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Conducting an Enterprise Architecture Impact Study (EAIS) for Recommendations On Developing and Implementing Health Registries to Improve Data Collection and Public Health Surveillance

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Abstract
This thesis written document discusses the deliverables related to developing an Enterprise Architecture Impact Study (EAIS) for recommendations on new emerging technologies and its capabilities. Documentation of the EAIS project will enable decision making on selecting the appropriate solution that aligns with the public health mission and goals of an organization.

In this instance, the EAIS is applied to gathering problem statement, background, facts, assumptions, requirements, communication skills, project management, resources, data architecture, data analysis, system components alternatives, evaluation criteria, alternative analysis and recommendations needed to develop and implement the following database registries: Travel Electronic Immunization Registry (TEIR), Chronic Kidney Disease (CKD) Registry and iCure Hepatitis Registry.

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1 PROBLEM STATEMENT & BACKGROUND

1.1 CHRONIC KIDNEY DISEASE (CKD REGISTRY)

The increase in incidence and prevalence of kidney failure, is as a result of chronic kidney disease (CKD), with poor health outcomes and high cost. CKD is a public health problem globally. In the United States, approximately 15% adults 18 or older have CKD[1]. CKD is said to be more prevalent in women that in men and more common in non-Hispanic black than in non-Hispanic whites at 18% versus 13% [1]. CKD is asymptomatic. Diagnosis is only through specific blood and urine tests. Early detection and treatment can slow the progression of the kidney disease for chance of survival. Currently, a comprehensive national chronic kidney registry database does not exist, just a few registries have available information on dialysis status. Implementing a national CKD registry will enable stakeholders to obtain pertinent health information such as data on laboratory results, medical history, blood type on varying stages of CKD for better management of disease.

In efforts to reduce cases of chronic kidney disease (CKD) and its associated problems, disability, economic costs and eventually death, developing a CKD registry is relevant for surveillance. Typically, Diabetes (DM) and Hypertension (HTN) are known to be the leading offender of CKD[2],[3]. Patients and insurance companies have incurred thousands of dollars in treating CKD, while on the other hand pharmaceutical companies have targeted affected patients, hospitals and physicians to benefit tremendously from increased profit revenue of drug treatment sales[2].

The chronic kidney disease registry is needed to identify patterns and trends such as causes and risk factors that has contributed to the increase of mortality rates related to chronic kidney disease. Physicians and other public health professionals will be able to monitor and evaluate the data collected to recommend solutions on how to remedy the increasing incidence of CKD and reduce burden. Another salient purpose for developing the CKD registry is to calculate the percentage of CKD cases attributed from diabetes and hypertension. This way physicians treating DM and HTN patients will have a better idea of how many of them will eventually end up as CKD cases. Keeping physicians abreast of such statistics will enable them to prepare a disease management plan at early stages, as well as educate their patients on behavioral and lifestyle changes to sustain their health.

1.2 ICURE HEPATITIS REGISTRY

For this specific project, I selected a non-profit organization that focuses on hepatitis and liver related diseases as the stakeholder to oversee the planning, design and implementation of the iCure Hepatitis Registry. For decades the Hepatitis Foundation International (HFI) has been

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[1] Diabetes Home. (2017, July 06). Retrieved November 03, 2017, from https://www.cdc.gov/diabetes/programs/initiatives/ckd-fact-sheet.html

[2] Navaneethan, Sankar D., et al. "Development and validation of an electronic health record–based chronic kidney disease registry." Clinical Journal of the American Society of Nephrology 6.1 (2011): 40-49.

[3] Ghaderian, S. B., & Beladi-Mousavi, S. S. (2014). The role of diabetes mellitus and hypertension in chronic kidney disease. Journal of Renal Injury Prevention, 3(4), 109–110. http://doi.org/10.12861/jrip.2014.31

at the forefront of advocating for hepatitis issues to promote wellness and find cures for the constituents they serve. In the project documentation, I serve as the Project Manager at HFI. The Hepatitis C virus (HCV) is the most common chronic blood borne infection in the United States with 3.9 million persons chronically infected[4] (CDC 2017), while 2.2 million are chronically affected by HBV[5] (CDC, 2016).

Currently, there's vaccination available for HBV, but not for HCV. On the other hand, HCV is treatable while HBV is incurable[4,5]. With the complexities of managing and treating hepatitis C (HBV) and hepatitis C (HCV), health practitioners have recognized the importance of gathering relevant data to better understand the disease pattern and epidemiology. Thus the information retrieved will be useful in developing innovative approaches for HBV and HCV disease management.

The proposed a business solution is to develop and implement a web-based hepatitis registry. The intended purpose of the iCure Hepatitis Registry is to harness a patient-powered research network that provides the methods and tools for patients, caretakers, families and communities to fully participate and drive patient-centered research on a large-scale within the healthcare system. In doing so, the participants will be able to share health data and feedback to inform research priorities for clinical research and trials.

In introducing the iCure Hepatitis registry, HFI hopes to increase the number of persons who are aware of their viral hepatitis infection, as an inadvertent consequence of the registry, thereby reducing the number of new HCV cases from transmission of the hepatitis C virus.

1.3 TRAVEL ELECTRONIC IMMUNIZATION REGISTRY (TEIR)

In the era of global pandemics and mass travel, the public health of U.S. citizens as well as citizens across the world is closely related to diseases occurring in other countries. When traveling across borders, getting properly vaccinated is just as (if not more) important than having a passport and securing the appropriate visas. Vaccinations are important to the prevention of many diseases that have become rare in the United States, such as measles and pertussis, which are still common in other parts of the world.[6] In addition, some types of international travel, especially when traveling to developing countries and rural areas may have higher health risks (e.g. Yellow Fever, Ebola, and Polio). These examples are important because they are vector borne diseases with available vaccinations. Vector-borne diseases as a whole account for more than 17% of all infectious diseases, causing more than 1 million deaths annually[7]. Vectors are living organisms that can transmit infectious diseases between humans or from animals to humans. In addition, Yellow Fever is an important example because forty-seven countries in Africa (34) and Central and South America (13) are either endemic for, or have regions that are endemic for, yellow fever. A modelling study based on African data

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4 Centers for Disease Control and Prevention (CDC). 2017. Hepatitis C FAQs for Health Professionals. Available from CDC website: https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm#section1

5 Centers for Disease Control and Prevention (CDC). 2016. Hepatitis B FAQs for Health Professionals. Available from CDC website: https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm#overview

6 Centers for Disease Control and Prevention. Retrieved June 1, 2017. https://www.cdc.gov/features/vaccines-travel/index.html

7 The World Health Organization. Vector Borne Diseases. Retrieved June 22, 2017. http://www.who.int/mediacentre/factsheets/fs387/en/

sources estimated the burden of yellow fever during 2013 was 84 000–170 000 severe cases and 29 000–60 000 deaths. Occasionally travelers who visit yellow fever endemic countries may bring the disease to countries free from yellow fever. In order to prevent such importation of the disease, many countries require proof of vaccination against yellow fever before they will issue a visa, particularly if travelers come from, or have visited yellow fever endemic areas.[8]

Furthermore, The World Health Organization (WHO) has argued that, "A crucial element in vector-borne diseases, such as Yellow Fever, is behavioral change. WHO works with partners to provide education and improve awareness so that people know how to protect themselves and their communities from mosquitoes, ticks, bugs, flies and other vectors."[9] In an effort to assist governments with improving awareness and understanding the vaccination status of foreign travelers, The Travel Electronic Immunization Records (Travel EIR) project will focus on the development of an electronic immunization application to replace The World Health Organization's paper international certificate of vaccination or prophylaxis also known as the "Yellow Card Booklet" with an electronic format that can be scanned and validated at port of entry similar to the passport and visa process.

Moreover, according to healthy people 2020, the goal is "increase immunization rates and reduce preventable infectious diseases."[10] Timely, accurate data is necessary to accomplish this goal. Informatics will play a vital role in the development of the Travel EIR system by improving:

- Data collections – e.g. moving from paper to electronic data capture increases efficiency and accuracy in understanding the vaccination status of travelers
- Data management – e.g. allows officials (the country traveled to and the country traveled from to understand the current vaccination status of foreigners to the country as well as citizens abroad)
- Data analysis – e.g. allows quick analysis of potential travelers who have been impacted by an epidemic as well as others they have come in contact with or areas that were visited.

[8] The World Health Organization. Yellow Fever. Retrieved June 22, 2017. http://www.who.int/mediacentre/factsheets/fs100/en/

[9] The World Health Organization. Vector Borne Diseases. Retrieved June 22, 2017. http://www.who.int/mediacentre/factsheets/fs387/en/

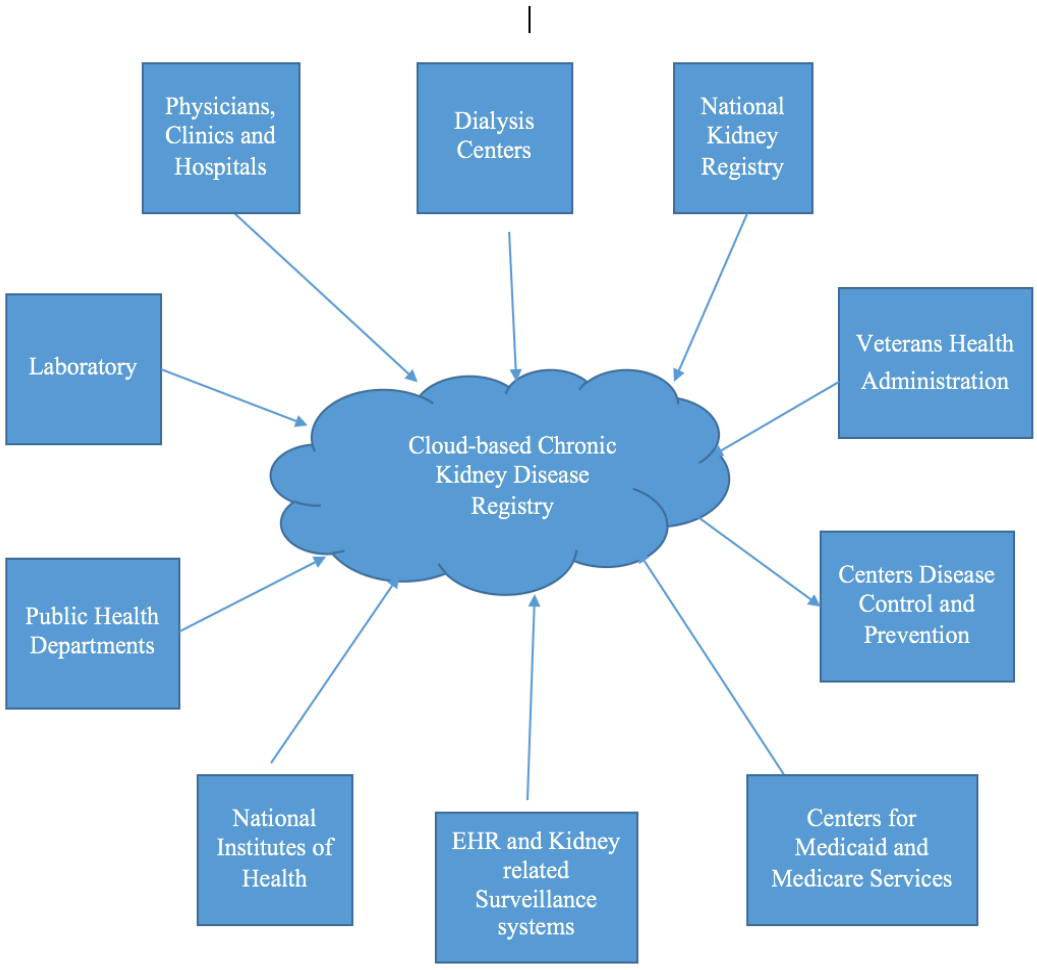
[10] Healthy People 2020. Immunization and Infectious Diseases. Retrieved May 20, 2017 https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases

2 COMMON KEY DELIVERABLES IDENTIFIED ACROSS THE EAIS PROJECTS

2.1 DEVELOPING AN INFORMATION FLOW DIAGRAM

The purpose of an information flow diagram is to demonstrate to flow of data (send and receive) within the registry and across networks.

2.1.1 CKD REGISTRY INFORMATION FLOW DIAGRAM

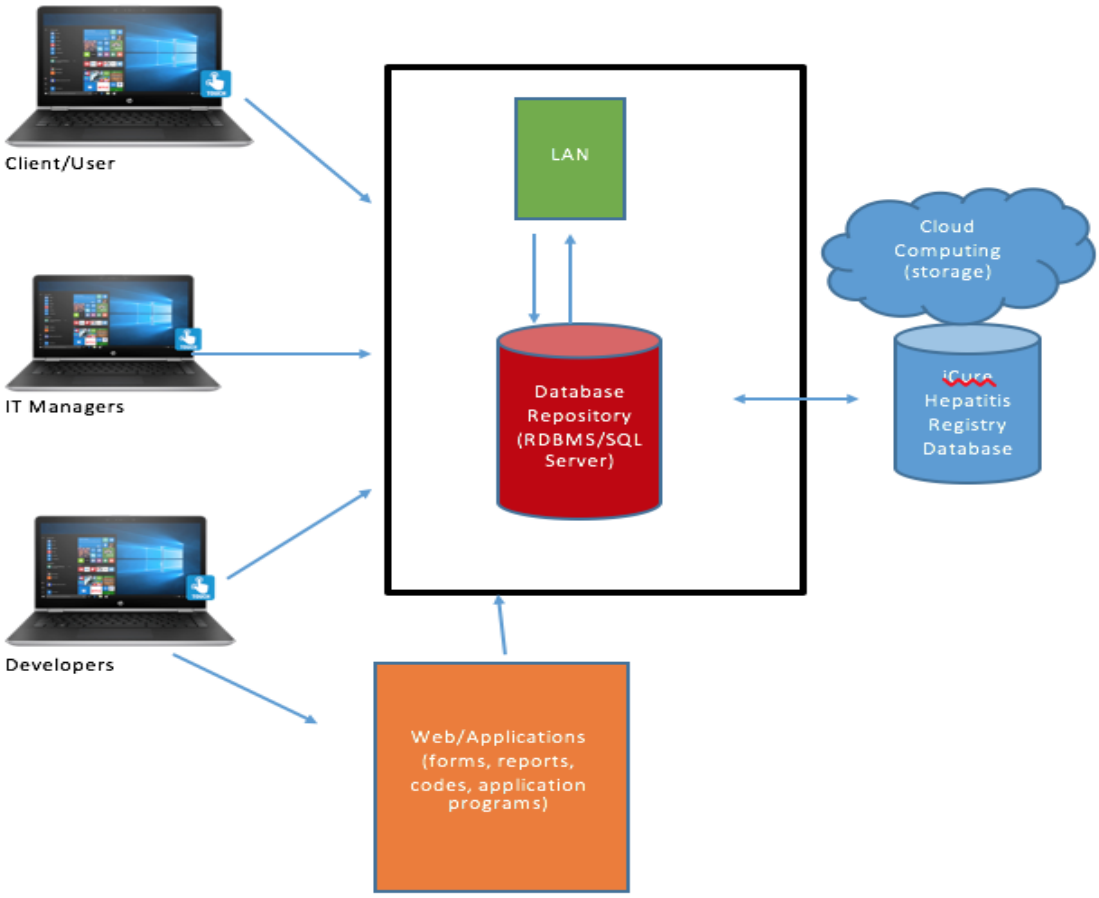


The CKD registry information flow model includes all stakeholders involved in capturing the appropriate data for the CKD registry. Each stakeholder has a role they play in ensuring that data collected to the repository are reliable and accurate for real-time data analysis. Stakeholders for the CKD registry include patients, caregivers and their families, physicians, clinical researchers, hospitals, clinical laboratories, health departments and other related

registries. Together the stakeholders provide the health data needed to be deposited in the registry. Below outline the events of the stakeholder's engagement in information flow transactions:

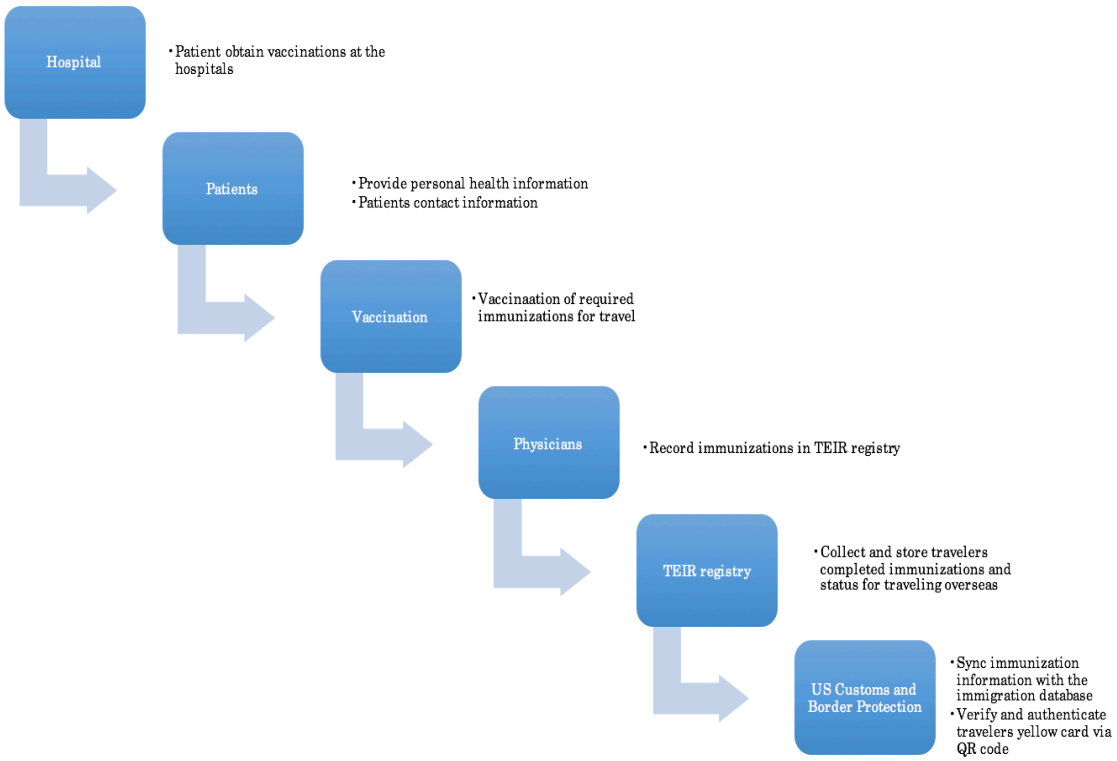
Use Case	CKD Tracking and Monitoring Information Flow
Actors/Stakeholders	Patient, physician, CKD registry (IR) staff, EHR system, labs, public health departments, CKD registry, providers
Flow of events	1. Patient arrives at the hospital for check up 2. Personnel at the reception collects patient contact information and insurance details to open or update a patient file 3. Patients sees physician 4. Physician orders for lab tests 5. Physician provides lab results for blood pressure, sugar levels, GFR, progression of disease, etc. 6. Physician makes notes of patient health info 7. Data entry personnel will record information to HER 8. Relevant health data is shared or transferred to the CKD registry
Entry conditions	EHR system
Exit conditions	CKD registry
Quality	Real time daily updates

2.1.2 iCure Hepatitis Registry Information Flow Diagram



The iCure Hepatitis registry information flow diagram above describes the components needed for the proposed solution to function properly. The information flow includes the patients who will participate in the survey and the IT developers and managers that will create and manage the flow of data within the database. The local area network (LAN), web applications, database repository (relational database management system/SQL server) and cloud-based computing comprises of the services and infrastructure needed for data collection and storage.

2.1.3 TEIR INFORMATION FLOW DIAGRAM



The TEIR registry information flow model above shows how the TEIR system is to electronically link a traveler's immunization record to their Passport/Visa information that can be scanned and validated at port of entry as opposed to the validation of paper immunization records via the current WHO "Yellow Card Booklet".

2.2 DEVELOPING HIGH-LEVEL REQUIREMENTS

The high-level requirements define documents and tracks the necessary information required to effectively define impact, scope, business, application, design, interdependencies, technical, functional and non-functional requirements. The Requirements Definition document is created during the Planning Phase of the project. Its intended audience is the project manager, project team, project sponsor, client/user, and any stakeholder whose input/approval into the requirements definitions process is needed.

Below is a brief description of the requirements stated for each registry:

- Scope: Outlines the project goals, features, activities, deliverables, timeline and cost of a project
- Business requirements: Defines project objectives, criteria, facts, assumptions, risks, constraints, business processes for project success
- Interdependencies: Describes the relationships between project tasks. A prior task must be completed to enable the succeeding task to be performed

- Security requirements: Outlines security policies and procedures to minimize potential risks and have the ability to respond to security incidents
- Design requirements: Defines the project components, capabilities and methods for development
- Technical requirements: Outline the technical issues such as reliability and and availability to be considered for a successful completion of project
- Data requirements: Outlines data standards and reporting for quality assurance
- Functional requirements define the system components function while the non-functional requirements describe the characteristics of the system.
- The business requirements identify business needs, stakeholders, requirements and others for better understanding to influence decisions that guides the implementation of the proposed project.
- The technical requirements outline the technical issues such as reliability and performance that has to be addressed to successfully build and utilize the registries.

2.2.1 CKD REGISTRY HIGH-LEVEL REQUIREMENTS

2.2.1.1 SCOPE

In compliance with HIPAA Privacy and Security Rules to protects patients' personal health information, the project documentation outlines the requirements, activities and deliverables to design and develop a CKD registry for tracking and monitoring the disease in the United States.

The intended purpose of the registry is to make CKD incidence and mortality data available nationally. New trends and patterns of the disease would also be identified to support clinical research. This data would provide timely and accurate information for federal, state and local health departments for program planning and evaluation.

2.2.1.2 BUSINESS REQUIREMENTS

2.2.1.2.1 The registry must support Healthy Peoples 2020 objectives for reducing new cases of CKD and its related complications disability, mortality and economic costs.

2.2.1.2.2 The solution must be interoperable across networks

2.2.1.2.3 The solution should be accessible and available at all times

2.2.1.2.4 The solution must be standardized and updated regularly based on business needs

2.2.1.2.5 The solution's privacy laws policies must be implemented to protect the patients' personal health information in compliance with HIPAA regulations

2.2.1.2.6 Puppet must be utilized to maintain and manage all cloud based components

2.2.1.2.7 Must create and design systems infrastructure for the monitoring and tracking the registry to accept HL7 messages of CKD records.

2.2.1.2.8 Must update the programming language to meet current standards that can adapt to future requirements, if deemed necessary.

2.2.1.2.9 Must request and receive patients' medical history periodically for forecasting and evaluation performance to improve analytics and data quality

2.2.1.2.10 Must use a system that expert developers can understand, provide maintenance and technical solutions to system errors when needed

2.2.1.2.11 Must create a new that can track multiple stages of CKD trends for race, ethnicity and age to increase recommended treatment

2.2.1.3 FUNCTIONAL REQUIREMENTS

2.2.1.3.1 Contact information (e.g., name, address, contact numbers, unique identifiers) of all stakeholders and organizations that interact with the registry must be captured and stored in the system.

2.2.1.3.2 The system must be able to track population and demographic data such

2.2.1.3.3 The system must be able to generate and send analytic reports to authorized persons

2.2.1.3.4 The system must be able to track adverse events related to the disease to improve on management of care

2.2.1.3.5 The system must be able to automatically implement best practices guidelines for data entry

2.2.1.3.6 The system must be able to track diagnosis and treatment information such as dialysis, drugs, dosage, etc.

2.2.1.3.7 The system must be able to track requests for official report of patient and immunization records generated, the purpose of request and to whom it was delivered to

2.2.1.3.8 The system must be able to track adverse events related to CKD to improve management of care

2.2.1.3.9 The system must be able to use HL& standards to support electronic exchange of health records

2.2.1.3.10 The system must be able to send alerts of increase incidence and prevalence of CKD in high burden areas for evaluation and forecasting

2.2.1.3.11 The system must be able to support canned and ad-hoc report

2.2.1.4 NON-FUNCTIONAL REQUIREMENTS

2.2.1.4.1 The system must have an easy to use interface.

2.2.1.4.2 Performing a task on the system must be understandable by the user

2.2.1.4.3 The system interface must support accessibility to all users including users with impaired vision, hearing or loss of motor skills.

2.2.1.4.4 The system must be scalable to support additional stakeholders.

2.2.1.4.5 The system must be flexible to support current and future standards

2.2.1.4.6 The system must be compatible to work on common operating systems for mobile devices and tablets for availability everywhere

2.2.1.4.7 Response time speed for screen refresh must be 2 seconds on the average

2.2.1.4.8 The system must include on-line help.

2.2.1.4.9 The help desk specialists must be trained to use the applications to support the system.

2.2.1.4.10 Users must be able to recover or reset lost passwords on the system

2.2.1.4.11 The system must include standards for encryption to protect the confidentiality of a patient's health information

2.2.1.4.12 The system must be operated on a secure hardware and software with back up storage that meets technology standards to protect personally identifiable information

2.2.1.4.13 Must provide login credentials and multi factor key authentication for authorized users at every access level

2.2.1.4.14 Must adhere to all written confidentiality and privacy to all written confidentiality and privacy practices applicable by law to protect patients' privacy whereby the system contains their health information

2.2.1.4.15 The system must support providers to achieve the goal for CKD in Healthy People 2020

2.2.2 iCURE REGISTRY HIGH –LEVEL REQUIREMENTS

2.2.2.1 SCOPE/IMPACT

2.2.2.1.1 Insert general guidelines for completing the survey questions

2.2.2.1.2 Provide the participant the ability to withhold making a decision regarding data access, export and/or use of otherwise confidential information until receiving greater specificity concerning the exact nature of the intended use, the identity of the individual seeking such expanded access rights, and his or her background may help to inform a meaningful choice between consenting to such data access or declining to grant such private access right.

2.2.2.1.3 Track and alert participants to complete and update survey questions as needed

2.2.2.2 DATA REQUIREMENTS

2.2.2.2.1 Create simple standard forms for data entry by staff and users to minimize data errors

2.2.2.2.2 Provide a unique identifier per patient to protect their privacy and security

2.2.2.2.3 Ensure the usability and functionality of registry to track data recorded by participants regularly.

2.2.2.2.4 Implement an iCure Hepatitis Registry that is easily accessible for data entry anywhere and at anytime.

2.2.2.3 SECURITY REQUIREMENTS

2.2.2.3.1 Implement policies for workforce management

2.2.2.4 TECHNICAL REQUIREMENTS

2.2.2.4.1 Develop standards that allows data to be shared between systems and networks

2.2.2.4.2 Ability to sync devices when offline

2.2.2.4.3 Create login access for authorized users

2.2.2.4.4 Require passwords for access

2.2.2.4.5 Enable two-factor authentication method

2.2.3 TEIR HIGH-LEVEL REQUIREMENTS

2.2.3.1 SCOPE OF WORK

The scope of work for the EIR project includes all initiation, planning, design, defining project goals and objectives, work breakdown structure, execution, testing and evaluation for acceptance of project. The EIR Alliance is responsible for all phases of the project to ensure proper implementation for optimal results. However, EIR Alliance will outsource the language translation services for the app as a subcontract. The subcontractor will follow WHO's translation and adaptation guidelines of English elements to achieve different language versions in targeted countries. Thus, ensuring that international travelers can access and utilize the app in their country dialect, if necessary.

2.2.3.2 PERIOD OF PERFORMANCE

The EIR project will commence September 4, 2017 and end September 7, 2018. The period for performance is 12 months. Based on EIR Alliance fixed price contract all phases of the project will be scheduled to be completed within project duration.

2.2.3.3 DESIGN REQUIREMENTS

2.2.3.3.1 Insert general guidelines for patient immunization records

2.2.3.3.2 Track certificate of immunization verifying prophylaxis, date of receipt, signature and status of clinician, vaccine manufacture and lot number, expiry date of certificate, and official stamp of administering center.

2.2.3.3.3 Update all vaccination administration records in a timely manner

2.2.3.3.4 Determine the immunization status of a patient

2.2.3.3.5 Link patient immunization records to the passport database system

2.2.3.3.6 Track and alert patients to complete or renew their yellow card requirements prior to travel

2.2.3.3.7 Create a proof of immunization QR code and validation keys for verification at international borders

2.2.3.4 APPLICATION REQUIREMENTS

2.2.3.4.1 Include WHO's immunization form to the app for data entry

2.2.3.4.2 Provide a unique identifier per patient to protect their privacy and security

2.2.3.4.3 Provide an interoperable mobile application or QR codes that can verify the validity of records shown by travelers

2.2.3.4.4 Ensure the usability and functionality of EIR to track immunization records for regularly

2.2.3.5 INTERDEPENDENCIES

2.2.3.5.1 Track immunization schedule including a list of vaccines completed and unfinished. This would require a linkage to immunization recommendation schedules that is updated regularly.

2.2.3.5.2 Generate automated monthly reports per jurisdiction to be disseminated among international borders. This would entail discrete elements (ministration type and date) to enable immediate logging in of immunizations.

2.2.3.6 TECHNICAL REQUIREMENTS & SPECIFICATIONS

2.2.3.6.1 Develop standards that allows data to be shared between systems and networks for interoperability

2.2.3.6.2 Store systems in a safe locked environment

2.2.3.6.3 Encrypt all data, as well ability to decrypt data when authorized

2.2.3.6.4 Create login access for authorized users

2.2.3.6.5 Require passwords for access

2.2.3.6.6 Enable two-factor authentication method

2.2.3.6.7 Monitor individual activity via audit logs

2.2.3.6.8 Must host via digital application

2.2.3.6.9 Must be accessible via tablets, computers and mobile devices

2.3 ANALYSIS OF TECHNOLOGY APPLICATIONS SELECTED

In deciding the best means to gather and compile all patient data, several emerging

technologies were considered for data collection, as well as, to support the storage of data in a centralized database registry. The new emerging technologies selected for the registries were based on an alternatives assessment via an evaluation matrix. The total score of each technology was calculated to indicate the best solution that aligned with the projects' strategic initiatives. To arrive at this decision, the emerging technologies were evaluated based on its functionality, interoperability, integration, data and data sources, productivity, efficiency, cost, infrastructure, improved health outcomes, privacy and security as well its limitations. Below are the selected tools and applications for the different projects.

Below is an example of an evaluation matrix assessment used to assess the appropriate tools and applications for deployment:

Criteria	Web-Based Application	EHR	Social Media Data Mining
Increase Productivity	5	4	3
Increase Efficiency	5	5	2
Decrease Costs	5	4	2
Improve health outcomes	5	5	3
Interoperability	5	4	3
Infrastructure - current	5	4	2
Information Security and Privacy	3	2	1
Meaningful Use	5	5	2
Business Architecture Strategic Alignment	5	5	3
Information Architecture Strategic Alignment	5	4	3
Technical Architecture Strategic Alignment	5	4	2
TOTAL SCORE	**53**	**46**	**26**

Applications can be rated on a scale of 1 – 5, with ratings as follows with ratings as follows:

- 0 – inadequate
- 1 – weak
- 2 – Satisfactory
- 3 – Good
- 4 – Excellent
- 5- Ideal

2.3.1 TECHNOLOGY APPLICATIONS SELECTED FOR CKD REGISTRY

The system will include a layout of multi-tier cloud application i.e. Amazon Cloud-based Services shown in a layered approach. End user requests from applications such as browsers, desktops and mobile applications via HTTP will be accepted and handled via the systems to be delivered to the appropriate database servers. For security purposes, firewalls will be implemented to protect the system from vulnerable threats.

Puppet will be employed as the appropriate technology application used to build the architecture and infrastructure of the CDK registry.[11] As public health continues to evolve, the use of puppet will help automate the data components and business requirements needed to be integrated, as well as manage cloud based components for successful implementation and performance of the registry. As an open source software management tool, puppet will support storage, datacenter automation, networking and cloud monitoring to manage the lifecycle of the system. The systems cloud based provider is Amazon Web services.

Puppet Capabilities for the Registry Includes:

- Ensures privacy and security by centrally managing shared accounts and passwords, as well as adhering to HIPAA compliance
- Ability to correlate relationships between logical, physical and virtual environments to quickly resolve technical issues.
- Puppet configuration manager ensures reliable deployment of infrastructure
- Scalable to add on larger deployments for the registry
- Puppet offers a highly useful user interface such as advanced reporting capabilities, easy monitoring via dashboards and unified installer to avoid writing repetitive commands
- Supports all major operating system: Linux, Windows, and MacOS for the registry operation
- The availability of the open source puppet module repository allows commands to be tested quickly, reused and shared for automated tasks to setup the different components of the registry
- Allows for integration with 3rd party and proprietary components to support automation, measurement and sharing of data, while enabling continuous integration
- Track and monitor data for analytics
- Describe the systems resources and its state using Puppet's declarative language or Ruby DSL (domain specific language). Puppet writes its own programming language or commands for system configuration.

2.3.2 TECHNOLOGY APPLICATIONS SELECTED FOR ICURE HEPATITIS REGISTRY

The web-based application has the features to host the registry platform tool which will be used in collecting all the required data. As the registry is participant led, choosing the web based application allows for participants to have access to the platform at anytime and everywhere, as long as Wi-Fi is available. Not only participants will have access to the platform via web application. Authorized stakeholders and project team will also have access to the platform. Consistent standardization is possible due to the fact that the data can be entered and retrieved from one centralized location eliminating the transfer of data across multiple system networks. On the web application access control policies can be implemented to ensure the highest form of privacy and security.

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[11] Deploying applications with Puppet Application Orchestration: workflow. (n.d.). Retrieved November 24, 2017, from https://puppet.com/docs/pe/2017.3/managing_applications/deploying_applications_workflow.html

In terms of privacy, the platform can build in consent decisions in favor of PrivacyLayer's more granular privacy preference settings and the inherently dynamic potential enabled by incorporating "Ask Me" as an alternative to "Allow" and "Deny".[12] One of the fundamental attributes of PEER platform are its dynamic consent tools that empower a participant to modify his or her settings as conditions, needs, or perspectives change over time, or to designate a wish to be expressly asked before specific rights will be considered.[12] The ability to withhold making a decision regarding data access, export and/or use of otherwise confidential information until receiving greater specificity concerning the exact nature of the intended use, the identity of the individual seeking such expanded access rights, and his or her background may help to inform a meaningful choice between consenting to such data access or declining to grant such private access right. The risk is minimal or less, given the protections within PEER and managed under PrivacyLayer.[12] The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life, with the exception of the release of sensitive health information.

The only anticipated inconvenience for participants is the time taken to complete surveys within PEER, especially as an online survey. Cost is low as tools deployed and operation are centralized.[12] Long term implementing a centralized database will reduce the cost of data collection and entry burden, and may produce a net decrement in public health and a net increase in long-term costs because evidence based treatments will be applied for cure.

2.3.3 TECHNOLOGY APPLICATIONS SELECTED FOR TEIR REGISTRY

The proposed IIS system will have a database system that allows travelers to self-register immunizations at minimum seven days prior to travel. The primary key for linking the databases and IIS system would use the unique passport card number which is similar to the social security number.

Immunization data can then be validated by a QR Code stamped by the healthcare facility administering the immunization. Immunization data will be extracted from the vertical and horizontal data from the patterns.[13] Travelers will be advised to self-register at least 14 days prior to travel. QR codes are an excellent method of transmitting international immunization data for international travelers. Today, first responders are using these codes to provide care for individuals in need of emergency care.[14]

From an international standpoint, ISO technical standards support interoperability which would be a great standard to implement to electronically read and link immunization data for international travelers.[15] Therefore, implementation of the IIS system and database will reduce timeliness and accuracy of data that is critical to strengthen timeliness, validity and accuracy of data in international countries.

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[12] Platform for Engaging Everyone Responsibly. (n.d.). Retrieved September 20, 2017, from http://www.geneticalliance.org/programs/biotrust/peer

[13] 2017 Wikipedia. QR Code. Retrieved June 21,2017 from https://en.wikipedia.org/wiki/QR_code

[14] 2012 Mobile Commerce News. ERMedStat Adopts QR codes as a way to better serve people in emergency situations. Retrieved June 21, 2017 from http://www.qrcodepress.com/ermedstat-adopts-qr-codes-as-a-way-to-better-serve-people-in-emergency-situations/857224/

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2.4 DEVELOPING A RISK MANAGEMENT AND MITIGATION PLAN FOR PROJECT DEVELOPMENT, IMPLEMENTATION AND MAINTENANCE

2.4.1 RISK PURPOSE

Risk management plan entails performing a risk analysis to develop a risk management log to identify the current risk status, Risk impact, Risk probability of occurrence, Risk map, Risk description, Project impact, Risk area, Risk trigger, Risk preferred response strategy, and appropriate response strategy of a system or project.

These processes help to identify, assess, respond to, monitor and report risks. Overall the risk management plan helps to prepare for potential risks, estimate impact and develop mitigation response for future use.

2.4.2 RISK PROCEDURE

The project team will work with stakeholders and contractors to to actively identify, analyze, monitor and manage risks throughout the project's lifespan. The risks will be identified as early as possible in each phase of registry implementation so as to minimize impact.

2.4.3 RISK IMPACT

The risk impact level is categorized as:

- High: Risk that has the potential to greatly impact project cost, project schedule or performance
- Medium: Risk that has the potential to slightly impact project project cost, project schedule or performance
- Low: Risk that has relatively little impact on cost, schedule or performance

2.4.4 RISK RESPONSE

For risk response, one of the following responses will be selected to address risk issues:

- Avoid: Eliminate the threat by eliminating the cause
- Mitigate: Identify ways to reduce the probability or the impact of the risk
- Accept Nothing will be done
- Transfer: Make another party responsible for the risk

2.4.5 RISK LOG

The tables below are examples of risks identified, potential impact and probability of risks on the projects and the project team mitigation response

2.4.5.1 CDK REGISTRY RISK PLAN

RISKS	PROBABILITY	POTENTIAL	MITIGATION
Security Breach	Medium	Medium	1. Add web application security such as firewall 2. Ensure VPN connectivity 3. Add a two factor authentication 4. Apply a secure application

RISKS	PROBABILITY	POTENTIAL	MITIGATION
			segmentation
Failure to transmit codes and messages to the appropriate networks	Medium	Medium	1. Perform frequent IT audits 2. Data encryption
Data Loss on Relational Database Management System	High	High	1. Create storage backup on AWS server
Data access and ownership	High	High	1. Create authorizations levels for access based on hierarchy 2. Use unique identifiers to de-identify personal identifiable information 3. End-to-end encryption of data
Configuration Issues	High	High	1. Ensure compatibility with other with applications by downloading and updating necessary plugins for functionality
Offline Server and Server Intrusion	Medium	Medium	1. Control network access via Amazon EC2 firewall settings 2. Isolate data in Virtual Private Clouds 3. Database encryption via Amazon S3 4. Create database backup creation via Amazon S3

2.4.5.2 iCURE HEPATITIS REGISTRY RISK PLAN

RISKS	PROBABILITY	POTENTIAL	MITIGATION
Security and Privacy Issues	Medium	Medium	1. Two-factor authentication 2.Data should be encrypted when at rest or in motion
Lack of Patient Participation	Medium	Medium	1. Helpline to assist patients 2. Access to computers at community health centers 3. Provide health counselors for stigmatized patients 4.Community outreach programs
Funding Issues	High	High	1. Identify organizations that have aligned goals to seek for sponsorship. 2. Continuous applications of grants.
Lack of Cooperation	High	High	1. Provide transparency of project details. 2. Engage all stakeholders from

RISKS	PROBABILITY	POTENTIAL	MITIGATION
			commencement of project. 3. Communicate information, outcomes and results at each phase of the projects
Low Data Usage	High	High	1.Promote the data registry by communicating to medical professionals, scientific communities 2. Publishing in medical journals and on the organization's social media platforms and website
Interoperability issues	Medium	Medium	Provide information on computer oftware updates for users Improve web functionality to be ompatible will all web browsers.
Outdated Data Elements	Low	Medium	1. Data elements should be reviewed and updated frequently to enhance data quality

2.4.5.3 TEIR REGISTRY RISK PLAN

RISKS	PROBABILITY	POTENTIAL	MITIGATION
Funding: Risk of project funding not meeting the estimated costs for unanticipated requirements	Medium	Medium	1. Engage with contracting office to review and adjust costs ensure all contracting documentation are available as per project schedule.
Risks of insufficient service level agreements exchange which could negatively impact user adoption.	Low	High	1. Service level agreement should be signed alongside of the contract
Defining and providing exchange requirements: Risks of lack of standards associated with implementation of Electronic Immunization Records (EIR). In public health, standards are imperative when it comes to interoperability. Each state needs to ensure national standards of data exchange.	Medium	High	1. Ensure that metadata, standards of exchange and data governance have been agreed upon guided by the interoperability team

RISKS	PROBABILITY	POTENTIAL	MITIGATION
Hardware re-use: Re-use of the available phone models for the application may present a varied compatibility issues	High	High	1. Include application customization cost for all the available hardware specifications or consider procuring new hardware meeting the required specifications
Degree and frequency of change of WHO immunization form source tool and paper immunization certification intended to inform application design	Low	High	1. Continue to collaborate with the immunization travel advisory boards and clinics to establish a change control board during and after implementation of travel EIR
Being able to meet each and every State's need in terms of data security for data in transit through various platforms for data transmission and storage	Medium	High	1. Identify unique security needs for data and include this in the information security plan with support from the information Federal Information security department.
Triage for multi user support; Lack of a coordinated triage for helpdesk user support	Low	Medium	1. Opt for automated user support to cut down on cost and response time.

3 PROJECT DELIVERABLES/ MILESTONES

Project deliverables are sets of asks that have to be met to accomplish a milestone within a project. Each registry has a unique deliverable developed aligned with its goals.

3.1 CKD REGISTRY DELIVERABLE

The table provides a detailed oultline for developing the CKD registry proposal for funding.

Proposal Deliverable	Timeline
Selection of public health use-case and description of the needs/intent.	Sept. 13
Peer Review	Sept. 20
Process and Methodology Chapter	Sept. 27
Exploration of new technology directions to determine best fit solutions and effectiveness	Oct. 8

Proposal Deliverable	Timeline
Draft write up for each critical component in the solution, data schema /structures as related to phases and processes	Oct. 18
Proposed analytics and visualization methods	Nov. 1
Draft Results/Deliverable Chapter	Nov. 12
Final Project	Nov. 17/18
Final Presentation	Nov. 17/18

3.2 iCure Hepatitis Registry Deliverable

The table presents below the major deliverables that the project's product (iCure Hepatitis Registry), service or result must meet in order for the project objectives to be satisfied.

Major Deliverable	Deliverable Description
Complete Institutional Review Board Approval (IRB)	Get IRB approval for human subjects research
Create PEER platform	Create peer platform to to host survey questions and data collected
Develop survey instrument	Develop data elements and questionnaires to be integrated in PEER platform
Recruit participants	Recruit patients to participate in the registry
Collect Data for sharing	Collect, analyze and translate data for research purposes

3.3 TEIR Registry Deliverable

The table below shows the deliverables that has to be met during project implementation

Deliverables	Timeline
Planning	9/4/17 - 9/5/17
Installation and Set-up	9/6/17 - 9/7/17
Data Analysis	9/8/17 - 9/11/17
Data Model	9/12/17 - 9/13/17
Staging to Dimensional Model	9/14/17 - 9/15/17
Installation and Set-up	9/18/17 - 9/29/17
Repository Development	10/2/17 - 12/22/17
Training	1/4/18 – 2/2/18
Project deployment, pilot testing, monitoring and evaluation, recommendations and upgrades completed	2/5/18 – 9/5/18
Project completed and ended	9/7/18

4 CONCLUSION

Documentation of the high level approach and its deliverables describes why resources should be spent on the proposed solution, how it would be accomplished, how the new capability will support the organization's mission and to develop a decision to advocate for the appropriate solution. The key deliverables outlined in the documents provides a high level strategic plan for a successful implementation of the proposed EAIS project.

APPENDIX A

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