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Signature of Student (Neelima Atluri) Date

Utilizing Emerging Technology to Create Surveillance and Registry Systems with Meaningful Data Analysis and Visualizations

BY
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Executive MPH

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INTRODUCTION

The following is a series of informatics projects completed during the EMPH APHI program at Rollins School of Public Health of Emory University. These informatics projects all demonstrate “Utilizing Emerging Technology to Create Surveillance and Registry Systems with Meaningful Data Analysis and Visualizations”. Using emerging technology to improve data collecting informatics systems improves the meaningfulness of the data and the ability to create informative visualizations that public health decision makers can use to more effectively target public health programs and interventions.

CKD Re-Source – A National Registry of Chronic Kidney Disease Patients

by Neelima Atluri

Executive Summary

The prevalence of Chronic Kidney Disease (CKD) in the United States is 14%. Each year, kidney disease kills more people than breast or prostate cancer. In 2013, more than 47,000 Americans died from kidney disease. CKD can lead to End Stage Renal Disease (ESRD) requiring dialysis or a kidney transplant. CKD is categorized by stages 1 through 5 at different Glomerular Filtration Rates (GFR), the rate at which kidneys filter waste and other fluids from the blood. The stages are defined below:

- Stage 1: Kidney damage with normal kidney function (estimated GFR ≥90 mL/min per 1.73 m^2) and persistent (≥3 months) proteinuria (urine has higher than normal amounts of the protein albumin).
- Stage 2: Kidney damage with mild loss of kidney function (estimated GFR 60-89 mL/min per 1.73 m^2) and persistent (≥3 months) proteinuria.
- Stage 3: Mild-to-severe loss of kidney function (estimated GFR 30-59 mL/min per 1.73 m^2).
- Stage 4: Severe loss of kidney function (estimated GFR 15-29 mL/min per 1.73 m^2).
- Stage 5: Kidney failure requiring dialysis or transplant for survival. Also known as ESRD (estimated GFR <15 mL/min per 1.73 m^2).

Because CKD is often asymptomatic, less than 10% of patients with Stages 1 through 3 are aware that they have it. If they were aware that they had it, it could be treated earlier and possibly prevent its further progression. Those with CKD are at higher risk for Cardiovascular Disease (CVD). Nearly half of those with

CKD also have diabetes and/or CVD. Having CKD further complicates the treatment of CVD. Medicare spending for patients with CKD ages 65 and older exceeded $50 billion in 2013 and represented 20 percent of all Medicare spending in this age group. (The National Institute of Diabetes and Digestive and Kidney Diseases, 2017)

Because of the unawareness and the progression of the disease, identification of patients and improved monitoring and quality of care are needed. CDC's objective of a national surveillance registry requires data sources with information on CKD patients from Electronic Medical Records. Guidelines for treatment for providers were published by the National Kidney Foundation called Kidney Disease Outcome Quality Initiative (KDOQI) but there needs to be a way to monitor and track providers' adherence to the guidelines. (Navaneethan, 2011)

This national registry, CKD Re-Source aims to fulfill these needs by providing a registry that allows providers a way to search for and identify all of their own CKD patients in one place as well as a source for providers to see what treatment is working for other patients. In addition, the CKD Re-Source will provide a way to monitor whether providers are adhering to the KDOQI guidelines.

The data needs to include comorbidities, pharmaceuticals prescribed, procedures, physician visit dates and notes, lab results, blood pressure, GFR, proteinuria status and start date, clinic or hospital visited and dates, lab visited and dates, stage categorization, and demographics. Sources included labs, pharmacies, and provider EMRs. This data will be used to identify, track and

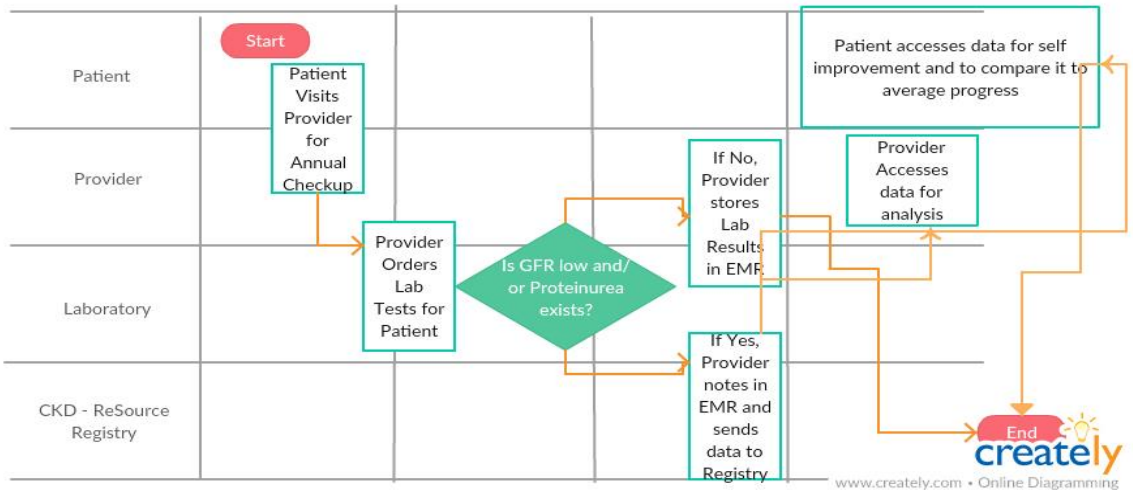
monitor CKD patients as a population and in individual visits and will provide administrators with a way to track provider adherence to guidelines. The end user (either the provider, administrator, or even the patient themselves in a patient view) will be able to graphically display a time series of their measurements over a historical period of time. The patient view will be limited to their own results but can also see how their progress may compare to the average CKD patient. The provider and administrator will be able to monitor the population as a whole as well as at an individual level, with visualizations that will provide them with decision making support. For example, the patient can see their GFR over the past year. A provider can view this for the individual or averages of the GFR for their population of CKD patients over the year.

Project Plan and Timeline

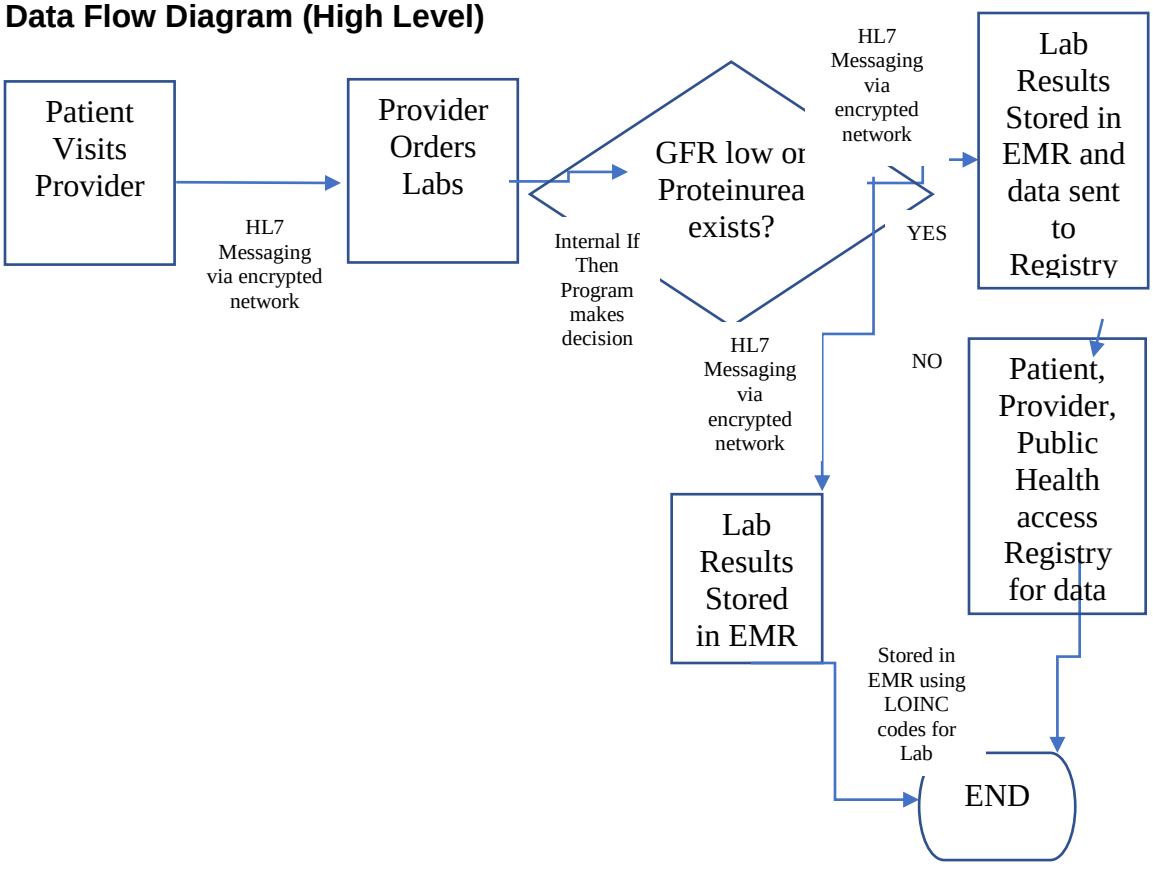
Business Needs	Sept 18
Peer Review	Sept 20
Requirements Gathering	Sept 24
Process and Methodology	Sept 27
Literature Review, SME discussions with providers/patients	Oct 3
Exploration of new technology directions to determine best fit solutions and effectiveness	Oct 8
Communication Plan	Oct 13
Draft write up for each critical component in the solution, data schema/structures as related to phases and processes	Oct 18
Risk Management and Analysis	Oct 23

Proposed analytics and visualization methods	Nov 1
Testing Phase	Nov 6
Draft Results/Deliverable Chapter	Nov 12
Final Project	Nov 17/18
Final Presentation	Nov 17/18

Swim Lane Diagram



Data Flow Diagram (High Level)



Critical Components

Component	Technology/Standard
User Interface with Patient, Provider, and Public Health Views including a separate data portal.	Both Mobile and Desktop application versions built using **SMART on Open API FHIR**
Authentication/Security	Data in Motion: **OAuth2**, and **HTTPS** and **SSL** encrypted website Data at Rest: **firewalled** and **WPA2** secured network Data in Use: **Duo Authentication** using encrypted technology such as a smart card or biological identification in addition to a password. Different permissions and views for types of user including: Patient/Provider/Public Health.
Database	**MongoDB NoSQL** database
Storage	**AWS GovCloud** – Complete Database records will be

Component	Technology/Standard
	stored in **MongoDB** in a **Data Lake** with a **Shared Ledger** and **BitCoins with** different data fields from different types of providers (i.e. lab results from labs will be on one BitCoin) will be used on **Docker containers**.
Patient Qualifier Program	**Natural Language Processing Machine Learning (Amazon AI)**
EMR Interface	**SMART ON FHIR OPEN API** interface, **HL7** Messaging for data flow.
Clinical Study Search/Qualification Tool	NLP Machine Learning qualifier, Web interface is SMART on FHIR
Lab Results receipt from Lab/EMR	**LOINC** coded results collected in EMR and shared with registry via secured network and **HL7** Messaging.
Visualization Tool	Interface will include a

Component	Technology/Standard
	separate area for a data portal and **R Shiny** will be the freeware tool used to create user selected visuals for public health, providers, and patients.
Management of Server	**Puppet** – Overall Lifecycle Client-Server mgt (see below) Main Client and the Servers will be Docker containers **Docker** – BitCoins will be contained in each container **Jenkins** – Continuous integration

Data Sources/Access points:

- EMR
- Lab
- Provider
- Patient
- State Depts of Health
- CDC
- Clinical Study Administrators

- Dialysis provider

Data Elements:

Demographic Data: De-identified medical record number (will be removed from public view), age, sex, race, ethnicity, city and state of residence (From **EMR)**

Vitals at Provider visitation: Blood Pressure, Temperature, Weight, Pregnancy (Yes/No coded) (From **EMR**)

Lab Results: Proteinuria, Albuminuria, Creatine, GFR, test result date, test location (From **Lab and/or EMR**)

CKD Stage: 1-5 according to lab results (**EMR or Machine Learning** based on GFR lab results)

Treatment: Provider prescriptions or therapies (From **EMR**)

Comorbidities: CVD, Diabetes, others?

Comorbidity Treatments/Therapies/Procedures, Date prescribed, date of procedure or therapy (**EMR**)

Provider info: Name, Specialty, Location, Visitation Date (From **EMR**)

Puppet use:

- A Puppet Master server will be utilized to control sending code to each node (Docker container).
- Puppet agents/nodes (Docker containers) will be utilized for each of the critical components.
- Puppet will then distribute repetitive tasks to each node.
- The registry will be stored on the virtual server in the cloud and each of the components will be processed at the nodes.

Metrics:

- Baseline average GFR at time 0, and average GFR at time 1.
- Percentage of patients with routine lab test results at time 0 and at time 1
- Quality of Care Outcomes metrics: percentages of patients at stages 1-5 at time 0 and at time 1.
- Number of patients qualified for clinical trials at time 0 and time 1

References:

Navaneethan, S. D. (2011). Development and Validation of an Electronic Health Record–Based Chronic Kidney Disease Registry. *Clinical Journal of the American Society of Nephrology, 6*(1), 40-49.

The National Institute of Diabetes and Digestive and Kidney Diseases. (2017, 9 15). *Kidney Disease Statistics for the United States*. Retrieved from Health Information/Health Statistics: https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease

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https://www.healthit.gov/sites/default/files/11-74-ablockchainforhealthcare.pdf

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Design and implementation of the first nationwide, web-based Chinese Renal Data System (CNRDS), https:/www.ncbi.nlm.nih.gov/pmc/articles/PMC3309940/

MY MEDS TRACKER

AN ADVERSE DRUG EVENT SURVEILLANCE SYSTEM AND PERSONAL MEDICATION ADHERENCE GUIDE WITH PRESCRIPTION HISTORY

Project Charter

Version *<1.0>*

<09/17/2017>

VERSION HISTORY

Version #	Implemented By	Revision Date	Approved By	Approval Date	Reason
1.0	*Nina Atluri*	*09/17/2017*			*EAIS Assignment 1 Business Need*
2.0	Nina Atluri	10/10/2017			EAIS Assignment 2
3.0	Nina Atluri	11/12/2017			EAIS Decision Brief, Outline, Portfolio

UP Template Version: 11/30/06

Executive Summary

MyMedsTracker Pilot Implementation

The CDC/CSELS Branch has a mission to reduce Adverse Drug Events among seniors. The senior population is growing as are the healthcare costs from hospitalization and ER visits due to Adverse Drug Events. This pilot implementation will focus on seniors with chronic heart failure which is a subgroup of seniors with higher and more serious Adverse Drug Events due to the comorbidities, number of drugs taken, and the potential consequences of the Adverse Drug Events for those drugs requiring blood level monitoring.

Problem:

More and more seniors who are living longer and with chronic diseases such as heart failure, are choosing to live independently with the assistance of technology. Seniors with Chronic Heart Failure may see many providers over time that prescribe new medications and each new provider may not know the medications the previous or concurrent other providers have prescribed. In addition, when patients arrive at a hospital or ER for treatment of an Adverse Drug Event, they may not have a record of what the patient recently took (medication adherence data) or the prescription history. With these patients taking so many medicines, some of which require blood level monitoring, coupled with their declining memories, it is difficult for these patients to adhere to their medication regime. Elderly use over 30% of the drugs prescribed and experience over 33.6% of severe or serious ADEs which are defined by the FDA as resulting in death, disability, or hospitalizations. [i] Twenty percent of ADEs are caused by medication errors and are preventable. Twenty-six percent of medication errors

are caused in the administration stage.[ii] Administration errors include taking the wrong dose, wrong drug, with the wrong technique, at the wrong time, or missed dose. [iii]

Solution:

The MyMedsTracker is a SMART on FHIR mobile application which stores pharmaceutical history, medication adherence history, and medication instructions with a schedule tied to a wifi-enabled pill dispenser. The app contains a voice narrated guide to medication times. The app records medication adherence data and sends text alerts to caregivers and family members to follow up when a medication time is missed, or the patient hits an emergency button to report symptoms of serious adverse drug events. This data is stored in the patient's EMR under a medication reconciliation tab where the provider or care coordinator for senior CHF patients can follow up with the patient and will be sent weekly to the CDC/CSELS surveillance system.

Objectives:

The objectives of the *MyMedsTracker* are as follows:

- Healthy People 2020 Objective MPS-5: Reduce emergency department (ED) visits for common, preventable adverse events from medications
- Healthy People 2020 Objective MPS-3: Reduce the number of adverse events from medical products (Note: Objective previously archived due to lack of a viable data source. This project aims to resolve this issue.)
- Healthy People 2020 Objective MPS-1: Increase the proportion of medical-surgical hospitals that report adverse drug events (This application will integrate hospitalizations and ED visits due to ADEs

within the EMR data which will be sent to the CDC My Meds Tracker Surveillance System.)

Funding and Timeframe:

Software used for this application will be mostly free and open source and will be stored on the AWS Gov Cloud. The budget will be $1.5 million from development to pilot implementation for seniors with CHF in one regional health plan.

DECISION BRIEF OUTLINE

1. Problem Statement & Recommendation

Adverse Drug Events cause approximately $3.5 billion of annual excess medical costs in the U.S. We may be able to prevent 40% of costs related to ambulatory (non-hospital) Adverse Drug Events. [iv] Elderly use over 30% of the drugs prescribed and experience over 33.6% of severe or serious ADEs which are defined by the FDA as resulting in death, disability, or hospitalizations. [v] Twenty percent of ADEs are caused by medication errors and are preventable. Twenty-six percent of medication errors are caused in the administration stage.[vi] Administration errors include taking the wrong dose, wrong drug, with the wrong technique, at the wrong time, or missed dose. [vii] The problem is exacerbated by the lack of a useful Adverse Drug Event surveillance system that could provide data to more appropriately target interventions. In order to reduce the costs of Adverse Drug Events in seniors, this pilot implementation of a mobile SMART on FHIR application; MyMedsTracker, will provide a medication guidance tool, prescription history record, caregiver and family member alert system, and a

medication adherence history integrated with the patient's EMR under a Medication Reconciliation Tab. This data can be sent to a surveillance system of Adverse Drug Events at the CDC/CSELS branch weekly. The pilot implementation will focus on seniors with Chronic Heart Failure in one regional health plan. In the future, this can be implemented for seniors throughout the nation.

2. Background Information

- Adverse Drug Events cause approximately $3.5 billion in healthcare costs per year
- Seniors use over 30% of the drugs prescribed and experience 33.6% of serious or severe Adverse Drug Events
- 40% of the costs of ambulatory (non-hospital) Adverse Drug Events are preventable
- 20% of Adverse Drug Events are caused by medication errors and are preventable
- The senior population is growing
- Seniors take multiple drugs for multiple co-morbidities and chronic diseases such as Chronic Heart Failure
- Seniors are living longer and choosing to live independently with the use of technology

3. Facts, Assumptions, & Requirements

Facts:

- There is currently no single prescription history shared and accessible by all providers for each patient.

- There is no printable history of medications taken by the patient recently.
- The healthcare costs associated with Adverse Drug Events in seniors can be reduced and will impact public health.
- Pilot implementation will be for seniors with Chronic Heart Failure in one regional health plan and will expand to all health plans across the nation in the future.

Assumptions:

- AWS GovCloud will be utilized as it is familiar to CDC and has a history of 10 years which its main competitor for government cloud applications, MS Azure Government does not have.
- This app will be built with SMART on open-source FHIR API.

Requirements:

- Budget of $1.5 million
- Time limit of 18 months for development to implementation.
- Must be Scalable, Flexible, Available to multiple users in different locations
- Must require minimal skills or low learning curve

4. Alternatives:

Alternatives to AWS GovCloud:

- MS Azure Government cloud
- MS Azure Commercial cloud
- Salesforce Government Cloud
- Verizon Enterprise Cloud Federal Edition (ECFE/VCFE)

Alternatives to SMART on FHIR:

- EMR Vendors alone
- Custom extensions
- HL7 V2

Alternatives to Puppet deployment tool:

- Chef
- Ansible
- Docker
- Jenkins
- Kubernetes
- Riverbend

5. Evaluation Criteria:

- Cost
- Scalability
- Flexibility
- Interoperability
- Learning Curve/Skills Needed
- Functionality

6. Analysis of Alternatives:

Criteria	Puppet	Chef	Ansible	Docker	Jenkins	Kubernetes	Riverbend
Cost	5	2	5	3	5	5	1
Scalability	5	4	1	4	4	5	4
Flexibility	5	4	5	4	4	5	3
Interoperability	5	5	5	5	5	4	4
Learning Curve	4	4	5	4	4	4	4
Functionality	5	4	4	4	4	4	3
TOTAL	**29**	23	25	24	26	27	19

7. Recommendation:

Overall, Puppet is the optimal choice as a cloud deployment tool for MyMedsTracker. This will be a SMART on FHIR Open API built app stored in the AWS GovCloud using Puppet as the deployment tool which will integrate with the health plan's EMR system and send data to the CDC/CSELS surveillance system of Adverse Drug Events.

1 INTRODUCTION

1.1 PURPOSE OF PROJECT CHARTER

The *MyMedsTracker* project charter documents and tracks the necessary information required by decision maker(s) to approve the project for funding. The project charter should include the needs, scope, justification, and resource commitment as well as the project's sponsor(s) decision to proceed or not to proceed with the project. It is created during the Initiating Phase of the project.

The intended audience of the *MyMedsTracker* project charter is the project sponsor and senior leadership.

2 PROJECT AND PRODUCT OVERVIEW

MyMedsTracker is a personal medication adherence guide smart phone application connected to a Wi-Fi enabled pill dispenser with a prescription history as well as a medication adherence history that records medication times, missed meds, and both prescription and over the counter meds taken and sends an alert to a caregiver and family member for potentially serious missed meds (such as those that require blood tests) that can lead to serious Adverse Drug Events. This information is stored in the EMR and then sent to the CDC Adverse Drug Event active surveillance system on a weekly basis. A print out of prescription history including refills and prior prescriptions which were stopped, as well as a printout of the prior week's actual medication history is available. This project will take 18 months from development to implementation. The budget for this project is $1.5 million. This pilot project will target seniors with Chronic Heart Failure in one regional health plan.

3 JUSTIFICATION

3.1 BUSINESS NEED

The senior population is growing and more and more seniors are choosing to live at home independently. ADEs among seniors constitutes a large portion of the U.S. healthcare cost in hospitalizations and ED visits. Currently, there are mainly passive surveillance system of ADEs and with the FDA Adverse Event Reporting System, it is voluntary and there is no denominator showing the number of patients that took the medication or were prescribed the medication (which can come from EMRs and pharmacies) and it is also unknown as to the percentage of ADEs that are even reported. Currently ADEs are reported voluntarily when there is a hospitalization, ED visit, or fatality. Many of these ADEs amongst seniors with CHF are due to memory loss and taking many pills without assistance or guidance. They may visit many providers who prescribe medications without the knowledge of their existing medications. They may also be taking over the counter medications that the provider is unaware of. Some of the pills that seniors with CHF take can lead to serious ADEs if not taken properly, and these require blood tests. Many of these ADEs are preventable with the right guidance and intervention.

3.2 PUBLIC HEALTH AND BUSINESS IMPACT

MyMedsTracker creates both a prevention and alert system and a centralized record of all prescription, medication adherence, and adverse drug events. This is a personal application that creates a federal surveillance system of adverse drug events in seniors with CHF with crowdsourced data that is collected in the

EMR. This integrates healthcare with public health and improves a serious public health problem at the local, regional, state, and federal levels.

3.3 STRATEGIC ALIGNMENT

Goal	Project Response Rank	Comments
Scale: **H** – High, **M**- Medium, **L** – Low, **N/A** – Not Applicable		
NC / Division / Branch Strategic Goals:		
CDC Strategic Goals:		
Strategic Priority #1: Improve health security at home and around the world	M	
Strategic Priority #2: Better prevent the leading causes of illness, injury, disability, and death.	H	
Strategic Priority #3: Strengthen public health and healthcare collaboration.	H	
Department of Health and Human Services (DHHS) Strategic Goals:		
Strategic Goal 1: Strengthen Health Care	H	
Strategic Goal 2: Advance Scientific Knowledge and Innovation	H	
Strategic Goal 3: Advance the Health, Safety, and Well-Being of the American People	H	
Strategic Goal 4: Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs	M	
DHHS IT Goals:		
Goal 1: IT Workforce Aim—Acquire, deploy, and sustain a technology-enabled workforce	L	
Goal 2: Cybersecurity and Privacy Aim—Protect critical systems and data	M	
Goal 3: Shared Services Aim—Optimize ability to accomplish mission by sharing business systems and services	H	
Goal 4: Interoperability and Usability Aim—Promote usability, interoperability, data sharing, and integration	H	
Goal 5: IT Management Aim—Mature IT management and governance to improve stewardship of IT investments and acquisition	M	

4 SCOPE

4.1 OBJECTIVES

The objectives of the *MyMedsTracker* are as follows:

- Healthy People 2020 Objective MPS-5: Reduce emergency department (ED) visits for common, preventable adverse events from medications
- Healthy People 2020 Objective MPS-3: Reduce the number of adverse events from medical products (Note: Objective previously archived due to lack of a viable data source. This project aims to resolve this issue.)
- Healthy People 2020 Objective MPS-1: Increase the proportion of medical-surgical hospitals that report adverse drug events (This application will integrate hospitalizations and ED visits due to ADEs within the EMR data which will be sent to the CDC My Meds Tracker Surveillance System.)

4.2 HIGH-LEVEL REQUIREMENTS

The following table presents the requirements that the project's product, service or result must meet in order for the project objectives to be satisfied.

Req. #	Requirement Description
1	Increase medicataion adherence among seniors with CHF by 50%
2	Increase reports of hospital and ED visits for ADEs among seniors with CHF by 50%
3	Reduce ADEs due to unknown prescription or medication history.

Req. #	Requirement Description
4	Create a viewable history to monitor the medication adherence of the population of senior patients with CHF through data visualization tools

RISKS

Risk	Mitigation
Senior patients will not adopt technology and app	Health Plan will provide volunteers with discounted or cash back on monthly premiums based on health outcome improvement with use of app.
Providers will fear workload increase	Training and marketing on the public health impact and the visualization tools and benefits of management of patient groups will be provided. Workload will managed by care coordinators and EMR techs and providers will receive benefits of data visualization and ease of treatment management and ADE prevention.
Patients will not want to be monitored	Patients will be given training and demonstrations that show how this app will allow them to live more independently with minimal assistance from family members.

4.3 MAJOR DELIVERABLES

The following table presents the major deliverables that the project's product, service or result must meet in order for the project objectives to be satisfied.

Major Deliverable	Deliverable Description
SMART FHIR APP	Application built on FHIR that tracks medication prescription history and medication adherence data, and provides voice guidance for patient medication times. This application also records the times that the prefilled wifi dispenser is opened.
Caregiver and family member alert system	Text message alert system for missed drugs which could potentially cause serious ADEs (those requiring blood tests)
HL7 messaging of data to EMR	Sends weekly reports to the patient's EMR.
HL7 messaging of data to CDC	The data is sent from the EMR to the CDC once it is collected into the EMR on a weekly basis. This creates a denominator of number of patients who took and were prescribed the medication as well as the number who experienced ADEs.

4.4 BOUNDARIES

The scope of this pilot project includes seniors with Chronic Heart Failure and will begin its implementation with one regional health plan and then be implemented to other plans, other states, and nationwide. The assumption is that the states will want to be onboarded and participate in a nationwide active surveillance system of ADEs in seniors with CHF. It is assumed that the patients' family members and caregivers will participate.

5 ENTERPRISE ARCHITECTURE IMPACT

5.1 BUSINESS NEED AND SOLUTION

Adverse Drug Events in the senior (65+) population account for a major portion of Adverse Drug Events in the United States which constitutes a large portion of healthcare expenditures in the United States. These Adverse Drug Events are

mostly attributed to certain drugs that are used to treat major diseases, especially within the senior population. These Adverse Drug Events are counted when a patient is hospitalized for an emergency resulting from the adverse drug interaction or reaction.

Adverse Drug Events (ADEs) are reactions and events associated with prescription medications. They occur for many reasons including medication errors that occur in the ordering, transcribing, dispensing, and administration stages. Twenty percent of ADEs are caused by medication errors and are preventable. Twenty-six percent of medication errors are caused in the administration stage.[viii] Administration errors include taking the wrong dose, wrong drug, with the wrong technique, at the wrong time, or missed dose. [ix]They may be caregiver errors, while many occur from self-medication errors in the patient's own home. The outcomes can be significant including an Emergency Room visit resulting in further hospitalization, disability, or death. Elderly use over 30% of the drugs prescribed and experience over 33.6% of severe or serious ADEs which are defined by the FDA as resulting in death, disability, or hospitalizations. [x] With interventions, these human administration errors can be prevented. There is a need for a tool to use as an aid to assist them with remembering when, how, and what drugs to take. And they need to be able to communicate with their family member or caregiver when they are unattended.

The current post-market surveillance system for ADEs is the Federal Drug Administration's Adverse Drug Event Reporting System (FAERS). Drug manufacturers are required to use it and it is voluntary for physicians/providers

and patients. This is a passive surveillance system and reports are made after an Emergency Room visit, hospitalization, or death, or otherwise voluntarily reported from consumers directly. The current FAERS system was implemented in the 4th quarter of 2012 and data from the quarterly reports are publicly available. Prior to 2012, there was a legacy AERS surveillance system for ADEs, which was active from 2004 until the 3rd quarter of 2012 and those quarterly reports are also publicly available. The FDA FAERS data are limited in their use since they are voluntary and do not capture details such as the diseases of the patient. The Government Accounting office reported in 2005 that FAERS captures only 1% to 10% of ADEs. Although a recent article stated that the number of reported ADEs in the FAERS system has increased fivefold in 12 years from 2004 to 2015, it is still estimated to be capturing only 10% of ADEs due mostly to its voluntary nature [xi]Because of its voluntary nature and the fact that reports can come from consumers, physicians/providers, and must be reported by drug companies, another issue with these reports in this passive surveillance system could be duplicated reports from multiple sources since the information is publicly available and needs to remain deidentified.

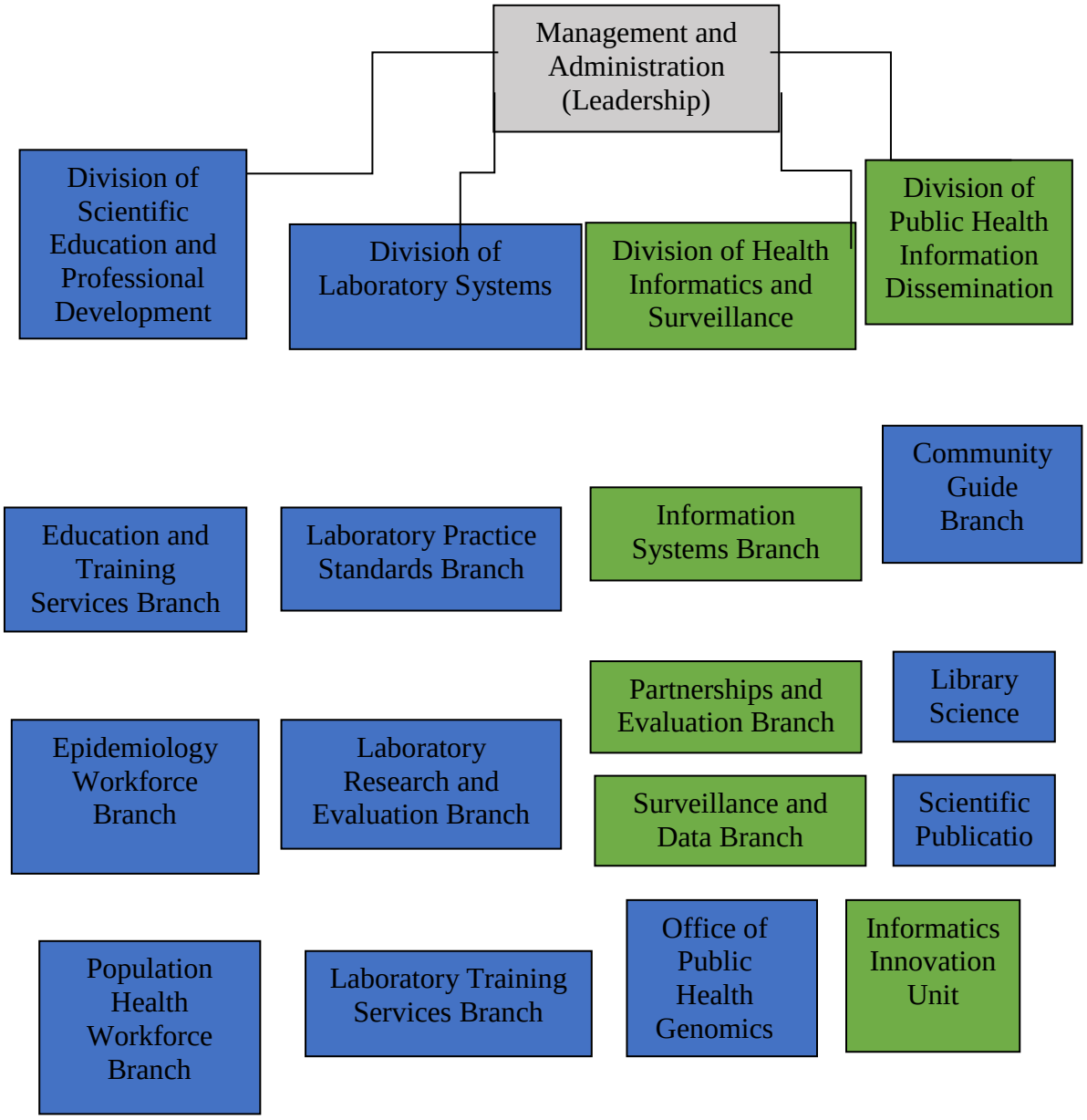
Seniors are twice as likely to visit an Emergency Room for an ADE with 177,000 visits per year, and seven times as likely to be hospitalized. Most of these are from drugs which are known to require monitoring. [xii] The numbers of hospitalizations and deaths in the elderly population due to ADEs along with trends in cost data from the Healthcare Cost and Utilization Project in the U.S (HCUP-US) depicts a picture of the severity and cost of ADEs in the elderly population. Publicly available graphs show that among all the age groups, that in

the 10-year trend from 2005 to 2014, the age group with the highest average total hospital cost is the 65-74 years old group. This cost has also steadily increased slightly throughout the 10-year period. The age group of 75+ years is the group with the third highest cost.[xiii] This coupled with the fact that the number and portion of ADEs is growing and that they are 7 times more likely to be hospitalized [v], shows that their hospitalization outcomes are the costliest ADEs for our healthcare system. We learned that 20% of these ADEs are preventable [i] so we need to put a halt to this growth in ADEs, particularly in the elderly population, and their cost to our healthcare system. Since 26% of these ADEs occur at the medication administration stage [i], we can focus an intervention on this stage at the patient and caregiver level.

The solution to the problems of preventing ADEs as well as creating an active and representative surveillance system of ADEs in the U.S. can be found in the use of a SMART on FHIR application that combines a medication adherence guide, prescription and medication history, caregiver and family member alert system, and an Adverse Drug Event reporting system. The new system will be implemented by the CDC/CSELS division which has the experience of implementing other nationwide disease surveillance systems. This system will collect information on all medication history of one health plans senior members with Chronic Heart Failure which will represent a pilot project. By collecting data on both normal medication and adverse drug event data, the progress of the intervention and surveillance system can be more accurately monitored. This data will be crowdsourced from the SMART on FHIR application into the EMR system and then sent to CDC on a weekly basis. Ideally, a Care Coordinator or

Population Manager will be monitoring the EMR data on Adverse Drug Events and medication adherence on a regular basis. Data visualization tools will allow them to track the progress of a particular population over time.

5.2 CDC/CSELS ORGANIZATIONAL INFRASTRUCTURE



Initially for the pilot project, the Branches and Divisions in green in the chart above will be directly affected and involved. After the pilot implementation in one

health plan's senior CHF population, when this project can be implemented to other populations or in a broader scope nationwide, other divisions and branches may be affected, i.e. training for a Population Health Workforce, and even expanding the laboratory history connection for those serious drugs requiring blood monitoring. Right now, the EMR contains the labs which will be sent to the CDC system. When the system expands nationwide, CDC's own labs may be directly involved. [vii]

5.3 ENTERPRISE ARCHITECTURE

The CDC and HHS are governmental organizations which both utilize the Federal Enterprise Architecture Framework.

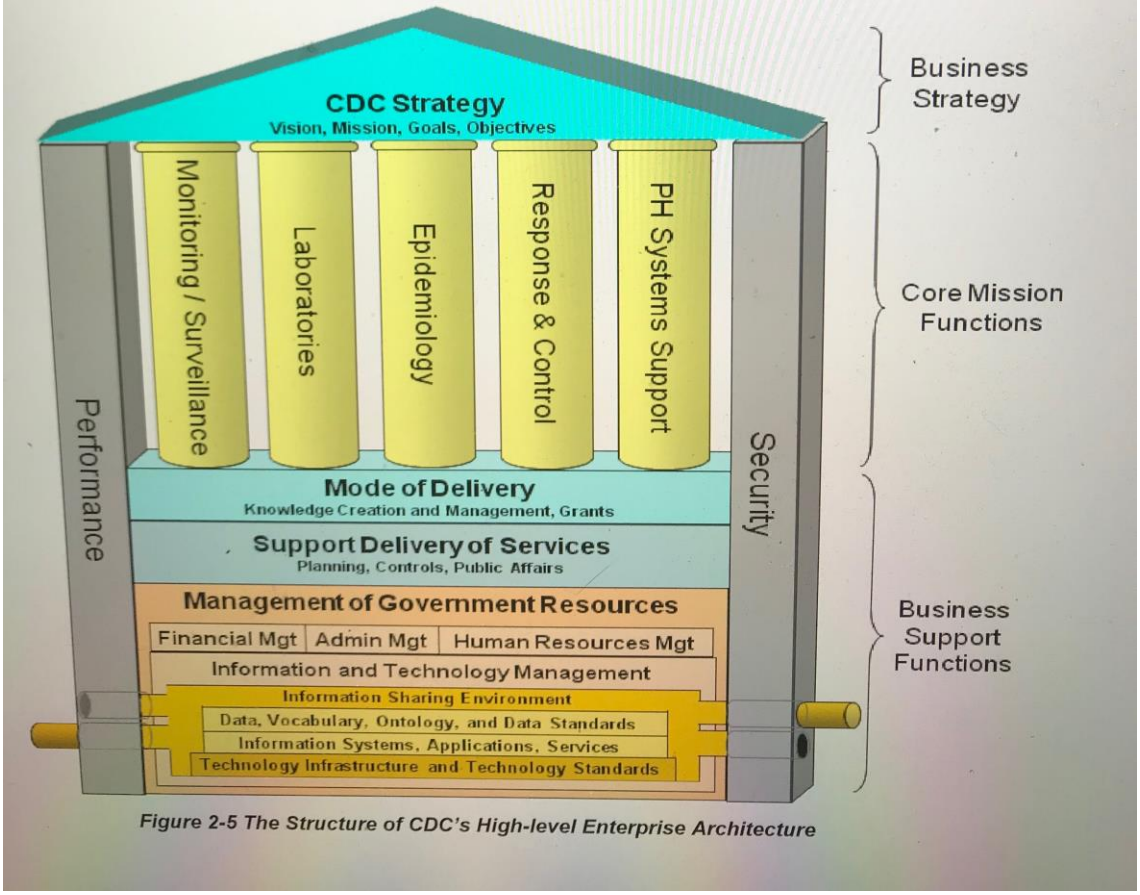


Figure 2-5 The Structure of CDC's High-level Enterprise Architecture

https://wiki.phdsc.org/images/d/d6/CDC-EA-ReferenceGuide.pdf

The figure above is from the CDC Enterprise Architecture Reference Guide, V. 1.0, 10/20/2010. It depicts the high level enterprise architecture at CDC which shows how its Information Technology , Standards, and Services support its core Business Strategy. The Center for Surveillance, Epidemiology, and Laboratory Services division adhere's to CDCs overall Enterprise Architecture. As discussed in the organizational infrastructure section above, this SMART on FHIR application will affect the Information and Technology Infrastrutures when CDC receives data from EMR systems and allows providers access to the information with its visualization tools. While the pilot will be limited to one specific health plan's EMR, eventually its expanded implementation will allow providers across the nation access and use of this data. During the pilot phase, only IT divisions will be involved and as the implementation is expanded nationwide, more of the business and administrative divisions will be involved.

5.4 BUSINESS PROCESSES

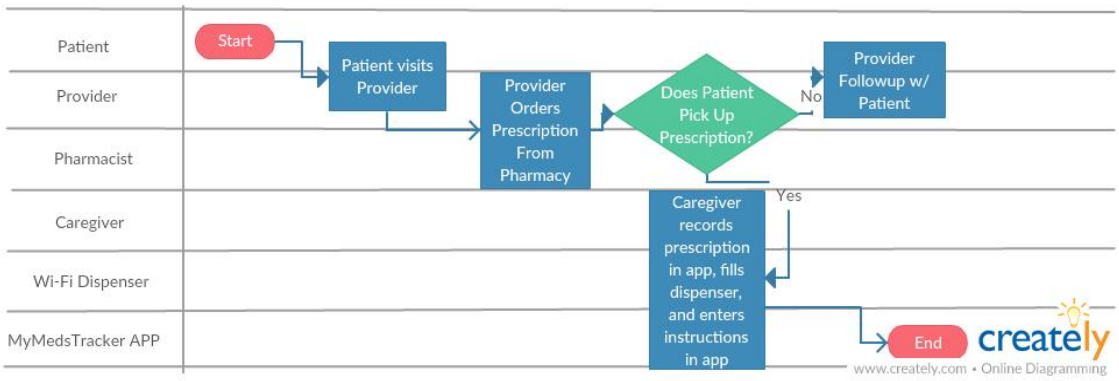
Process	Description
Prescription Acquired/Dispenser Filled/App programmed	The prescription is filled by the pharmacy and placed into the Pharmacy record of the app and then the corresponding meds are put into the Wi-Fi enabled pill dispenser for the week by the caregiver and the caregiver programs the app with the schedule and instructions for medication times.
Medication Guidance in App	The app comes on at scheduled medication times and guides the patient with their medication instructions and offers post medication questions for the patient to respond to. It records responses and medication time in the app.

Process	Description
Missed Meds Alert System/Emergency button in App	If the medication dispenser is unopened 2 hours after the medication time or there is no response to the app after the dispenser is opened, the application sends a text message to the caregiver and family member to contact the patient. These alerts are coded by level of significance so that those drugs that can cause potentially serious ADEs such as those requiring blood tests are sent a coded text message which relays the severity of the missed or doubled medication. If the patient is experiencing any symptoms or reaction there is an emergency button in the app which will contact 911.
Medication Adherance/ADEs data sent to EMR	The record of actual medications taken and history of adherance and ADEs is sent to the EMR using HL7 messaging, weekly.
Data sent to CDC Surveillance system	Data is sent from the EMR to the CDC Surveillance system weekly using HL7 messaging.
Data Visualization	Providers can access data and create and view historical visualizations by patient within the EMR or groups of patients within the EMR. The patient can view their own history graphically.

Prescription Acquired/Dispenser Filled/APP Programmed Process – Business Matrix

OBJECTIVE(S)	BUSINESS RULES	TRIGGER	TASK SET	INPUT	OUTPUTS	MEASURABLE OUTCOMES
Store actual Prescription History	Data is owned by patient and shared in the EMR and with Pharmacists and Providers with patient consent following HIPAA rules. Storage and access is encrypted and authenticated.	Prescription Filled and Purchased	Provider prescribes and orders prescription from pharmacy, pharmacy dispenses prescription, patient purchases and picks up prescription, pharmacist records this in the app	Prescription purchase	Prescription history record with date, location, provider, pharmacist, and prescription list with number of refills allowed and number of refills filled.	Number of prescriptions patient is taking matches the number of medications prescribed by any provider. Medication Reconciliation.
Create medication guide and post medication checking prompts	Guide is used to ensure patient is taking medication properly and prompts are meant to check this interactily	Medication dispenser is filled and app is programmed with instructions and schedule	Caregiver fills medication dispenser and programs medications, instructions, and schedule in app.	Prescriptions	Medication Guide and Tracker	Medication Adherance History, Adverse Drug Event history and reports, Actual Medications taken with dates and times. Number of potential ADEs adverted with alert system recorded.

Prescription Acquired/Dispenser Filled/App Programmed – Process Task Flow Diagram



Functional Requirements for Prescription Acquired/Dispenser Filled/App Programmed

ID	Business	Activity	Requirement	Comments
1	Prescription Acquired	Patient visits Provider	Collect Provider and visit Info including contact info and date.	Stored in the prescription record of the app.
2	Prescription Acquired	Prescription for medicine given to patient and sent to pharmacy.	Collect prescription info including name of drug(s), dosage, instructions, and number of refills allowed.	Stored in the prescription record of the app.
3	Prescription Acquired	Pharmacy fills prescription and patient picks up order.	Collect pharmacy and pharmacist info and date prescription purchased.	Stored in the prescription record of the app.
4	Dispenser Filled	Caregiver fills Wi-Fi Dispenser with	Collects info on the schedule and names of	Each time a new prescription

ID	Business	Activity	Requirement	Comments
		medications for one week along with the list of medications and instructions	medications to take at each time. Photos of medications can be stored in the app.	or refill is acquired, the caregiver can take new photos or adjust the prescription record and medication schedule
5	App Programmed	App is programmed to alert the patient at medication times and provide post medication prompts.	App stores patient responses to prompts and times of medication.	The app can also take a video recording of the medication times if the patient is able to mount the smart phone app on a holder.

Missed Meds Alert System/Emergency button in App Process -

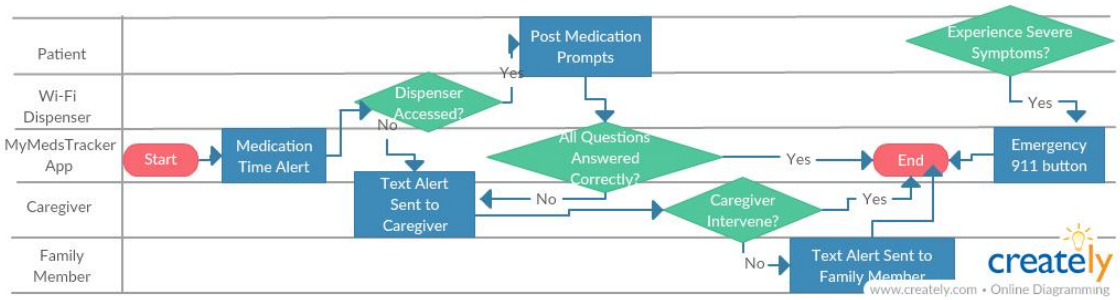
Business Process Matrix

OBJECTIVE(S)	BUSINESS RULES	TRIGGER	TASK SET	INPUT	OUTPUTS	MEASURABLE OUTCOMES
Create a caregiver/family member alert	Caregiver and family member must agree to be contacts.	Patient doesn't respond to app post medication prompts	Caregiver and family member missed meds alert text message sent from app.	OBJECTIVE (S)	Alert text message to caregiver and forwarded to family	Caregiver or Family Member intervenes and missed medication is reconciled, potential ADE is prevented. Reduced number of ADEs.

OBJECTIVE(S)	BUSINESS RULES	TRIGGER	TASK SET	INPUT	OUTPUTS	MEASURABLE OUTCOMES
	Patient must agree to send alerts to caregiver and family member. Must abide by HIPAA rules.	within 2 hours of scheduled medication time.			member if caregiver is unable to respond.	
Create a direct button to 911 when serious symtomps arise	Patient must use the button to contact 911 in emergencies. Button on app must be FCC compliant.	Patient experiences severe symptoms.	Patient presses emergency button on app and 911 is contacted, text message sent to caregiver.	Patient experiences serious symptoms	911 Emergency is contacted. Caregiver and Family Member notified.	Reduced number of ADEs. Reduced mortality.

Missed Meds Alert System/Emergency button in App Process

Task Flow Diagram



Functional Requirements for Missed Meds Alert System/Emergency Button in App Process

ID	Business	Activity	Requirement	Comments
1	Medication Time Alert	Sound alarm notification sent to patient.	App is prescheduled with medication times. Smart on FHIR app is on a smart phone near or with patient.	The app and dispenser are connected.
2	Medication Time	Dispenser Unlocked and accessed.	Dispenser pre-filled and unlocks at programmed time. Detected opening time is recorded in app.	
3	Post Medication Prompts	Queries patient about medications taken.	Patient took medications and responds to SMART app prompts which are preprogrammed according to the correct schedule and	

ID	Business	Activity	Requirement	Comments
			medications.	
4	Text Alert to Caregiver	If dispenser is unopened within 2 hours of scheduled time or if patient does not respond to post medication prompts, text message alert is sent to caregiver.	Dispenser and app are connected and the dispenser sends the app a notice when it is opened which the app records. The app is preprogrammed to send the alert after the dispenser has not been opened 2 hours after the scheduled medication time or if the patient does not respond to the prompts within 2 hours.	If caregiver does not respond or cannot intervene when prompted, the text alert is then forwarded to the family member.
5	Text Alert to Family Member	Text alert sent to family member if patient is unresponsive and caregiver cannot intervene. This is given a priority based on the potential severity of ADE depending on the medications.	Caregiver is unresponsive or responds that they are unable to intervene.	
6	Emergency 911 Button	A button on the home screen of the app is directly connected to 911 should the patient be	The app will ask if the patient is experiencing any severe symptoms and guide them to	Caregiver and Family Member are also sent a text message when the

ID	Business	Activity	Requirement	Comments
		experiencing any severe symptoms.	press the Emergency button if they are. They will also be shown how to do this the first time they use it so they know to press this at any time.	patient uses the Emergency button.

5.5 MITA BUSINESS PROCESS TEMPLATES

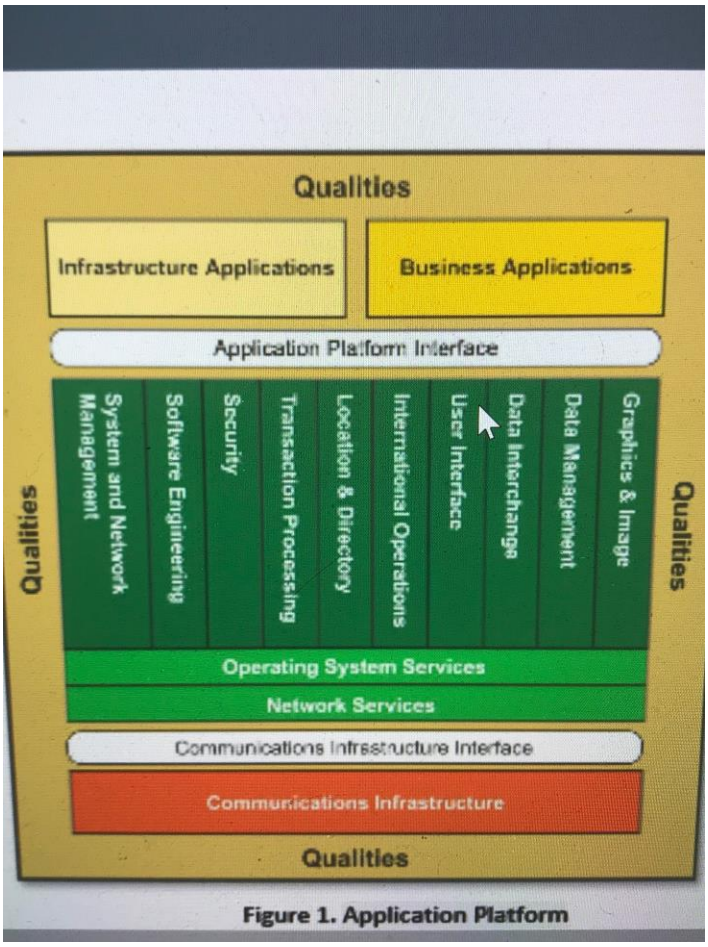
Prescription Acquired/Dispenser Filled/APP Programmed	
Description	App records filled prescriptions, caregiver fills medication dispenser accordingly, and programs app with medications and schedule.
Trigger Event	Prescription filled and purchased.
Result	App provides medication guidance and tracks medication adherence and ADEs.
Business Process Steps	1. Patient picks up filled prescription from pharmacy. 2. Caregiver enters prescription record into app. 3. Caregiver pre-fills Wi-Fi enabled medication dispenser. 4. Caregiver programs MyMedsTracker app with list of medications, schedule, and optional photos as well as questions for post medication prompts.
Shared Data	Medication adherence data, prescription data (historical and current), and pharmacist and provider info, caregiver and family member contact info stored in the app to be sent to patient's EMR then to CDC.
Predecessor	Provider prescribed new medication

	to patient.
Successor	App records medication times and post medication responses.
Constraints	Federal, state, and local regulations, HIPAA rules, similarities of pills, changes in appearance of one medication by manufacturer.
Failures	Caregiver improperly fills medication dispenser or programs app incorrectly.
Performance Measures	Reduced missed medications. Reduced ADEs. Increased reporting of medication adherence and number of drugs actually taken.

Missed Meds Alert System/Emergency button in App created	
Description	Text alert system created for caregiver and family member in the event that patient missed meds or is unresponsive. Emergency button with direct access to 911 created.
Trigger Event	Patient missed meds or is unresponsive.
Result	Caregiver and/or family member is contacted to intervene.
Business Process Steps	1.App sends sounding alarm to patient at medication time. 2. Wi-Fi dispenser unlocks. 3. App records time that dispenser is opened. 4. App asks patient post medication prompts 10 minutes after dispenser is open and again in 2 hours if dispenser is unopened. 5. App records patient's answers or sends caregiver a text alert if dispenser is unopened 2 hours after medication time. 6. If caregiver is unresponsive or responds that no they cannot intervene, then a text alert message is then sent to the family member. 7. If patient experiences severe symptoms at any time, they can press the Emergency button in app to call 911. Caregiver and family member will be sent a text notification if so.

Shared Data	Caregiver and Family member contact info, patient self-medication history stored in app to be sent to EMR and CDC.
Predecessor	Patient missed medication(s) or is unresponsive.
Successor	Caregiver or family member attempts to intervene and follow up or provide correcting instructions. Notes are recorded in app by caregiver or family member.
Constraints	Depends on senior patients' adoption and use of technology. Assumes Wi-Fi dispenser and SMART on FHIR app can work together and communicate.
Failures	Patient does not respond to prompts truthfully or accurately and ADE still occurs without contacting caregiver or family member.
Performance Measures	Increased medication adherence. Decreased ADEs. Increased record of actual medications taken upon an ER visit.

5.6 INFORMATION ARCHITECTURE (IA)



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The following Service Categories are impacted by the MyMedsTracker application and solution:

System and Network Management:

The SMART on FHIR application must integrate with a Wi-Fi enabled medication dispenser on a home network and then must communicate with the caregiver and family member via text messaging on a mobile network and be able to communicate with the 911 Emergency system via cellular network.

Software Engineering:

The MyMedsTracker SMART on FHIR app must be able to store various types and formats of data including Pharmacy records, Prescription medication instructions, Prescription medication photos, and potentially video recordings of medication times should the patient want that option. The app must also be able to send data to the EMR and receive notes from a provider, caregiver, or family member who can all access the app on their own phone or computer and then synchronize this data with the patient's stored record before the record is sent to the EMR weekly.

Security:

Patient medication adherence data will be sent from the application to the patient's EMR over an encrypted network. The caregiver and family member may be given certain permissions to enter their notes on the record. The caregiver will have the most privileges to program the app with scheduling and prompting guidance. The app will use duo authentication and the least privileges security model and data will be sent to the EMR over an encrypted network. Data will be secure at rest and in motion.

User Interface:

The user interface must be senior patient friendly and must be designed for ease of use and visibility. The caregiver and family member will have one backend user interface where they will enter their notes and the patient view will be the

simplest where the Emergency button is easy to get to and there are not too many buttons for the patient. The guide will have verbal prompts.

Data Interchange:

The data will be transferred to the patient's EMR via HL7 messaging weekly. The Pharmacy and Provider will be able to print records from the app, or request that the caregiver bring a printout of the pharmacy history or medication adherence history.

Data Management:

The app will store data on the patient's medication adherence, pharmacy prescription history, and ADEs.

Graphics & Image:

The app will optionally store pictures of medications as well as video recordings of patient medication times. The prompts can use the pictures of medications to aid in the post medication prompting of patients.

5.7 TECHNICAL ARCHITECTURE

(TA)

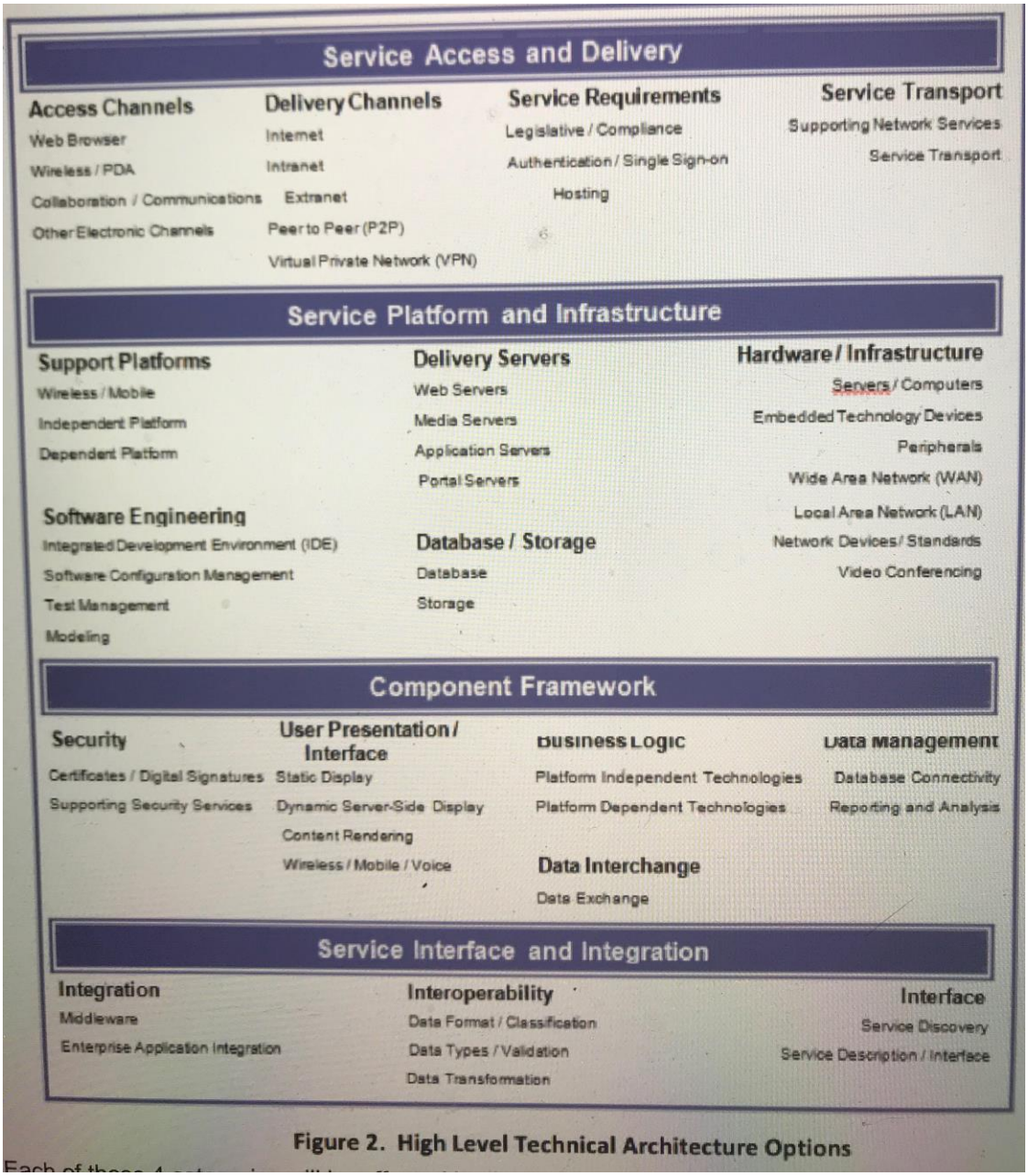

Figure 2. High Level Technical Architecture Options

Each of these 4 categories will be impacted by the solution as follows:

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Service Access and Delivery:

Access Channels will include a wireless PDA for the patient and may include a Desktop Web Interface for the caregiver, family member, and provider. Collaboration/Communications will be impacted as the SMART on FHIR app must collaborate with the Wi-Fi enabled medication dispenser and communicate with the patient's EMR. The Delivery Channel will be the Internet as the data will be sent via the Internet to the EMR system. Service Requirements include federal, state, local legislation including HIPAA compliance. Authentication will be impacted with the least privileges principle for the Provider, Caregiver, Pharmacist, Family Member, and Patient. Service Transport will be impacted as the data will be sent via the Internet with an encrypted and secured connection.

Service Platform and Infrastructure:

Support Platform: wireless/mobile on the patient's smart phone. Delivery Servers: Application Servers collect info from patient, Web Servers will collect info into the EMR and from Caregiver, Provider, and Family Member optionally. Hardware/Infrastructure impacted is Wireless Area Network (WAN) on which the medication dispenser and app communicate and collaborate, and Network Devices and Standards will be impacted as the data will be sent to the patient's EMR over the Internet and there is a modem and router and standards for the network. Database/Storage will be impacted because this app will store all of the medication adherence data as well as pharmaceutical history.

Component Framework:

User Presentation/Interface will utilize voice guidance. Data Management will have visualization tools so that the provider can visually graph trend data per patient or groups of patients.

Service Interface and Integration:

Integration will be impacted within Enterprise Application Integration as the data will get integrated into the patient's EMR in a specific Medication Reconciliation Tab that will be monitored by a Care Coordinator that can monitor the group of Seniors with CHF and view the group's medication adherence and ADE statistics and history.

5.8 Skills/Roles Needed for Project Implementation

1 Informatician will be needed that will have high level Data Science, Data Management, Business Analysis, and Integration and Implementation skills.

2 System Architects with knowledge and skills for Enterprise, Information, Technical and Application/Data Architecture will be needed.

1 Project Manager with Project Management and Risk Mitigation skills is required.

5.9 RISK MITIGATION

We will assign risk probability of occurring and impact level as well as a contingency plan to the risks and mitigations listed in section 4.2 of this document. **P** = Probability (C=Certain, E= Expected, L=Likely, P=Possible, U=Unlikely). **I** = Impact (H = High, M=Medium, L=Low)

Risk	Mitigation	P	I	Contingency Plan
Senior patients will not adopt technology and app	Health Plan will provide volunteers with discounted or cash back on monthly premiums based on health outcome improvement with use of app.	E	H	Incentives will be provided and training will be given to Caregiver and Care Coordinator will visit with the patient and provide hands on assistance and training to patient.
Providers will fear workload increase	Training and marketing on the public health impact and the visualization tools and benefits of management of patient groups will be provided. Workload will managed by care coordinators and EMR techs and providers will receive benefits of data visualization and ease of treatment management and ADE prevention.	C	L	Care Coordinator or Medication Technician will have the responsibility of group medication reconciliation but providers will see the benefit of data visualization and progress monitoring which can be tied to their benefit system.
Patients will not want to be monitored	Patients will be given training and demonstrations that show how this app will allow them to live more independently with minimal assistance from family members.	P	M	Incentives will be provided and patients can be shown the security of the text alert features and emergency button features that will allow them to live more independently.

6 ANALYSIS OF ALTERNATIVES

Emerging Technologies

For this project which will combine a medication adherence guide and tracker with Adverse Drug Event surveillance, we will consider creating a SMART on open FHIR API application with a mobile user interface for the patient and a database which will be launched in the AWS Govcloud and deployed with Puppet and integrated with an EMR system. This pilot project will be launched for seniors with Chronic Heart Failure in one regional health plan's EMR system. This solution satisfies the following major goals:

- Increase medication adherence in seniors with Chronic Heart Failure
- Reduce Adverse Drug Events in seniors with Chronic Heart Failure
- Improve quality of life and independence of seniors with Chronic Heart Failure
- Improve reporting and surveillance of Adverse Drug Events in seniors with Chronic Heart Failure
- Decrease healthcare costs associated with Adverse Drug Events in seniors with Chronic Heart Failure
- Facilitate Provider Medication Reconciliation

Alternatives

Alternatives for the entire system could include other cloud providers, other cloud deployment tools, other standards aside from FHIR, or EMR Vendors alone without utilizing SMART on FHIR integration. Some alternatives for each include:

Alternatives to AWS GovCloud:

- MS Azure Government cloud
- MS Azure Commercial cloud
- Salesforce Government Cloud
- Verizon Enterprise Cloud Federal Edition (ECFE/VCFE)

Alternatives to SMART on FHIR:

- EMR Vendors alone
- Custom extensions
- HL7 V2

Alternatives to Puppet deployment tool:

- Chef
- Ansible
- Docker
- Jenkins
- Kubernetes
- Riverbend

Facts:

This is a pilot project that will be implemented with one regional health plan's EMR system and the population that this will be deployed to will be seniors with Chronic Heart Failure as a subset of the health plan's members. In the future, this will be expanded to other populations, other health plans, and nationwide.

Assumptions:

For this project, it is assumed that AWS GovCloud will be utilized as it is familiar to CDC and has a history of 10 years which its main competitor for government cloud applications, MS Azure Government does not have. Amazon has more history with open source applications. For costs and availability to patients, this app will be built with SMART on open-source FHIR API. This pilot project also assumes that SMART on FHIR will be utilized as most interoperable healthcare EMR systems and applications are now utilizing SMART on FHIR as opposed to the EMR system alone or custom extensions and FHIR is an improvement of the HL7 V2. We will evaluate alternatives for cloud deployment tools.

Requirements:

This pilot project has a budget of $1.5 million and must be deployed within 1.5 years. It must be scalable to other health plans, EMRs, and across the nation in the future. It must be flexible to be used by providers with different types of platforms and operating systems. It must be secure since it will contain patient data and be integrated with patients' EMRs. The deployment tool must be easily implemented with AWS GovCloud and SMART on FHIR open API.

Evaluation Criteria:

Cost: The deployment tool needs to fit within the budget and allow for the purchase of the other requirements and resources.

Scalability: This is a pilot implementation with the goal of deploying identical systems nationwide in the future.

Flexibility: This needs to be able to support users across different platforms and operating systems in different locations.

Interoperability: This needs to work with the other tools being utilized including AWS GovCloud, and SMART on FHIR open API.

Learning Curve/Skills Needed: This needs to be deployed within the time of 1 year and with minimal resources.

Functionality: The tool must build, deploy, scale, and maintain the system with minimal use of additional tools.

The deployment tools will be compared using a 5-point scale for each of the criterion.

6.1 EVALUATION MATRIX

Criteria	Puppet	Chef	Ansible	Docker	Jenkins	Kubernetes	Riverbend
Cost	5	2	5	3	5	5	1
Scalability	5	4	1	4	4	5	4
Flexibility	5	4	5	4	4	5	3
Interoperability	5	5	5	5	5	4	4
Learning Curve	4	4	5	4	4	4	4
Functionality	5	4	4	4	4	4	3
TOTAL	29	23	25	24	26	27	19

Overall, Puppet is the optimal choice as a cloud deployment tool for MyMedsTracker.

7 STRATEGIC PLANNING

7.1 PROJECT PLAN FOR CREATION OF STRATEGIC PLAN

Action or Step to be Completed	Timeline	Milestones	Person(s) Responsible	Status/ Completion Date
Problem Statement, Desired Public Health Outcome Established, Via Lit and Data Review,	Weeks 1-2	1.Business Analysis 2. Executive Summary	Business Analyst, Project Mgr	July/16/2017
Stakeholder Identification, Assumptions established, Risk Analysis, and Timeline Established	Weeks 3-5	1.Stakeholder Analysis 2.Risk Mitigation Plan 3.General meetings schedule and overall timeline	Project Mgr, Risk Mgr, Project Mgr	Aug/6/2017
Requirements Gathering, Resource Planning, Deliverables defined, Initial Project Planning Via Subject Matter Expert and Stakeholder meetings	Weeks 6-8	1. Requirements Table 2. Deliverables/Millestone Deadlines 3. High Level Project Plan	Business Analyst, Project Mgr, Project Mgr	Aug/27/2017
Mission, Vision, Values Established Via Organization Administration and Stakeholder meetings	Weeks 9-10	1. Mission, Vision, Values 2. IT Project Goals	CEO, Project Mgr, plus all stakeholders	Sept/17/2017

Action or Step to be Completed	Timeline	Milestones	Person(s) Responsible	Status/ Completion Date
Environmental Scan – Discover limitations of existing data and collect new data Via data exploration and stakeholder meetings.	Weeks 11-12	1. Review of Existing Data 2. Acquire New Data	Data Analyst	10/1/2017
Strategy Analysis Via SWOT/SWOC	Week 13	1. SWOT/SWOC Analysis	Business Analyst,Risk Mgr	10/08/17
Develop Strategic Plan and Implementation Plan	Weeks 14-16	1. Strategic Plan 2. Implementation Plan	Business Analyst, Risk Mgr, Project Mgr	Ongoing 10/29/17
Implementation, Monitoring, Revising as Needed	Weeks 17-End of Project	1. Deliverables Completed 2. Project Plan Modified	Business Analyst, Project Mgr, Risk Mgr, Data Analyst, Developers	Nov/17/2017 – Nov/17/2018

7.2 MISSION

The mission of the MyMedsTracker project team of the CDC/CSELS/DHIS branch is to reduce the Adverse Drug Events in seniors by increasing medication adherence and improving medication reconciliation, and to create a meaningful surveillance system of Adverse Drug Events in seniors using crowdsourced data directly from the patients.

7.3 VISION

- MyMedsTracker strives to create a pilot solution to a public health problem with the following assumptions:
- The senior population in the U.S is expected to continue to grow exponentially.
- Seniors with multiple co-morbidities, declining memories and cognitive function, polypharmacy (taking many medications), and the desire to live independently are at greater risk for Adverse Drug Events.
- The cost of Adverse Drug Events (hospitalizations, ER visits) constitutes a large portion of the U.S. annual healthcare costs.
- The current surveillance system of ADEs is voluntary and it is unknown of what percentage of ADEs are even reported. The data does not provide a meaningful use as it does not include the co-morbidities of the patient that the case was reported for, nor does it include a denominator of total number of people taking the drug.
- Those with severe chronic illnesses such as Chronic Heart Failure must take drugs which have more severe potential ADEs which require blood level monitoring.
- Seniors with CHF would like to have guidance on taking their medications while living independently.

The vision of the MyMedsTracker project team is a future that:

- Integrates the MyMedsTracker data with a Medication Reconciliation tab within the patients' EMRs.

- Compels informed patients to consent to their data being collected both for their own health as well as public health.
- Incentives patients to follow the guide and track their medication adherence based on their health improvement and outcome from their baseline, via a percentage returned on their annual healthcare premiums.
- Establishes one interoperable record of pharmaceutical prescription history, medication adherence history, adverse drug events, and required lab tests results. This application will enable a printout that can be accessed or provided to the provider, care coordinator, caregiver, designated family member, lab administrator, pharmacist, specialists, ER physician, and hospital admitting physicians.
- Utilizes crowdsourced data for a meaningful use purposed surveillance system of Adverse Drug Events.

7.4 IMPACT

The MyMedsTracker will impact the CDC/CSELS/DHIS strategic plan in its CDC Surveillance Strategy (https://www.cdc.gov/surveillance/) by improving two of its four initiatives including:

- Enhancing situational awareness
- Modernizing Mortality Surveillance Systems

It furthers the division's strategic goals of improving surveillance (https://www.cdc.gov/surveillance/Improving-Surveillance-Background.html) by:

- Improving availability and timeliness of data

- Advancing the use of electronic health records, mobile technologies, and cloud computing
- Retiring redundant systems and reduce reporting burden on health departments
- Maximize performance and effectiveness of agency resources

7.5 References

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[iv] https://www.cdc.gov/medicationsafety/basics.html

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https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm

CONCLUSION

The two informatics projects discussed in this thesis consist of the Chronic Kidney Disease registry; CKD-ReSource, and the mobile application medication guide that created a data source for a surveillance system of Adverse Drug Events; MyMedsTracker. In both projects, emerging technology was recommended to create systems which offer public health decision makers tools to create more meaningful data analysis and visualizations. In both examples, the informatics project offers patient, provider, and public health benefits, making patients become a more active participant in their own healthcare. Both projects also strive to make public health and healthcare delivery systems interoperable with the use of shared data.