wearable devices and only targeting diabetic patients and diabetes management. Glooko provides mobile application that basically integrates with various diabetes related wearables and a cloud based platform is used to store and share this captured data. APIs can be used to integrate this data with EHRs as well but the API documentation is not openly available [17].

2.3.3 Fast Healthcare Interoperability Resources

Fast Healthcare Interoperability Resources known as FHIR is an international standard that was developed by Health Level Seven International (HL7) which is a non-profit organization that was established to regulate exchange of information in healthcare industry and standardized the interoperability among distinct information systems. FHIR subsequently has become a key player when it comes to exchanging data in healthcare arena and serve as a next generation practice in order to facilitate wellness data and patient health records. Apparently, the relationship of patients' health records and wellness data broaden the possibilities to transform the healthcare industry. However, the adaptability of FHIR in accordance to wellness data has not completely demonstrated yet. According to a research conducted in 2015, it was documented that 90 FHIR resources were published by Health Level Seven International (HL7) respectively. At present, there are resources such as diagnostics, medication, administration, infrastructure and other clinical resources for device interactions but apparently there is no resource particularly dedicated for wellness data [7]. Therefore, the scope of this research is to examine the adaptability of FHIR related to wellness data.

The chief idea to introduce FHIR was to reduce the technical obstacles that are related to the prevailing healthcare standards and optimize the practices of HL7 in order to effectively deploy the semantically rich HL7 RIM technique. Additionally, increasing developments in the technology arena, exponentially growing consumer usage with android, iOS, IOT and convenience of RESTful web services consolidates a lean standard in order to optimize the acquisition of wellness data via FHIR.

The core element of FHIR standard is a resource which can be perceived as a single healthcare container. Apparently, these containers or blocks are required to be aggregated and form the required model. Distinct FHIR resources are combined to attain a purpose such as formation of EHR or collect mandatory patient information in order to share. The default technical architecture of FHIR supports REST web services which enables the users or system to gain access to the resources over the secure HTTP protocol. As shown in the figure below, there is a representation of user health data using FHIR resources which includes observation, medication, procedure, immunization, Care plan, condition, diagnostic reports, allergies etc [15].

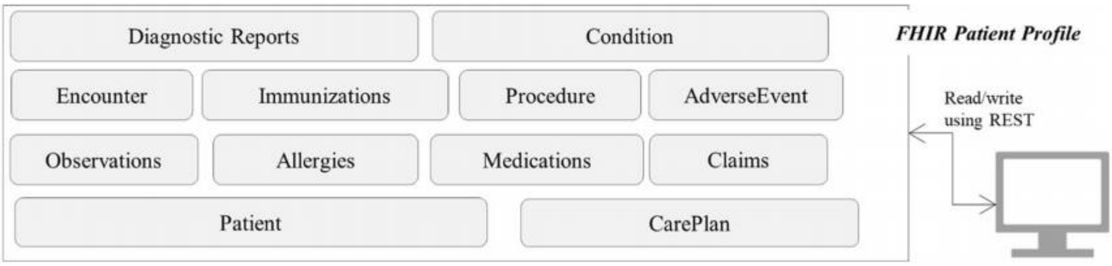

Figure 6: Using FHIR resources to build a patient profile [15]

The distinct features of FHIR standard includes modular plug-n-play approach that was achieved through utilization of resources in order to establish a patient user profile. Secondly, the integration of REST web services into the FHIR standard enables the resources to establish the communication via HTTP. Thirdly, the lean learning curve which plays a subsequent role in contrast to the prevailing standards and makes FHIR far more adaptable in terms of interoperability. As per the technical architecture, the FHIR resource is a class uses attributes with an assigned data type. Furthermore, the attribute type can be classified as datatype such as double, integer etc. or FHIR datatypes such as name, address and code or any resource [15].

One of the key features of FHIR is that is highly extensible and can be profiled based on the local need of the health organization. This is by changing the existing resource or adding a new one to meet any existing or new healthcare system requirements e.g. collecting wearables data.

2.3.4 Open EHR with FHIR

FHIR standard emphasis on HIE between existing systems while openEHR is an approach used in building new applications which automatically removes some interoperability barriers by reflecting the OpenEHR data model directly in the database of the applications. However, FHIR is basically developed to exchange health data catering for various setups of the applications and middleware as well as the data model. FHIR can still be used to model and store data but if there is complexity in datasets then openEHR is recommended approach. For example, observation can only be used as a generic resource in FHIR but with openEHR it’s possible to model different types of observations. Nowadays, there are many health organizations and vendors which are developing application based on OpenEHR standard [19]. OpenEHR is a platform approach for modelling clinical data that is created and utilized in healthcare processes rather than specification or set of standards [20] [21]. Reference Model is an information model in openEHR that includes logical structure rather than physical data schema of patient demographics and EHR. Basically, this interoperable data requires a reference model and EHR data follow reference model. Furthermore, there is a library of reusable and independent data groups which is called archetypes and required to present data element in clinical data. All openEHR systems are developed with the help of templates which is a way to create datasets from data elements present in library in order to implement specific use cases [22].

OpenEHR is an open standard which offers management, storage, exchange, and retrieval of EHRs. It has been researched that OpenEHR defines data structure related to physical activity in PhysicalActivity archetype which captures general activity and physical exercises data. Furthermore, OpenEHR is compatible with FHIR and customized to use with FHIR resource [15]. If there is a requirement of data exchange between openEHR system and non openEHR vendor systems, then it’s compulsory to use interoperability solution such as FHIR to share data between such systems [23].

3 Methodology

In this chapter, research methodologies are stated that have been used to conduct this thesis:

1. ENTREQ for reporting systematic review
2. Thematic Synthesis of Qualitative Research
3. Expert Opinion regarding FHIR implementation to access wearable health data in EHR
4. Use-case for Data Mapping of wearable-generated data to FHIR resource

3.1 ENTREQ - Enhancing Transparency in Reporting the Synthesis of Qualitative Research

ENTREQ framework was developed to facilitate researchers and reviewers in reporting of synthesis of qualitative research. The syntheses of various qualitative studies combine data across different sources and provide evidence for the evaluation, development and implementation of health intervention. The reporting guidelines of ENTREQ (Enhancing Transparency in Reporting the Synthesis of Qualitative Research) can be useful for qualitative systematic reviews. The Enhancing Transparency in Reporting the Synthesis of Qualitative Research consists of 5 main groups named as introduction, methods, literature search and selection, appraisal and synthesis of findings [24].

The systematic review of this study was performed with ENTREQ methodology and the given checklist and 4 phases flow diagram was used to determine relevant articles for the study. At the initial stage, the articles were found in all the well-known journals databases and conferences with the identified keywords. The next step was to examine all the titles and abstracts and then exclude all the articles which do not meet inclusion criteria. In the end, full text of these articles was analyzed thoroughly and only relevant studies were included for systematic review.

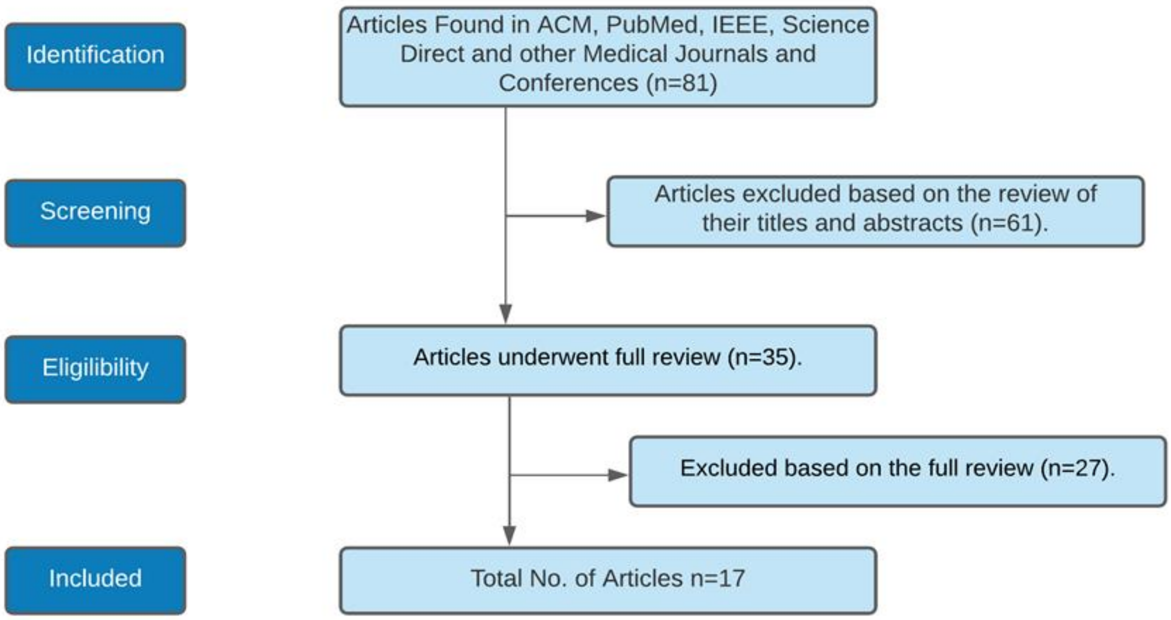

Figure 7: ENTREQ flow diagram of systematic review

3.1.1 Articles Selection for Systematic Reviews

The main aim of this study is to examine the challenges and issues in transferring data from wearables to EHR and these barriers will be identified with the help of existing literature and articles. The results based on the systematic reviews of the selected articles will be presented in a refined way to make it clear and easier to understand the current interoperability and data quality issues in existing approaches. Later, the suitability of FHIR standard implementation to capture wearables data and transfer this data to EHR will be analyzed. In order to perform this systematic review, the inclusion and exclusion criteria has been identified first and ENTREQ methodology was followed based on this inclusion and exclusion criteria. On the basis of detailed information and qualitative data gathered from systematic reviews, thematic analysis was performed in the end to combine and integrate findings of selected qualitative studies.

3.1.2 Inclusion and Exclusion Criteria

In order to set the inclusion and exclusion criteria for the articles selection, the relevant keywords were identified to search the articles from the scientific databases such as PubMed, Science Direct, IEEE, ACM, Medical Journals etc. Two sets of keywords were recognized and ''AND'' boolean operator was used between these keywords to achieve the required articles results. The inclusion criteria of articles were limited to English language. Secondly, the selected research must be published in an academic journal or conference paper. Furthermore, to enhance the quality of research and attain relevant developments that are related to wearable devices the selection criteria was narrowed down to those papers that were published since 2011.

In the below figure, the identified keywords, inclusion/exclusion criteria and the search outcomes can be observed:

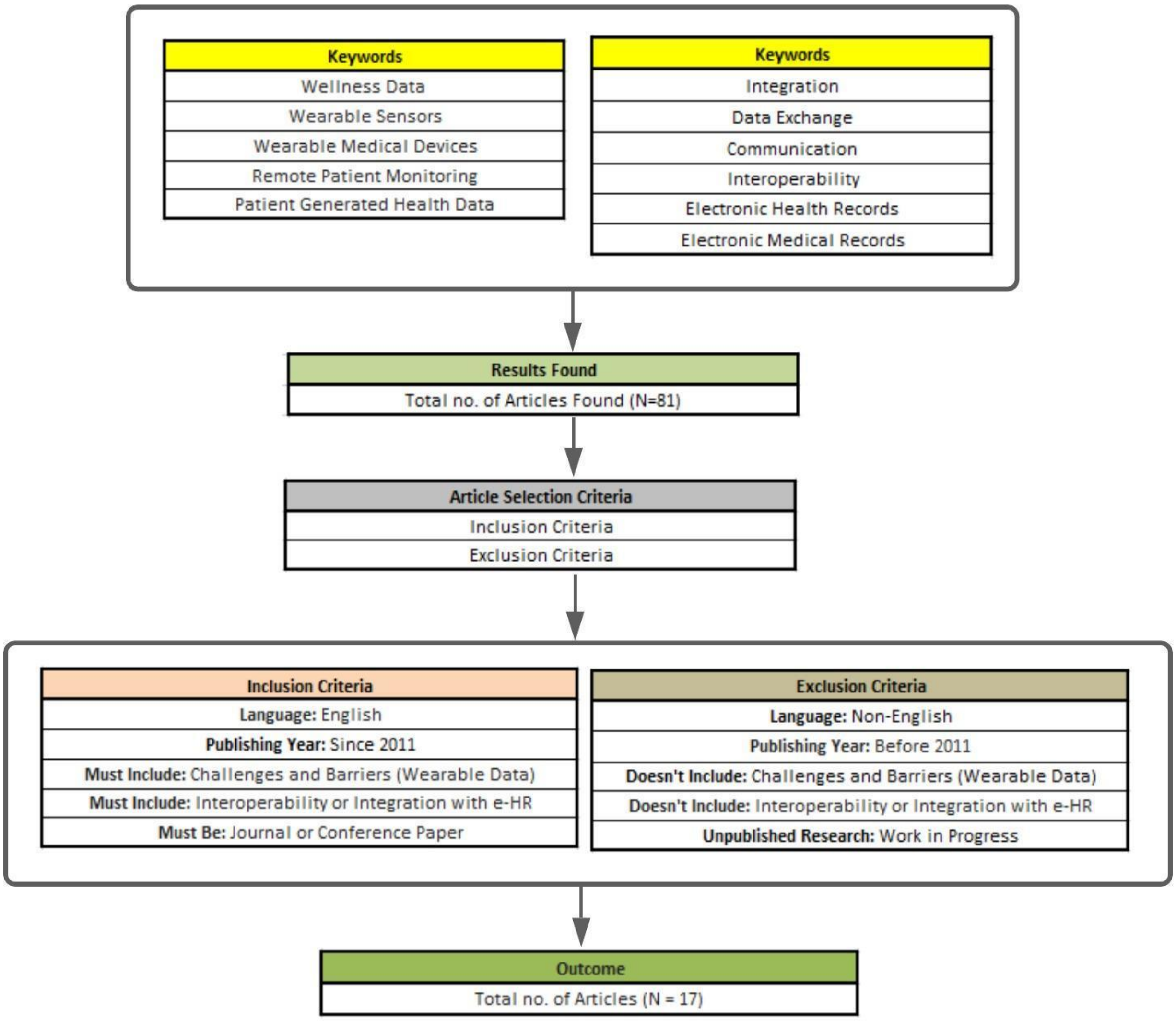

Figure 8: Inclusion and Exclusion Criteria

3.2 Thematic Synthesis of Qualitative Research

Thematic synthesis is one of the well-known methods used to analyze data in primary qualitative studies or research and consist of three phases i.e. coding of text 'statement by statement', developing descriptive themes and finally creation of analytical themes. The development of descriptive themes phase is more related to primary studies and analytical themes phase creates new hypotheses and explanations [25].

In this thesis, thematic analysis is used for systematic reviews to identify themes or patterns and integrate the findings of different studies. Thematic synthesis is a quite systematic and comprehensive approach which facilitates to make thorough and composite analysis of qualitative data which can be extracted from the selected articles. In addition to that, thematic analysis will be conducted with open-source software known as RQDA. The text from selected studies was extracted into this software RQDA and analyzed line by line to develop descriptive and analytical themes in order to determine the findings of different studies, visualize the insights and identify the differences and similarities in outcomes.

3.3 Expert Opinion

During this thesis, distinct e-health experts Simona Carini (Co-Founder of Open mHealth and Professor of Medicine at UCSF), Eric Haas (Health eData expert) and others from OmHealth were contacted. These experts are currently working on "OmH on FHIR" project and researching the components and steps required to implement FHIR to make health data from wearable technologies accessible in EHR. Furthermore, these experts provided their submitted AMIA conference proceedings, recorded presentations focused on OMH to FHIR, Open mHealth to HL7 FHIR implementation guide and OMH to FHIR mapping spreadsheets which were quite useful to identify the capability of FHIR standard and to map common schemas with FHIR resource in the discussion section of thesis.

3.4 Use-case for Data Mapping of wearable-generated data to FHIR Resource

Data mapping is an essential process of data integration and data migration. In this process, the data fields from data source of one system is matched with target fields of another system [26]. Furthermore, data mapping is a method to bridge two different systems or data models so the data can be useful after the transformation at the destination. This process deals with both structured and unstructured data formats [27].

Data mapping prevents data errors, disparities, inconsistencies, and inaccuracies in the data transformation phase. Moreover, this process also assists standardization of data make destination system easier to understand and enhance the quality of data for better data analysis [26]. This process of data mapping can be used to collect healthcare data from distinct systems such as Electronic Health Records, Electronic Medical Records and other sources of data in order to health data exchange and other patient information. There is various list of standards such as ICD 10, HL7, CDA, LONIC, SNOMED etc. published by Healthcare Information Technology Standards Panel (HITSP). These standards are being developed to achieve interoperability and achieving accuracy [28]. Moreover, the data mapping process supports healthcare professionals to view and share patients' data and achieve better outcomes.

There are various wearable health technologies such as activity/fitness trackers, smart watches, smart clothing, patches, smart glasses etc. are present in the market. In this study, activity trackers as prominent example of wearables in the market, have been selected as the use case for data mapping due to following reasons:

i. Activity Trackers such as Fitbit, Apple Watch contain largest share in the wearable healthcare devices industry [29].

ii. Assist in prevention and management of chronic diseases such as cardiovascular disease, chronic obstructive pulmonary disease, diabetes mellitus, cancer, obesity, depression, anxiety, osteoarthritis and other chronic pains [30], [31]. Moreover, these are the most common diseases causing the deaths worldwide [32].

iii. According to a recent survey, most of the respondents are likely to purchase activity tracker among other wearables in next 12 months [33].

For this study, physical activity tracker will be discussed as use case for FHIR implementation and all the data fields and attributes will be identified and analyzed. The data mapping technique will be used in this study to map the attributes between

FHIR resource and activity trackers' such as FitBit data elements which may allow the data to be shared with an EHR via interoperable data model. Data mapping will be performed after evaluating the potential of FHIR standard in the discussion section.

4 Results

4.1 Challenges and Opportunities towards Transferring Health Data from Wearable Devices to EHR

In this section, the identified barriers and enablers during the systematic review of 17 papers have been presented in order to understand the existing issues and their potential solutions for the future implementation. The following table of key findings includes the authors, published year, aim of study, platforms or standards being used and identified challenges and opportunities of sharing data from wearables to EHR.

<table>
<tr><th colspan="2">Study 1: Wearable sensors with possibilities for data exchange</th></tr>
<tr><td colspan="2">Author & Year: Muzny et al., 2020</td></tr>
<tr><td colspan="2">Study Aim: Provide a summary of wearable sensors with possibilities of data exchange</td></tr>
<tr><td colspan="2">Platform: Direct and 3rd party integration with health platforms (mHealth) via smartphone application (Google Fit, Apple Health etc.)
Middleware (Shimmer, Tidepool, Glooko)</td></tr>
<tr><td>Challenges:
▪ Wearable manufactures have their own data schemas.
▪ Non-compliance with GDPR and HIPAA which raise concern about secondary use of data
▪ Captured data from middleware is readable by EHR but only limited health wearable devices support middleware.
▪ Limited wearable devices support smartphone health platforms.
▪ Developers are unable to utilize full potential of devices.
▪ No standardized format for data transfer.
▪ Limited number of health wearables are FDA approved which raise concern about reliability of data.</td><td>Opportunities:
▪ REST API supports interoperability with various 3rd party integration apps.
▪ Proposing the need of wider use of standardization and open communication protocols.
▪ Data reliability can be achieved by ensuring standardization, privacy and security.</td></tr>
</table>

<table>
<tr><th colspan="2">Study 2: Smart Healthcare Challenges and Solutions using IoT</th></tr>
<tr><td colspan="2">Author & Year: Zeadally, Siddiqui, Baig & Ibrahim, 2019</td></tr>
<tr><td colspan="2">Study Aim: To identify the challenges in deployment and adoption of smart health technologies</td></tr>
<tr><td colspan="2">Platform: IoT, Big data technologies such as Hadoop MapReduce, Apache Spark etc.</td></tr>
<tr><td>Challenges:
▪ Threat to user’s security and privacy.
▪ Compliance and Regulation issues
▪ Sensors collect data and communicate in their own language with server.
▪ Incompatibility with legacy systems.
▪ Lack of interoperability among different platforms.
▪ Risk to confidentiality and privacy.
▪ Each device manufacturer has own proprietary protocol.
▪ Lack of standardization of protocols.
▪ Data captured from wearables to cloud is vulnerable to spoofing, RF jamming, cloud polling, DDOS etc.
▪ Data from different wearables is collected in various formats and need standardized data formats.
▪ Risk of data integrity and inaccuracy.
▪ Big data analysis should be more efficient in the form of valuable insights instead of reports and not easy to use by Physicians.</td><td>Opportunities:
▪ Development of standards for wearables used in IoT.
▪ Use of efficient data analytical tools and algorithms.
▪ Data protection during the collection, storage and transfer process such as secure transmission protocols, encryption.
▪ Use of statistical data reporting methods.</td></tr>
<tr><th colspan="2">Study 3: Wearable Technology and Physical Activity in Chronic Disease</th></tr>
<tr><td colspan="2">Author & Year: Phillips, Cadmus-Bertram, Rosenberg, Buman & Lynch, 2018</td></tr>
<tr><td colspan="2">Study Aim: Challenges to use wearables in chronic disease prevention and management</td></tr>
<tr><td colspan="2">Platform: N/A</td></tr>
</table>

<table>
<tr><td>Challenges:
▪ Integration with EHRs.
▪ Data is not aggregated and harmonized.
▪ Need of accurate and effective algorithms
▪ Healthcare professionals need education and training to perceive wearables data.</td><td>Opportunities:
▪ Create practices for storing, processing, analysis and integrating wearable data with other data.
▪ Develop standards to interpret and process data.
▪ Educate and train healthcare professionals to view and observe wearables data</td></tr>
<tr><td colspan="2" align="center">Study 4: Integrating Physical Activity with Electronic Health Record</td></tr>
<tr><td colspan="2">Author & Year: Saripalle, 2019</td></tr>
<tr><td colspan="2">Study Aim: Design an interoperable model or structure using existing healthcare standard</td></tr>
<tr><td colspan="2">Platform: HL7 and FHIR</td></tr>
<tr><td>Challenges:
▪ HL7 V2 is not supported by structured and semantic software model.
▪ HL7 RIM can capture limited set of activity data
▪ Lack of interoperable model/structure to capture activity data
▪ Not possible to share wearables data across different healthcare systems.
▪ Lack of semantic standard to standardize physical activity data and terminologies.
▪ Logs are used to store exercise data which is a non-digital format and same issues as paper-based records.
▪ Data from wearables is collected in non-standard format and accessible via API in the organization own format.
▪ Information is being reported in the form of Data Silos.</td><td>Opportunities:
▪ FHIR can be extended to design a new data model for physical activity data
▪ New resource can be designed, or existing resource can be customized to fulfil any requirement.
▪ A new resource Physical Activity can be created and used.
▪ HAPI library can be utilized to capture FHIR resource data and transfer them to server via REST and can be obtained in customized OpenEMR.</td></tr>
<tr><td colspan="2" align="center">Study 5: Sharing Patient-Generated Data in Clinical Practices</td></tr>
<tr><td colspan="2">Author & Year: Zhu H, Colgan J, Reddy M & Choe EK, 2017</td></tr>
</table>

Study Aim: Provide potential barriers and enablers in sharing wearables data with clinical setting i.e. EMR	
Platform: Patients share wearables data with doctors through patient portal	
Challenges: ▪ Privacy Burdens on Hospitals ▪ Strict protection laws from HIPAA ▪ Technical, social, organizational challenges ▪ Unable to transfer wearable data to EHR due to integration issue ▪ Data security and Privacy concerns ▪ Healthcare professionals have limited time slot for each patient. ▪ Healthcare professionals cannot response to wearables data as its violation of HIPAA regulation ▪ No good interface for wearable data in EHR ▪ Unable to store and share wearables data in EHR ▪ No proper visualization or insights available for data from wearables and doctors are unable to use this data. ▪ Inaccuracy and unreliability of self-reported data.	**Opportunities:** ▪ Development of technical infrastructure to transfer data from wearable to EMR. ▪ Data visualization, insights and analysis can be very useful. ▪ Healthcare professionals need wearables data to be integrated in their workflows.
Study 6: Development of Health Monitoring Application with the help of IoMT	
Author & Year: N. Boutros-Saikali, K. Saikali and R. A. Naoum, 2018	
Study Aim: Implementation of IoMT platform that provide solutions to existing challenges	
Platform: IoMT	
Challenges: ▪ Currently, no standard exists to structure and share wearables data. ▪ Different manufactures don't adopt same data structures. ▪ Manufactures store data in their own data centers ▪ Less usability as users need to install application for each new device.	**Opportunities:** ▪ Multiple connectors can read data from different wearable devices to provide standardized API. ▪ Convert normalized data captured from devices into OmH in order to map with FHIR resource.

▪ No simple aggregation of data from different wearables for both developers and users ▪ Scattered data in different data storages of wearables which is challenging for developers ▪ Not capable to integrate with 3rd party systems and HIS ▪ Prevention of unauthorized access in rest and transit ▪ Lack of compliance with regulations such as HIPAA and FDA	▪ Conversion to FHIR observations can be used in future. ▪ Use of encryption mechanisms ▪ Compliance with HIPAA and FDA to ensure data protection.
Study 7: Challenges and Requirements of Aggregated Health Data into EHR	
Author & Year: A. Koren, M. Jurčević and D. Huljenić, 2019	
Study Aim: Inclusion of wearables data in EHR of Croatia's central health information system	
Platform: e-Karton in Central Health Information System, HL7 FHIR	
Challenges: ▪ Data maintained in wearables is not structured and standardized. ▪ Data in wearables is irrelevant to EHR. ▪ Manufacturers use private protocols. ▪ Manufacturers force users to download their own app. ▪ Handling data receiving from different platforms and sources. ▪ Collecting, linking and mapping data from different sources is time consuming. ▪ Security and Privacy ▪ Risk to breaching privacy from insecure wearables.	**Opportunities:** ▪ FHIR next generation standards framework to exchange HIE with EHR. ▪ mHealth mobile app can be used to share this information via HL7 FHIR resource. ▪ Merge different data sets into single a single common schema ▪ Data transformed or mapped from 3rd party apps into HL7 FHIR format can ensure the data structure and make it easier to understand. ▪ Results can support in implementation process of standardization, transformation, and visualization of data. ▪ Proper authorization by smart ID and different access control levels i.e.

	patients can authorize physicians to access their EHR. ▪ Data will only be integrated to central health information system after approval by patient. ▪ Need a simple, extensible and valid schema to combine health data from wearables into a single component.
Study 8: Integration of Aggregated Fitness Data in Healthcare	
Author & Year: Gay and Leijdekkers, 2015	
Study Aim: Demonstrate that mobile app can aggregate fitness data and discuss interoperability challenges while integrating this data.	
Platform: myFitness Companion App connected with EHRs	
Challenges: ▪ Different wireless protocols are used to connect with wireless devices. ▪ All vendors develop their own protocols and data formats to retrieve and send data to devices. ▪ Lack of standards usage such as HL7 and not even a single app server used HL7 which led to rewrite each server specific software to interpret data. ▪ Data reliability as it varies and depends upon the correct and incorrect use of the user.	**Opportunities** ▪ myFitness Companion can exchange health data via API with different servers such as GoogleFit, FitBit. ▪ OAuth is used by fitness app servers for authorization. ▪ HL7 Compliance for health information exchange in apps ▪ Only limited vendors such as FitBit work with proprietary protocols which facilitate 3rd party developers to communicate with devices. ▪ In the near future, more vendors also have to offer wearable devices with open protocols so developers can read data from device.
Study 9: Integration of self-collected data by patients into Medical Systems	
Author & Year: Giordanengo et. al, 2017	
Study Aim: Present state of art review on self-collected data by patients in wearables to EHRs.	
Platform: Android App (Google Fit, Fitbit and others), HealthKit, ResearchKit, PMHR,	

<table>
<tr><td>Challenges:
Closed and Proprietary Applications, interfaces and protocols
Lack of legal framework for security, privacy and transparency of devices with self-collected data.
Large amount of self-collected data required efficient ways for analysis.
Complexity of integrating international and external aggregators and ensuring Semantic Interoperability
Manufacturers use their own protocols and standards and force patients to use their own application in order to consult data.</td><td>Opportunities:
Use of the HL7 standards to ensure interoperability such as FHIR, CDA, SNOMED, LONIC, ICD, DICOM
Need of access controllers and processors to ensure security.</td></tr>
<tr><td colspan="2">Study 10: Semantic Integration Framework for Wearables Data in EHR based on FHIR</td></tr>
<tr><td colspan="2">Author & Year: Dridi, Sassi, Chbeir & Faiz, 2020</td></tr>
<tr><td colspan="2">Study Aim: Proposing a semantic integration framework for IoT wearables data in EHR system.</td></tr>
<tr><td colspan="2">Platform: IoT, SF4FI-EHR and HL7 FHIR</td></tr>
<tr><td>Challenges:
80% of clinical data is unstructured.
Data is collected as free text without any standard content specifications.
Missing values in data, noisy data and irrelevant values</td><td>Opportunities:
3rd party apps such as myFitness Companion can be used with FHIR resource to integrate data.
SF4FI-EHR is based on HL7 FHIR and process non standardized data, create structured, readable and meaningful data, and seamlessly integrate to consistent format.
Preprocessing step is required to fill missing values, smooth noisy data and eliminate irrelevant data.
Unstructured Data can be processed by MetaMap and converted to FHIR resources.</td></tr>
</table>

<table>
<tr><td></td><td>Mapped Data to FHIR ontology can be fully integrated to EHR</td></tr>
<tr><td colspan="2">Study 11: Integration of Wearable Technologies into Patients’ Electronic Medical Records</td></tr>
<tr><td colspan="2">Author & Year: Al-Azwani and Aziz, 2016</td></tr>
<tr><td colspan="2">Study Aim: Introduce advantages and challenges of wearables application in healthcare industry</td></tr>
<tr><td colspan="2">Platform: N/A</td></tr>
<tr><td>Challenges:
High cost associated with synchronization of data with healthcare systems
Large amount of data requires more storage, servers and backups.
Privacy and Security
Reliability and validity of wearables data
Need integration and interoperability features.
Different manufacturers use different algorithms with range of different characteristics</td><td>Opportunities:
Single and standard algorithm is required to integrate data with EMR.</td></tr>
<tr><td colspan="2">Study 12: Potential and Challenges of Patient-Generated Health Data for High-Quality Cancer Care</td></tr>
<tr><td colspan="2">Author & Year: Chung and Basch, 2015</td></tr>
<tr><td colspan="2">Study Aim: Demonstrate the potential and challenges of patient generated health data from wearables and other technologies.</td></tr>
<tr><td colspan="2">Platform: N/A</td></tr>
<tr><td>Challenges:
Missing data values
Manage large volume of asynchronous or continuous data
Incorporate data into clinical workflows
Lack of interoperability standards for devices, sensors and PGHD data
Security and Privacy Issues
Lack of necessary EHR functionalities such as reporting</td><td>Opportunities:
HL7 actively working on interoperability and standardization issues.</td></tr>
<tr><td colspan="2">Study 13: PGHD management and quality challenges in remote patient monitoring</td></tr>
<tr><td colspan="2">Author & Year: Abdolkhani, Gray, Borda and DeSouza, 2019</td></tr>
</table>

Study Aim: Identify the PGHD management and quality challenges.	
Platform: Mobile App, Wearables Manufacturers' Remote Platform, Patient Portal, Healthcare Professional Portal	
Challenges: ▪ Lack of interoperability ▪ Lack of interfaces for healthcare professionals ▪ Lack of data accuracy ▪ Unreliability and Irrelevancy of Data ▪ Data from different wearable is inconsistent and unstructured. ▪ Lack of knowledge and guidelines in clinical settings and incorporation into workflows. ▪ Patients don't understand data and unmotivated to use wearables. ▪ No current possibilities for wearables data analysis ▪ Current infrastructure doesn't allow integration of data with EMR ▪ Large amount of data needs cleaning ▪ Lot of time spent to find useful information from large amount of data. ▪ Difficulty in data sharing ▪ Data not available on real time basis ▪ Ensuring cyber security of wearables ▪ Lack of funding and expertise for integration ▪ Different reports from different wearables is difficult to understand for healthcare professionals.	**Opportunities:** ▪ Possibility to use interfaces to incorporate into workflows. ▪ Recent developed standards to provide interoperability of wearables data via FHIR ▪ Health information professionals have an essential role in standardizing, normalizing and cleansing data to provide meaningful information to healthcare professionals.
Study 14: Wearable Health Technology and Electronic Health Record Integration	
Author & Year: Dinh-Le, Chuang, Chokshi and Mann, 2019	
Study Aim: Review the wearable health technologies and data integration to EHRs.	
Platform: Apple HealthKit, Data Analytics and Remote Monitoring, MyChart Integration, GoogleFit	
Challenges:	**Opportunities:**

<table>
<tr><td>

- Confidentiality and Privacy of Patients.
- Limited evidence of security in wearable devices.
- Essential need of policies and standards for patient data integration to EHR and privacy.
- Lack of platforms to retrieve data from different wearable devices.
- Wearable devices and EHR vendors use different, proprietary, and closed communication methods which leads to lack of interoperability.
- Data collected from wearables cannot be integrated easily to historical data of patients.
- Compilation and interpretation of large amount of data

</td><td>

- Increased collaboration between manufacturers of devices to achieve interoperability.
- AI algorithms have potential to collect and analyze the data and provide opportunities to visualize and monitor meaningful data.

</td></tr>
<tr><td colspan="2">Study 15: Quality Management of PGHD in Remote Patient Monitoring Using Medical Wearables</td></tr>
<tr><td colspan="2">Author & Year: Abdolkhani, Borda and Gray, 2018</td></tr>
<tr><td colspan="2">Study Aim: Analyze the current situation of quality management of PGHD in wearables</td></tr>
<tr><td colspan="2">Platform: N/A</td></tr>
<tr><td>

- **Challenges:**
- Lack of integration of wearables with EMR
- Unable to facilitate real time data flow
- Inconsistency in data structure and variations in measurements of wearables.
- Accessibility issues such as data aggregation, data drop
- Data accuracy issues such as wearables measurement errors, wearable and patient authenticity, patient negligence and trust, transmission error etc.
- Wearables data synchronization and low battery lifetime.

</td><td>

- **Opportunities:**
- New data quality management model, guidelines and practices are required at each stage of data flow.
- A set of guidelines using HL7 and FHIR can facilitate security, reliability, accuracy and integration of data from wearables to EHRs.

</td></tr>
<tr><td colspan="2">Study 16: Suitability of Fast Healthcare Interoperability Resources (FHIR) for Wellness Data</td></tr>
<tr><td colspan="2">Author & Year: Pais, Parry and Huang, 2017</td></tr>
<tr><td colspan="2">Study Aim: Analyze the interoperability issues and evaluate FHIR data for wearables data into EHR</td></tr>
</table>

Platform: HL7 FHIR	
Challenges: ▪ FHIR resources are not specifically designed for wearables data. ▪ HL7 V2 is not compatible with wearable technologies and mobile apps and HL7 3 takes longer time for development and complex. ▪ FHIR is a draft version to use.	**Opportunities:** ▪ APIs can facilitate in sharing wearables data. ▪ Open mHealth has common data schemas for each data type of wearables. ▪ Data schema for wearable data in FHIR can be integrated to EHR. ▪ EHR system can import data in HL7/CDA format. ▪ Observation resource in FHIR can be used to manage wearables data and all data items identified in wearables data model can be organized in Observation resource. ▪ FHIR resource can be extended for new data types of wearables.
Study 17: Potential of FHIR for Integration of Activity Data with EHR	
Author & Year: Saripalle, 2019	
Study Aim: Address the interoperability issues and leveraging FHIR standard for integration	
Platform: HL7 FHIR with OpenEMR	
Challenges: ▪ EHRs and Health Information systems should be FHIR compliant in order to use FHIR Physical Activity Resource. ▪ Mapping of FHIR Physical Activity Resource to existing and new activity formats is required if wearable organization prefers using their own data models.	**Opportunities:** ▪ Mapping of physical resource with attributes of wearables data format enables capturing data into interoperable data model which can be communicated with EHR ▪ Open mHealth captures activity data from Fitbir, GoogleFit etc. ▪ HAPI library can be utilized to capture FHIR resource data and transfer them to

	server via REST and can be obtained in customized OpenEMR.

Table 1: Key Findings related to Challenges and Opportunities from Papers Review

From the above table, it can be observed that almost all of the studies stated a very high requirement of standardization in order to ensure interoperability between wearables and EHR. 9 out of 17 researches stated HL7 FHIR have not specifically designed for wearables but can be used as a potential interoperability standard to fulfil this purpose. Few studies also proposed FHIR as a solution of interoperability after the customization of the existing FHIR resource or adding a new resource to capture physical data and mapping data elements of wearables data with this FHIR resource. Furthermore, there is another main interoperability issue related to wearable vendors mentioned in 7 studies which includes lack of collaboration, closed communication protocols, distinct data formats and storages which can only be solved with collaboration between vendors, use of standard formats such as HL7 in wearables and open communication protocols. In addition to that, there were security and privacy concerns in 11 studies which includes lack of compliance with regulatory bodies such as HIPAA, GDPR and FDA, vulnerabilities of wearable devices and requirement to use strong authorization methods. Similarly, there were data quality issues mentioned in 11 studies such as inaccuracy, unreliability, inconsistency and unstructured, scattered, noisy and missing data. In various studies, the proposed solutions to improve the quality of data were compliance with HL7 standards to ensure reliability and accuracy of data, using pre-processing data techniques to eliminate noisy, irrelevant and inconsistent data and use of data analytical tools for better visualization and insights.

4.2 Qualitative Data Analysis with RQDA

In this section, the thematic analysis is briefly explained which is based on qualitative data analysis that was performed through R studio via RDQA tool.

In order to categorize the research studies, the themes are segregated on the basis of enablers and barriers related to security and privacy, interoperability and data quality respectively. Furthermore, the codes or keywords are created in RQDA to link the text of the published research papers and further linked those codes to specific categories to estimate the outcomes of thematic analysis and plot the enablers and barriers that will impact the wearable health technology to improve data quality in EHR via FHIR.

Themes
Enablers and Barriers
Security and Privacy
Interoperability
Data Quality

Table 2: Themes for Qualitative Data Analysis

4.2.1 Barriers towards Sharing Wearables Data with EHR

Security and Privacy

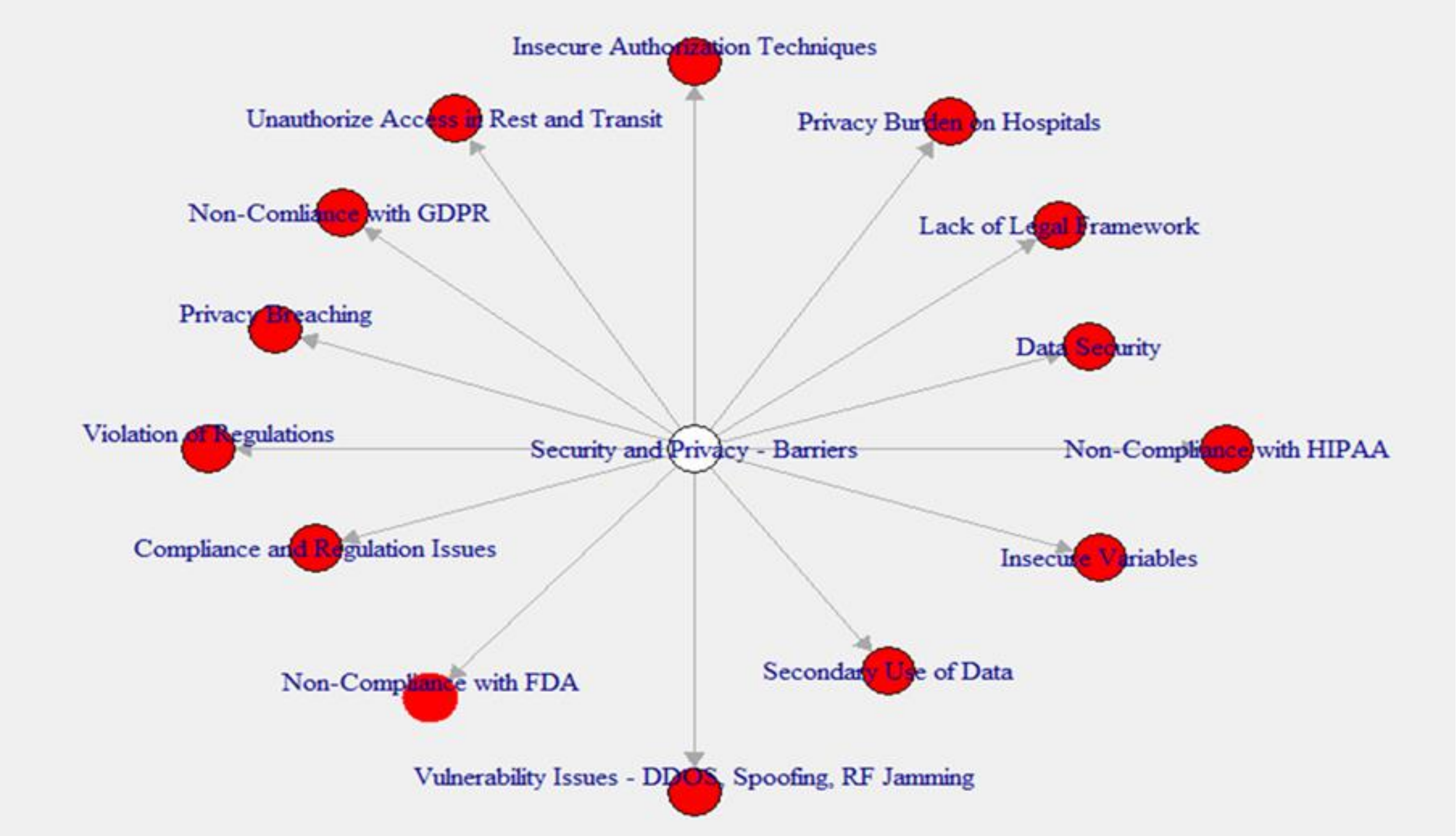

Figure 9: Barriers towards Security and Privacy of Wearables Data

As seen in the above figure, there are various challenges identified as barriers related to security and privacy which includes vulnerability issues such as DDOS, Spoofing etc. Similarly, privacy breaching, compliance and regulatory issues put additional burden on the hospital in order to use wearable data for wellness purposes.

Interoperability

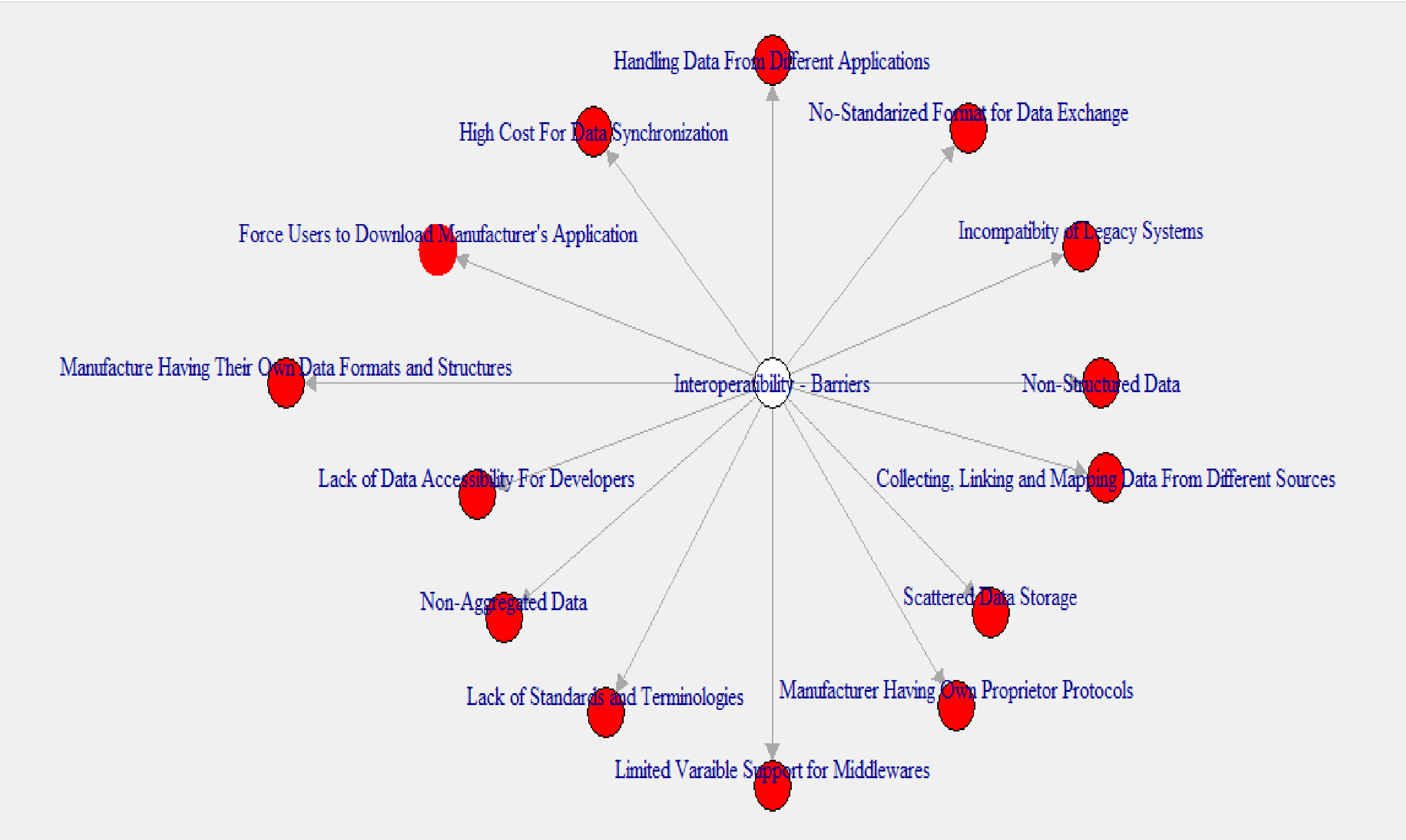

Figure 10: Barriers towards Interoperability of Wearables and EHR

It can be seen from the above image that there are significant constraints related to interoperability which includes incompatibility with legacy systems, non-standardized format for data exchange, collecting, linking and mapping data from different sources, distinct manufacturer having own proprietary protocols, scattered data storage and many more to count which subsequently hinder the overall interoperability of wearable data.

Data Quality

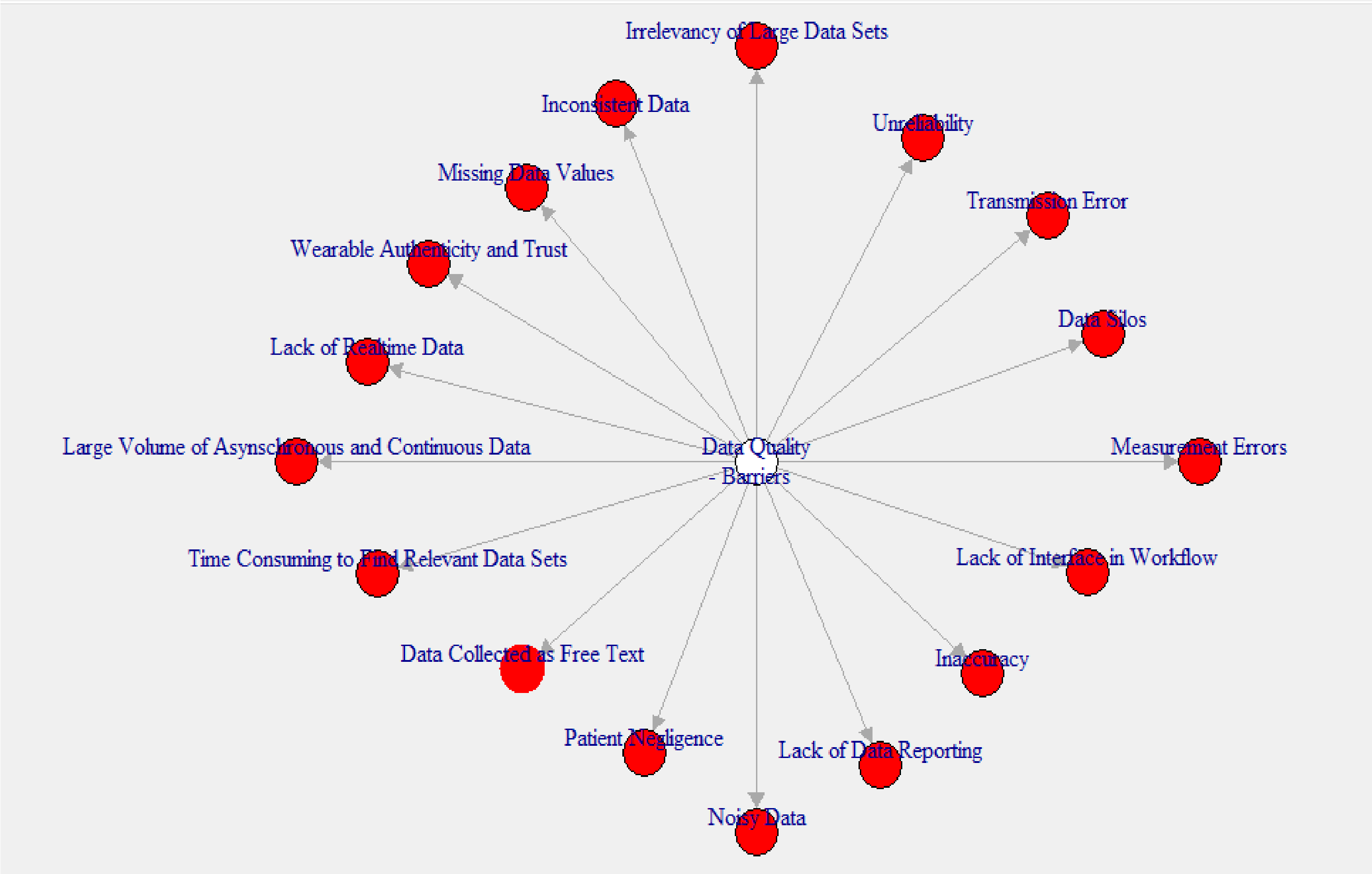

Figure 11: Barriers for Quality Data of Wearables in EHR

In the above figure, distinct data quality barriers such as inconsistent data, irrelevance of large data sets, measurement errors, data silos, patience negligence etc can be observed. There are numerous challenges associated with the quality of data which influence the effectiveness of EHR in terms of wearable devices.

4.2.2 Enablers towards Sharing Wearables Data with EHR

Security and Privacy

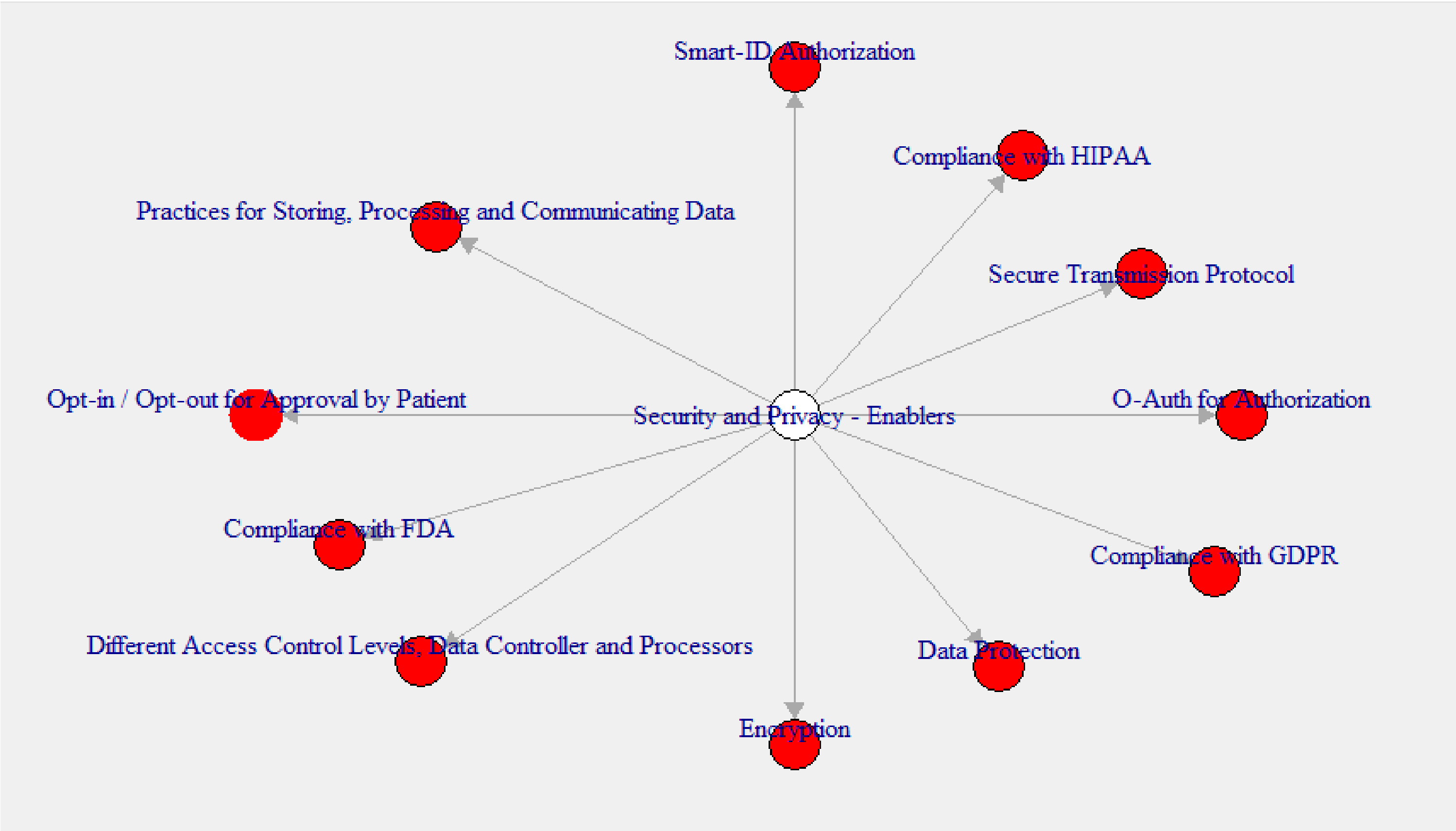

Figure 12: Enablers towards Privacy and Security of Wearables s Data in EHR

It is highly recommended to focus on the security and privacy component of wearable data which includes encryption, smart-ID authorization, compliance with FDA, GDPR and HIPAA etc in order to transmit data from smart wearable to e-HR via FHIR standards.

Interoperability

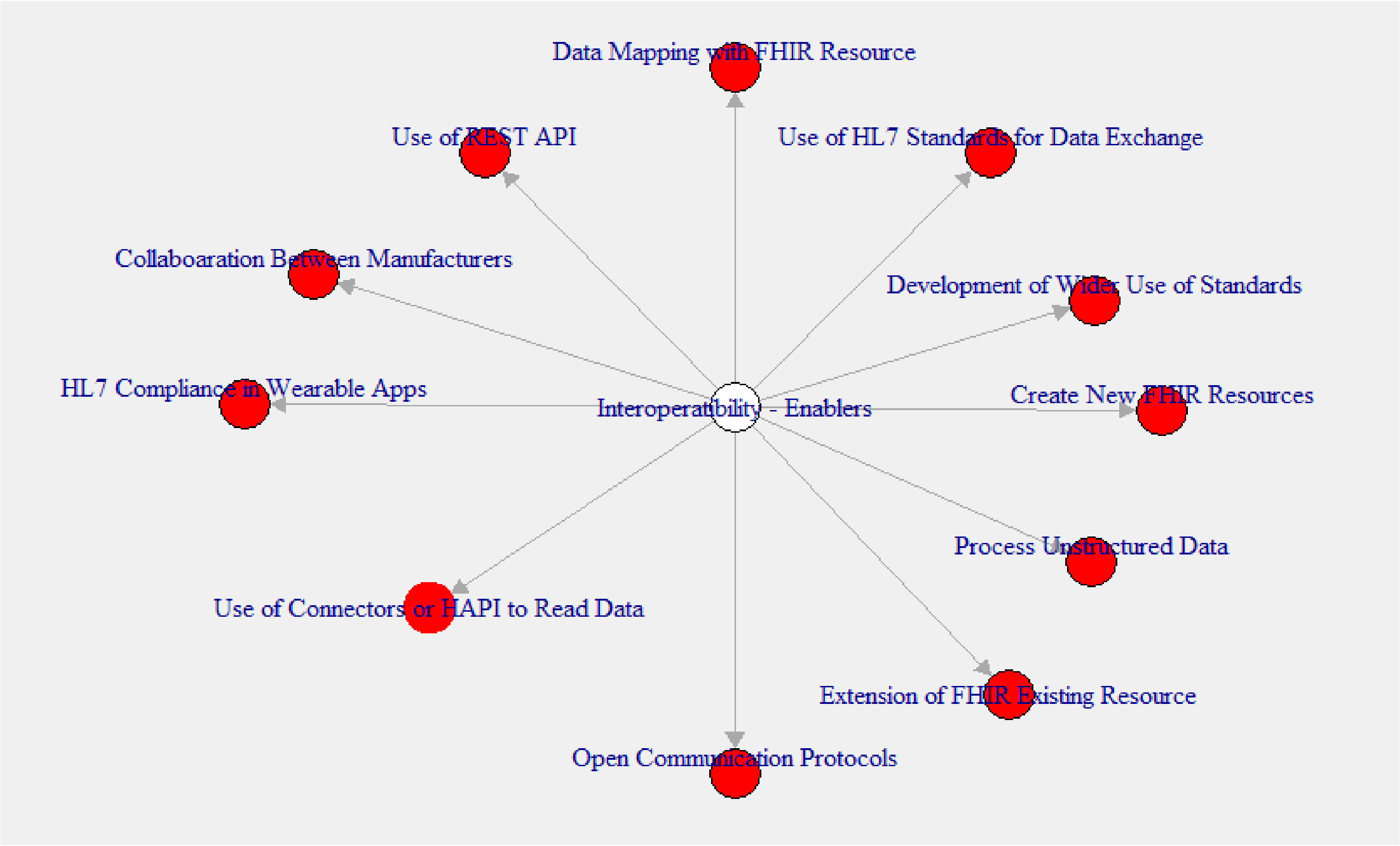

Figure 13: Enablers towards Interoperability of Wearables and EHR

In the above figure, the enablers can be observed which can support in the interoperability of wearable data and EHR. The HL7 compliance in wearable apps is highly essential in order to deploy HL7 standards for exchange of data. Similarly, creating new FHIR resources, deployment of wide use of standards, use of Rest API, data mapping with FHIR and other necessary components are highly desirable to strengthen the interoperability to EHR through FHIR.

Data Quality

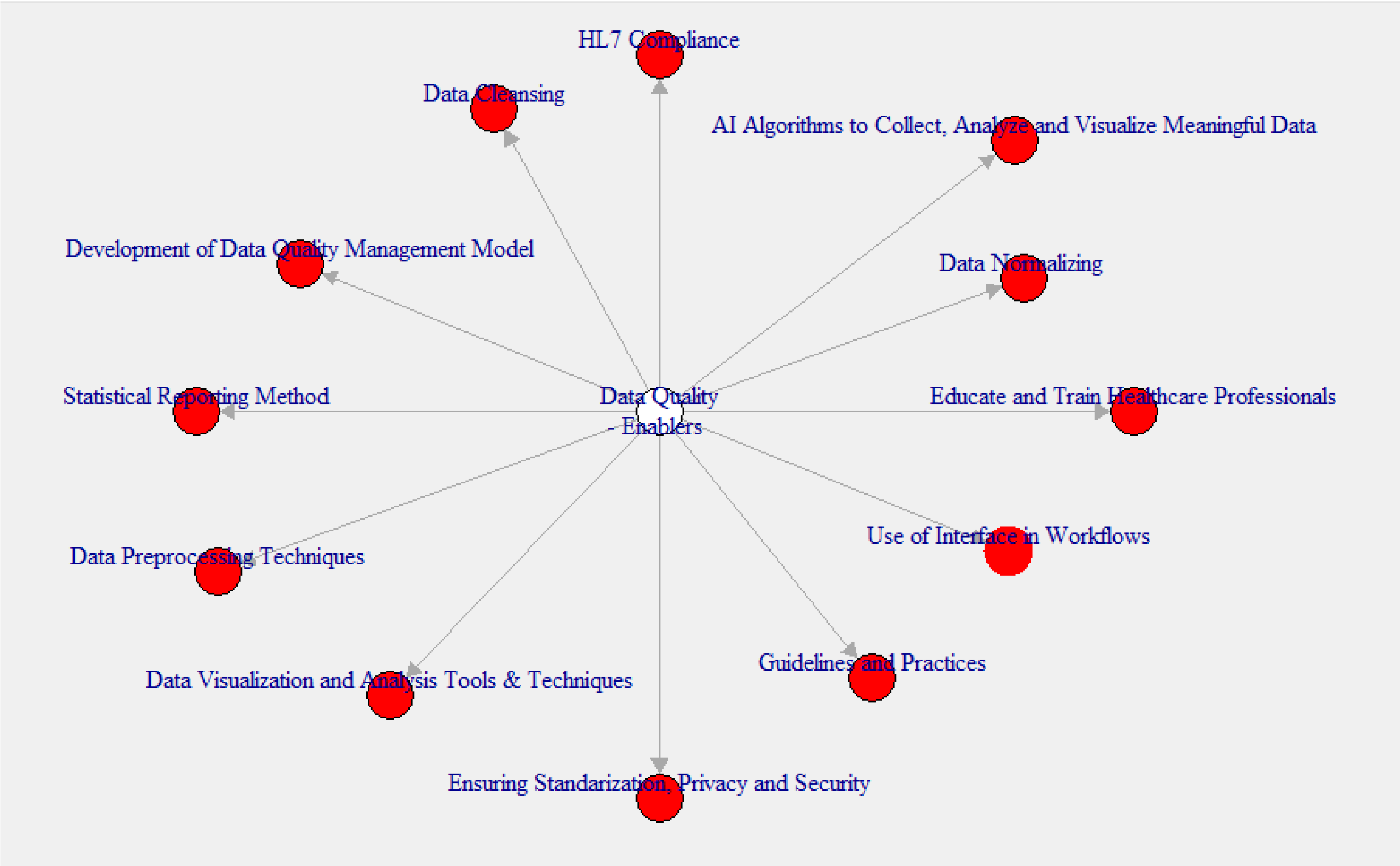

Figure 14: Enablers towards Quality Data of Wearables in EHR

Data quality considered as an important factor which includes development of data quality management model, AI algorithms to collect, analyze and visualize meaningful data, deployment of processing techniques and use of interface in workflows etc will serve as enablers in order to monitor wearables data in real time.

4.3 Suitability of FHIR Resource for Exchanging Data in Wearables

During the review of studies, it has been analyzed that standardization is essential to adopt latest wearable technologies in healthcare industry and resolve interoperability to share wearables data with EHRs. In below figure, 9 out of 17 studies clearly stated FHIR as a potential interoperability solution for exchanging wearables data with EHR, while 3 studies mentioned there should be compatibility with HL7 standards to ensure interoperability which also directs towards the use of FHIR resource. Moreover, other studies clearly stated there must be some development of standards or technical infrastructure to make it possible to exchange wearables data with EHR.

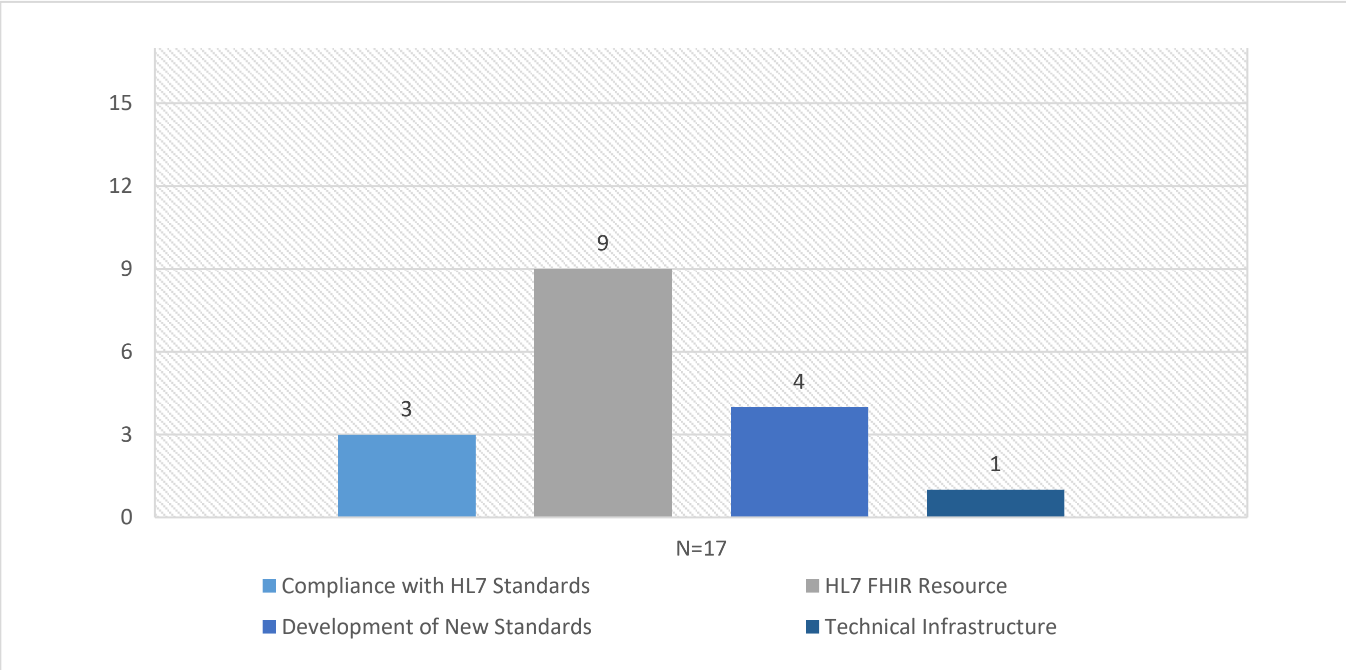

Figure 15: Proposed Solutions for Wearables Data Integration in HER

5 Discussion

This section will explain the analysis and interpretation of the results based on systematic reviews and FHIR standard will be assessed practically with the help of expert opinions and their provided resources. The study limitations and proposed future work will be discussed at the end of the chapter.

5.1 Analysis of Results

The first research question of this thesis was based on identification of barriers and enablers of transferring health data from wearable technologies to EHR. To identify these barriers and enablers, systematic review was conducted by using ENTREQ technique and thematic synthesis was performed to generate codes and qualitative results. The barriers and enablers were further divided into three categories based on the major findings in the systematic review. These categories are interoperability, data quality and security and privacy stated as the themes in the results section and will be discussed in detail below.

In various studies, the possibilities of data exchange between wearables and EHR are evaluated, and several challenges quoted in these studies have been analyzed in the results section. During reviewing the interoperability challenges, it has been analyzed that there is a lack of interoperability between platforms due to lack of standardization and use of distinct data formats for the wearable devices issued by different manufacturers [5], [6] [34], [35], [36]. Similarly, the need of consistent standards and open-end communication protocol for sharing wearables data with EHR was consistent in most of the studies [35], [37]. While, identifying the enablers, it has been found out that mapped data from 3rd party apps into HL7 FHIR format can ensure the data structure and standardization [38]. The results also demonstrated that several studies recommended FHIR as a potential solution of interoperability after the customization of the existing FHIR resource to capture physical data. As it is not specifically designed for this purpose, customization or addition of new FHIR resource is required [6], [7], [15], [39].

The analysis found the evidence of security and privacy barriers which include non-compliance with regulatory standards such as HIPAA, GDPR and FDA, threat to privacy, vulnerabilities of wearable devices and necessity of strong authorization methods [34], [35], [40]. Similarly, the results also demonstrated data quality issues such as inaccuracy, unreliability and unstructured data. Furthermore, noisy, scattered and inconsistent missing data values were mentioned in the studies. In the findings, the enablers to improve the quality of data were compliance with HL7 standards to ensure reliability and accuracy of data, using pre-processing data techniques to eliminate noisy and inconsistent data and use of data analytical tools for better visualization and insights [35][38][39].

The second research question of this thesis was to evaluate the potential of FHIR standard in order to share health data from wearables to EHR. To analyze the FHIR standard for sharing health data from wearables to EHR, findings from systematic review were analyzed. The results provide an evidence that several researchers recommended FHIR

FHIR resource is proposed as a potential solution to achieve interoperability in various ways. For example, Pais et. al (2017) suggested to use existing FHIR resource ''Observation'' to manage wearables data. Observation resource can capture data items and related information such as device, interpretations, status etc. Different types of readings are identified by existing LONIC codes such as blood pressure and blood glucose. Additionally, Observation resource can only contain this multiple wearables data values as a list, but wearables data is required to be organized as individual resources. This can be solved by using ''Bundle'' feature in FHIR which can be used to manage bundled resources and share them at a time with server [7].

In multiple studies, Saripalle (2019) defined a new FHIR resource named as ''PhysicalActivity''to capture data related to physical activity and exercise. FHIR resource is basically a class having different data attributes with data types. The data model of this PhysicalActivity FHIR resource is developed with the help of existing schemas such as Open mHealth and demonstrated by using HAPI library and OpenEMR. Similarly, Dridi et. al (2020) proposed a semantic framework to capture unstructured data from heterogenous wearables sources and convert them into FHIR resources after pre-processing. Later, this obtained data is mapped to FHIR OWL ontology and stored in FHIR RDB database format in order to achieve interoperability [6][15].

Koren et. al (2019) also shared the possibility of mapping data from 3rd party apps such as Open mHealth into HL7 FHIR resource which can ensure the data structure and make it sharable with EHRs [38]. Likewise, other studies mentioned capabilities and possibilities of using HL7 FHIR in the future to share wearables data with EHR but have not specifically discussed any solution for data mapping or data modelling.

In addition to that, experts in this specific domain have been consulted to observe FHIR standard as a practical solution to share health data from wearables to EHR. According to experts, health wearable devices have been developed as incompatible systems which are difficult to read, write and integrate due to inconsistent format and lack of standardization [41]. From the result analysis, the suitability of FHIR to transfer data from health wearable technologies to EHR via FHIR resource is quite evident and many experts in this domain have already started development in this regard. These experts are promoting and developing common data schemas and open-source tools to retrieve data from distinct health wearable devices in a standardized format and using FHIR interoperable standard to transfer this retrieved data to EHR [41] [42].

In the next section, factors and components proposed by the experts that should be considered while implementing FHIR, data mapping from common schemas to FHIR resource and high level architecture in order to transfer data from activity tracker to EHR will be explained thoroughly.

5.2 Implementation of FHIR in Physical Activity Tracking Use Case

5.2.1 Description of Use Case

Figure 16: A Use Case to Monitor Physical Activity Data [43]

As mentioned in this study there are large number of health wearables present in the market but the main focus of this study is to target only activity tracker wearables and discuss its usecase as an example for implementation. In the below diagram, it can be viewed that patient with moderate cardiovascular risk is advised by the healthcare professional to increase physical activity and achieve target of 4000 steps per day. Now, this activity is being recorded in the data storage of patient’s activity tracker application and should be accessible by healthcare professional in their EHR system to monitor patient's health data and make better decisions about patient's treatment.

In this scenario, healthcare provider have to view health data in EHR of different patients who are using different activity trackers. Furthermore, it has been analyzed in the results section that various wearable technologies are collecting health data in inconsistent and not standardized formats which cannot be integrated directly to EHR. Since 2011, Open mHealth has been developing common data schemas to retrieve health data from various wearable devices in standardardized format and already in the process of becoming IEEE standard but still unable to transfer this data to EHR as stand alone application [41]. These common data schemas in Open mHealth are basically the standardized data structures for each type of health data in wearables such as blood pressure, body temperature, blood glucose etc. and provides further associated information e.g. time period, diastolic and systolic blood pressure readings in blood pressure common schema [44]. According to industrial experts, these available schemas in Open mHealth can be helpful to view this data in EHR if used with FHIR. In addition to that, HL7 also stated that vital signs e.g. heart rate, body temperature and blood pressure measurement associated with patient can be recorded, fetched and searched by using FHIR observation resource. Now, the main challenge in this scenario is transffering this aggregated activity tracker's data from Open mHealth data storage to EHR via FHIR resource.

5.2.2 Components to Implement Physical Activity Use Case

Industrial experts are working on the project to bridge this gap of integrating health data extracted from activity trackers in Open mHealth data storage to EHR with the help of FHIR. In order to implement this usecase, these experts proposed the following 4 main components [41][42]:

- A patient should have a device account supported by Open mHealth e.g. Fitbit, GoogleFit in order to authenticate the retrieval of health data in EHR and allow healthcare professional to view this data [41][42].

- A mechanism is required to retrieve activity tracker's data in the native wearable's format using API and then convert this data into OmH format. Shimmer API is recommended in this case as Shimmer works as an middleware to convert data from activity tracker into OmH format [41][42].

- Data Mapping of OmH formatted data to FHIR Observation resources is the main task in this process so data in correct format can be sent to EHR FHIR server [41][42]. Data mapping approach will be explained thoroughly in the next section.

- Retrieval of FHIR observation resource data and visual display this data for healthcare professional in EHR workflow. In this scenario, experts designed a SMART app which can be launched by EHR with the help of SSO and Oauthorization [41][42]. The high level architecture of SMART/OmH on FHIR will be explained in section 5.3.

5.2.3 Data Mapping from OmH to FHIR for Physical Activity Usecase

Industrial experts provided an implementation guide which explains how can Open mHealth is utilized together with FHIR to extract health data from 3rd party APIs such as smartphone fitness apps. The health data is available to OmH on FHIR/SMART client application in FHIR Observation resource format using OmH Shimmer application. There are few OmH schemas which are already mapped to FHIR such as OmH Step Count and OmH heart rate but still there are many high priority schemas which are still needed to be mapped in order to use with EHR [43].

Open Health Schemas are based on design principles such as automiticity, implication of clinical data standards such as SNOMED and LONIC, simplicity, accuracy etc. whch helps to structure the data. Each data point in schema consists of header, body and annotation to health data standards. OmH Schemas roughly associates to FHIR value sets and datatypes. In addition to that, there are so many similarities between OmH schemas and FHIR resources. For example, both OmH Schemas maintain atomic data, follow common schema covering 80/20 health needs, use restful API and JSON and extendable [44][45].

The tables and templates provided in the formal implementation guide of OmH to FHIR mapping published by experts has been used to create mapping between OmH schema elements to FHIR resource elements in this study [43]. These spreadsheets used for data mapping have been added in Appendix B. As the main focus of this thesis is activity tracker wearables so two examples of OmH schemas ‘’Steps Count’’ and ‘’Heart rate’’ examples have been provided for data mapping. Each OmH schema consists of header and body elements and the data mapping of the OMH head and body elements of Steps

Count and heart rate OmH Schemas to the corresponding OMH to FHIR Observation Profile elements have been created below:

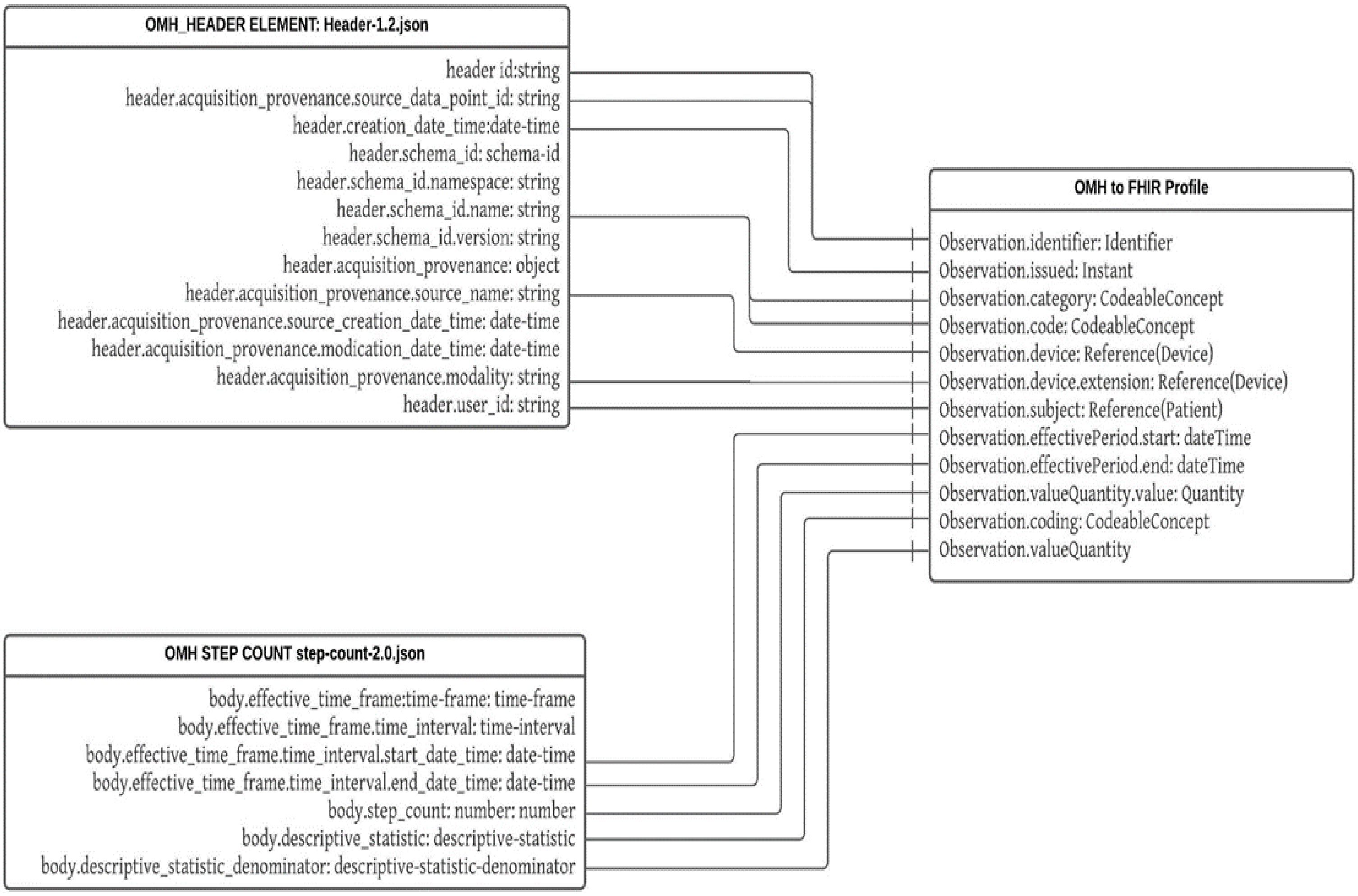

Figure 17: Steps Count OmH Schema Mapping to FHIR

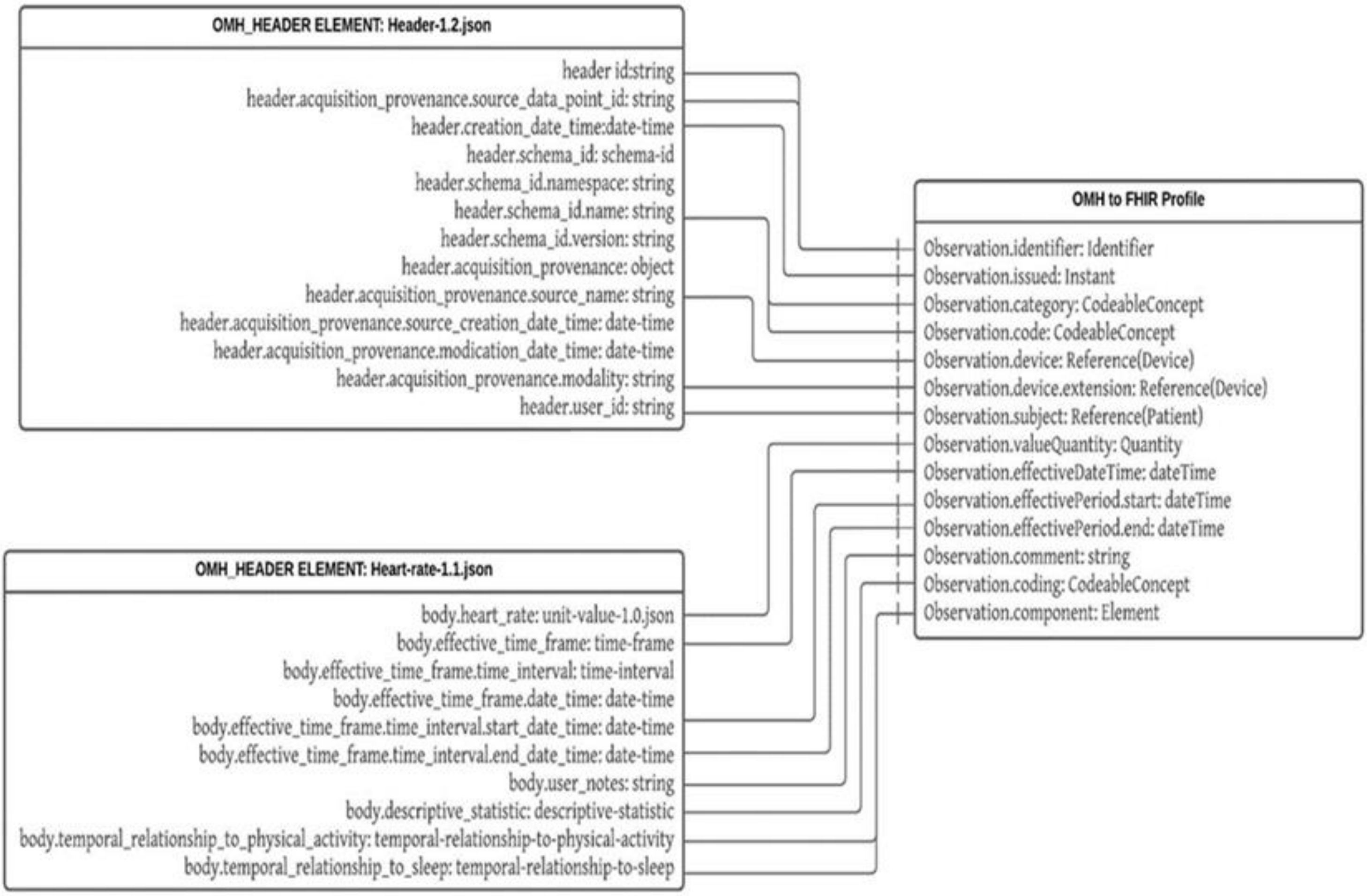

Figure 18: Heart Rate OmH Schema Mapping to FHIR

In the above diagrams, it can be observed that each OmH datapoint schema is represented by header.schema._id.name element and mapped to FHIR observation category and codes for measurements. In the above given use case which is used for data mapping, it can be observed that each observation code in FHIR use medical terminologies such as LONIC codes. Below tables of step counts and heart rate schemas explain how Observation Code and Category can be used for quantitative measures in FHIR:

Header.schema_id.name	Step_count
Observation.category.code	physical-activity
Observation.code.system	http://loinc.org
Observation.code.code	55423-8

Observation.code.display	Number of steps in unspecified time Pedometer
observation_value_quantity_unit(s)	[‘steps’]
descriptive_statistic	True
descriptive_statistic_denominator	True
components	[]

Table 3: Step_Count Observation Code and Category [46]

Header.schema_id.name	Heart_rate
Observation.category.code	vital-signs
Observation.code.system	http://loinc.org
Observation.code.code	8867-4
Observation.code.display	Heart rate
observation_value_quantity_unit(s)	[‘beats/min’]
descriptive_statistic	True
descriptive_statistic_denominator	False
components	[‘temporal_relationship_to_physical_activity’, ‘temporal_relationship_to_sleep’]

Table 4: Heart_rate Observation Code and Category [46]

5.2.4 High Level Architecture of OmH on FHIR

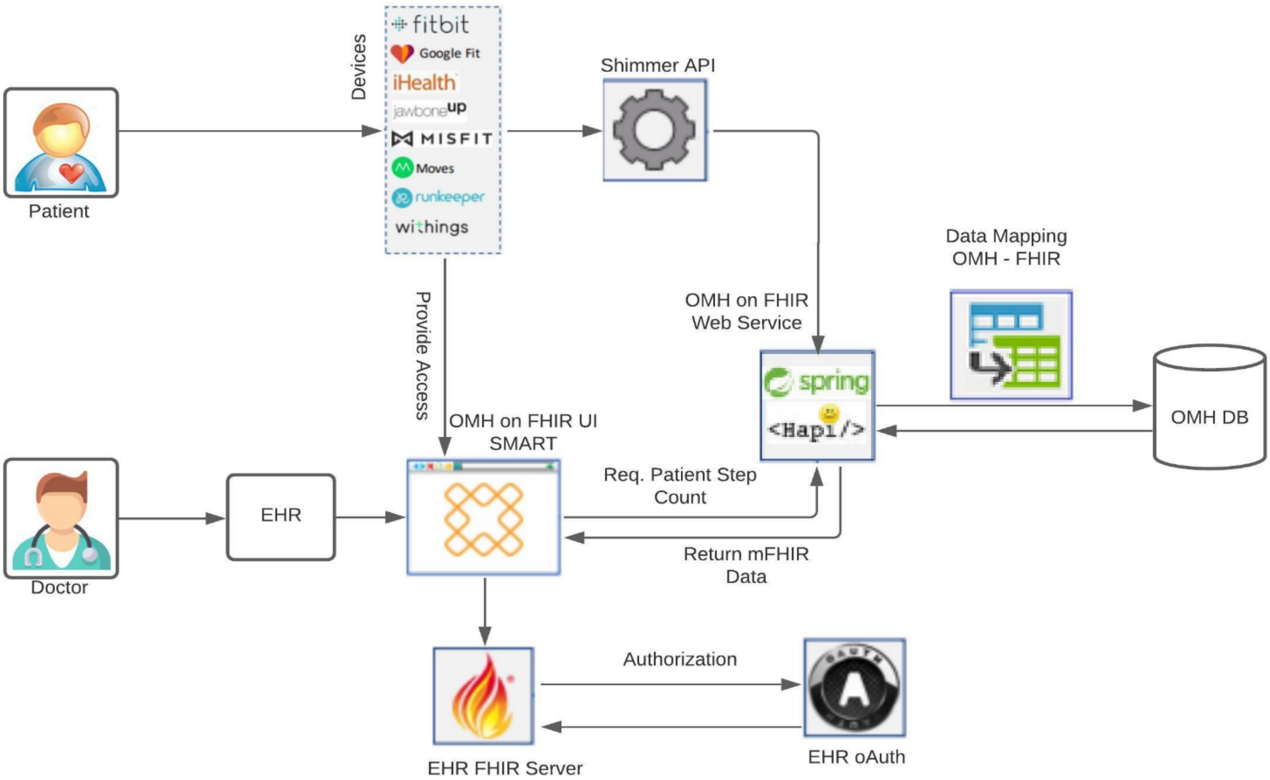

Figure 19: High Level Architecture of OmH on FHIR

In the above diagram, the high level architecture of the server and client side components of the reference application ''Open mHealth on FHIR'' also known as SMART app is displayed which can be launched from the EHR. This application provides a framework for authentication and simplified the process of data retrieval from FHIR server. Furthermore, healthcare providers can access this application within EHR with the help of Single Sign On and there is no need to access this application separately. In addition to that, SMART uses the context id of current patient so that correct patient's information is loaded when healthcare provider opens OmH on FHIR app from EHR. The OmH on FHIR server contains SMART UI which is launched from EHR, OmH Shimmer API which is used to convert data from native device formats into Open mHealth format and the database of OmH on FHIR which is used to store authentication tokens so the patients need to authenticate and give permission to access activity tracker's data only single time from their device account such as Fitbit, GoogleFit etc. In this way, the authentication is processed via FHIR tokens and no protected health information is accessed from

EHR..The data stored in Open mHealth format is mapped and converted to FHIR Observation resource and sent to SMART app so this health data can be displayed from EHR by healthcare provider. The patient must provide the access to Open mHealth on FHIR application via their device's account in order to allow healthcare provider to view their activity data in EHR [41][42].

The user interfaces of OmH on FHIR (SMART) app launch and patient's authorization process can be seen in Appendix D.

5.3 Limitations

The following limitations have been identified while conducting this research related to transferring health data from wearable technologies to EHR via FHIR:

- The concept of integrating health data from wearable technologies to EHR is quite new and the importance of wearables health data in EHR has been recognized in the recent past. As the development has been started over the past few years, not considerable amount of work has been published in this domain and limited number of studies were available to conduct review.

- It has been identified that many research studies proposed FHIR as a potential standard and interoperable solution to integrate wearables health data into EHR but this work is still in progress. Experts and developers are still working to aggregate data from distinct health wearables devices and provide a standard solution for inconsistent data formats in the form of common schemas. Currently, only high priority schemas have been designed and ready to use from implementation guide.

- The scope of this research is limited to examine the capability of FHIR standard for the integration of wearables data in EHR and recommendations of health experts and professionals to use FHIR as an interoperable solution has been demonstrated via simulated EHR and test application. This solution has not implemented in the real world and the practical implications has yet to be assessed in real time EHR environment.

5.4 Future Work

In future, contributions to the ongoing efforts of standardizing mHealth data and metadata and of mapping such data to FHIR resources are extensively required to resolve the main barrier of inconsistent data formats and lack of standardization. At present, only few highest priority OmH common schemas are mapped to FHIR resources in the given implementation guide by experts. Furthermore, there is a core requirement to implement the proposed plan described in the implementation guide and make it feasible to use with EHRs. In addition to that, the proposed solution in implementation guide provided by experts should be assessed in real time environment so thorough results can be analyzed and it can be observed how healthcare professionals and patients adapt with this intervention.

6 Conclusion

I would like to conclude by stating that the ability to capture, analyze and integrate data into EHR can provide more accurate and comprehensive assessment of health situation of patient. These wearables can support healthcare providers to have a better insight of patients' health outside examining centers, hospitals and clinics and can also assist in remote patient monitoring and preventions against chronic illness.

The integrated data from wearables to EHR can be utilized for more efficient diagnosis, better clinical decision and improvement of service quality and care coordination. It has been also identified from previous research that if this data is integrated to EHR, it may reduce number of appointments as patients will avoid unhealthy behaviours, adopt healthy lifestyle and take prescribed medications regularly because they believe that their behaviours are continuously monitored.

In this study, there are several barriers identified in transferring health data from wearable technologies to EHR such as lack of standardization, use of inconsistent data formats in distinct devices, security issues, incompliance with regulatory standards, data quality issues such as unstructured data, inaccuracy, missing values. In order to remove these barriers and successfully transfer health data to EHR, there is a great need of standardization and FHIR standard of HL7 has a potential to transfer data from health wearable technologies to EHR which is quite evident in previous studies and research work.

Additional technologies such as Open mHealth and Shimmer (middleware) if combined with FHIR can be used to aggregate inconsistent data from 3rd party APIs such as Google Fit, Fitbit, Apple Health in standardized format and provide common schemas to map this data with FHIR resource ''Observation'' which is compliant to EHR. Industrial experts already demonstrated the bridging between Open mHealth and FHIR standards and developed content mappings between highest priority OmH schemas and FHIR resources in their implementation guide which can be used by healthcare service providers. Additional contributions are still needed to the ongoing work of standardizing mHealth data collected from health wearables technologies and mapping of such data to FHIR resources.

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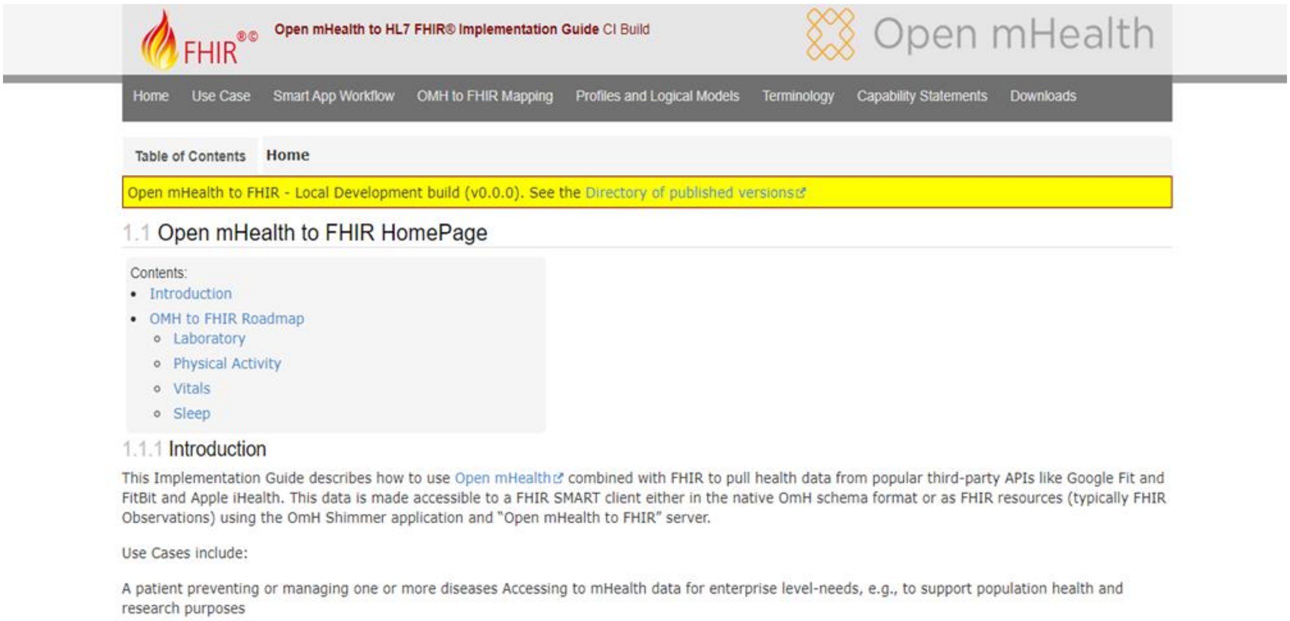
Appendix A – Data Sources

1. PubMed
2. ACM
3. IEEE
4. Springer
5. Science Direct
6. Europe PMC
7. Scholar Space
8. JMIR Publications
9. Semantic Scholar
10. iMedPub
11. PMC

Appendix B – FHIR Implementation Resources

1. Open Source Open mHealth to HL7 FHIR® Implementation Guide available at: https://healthedata1.github.io/mFHIR/index.html



OmH to FHIR Implementation Guide

2. HL7 FHIR Resource List available at: https://www.hl7.org/fhir/resourcelist.html

3. Open Source Code for Shimmer - Middleware for reading health data from APIs such as Fitbit, GoogleFit, iHealth. available at: https://github.com/openmhealth/shimmer

4. Open mHealth Schema Data mapping Tables to FHIR resources available at: https://github.com/Healthedata1/mFHIR

5. Implementation of OmH on FHIR/SMART application available at: https://github.com/gt-health/OMH-on-FHIR

6. SMART (OmH on FHIR) App Launcher available at: http://launch.smarthealthit.org/

7. OmH on FHIR application (2019) Open mHealth available at: https://goo.gl/JtSGcF

Appendix C – OmH to FHIR Mapping Spreadsheets

OMH Header Element					ition (IF	HL7 FHIR STU3 Observation				
Index	Name	JSON Data Type	ardinali	Description		FHIR Attribute	Data Type	Cardinality	Data Type Mapping	Derived Mapping
1	header-1.2.json	JSON schema object ("http://json-schema.org/draft-04/schema#)		This schema represents the header of a data transaction.		OMH to FHIR Observation Profile				
2	header.id	string	1..1	The identifier of this data point. We strongly recommend this to be a globally unique value.		Observation.identifier	Identifier	1..*	header_id	
3	header.creation_date_time	date-time	1..1	The date time this data point was created on the system where data is stored.		Observation.issued	Instant	1..1		
4	header.schema_id	schema-id	1..1	The schema identifier of the body of the data point.		None				
5	header.schema_id.namespace	string	0..1	The namespace of the schema. A namespace serves to disambiguate schemas with conflicting names.		None				
6A	header.schema_id.name	string	1..1	The name of the schema.		Observation.category	CodeableConcept	1..*	id_name_category	data_point_mapping_table
6B	header.schema_id.name	string	1..1	The name of the schema.		Observation.code	CodeableConcept	1..1	id_name_code	data_point_mapping_table
7	header.schema_id.version	string	1..1	The version of the schema, e.g. 1.0.		None				
8	header.acquisition_provenance	object	0..1			None				
9	header.acquisition_provenance.source_name	string	1..1	The name of the source of the data.		Observation.device	Reference(Device)	1..1	source_name	
10	header.acquisition_provenance.source_data_point_id	string	0..1	The identifier of this data point at the source (immediately preceding step)		Observation.identifier	identifier	0..*	data_point_id	
11	header.acquisition_provenance.source_creation_date_time	date-time	0..1	The date time (timestamp) of data creation at the source.		None				
12	header.acquisition_provenance.modication_date_time	date-time	0..1	The date time (timestamp) of last data modification at the source		None				
13	header.acquisition_provenance.modality	string (enum)	0..1	sensed' | 'self-reported' The modality whereby the measure is obtained.		Observation.device.extension	Reference(Device)		source_name	
14	header.user_id	string	0..1	The user this data point belongs to.		Observation.subject	Reference(Patient)		user_id	

OmH Header Element to HL7 FHIR Observation

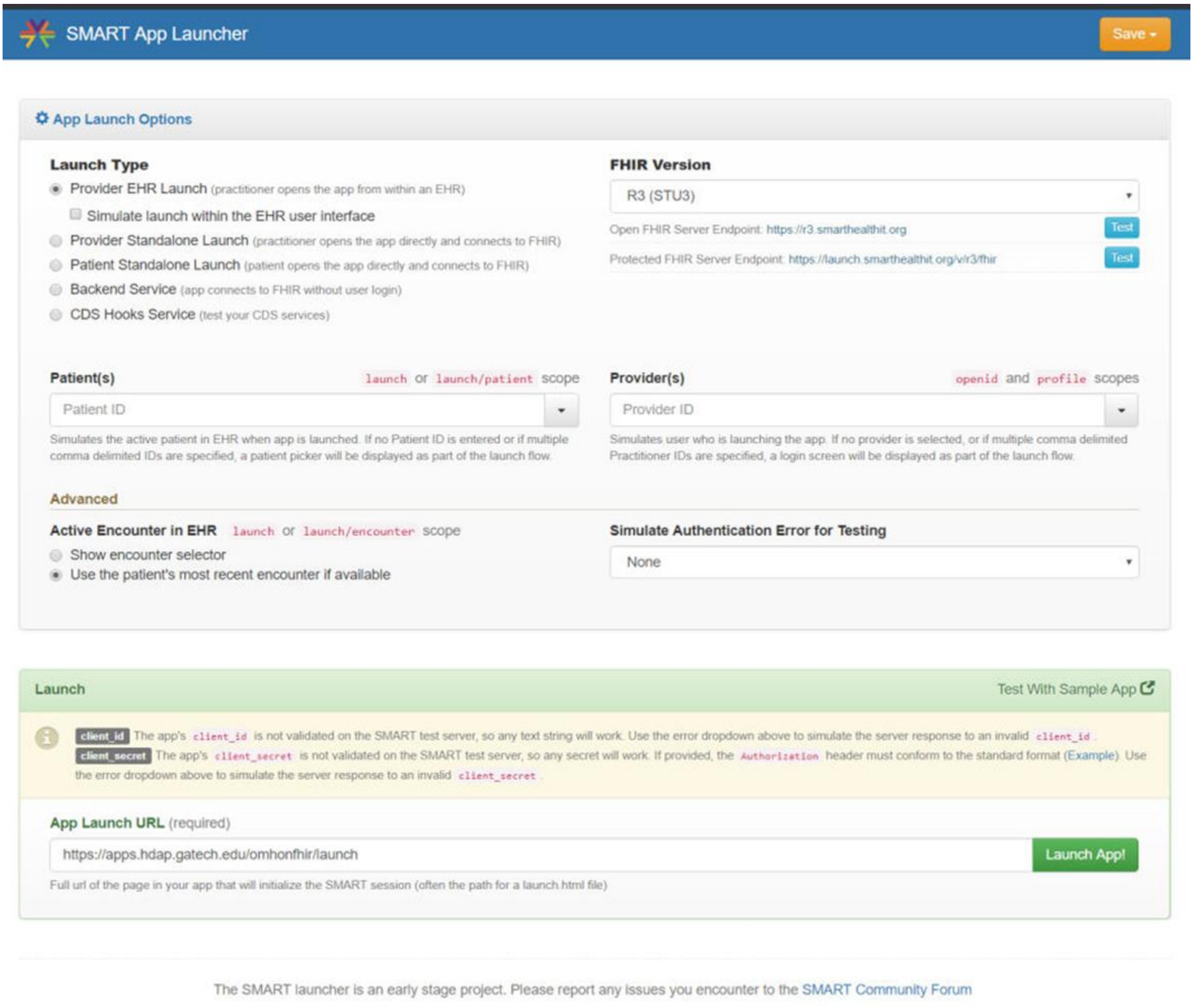
	OMH Step Count				lition (IF T	HL7 FHIR STU3 Observation				
Index	Name	JSON Data Type	Cardinality	Description		FHIR Attribute	Data Type	Cardi	Data Type Mapping	Derived Mapping
1	step-count-2.0.json	JSON schema object ("http://json-schema.org/draft-04/schema#)		This schema represents number of steps.		OMH to FHIR Observation Profile				
2	body.effective_time_frame	time-frame	1..1	As a measure of a duration, step count should not be associated to a date time time frame. Hence, effective time frame is restricted to be a time interval.		None				
3	body.effective_time_frame.time_interval	time-interval	1..1	This schema describes an interval of time. In the absence of a precise start and/or end time, the time interval can be described as a date + a part of the day (morning, afternoon, evening, night). No commitments are made as to whether the start or end time point itself is included in the interval (i.e., whether the defined interval includes the boundary point(s) or not).		None				
4	body.effective_time_frame.time_interval.start_da	date-time	1..1	represents a point in time (ISO8601)		Observation.effectivePeriod.start	dateTime	1..1		
5	body.effective_time_frame.time_interval.end_dat	date-time	1..1	represents a point in time (ISO8601)		Observation.effectivePeriod.end	dateTime	1..1		
6	body.step_count	number	1..1	number of steps		Observation.valueQuantity.value	Quantity	1..1	ds_value_quantity	data_point_mapping_table
7	body.descriptive_statistic	descriptive-statistic	0	The descriptive statistic of a set of measurements. A measurement value can be the result of combining various measurements and calculating descriptive statistics like average, maximum, minimum, etc. Additional descriptive statistics will be added as the need arises. A measurement value without a descriptive statistic is interpreted as being the result of an individual measurement.		Observation.coding	CodeableConcept	0..1	descriptive_statistic	
8	body.descriptive_statistic_denominator	descriptive-statistic-denominator	0..1	If the value needed is a standard unit of duration, select from the duration-unit-value value set.		Observation.valueQuantity			ds_value_quantity	

OmH Step Count to HL7 FHIR Observation

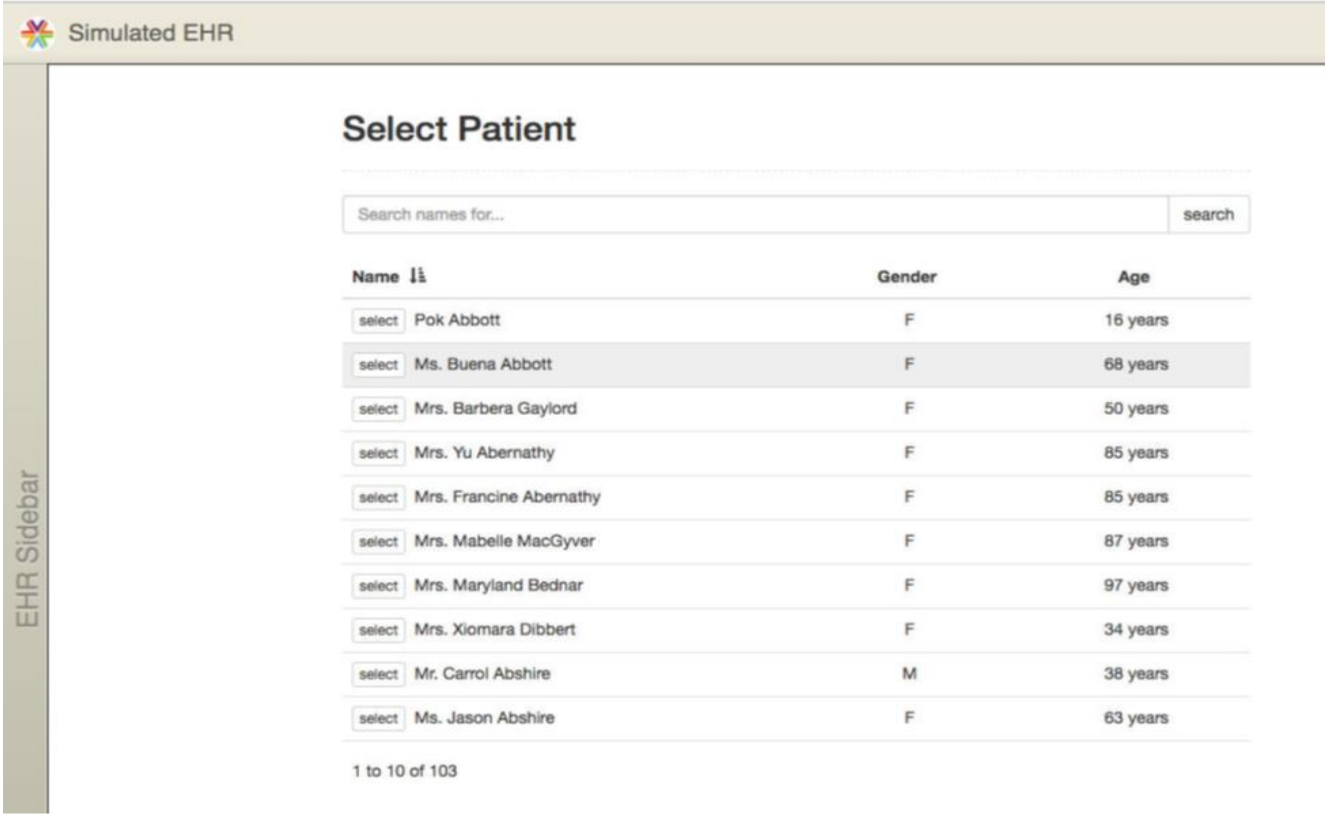
		OMH Heart Rate			dition (IF T	HL7 FHIR STU3 Observation				
Index	Name	JSON Data Type	Cardinality	Description		FHIR Attribute	Data Type	Cardi	Data Type Mapping	Derived Mapping
1	heart-rate-1.1.json	JSON schema object ("http://json-schema.org/draft-04/schema#)		This schema represents a person's heart rate.		OMH to FHIR Observation Profile				
7	body.heart_rate	unit-value-1.0.json	1..1	heart rate		Observation.valueQuantity	Quantity	1..1	value_quantity	
2	body.effective_time_frame	time-frame	0..1			None				
3	body.effective_time_frame.time_interval	time-interval	1..1	This schema describes an interval of time. In the absence of a precise start and/or end time, the time interval can be described as a date + a part of the day (morning, afternoon, evening, night). No commitments are made as to whether the start or end time point itself is included in the interval (i.e., whether the defined interval includes the boundary point(s) or not).		None				
4	body.effective_time_frame.date_time	date-time	0..1	represents a point in time (ISO8601)		Observation.effectiveDateTime	dateTime	0..1		
5	body.effective_time_frame.time_interval.start_date_time	date-time	0..1	represents a point in time (ISO8601)		Observation.effectivePeriod.start	dateTime	0..1		
6	body.effective_time_frame.time_interval.end_date_time	date-time	0..1	represents a point in time (ISO8601)		Observation.effectivePeriod.end	dateTime	0..1		
8	body.user_notes	string	0..1			Observation.comment	string	0..1		
9	body.descriptive_statistic	descriptive-statistic	0..1	The descriptive statistic of a set of measurements. A measurement value can be the result of combining various measurements and calculating descriptive statistics like average, maximum, minimum, etc. Additional descriptive statistics will be added as the need arises. A measurement value without a descriptive statistic is interpreted as being the result of an individual measurement.		Observation.coding	CodeableConcept	0..1	descriptive_statistic	
10	body.temporal_relationship_to_physical_activity	temporal-relationship-to-	0..1	The temporal relationship of a clinical measure or assessment to physical activity.		Observation.component	Element	0..*	component_map	component_mapping_table
11	body.temporal_relationship_to_sleep	temporal-relationship-to-	0..1	The temporal relationship of a clinical measure or assessment to sleep.		Observation.component	Element	0..*	component_map	component_mapping_table

OmH Heart Rate to HL7 FHIR Observation

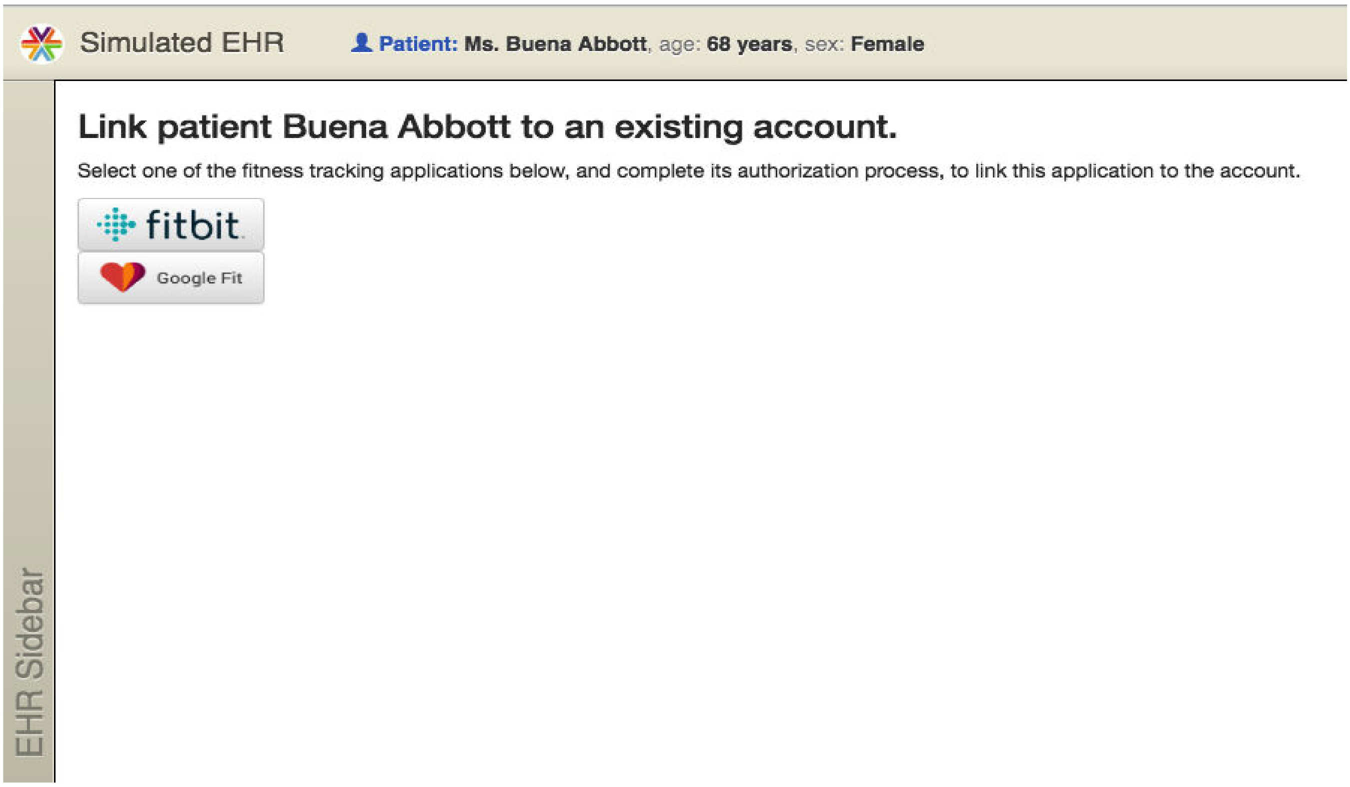
Appendix D – OmH on FHIR (SMART) UI



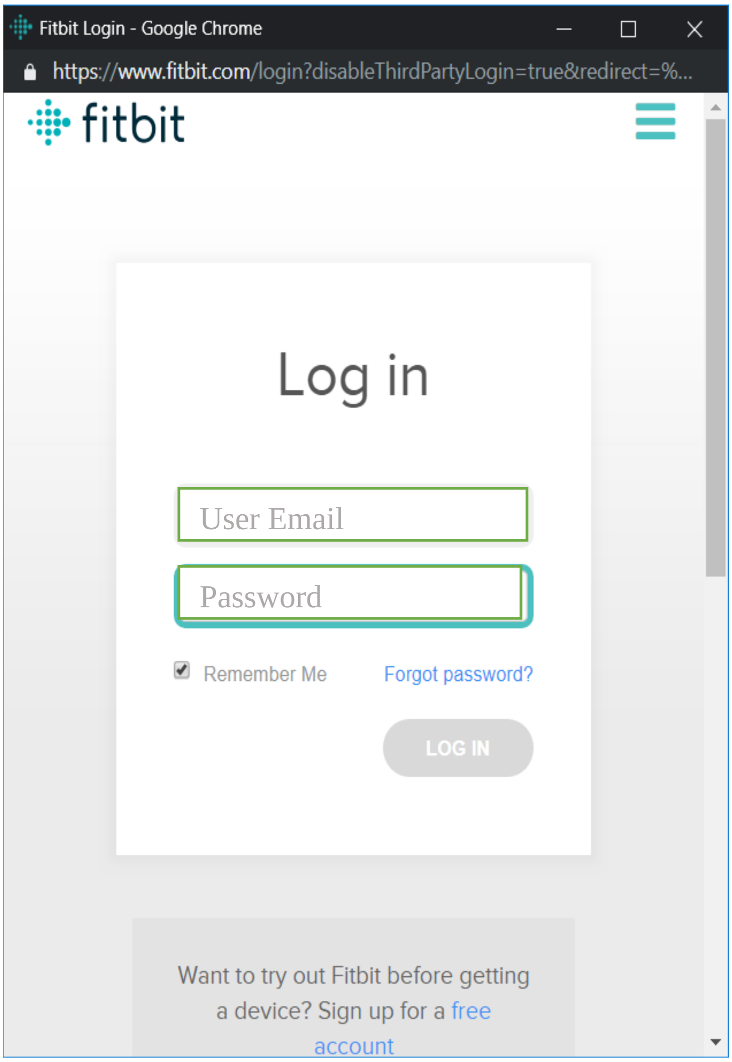
Launch with SMART App Launcher



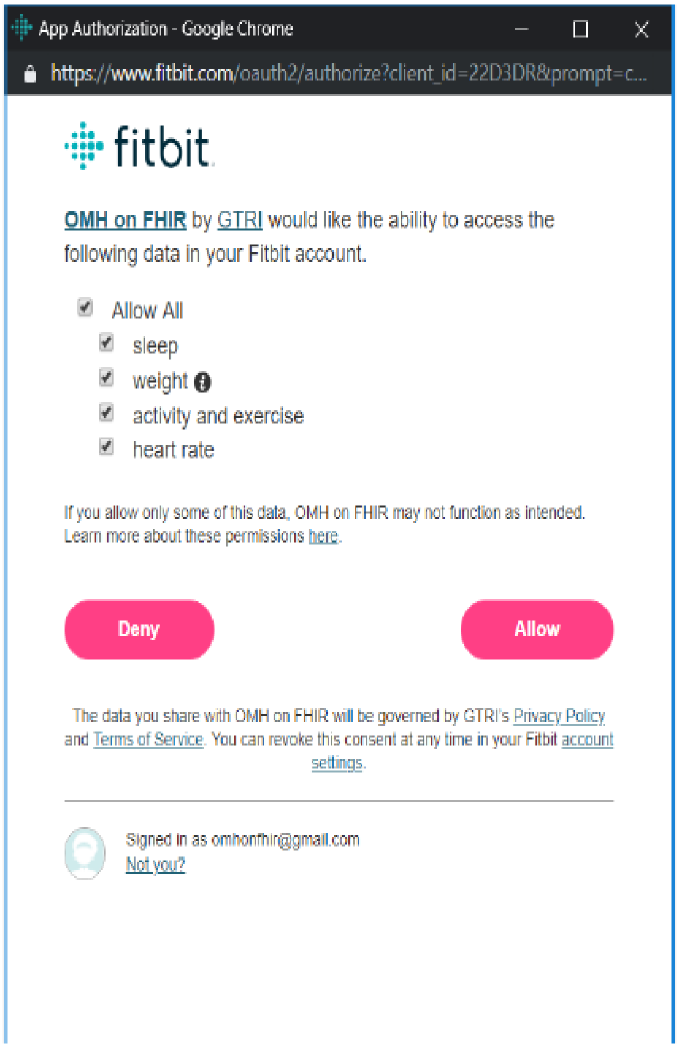
Patient Selected in Simulated EHR



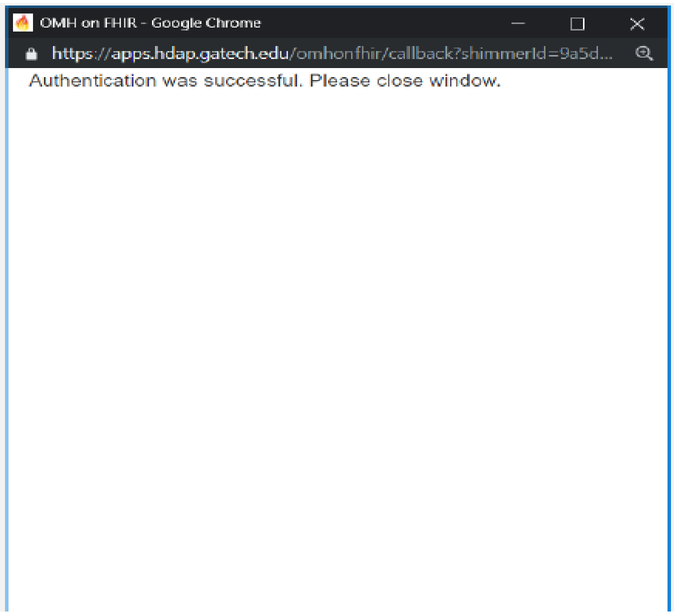
Select Patient’s Account



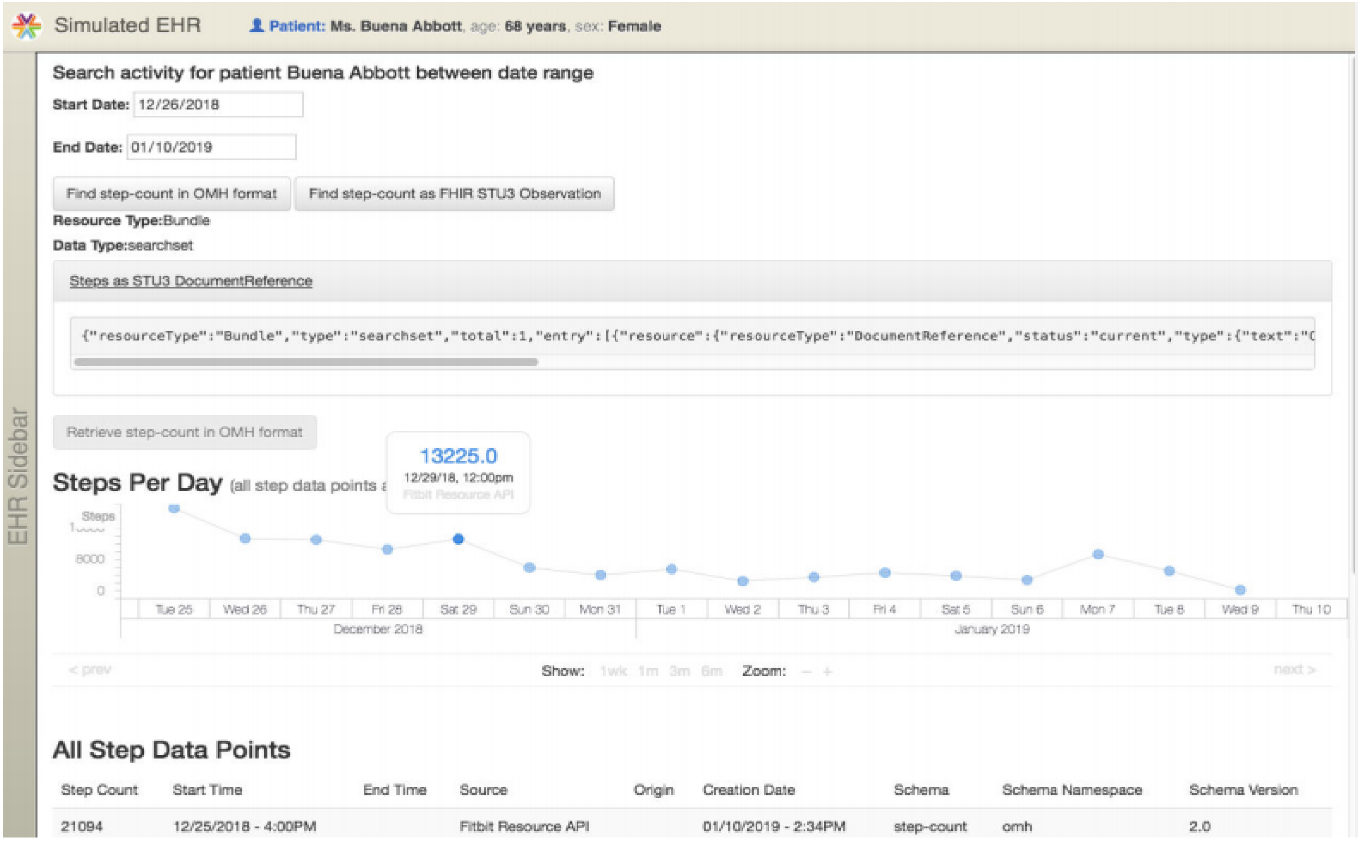
Patient Login with Fitbit Credentials



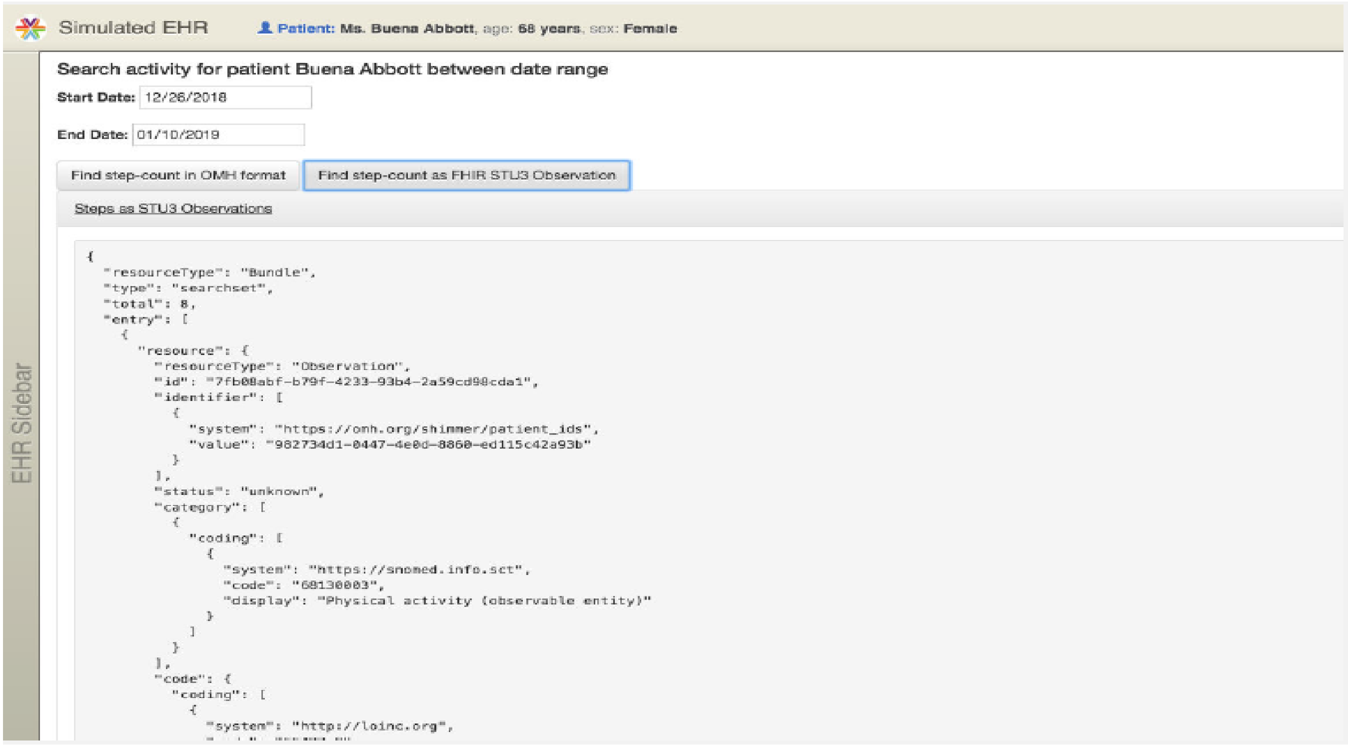
Patient Allows Data for Access



Complete Fitbit Authentication



Step Count Data in Simulated in EHR



Step Count as FHIR Observation