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RECOMMENDATIONS FOR DATA EXCHANGE
STANDARDS UPDATES AND REGISTRY
IMPLEMENTATION

By

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Abstract

This thesis documents recommendations for data exchange standards that is important in public health today. The reasons for this are numerous and complex, however, inadequate data to support public health and healthcare entities has been identified as an area which is essential to making both healthcare and public health efforts more effective. Specially, lack of data collection from electronic health records (EHR) and; electronic laboratory reports (ELR) has been identified as a key challenge.

Georgia Department of Public Health identifies inadequate data collection as a reason for limited funding. Technology can help change this trend by collecting required data attributes. Bridging data gaps will ensure generation of electronic case reporting (eCR) form the electronic health records encounter form which is transmitted online through State Electronic Notifiable Disease Surveillance System (SENDSS).

Additionally, recommendations to implement a Chronic Kidney Disease registry to determine incidence of increased deaths.

In the United States, the Centers for Disease Control and Prevention (CDC) estimate adults diagnosed with diabetes might be predisposed to CKD. As individuals age, kidney disease worsens even though medical intervention and treatment is administered. Over time, individuals may need a kidney transplant and dialysis while waiting for a donor. There is a need to build a national cloud based commercial compliant kidney registry.

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CHAPTER 1: INTRODUCTION

1.1 INTRODUCTION DATA EXCHANGE & REGISTRY IMPLEMENTATION

The purpose of the thesis will make recommendations for data exchange standards and recommendations for new healthcare registry.

Specially, lack of data collection from electronic health records (EHR) and; electronic laboratory reports (ELR) has been identified as a key challenge. Additionally, according to Georgia Department of Public Health (2017), "incomplete reporting leads to under-estimation of the impact of HIV in Georgia limits funding for services among HIV populations."[1]

Despite the focus on sexually transmitted infections (STIs) interventions, HIV/AIDS has increased in Georgia. The reasons are numerous and complex. However, inadequate data to support public health and healthcare entities has been identified as an area which is essential to making both healthcare and public health efforts more effective.

The data exchange gap between electronic health records (EHR) and electronic laboratory reporting (ELR) systems is due to lack of reportable condition trigger codes (RCTC).

Technology can help change this trend by collecting required data attributes. Bridging data gaps will ensure generation of electronic case reporting (eCR) form the electronic health records encounter form which is transmitted online through State Electronic Notifiable Disease Surveillance System (SENDSS).

For the new registry implementation, FHIR (Fast Healthcare Interoperability) framework as new emerging technologies to enhance or upgrade current ELR, EHR, and SENDSS data collection processes to support existing public health informatics architecture. FHIR API framework supports interoperability of data exchange between public health entities which is not possible with current health language seven version 2 (HL7 V2). Further, this framework includes features from HL7 versions 2 and 3 utilizing the latest web technologies.[2] The intended audience for the FHIR API recommendations.

- Hospitals
- Clinics
- Local health departments
- Georgia Department of Public Health (GDPH)
- Centers for Disease Control & Prevention (CDC)

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[1] The Georgia Department of Public Health 2015. HIV Surveillance Fact Sheet, Georgia 2015. Retrieved on January 31, 2017 from https://dph.georgia.gov/sites/dph.georgia.gov/files/HIV_EPI_Fact%20Sheet_Georgia%202015_04.14.17.pdf

[2] Core Point Health. HL7 FHIR Resources. Retrieved on September 17, 2017 from https://corepointhealth.com/fhir

2.1   DATA EXCHANGE BACKGROUND

There is a business need for this recommendations due to current spending by the federal government. Spending is estimated at $27 million each year in the United States on HIV/AIDS programs and research. [3] In the United States, over one million individuals are living with HIV/AIDS and one out of eight individuals are unaware they are infected.[4] Also, data reporting barriers when reporting new cases of HIV/AIDS. The federal government is aware of the burden and has generated federal funding to decrease this burden. In the past reporting was specific to a geographical area.[5]

Therefore, there is a business need for accurate and timely data collection and exchange from ELR and EHR systems. It is necessary from a national surveillance standpoint; critically imperative for policy changes and strategies' in accordance with Healthy People 2020 goals of prevention and reduction of this epidemic.[6]

ELR and EHR adequate data collection and exchange methods between federal, state and local level will assist with monitoring prevalence, incidence, morbidity and mortality rates for populations at high risks in an effort to prevent new infections and improve health outcomes.

Data exchange is vital to public health national initiatives which can become impeded when case data is not collected according to public health standards outlined which affects timeliness and sensitivity of data.   The goal is to reduce the number of incomplete case data reported via ELR and EHR.

Further, FHIR new technology recommendation will support high data quality critical to surveillance systems since useful data drives resource allocation, prevention, treatment, and new policies reducing risks in an effort of creating positive health outcomes.

Improving the number of incomplete HIV/AIDS case data reported via ELR and EHR. Additionally, reduce the number of new HIV/AIDS infections in accords with Healthy People 2020 objective. The objectives of the EAIS for Electronic Lab Reporting are as follows:

- Increase data elements and completeness of data collected and exchanged from ELR and EHR.

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[3] HIV.gov 2017. Budget. Retrieved on September 14, 2017 from https://www.hiv.gov/federal-response/funding/budget
[4] Centers for Disease Control and Prevention. HIV in the United States: At A Glance. Available from: https://www.cdc.gov/hiv/statistics/overview/ataglance.html
[5] NCBI. Monitoring HIV Care in the United States: Indicators and Data Systems. Retrieved on November 12, 2017 from https://www.ncbi.nlm.nih.gov/books/NBK201369/
[6] Healthy People 2020.gov. HIV Overview. Retrieved on September 17, 2017 from https://www.healthypeople.gov/2020/topics-objectives/topic/hiv

- Improve timeliness of case data collected and exchange necessary for epidemiological investigations.

The high level requirements for the data exchange recommendations are listed below in the following defining the product, service or result must meet in order for the project objectives to be satisfied.

2.2 DATA EXCHANGE TABLE 1 HIGH LEVEL REQUIREMENTS

Req. #	Requirement Description
1	FHIR API Development
2	Architecture Development
3	Network and Secutiry
4	Cloud Solutions
5	Patient Privacy

The major deliverables for the data exchange recommendations are listed below in the following table defining the product, service or results that must meet in order for the project objectives to be satisfied.

2.3 DATA EXCHANGE TABLE 2 MAJOR DELIVERABLES

Major Deliverable	Deliverable Description
Approval	Acquire project approval.
Funding	Acquire funding.
Agreement	Agreement secured for data sources used.
Architecture & Infrastructure	Project deployment and go live.
Data Collection & Exchange	Identify interoperabilities strategies for health nformation exchange.
Issues Log	Identify issues and solutions.

The inclusive and exclusive boundaries of this thesis project will be implemented in the United States. The goals exclude measuring outcomes related to other sexually transmitted infections such as:

chlamydia, herpes, syphilis and gonorrhea. This project application will be limited to ELR and EHR systems.

Patient privacy's is a major concern, so only restricted access to patient information will be available. For those receiving treatment and not using governmental or private insurance payors will be omitted.

2.4 DATA EXCHANGE PROBLEM STATEMENT

HIV/AIDS is an epidemic in the United States approximately 1.2 million individuals living with this disease. HIV/AIDS diseases burden has greatly affected the federal resources allocation for prevention and treatment programs in geographical areas affected most in certain populations.

CDC data on diagnosis during 2010 - 2015 provides evidence:

- Based on age; ages 25 – 29 are highest risks group.
- Based on ethnicity blacks or African Americans cases range 44.3%
- Based on transmission categories adolescent/adult males account for approximately 24.4% [7]

The proposed solution will make recommendations for standard enhancements to current ELR and EHR systems. Additionally, inadequate data collected from ELR and EHR processes of transmitting data to CDC eHARS surveillance system. Aside from data collection methods, this project will investigate clinical workflows to identify deficiencies.

Data exchange is vital to public health national initiatives which can become impeded when case data is not collected affecting timeliness and sensitivity of data. The goal is to reduce the number of incomplete case data reported via ELR and EHR.

These recommendations will support high data quality which is critical to surveillance systems since useful data drives resource allocation, prevention, treatment, and new policies reducing risks in an effort of creating positive health outcomes.

Additionally, this data can be utilized for research, resources allocation, new policies and treatment plans. Improving HIV/AIDS evidence based practices.

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[7] CDC 2017. HIV Surveillance Report. Retrieved on October 7, 2017 from
https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2015-vol-27.pdf

Constraints include delays in utilization of new exchange standards between local hospitals, laboratories, health departments and correctional facilities.

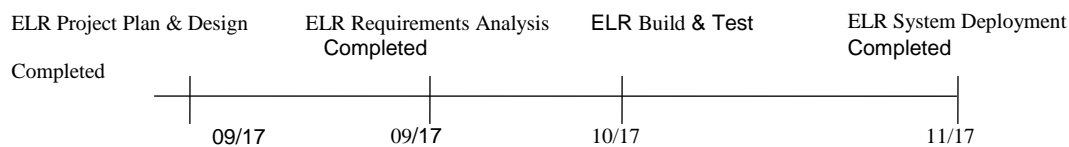## 2.5   DATA EXCHANGE TIMELINE, RESOURCES & QUALITY

The high-level timeline projected to enhance or upgrade current ELR, EHR, and SENDSS data collection processes to support existing public health informatics architecture is 2–3 months. The estimated budget of $750,000 to $1,000,000 is being requested. This budget includes new equipment, software and services needed for this ELR update.

The level of effort needed for design, build, test and deployment of project are:

- Project Manager
- Developer
- Business Analyst
- Network Administrator
- Data Architecture

2.6   DATA EXCHANGE FIGURE 1 TIMELINE

Below figure 1 projected timeline illustrates dates design, build, testing and deployment:

ELR Project Plan & Design Completed	ELR Requirements Analysis Completed	ELR Build & Test	ELR System Deployment Completed
09/17	09/17	10/17	11/17

Next, the proposed solution will support interoperability of standard HL7 health exchange standards transmitting clinical data and integrating ELR, and EHR systems. Additionally, inadequate data collected from ELR and EHR processes. Further, complete data sets will be transmitted into eHARS surveillance system.

Current data collection methods/techniques illustrate gaps and barriers in how data is collected.

According to NCBI, majority of the barriers are associated with data collection methods/techniques.[8] Resulting in underreporting and the need data recapture that delays reporting to CDC.

The following system areas will be affected:

- **Health Information Exchange (HIE):** The health information exchange will send results to the state department DPH SendSS system.

- **Electronic Laboratory Reporting System:** The new FHIR technology will be utilized by hospitals, laboratories (ARUP, References Lab, LabCorp & Quest), public health departments and correctional facilities will require new architectures such as server.

- **Public Health Subsystems:**

    o Georgia Department of Public Health (GDPH): SendSS reporting system collects data on HIV/AIDS for surveillance purposes.

    o Centers for Disease Control & Prevention (CDC): eHARS reporting system collects data on HIV/AIDS for surveillance and policy making purposes.

2.7   DATA EXCHANGE INFORMATION FLOW

Information will flow diagram in figure 2 illustrates patients: hospitals, clinics, laboratories, public health departments and correctional facilities. The infrastructure and software services needed are: hospital servers, lab servers, correctional facility servers, GDPH SendSS web application and CDC eHARS Surveillance system.

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[8] NCBI. Monitoring HIV Care in the United States: Indicators and Data Systems. Retrieved on October 8, 2017 from https://www.ncbi.nlm.nih.gov/books/NBK201369/

FIGURE 2 INFORMATION FLOW DIAGRAM
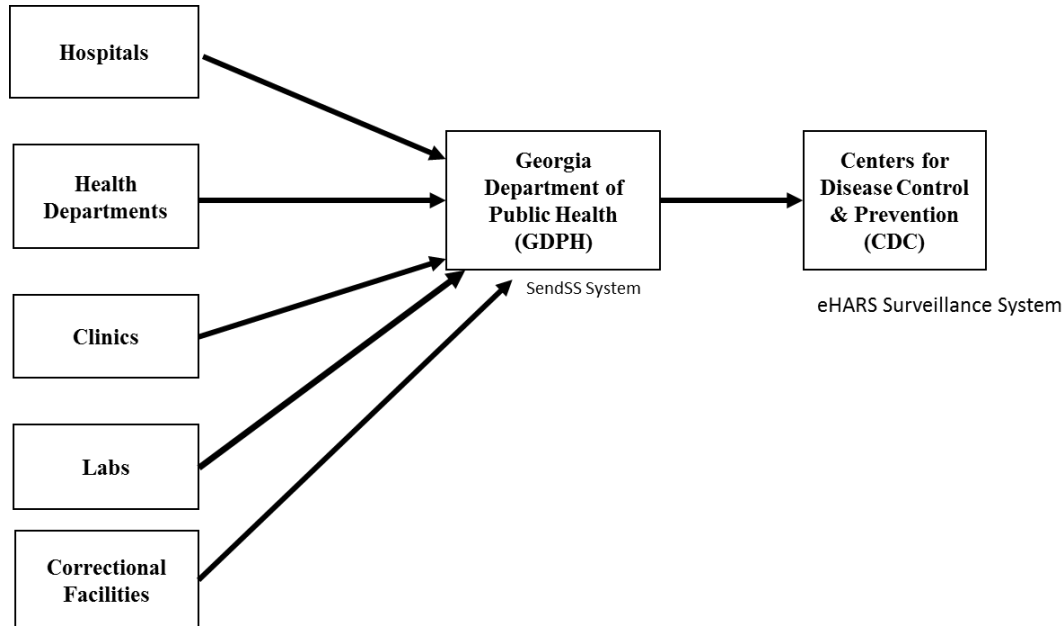
Data exchange from population health systems.

The business process is collection of data for HIV/AIDS Surveillance System. The trigger event creates an alert from las ELR, EHR lab module from hospitals, and health departments are trigger from data warehouse when positive or confirmed cases of HIV/AIDS lab results are received. Data sent to GDPH SendSS reporting system for analysis. Incomplete or inaccurate files are held for data recapture. Complete data sets are transmitted into CDC eHARS system.

The business process model for this thesis Electronic Lab Reporting starts with a trigger event. The trigger event is a positive or confirmed case of HIV/AIDS lab report. Georgia regulation (O.C.G.A. §31-12-2(b))[9] , requires new positive results be reported to GDPH via SendSS system. The business rules validate patient demographic data, data of birth, address, CD4 count, viral load, transmission category and other pertinent data listed on adult case reporting form (ACRF). This information is important for monitoring if patients are receiving medical care.

Also, the data is vital to identifying trends and determining healthcare disparities between populations. Further, the collection of HIV/AIDS surveillance data provides a better understanding of the burden of this disease and effects from a local, state and federal perspective.[10]

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[9] Justia US Law. 2010 Georgia Code TITLE 31 – HEALTH CHAPTER 22 - CLINICAL LABORATORIES
 § 31-22-9.2 - HIV tests -- Report of positive results; counseling; violations; exception for insurance coverage; exposure of health care provider. Retrieved on September 8, 2017 from http://law.justia.com/codes/georgia/2010/title-31/chapter-22/31-22-9-2
[10] CDC 2015. Centers for Disease Control and Prevention. HIV/AIDS.
Retrieved on October 9, 2017 from https://www.cdc.gov/hiv/statistics/surveillance/systems/index.html

Business processes are validated based on data elements transmitted each night to the SendSS reporting system. The next business day after a file is received this file is processed by GDPH utilizing a SAS file to validate date based on all data attributes outlined in the ACRF. Records with complete data elements are then exported into CDC eHARS systems. Inaccurate and incomplete records are held to recapture data as files are transmitted daily.

The business architecture identifies public health entities, stakeholders, strategies and key objectives of hospitals, clinics, public health departments, and CDC related to data exchange.

- Lab results in the data/information being sent utilizing HL7 data exchange standards.
- This data of information is transmitted to Department of Public Health for analysis of complete de-identified data which are needed before being exported into CDC eHARS Surveillance system.
- Hospitals, laboratories, public health departments, and correctional facilities transmit lab results to Georgia Department of Public Health.

The information architecture identifies the data types, sources of data, validate data and identify data inequalities between population and public health.

- HL7 version 2 and 3 supports interoperability to data exchange between population and public health entities.
- Only surveillance data will be added to the new surveillance system.
- Data from external sources such as: hospitals, health departments, correctional facilities and laboratories.
- Data can be queried from application/surveillance system to ensure accuracy. Additionally, a SAS preload process will be included to ensure accurate and complete data.

Additionally, the following areas of the information architecture will be affected:

- **System & Network Management:** updates to current network configuration will be needed to interface with new technology.
- **Software Engineering:** API will need updating in order to query data for using the new technology.
- **Secuirity:** Data encryption will be needed since PHI informaiton will be stored in database. Security will be needed for data at rest and in motion.
- **Transaction Processing:** no updates are needed related to tranasction processing. Processing of data will remain the same.

- **Location and Directory:** only file updates to the location and directory will be necessary.
- **Operations:** updates to current operations will be necessary to maintain current operational processes.
- **User Interface:** a new API will be needed to query data from the database.
- **Data Exchange:** a new exchange standard installantion will be needed since moving from HL7v2 to HL7v3.
- **Data Management:** an update to the current database will be needed to ensure data exchange standards are capture and stored in the database.
- **Graphics ans Images:** a new API graphic will be needed for this upgrade.

Below are a list of four areas below will be affected:
- **Service Access and Delivery:**
  - Communication will affect since new emerging technology standard implementation will result in new data elements transmitted.
  - VPN will be setup between hospitals, clinics and state public health departments in which data exchange occurs.
- **Service Platform and Infrastructure:**
  - Access to data on new databses testing will be need prior to implementtion.
  - New servers with notificcation capabilities of HIE.
  - A new datbases will be createdd to store new required data elements.
  - Data will be encrypted and stored on the new database.
  - WAN and LAN will be affected by additional data transmitt4ed via network so there will be an increase in traffic.
- **Component Framework:**
  - Digital signatures will be necessary for transmitteing data from EHR, ELR module to ELR modules.
  - Data exchange will expereince an impact due to new data elements being transmitted.
- **Service Interface and Integration:**
  - Middleware data will be ibppted from ELR and databases during integration.
  - The format of data flowing one way should not be an issue. Therfore, interoperability should not be an issue. If data needs change and data needs to be exchange in either direction HL7 shoulld be in a format to support interoperability.
  - Data transmformation: data should be exchanged in a format that can readily be analyzed.

The roles needed for the data exchange thesis project recommendations are as follows:

- Architect:
    - Enterprise Architecture
    - Application Architecture
    - Data Architecture
    - Technology Architecture
- Project Manager
- Software Engineer
- Data Scientist

2.8 DATA EXCHANGE IMPLEMENTATION PLAN

This implementation plan in table 3 below outlines this system is necessary decrease reporting barriers when reporting new cases of HIV/AIDS. In 2008, the United States initiatives confidential reporting which means those testing positives for HIV/AIDS are reported to public health entities.[11] An analysis of HIV/AIDS surveillance data by the CDC surveillance system illustrates missing data elements as a barrier of underreporting.[12] Listed below are major tasks for implementation:

2.9 DATA EXCHANGE TABLE 3 IMPLEMENTATION PLAN

Task Name	Deadline
Planning & Coordination	September 13, 2017
Upgrade Architectural Infrastructure	September 17, 2017
Installation of Software	October 1, 2017
Data Conversion & Mapping HL7	October 15, 2017
Testing	November 2, 2017

[11]Ford, Moragan A., Spicer, Mason Carol. Institute of Medicine of the National Academies. Monitoring HIV Care In the United States. Indicators and Data Systems
https://books.google.com/books?id=CzbbOvkbLiMC&pg=PA237&lpg=PA237&dq=HIV+%22reporting+barriers%22&source=bl&ots=-27rLGZ8an&sig=xp0HjTsJ_0AN_1Jjse3l8LW95Sw&hl=en&sa=X&ved=0ahUKEwihhOj037zXAhXJ44MKHekiCz4Q6AEIODAD#v=onepage&q=HIV%20%22reporting%20barriers%22&f=false
[12] CDC. Morbidity and Mortality Weekly Report (MMWR). Prevalence of Diagnosed and Underdiagnosed HIV Infection - United States, 2008 – 2012. Retrieved on November 13, 2017 from
https://www.cdc.gov/hiv/pdf/policies_13_238558_HIVSurveillance_NHAS_v6_508.pdf

Issue Risk Management	November 19, 2017
Training of Personnel	November 19, 2017

2.10 DATA EXCHANGE OBJECTIVES

The major objectives of this project are to implement FHIR as the new emerging technology standard to eliminate new cases of HIV/AIDS infections and improve outcomes by supporting all individuals affected by HIV/AIDS. Also, eliminating health disparities that exist among certain populations.[13]   Strategies aimed to increases awareness, promote educations and increase access to care. These strategies along with adequate clinical data collection and exchange:

- Support the collection and dissemination of clinical data exchange standards between public health entities.
- Identify best practices centered on prevention and treatment of those affected by HIV/AIDS.
- Support FHIR new emerging technology standard for dissemination evidence based information to all public health entities.

There were a number of mew emerging technologies considered for architectural impact study.   FHIR API was selected because it can capture and exchange data from population health to public health surveillance systems. Additionally, it supports data exchange and interoperability in which previous versions of HL7 standards were not capable. Even EHR vendors: Cerner, Epic, Allscript have adopted mobile applications. The advantage of the mobile implementation reduces build or development time and improve efficiency of clinical workflows.[14] A second advantage of FHIR is an open standard framework which can operate across population health EHR system and public health surveillance systems. Centralization of the library of applications will improve quality of care, research and public health.[15]

The communication of healthcare application and EHR uses restful web services. Restful web services will allow real time data exchange of HIV/AIDS new cases data exchange to be transmitted in real time.

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[13] HIV.gov. National HIV/AIDS Strategies Updated to 2020. Retrieved on November 5, 2017 from https://www.hiv.gov/federal-response/national-hiv-aids-strategy/nhas-update
[14] Corepoint Health.   on FHIR: A future framework for EHR integrations. Retrieved on November 5, 2017 from https://corepointhealth.com/-fhir-new-model-ehr-integrations
[15] : An App Platform for Healthcare. Retrieved on November 5, 2017 from https://healthit.org/

The mission the Division of HIV/AIDS (DHAP) mission is prevention and decrease new cases of HIV/AIDS transmissions and deaths in the United States.[16] Adequate data collection and exchange methods between federal, state and local level should support, monitor prevalence, incidence, morbidity and mortality rates for populations at high risks in an effort to prevent new infections and improve health outcomes. Therefore, data management processes and the FHIR API framework as new emerging technologies to support existing public health informatics architecture.

The vision of these recommendations is not only to focus on the Healthy People 2020 goals of prevention and reduction of this epidemic. Additionally, reduce the number of incomplete case data reported via ELR and EHR for those with HIV/AIDS. In the United States, over one million people are living with HIV/AIDS who may need resources to live long healthy lives. In order to balance resources, adequate data is needed to identify populations so federal funding is made available to these populations. Inadequate data leaves these populations without treatment and resources. Adequate data collection, standards and case definitions are to CDC eHARS surveillance system. CDC and other public health entities acknowledge reporting delays contribute to data inadequacies and collection techniques. CDC with the assistance of surveillance programs within their organization evaluate underreporting and delays in reporting. For this reason, CDC offers jurisdictions technological assistance for enhancing their ELR systems.[17]

So, adequate data collection is imperative to public health national initiatives. Therefore, recommendations of FHIR framework to upgrade current ELR, EHR, and SENDSS will no doubt improve timeliness and sensitivity of data.

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[16] CDC. National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Strategic Plan. Division of HIV/AIDS Prevention 2011 – 2015. Retrieved on September 8, 2017 from https://www.cdc.gov/hiv/pdf/policies_dhap-strategic-plan.pdf
[17] NCBI. The Status of the National HIV Surveillance System, United States, 2013. Retrieved on November 12, 2017 from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4037459/

3.1   REGISTRY IMPLEMENTATION BACKGROUND

This new registry will analyze death certificates within the last eighteen months. Epidemiologist in Georgia have observed an increased number of deaths as a result of chronic kidney disease Chronic Kidney Disease (CKD). Currently, there is no historical surveillance data regarding death due to kidney disease from a state or federal level. There appears to be a pattern of increasing incidence.   To determine if suspicions are true, a chronic kidney registry is needed.

The incidence of chronic kidney disease cases has increased over the past ten years. Healthy People 2020, clinical studies illustrated recipients receiving kidney transplants over a 3-year period has decreased approximately by 5% between 1990 and 1999.[18]

There is a need to build a national cloud based commercial compliant kidney registry. It must meet compliancy according to Health Insurance Portability and Accountability Act (HIPAA) since one does not exist that supports paired donation.[19] Paired donation is the process or transplant option of donating a kidney.

Further, this registry should meaningful share data between entities such as the Department of Motor Vehicle (DMV), local hospitals electronic health records and chronic surveillance systems.

Next, since there are more recipients than donor. A registry is needed to store antibody and blood type, tissue type and other pertinent data needed to compatibly match donor and recipients.

Short term effects of this registry is to measure impact of interventions, identify the burden of Chronic Kidney Disease (CKD), identify comorbidities and track outcomes.

Long term effects of this registry will decrease incidence of kidney disease, treatment effectiveness, reduce costs, disabilities, improve health disparities and decrease morbidity according to health people 2020 goals and objective. [20]   Ultimately, the goal is to exchange data nationwide in an effort to reduce incidence and implement intervention and treatment programs.

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[18]Healthy People 2020. Chronic Kidney Disease. Retrieved on September 5, 2017 from
https://www.healthypeople.gov/2020/topics-objectives/topic/chronic-kidney-disease
[19] University of Pennsylvania 2014. Ellison, Black.   A Systemic Review of Kidney Paired Donation: Applying Lessons from Historic and Contemporary Case Studies to Improve US Model. Retrieved on September 5, 2017 from
http://www.kidneyregistry.org/pages/p365/fulltxt.php
[20] Healthy People 2020. Chronic Kidney Disease. Retrieved on September 5, 2017 from
https://www.healthypeople.gov/2020/topics-objectives/topic/chronic-kidney-disease

3.2   **REGISTRY IMPLEMENTATION PROBLEM STATEMENT**

Data needs for this registry can be classified as primary or secondary based on variable in the registry. Primary data sources are relevant and reliable which are collected for this registry. This registry will collect data directly from Chronic Kidney Disease (CKD) patients. Collection of Chronic Kidney Disease (CKD) primary data will increase reliability, accuracy and completeness of data since requirements are outlined and tracked for accuracy. [21]

An advantage of primary data validates the reliability, timely, and completeness of data collected for the registry. Analysis of this data is performed routinely to ensure it meets the registry needs.

Secondary data is data collected from other sources and transmitted or imported from other sources into the registry. Other data sources would include: electronic health records systems (EHR), insurance claims manager/reimbursement systems, U.S. Census Bureau systems, other registries, and National Death Index databases.[22]

Limitations of secondary data are: receiving the data in an unstructured format. The data would require data cleaning to transform the data in a structured format. Additionally, increase probabilities:

1. Error rates increase
2. Duplicate data
3. Inconsistent data

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[21] NCBI 2017. Registries for Evaluating Patient Outcomes: A User's Guide [Internet] 3rd Edition. Data Sources for Registries. Retrieved on September 26, 2017 from https://www.ncbi.nlm.nih.gov/books/NBK208611/
[22] Publication Coursehero, HIM 317 Retrieved on September 5, 2017 from https://www.iarc.fr/en/publications/pdfs-online/treport-pub/treport-pub43/IARC_Technical_Report_No43_4.pdf

3.3 REGISTRY IMPLEMENTATION TABLE 4 PRIMARY DATA ELEMENTS

Column Name	Column Length	Data Type
OrgID	5	Numeric
Org Name	50	Alpha/Numeric
Patient Id/ MRN #	10	Numeric
Patient Last Name	25	Alpha
Patient First Name	25	Alpha
Date of Birth	6	Numeric
Address	30	Alpha/Numeric
City	20	Alpha
County	20	Alpha
State	2	Alpha
Zip Code	5	Numeric
Country	20	Alpha
Race/Ethic Group	15	Alpha
Gender	1	Alpha
Martial Status	1	Alpha
Sex	1	Alpha
Age Diagnosed Chronic Kidney Disease (CKD)	2	Numeric
Birthplace	30	Alpha
Country of Birthplace	30	Alpha
Citizenship Status	20	Alpha
Religion	10	Alpha
Vital Signs (Temperature, Pulse, Respirarion, Blood Pressure)	40	Numeric
ICD-10 Codes	10	Alpha-numeric
Lab Results	30	Alpha
Medications	40	Alpha-numeric

According to Health Language Seven (HL7), this is the current messaging standard for exchanging administrative and clinical data across multiple healthcare entities in an enterprise application system. These enterprise application systems are complex platform supporting scalable and interoperable solutions.[23] More specifically, HL7 version 3 is the standard version for registries.[24]

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[23] HL7 2016. Health Language Severn International. Retrieved on September 5, 2017 from
http://www.hl7.org/implement/standards/

3.4   REGISTRY IMPLEMENTATION DATA STORAGE

Data storage recommendations for the registry implementation is Amazon Simple Storage Service abbreviated Amazon S3. This storage is scalable for collection, analyzing and storing big data.[25] Additionally, Amazon S3 has the capacity of capturing structure and unstructured data. Security standards used to protect data in motion are SSL (secure socket layer) and TLS (transport layer security). Security of data at rest is costly and complicated. However, if PHI (protected health information) such as social security numbers in the Chronic Kidney Disease registry the system administrator should encrypt the field or the entire registry.

3.5   REGISTRY IMPLEMENTATION CONCEPTS OF VISUALIZATION / REPORTING

The visualization business intelligence and analytical software to be implemented is Tableau. Tableau interface is easy to use, secure and supports data governance. Data governance will ensure trusted data sets are utilized. This BI visualization can be easily understood by healthcare professionals, managers and technical professionals. Further, datasets can be rapidly created for analysis.

Tableau elements available for public view:

- The percentage of prevalence's and incidence of Chronic Kidney Disease (CKD).
- Research and genomic sequencing for defining or identifying inherited kidney diseases and risk factors.

Tableau elements available for private view:

- Familial history of Chronic Kidney Disease (CKD) and other morbidities that could result in Chronic Kidney Disease (CKD).
- The number of recipients matched with donors.
- Clinical trial studies can determine effectiveness of procedure, medical device, and or a pharmacologic drug used to treat Chronic Kidney Disease (CKD). Clinical trials provide information related to diagnosis, intervention, treatment and other health problems that may contribute to Chronic Kidney Disease (CKD). Additionally, analyze trends based predisposing factors, genetics, population and geographic locations.

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[24] HL7 2016. HL7 Version 3 Standard: Registries: Real Time Location Tracking, Release 1 Retrieved on September 5, 2017 from http://www.hl7.org/implement/standards/product_brief.cfm?product_id=212
[25] Amazon Web Services. Amazon S3. Object storage built to store and retrieve any amount of data from anywhere. Retrieved on September 7, 2017 from https://aws.amazon.com/s3/?p=tile

The frequency of updates for Tableau will occur publicly monthly and private real-time dates.

3.6   REGISTRY IMPLEMENTATION KEY STAKEHOLDERS

The information flow diagram identifies all stakeholders that will collect data for Chronic Kidney Disease (CKD) registry. All stakeholder will ensure data quality standards are met. Stakeholders that will collect data for this Chronic Kidney Disease (CKD) registry are: Centers for Medicaid and Medicare (CMS), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), Public health regulatory authorities, Department of Motor Vehicle (DMV), Other Surveillance Systems, hospitals, physician offices, and dialysis clinics.

- Centers for Medicaid and Medicare (CMS)
- Centers for Disease Control and Prevention (CDC)
- National Institutes of Health (NIH)
- Agency for Healthcare Research and Quality (AHRQ)
- Public health regulatory authorities
- Department of Motor Vehicle (DMV)
- Other Surveillance Systems
- Hospitals
- Clinics
- Physician Offices
- Death Registries
- Dialysis Clinics
- Congress

3.7 **REGISTRY IMPLEMENTATION INFORMATION FLOW DIAGRAM**
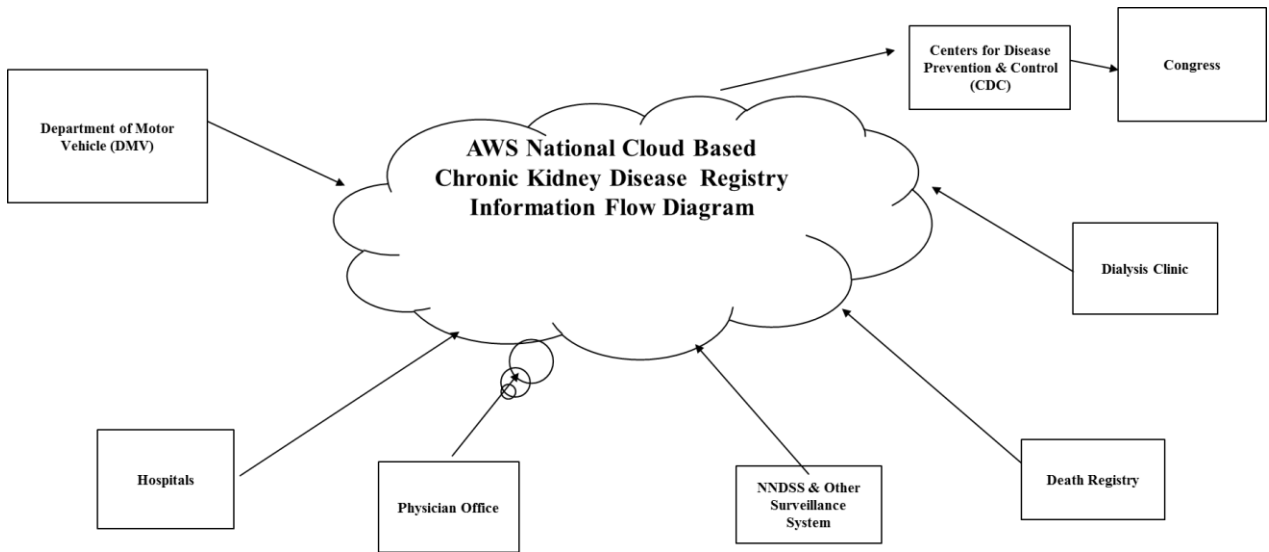
3.8 **REGISTRY IMPLEMENTATION PROJECT PLAN**

The project plan is imperative to Chronic Kidney Disease (CKD) Registry so the information technology team will have a plan to guide them through the process. The project plan will include the following documents:

Deliverables	Due Dates
Scope Management Plan	September 13, 2017
Schedule Management Plan	September 17, 2017
Cost Management Plan	October 1, 2017
Quality Management Plan	October 15, 2017
Staffing Management Plan	October 20, 2017
Communication Plan	October 17, 2017
Procurement Plan	November 6, 2017
Risk Management Plan	November 19, 2017
Project Presentation	November 19, 2017

3.9   REGISTRY IMPLEMENTATION PURPOSE & OBJECTIVES

Since public health changes, as Informaticians we must readily adopt new applications, infrastructure and architecture to solve public health issues. These critical components and data structures for this newly recommended Chronic Kidney Registry (CKD) will use Puppet to manage the cloud based components. Puppet is an open source management tool supporting: storage, computing, and effective scaling of workloads. One thing, we must decide is what cloud environment will be utilized. Will it be private of public clod provider such as: Amazon Web Server, Microsoft, or VM Ware.

The advantage of Puppet open source management tool is:

- Automation so can build new module for Chronic Kidney Disease (CKD) registry as standards change.
- Chronic Kidney Disease (CKD) registry will have reliable virtual networks.
- Security and HIPAA compliance
- Chronic Kidney Disease (CKD) low cost build, deployment and maintenance

Since public health changes as Informaticians we must readily adopt new applications, infrastructure and architecture to solve public health issues. The newly developed chronic kidney registry will use Puppet to manage the cloud based components. Puppet is an open source management tool supporting: storage, computing, and effective scaling of workloads. One thing, we must decide is what cloud environment will be utilized. Will it be private of public clod provider such as: Amazon Web Server, Microsoft, or VM Ware.

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- Chronic Kidney Disease (CKD) low cost build, deployment and maintenance

The table below illustrates data, data sources and a description of the data sources recommended for the registry implementation project.

Data	Data Sources / Application	Description
Motor Vehicle Data	Department of Motor Vehicle (Driver Application System)	Data of available donors in given population.
Centers for Disease Control & Prevention (CDC)	Chronic Surveillance System	Data related to chronic conditions such as: hypertension (HTN), diabetes (DM), myocardial infarction (MI), cerebrovascular accident (CVA) and other long term health conditions.
Clinician Reported Data	Hospitals Electronic Health Records (EHR: Allscripts, Cerner, Epic)	Data is specific and relevant.
Electronic Health Records (EHR)	Georgia Public Health Departments	Data contain routine exam, other encounter level data and clinical claim data.
Death Registry	Georgia DPH Vital Records (Registry)	Complete centralized death data. Mortality data complete so can track patient within care/treatment & lost to care. Updated weekly.
Electronic Health Records (EHR) Data Abstraction	Electronic Health Records (EHR: Allscripts, Cerner, Epic)	Data contain routine exam, other encounter level data and clinical claim data.
U.S. Census Bureau	US Censuses Database	Population data based on extensive range specificity from federal, state, local & household.
Registries	Other Registries	Merge data with CHRONIC KIDNEY DISEASE (CKD) data

		for comparison.

Below is an application schema for the registry implementation recommendations.
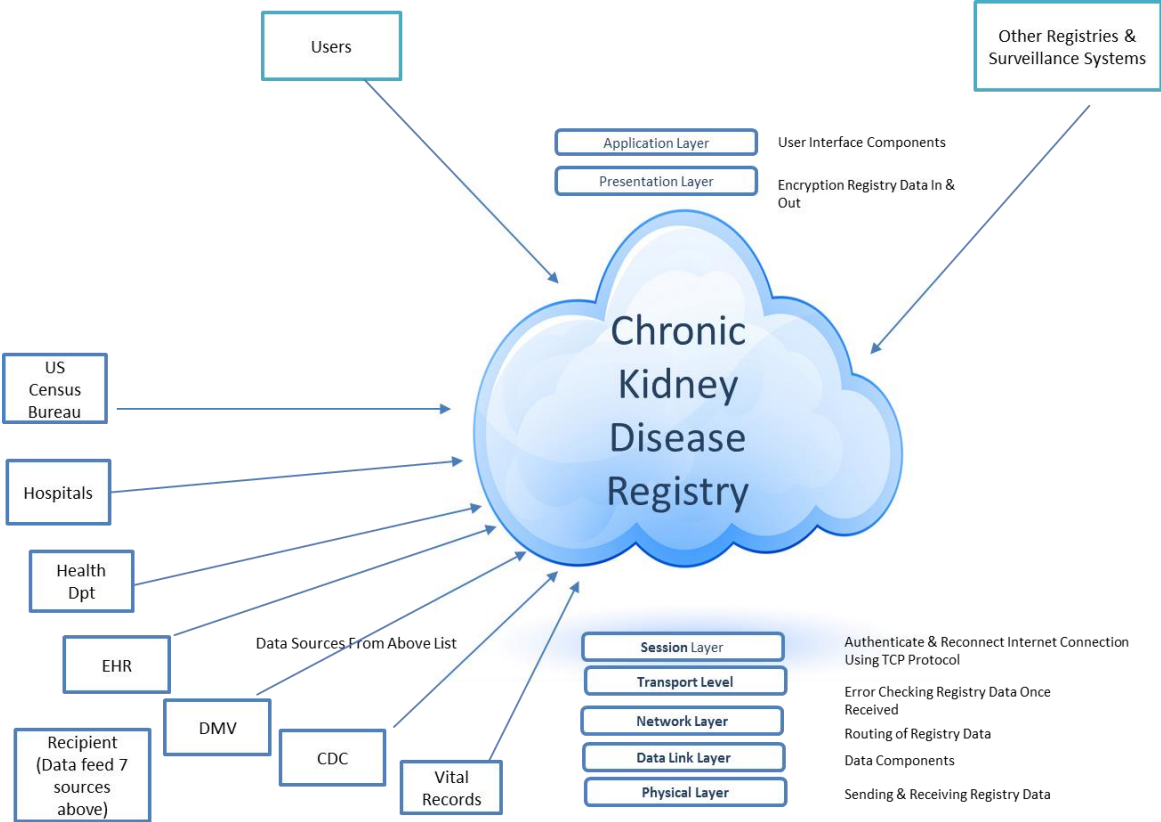
3.10   REGISTRY IMPLEMENTATION & MITIGATING RISKS

New emerging technology has a higher probability of risks compared to older technologies. FHIR API utilization for this registry identified risks are as follows:

- Risk of loss of service due to internet outage.
- Risk of unauthorized user accessing data and possible installation of malware.
- Risk of possible security and data breach.
- Risk of inability to track, investigate issues and connectivity issues.
- Risk of HIPAA privacy and security compliancy.

- Risk of data loss.

To mitigate the above mention risks for the Chronic Kidney Disease (CKD) registry, the plan is to:

1. Regularly review and upgrade cloud security protocols and hire vendors that specialize in cloud security to make recommendations regularly.
2. Implement two factor authentications using a google smart phone application such as DUO or Authy.
3. Make sure the cloud computing organization encrypts data at rest and in motion.
4. Single Sign On which allows a user to sign on one time to applications and is automatically signed into other applications for which permission has been granted.
5. Ensure current web browsers are up to date and upgraded when new versions are released.

Public health consistently changes and response to healthcare threats are imperative especially based on populations affected. Therefore, I highly recommend puppet open source management tool due to scalability, user interface and readily available source code package in this tool. As epidemiologist working Georgia Local Health Department, the need to determine the incidence of Chronic Kidney Disease (CKD), this registry collection of surveillance data can serve to identify trends, risk factors and determine treatment plan for those affected.

3.11 REGISTRY IMPLEMENTATION SCHEMA & DATABASE DESIGN

Below is the Chronic Kidney Disease (CKD) database schema which illustrates the patient table as a many to many relationships with the gender, organization and ICD10 tables. The gender, organization and ICD10 table have a one to one relationship to the patient table.
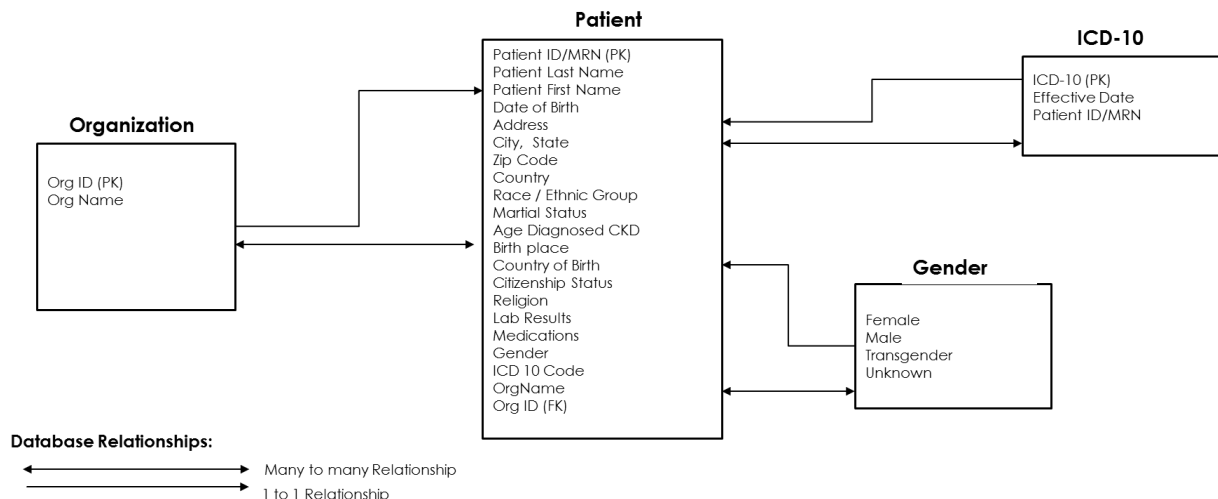
4.1 DATA EXCHANGE & REGISTRY IMPLEMENTATION CONCLUSION

Recommendations for new proposed data exchange and registry implementation identified inadequate data exchange between population health and public health entities as a challenge. The Centers for Disease Control and Prevention (CDC) and the Division of HIV/AIDS (DHAP) mission is prevention and decrease new cases of HIV/AIDS transmissions and deaths in the United States.[26] As a result, CDC Enhanced HIV/AIDS Reporting System (eHARS) surveillance de-identified data suggest 50,000 new individuals infected each year.[27] From a state perspective, Georgia Department of Public Health (GDPH) State Electronic Notifiable Disease Surveillance System (SendSS) data suggest of Georgia's population less than half are receiving treatment due to inadequate data to support public health and healthcare entities has been identified as the primary reason.

Georgia regulation (O.C.G.A. §31-12-2(b))[28] require new positive results reporting to GDPH. In the United States, the federal government yearly spends over $27 billion[29] on prevention, treatment and research programs. This illustrates HIV/AIDS epidemic is a serious public health threat.

In 2013, approximately 11,200 people died from HIV/AIDS and related medical conditions.[30] Specially, lack of data collection from electronic health records (EHR) and; electronic laboratory reports (ELR) has been identified as a key challenge. Additionally, GDPH suggest lack of complete data reported has led to limited funding for individuals infected affected by HIV/AIDS. Resulting in reduction of research, federal funding and healthcare resources.

Further, these recommendations for an ELR system will utilize FHIR API is an open standard framework that can operate across population health EHR system and public health surveillance systems.

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[26] CDC. National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Strategic Plan. Division of HIV/AIDS Prevention 2011 – 2015. Retrieved on September 8, 2017 from https://www.cdc.gov/hiv/pdf/policies_dhap-strategic-plan.pdf

[27] Prejean J, Song R, Hernandez A, Ziebell R, Green T, et al. (2011) Estimated HIV Incidence in the United States, 2006–2009. PLoS ONE 6(8): e17502. doi:10.1371/journal.pone.0017502 Retrieved on September 8, 2017 from www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0017502

[28] Justia US Law. 2010 Georgia Code TITLE 31 – HEALTH CHAPTER 22 - CLINICAL LABORATORIES § 31-22-9.2 - HIV tests -- Report of positive results; counseling; violations; exception for insurance coverage; exposure of health care provider. Retrieved on September 8, 2017 from http://law.justia.com/codes/georgia/2010/title-31/chapter-22/31-22-9-2

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These proposed solutions / recommendations will monitor prevalence, incidence, and morbidity and mortality rates for populations at high risks in an effort to prevent new infections and improve health outcomes. Additionally, FHIR framework will provide data to identify effective treatment options. These data exchange standards and open standard framework can effective and efficient operate across population health and public health entities. The infrastructure for this registry currently exist and was implemented during the early stages of meaningful use. So, HL7 standards of exchanging population health data to this registry will meets all necessary standards of exchange. The architectural infrastructure currently exist and was implemented during the early stages of meaningful use for both proposed solutions.

In conclusion, these solutions will align with Healthy People 2020 goals and objective of decreasing the incidence of kidney disease and new cases of HIV/AIDS. Leading to treatment effectiveness, reduced costs, disabilities, improve health disparities and decrease morbidity according to health people 2020 goals and objective. [31] While, improved and increasing:

1. Research
2. Federal funding
3. Healthcare resources
4. Access to quality care

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[31] ODPHP Office of Prevention and Health Promotion Healthy People 2020. Chronic Kidney Disease. Retrieved on September 5, 2017 from https://www.healthypeople.gov/2020/topics-objectives/topic/chronic-kidney-disease

APPENDIX A

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