**Motivation:**

One of the major trends in healthcare is an increasing desire for patients to exert more control over their Protected health information (PHI) which contains data that they create and control and data that is maintained in the different health information technology systems that are deployed at hospitals, clinics, medical offices, test laboratories, imaging centers, pharmacies, etc. The work of (Sujansky et al., 2010) allows patients to define fine-grained access control policies for data in personal health records (PHRs)[[1]](#footnote-1) such as: ‘‘Anyone whom I designate as a family member may view my medication list, except for one of my medications that I’d rather not share. . .”; ‘‘Anyone whom I designate as a health care provider may view my medication list and my history of office visits and hospitalizations, but not modify these data. . .; ‘‘My primary physician, Dr. Albright, may view and modify my medication list and may view and annotate my log of meals and physical activities. . .”’ and, ‘‘Dr. Albright’s (Electronic Health Record) EHR system may automatically add new items to my medication list, but it may not change or retrieve any items unless Dr. Albright is logged in.” In another effort (Caine and Hanania, 2013) a study of patients as conducted that focused on the type and granularity of health and other information that they wanted control of their data in electronic medical records (EMRs). For a given patient, this effort highlights the potential recipients of the information (e.g., primary physicians, mental health providers, spouse, family, emergency medical providers, etc.) and the type of information to be controlled (e.g., contact info, current conditions, medications, recent test results, mental health information, genetic information, etc.). In such a setting, patients are also interested in actually defining specific fine-grained access control (Sujansky et al., 2010) by designating access by role, for example: a family member may view my medication list (but not all of them), a medical provider may view my medication list and history of hospital visits (but not modify), my personal physician may both view and modify my health care and fitness data, etc. Table 1 excerpted from the paper is shown in Figure 1 defines the various recipients and a wide range of data items (lower half) including: contact information and demographics; information relevant to current conditions; medications; recent test results; past medical history; history of substance abuse and treatment; mental health information; sexual health information; records relating to domestic violence, reproductive health records; genetic information.



In addition to tracking this traditional medical/health information, the other major market force is the enormous growth of mobile computing. Mobile computing devices and applications have exploded in the marketplace, with the Gartner group forecasting worldwide shipments in 2015[[2]](#footnote-2) of 1.9 billion mobile phones and 230 million tablets, which is outpacing PC/laptop sales significantly (300 million estimate). In the United States, a PEW Research Center report of smartphone usage[[3]](#footnote-3) found that as of October 2014, 64% of American adults own a Smartphone while as of January 2014, 42% own a Tablet, and 32% own an e-reader. Predictive statistics project that tablet users will surpass 1 billion in 2015 worldwide[[4]](#footnote-4) while the total of mobile devices will exceed 12.1 billion by 2018.[[5]](#footnote-5) In addition, Cisco reported[[6]](#footnote-6) in 2014 that 497 million mobile devices were added that year, and 88% of that growth is accounted to smartphones and, predicted that by 2019, there will be approximately 1.5 mobile devices per capita giving a total of 11.5 billion mobile devices around the world. As mobile devices become more mainstream, they have begun to serve as a replacement for traditional PC-based computing in major consumer and industrial markets.

As individuals rapidly change the ways they access data and information, there is a profound impact on the way that users must be authorized and authenticated. Accessing data and executing apps on a mobile platform is substantially more dynamic than traditional computing on laptops and desktops. A mobile device user may have a myriad of open applications including email accounts (corporate, Gmail, yahoo, etc.), browsers, social network apps (Facebook, Twitter, LinkedIn, etc.), communication apps (Skype, Snapchat, SMS, etc.), shopping apps (Amazon, JCPenney, Walgreens, etc.), health and fitness apps (CVS Health, Microsoft HealthVault, MyQuest, etc.), games, etc. In such a setting, users are often logged onto and authenticated to all of these apps simultaneously and move among them throughout the day, providing them with the ability to store, exchange, and view both personally identifiable information (PII) and personal health information (PHI). The drawback is the need for users to be authenticated on each individual application and often re-authenticated during sessions that can last for long periods of time. The challenge in this situation is to provide a means for user authentication for mobile computing in order to provide a more seamless experience for users.

One such domain that is exploding is healthcare, where there is a growing desire for an individual seeking to PHI and PII. For example, consider the proliferation of health and fitness applications on multiple mobile platforms for: pharmacies and organizing medications (myCVS,[[7]](#footnote-7) MEDWatcher,[[8]](#footnote-8) Drugs.com Medication guide and Pill Identifier Applications,[[9]](#footnote-9) etc.); personal health record (PHR) applications (CAPZULE PHR,[[10]](#footnote-10) MTBC PHR,[[11]](#footnote-11) suite of WebMD Applications,[[12]](#footnote-12) etc.); a wide array of fitness devices[[13]](#footnote-13) and applications that work with phones and wearables;[[14]](#footnote-14) Apple’s HealthKit app[[15]](#footnote-15) and the Google Fit fitness tracker,[[16]](#footnote-16) where both companies have pushed strongly into the smartwatch market to track activity, heart rate, blood pressure, etc.;[[17]](#footnote-17) and, Apple’s ResearchKit, which is an open source framework for mobile applications to support medical research.[[18]](#footnote-18) Patients also seek to have access via their mobile devices to the electronic medical records (EMRs) utilized by their medical providers, as well as various health information technology (HIT) systems that contain medical testing results[[19]](#footnote-19) or results from imaging testing.[[20]](#footnote-20) In addition, there is an increasing interest for the use of mobile apps for chronic disease management – as published in the literature[[21]](#footnote-21) and with the numerous results from a Google Search (“tracking chronic diseases with mobile apps 2015”).[[22]](#footnote-22) Further, many of the medical devices that are involved in tracking and monitoring chronic diseases are blue-tooth enabled devices. For example, the Microsoft HealthVault PHR[[23]](#footnote-23) can accept patient supplied data from a wide range of devices[[24]](#footnote-24) that include glucometers (for diabetes), weight scales, blood pressure monitors, peak-flow monitors, ECG (heart), etc. All of these systems must adhere to the Health Insurance Portability and Accountability Act (HIPAA)[[25]](#footnote-25) for the security, availability, transmission, and release of a patient's medical information. There are also corresponding efforts that highlight a strong need to achieve fine grained role-based level of security to allow patients to define who can see and/or modify what portions of their health/fitness data other individuals can view/modify using mobile applications for health care, where the mobile application itself can be customized based on role to meet the permission definition provided by the patient (Peleg et al., 2008).

**Challenge:**

Patients are interested in tracking all of the data associated with fitness devices (wearable and others such as treadmills), medical devices for chronic disease management that patients own and control, and medical devices given to patients by medical providers in order to conduct certain tests at home under their supervision such as a Holter monitor for 24 hours.[[26]](#footnote-26) This information from a myriad of different and non-integrated sources needs to be collected and made available to patients, and be easily provided to medical providers in either detailed or summary form. A patient may be utilizing multiple mobile apps to manage the different fitness and medical devices, each of which has their own data repository (perhaps SQL lite on a phone or SQL DB on a server) with limited ability to collect the data in a consistent format from multiple sources so that the information can be integrated. Further, medical providers (hospitals, clinics, MD offices, pharmacies, imaging centers, etc.) all have their own health information technology (HIT) systems to manage healthcare and medical data on patients. Challenges include:

* Patients needing the ability to be able to manage health/medical/fitness/chronic disease data across a wide range of applications (may be both mobile and web-based) that involve separate and independent repositories.
* Patients needing the ability to share such information with specific stakeholders that could include: patient him/herself, family members (child care, elder care, spousal care), nutritionists, personal trainers, therapists (physical, occupational, pulmonary), home health care aides, internist, family medicine MD, nurse practitioner, physician assistants, pediatricians, cardiologists, ENTs, orthopedic surgeons, physiatrist, phycologist, therapist, etc. Some of these stakeholders may be using mobile apps (family members, trainers, etc.) while others will need the data provided in a manner that integrates with the treatment workflow (into the EMR).
* Medical providers which need to have access to both granular and aggregated health/medical/fitness/chronic disease data that patients can provide within a wide range and type of Electronic Medical Record (EMR) systems which they interact with for patient care. Medical providers each have their own EMRs and the ability to share information among providers is not easily achieved in practice. Medical providers need this information in their systems since they are disinclined to use multiple systems and want data to be presented in a unified view integrated into their current workflow and systems.
* Medical providers who provide medical devices to patients to collect data over a specific time period (Holter monitor) that could be delivered back to the medical provider by phone, internet, or by returning the device itself.

The purpose of the Individual/Team Design/Development Project is to explore all of these different issues utilizing a variety of health information technology standards, frameworks, and systems. Throughout the semester, we will develop a working group of the entire class that will leverage the varied skill sets (mobile app design/development, interacting with devices, databases, APIs) by exploring, evaluating, and utilizing a wide range of HIT standards, frameworks, and actual systems.

**Standards, Frameworks and Systems**

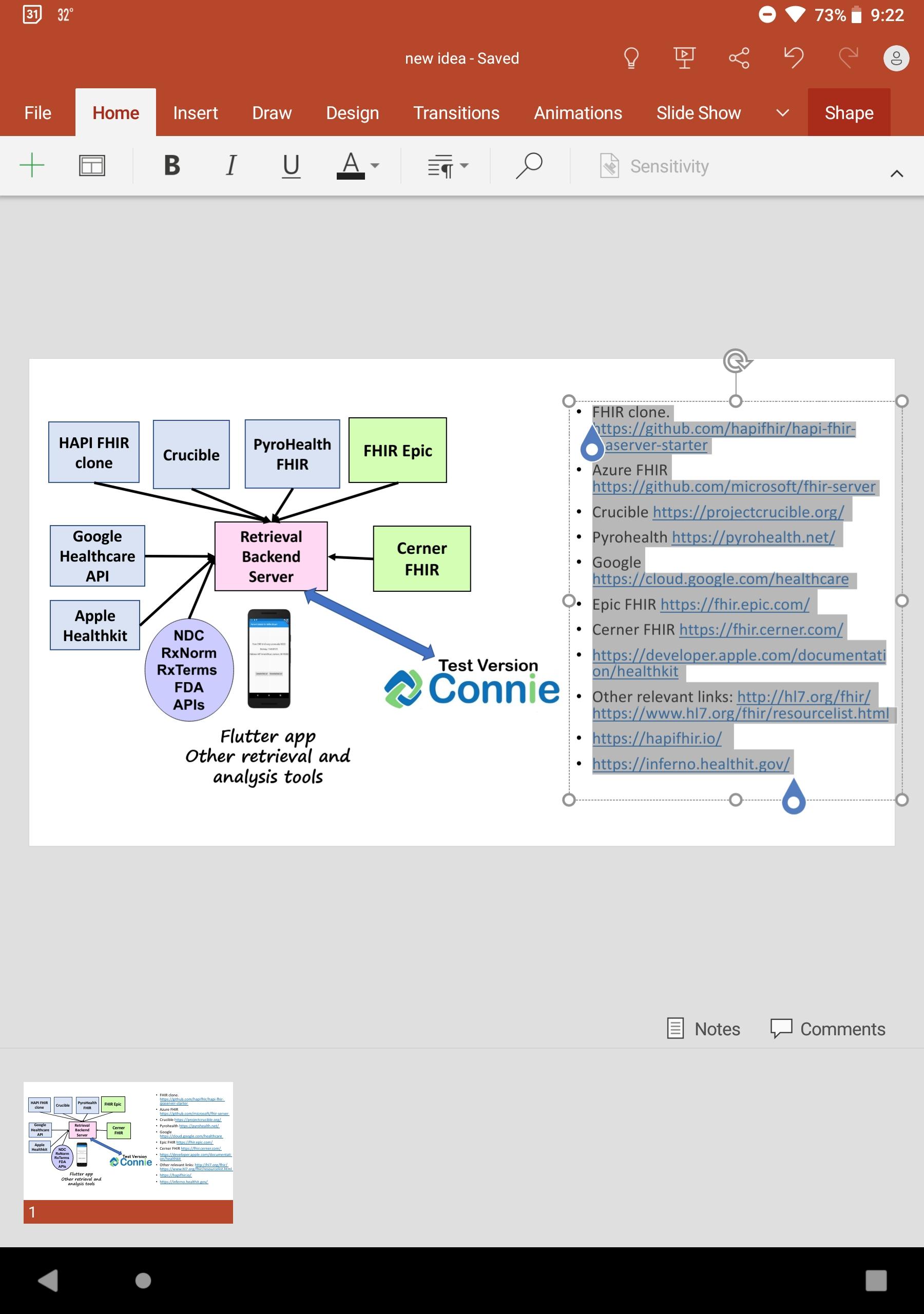
Standards include:

* JSON: <http://www.json.org/>
* RDF: <https://www.w3.org/RDF/>
* XML: <http://www.w3schools.com/xml/>
* HL7: <http://www.hl7.org/implement/standards>
* HL7 CDA: <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7>
* HL7 CCD : <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=6>
* ICD-10: <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/data-and-systems/icd-coding/icd.html>
* FDA Drugs: [https://www.fda.gov/Drugs/Informat ionOnDrugs/ucm142438.htm](https://www.fda.gov/Drugs/Informat%20ionOnDrugs/ucm142438.htm)
* RxNorm: <https://www.nlm.nih.gov/research/umls/rxnorm/>
* RxTerms: <https://mor.nlm.nih.gov/RxTerms/>
* RxNav: <https://rxnav.nlm.nih.gov/>

Frameworks include:

* FHIR: Fast Healthcare Interoperability Resources <https://www.hl7.org/fhir/overview.html> and <https://www.hl7.org/fhir/index.html>
* SMART: An App Platform for Healthcare <http://smarthealthit.org> with multiple apps <https://gallery.smarthealthit.org/> and the usage of FHIR <http://smarthealthit.org/smart-on-fhir/>
* Open mHealth: Open Source Code to Integrate digital health data <http://www.openmhealth.org>

Other relevant technologies:

* **HAPI FHIR** [**https://hapifhir.io/**](https://hapifhir.io/)
* **Azure FHIR** [**https://github.com/microsoft/fhir-server**](https://github.com/microsoft/fhir-server)
* **Crucible** [**https://projectcrucible.org/**](https://projectcrucible.org/)
* **Pyrohealth** [**https://pyrohealth.net/**](https://pyrohealth.net/)
* **Google** [**https://cloud.google.com/healthcare**](https://cloud.google.com/healthcare)
* **Epic FHIR** [**https://fhir.epic.com/**](https://fhir.epic.com/)
* **Cerner FHIR** [**https://fhir.cerner.com/**](https://fhir.cerner.com/)
* [**https://developer.apple.com/documentation/healthkit**](https://developer.apple.com/documentation/healthkit)
* **Other relevant links:** [**http://hl7.org/fhir/**](http://hl7.org/fhir/)[**https://www.hl7.org/fhir/resourcelist.html**](https://www.hl7.org/fhir/resourcelist.html)
* **Inferno** is a rich and rigorous testing suite for HL7® Fast Healthcare Interoperability Resources (FHIR) to help developers implement the FHIR standard consistently. [**https://inferno.healthit.gov/**](https://inferno.healthit.gov/)
* **HAPI FHIR clone** has been developed by one of my CSE undergrads that includes the loading of a feed of data from synthea to set up a server that has realistic simulated data. Based on:[**https://github.com/hapifhir/hapi-fhir-jpaserver-starter**](https://github.com/hapifhir/hapi-fhir-jpaserver-starter)and there will be a version made available as a zip file that is installable as a docker container

**Scope:**

One focus of the project is to identify an define all of the fitness, medical, and health data that a patient is interested in tracking, which includes chronic disease data. One approach to take for the semester is to define a entity relationship database schema (via MySQL Workbench) to store the information from the perspective of the patient that would be contain information that is stored across multiple mobile and other applications from different sources. This will give us the ability to have a common repository for all of the information that must be staged to and from the patient and back and forth to the different sources. We can investigate the different framework (SMART, FHIR, etc.) and what they have has in terms XML and/or JSON to model all of this information, or if any part of the FHIR standard can be utilized to model or encapsulate this information. The open mHealth platform is also a possibility. Another possible is to explore what Google Fit and Apple Healthkit offer. For example, Google has fitness data types for both raw and aggregate data.[[27]](#footnote-27) There have also been standards approved for personal health data[[28]](#footnote-28) with efforts that emphasize the need to share information across multiple sources.[[29]](#footnote-29)

Different team members of the class can focus on modeling different aspects of the health fitness medical and chronic disease data. Then we can unify the different ER models into one common model. On the mobile side we can use SQLite in order to support the usage of the model by mobile apps, and use a regular MySQL database to store  the information.  We can also explore the usage of openEMR and openMRS or other open source electronic medical records systems to store the information, since using one of these systems will give us the security required for HIPPA compliance.  Alternatively, we need to examine the degree that FHIR can be utilized to support interoperability across multiple sources that are storing health fitness medical and chronic disease data.

**Project Possibilities:**

The following is an initial list of possible topics and projects to be assigned to both individuals and teams of individuals during the semester.

* Explore standards available for Health/Fitness/Medical/Chronic Disease data.
* Investigate what Fitness/Wearable Devices[[30]](#footnote-30) support in terms of Storing/Analyzing Data collected by users and the way that information can be collected from different platforms.
* Investigating the usage of FHIR to support Health/Fitness/Medical/Chronic Disease data including the development of a proof of concept prototype.
* Investigating the usage of SMART to support Health/Fitness/Medical/Chronic Disease data including the development of a proof of concept prototype.
* Design an ER Diagram for Health/Fitness/Medical/Chronic Disease data collected by patients.
* Applications in Android (using Google Fit) or iOS (using Apple Healthkit).
* Linking up Bluetooth devices (Fitness, Scales, Glucometers, BP, etc.) to a mobile app, the database on health/fitness/medical/chronic data being defined
* Ability to feed from Bluetooth devices into an EMR via REST APIs, FHIR, SMART, etc.
* Server/REST Infrastructure to allow data from multiple sources (different data repositories) to be staged back and forth to a mobile app and interaction with EMRs.

Note: Relevant fitness and Bluetooth devices will be purchased as needed to support the work during the semester.

**Background:**

Part of the patient collected information for patients can include tracking of major chronic diseases including: diabetes, CHF, Asthma, and obesity. These different chronic diseases are reviewed to highlight the information that needs to be tracked for patients (entered by patients). Note also that you may need to do some web searching on the chronic diseases in order to fully explore the domain requirements.

**Diabetes:**

Diabetics must measure their glucose using glucometers (<http://en.wikipedia.org/wiki/Glucose_meter> ) on a regular basis. These values are used to denote different things based on their interpretation. For example when the fasting values (glucometer taken with no food for last 8 hours) are below 40mg/DL for women and 50 mg/dL for men, these are considered too low. Also, a patient may be diagnosed with Diabetes and have high glucose levels if glucose level at any time is >= 200 mg/dL or if a fasting glucose is >= 126 mg/dL. Diabetes patients try to keep values above low value level and below the high value level. This issue could be addressed by tracking glucose values over time via decision support software for patients that a). yo-yo from below the low and above the high b). are always too high, and c). are always to low. Part of our work for later in the semester will be to potentially design and implement an algorithm that considered the low/high glucose values in conjunction with type of test (fasting, casual, etc.) over some variable time period, and graphing for patients/providers or sending email alerts. The data that must be tracked includes, but is not limited to:

1. Time stamp for the entire entry entered by patient
2. Type of test: Fasting (no eating for at least 8 hours), 2 hours after eating, casual (any time during day)
3. Glucose Level measured in mg/dL taken from meter
4. Insulin taken (value comes up from the meter after testing)
5. Carbohydrates

Other info that may be needed is when was the insulin taken, which is often 30-60 minutes before eating.

**Congestive Heart Failure/High Blood Pressure**

Patients with congestive heart failure or high blood pressure need careful monitoring. Blood pressure values such as 120/72 measure the systolic pressure in mm Hg – upper number, and the diastolic pressure in mm Hg –lower number. In terms of values, values (systolic/ diastolic) are: Normal is less than 120/less than 80, Prehypertension 120-139/80-89, High Blood Pressure Stage 1 140-159, 90-99, High Blood Pressure Stage 2 160 or higher, 100 or higher, Hypertensive Crisis 190 or higher, 110 or higher.

Again, if this information is tracked over time, then it can be correlated to determine if a patient is running too high or too low and may need to get in to see a physician for a medication adjustment. Data that must be tracked includes:

1. Time stamp for the entire entry entered by patient
2. Pulse
3. Blood Pressure (systolic mm Hg – upper number, Diastolic mm Hg –lower number)
4. Respirations per minute
5. Pulse Ox – out of 100%
6. Peak Flow Meter PERF L/min (adults http://www.peakflow.com/pefr\_normal\_values.pdf and children http://www.peakflow.com/paediatric\_normal\_values.pdf)

Food intake may also play a role, if the patient is on a salt-free or low fat diet, or if a patient is on a blood thinning medication which requires avoidance in foods that are high in vitamin K (which causes blood clotting in high amounts).

**Asthma**

Asthma requires careful monitoring of patients pulse, respiration, etc., to insure that a patient is manaing their condition. There is always the potential for asthmatics to have environment or allergic reactions that have the potential to cause a life threatening condition. The data that must be tracked includes, but is not limited to:

1. **Time** stamp for the entire entry entered by patient
2. Pulse
3. Respiration
4. Pulse Ox – out of 100% (now available on mobile phone – see <http://www.ncbi.nlm.nih.gov/pubmed/22954855> )
5. Peak Flow Meter PERF L/min (adults http://www.peakflow.com/pefr\_normal\_values.pdf and children http://www.peakflow.com/paediatric\_normal\_values.pdf)

Note that there may also be the need to carefully track the inhalers and other pulmonary devices (nebulizer). A provider may want a patient to enter in when they are taking their medications on a daily basis, since there is a potential correlation with medications and pulmonary health. Also, if they have to use a rescue inhaler, that should be tracked.

**Obesity**

Most of the information tracked for obesity is weight and diet/nutrition related. Weight will likely not be entered on a daily basis (since weight can vary day to day and within the same day), but there may be some set schedule that is required. Data on diet and nutrition might be collected, including calorie totals. A patient may be on limited calories in order to manage weight. The data that must be tracked includes, but is not limited to:

1. Time stamp for the entire entry entered by patient
2. Weight (entered daily? Weekly? Set differently for different patients?)
3. Blood pressure
4. Calories/Diet (How do we gather this information? What is available out there already?)
5. Pulse and Blood Pressure after exercise

Note that there may be a link from Obesity related classes to other classes (like exercise) that are defined. Note also that a patient may have multiple chronic conditions; in this case, PHA would need to try to limit the input of duplicate information.

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