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Litty Susan Daniel Date

Architecting a cloud-based system for effective treatment planning in Emergency care among ESRD (Chronic Kidney Disease) patients

By

Litty Susan Daniel
Degree to be awarded: MPH

Executive MPH

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By

Litty Susan Daniel B.S.

Rollins School of Public Health

2019

Thesis Advisor: Kelley G. Chester, DrPH, MPH

An abstract of
a Thesis submitted to the Faculty of the
Rollins School of Public Health of Emory University
in partial fulfillment of the requirements of the degree of
Master of Public Health in the Executive MPH program
2019

Abstract

Architecting a cloud-based system for effective treatment planning in Emergency care among ESRD (Chronic Kidney Disease) patients

By Litty Susan Daniel

Background: Various medications are cleared by kidneys; therefore, dialysis patients are at risk for adverse drug events. Patients with end-stage renal disease need frequent, ongoing dialysis care and many end up in Emergency care due to other medical conditions. ER providers and dialysis providers are challenged by incomplete or delayed transfer of pertinent clinical data from hospitalizations. A system-thinking approach is needed to overcome the information gap between outpatient dialysis providers and hospitals sharing clinical information through a health information exchange (HIE). Use of cloud based datahub, and emerging HL7 FHIR messaging systems to transfer data in this will support in the architecting of this solution.

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ACKNOWLEDGEMENTS

I would first like to thank my thesis chair Kelley Chester. She consistently made sure the execution of this paper was my own work but steered me in the right direction whenever I needed it. I gratefully thank her for sharing her applied sets of expertise and advice, valuable time and patience throughout the process of completing this work. I would also like to thank Mark Conde, who shared his technical expertise and knowledge in public health sector and guided me through the technical aspects of this thesis. I would also like to thank Dr. Deepu Daniel DO, Nephrologist at Caritas Medical Center and Marina Paul RN at Atlanta VA Medical Center for sharing their knowledge, expertise and concerns about the current emergency department process. Without their passionate participation and input, this thesis could not have been successfully developed.

Thank you, in particular, to Laurie Gaydos and Zelda Ray for their continued support and for always keeping me on track while completing the thesis.

I would also like to acknowledge Biju Oommen for his technical expertise and support and my brother Jeree Paul Daniel for being the co-reader of my thesis. I have very profound gratitude for my sister, parents, husband, and other family members and friends who provided me with unfailing support and continuous encouragement even from overseas, throughout my years of study.

Finally, I must express my very profound gratitude to my loving kids, Anya and Josif for pushing me through the process of researching and writing this thesis and baby Benjamin for his tolerance while trying to survive without me. This accomplishment would not have been possible without their understanding and support. Thank you.

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CHAPTER I: INTRODUCTION

Introduction and Rationale

Kidney failure, also called end-stage renal disease (ESRD) is the last stage of Chronic Kidney Disease (CKD) which leads to dialysis or a transplant (American Kidney Fund, 2016). Kidney failure occurs when the kidneys have stopped working and the patient needs dialysis or a transplant to survive long term. Often, dialysis patients visit the Emergency Department (ED) for multiple chronic conditions, including CKD, (Patzer, Schrager, & Pastan, 2017b) and the ED physician needs the patient's past health history and treatment information to provide a suitable treatment plan. In order to meet the information needs of the ED physician, emergency service (EMS) personnel or the ED team must have access to the patient's past healthcare data immediately. In most situations either the patient or family member will provide information which may not have enough clarity, or the ED physician must wait until the patient records are released from the doctor's office to provide the correct care. According to an article published in Patient Safety Network website (David Shapiro, 2013), many cases of CKD that come into the ED lack proper treatment or follow-up due to lack of patient information that includes recent test results. In several cases, the patient was discharged despite the severity of the problem which can lead to major complications.

Sharing patient data electronically can help providers reduce readmissions, decrease duplicate testing, avoid medication errors and other medical errors due to data replication (HealthIT.gov, 2018). Timely data sharing can also aid in reducing miscommunication and patient care in the emergency department. In addition to the

clinical and patient-facing use cases, data sharing is essential for ensuring best practices that can be shared between healthcare organizations and outside entities such as financial institutions and government agencies. (Snell, 2012-2019) Electronic Health Information Exchange (HIE) allows doctors, nurses, pharmacists, other health care providers, and patients to appropriately access and securely share a patient's vital medical information electronically (HealthIT.gov, 2018). HIEs across the nation are working to develop an ideal infrastructure for patient record sharing. Timely sharing of patient record information can improve the health outcomes of those who visit the ED with complications from ESRD and CKD (NIH, 2015).

Review of the Literature

End Stage Renal Disease and Chronic Kidney Disease

According to an article by Patzer, Schrager, and Pastan (2017a), treatment of medically complex patients with CKD or ESRD are increasingly performed in the Emergency Department (ED). Patients with ESRD have six times higher than the median for United States adults' ED usage and dialysis patients are at risk for adverse drug events (ADEs) due to impaired renal function. According to a study by (Chan et al., 2018), Emergency Department visits for Adverse Drug Events (ADEs) are substantially higher in dialysis patients than non-dialysis patients. The top medication category associated with ED visits for ADEs in dialysis patients is agents primarily affecting blood constituents. After propensity matching, a technique that attempts to estimate the effects of treatment, patient admission was higher in dialysis patients than non-dialysis patients. A study conducted by Lovasik, Zhang, Hockenberry, et al. (2016), that includes over 700,00 patients

with ESRD shows that more than one half of patients with ESRD visit the ED within their first year of dialysis. In order to provide efficient treatment, the ED physician needs the patient's medical records which could typically located in an external electronic health record (EHR) at another facility or provider's office. The amount of time taken through the whole process of requesting the medical records to receiving the records is a major lag time in the case of a patient who is on dialysis. An article by (Hirsch, 2015), clearly states the importance of integrating real time data to improve outcomes in Acute Kidney Injury. The article explains that a major barrier to provide effective care is the traditional dissociation of dialysis device data from other clinical information systems or EHRs. The lack of integration and the resulting manual documentation leads to errors and biases in documentation and missed opportunities to intervene in a timely fashion.

Existing Emergency Department (ED) Processes

In Emergency departments where things often happen fast, the push for interoperability sometimes sets up a technology mismatch that creates challenges that are evident (Luthra, 2016). The Emergency Department's culture and pace can amplify the risks of human error when the Electronic Health Record (EHR) is less than user-friendly. Errors become quite prevalent after hectic long hours in an ED.

Emergency department teams need patient treatment history quickly in order to diagnose and provide treatment for patient. ED Physicians often must call the provider who is on-call and talk about the patient's current situation or leave a message and wait for return call (Holzwart, 2011). In order to get the medical records, the ED physician or ED team member must request the patient health records from outpatient clinic or other

hospital and the data is exchanged via fax. Thus, patient care is now happening based on "word of mouth" discussions that'll never be officially documented or via other insecure channels. All these factors increase the time lag to provide the right treatment. In some cases, dialysis patients come to ED for other medical conditions, where the chances of an Adverse Drug Event (ADE) occurring increase. (Chan et al., 2018)

The lack or delay of patient data also causes other issues. The ED physician may order medical tests that the patient might have done within the past 30 days (Robert Glatter, 2015). This will increase the patient medical costs and reduce the provider's reimbursement. In an article published by University of Michigan (Lammers, Adler-Milstein, & Kocher, 2014), the authors discussed that fewer emergency patients received repeated medical tests when they went to a hospital that takes part in an HIE. This shows the effectiveness of HIEs and the necessity of interoperability between systems for patient record sharing.

Data Sharing

Patient data sharing is an emerging need and in order to achieve effective data sharing, interoperability between different systems is critical. An interoperable health IT ecosystem makes the right data available to the right people at the right time across organizations in a way that can be relied upon and meaningfully used by recipients. The national health IT policy as articulated by the Office of the National Coordinator (ONC) is focused on building a nationwide electronic health information infrastructure, in order to avoid medical errors, measurably improve clinical performance, improve patient access to their own health information, and reduce disparities in healthcare ("Health Information

Technology Advisory Committee (HITAC)," Rev 2019). Interoperability of health data is a key part of the solution.

One key barrier in achieving interoperability of systems are legacy systems. In Healthcare IT, a legacy system is any older clinical technology system that could be considered for replacement by newer technology, usually because it does not meet the needs of the organization (Newman, 2016). For example, a homegrown software product that does not communicate with other systems. Lack of system minded planning while designing systems, compatibility issues, lack of integration capabilities, changing software and hardware technologies are some of the reasons that leads to lack of communication between legacy systems. Legacy systems must rely on packaging up different pieces of data into a text file and transmitting it securely to someone else.

In current healthcare infrastructure, web-based health IT is an emerging technology. Although many web-based solutions are existing, none are effective in sharing patient records even in near real-time (Banerjee, 2019; Bhavesh Modi, 2019).

Health Information Exchange

Health Information Exchange is a dynamic and evolving landscape; it is the electronic transmission of healthcare data among medical facilities, and health information organizations (HealthIT.gov, 2018). HIE helps facilitate coordinated patient care, reduce duplicative treatments and avoid costly mistakes.

The purpose of HIE is to promote the appropriate and secure access and retrieval of a patient's health information to improve the cost, quality, safety and speed of patient care. HIE helps enable care coordination between multiple participants and this enhanced

communication offers healthcare providers a more complete view of a patient's health and reduces the risk of errors, duplicate treatments or tests, and readmissions, while improving patient safety and outcomes. Thus, there will be decreased opportunities for human errors and healthcare can work toward its goal of interoperability in the transition to value-based care. (Chen, Guo, & Tan, 2019)

As technology continues to evolve and the options for transferring and receiving information increase, HIE is critical for improving interoperability. Standards and interoperability affect health information exchange to a great extent. For two systems to be interoperable, they must be able to exchange data, and subsequently present that data such that a user can understand it. In order to ensure interoperability, the use of standards enable data to be shared across disparate healthcare settings regardless of the application (HIMSS.org, 2019). HIE can be used to improve population health.

Georgia Health Information Network (GaHIN)

Georgia Health Information Network (GaHIN) is a nonprofit organization with a vision to create a healthier Georgia by the use and exchange of electronic health information, so providers have the information they need at the point of care. The result is improved quality of care, better health outcomes and reductions in cost. GaHIN members includes hospital systems, regional HIEs, physician groups, individual practitioners, payers, wellness partners and other health care stakeholders. GaHIN have two products that are available to qualified healthcare professionals at no cost.

- GeorgiaDirect - gives providers a personalized email address that allows them to securely transmit patient health information to other authorized healthcare professionals
- Georgia ConnectedCare - an innovative technology that enables providers to securely access a patient's complete health record through their EHR system.

GaHIN's technology gives members the ability to access a more complete view of their patients' health information directly from their EHR systems ("Georgia Health Information Network," 2019).

Problem Statement

CKD and ESRD patients are at high risk of adverse drug events. There is a need to access patient history data without time lag for ESRD and CKD patients to create an ideal individualized treatment plan while in emergency care. To better track and securely share patients' complete medical histories, healthcare providers must be participating in health information exchange.

The lack of unification of CKD patient data acts as barrier to implementing quality improvement efforts among the patient population. Sharing of patient health data can decrease medical expenditures for the CKD patient population by knowing the patterns of the disease, early detection of disease and by creating awareness.

Overall, there is an urgent need to improve health information exchange between hospital emergency departments and other care providers to promote better care.

Purpose

The main goal of this thesis is to propose a system prototype that utilizes Amazon Web Services (AWS) technologies and involves sharing ESRD patient data for use in the hospital emergency department. The benefits of this system are to improve patient safety and monitoring and increase efficiency in providing effective care and treatment. The proposed system can be connected to the Georgia Health Information Network (GaHIN) for statewide access which will help to close the patient information gap across statewide hospital emergency departments and other care settings. This is significant in the case of an ESRD patient where a missing piece of information during traditional ways of data exchange may cost their life.

The topic of this thesis is significant because not many studies or research have been conducted on using AWS technologies on the patient data sharing aspect among ESRD patient population. By working together, healthcare providers can build systems that can support the up-front exchange of current and accurate data. As part of the proposed system, patient data will be ingested into the system by the participating patient's provider to and from ED after the visit. IT leaders in healthcare industry can take several steps to prepare and support the systematic changes for sharing healthcare data. Below are two steps that can be taken in order to drive organizations towards health information exchange.

- Engaging EHR vendors to develop native capabilities to support data exchanges.

- Make interoperability a priority and encourage healthcare organizations to make sure their technology stacks are optimized and ready to meet the Fast Healthcare Interoperability Resources (FHIR) standards and proposed new federal regulations.

The proposed solution acquired from these steps thus will achieve interoperability between organizations among the CKD patient population. Architecting for Health Insurance Portability and Accountability Act (HIPAA) compliant healthcare data application is a challenge but at the same time there is a great flexibility in how to meet the encryption requirements for Protected Health Information (PHI) (HHS Office of the Secretary, Office for Civil Rights & Ocr, 2015).

Why AWS? AWS is a comprehensive, evolving cloud computing platform provided by Amazon. AWS helps you add agility, scalability, improve collaboration, and makes it easier to incorporate new technological innovation (AWS, 2019b) Maintaining proper HIPAA compliance is not a onetime job; it is an ongoing job that needs constant monitoring using services like AWS CloudWatch. Amazon Web Services now has a wide set of HIPAA eligible services. During the 2019 HIMSS Global Conference & Exhibition, AWS Director of Worldwide Healthcare and Life Sciences Shez Partovit stated that, “AWS provides access to over 95 HIPAA-eligible features and services, enabling Change Healthcare to support the delivery of medical information from a variety of sources across the healthcare industry." (Sullivan, 2019)

Decision making on what level of encryption is needed is the preliminary step and then from signing a Business Associate Agreement (BAA) with AWS to other steps that includes

encryption on application layer, database layer and monitoring layer are vital while creating AWS infrastructure. The BAA is an AWS contract that is required under HIPAA rules to ensure that AWS appropriately safeguards protected health information (PHI). HIPAA requires covered entities (CEs) such as hospitals to sign BAA with business associates (BA) who are cloud-service providers, that impose the same requirements as the latter. In the proposed solution, all parties involved in the BAA has shared responsibility in managing administrative, technical and, physical safeguards to maintain compliance in AWS.

Data sharing between clinical systems is always a challenge in terms of security, reliability, and compliance. HL7(Health Level 7) is used for the exchanges of clinical data between healthcare applications.

The main purpose of using this technology for the proposed solution is the cost. Interoperability requires more than communication between EHRs, it requires patient's past and current health data accessible and records must be kept secure, understandable, and constantly updated. Meanwhile the records will remain sharable with other organizations. Interoperability service on AWS can leverage open standards like FHIR, HL7 and APIs effectively. A cloud system is nowadays considered as the most affordable administrative solution than traditional on-premise systems.

Project Addressed

The assumptions for this project include:

- The system prototype will utilize the HIPAA compliant AWS services
- The Level of Encryption is identified

- Patient's Primary Care provider (PCP) and hospital Emergency Department (ED) agrees on data sharing

Significance Statement

This thesis is significant due to the fact that patient data sharing is vital for providers in developing an appropriate treatment plan to provide better care. Dialysis patients are always at high risk of comorbidities. While the prevalence of comorbidities increases as CKD progresses, there are increased chances for frequent ED visits. The proposed solution provides quick access to patient medical record and thus deliver value to treatment among ESRD patients.

Definition of Terms

ADE	-	Adverse Drug Event
AWS	-	Amazon Web Services
BAA	-	Business Associate Agreement
CEHRT	-	Certified Electronic Health Record Technology
CKD	-	Chronic Kidney Disease
CMS	-	Centers for Medicare & Medicaid Services
ED	-	Emergency Department
EHR	-	Electronic Health Record
EMR	-	Electronic Medical Record
ESRD	-	End Stage Renal Disease
FedRAMP	-	Federal Risk and Authorization Management Program
FHIR	-	Fast Healthcare Interoperability Resources

HIE	-	Health Information Exchange
HIPAA	-	Health Insurance Portability and Accountability Act
HL7	-	Health Level 7
IaaS	-	Infrastructure as a Service
IAM	-	Identity Access Management
MQ	-	Messaging
ONC	-	Office of the National Coordinator
PaaS	-	Platform as a Service
PCP	-	Primary Care Provider
PHI	-	Protected Health Information
POC	-	Proof of Concept
RBAC	-	Role-Based Access Control
SCP	-	Service Control Policies
SFTP	-	Secure File Transfer Protocol
VPN	-	Virtual Private Network

CHAPTER II: METHODOLOGY

Introduction

Healthcare organizations use a large number of discretely-developed IT applications. HIEs benefits include that they decrease time to access medical records, minimize service duplication, avoidable admissions, length of stay and associated costs. The proposed solution is a cloud-based datahub that have the potential to be part of the GaHIN, the state's nonprofit health information exchange (HIE); where patient records will be readily available to refer to and upon discharge add an event layer to the patient record about the ED visit. The same process can also be followed by participating outpatient clinics, dialysis centers, or hospitals. After completing a follow-up visit, the provider can add the visit details to the patient record and the dialysis center can add the details after each dialysis.

Data Type and Description

In order to identify the problem and to assess the need of a solution, several data sources were used. Data sources include interviews with subject matter experts (SMEs) like, ED personnel, Nephrologist and Nurse Practitioner. A set of questions was used to gather the information. The data was collected and compiled from the responses received from the SMEs. Research was also conducted on finding an existing solution for similar problems utilizing websites like HHS.gov, HealthIT.gov, Health Level 7, HIMSS.org which also provided information about current necessities on healthcare systems interoperability.

In 2015, the ONC's Roadmap (HealthIT.gov, 2015) describes how interoperability is necessary for a 'learning health system' in which health information flows seamlessly and

is available to the right people, at the right place, at the right time. Achieving this requires taking steps beyond just technical requirements for the exchange of standardized information. The data sources that are potential inputs to HIE includes EHR data, laboratory system, pharmacy system, admissions & billing systems, and real-time capture from medical devices.

Project Design

The proposed methods for this project are listed below, these methods will be discussed in detail later in this section.

1. Determine existing procedures in ED: I will interview a mix of ED Physicians, ED patient administrators and EHR personnel's who work in Hospital Emergency Departments.

2. Use of access control policies for healthcare personnel based on their privilege principle.

3. Design a cloud-based compliance-ready system model using AWS services to access and retrieve patient history data while in Emergency Care.

4. Use HL7 for integrating the application with EHR: I will research the steps to integrate HL7 with application and EHR.

5. Identify the challenges in implementing the new application that involves EHR & HL7 integration.

This thesis is designed as a project proposal to build a cloud-based system that holds data from disparate systems under one umbrella. This will provide immediate access to ESRD patient data during an ED visit. In order to build the proposed system, the preliminary steps are:

- Identify the level of encryption

- Identify the level of authorized personnel who gets access to the system.
- Decision making on the triple constraints: scope, time and cost
- Level of participation from all types of internal and external care providers
- Proposing a Business Associate Agreement with AWS
- Propose collecting mandatory approval from patient for data sharing

The ED personnel and individuals who have access to the system will have to go through the proposed authorization steps. All data will be encrypted while data are at rest and in motion.

Procedures

The procedures include interviews, analyze existing ED process, by reviewing research papers and identifying technical solutions.

Instruments

For the purpose of assessing the need for a cloud-based system that allows immediate access to patient medical record, the first step is to interview ED team members.

The data will be collected by interviewing several individuals who are part of emergency department team. The questions used to collect the necessary details are:

1. Do kidney patients visit Emergency Department?
2. How often dialysis patients or patients with kidney disease visit ED?
3. What are the reasons for patients ED visit?
4. Will the patient bring medical records with them?
5. If not, what's the next step from ED team?

6. How do you get access to patients' medical records?
7. How long will it take to receive the medical records?
8. Do you wait until you receive the medical records to provide treatment?
9. Will the ED send the treatment details to the patient's primary care provider upon discharge?

In order to develop the proposed solution, information will be collected from multiple resources. The major information sources utilized include articles in PubMed, Google scholar searches, publications in clinical journals, Google searches, blogs, articles published in websites, and websites like Amazon Web Services, Health Information Exchange, HL7, HHS, and HealthIT.

Data Analysis

A multiple-case study was performed using qualitative methods among healthcare providers in Atlanta metro area. An interview-based survey was conducted onsite and by telephone with emergency department personnel and nephrologists and examined the process of patient record transfer among multiple providers. Based on the responses received, an analysis was done in an effort to bridge the gap between current state and future state of patient data sharing

Key Findings from ED Interviews

As a result of interviewing Emergency department personnel and nephrologists to understand the existing procedures, it was evident that the magnitude of ED utilization among patients with CKD and patients with ESRD is quite high. There are multiple

reasons for ED visit by ESRD patients; that includes complications due to missed dialysis, comorbid medical conditions like respiratory abnormalities, congestive heart failure and chest pain and catheter associated problems such as infections.

The first step that the ED team takes to get access to the patient's record and the patient's treatment history, the ED physician will give a call or page the primary care physician on-call, who might not have any knowledge about the patient or access to the patient's records. In this case, there will be a delay in providing care. In certain cases, the ED team will not wait for the patient records or be able to contact patient's PCP to provide the needed information. This may lead to other complications including adverse drug events (ADEs).

Another issue are delays that occur in providing care due to administrative tasks that should be done in ED-EHR system upon arrival. In emergency departments, the fast-paced environment contributes to errors in the patient's record. For example, if a patient with same first and last name but with a different suffix visited ED in an unstable stage, and there are higher chances of pulling up the wrong record by the administrative personnel at the ED.

The key questions that helped to identify the real problem and to propose the solution were:

1. How do you get access to patients' medical records?
2. How long will it take to receive the medical records?
3. Do you wait until you receive the medical records to provide treatment?

The experts were allowed to provide suggestions on their expectations on the situation. Some of the suggestions are:

"Instead of getting notified that our patient is in the emergency room and then having to manually call the emergency room and fax something there, there should be system that is capable of getting treatment history"

"We want to use patient medical record received electronically from outside providers before treating patients"

CHAPTER III: RESULTS

Proposed Solution Design

Care coordination in emergency department draws on many sources of information, including the patient, family members, the patient's usual primary care physician (PCP) and patient medical record. Based on the results from the ED staff interviews and findings from the literature, the proposed solution details are explained below.

Cloud Computing

Cloud computing is the delivery of on-demand computing services that ranges from applications to computing power, and database storage through a cloud services platform via internet and on pay-as-you-go basis. Rather than owning and maintaining their own IT infrastructure by paying upfront cost, companies can rent access to the necessary cloud services and pay for what they use, and when they use it.

Figure 1 is an illustration of a high-level design of the proposed solution, a cloud-based datahub application. This datahub application shows the encryption at different levels, authorization steps for individuals who needs access to the system, and tools, services and mechanisms that can be used at the data sharing level.

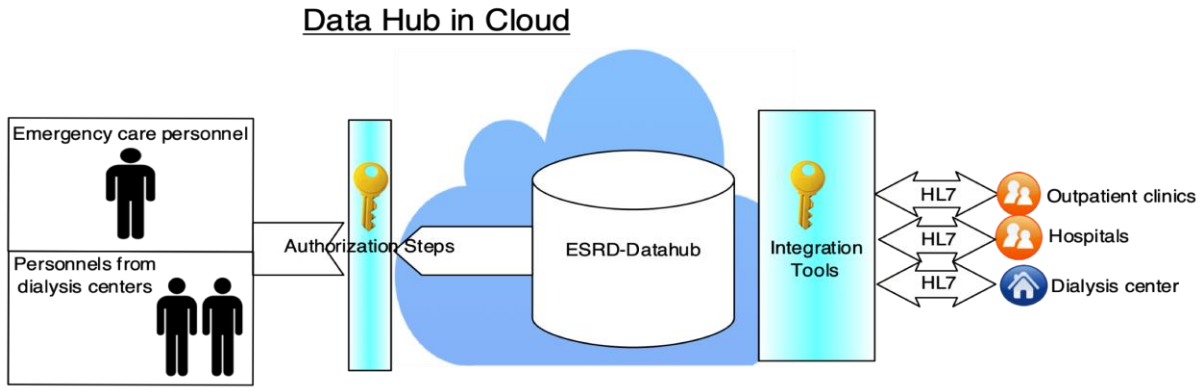

Figure 1: High Level Architecture for the Proposed Solution

Based on the requirements, the factors that will be affecting the system configuration, performance and quality of the proposed system are

- Only authorized users should be able to access the service
- It should support resource sharing based on cloud computing
- It should be user-friendly
- It should provide a stable service environment

Amazon Web Services (AWS)

Amazon Web Services (AWS) is a comprehensive, evolving cloud computing platform. It provides a mix of infrastructure as a service (IaaS), and platform as a service (PaaS). Amazon supports HIPAA compliance, and services provided by AWS are under Health Insurance Portability and Accountability Act (HIPAA) and/or Federal Risk and Authorization Management Program (FedRAMP) frameworks. In order to use HIPAA compliant services, a Business Service Agreement (BAA) must be in place.

Along with HIPAA compliant AWS services to store, and process protected health information (PHI,) additional supporting can be provided by using service control policies (SCPs) for added security. To date, AWS has released 51 HIPAA-eligible services. Several AWS services can be used in order to achieve the proposed solution. The example architecture shows some services that has the potential to be used for the efficiency of the proposed solution (See Figure 3). Some important tools that might be used in the proposed architecture to meet the business need are mentioned below.

Amazon EC2 (Elastic Compute Cloud) – A scalable, user-configurable compute service that supports multiple methods for encrypting data at rest.

Amazon S3 (Simple Storage Service) – A scalable, high-speed, web-based cloud storage service. S3 is an economic data storage service with a pay-as-you-go pricing model that expand with customer's requirements.

Amazon Kinesis – Kinesis Data Streams can be used to collect and process large streams of data records in real time. As the amount of data that will grow and the increase in the value of data, real-time streaming and processing of data is required in the future. So, for the meaningful use of data and long-lasting efficacy of the proposed solution Amazon kinesis service is significant.

AWS Lambda – Serverless compute service. AWS Lambda is an event-driven computing cloud service that allows developers to provision resources for a programming function on a pay-per-use basis without having to be concerned about what Amazon storage or compute resources that will support it. So, instead of running a server for a month by a participating member, lambda can be used to reduce the cost.

AWS SQS (Simple Queue Service) - Amazon Simple Queue Service (SQS) is a fully managed message queuing service that enables you to decouple and scale microservices, distributed systems, and serverless applications. As the proposed solution evolve with the increase in users, Amazon SQS can be used to build HIPAA-compliant applications and store and transmit messages between healthcare systems, including messages containing protected health information (PHI).

AWS Glue – A fully managed Extract, Transform and Load (ETL) service that can read data from a JDBC-enabled, on-premise database and transfer the datasets into AWS services like Amazon S3, Amazon Redshift, and Amazon RDS. This service can be used in the future of the proposed solution to prepare CKD patient data for analysis in order to elevate health and quality of life of kidney patients.

AWS CloudTrail – A service that supports activity monitoring. CloudTrail is a vital service for the proposed solution due to the increasing number of users.

AWS API Gateway – A service for creating, publishing, maintaining, monitoring, and securing REST and WebSocket APIs.

Integration Tools

Existing healthcare applications Healthcare integration engines solve the problem of sharing and exchanging data between healthcare applications. In healthcare IT, there are several bi-directional integration engines. The patient data can be transferred using several technologies. *Figure 2* shows high-level architecture on data hub integration.

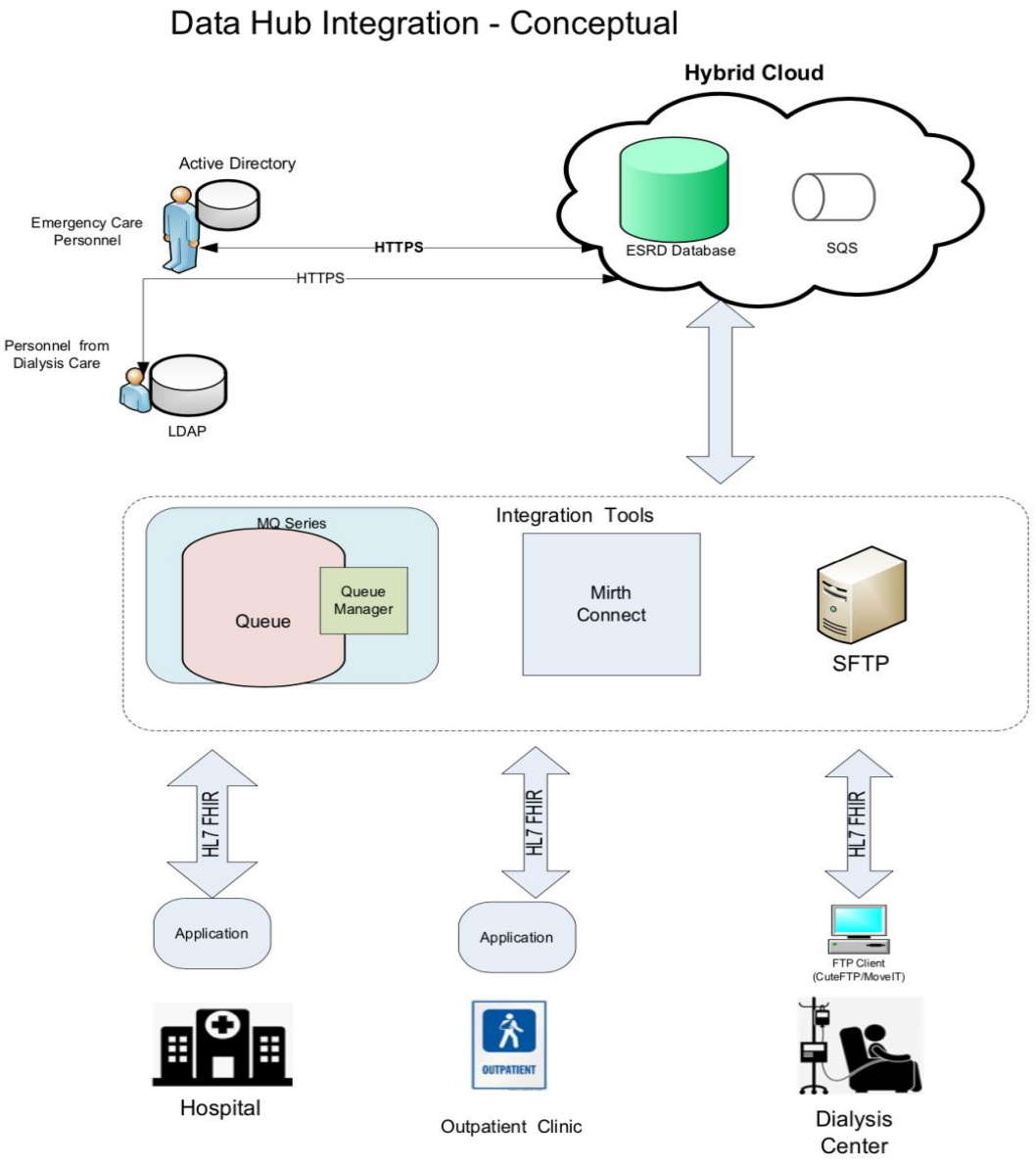

Figure 2: Integration Architecture example

API (Application Programming Interface)

An API is an interface that allows unrelated software programs to communicate with one another. APIs act as bridge between applications, allowing data to flow regardless of the original design of each application. The patient data will be transmitted through an API (Application Programming Interface).

As healthcare organizations continue to add new tools because of the changing technologies, interoperability needs to be a high priority. An API can make it easier to securely exchange health data within and outside of a health system. A REST API is a method of allowing communication between a web-based client and server that employs representational state transfer (REST) constraints. REST API is useful for building large, scalable systems. With REST API, the emerging standard Fast Interoperability Resources (FHIR) specification can easily be codified within the API on Amazon API Gateway service (HL7.org/FHIR, 2018).

Load balancer can be used for the distribution of workloads and the data will be loaded to the database server. At the integration stage, the data will be queued for processing and storing in the cloud. The message queue integration can be performed using multiple integration techniques depends on IT capabilities of 3 data parties. The data can be moved to ESRD database hosted in Cloud. *Figure 3* is an illustration of an example API architecture for the proposed solution and detailed below.

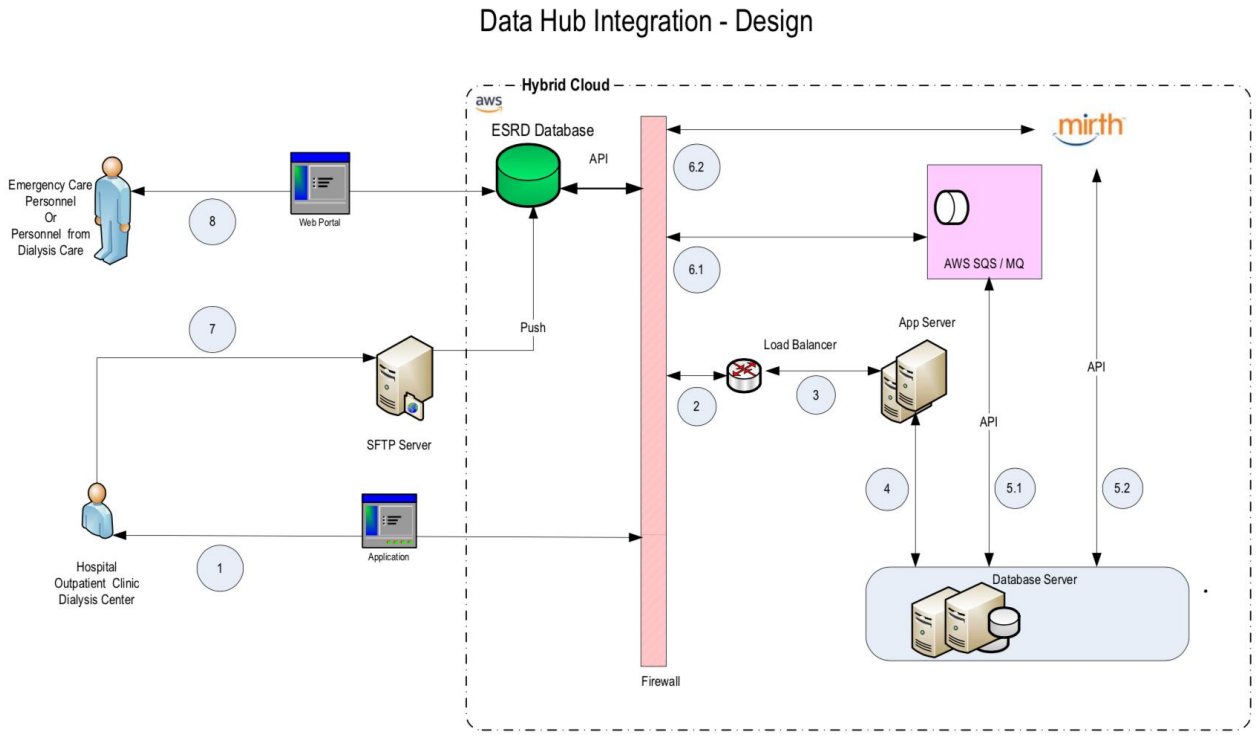

Figure 3: API Architecture example

Data flow diagram

The proposed solution is available for use by various care providers. *Figure 3* is an example architecture that involves two sets of care providers;

- Hospital, outpatient clinic and dialysis center
- Emergency care personal

Steps (1) through (8) shows the Data Flow Diagram of the proposed system.

(1) Users from hospital, outpatient clinic and dialysis center launch application to access the patient information.
(2) The request pass through the load balancer through firewall.
(3) Based on the traffic the load balancer routes the request to the appropriate application server.
(4) Application server communicate with database server.
(5.1) and (5.2) - Based on request type, the request will either connect to AWS or Mirth.
(6.1) and (6.2) - AWS or Mirth will push the data to ESRD.
(7) The users who use SFTP can push the data directly to ESRD.
(8) Emergency care personal /dialysis care can directly access the data in ESRD using web portal.

Hybrid Cloud

The proposed solution is a hybrid cloud solution since it involves private and public cloud (*See Figure 3*). The advantage of the hybrid cloud model is that it allows workloads and data to move between private and public clouds in a flexible way as demands, needs, and costs change, giving healthcare systems greater flexibility and more options for data deployment and use (AWS.Amazon.com/Enterprise/hybrid, 2019). The benefits of adopting hybrid cloud includes flexible infrastructure, better security, low chances of complete system outages, cost controls, faster speeds on data transfers.

Legacy Systems

In order to transfer data between applications multiple integration tools are used. The legacy healthcare systems prefer to build integration solutions by reusing existing infrastructure. When applying the triple constraint theory on the project, the cost is always a major challenge in order to build a quality product. In that case, reusing existing infrastructure is a cost-effective method. As part of the proposed solution for legacy systems in *Figure 3,* the integration tools recommendations are MQSeries, SFTP and MirthConnect.

MQSeries, now known as WebSpere MQ is an IBM software to enable applications to communicate at different times in many diverse environments. MQ sends and receives data between applications, and over networks (*See Figure 3: Step 6.1*). MQ Message Encryption is a solution that provides encryption for MQ message data while it resides in queue and while all data at rest. IBM Integration Bus Healthcare Pack builds on IBM Integration Bus to provide support for applications in healthcare environments. It can

connect to a wide variety of healthcare systems, including medical devices, clinical applications, billing systems and health information exchanges (IBMKnowledgeCenter, 2015; Luthra, 2016).

SFTP stands for Secure File Transfer Protocol, or SSH File Transfer Protocol, which facilitates data access and data transfer over a Secure Shell (SSH) data stream. SFTP along with either Managed File Transfer (MFT) or algorithms that meet National Institute of Standards and Technology (NIST) standards can ensure HIPAA compliance. Thus, the smaller firms like dialysis centers can still use SFTP to transfer patient records *(See Figure 3: Step 7)*. For the proposed cloud-based solution, *AWS Transfer for SFTP* service is ideal in order to transfer files into and out of Amazon S3.

Mirth Connect is an open-source, cross-platform that supports bi-directional sending of HL7 messages between systems and applications NextgenHealthcare (2018). It makes the communication and interoperability of computer systems possible. It is a middleware that connects health information systems and allows messages to be filtered, transformed, and routed based on user-defined rules. Mirth Connect can parse HL7 messages and communicate using HL7 message protocol. Mirth Connect is Electronic Medical Records (EMR) agnostic which means it is interoperable with EMR and has cross-platform functioning capability. AWS architected an efficient way to create a healthcare Data Hub with Mirth Connect.

Cutting-Edge Systems

The AWS provides its own integration tools. Amazon SQS (Simple Queue Service) is a fully managed message queuing service that enables to decouple and scale

microservices, distributed systems, and serverless applications. Amazon SQS requires no administrative overhead and little configuration and it works on a massive scale, processing billions of messages per day.

On other hand, if organization want to use messaging with existing infrastructure, Amazon MQ is an ideal service to consider in order to move data to cloud. Amazon MQ is a managed message broker service for Apache ActiveMQ that makes it easy to set up and operate message brokers in the cloud.

Data Linkage

The Patient Identifier Information can be stored in an encrypted Amazon S3 bucket. AWS S3 bucket policies and IAM policies can be applied to restrict access to the encrypted bucket. A policy is an entity that, when attached to an identity or resource, defines their permissions (AWS-IAMPolicies, 2019). Using identifier fields, records are linked at the individual level. Records of all patients from all sources can be stored in a common staging table which includes each individual's last name, first name, sex, date of birth and residence address. Information like Social security, Medicaid, or health insurance numbers can be stored in another table. Using a combination of this information, the patient's unique identifier can be created. *Figure 4* shows the data linkage for the proposed system model.

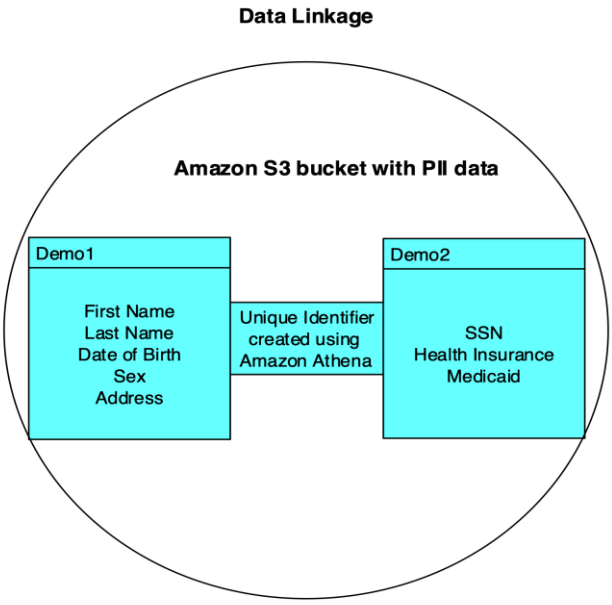

Figure 4: Data Linkage for the Proposed System

Access Control policies

Access control policies are high-level requirements that specify how access is managed and who may access information under what circumstances. In healthcare system, a more sophisticated and complex control is required. With the normal authentication mechanism such as a password, access control is concerned with how authorizations are structured. To maintain the privacy of the information, the authorization must be based on the sensitivity level of various documents in the patient records. Users who want access to the system must go through the identification process that spans from username, Multi-Factor Authentication, digital certificates to biometrics interaction via services like CloudGate UNO. The role-based access control (RBAC) is ideal in the field of medical information system to address the information security issue.

AWS Identity and Access Management (IAM) service, including identity-based polices and resource-based policies are imperative. The development of mobile healthcare application on cloud computing environment deploys the data retrieval, availability of resources, security and privacy.

Access control policies and log-in credentials of an ER personnel who should have access to the system must be linked closely to the user's employment status. Once the user is identified, the next step is to determine the privileges that user has in terms of accessing services and information. In the proposed solution, creating an access control list is ideal and depending on the ER personnel work schedule, access to system can be implemented.

Health Level 7 (HL7)

HL7 is a framework for the exchange, integration, sharing, and retrieval of electronic health information. An HL7 standard defines a method of moving clinical data between independent medical applications, often in near real time (HL7International, 2007-2019). HL7 Version 3 variants, HL7 Version 2.x and CDA are the current commonly acknowledged healthcare industry standards for exchanging clinical data among disparate healthcare systems. Each HL7 v2 message is made up of:

- Fields
- Segments
- [] indicates optional segment, () indicates repeating segment
- Message Type
- Control Characters

The main content-standard for these files has been Health Level 7 (HL7). As specified in HL7 Version 2.3, Chapter 1, "HL7 provides a common framework for implementing interfaces between disparate vendors". The HL7 standard offers great flexibility to accommodate data model differences between applications, such as the number of patient identifiers a system can store, and workflow process differences between hospitals or departments, such as whether an order can be placed without an encounter number.

Legacy systems must rely on packaging up different pieces of data and transmitting it securely between systems which will make the healthcare industry drive towards accepting the emerging standard FHIR (Fast Healthcare Interoperability Resource), which is a draft data standard developed and nurtured by HL7 International.

HL7 FHIR

HL7 FHIR (Fast Healthcare Interoperability Resources) is a new and emerging standard for exchanging healthcare information electronically. The Fast Healthcare Interoperability Resource, commonly known as FHIR, has quickly become one of the most popular protocols for joining disparate systems together, and holds great promise for the development of an application-based approach to interoperability and health information exchange.

FHIR solutions are built from a set of modular components called "Resources". All exchangeable content is defined as a resource. Resources all share the following set of characteristics:

- A common way to define, represent, and build them from data types that define common reusable patterns of elements.
- A common set of metadata
- A human readable part

A resource has 3 parts;

- Extensions
- Narrative
- Defined structured data

An FHIR resource can contain data about a patient, a device, an observation, and more. Resources refer to each other using URLs. The emerging HL7 FHIR standard will make a huge impact on interoperability. FHIR provides flexibility without modifying underlying systems or integration engines by its ease of implementation, easy extensibility for adapting the existing resources, and human readability of the source data. *Figure* 5 that shows below is a sample partial HL7 FHIR message.

```
{
  "resourceType": "Patient",
  "id": "f001",
  "text": {
    "status": "generated",
    "div": "<div xmlns=\"http://www.w3.org/1999/xhtml\"><p><b>Generated Narrative with Details</
b></p><p><b>id</b>: f001</p><p><b>identifier</b>: 738472983 (USUAL), ?? (USUAL)</p><p><b>active
</b>: true</p><p><b>name</b>: Pieter van de Heuvel </p><p><b>telecom</b>: ph: 0648352638(MOBIL
E), p.heuvel@gmail.com(HOME)</p><p><b>gender</b>: male</p><p><b>birthDate</b>: 17/11/1944</p><p>
<b>deceased</b>: false</p><p><b>address</b>: Van Egmondkade 23 Amsterdam 1024 RJ NLD (HOME)</p><
p><b>maritalStatus</b>: Getrouwd <span>(Details : {http://terminology.hl7.org/CodeSystem/v3-Mari
talStatus code 'M' = 'Married', given as 'Married'})</span></p><p><b>multipleBirth</b>: true</p>
<h3>Contacts</h3><table><tr><td>-</td><td><b>Relationship</b></td><td><b>Name</b></td><td><b>Tel
ecom</b></td></tr><tr><td>*</td><td>Emergency Contact <span>(Details : {http://terminology.hl7.o
rg/CodeSystem/v2-0131 code 'C' = 'Emergency Contact)</span></td><td>Sarah Abels </td><td>ph: 069
0383372(MOBILE)</td></tr></table><h3>Communications</h3><table><tr><td>-</td><td><b>Language</b>
</td><td><b>Preferred</b></td></tr><tr><td>*</td><td>Nederlands <span>(Details : {urn:ietf:bcp:4
7 code 'nl' = 'Dutch', given as 'Dutch'})</span></td><td>true</td></tr></table><p><b>managingOrg
anization</b>: <a>Burgers University Medical Centre</a></p></div>"
  },
  "identifier": [
    {
      "use": "usual",
      "system": "urn:oid:2.16.840.1.113883.2.4.6.3",
      "value": "738472983"
    },
    {
      "use": "usual",
      "system": "urn:oid:2.16.840.1.113883.2.4.6.3"
    }
  ],
```


Figure 5: Sample HL7-FHIR message

FHIR Integration

FHIR solutions are built from a set of modular components called 'Resources'. Many elements in the FHIR resources have a coded value: string of characters assigned elsewhere that identifies some defined "concept". The string and its meaning may be defined in one of several places including a locally maintained dictionary, an HL7 specification or external terminology such as LOINC. The coded values are treated as a pair of 'system' and 'code', where system is a URL that identifies the code system. Using the following four elements, the general pattern of coded elements is represented; system, version, code, and display. ("HL7 FHIR ", 2018)

FHIR messages allows request/response behavior with bundles for both request and response. FHIR messages are event-driven and can be asynchronous.

Along with other benefits, adapting FHIR has major benefit in controlling the cost. Several factors that will drive down the cost of integration and interoperability are its ease to develop, troubleshoot, and leverage in production.

Since the proposed solution suggests using hybrid cloud, depending on the business associate agreement between covered entity and business associate, the parties can decide what information must stay in-house. And by link encryption the data can be secured. The agreement must include all the information related to data security between involved parties. A common existing procedure to exchange information with an HIE on a unique patient is using the direct secure messaging update on patient information monthly.

- Establish an encrypted virtual private network (VPN) for the HL7 FHIR messages
- Incorporate Health Information Exchange (HIE) into daily workflow
- Manage user access

Summary

The proposed solution can capture and store CKD patient's data for immediate access. The benefit of getting all data at one place gives the opportunity to open a new world to analytics. The analysis on population health data can improve both clinical outcomes while lowering costs. The population data is capable of providing actionable analytics for providers to help improve efficiency and patient care. The data will give real-time insights to clinicians and healthcare administrators to identify and address the care gaps within the patient population.

It is important that the details about the patient's visit must be shared, whether visit occur in ER or at the dialysis center as a regular visit. The outcome of this solution once implemented is that the dialysis patients who visits Emergency Department will get effective care. Emergency care team will be able to get access to patient records in near real-time and will be able to come up with a better treatment plan. This will also decrease the healthcare cost that will occur due to redoing any medical tests, which might have done recently. Another valuable advantage is that by using this solution, majority of Adverse Drug Events (ADEs) that happens among dialysis patient can be avoided.

Overall, developing a cloud-based data hub application solution leads to suitable and effective results in patient record sharing, even if the improvement is negligible. There are several achievable use cases and architecture strategies provided by AWS, though it is recommended that each architecture must be implemented with due diligence and proper testing of each process, provided by each AWS service.

Using integration services, the data hub application can be integrated to EHR system, data can be transmitted. HL7 exchanges data between healthcare applications from different vendors. For the proposed solution, Mirth Connect, an open-source integration software is used to transform HL7 messages content between two applications or EHRs. HL7 FHIR (Fast Healthcare Interoperability Resources) is an emerging standard being developed under Health Level 7 (HL7) organization. HL7 FHIR have many improvements over old HL7 versions; it is open-source and provide support for modern web standards.

CHAPTER IV: DISCUSSION

Introduction

As part of encouraging providers to adopt, implement, upgrade, and demonstrate meaningful use of certified electronic health record technology (CEHRT), Centers for Medicare & Medicaid Services (CMS) established Promoting Interoperability Programs (CMS.gov, 2019; Robert Glatter, 2015). The proposed system in this thesis has the potential to achieve the interoperability standards for healthcare systems needed to provide better care for the CKD population.

Summary of project

Developing quality measures related to emergency department (ED) utilization by individuals with ESRD who are receiving dialysis is challenging but is imperative. A cloud-based solution is proposed in order address the issue and to achieve healthcare interoperability.

Implications

The goal of Meaningful Use Stage 3, *which is now renamed as Medicare and Medicaid Promoting Interoperability Programs*, is to improve the quality of health information exchanged, which will lead to improve for patients on a large scale. The proposed solution once implemented will have the benefits of providing improved quality of care, patient data safety, efficiency, and reduced health disparities.

The proposed system lets ED staff know more information about the patient, including:

- if the patient has already had certain tests done at other hospitals and results of those tests.
- if the patient is allergic to any medications which might lead to an Adverse Drug Event.

The near real-time patient data thus shared can be helpful in identifying high-risk patients and populations and to identify gaps in providing patient care.

The REST API of the proposed solution will be based on multi-tenant architecture which means the API can be consumed by different client applications. This way the proposed system can serve several tenants with one database. Based on the existing IT infrastructure of all 3 parties, the solution can be customized. If small firms like dialysis centers prefer using existing application and only needed the storage, then transferring record via SFTP is the best option. All parties can use the web portal to access the patient medical record as needed.

Limitations

The approach utilized suffers from the limitation that this solution is not applied in AWS environment and lack of knowledge of the overall cost due to the vast amount of patient data. Without the support of integration engines, processing HL7 FHIR messages to store and use by AWS services is not possible. Although Mirth Connect is an open source software, it is not free. Even though the homegrown or packaged message queueing systems can be used to transfer large volumes of data it requires ongoing hardware maintenance and system administration resources. Even though HL7 FHIR is an emerging standard in exchanging electronic health record, it does have some challenges.

Security with FHIR is incomplete. Usage of SMART (Substitutable Medical Applications, Reusable Technologies) App is still in evolving stage (HL7.org/fhir/smart-app-launch, 2018). FHIR is not real-time protocol.

Challenges in Implementing the Proposed System

- Creating an efficient BAA between covered entities and business associate is a challenging process. Sample use cases to consider are:
    - Decision making on the eligibility of authorized users of member/organization.
    - The security level of each entities own EHR systems
- Ground-to-cloud integration: Switching from an on-premises installation to the cloud means changing the entire structure and method of handling tasks. Healthcare providers planning to implement a cloud solution must ensure that everybody comes up to speed with how to work on the cloud efficiently. Failure to foresee and ensure this challenge may result in risks of downtime, improper handling of data, or data breaches.
- Today, every company using the FHIR standard has created its own custom version. So, while it might be easier to connect applications together, there is no commonality across the healthcare industry for how data is identified or stored.
- Lack of semantic interoperability is a major challenge where every participating member must agree on every aspect, from gender identification to terminology around each health condition.
- Insufficient documentation of existing systems

- Lack of good project management cause difficulty in planning and analyzing workloads which leads to underestimating the cost of resource requirements.
- Implementing network segmentation when moving resources to AWS is a major concern.
- In terms of hybrid cloud, disparity between on-premises, AWS tools, and operating procedures makes centralized monitoring impossible
- Lack of trained developers, network support engineers who can support cloud systems is another challenge.
- Misinterpretation due to poor HL7 data semantics
- More than understanding the data values, applications must understand the meaning of the values. For instance, a value of "3" may indicate that a patient is a nonsmoker in one system, but in another, the same value may indicate as "unknown". These kind of misinterpretations, and quality of data, have serious implications for patient care delivery.
- Use of different HL7 versions: To Exchange patient information between various and numerous healthcare applications HL7 standards are used, to add to the complexity, there are several standards available to use including:
    - HL7
    - HL7 Clinical Document Architecture (CDA)
    - HL7 Continuity of Care Document (CCD)
    - Continuity of Care Record (CCR)

    - EHR-Lab Interoperability and Connectivity Specification (ELINCS)
    - Digital Imaging and Communications in Medicine (DICOM)
- Applications lack of support on all HL7 datatypes. Encoding and decoding capabilities are a vital when using HL7 standards to exchange data between systems. For example, in order to share image as part of a medical test, HL7 2.X Encapsulated Data (ED) type is used. But the key issue is if the remote application supports the ED data type and the type of file that is being moved.

AWS website provides several use cases and architecture strategies that are feasible. AWS website itself is a great resource in doing further research and applying in order to achieve the proposed solution. Nevertheless, AWS documentation does not clarify how the private networks are implemented. Even though Amazon Web Services (AWS) came a long way in adding value to healthcare IT, there is still a long way to go in order to achieve interoperability.

Recommendations and next steps

A proof of concept (POC) approach can allow for testing the functionality of the architecture and evaluate them in existing IT environments. In order to succeed in this initiative good project management and staff commitment is a necessity. Mirth Connect is an excellent software product for developing POC projects before committing to purchase the full commercial versions.

Cost

Amazon Web Services offers reliable and scalable cloud computing services. There are introductory period offers that are valid for the first 12-months and there are non-expiring offers too (AWS, 2019a). AWS Lambda and CloudWatch are popular free-tier offers in this category. The fundamental characteristics that have the greatest impact on price are compute, store, and outbound data transfer. Most of the AWS services are on-demand which means you must pay as you go. The compute services will be charged on a per hour basis for the active EC2 instances whereas storage and data transfer services will be charged on a per gigabyte basis (AWS, 2019d).

Depending on the size of the organization, on-premise payroll costs for network engineers, security engineers, remote delivery engineers must also be accessed. The proposed solution can be owned by the hospital system. Based on data storage and transmission of data, cost of the service can be shared between the 3 parties.

Conclusion

The proposed solution can be applied not only for the benefit of CKD patient data processing but also in other branches in healthcare. Due to the complexity of disparate systems, not many studies have been done on patient data sharing in real-time among ESRD patients. This solution will act as a one-stop for kidney patients' data which can be accessed by statewide EDs and outside clinics and the data can also be used for population health.

CHAPTER V: EXECUTIVE SUMMARY

In moments of pain, confusion, and distress, the emergency department patients are often are limited or unreliable historians. Primary care providers should be involved in the care coordination process either directly or through information they placed in EMR. Primary care physicians often share call responsibilities with other physicians in their group who may or may not have consulted the patient or have access to the patient's medical records. An emergency physician trying to reach patients PCP after hours might speak to one of their partners; this will create a time lag in getting access to the patient medical history record or through a conversation.

Patients with end-stage renal disease need frequent, ongoing dialysis care and many end up in ED due to other medical conditions. ED providers and dialysis providers are challenged by incomplete or delayed transfers of pertinent clinical data from hospitalizations. Various medications are cleared by kidneys; therefore, dialysis patients are also at high risk for adverse drug events.

In order to help organizations, modernize hospitals' IT environments for providing a value-based patient care, and to remain competitive in today's evolving landscape, access to clinical data in a near real-time fashion is significant. A system-thinking approach is needed to overcome the information gap between outpatient dialysis providers and hospitals. Sharing clinical information through a health information exchange (HIE) is a great systems-minded solution. The desired outcome is a system that can hold the CKD patients' medical records on a single platform and the care providers at Emergency Department have access to the patient records in near real-time.

The proposed solution is a cloud-based system that can provide enough security measures to secure PII (Personally Identifiable Information) and PHI (Protected Health Information) data as regulated by HIPAA Privacy Rule. Factors that will provide great support in the architecting of this solution are the use of cloud based datahub application, use of emerging HL7 FHIR messaging standards to transfer data, and the tools available to integrate data between systems. The proposed solution can be connected to GaHIN for statewide access by its members.

Previous data breaches that led to HIPAA violation is considered as a major reason why providers are hesitant to share data. But HIPAA privacy rule defines the circumstances in which a Covered Entity (CE) may use or disclose an individual's Protected Health Information (PHI). HIPAA provides many pathways for permissibly exchanging PHI, which are commonly referred to as HIPAA Permitted Uses and Disclosures (AWS, 2019c; HealthIT.gov, 2019).

The purpose of this thesis is to propose a cloud-based application that can interoperate with EHR system. The application will collect history data of ESRD patients to provide immediate care safely while in Emergency Care. This will pave our way to interoperability between systems in healthcare.

The proposed solution recommends using AWS as a cloud service provider because AWS reduces the time and effort required to run existing workloads. AWS provides access to quality infrastructure and component, and numerous resources and services that are already HIPAA compliant. AWS offers pay-as-you-go model, that is you only pay for what you use. With this auto scalability feature provided by Amazon EC2 service, cost can be

managed efficiently. Upon successfully implementing the proposed solution, meaningful use stage2 can be successfully achieved among Chronic Kidney Disease (CKD) patient population.

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