Developing and Evaluating a Prototype Communicable Disease Web-based Clinical Reporting Tool

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Abstract

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Reporting reportable diseases within a timeframe is considered a cornerstone of any public health surveillance system. The purpose of surveillance is to empower decision makers to act by providing timely and accurate data. Conducting surveillance requires a cycle of collecting and reporting individual cases by solo healthcare providers or healthcare facilities to the local/public health department. Healthcare providers are familiar with the requirements to report reportable diseases, but compliance is a challenge.

Novel influenza has been a reportable disease since the 2007 legislation. Pandemic influenza is caused by novel influenza that is introduced into a population where some of this population has low immunity to the novel influenza, which increases the mortality rate. In the past 120 years, there have been six well-known international novel influenza spread. The deadliest novel influenza epidemic happened in 1918. That year the Spanish Influenza (H1N1) infected about 500 million people and caused the death of an estimated 20 – 50 million. Other novel infections similarly need to be reported and track. Two examples in the last five years are Middle East Respiratory virus and Zika virus.

I developed a Web-based reporting tool prototype to help healthcare providers in reporting communicable diseases that are required to be tracked such as novel influenza cases to authorities based on the state's official case report form. The overarching goal was to de-

velop and evaluate this prototype. My aims were: 1) Understanding the problems within the reportable diseases reporting process from healthcare providers to healthcare authorities, 2) Develop and test a prototype Web-based reporting tool to help to improve the process, and 3) Evaluating the prototype communicable Web-based clinical reporting tool.

The result of Aim 1 was identifying gaps between states' reporting guidelines and states' case report forms at individual state level and across states. The identified gaps helped to generate a collection of all the data fields used in novel influenza states' reporting guidelines and states' case report forms. The identified data fields were ranked based on the most used data fields across all the participated states. The ranked data fields across all the participated states helps healthcare providers and policymakers to get insight into other data fields required by other states to develop future guidelines and case report forms.

The result of Aim 2 was a tool that maps the required data from a database simulating Electronic Health Records (EHRs) with a different granularity of data to one or more state's official case report forms. The tool does this through query mapping and pre-population of as much data into a given state's case report form as the granularity of a given EHR data permit. This feature helps in reducing the manual data entry and increase the accuracy and completeness of submitted data to authorities. The tool converts the submitted case report form into Clinical Document Architecture (CDA) format, which is a recommended standard by Health Level Seven International (HL7).

For Aim 3, a combination of usability evaluation methods was implemented to evaluate the Web-based reporting tool from Aim 2. The main objectives of the implemented usability evaluation methods are to measure the usability of the tool. The usability refers to the quality of a user's experience when interacting with the tool and to measure the user's overall satisfaction. Aim 3 was designed and performed by the developer due to shortage in resources, which was a limitation. For better results, the evaluation testing process should be conducted by multiple evaluators and coders who have no connection to the project. The

Key finding from Aim 3 was that the prototype communicable disease Web-based clinical reporting tool is an acceptable tool by potential users. The evaluation study generated qualitative and quantitative results. Also, the results generated a list of usability problems for future development and considerations.

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DEDICATION

This dissertation is dedicated to the memory of my beloved late parents.

Chapter 1

INTRODUCTION

States and local health departments are responsible for diseases surveillance to protects the population's health. The primary goals of disease surveillance are to understand the existence of a disease to evaluate the current disease risks to plan an intervention. The process of diseases reporting is different from a state to another state. Each state has a list of reportable diseases and might vary over time. Each state has its laws and requirements for reporting diseases regulations.

Healthcare providers are generally aware of the requirements to report reportable diseases, but compliance is a challenge. Advances in technology can help in complying with the reporting requirement, and electronic reporting tools can help in increasing reporting rate and communicable disease early recognition [1]. Early recognition can help healthcare authorities to make decisions and intervene quickly to stop the spread of diseases to improve public health outcomes.

Reporting communicable diseases within a time-frame is considered a cornerstone of any public health surveillance system. Conducting surveillance requires a cycle of collecting and reporting individual cases by a solo healthcare provider or healthcare facility to a local public health department. The purpose of surveillance is to empower decision makers to act by providing timely and accurate data.

There are different methods to exchange data between healthcare providers and healthcare authorities, but there is no explicit standardized method and format. There is variation in conditions and diseases reporting lists among states, Also, the variation extends to the time frames for reporting, persons required to report and healthcare authority receiving reports. Also, there is variations in the case report forms and guidelines. There are many

reporting systems and tools that designed to help healthcare providers to report conditions or diseases and help healthcare authorities to collect data; Section 2.1 covers more details on the resources of data collections. The complexity and variability in disease reporting suggests there might be opportunities for improving upon the current state through the creation of new informatics tools. This dissertation will help to understand the required reporting data to be reported by following guidelines, collected data by case report forms, and the available data in EHRs. Identifying the gaps between what is required and what is available will help to emphasize the needs for common data elements to provide a basis for best practice. Identifying the gap between guidelines and case report forms will help healthcare authorities on a state level to update forms or guidelines when they do not match each other or update both. Also, this thesis will help healthcare authorities on a state level to compare guidelines and case report forms with other states.

One critical disease that requires informatics intervention is influenza; it is a significant public health concern worldwide. CDC estimated that influenza caused in between 9 – 49 million illness, and in between 140,000 – 96,000 hospitalizations and about 12,000–79,000 death annually since 2010 in the US alone [2]. It is vital to track influenza accurately and in a timely fashion given its high rate of communicability, mortality rates, and incidence.

Pandemic influenza is caused by new novel influenza that introduced into a population where some of this population has low immunity to novel influenza. In the past 120 years, there have been six well-known international novel influenza spread. In 1918, the Spanish Influenza (H1N1) infected about 500 million and caused an estimated death of 20 – 50 million. In 2009, the Swine Flu or H1N1 caused about 18,000 deaths [3]. Other pandemic viruses might cause higher risks as well. As an example of another pandemic virus, in 2016, the Zika virus caused about 62,000 suspected cases in Puerto Rico Department of health; 29,000 cases were confirmed, and about 1,100 confirmed cases were in pregnant women [4].

As mentioned earlier, the list of reportable conditions and diseases varies from one state to another based on the state's law. Furthermore, in most states, there is a list of workers required to report individual cases within a specific time-frame. Reporting methods are

varied from one state to another and have different reporting methods such as phone, fax, mail and electronic reporting. Some states require standard case report forms for specific diseases while other states use general case report forms to report a list of notifiable conditions and diseases. Some states report by phone only with no required case report form.

The individual states' list of notifiable conditions varies, but generally covers notifiable conditions and those causing mortality. The human infection with Novel Influenza A virus infections is designated as a notifiable disease at the national level since 2007 [5]. The Epidemiology and Prevention Branch in the Influenza Division at the Centers for Diseases Control and Prevention (CDC) collects, aggregates and analyzes the reported year-round influenza activity in the USA and produce a weekly influenza surveillance report [6]. The reported influenza activity is a collaborative effort between the CDC and its partners in the local health department, state public health departments, laboratories, healthcare providers and facilities, and vital statistics offices.

CDC collected the reported information from the five influenza surveillance programs such as "Surveillance for Novel Influenza A Viruses" and "Outpatient Illness Surveillance" to identify where and when the influenza activities started and the circulating influenza viruses' types [6]. It also helps in tracking the influenza-related illness and the geographic spread of influenza. The reported information helps to determine the speed of spread and helps to detect any changes in influenza viruses. The collected data helps healthcare providers to determine the high-risk population. All the collected information helps the healthcare authorities to plan influenza vaccine components and assist healthcare providers and public health authorities in planning interventions.

1.1 Motivation for Research

The primary motivation for this dissertation work is to help the healthcare field in improving the communicable or infectious diseases electronic reporting cycle from healthcare providers to healthcare authorities, see Figure 1.1 . The research motivation was based on the importance of early reporting, EHRs adaptions and following reporting standards format to

comply with CDC and HL7 recommendations, and Meaningful Use plan recommendations.

Reporting communicable diseases to public health authorities is a keystone for events management on local, national and international levels. It helps public health authorities to gather data to assist any public health event. Reporting the collected data on an event from healthcare providers to local/public health authorities and share the collected data to national healthcare authorities will benefit other healthcare authorities on a national and international level. Therefore, it is going to improve the reporting cycle on a larger scale.

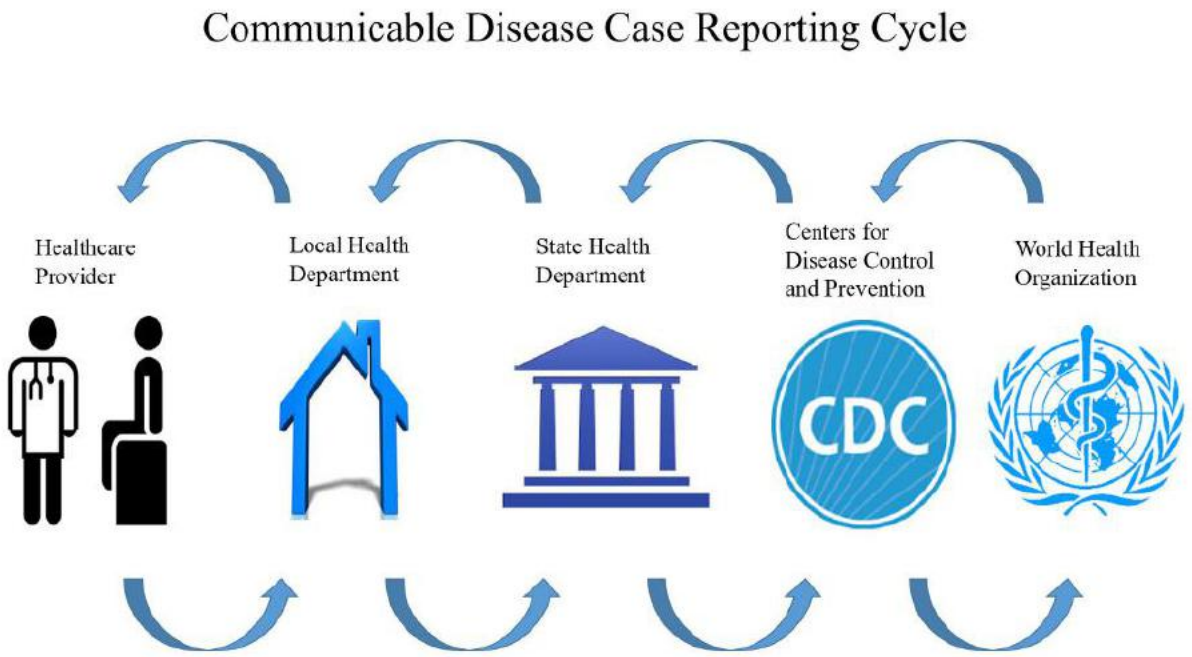


Figure 1.1: Communicable disease case report cycle [7].

Collecting and analyzing data on a novel influenza event and compare it to previously collected data could help public health authorities to predict potential changes and viruses' mutations, occurrence, distribution, trends, patterns, identify potentially exposed contacts, identify potential outbreaks, identify high-risk age groups, which will help public health authorities to plan actions. It also helps to compare data from one geographical location to

another and predict the speed and scope of virus spread.

Collecting and analyzing data on a novel influenza event helps public health authorities to design prevention, vaccination, treatment and resource distribution plans to prevent death, social distress, and economic losses. Collected and reported data help public health authorities to plan control strategies include surveillance, treatment, quarantine, isolation and contact tracing. It helps healthcare facilities to obtain consultation, laboratory support and on-site support in reportable diseases events.

Early reporting is a critical factor in an effective novel influenza management plan. Early reporting helps healthcare authorities to plan and act towards pandemics or communicable disease outbreaks. Collecting and analyzed early reported data help public health authorities to identify the sources and nature of the threats. It helps to identify actual infected cases and exposed contact to follow up, which helps to contain the spread of disease and ensure treatment. Early reporting helps public health authorities to provide information on the relative public health issues and pinpoints areas that need more actions.

Standardize the case reporting cycle is needed to ensure effective and timely reporting systems. Currently, there are different case report forms, reporting guidelines, reporting process, and protocols on how to collect and report data on communicable diseases to healthcare authorities. Standardization allows reporting systems to exchange meaningful information across healthcare systems and reduce the risk of losing the richness of information found within unstructured case reports. Data collection and sharing can help researches and stakeholders to identify needs and priorities to protect, maintain, and improve the health of individuals and communities.

Before the EHRs, healthcare providers used to collect a vast amount of patients' information. The patient's information included medical information (vitals, lab results, orders, medications, discharge summaries, and other information), as well as the medical information dictated to a patient health record and stored at the point of healthcare. Healthcare providers or patients used to share medical data through many methods such as manually copying records, via phone, sent by mail or fax. Coordination between healthcare providers

is slow, costly and healthcare outcomes are inconsistent. On many events, duplicates of lab work and imaging occur frequently.

The Federal Health IT Strategic Plan focuses on increasing the use and adoption of Electronic Health Records (EHRs) to enable the exchange of health data among providers and to the authorities. The expansion and use of Electronic Health Records is a critical goal established under the Health Information Technology for Economic and Clinical Health Act (HITECH ACT) with a vision to improve the performance of healthcare system.

The adoption of Electronic Health Records (EHR) in the healthcare organizations and clinics increased throughout the U.S. According to a latest updated published on 2019 by the Office of the National Coordinator for Health Information Technology, 86% of U.S. office-based physicians had adopted a type of EHR system and 80% had adopted a certified EHR system by the end of 2017 [8]. An EHR type has two meanings; the first meaning is that an EHR system is capable of more than the billing system. The second meaning of an EHR type is a basic EHR, which means that the EHR system is either all or partially electronic by having a specific set of functions [8].

The adoption of Electronic Health Record (EHR) systems and Electronic reporting tools to report data from healthcare providers to healthcare authorities can narrow the gaps in infectious disease surveillance and detection [1, 9] Electronic reporting tools have already made improvements in speeding the process of reporting data to healthcare authorities [10].

Simplifying communicable or infectious diseases reporting process is needed. Reporting diseases should be easy, straightforward, and trouble-free as much as possible for healthcare providers. Accessing data from EHR to fill case report forms and send it to healthcare authorities should be painless for those who are required to report diseases.

The primary objective of this dissertation is to help healthcare providers to improve case reporting process from the healthcare providers to local/public health authorities. Based on the following factors, I developed and evaluated a prototype Web-based clinical reporting tool: 1) The importance of overcoming the challenges of reporting communicable or infectious diseases from healthcare providers to healthcare authorities, 2) The broad adoption of

certified EHRs, 3) The promises of the electronic reporting , and 4) The recommendations to standardize the format of the submitted reported cases, which is the CDA. The dissertation aims are: 1) Understanding the problems of reporting reportable diseases cycle from healthcare providers end to healthcare authorities end, 2) Develop and test a Web-based reporting tool to help to improve the reporting cycle, and 3) Evaluate the Web-based reporting tool.

1.2 Solution Approach

The developed prototype communicable disease Web-based clinical reporting tool l is designed to ease the process of reporting diseases by helping providers to pre-populate the required data through query mapping form a database simulating EHRs into an official state's case report. Also, the tool allows providers to view and enter more data if needed and submit the case report forms in a standardized electronic format, CDA, to a specific healthcare authority.

The developed prototype communicable disease Web-based clinical reporting tool was developed by using HTML, JavaScript, PHP, Apache web server, and MySQL. The Web-based reporting tool used open source tools/software in developing the tool. The open source languages and technologies are free of cost and have a great online community where members share tips and discuss problems.

1.3 Dissertation Contributions

The result of Aim 1 was identifying gaps between states' reporting guidelines and states' case report forms on the state's level and among states. The identified gaps helped to generate a poll of all the data fields used in the novel influenza states' reporting guidelines and states' case report forms. The identified data fields were ranked based on the most used data fields among all the participated states. The identified most used data fields among all participated states helps healthcare providers and policymakers to view other data fields required by other states to helps in future guidelines and case report forms updates.

The result of Aim 2 was a tool that maps the required data from a database simulating

EHRs with a different granularity of data to one or more state's official case report forms. The tool does this through query mapping and pre-population of as much data into a given state's case report form as the granularity of a given EHRs data permit. This feature helps in reducing the manual data entry and increase the accuracy and completeness of submitted data to authorities. The tool converts the submitted case report form into Clinical Document Architecture (CDA) format, which is a recommended standard by HL7.

For Aim 3, a combination of usability evaluation methods was implemented to evaluate the Web-based reporting tool from Aim 2. The main objectives of the implemented usability evaluation methods are to measure the usability of the tool. The usability refers to the quality of a user's experience when interacting with the tool and to measure the user's overall satisfaction. The results of the usability evaluation study showed that the prototype communicable disease Web-based clinical reporting tool is an acceptable tool by potential users. The evaluation tool generated qualitative and quantitative results. Also, the results generated a list of usability problems for future development and considerations.

1.4 Dissertation Organization

This dissertation consists of four main chapters, and this section briefly describes the content of each chapter. Chapter 2 introduces the background literature and introduces the novel influenza disease then identifies communicable or infectious diseases reporting cycle from the healthcare provider to healthcare authorities. The Chapter identifies the benefits and challenges in reporting communicable or infectious diseases. Also, the chapter shows the current methods of collecting and reporting novel influenza cases. The chapter introduces on-going big projects showing the future of reporting communicable of infectious diseases. Finally, the chapter introduces the Clinical Document Architecture (CDA) and the Fast Health Interoperability (FHIR) standards.

Chapter 3 shows the process of contacting all the 50 states to participate in this study. Also, I showed the process of including states in this study based on inclusion and exclusion criteria. The chapter showed the steps of coding and analyzing the included documents in

this study to perform the finding and identify the gaps between a state official reporting guideline and a state official case reporting form. Then the chapter showed the gaps between all the included states in this study.

Chapter 4 showed the steps in developing a prototype communicable diseases Web-based clinical reporting tool. The chapter introduced the tools interface and the steps to report a case to healthcare authorities. The chapter explained on a high-level how to pre-populate the required data through query mapping form a database simulating EHRs into an official states case report.

Chapter 5 introduces the combination of evaluation usability methods in performing the tool's usability testing. The chapter introduced the Think-Aloud method and its popularity in the usability field and listed the benefits and challenging in applying the Think-Aloud method. Also, introduced the applied surveys such as After Questionnaire Survey (ASQ) and System Usability Questionnaire (SUS) and the purposes of applying the surveys. Also, the chapter showed the qualitative and quantitative results of the applied combination of usability methods. Finally, the chapter introduced the usability problems' severity levels, types and sources.

Finally, Chapter 6 describes the conclusion chapter. In this chapter, I will summarize the key findings from the dissertation study and list the challenges and limitations with this dissertation. Also, the chapter will point and suggest various future work directions and opportunities to improve the dissertation work and to build on this dissertation work.

Chapter 2

LITERATURE REVIEW AND SIGNIFICANCE IN RELATED WORK

In this chapter, section 2.1 covers an overview of the Novel Influenza, section 2.2 covers reporting communicable disease and types of reporting documentations, and section 2.3 covers the surveillance system quality indicators. Section 2.4 describes the Meaningful Use Program. Sections 2.5, 2.6, and 2.7 describes the Public Health Community Platform (PHCP), Digital Bridge: Electronic Case Reporting, and Reportable Conditions Knowledge Management System (RKMS) projects respectively. Sections 2.5–2.7 provide an overview of ongoing projects and collaborations between stakeholders to develop systems and tools to support medical data exchange and reporting cases from healthcare providers to public health agencies. The work of this dissertation aligns with these ongoing projects and collaborations projects where focusing on data reporting from healthcare providers to healthcare authorities such as local or state health departments.

2.1 Novel Influenza

Influenza is a common viral infection characterized by abrupt onset of fever, chills, myalgias and associated symptoms such as a cough, sore throat, and rhinitis. Influenza has three main types: A, B, and C. Influenza types A and B are most responsible for human disease [9]. Influenza type A is divided into subtypes based on two proteins hemagglutinin (H), which has 18 types and the neuraminidase (N), which has 11 types. Influenza A has many strains with the H1N1 and H3N2 being the most prevalent strains [11].

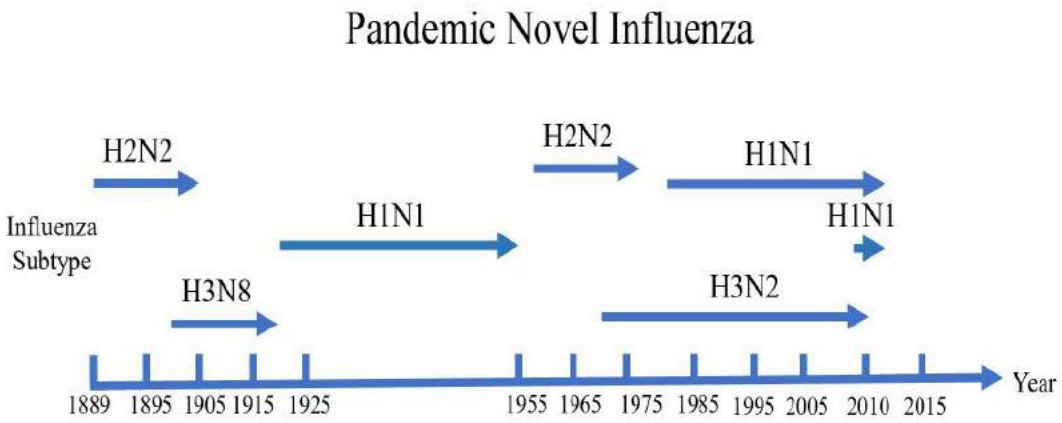
Influenza type B viruses are not divided into subtypes but rather broken into lineages and strains. Currently, there are two lineages: B/Yamagata and B/Victoria [11]. Influenza

type C is associated with a sporadic milder form of the illness mainly in children [9]. The CDC follows the World Health Organization (WHO) naming convention of influenza viruses, which include the antigenic type, host of origin, geographic origin, strain number, year of isolation and the hemagglutinin and neuraminidase description for Influenza type-A [11].

Both influenza types A and B can undergo either antigenic drifts (slow change) or antigenic shift (sudden, major change) [12]. Antigenic drifts account for the yearly seasonal epidemics where there is some protection from previous infections or vaccinations. Antigenic shifts typically involve re-assortments of antigens between human and nonhuman influenza viruses. This can lead to pandemics or global infections where individuals are immune naive and get more severe disease [9]. Novel Influenza virus is an influenza type A virus that is different from subtypes that spread in human. An Example is H7N9 and H5N1 viruses. When influenza viruses spread from pigs (swine) or birds (avian) to cause infections in humans are called variant influenza viruses such as H3N2v [12].

Over the last 100 years, four major influenza pandemics have occurred. The 1918-1919 pandemic caused an estimated 50 million deaths worldwide. The most recent pandemic occurred in 2009-2010 with the H1N1 or swine flu where around 18,000 deaths occurred. On a global scale, epidemics are caused by different Novel Influenza viruses which human population have no pre-existing immunity, see Figure 2.1 for more history on the influenza pandemics [14, 15]. The pandemics can have direct and indirect impacts on any healthcare system or global level. The direct impacts could be at the level of individuals or population and healthcare system while the indirect impacts could be at the level of economic loses.

Influenza surveillance is a combination of many surveillance systems working together rather than a single surveillance system; each system is responsible for reporting specific data and performing certain functions. The CDC relies on eight data sources from five data categories to collect data on influenza activity and seasonality in the USA, Table 2.1 has for a list of the data categories, the 5 data categories and the 8 data sources for influenza case reporting. The U.S. Influenza Virological Surveillance system is part of the Global Influenza Virological.



- 1899 Russian Influenza- H2N2 (Estimated 1 million death cases)
- 1900 Old Hong Kong Influenza- H3N8 (Estimated 1 million death cases)
- 1918 Spanish Influenza- H1N1 (Estimated death 20-50 million cases)
- 1957 Asian Influenza- H2N2 (Estimated 1 million death cases)
- 1968 Hong Kong Influenza- H3N2 (Estimated 1 million death cases)
- 2009 Pandemic Influenza H1N1 (Estimated death 18,000 cases)

Figure 2.1: Pandemic Influenza History [13].

Table 2.1: Data Categories and Sources of Influenza Surveillance

Data Categories	**Data Sources**
Virological Surveillance [16]	• U.S. World Health Organization (WHO) Collaborating Laboratories • National Respiratory and Enteric Virus Surveillance System (NREVSS) [17] • Human Infection with Novel Influenza A Viruses Surveillance [18].
Outpatient Illness Surveillance	• U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet)[19] • ILI Activity Indicator Map [*]
Mortality Surveillance	• 122 Cities Mortality Reporting System [20] • National Center for Health Statistics (NCHS) mortality surveillance data [18]. • Influenza-associated Pediatric Mortality Surveillance [18].
Hospitalizations Surveillance	Influenza Hospitalization Network (FluSurv-NET) [21]
Summary of the Geographic Spread of Influenza [18]	State and Territorial Epidemiologist's Reports [18].

[*] It has a network of over 3500 enrolled outpatient healthcare proviers.This activity indicator map uses the proportion of outpatient visits to healthcare providers for influenza like illness to measure the ILI activity level within and across states

Surveillance system where there is approximately a network of 140 U.S. WHO collaborating laboratories and National Respiratory and Enteric Virus Surveillance System (NREVSS) report to the U.S. Centers for Diseases Control and Prevention (CDC) [16]. The public health departments and hospital laboratories report the total number of tested respiratory specimens and the positive number of the tested specimens for influenza types A and B to the Virological surveillance system on weekly basses.

National Respiratory and Enteric Virus Surveillance System (NREVSS) is a collaboration of 50 laboratory systems in the U.S. The system goal is to monitor the time and the geographic locations at the regional and state levels for influenza patterns associated with the detection of Respiratory Syncytial Virus (RSV), human Para Influenza viruses (HPIV), respiratory and enteric adenoviruses and rotavirus [17]. In this surveillance system (NREVSS), participants voluntarily report weekly to CDC the total number of tests performed to detect influenza and the number of confirmed cases. Also, they report the specimen, date of specimen collection and locations.The CDC compiles and analyzes data from the 140 U.S. WHO collaborating laboratories and National Respiratory and Enteric Virus Surveillance System (NREVSS) to produce a weekly summary of national influenza activity and report to the WHO as well, see Figure 2.2.

The Human Infection with Novel Influenza A Viruses Surveillance data source collects information on the influenza A viruses' such as types and subtypes of viruses. The goal of the system is to track the total number of tested respiratory specimens in U.S. laboratories and report the number of the positive tested specimens for influenza type A or B [18].

122 Cities Mortality Reporting System is a national system. The goal of this system is to report the total number of death certificates from the Vital Statistic Offices in the 122 cities in the U.S. and the total number of death cases caused by influenza or pneumonia. This system is used to report the total number of death certificates where pneumonia or influenza is reported as the underlying or contributing cause of death, along with details such as age in order to compare it with baseline and epidemic threshold value [20].

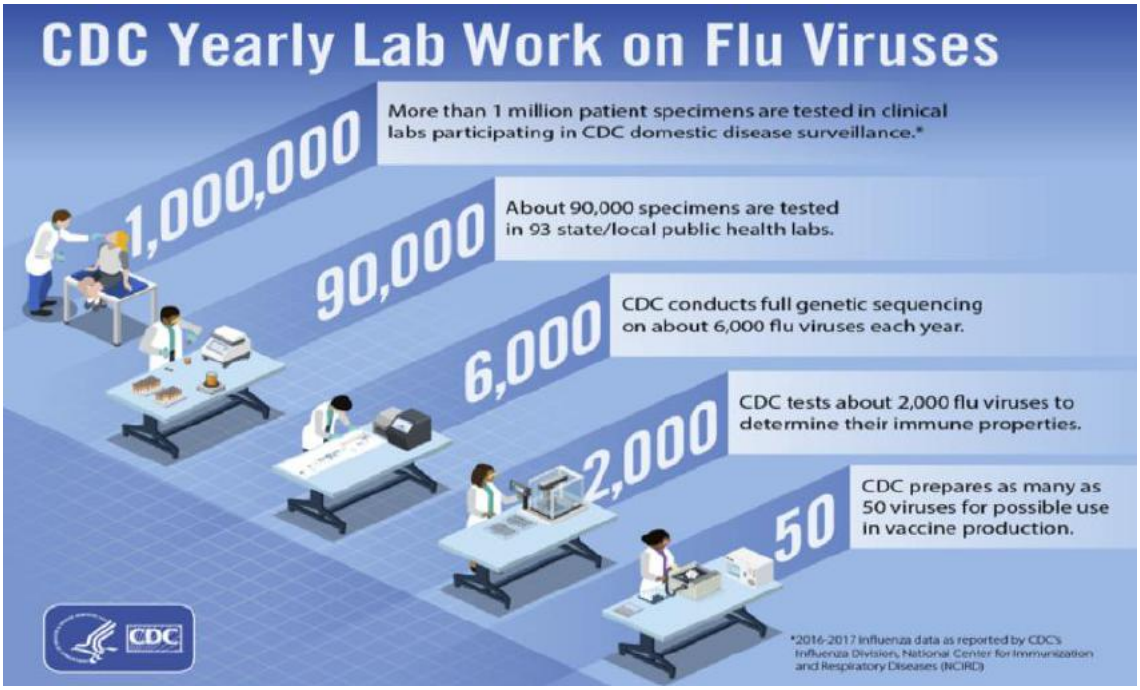


Figure 2.2: CDC Yearly Lab Work on Flu Viruses Infographic [22].

2.2 Reporting Communicable Diseases and Types of Reporting Documentations

There are many terms used in literature such as procedures, protocols, guidelines, standards, policy, and pathways to assist healthcare providers with decision making in patient care or management plan. These terms have differences and used to describe steps or plan to follow in handling and to report communicable diseases such as novel influenza. In the next few paragraphs I define these terms and delineate the differences. Beside the several types of documents, there are active and passive surveillance in reporting networks for regular diseases reporting.

Procedures are a sequence of detailed steps or a process map to be followed to achieve a result in healthcare delivery. The procedures could be performed to conduct diagnosis, treatment, management, surgery, and other healthcare services [23]. Procedures are step

by step instructions to be performed in a specific situation to accomplish an end. Practice procedure action could, for example, describe step by step how and for how long surgeons would wash their hands before walking to surgeries.

Protocols are detailed written instructions and statements to guide healthcare providers to deliver care to patients. They are problem oriented to provide an outline of a specific and logical sequence of steps to follow in certain circumstances. Protocols describe healthcare problems, provide guidance on when, how, what actions needs to be taken and by whom the care will be given. Importantly to mention that protocol could be considered as a set of procedures where they do not describe how to perform procedures, they only describe the instructions on how to do a task. Protocols and guidelines are developed to ensure clarity and consistency of healthcare practices to improve healthcare outcomes and quality [24, 25].

Guidelines are derived statements from research and scientific evidence-based to assist healthcare providers in delivering care for patients in specific cases to reduce variation in practices. Guidelines are intended to provide healthcare workers with support decision-making process to improve quality of clinical decision especially for healthcare providers who are uncertain about how to proceed or how to treat patients with certain circumstances [26–29]. Guidelines are not mandatory to follow, there are considered as best practices and have different forms such as general statements, recommendations, and instructions. Practice guideline action could result for example outline blood testing practice for patients who are taking blood thinners substances but does not describe how to perform the procedure.

Standards are written statements for healthcare providers to describe rules, steps, diagnostic and treatment to follow for a patient or illness under certain circumstances. Standards describe the process or rules to be used to support healthcare organization policy. Standards are designed to ensure that healthcare providers compliance with clinical guidelines when caring for patients [30, 31]]. An example of a treatment standard is to treat lung cancer patients with chemotherapy. One of the famous standard examples is to have 6-8 alpha-numeric characters as a password for an email account.

Policy is long-term, high-level managerial principles or statements designed to reach spe-

cific vision, objectives, and goals within healthcare organizations. Policies require mandatory compliance and applicable to all employees to ensure consistency of healthcare delivery [32]. Policy refers to decisions, plans, actions should be followed to achieve vision, objectives, and goals of a health organization. Policies are everywhere where you find dress code or internet use policy for a healthcare organization or public health policies such as tobacco control policy and vaccination policy. To see a figure describes the differences between procedures, protocols, guidelines, standards and policies, Figure 2.3.

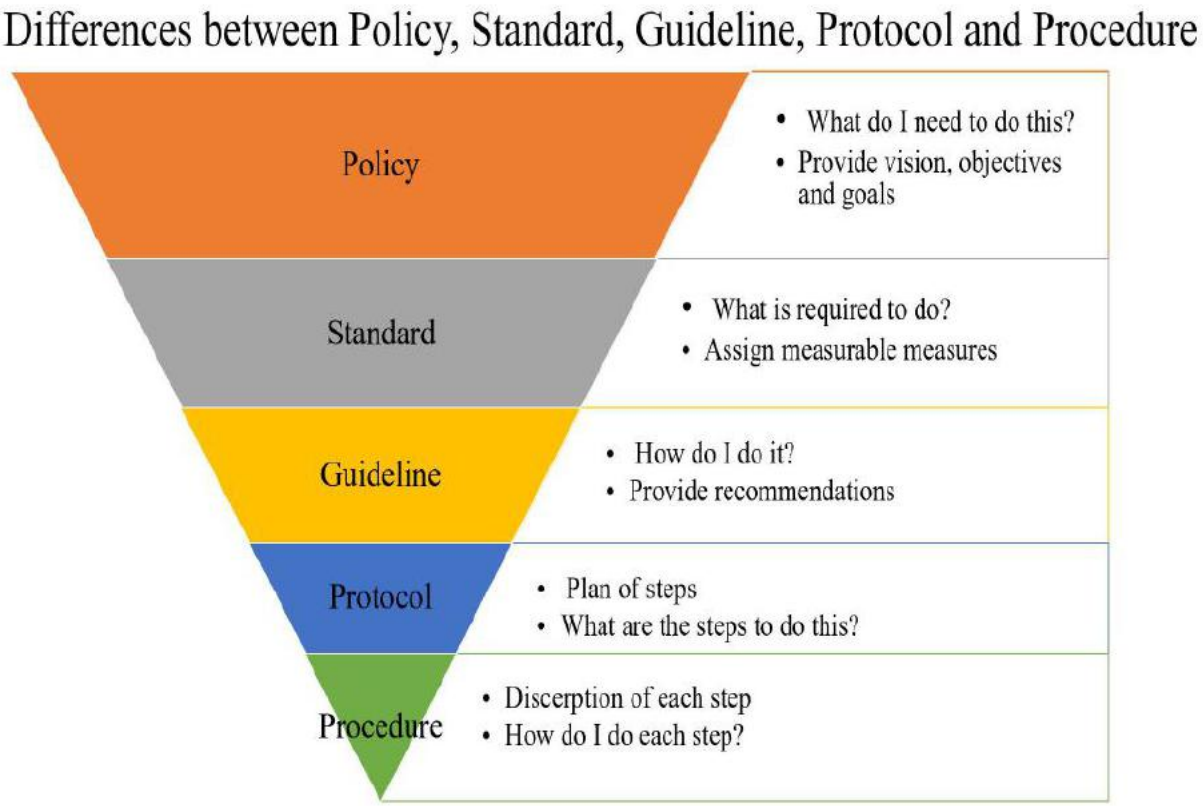


Figure 2.3: Differences between Policy, Standard, Guideline, Protocol and Procedure.

Pathways are multidisciplinary care plan to support the implementation of guidelines and protocols where multi teams such as clinical management (physicians, nurses and pa-

tient care technicians), non-clinical management (Medical transcriptionist, biomedical engineers, medical care workers) and financial management coordinate to improve efficiency of resources usage and finish work within time frames to improve healthcare quality and outcomes [33, 34]. Pathways are designed to provide detailed guidelines for each step during patient care management within a time frame to improve communication between multi teams, improve clinical outcomes by providing explicit standards of care, optimize usage and management of resources, which will lead to best practices. Pathways are different from guidelines and protocols by focusing on how to improve coordination of managed care plan and like guidelines and protocols by focusing on how to improve healthcare outcomes [34, 35].

Benefits of applying procedures, protocols, guidelines, standards, policy, and pathways are to facilitate the adherence with standards practice, compliance with regulations and requirements, reduce practice differences, standardize healthcare practice and workflow, ensure high-quality healthcare outcomes and adopt golden standards for best practices.

Reporting communicable diseases within a timeframe is considered a cornerstone of any public health surveillance system. There are active and passive surveillance in reporting networks for regular diseases reporting. Conducting active surveillance requires a cycle of collecting and reporting individual cases by a solo healthcare provider or healthcare facility to the local or state public health departments. Even though the active surveillance is an expensive and labor intensive process, it empowers decision makers to act by providing timely and accurate data. On the hand, passive surveillance provides a cheaper and easier alternative because it requires fewer resources than active surveillance. Passive surveillance relies on the cooperation of healthcare providers and facilities to report the occurrence of diseases. It involves the regular collection and reporting surveillance data to be sent on regular basis such a week or a month. Section 2.3 covers active surveillance quality indicators.

2.2.1 Benefits and Challenges of Reporting Novel Influenza Cases

The benefits of reporting novel influenza cases have been mentioned earlier in section 1.1 where I talked about the motivation for this research and mentioned the benefits of early

reporting. Reporting novel influenza cases helps healthcare authorities to plan and apply interventions plans in events of novel influenza spreads. Also, it helps healthcare authorities to understand the threat of the spread of the novel influenza and identify exposed contacts, potential infected cases and spread in geographic locations, see Figure 2.4 for more benefits on novel influenza early reporting.

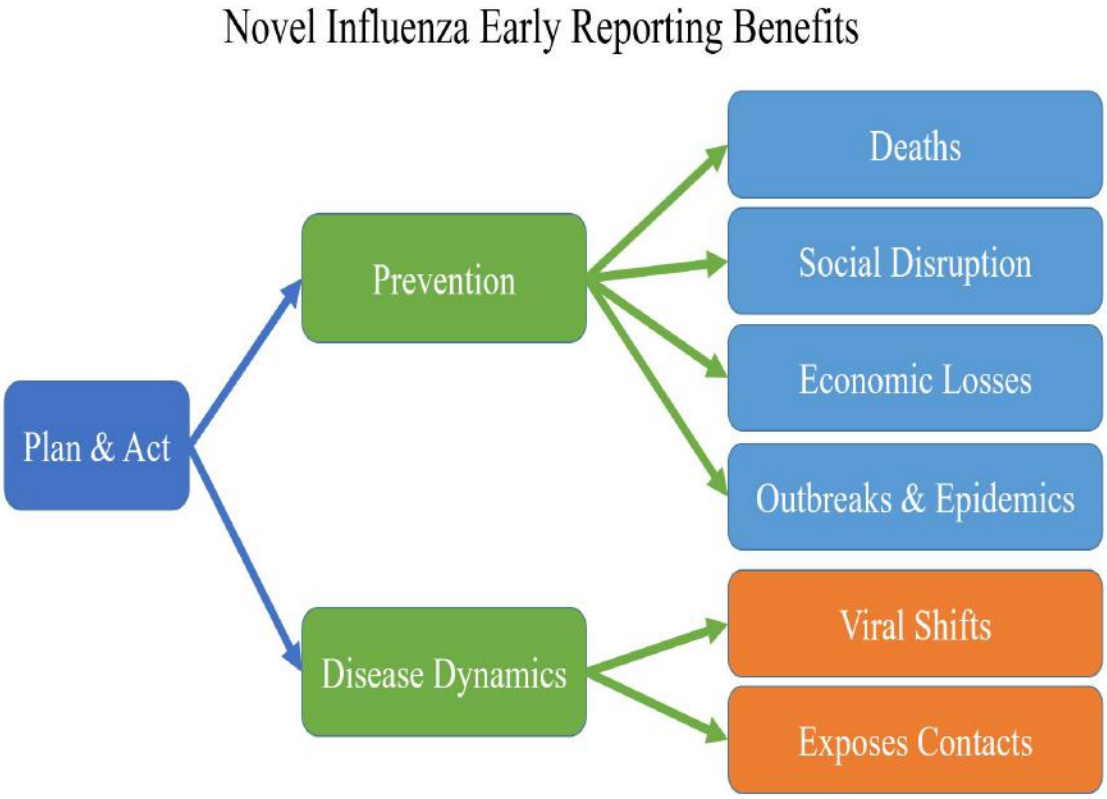


Figure 2.4: Benefits of novel influenza early reporting.

Similarly to communicable diseases, the novel influenza reporting process faces challenges on many levels starting from healthcare providers level to the reporting process level along to the recipient level. Some of the common communicable diseases and novel influenza challenges in the healthcare providers level are the shortage of human resources for reporting,

lack of reporting training, lack of staff awareness of reporting importance and rules, and reporting in a timely manner [8, 9, 12, 36], see Table 2.2 for more details.

Some of the common communicable diseases and novel influenza challenges in the reporting process level are lack of standards or reporting guidelines, diseases reporting systems inflexibility with EHRs, informal methods of reporting, different methods of reporting, not reporting in a timely manner, missing data on the case report forms, security issues with electronic reporting systems, technical challenges with electronic reporting systems and high-cost of novel influenza reporting training [8, 9, 12, 36], see Table 2.2 for more details.

Some of the common communicable diseases and novel influenza challenges in the report recipient level are the shortage of human resources, limited budget for disease reporting systems, sending feedback and updates to healthcare provider level, lack of electronic access methods to EHRs on healthcare provider level [8, 9, 12, 36] , see Table 2.2 for more details.

Table 2.2: List of challenges on healthcare providers, process and recipient levels.

Level of Reporting	**Challenges**
Healthcare Provider Level	• Shortage in human resources • Lack of reporting training • Lack of technical skills • Lack of financial incentives for reporting • Lack of staff awareness of reporting importance • Uncertainty of staff awareness of reporting rules • Lack of staff awareness of reporting process • Lack of staff awareness with different time frames for reporting specific conditions • Lack of staff clarity about reporting requirements • Lack of reporting standards or reporting methods • Difficulties incorporating case reporting during high workload for reporters • Difficulties of locating the required case reporting form at the healthcare facility • Overlap of reporting duties among different healthcare providers and facilities • Fear to violate patients' privacy • Delays in getting all the required data in a case report form

Reporting Process Level	• Lack of unified reporting standards • Lack of unified reporting methods • Lack of unified case reporting forms • Lack of reporting cases to authorities in a timely manner • Lack of reporting training • High-cost of reporting training • Diseases reporting systems inflexibility with EHRs • Missing submitted data to authorities due to communication difficulties with labs or other facilities • Missing or incomplete submitted documents or forms • Security issues with electronic reporting systems

Reporting Recipient Level	• Outdated reporting systems infrastructures • Shortage in human resources • Limited budget for disease reporting systems • Difficulties to obtain data from healthcare providers level • Difficulties to obtain data from healthcare providers level in a timely manner • Difficulties to obtain data from patients or contacts • Difficulties to communicate feedback and updates to healthcare providers level • Lack of electronic access methods to EHRs on healthcare providers level • Difficulties to obtain data from private healthcare providers level • Duplicate reported cases • Incomplete required data

2.3 Surveillance Systems Quality Indicators: Completeness and Timeliness

There are many quality factors for communicable diseases surveillance systems; reporting timeliness and completeness are keys to public health surveillance systems. These quality factors along with other factors, see Figure 2.5, must be a continuous process to maintain and improve any public health surveillance system.

States and local health departments in the U.S. have shifted their communicable and chronic surveillance systems to electronic laboratory reporting, which reflected in improvements in completeness and timeliness [37] . However, the required clinical data collection process is still heavily dependent on the surveillance tools such as telephone and fax to re-

port cases from healthcare providers to healthcare authorities and manual review process by surveillance staff [37] . The adoption of Electronic Health Records (EHRs) provides opportunities to improve the communicable diseases reporting process.

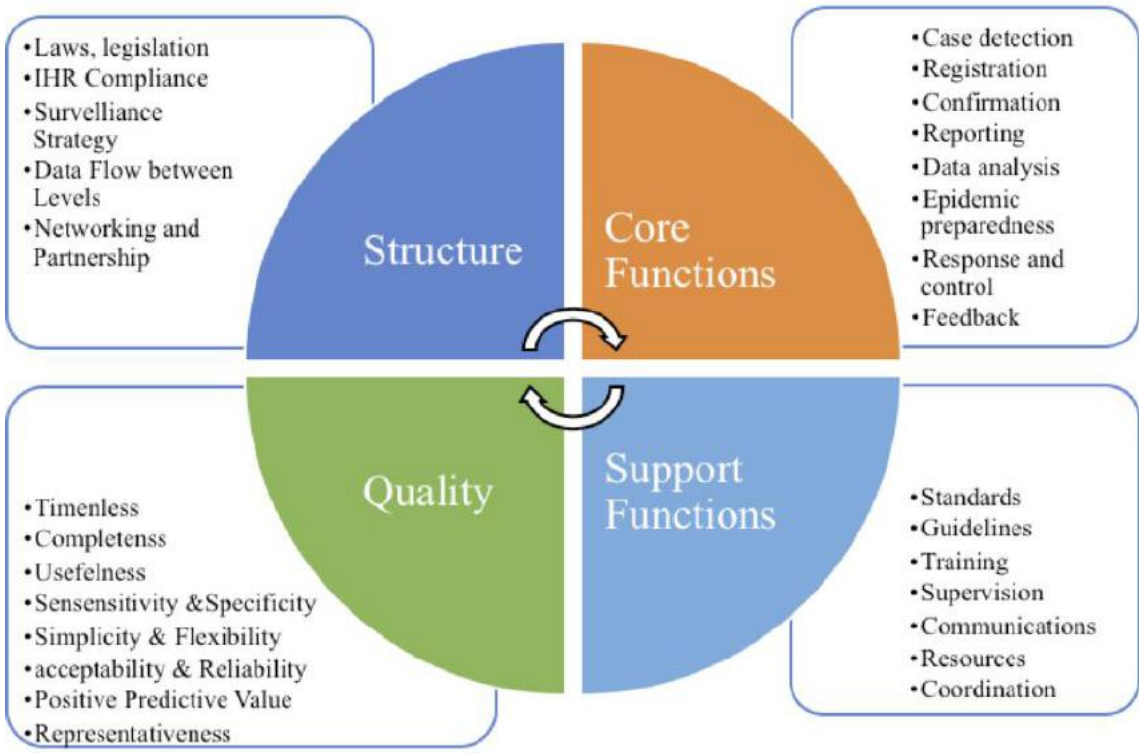


Figure 2.5: Theoretical framework of communicable diseases surveillance and response systems [38] .

Timeliness reflects the time between the disease symptoms onset until the reporting date to surveillance systems. Timeliness could be broken into stages based on diseases, but most likely to be divided from disease symptoms onset time until diagnosis time and from diagnosis time until reporting time [38, 39]. Timeliness reporting requirements might differ from disease to another; it might be required to be reported immediately or up to a week from diagnosis. Timeliness is a critical component to prevent secondary cases or outbreak infection. In addition, reporting timeliness might differ by condition, reporting protocol and

surveillance system [40].

A study has been published in 2017 to compare completeness and timeliness of notifiable disease reporting in Marion County Public Health Department in Indianapolis, Indiana. They gathered reports on seven diseases (highly, moderately and less prevalent diseases) over a period ranged from 3 months to 2 years based on the disease [41]. There were different reporting sources such as providers reports, faxed laboratory reports and electronic laboratory reports where timeliness median delay ranged from 1 to 5 days and this time was from the time of diagnosis to time of reporting [41].

In a literature review article published on communicable diseases surveillance in developed and developing countries, timeliness quality indicator did not function well in the USA [42]. It shows median national reporting delay for communicable diseases ranged from 12 to 40 days and less than 40% of cases were reported during one incubation period. In the same study, electronic reporting enhanced the number of reported cases and timeliness, where electronic reporting is faster than paper reporting [42]. A different study published on the timeliness of national diseases surveillance system in Korea based on six diseases, it shows a delay in reporting ranged from 6 to 20 days [43] . Another study published on the timeliness of reporting six infectious diseases in the Netherlands, it shows delays in reporting ranged from 12 to 22 days [44] .

Not all the included states in this study, 28 states, requires reporting the symptoms onset date in their case report forms, , which decreases the data quality reporting. For novel influenza cases, reporting the symptoms onset date helps to determine possible contacts during incubation periods. This will help healthcare agencies to plan prevention and control measurement plans. There are many studies compared paper- based reporting timeliness to electronic-based reporting timeliness in surveillance systems, but not many from the electronic reporting system to another [43, 44] .

Completeness is an important quality indicator for any surveillance system, and it helps healthcare providers to get a more accurate interpretation of surveillance information for disease control plan. The study of comparing completeness and timeliness of notifiable

dis- ease reporting in Marion County Public Health Department in Indianapolis, Indiana showed completeness ranged from 45% to 100% with an average ranged from 72% to 77%. Completeness rates show an area of improvement of the clinical workflow associated with public health reporting or reporting methods [41] .

Completeness has a positive relationship with timeliness, which they considered as main data quality dimensions and main factors in the process of reporting communicable diseases. Completeness and timeliness have a relationship where completeness considered as independent variable while timeliness considered as dependent variable. Incomplete data leads to delay in timeliness and complete data leads to faster timeliness in reporting process. Completeness and timeliness have an inverse relationship; when they vary in opposite directions, they will have an inverse relationship.

In the literature review article published on communicable diseases surveillance in developed and developing countries, completeness quality indicator did function better than timeliness in the USA [42]. It shows variation in reporting completeness from 9% to 99% where completeness was strongly associated with the reported diseases such as Immunodeficiency Syndromes, Sexually Transmitted Diseases, HIV/AIDS and Tuberculosis. The study published on the timeliness of national diseases surveillance system in Korea based on six diseases, it shows a range from 40% to 80% of completeness.

With the worldwide drive to scale up and speed responses to communicable diseases, public health surveillance systems need to review their workflow and framework in detecting, reporting and responding to communicable diseases. Continuous evaluation for reporting completeness, timeliness along with other quality measurements helps to evaluate public health surveillance systems. It helps to improve data quality, identify areas for improvement and share data and feedback with stakeholders. Receiving complete and timely information will save disease investigators from public health agencies time-consuming process to track down details through phone calls and medical records review process. It also helps stakeholders in diseases prevention, control plans, monitor trends, policy developments, research, distribute resources and priorities actions.

2.4 Meaningful Use Program

The US government introduced the Meaningful Use program as a part of the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act. The American Reinvestment and Recovery Act (ARRA) includes many measures to improve the healthcare system where they created the HITECH Act. The HITECH Act supports the principle of meaningful use of interoperable electronic health records between healthcare providers and organizations [45]. As mentioned earlier in section 1.1 for the motivation of this research, aligns with the reporting data from healthcare providers to healthcare authorities.

One of the Meaningful Use objectives is to overcome the problems of health information exchange between healthcare stakeholders. The Meaningful Use plan is going to use certified EHR technology to achieve goals to improve the quality, safety, and efficiency of healthcare outcomes. Also to improve care coordination and ensuring adequate privacy and security protections for patients' health information. Engaging patients and families in their healthcare are other goals for the Meaningful use plan [46].

The Meaningful use consists of three main stages or components [47], which are:

1. Use of certified EHR in a meaningful use such as using electronic prescriptions

2. Use of certified EHR to electronically exchange health information in between healthcare providers and healthcare authorities such as submitting a Novel Influenza case report form to a local health department or exchanging X-rays between providers

3. Use of certified EHR to submit clinical quality measures such as preventive care and screening for influenza immunizations or childhood immunization status.

The approaches or mechanisms to achieve the Meaningful Use goals are different. It establishes standards and information technology services to support the interoperability in order to help achieve and establish nationwide standards to exchange data between healthcare providers.

The Meaningful Use plan provides financial incentives to the healthcare providers to ensure that all certified Electronic Health Records have the capabilities to exchange data. For more information on the Meaningful Use Program adoption; see Figure 2.6, and for more information on the Meaningful Use plan stages, see Table 2.3.

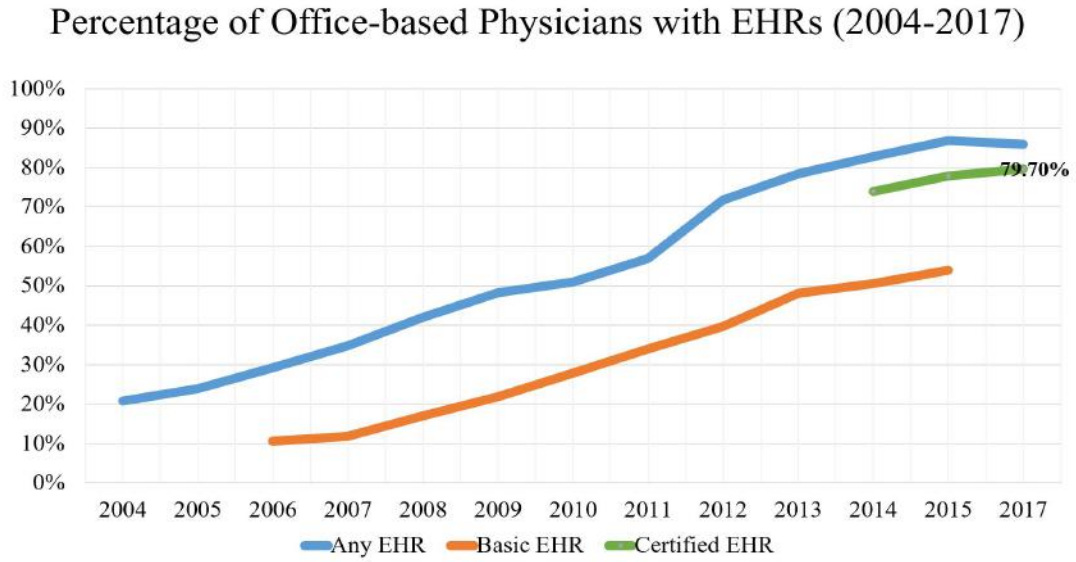


Figure 2.6: The percentage of office based physicians adoption of Electronic Health Records up to 2017 [48].

The Meaningful Use incentive program established the criteria, requirements, incentive and penalties for eligible healthcare providers and healthcare facilities to compliance with the program. The use and exchange of laboratory and clinical data are some of the core meaningful use program objectives. Other objectives within certified EHRs requires EHRs to be able to identify clinical data and provide specific information in communicable and diseases reporting, which improves interoperability and standardization in reporting communicable diseases reporting process.

Objectives of the Meaningful Use program includes enabling users to electronically create

Table 2.3: Meaningful Use stages and objectives [49]

Stage 1:2011-2012 Data Capture and Sharing	**Stage 2:2014 Advanced Clinical Processes**	**Stage 3: 2016 Improved Outcomes**
Electronically capturing health information in a standardized format	More rigorous health information exchange (HIE)	Improving quality, safety, and efficiency, leading to improved health outcomes
Using that information to track key clinical conditions	Increased requirements for e-prescribing and incorporating lab results	Decision support for national high-priority conditions
Communicating that information for care coordination processes	Electronic transmission of patient care summaries across multiple settings	Patient access to self-management tools
Initiating the reporting of clinical quality measures and public health information	More patient-controlled data	Access to comprehensive patient data through patient-centered HIE
Using information to engage patients and their families in their care		Improving population health

and submit patient's clinical problems list and lab results, which requires the use of medical standards such as the International Classification of Diseases- 9th Revision- Clinical Modification (ICD-9-CM) or Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT). Another key role of the Meaningful Use program is Computerized Physician Order Entry (CPOE) for laboratory test order. This role helps in documenting and standardizing the process of providers entering and sending treatment instructions orders.

2.5 Public Health Community Platform (PHCP)

The Public Health Community Platform (PHCP) is an ongoing project to integrate public health with clinical health data by sharing a bidirectional electronic diseases case reporting such as Novel Influenza reporting. The PHCP project where two organizations are partnered; the Association of State and Territorial Health Officials (ASTHO) and the Centers for Disease Control and Preventions (CDC) [50, 51] .

The similarities between the PHCP project and my dissertation that are both designed to help healthcare providers to report communicable diseases from health care providers to healthcare authorities and make use of the stored data in EHRs for reporting purposes. Also, they both use forms manger for reporting purposes. The PHCP project is a cloud base while my work is designed to be implemented in EHRs with no cloud reporting ability, which a major difference between the PHCP project and my work.

ASTHO is leading the joint development part, and CDC is leading the funding and cooperative support part [50, 51]. The vision and goals of this project are to develop a cloud-based public health information technology platform to support electronic medical data exchange. The PCHP is designed to be accessible, flexible, secure, where public health agencies and healthcare providers will be able to develop, compare, exchange interoperable solutions and allow access to common data such as electronic health records and public health surveys [50]. The PHCP is planned to be a public health community-owned and governed system where the PHCP will provide a centralized cloud space where jurisdictions and states public health agencies and users can exchange data, collaborate, share services to provide solutions to current or potential public health problems [52].

The development of the project is planned for five years, starting from 2013 until 2018 where it is divided into 3 phases [53].

Phase I: It is already completed by deciding on the use of HL7 standards and platform. HL7 CDA will be used for the initial case report structure and semantic for clinical documents exchange. HL7 Electronic Initial Case Report (eICR) will be used for initial case reporting

requirements. Also decided to use Reportable Conditions Knowledge Management System (RCKMS) as a shared community application as a platform.

Phase II: It is already completed by deciding on the initial implementation locations and stakeholders:

1. Utah Department of Health, Intermountain Healthcare, and Cerner

2. Illinois Department of Public Health, Northshore Medical Group, and Epic More locations and stakeholders are committed for future implementations for testing and analysis.

Phase III: This phase is still in progress phase where implementation happened in 2 locations, and more locations and different stakeholders will be next. The goal is to have this platform implemented as a nationwide and used by public health authorities.

The PHCP projects succeed to have more stakeholders on board, where ASTHO leads development, maintenance, and implementation. Other stakeholders are involved with other roles. Association of Public Health Laboratories (APHL) is involved with development and maintenance of APHL Informatics Messaging Services (AIMS). (What is AIMS). CDC is involved with funding multiple stakeholders to develop PHCP and other projects. Healthcare providers, EHR vendors, and public health agencies are involved with implementation, sending, receiving and testing messages, and initial case reports from EHRs to public health agencies [53]. Many organizations were represented in the PHCP including healthcare associations (ASTHO, APHL, CSTE), state and local health departments (Utah, Illinois, Washington, Michigan, Idaho, Tennessee, Southern Nevada, Virginia, Houston), electronic health record vendors (Cerner and Epic), healthcare providers' organizations (Northshore Medical Group, Intermountain Healthcare), and CDC [53].

The PHCP will establish two connections in the initial pilots of electronic case reporting (eCR). The first connection will be between the PHCP and an EHR vendor and the second connection will be between the PHCP and a public health agency. After the successful

connections, a standardized case report will be transmitted from EHR to a public health agency, see Figure 2.7.

Delivering the case report from an EHR to public health agency will go through 5 components [53] that are:

1. Locally map trigger codes: Reportable Condition Trigger Codes (RCTC), a standard that is under development where CDC and CSTE are working together to develop it, will be embedded in an EHRs to recognize reportable cases and generate initial report case to be sent to public health agencies.

2. Generate initial case report: where the embedded RCTC is triggered, an EHR will generate an Electronic Initial Case Report (eICR) which contains a standardized and structured set of data fields to be sent to public health agencies.

3. Association of Public Health Laboratories (APHL) Informatics Messaging System (AIMS) routing: This component is for the secured cloud-based platform connection. AIMS will provide many trusted secure transport protocols to send and receive information between users. This component will transmit eICR from one user to another through the cloud-based platform connection where the PHCP will be as a repository for users and information.

4. Reportable Condition Knowledge Management System (RCKMS): When eICR is received, the RCKMS will check eICR for reportability by a set of rules. When eICR is eligible to be reportable, the RCKMS will route eICR to the appropriate public health agency then notify submitting healthcare providers of reportability.

5. Forms manager for supplemental information requests: Required data fields for a condition may vary from a public health agency to another. When a similar case occurs; supplemental information will be required to be submitted to public health agencies. In the future of Electronic Case Reporting (eCR), the RCKMS will require healthcare

providers to submit additional supplemental information when needed to public health agencies such as traveling or exposure information to cases with certain conditions or high-risk age group.

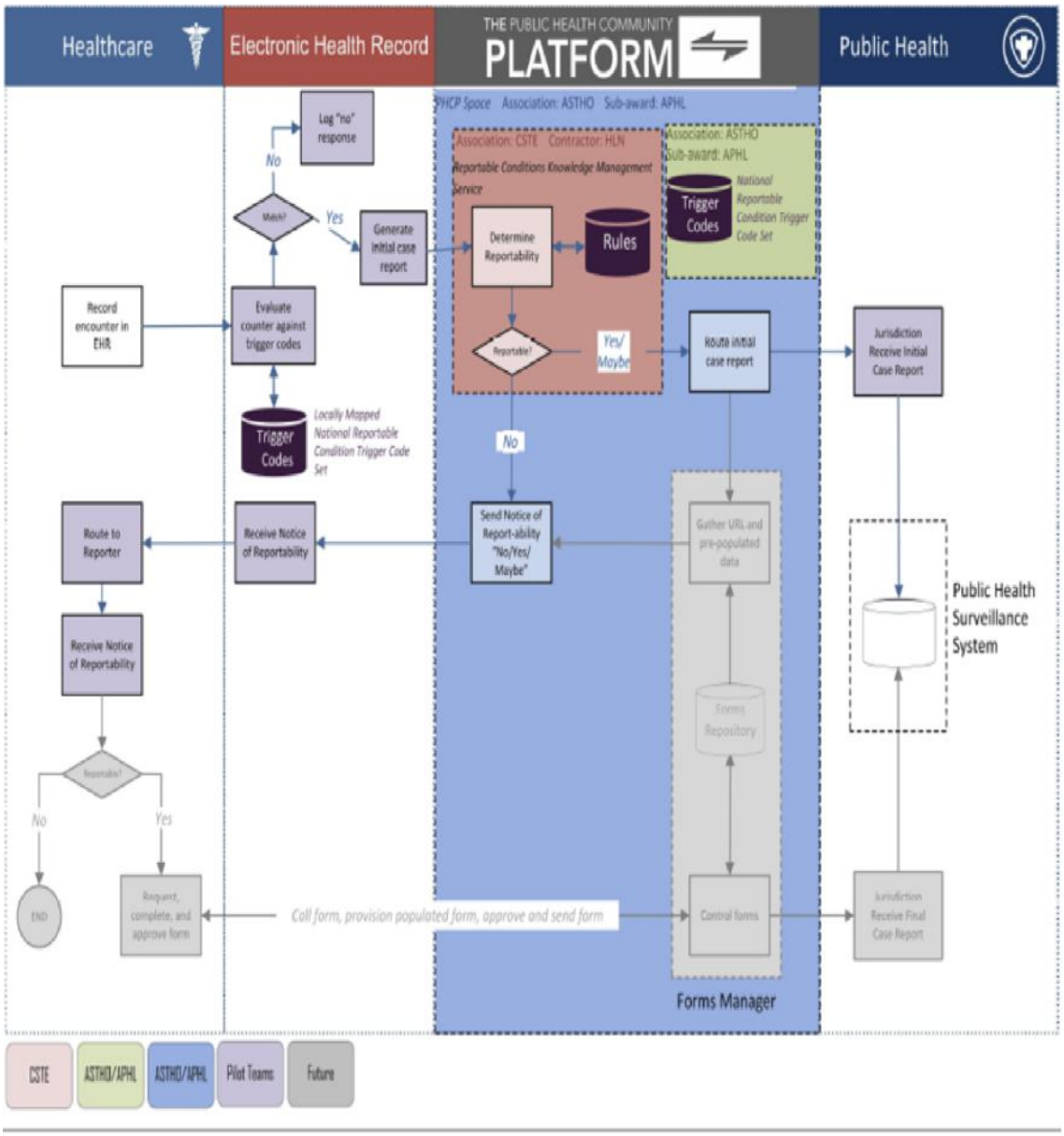


Figure 2.7: Initial eCR data flow from EHR to Public Health Surveillance System [54].

The PHCP comes with many challenges from technical to legal issues. Cybersecurity will be a major issue with the fear that an intruder can gain unauthorized access to public health data where the intruder can copy, alter and delete data. Another security issue when an intruder executes malicious code on a client's system then can gain unauthorized access to data on the PCHP [55]. The PCHP potential user will be caution when accessing public health data not to violate any local laws or it might require changes to current laws [55]. Also, users will be obligated to follow facilities or organizations' policies, which might conflict with partial or full access to public health data.

The use of the PHCP is tied to the access of other tools such as Reportable Condition Knowledge Management service and National Reportable Condition Trigger Codes Set, Operating, maintaining, monitoring and governing the PHCP will be costly when fully launched.

Users might not have full benefits with the PHCP with limited functionalities. Public health users might be only able to analyze a subset of the data, which might affect the results and findings [55]. Limited algorithm access will be a concern for users when they do not have full access to algorithm fits their needs [55].

2.6 Digital Bridge (DB): Electronic Case Reporting (eCR)

The Digital Bridge project is another ongoing project to enable healthcare providers to electronically report cases with notifiable conditions from healthcare providers to public health agencies through health delivery systems such as reporting Novel Influenza cases. The Digital Project aligns with the work of my dissertation where focusing on case reporting from healthcare providers to healthcare authorities.

The Digital Bridge project is based on a public/private partnership driven by shared goals and outcomes. The partnership is between health- care providers, Electronic Health Records vendors and public health organizations where it is governance body were formed in 2016. The Digital Bridge project was launched in June 2016, and it is funded by the Robert Wood Johnson Foundation (RWJF) and deBeaumont Foundation [56]. The Robert Wood Johnson Foundation (RWJF) agreed to be the neutral convener for a proof of concept phase

in the project. The program management of the project is provided by Deloitte Consultation and the Public Health Informatics Institute (PHII) [56].

One of the main project workgroup meeting outcomes is to provide a common vision for many stakeholders on how to exchange data and information from healthcare providers to public health authorities. The workgroup of the project agreed that the Electronic Case Reporting (eCR) approach would be the initial opportunity to apply the Digital Bridge vision [56]. Another workgroup activity is to plan and execute the initial implementation of eCR proof of concept pilot in various locations with different stakeholders. Another important workgroup meeting outcome is how can main stakeholders identify challenges in the initial implementation and work together to find solutions under the governance of the Digital Bridge program management [56].

The Digital Bridge project aims to help healthcare providers to exchange standardized, timely and accurate clinical health data between stakeholders' groups. The Digital Bridge initial focus is to enable Electronic Case Reporting (eCR) to improve public health surveillance by providing a ground for partnerships between public health, healthcare delivery systems and health IT vendors. It provides a forum for stakeholders to discuss challenges and issues of health information sharing and exchanging between stakeholders [56]. The forum will help stakeholders to discuss existing methods for clinical data to be captured and exchanged between stakeholders to increase the quality of public health surveillance data.

As mentioned earlier, the Electronic Case Reporting (eCR) was selected as an initial use case for the stakeholders' collaboration. The Digital Bridge approach for eCR is to use existed technology products and standards and not to replace any. eCR is intended to be embedded in the background of an EHR to be easily used by healthcare providers. This project will help public health agencies and healthcare providers on many levels. It helps stakeholders to improve detection of potential public health event to plan an intervention for epidemics or outbreaks. On another level, it enables public health agencies to send feedback and information to healthcare providers on how and manage their patients. This project has the promise to improve notifiable conditions reporting process, timeliness, data accuracy,

completeness, response time to local and state partners to meet their needs and reduce the burden of reporting cases to public health agencies [56].

The Digital Bridge through eCR is planned to enable bi-directional information exchange between healthcare providers and public health agencies. The step of reporting notifiable conditions from healthcare providers level to public health agencies level and receive feedback from public health agencies to healthcare providers enables bi-directional information exchange, which is an important feature for faster communication methods and health data exchange. On a larger scale, it helps to identify and manage the high-risk population in communities to improve healthcare outcomes [56].

Many stakeholders are engaged with the initial implementation in various locations and cities. Different states and cities will or already participated in the eCR implementation representing public health agencies, healthcare providers, and Electronic Health Record (EHR) vendors, see Table 2.4 [57]. The table 2.4 represents site participants in different states and cities where each implementation site has a public health agency, healthcare provider and EHR vendor [57]. Each implementation site has a public health agency, healthcare provider and EHR vendor. The initial implementation scheduled to start on 2017 and planned through 2018 where it will support five notifiable conditions: Pertussis, Gonorrhea, Chlamydia, Salmonellosis, and Zika at all sites across different states and cities [56], see Figure 2.8 for the current Digital Bridge eCR strategy.

An interim governance body with different rolls from many stakeholders' representations who engaged with the initial implementation, will focus on specific issues and challenges with initial implementation and how to solve the challenges. Public health organizations will focus on developing common trigger codes tool, policies, and technical standards. EHR vendors will focus on how to develop common technical standards and solution on how to enable eCR to be embedded with an EHR. Healthcare providers can focus on how to engage and participate in this proof of concept implementation and provide feedback to change the current notifiable conditions reporting process to an automated process.

The Digital Bridge eCR project comes with many challenges. The Digital Bridge project

Table 2.4: eCR Site Implementation Participants

Public Health Agency	**Healthcare Provider**	**EHR Vender**
California	UC Davis	Epic
Houston	Houston Methodist	Epic
Kansas	Lawrence Memorial Hospital	Cerner
Massachusetts	Partners HealthCare	Epic
Michigan	Local Public Health Clinics McLaren Health Center	NetSmart HIE-MiHIN
New York State & New York City	Institute of Family Health Upstate	Epic
Utah	Intermountain Healthcare	Cerner

builds on work already done by others like using medical terminology standards or still under developments like the reportable conditions trigger code will be a challenge, especially with updates. Embedding many standards in the eCR process in many steps will be a challenge. The governance process and communication of many stakeholders such as ASTHO, CDTE, CDC and HL7 with diverse needs and perspectives might delay the project or shift objectives [58]. Scaling connections to exchange data between thousands of healthcare stakeholders (hospitals, primary care physicians) would be a challenge [58]. Updating or creating policies to meet the Health Insurance Portability and Accountability Act (HIPAA) minimum necessary requirements will be a challenge for all potential users of the Digital Bridge eCR.

2.7 Reportable Conditions Knowledge Management System (RCKMS)

The Reportable Conditions Knowledge Management System (RCKMS) is an ongoing project designed to be as real time portal to improve the process of disease surveillance by providing

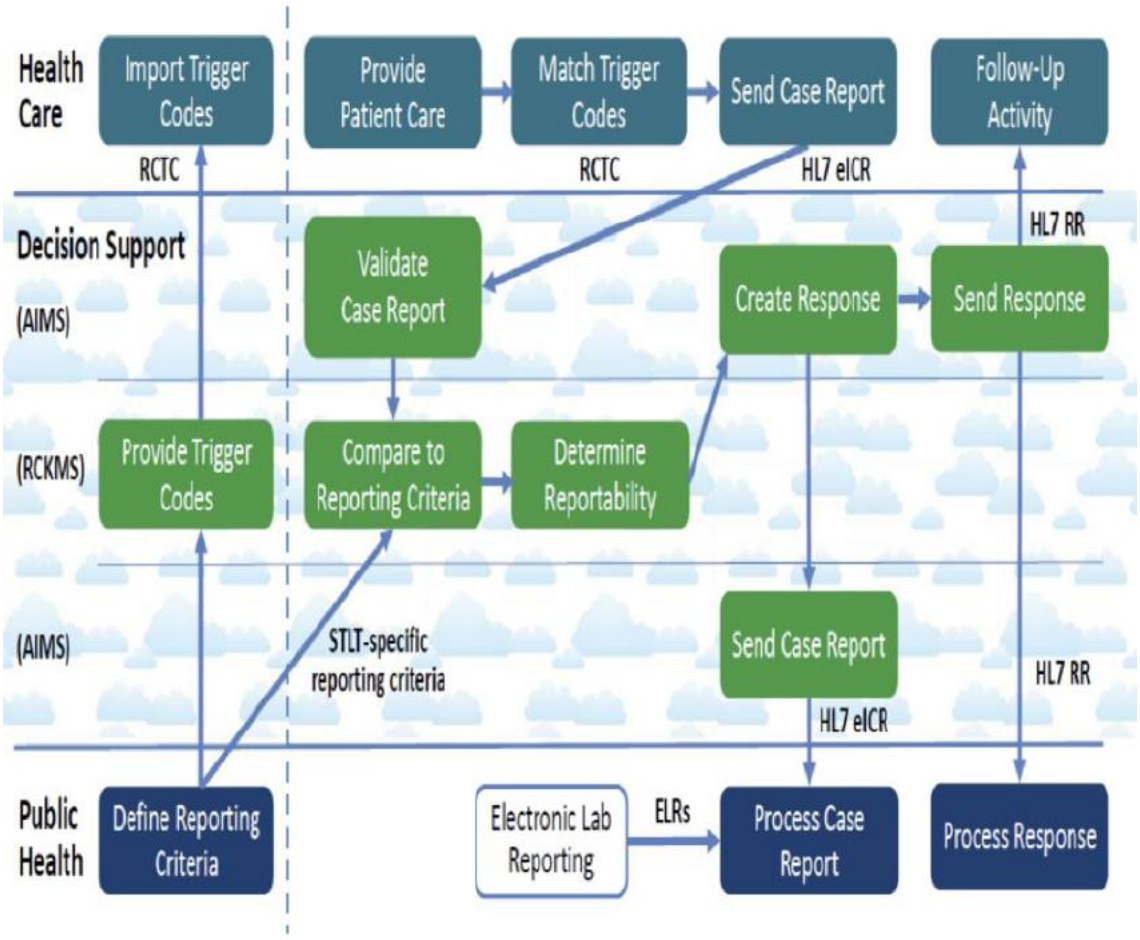


Figure 2.8: The Digital Bridge eCR Proof of Concept Process [58].

comprehensive information to providers. The information will help healthcare providers about who, when, what, where and how to report diseases to healthcare authorities [59]. The outcome of this project will narrow many of the current gaps and solve many challenges with reporting diseases from healthcare providers to healthcare authorities such as Novel Influenza reporting that discussed earlier in section 2.2.1.

The RCKMS project where two organizations are partnered on 2014; the Council of State and Territorial Epidemiologists (CSTE) and the Centers for Disease Control and Prevention

(CDC) [60]. The RCKMS vision is to provide a single, real-time, authoritative portal for public health to efficiently author, view, access and update computable information on reportable notifiable conditions as they change over time. The RCKMS is a step forward and to build on previous work has been done by the CDC such as the Reportable Condition Mapping Tables (RCMT) project and other initiatives related to case reporting [61].

The RCKMS objectives are to strengthen public health surveillance and provide a solution to improve timeliness reporting from healthcare providers to public health authorities [61]. The RCKMS is designed to be used by healthcare providers, healthcare facilities and health information exchange tools to meet existed or updated public health notifiable conditions requirements on jurisdiction or state levels [60, 62]. The RCKMS is designed to help healthcare reporters with accurate and current notifiable conditions reporting requirements to promote automated electronic case reporting.

Local jurisdictions and states have their lists of notifiable conditions that must be reported within a time frame to public health authorities. This list of notifiable conditions might vary from jurisdiction to another or a state to another. Factors like data completeness, timeliness and accuracy are critical to identify, investigate, and control communicable and non-communicable diseases. To meet these factors, reporters need to have accurate, clear, easy access and updated information on "who, how, what, when, and where" to report any notifiable condition. Currently, this information is distributed across many different resources and websites, which makes it difficult and time-consuming for human users to obtain and follow the latest requirements. The RCKMS planned to provide a specific location where healthcare providers can easily access an updated information on who, how, what, when, and where to report notifiable conditions to local or public health authorities [62].

RCKMS workgroup team members have diverse backgrounds to enable a wide range of viewpoints. The workgroup identified three domains of knowledge to represent data needed to meet the RCKMS's vision. The three domains are:

1. State Reporting Rules: The RCKMS will allow jurisdictions to make new reporting

specifications, changes or updates existing reporting specifications and make these recent changes in both human readable and machine processable formats. RCKMS will be able to electronically notify healthcare reports about the recent updates or changes [62].

2. Reporting Logic for National Surveillance: The RCKMS will provide jurisdictions the flexibility either adopt the existed reporting logics provided by CSTE or modify the reporting logic to meet local jurisdiction or state-specific requirements to report notifiable conditions [62].

3. Nationally Notifiable Conditions: Not every reportable condition within a jurisdiction or a state is a nationally reportable condition and must be reported to the CDC for national surveillance. The RCKMS will be able to check if any reported notifiable condition within a jurisdiction or a state is a nationally notifiable condition and therefore it needs to be reported to the CDC as a nationally notifiable condition for national surveillance [62].

The RCKMS workgroup team decided to use existed coded values and not replace them to represent key requirements for reportable notifiable conditions. They decided to use SNOMED-CT, ICD-9 CM, and ICD-10 CM standards to code clinical conditions and LOINC standard to code lab test names and clinical observations while SNOMED-CT standard will be used to code lab test results and clinical values and findings [62].

The RCKMS is envisioned to be as a tool or a service that can be deployed on the middle layer of a platform. RCKMS tool consists of three main parts [60], see Figure 2.9, these parts are:

1. Authoring Interface: This is a web portal service allows public health agencies flexibility to create, edit and manage local jurisdiction or state notifiable conditions reporting requirements. This service will pre-populate default reporting specification, and it

gives the authority for local jurisdictions to accept or modify notifiable conditions reporting requirements.

2. Knowledge Repository: This repository contains information on reporting specifications. When users create or modify reporting requirements, it would be stored in the knowledge repository and used by decision support service if required.

3. Decision Support Service: This service will be triggered when a potential notifiable condition case is flagged directly by an Electronic Health Record system or through a tool. The RCKMS Decision Support Service will provide healthcare reporter with information to specify if this case is a reportable case or not. Also, will help healthcare reporters to specify to what party this notifiable case it should be reported, local jurisdiction, state public health department or both.

The RCKMS will provide a single authoring interface for jurisdictions to create or edit notifiable conditions reporting requirements, which will make healthcare reporters have easy access to the most updated requirements and reporting information. More stakeholders are engaged with RCKMS pilot along with CDC and CSTE. 9 public health jurisdictions (Houston, Illinois, Virginia, Southern Nevada, New York, New York City, Utah, Colorado, Washington, and Delaware) and Intermountain Healthcare as a healthcare organization engaged with the RCKMS pilot. The RCKMS pilot is planned to develop more content to include more notifiable conditions and deliver technical content to develop and test authoring interface and implement machine processable reporting specifications [60].

The RCKMS is already envisioned to be a service in the Electronic Case Reporting (eCR) tool by Digital Bridge project. Also, RCKMS is envisioned to be used the Public Health Community Platform (PHCP) project. The RCKMS will be used in both projects as a layer to determine the reportability of notifiable condition case. Also, it will provide information on to which jurisdiction or agency reporting is required. The RCKMS is aligned with major national initiatives such as the HITECH Act and the Meaningful Usage stage 3 for public

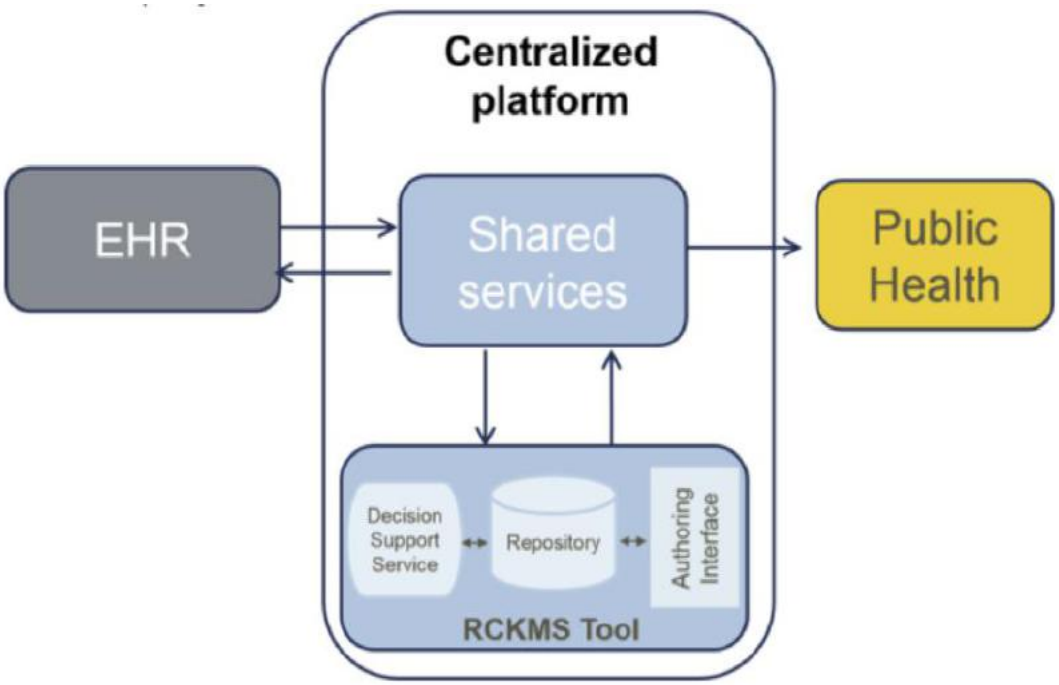


Figure 2.9: Reportable Conditions Knowledge Management System (RCKMS) and Electronic Case Reporting as a service could be installed as a tool in a platform [60].

health reporting objectives [61].

The RCKMS comes with many challenges from the notifiable conditions reporting requirements in different jurisdictions to the technical reporting requirements. The use of known standards terminologies such as LOINC, SNOMEM, ICD-9, ICD-10 and RxNorm requires a good understanding of value sets, constructions and how to express these standards and rules into logic for the RCKMS tool. These many standards terminologies will be used as resources for the RCKMS, so the relationships between reportable conditions, reporting criteria and resources might be complicated especially when introducing this new method of decision support system to public health domain.

Providing and evaluating the needed content to write the first jurisdiction notifiable condition reporting requirements for a condition would be a challenge since the reporting

requirements might be different from jurisdiction to another. Having different reporting requirements in different jurisdictions will lead to gaps, so identifying and closing reporting requirements gaps would be a challenge. Jurisdictions reporting requirements might change from time to time or based on nature of a disease, so supplying and updating the new reporting requirements might be a challenge.

2.8 Clinical Document Architecture (CDA)

The Clinical Document Structure (CDA) is a flexible markup standard started in 1996 and developed by the Health Level Seven International. HL7 CDA Release1 was published in November 2000 while Release 2 was published in 2005 [63]. CDA Release 2 became an American National Standard Institute (ANSI) standard in 2005 and 2009 became an International Organization for Standardization (ISO) standard [63]. CDA Release 2 is still the current version of the standard.

CDA defines the structure of medical documents to make medical documents exchange between providers, patients, and healthcare authorities easier. The goal of the CDA is not to exchange data only, but to make it useful. The CDA allows sharing individual healthcare data in many directions. It allows sharing data between healthcare providers, healthcare provider to a patient, and from a patient to a healthcare provider. The Meaningful Use plan requires the use of the CDA standard as a method to send electronic data between healthcare providers, patients, and healthcare authorities. There are many projects such as the ongoing project The Public Health Community Platform (PHCP), section 2.5, and the Digital Bridge, section 2.6, are using CDA in the project development. The CDA standard designed to enable the contents of the medical documents to be read by humans or processed by machines, CDA enable human-to-human communication and machine-to-machine processing.

CDA allows controlled terminologies to be included in clinical documents such as Systemized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) and Logical Observation Identifiers Names and Codes (LOINC) and others. This helps to enhance the semantic interoperability between healthcare providers to allow clinical documents to be stored in a

machine or transmitted to a different machine [64] . Besides the benefits of exchanging clinical documents, CDA could be used in different applications and support the capture, re-use, store, access, and display of clinical data. Also, it could be used for other purposes, such as quality managements and patient safety [65] .

2.8.1 CDA Document Characteristics

The CDA is an HL7 standard with multiple releases; it is a document markup standard that defines the semantic and structure of a clinical document to be exchanged among healthcare providers and patients. There are multiple versions of the CDA standard as it has evolved. The descriptions in this section are true of the CDA standard in general. For the implementation, release 2.1 was used. The structure of the CDA document provides a clinical document with the following characteristics:

1. Persistence: The CDA document can exist in an unchanged state for a pre-defined time by owners.

2. Stewardship: The CDA documents are maintained by the documents owner such as healthcare providers.

3. Potential for Authentication: The CDA documents are capable of being signed by the documents owner for legal authentication.

4. Context: The CDA documents provide details on the documented events or encounters in the document. The CDA document has a default context for every CDA document.

5. Wholeness: The CDA documents can provide full details on the documented event or encounter. Also, when the CDA is authenticated that would apply for the whole document.

6. Human Readability: The CDA documents are human readable.

2.8.2 CDA Structure

CDA are coded in XML, where HTML describes presentation and XML describes content. The general structure of the medical document in the CDA contains a header and a body, see Figure 2.10 for the general CDA structure. The header content consists of the document itself and enables the document to be exchanged across and within healthcare providers. The header contains data such as patient information, author, creation date, and confidentiality code.

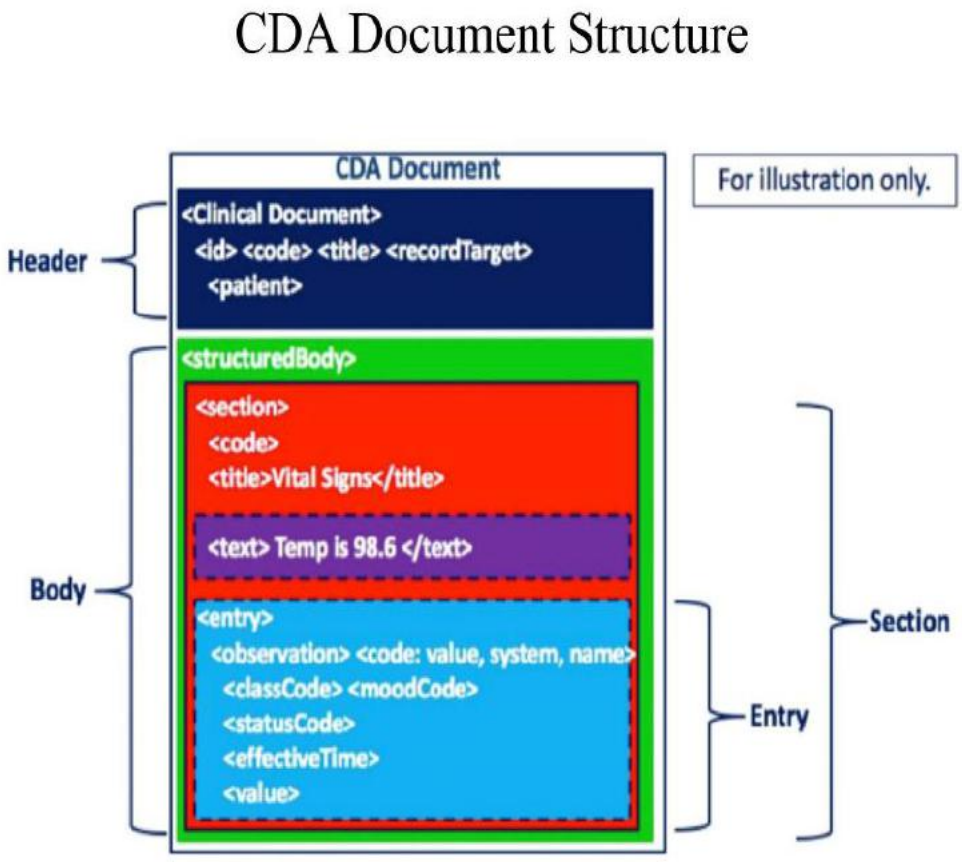


Figure 2.10: The general structure of the CDA document [66]

The CDA document body is a set of containers for information. The CDA body consists of at least one or multiple sections; each section could have zero entry or more thus technically allowing for the body to be completely empty. The CDA body contains medical data such as clinical details, diagnosis, encounters, medication, treatment plans, etc. The medical data could contain unstructured data such as images and text or structured data organized in one or more sections.

Each section contains at least one narrative block and can contain zero or many entries blocks. Treatments, allergies, demographic information are examples of what sections could contain. The narrative block within each section contains the human readable version of the document.

The entries block within each section contains the machine-readable version of the document. Both narrative and entries blocks represent the same information, the narrative block represents the human readable version while the entries block represents the machine-readable version of the clinical document, see Figure 2.11 for the CDA document hierarchy.

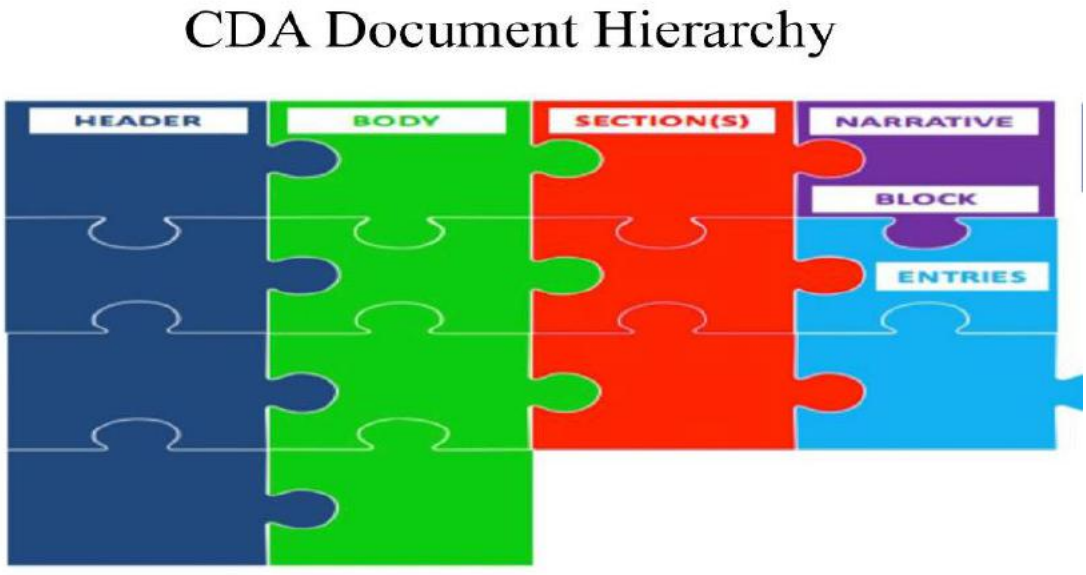


Figure 2.11: CDA document hierarchy [66]

2.9 Fast Health Interoperability Resources (FHIR)

There are more than 1500 certified EHR systems in the USA by 2016 [67], mostly they have been developed in the last few decades [68]. There are over 150 certified health IT developers supply certified health IT to healthcare providers and facilities. The certified health information technology meets the technological, functionality and security requirements specified by the Department of Health and Human Services. There about 10 health IT developers supplies about 98% of hospital with health IT by 2016, see Figure 2.12 .

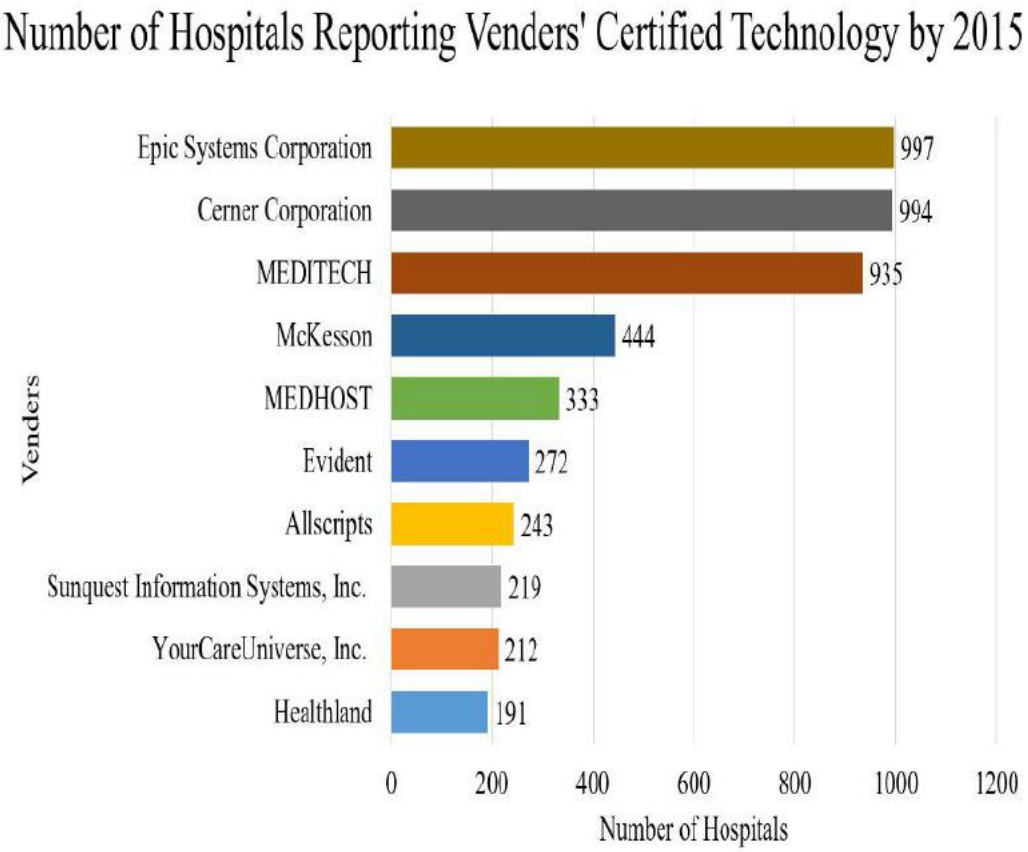


Figure 2.12: The top 10 vendors who supplies hospitals with certified health IT technology [69].

These EHRs support different HL7 standards such as HL7, v.2, v.3 and CDA. However, these standards have difficulties in interpretation and integration. The difficulties range from enforcing health IT interoperability standards or measurement standards across care settings and facilities to enable electronic data sharing and exchanging. Enforcing different health IT standards reduces or blocks the capability of sharing individual healthcare record since the health IT standards might have different structure and use. Different implemented or enforced IT standards between healthcare providers and facilities leads to difficulties sharing and integrating patient medical data into and across different vender platforms.

These difficulties support the needs to have a simple and accepted standard to allow data exchange between EHRs and stakeholders. Fast Health Interoperability Resources (FHIR) is the new standard in the HL7 standards family. HL7 claims that FHIR is simple, easy to understand and implement and it would have more acceptance in the future when the standard is more mature. This chapter will introduce the Fast Health Interoperability Resources (FHIR), main components, framework, resources structure, used technology, brief comparisons to few HL7 standards, benefits and challenges. Also, will cover SMART on FHIR .

Fast Health Interoperability Resources (FHIR) is developed and published by HL7. The HL7 FHIR is a standard to exchange healthcare information electronically, it is pronounced "fire". In 2014, HL7 released its first version FHIR standard labeled as Draft Standard for Trial Use (DSTU) to be used and developed [70]. In the following years, HL7 published more updates and new releases. In 2017, HL7 has published the latest FHIR release 3 as the first Standard for Trial Use (STU) and more to be released in the future [70]. The HL7 developed FHIR due to limitations in HL7 v.2 and 3 where HL7 sees the FHIR standard as the next generation standard framework where it combines the best features of HL7 v.2, HL7 v.3, and HL7 CDA standards [71].

FHIR is gaining more interest among healthcare stakeholders, big part of the enthusiasm is due to use of truly modern web services and standards [72]. The use of web services enables healthcare systems to get and exchange very specific and well-defined pieces of information.

The FHIR is designed to be built into Electronic Health Records itself along with all the used protocols and standards to improve authorization, authentication, access, security and interoperability. Over time, this will reduce if not eliminate the need for timely and expensive integration and implementation plans of new projects and services.

One of the main goals for the FHIR is to simplify healthcare information interpretation between healthcare systems. Another goal for the FHIR is to enable healthcare providers and individuals to access healthcare data on a wide range of devices such as computers, tablets and smart phones. Another goal of is allow applications developers to develop medical applications as third parties that can access Electronic Health Records [71]. HL7 FHIR standard is free to be used in any commercial manner unlike other HL7 standards where you need to be a member of the HL7 to use any standard.

The FHIR framework is built around the concept of "resources". Resources defined as a collection of information model to define the included data elements, constrains and relationship to healthcare domain. The FHIR uses resources, where resources are the basic units of structured data to be exchanged between healthcare systems. FHIR resources data definitions are agreed-on data elements that have consistent meaning among healthcare providers in healthcare practices. FHIR resources refer to each other using URLs and could be exchanged between healthcare systems using web services like RESTful API. The resources cover a wide range of healthcare data such as clinical data, administrative information and infrastructure information. The clinical data covers data such as medical problems, medication, past medical history and allergies. The administrative information covers patient's appointments and health insurances information. The infrastructure covers information on equipment's and purchasing lists.

2.9.1 FHIR Resources Framework

Resources in FHIR has a framework of predefined set of 6 main layers [73]:

1. Foundation Resources: It represents the foundation resources that are used for infras-

tructural tasks such as security and terminology

2. Base Resources: It is considered in the FHIR framework as the leaf nodes of a resource graph and the most used resources such as individuals and workflow. Typically, they would be referenced by other resources and not to reference many resources [37].

3. Clinical Resources: It represents the clinical data such as observations, treatments and other clinical data. These resources would be usually combined or reference other resources [37].

4. Financial Resources: It represents the financial resources such as billing and usually reference other resources [37].

5. Specialized Resources: It does not have many resources and it usually used to reference more specialized resources. This layer of resources consider the least used resources layer in FHIR framework [37].

6. Resource Contextualization: It does not contain resources, it contains graphs and profiles and used to extend the composition of the other 5 layers.

FHIR resources framework represents the healthcare domain into smaller sub-layers model [37]. The 6 sub-layers divided and structured in a way helps the resources to reference each other with consistency, integrity and organized based on their degree of frequency [37],Figure 2.13.

2.9.1.1 FHIR Resource Structure

The 6 main resources layers and their sub-layers contains about 119 freely available resources such as Patient, Practitioner, Medication, Observation, Immunization, Order, and many others. Each resource has a set of predefined units or stigmas, where each unit has a specific meaning from clinical perspective. For example; Patient resource has predefined fields such

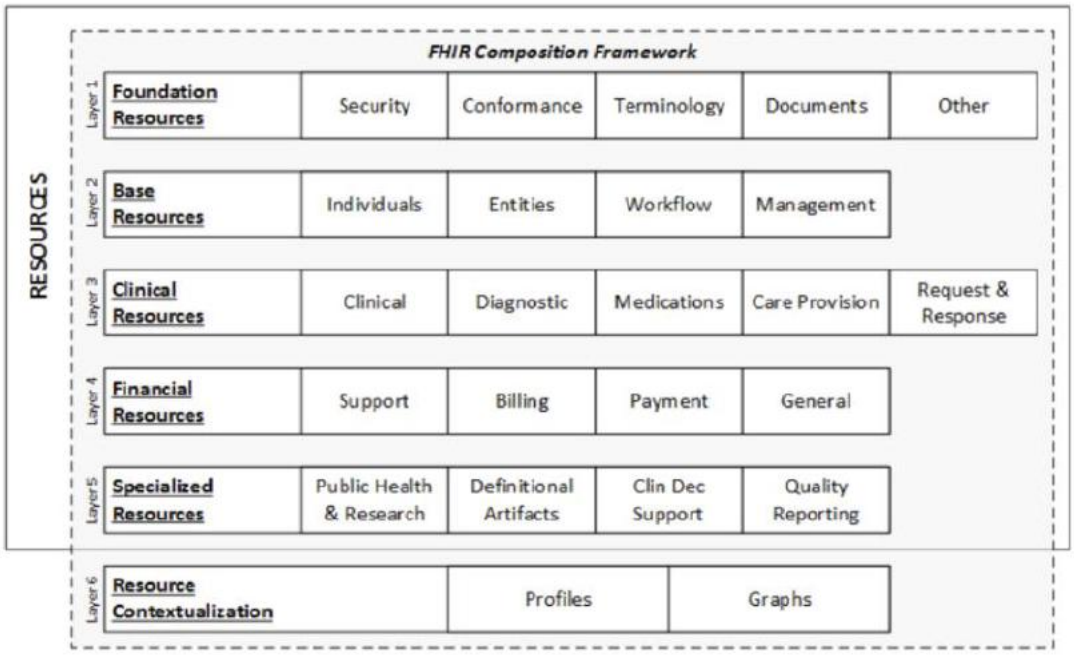


Figure 2.13: FHIR framework layers and resources sub-domains set [72] .

as identifier, name, gender, address, photo, marital status and other fields. Immunization resource has predefined fields such as identifier, vaccination code, site name, dose quantity, and other fields [73]. The same principle applies for the rest of 119 resources. To see an example of FHIR Resource structure, Figure 2.14.

In the top section of the figure, you can see resource identity and metadata section, it defines the ID, date and time on when a resource was last updated. The second top section you can see human readable summary section, it represents a resource content in a human readable format and structure. The third section from the top you can see the extension with URL to definition section, it provides a reference to the used definition(s). The extension with URL to definition is an optional property and it is different from the resource URL. The last section you can see the standard data section, it contains the structured elements as defined in the specification [74].

Figure 2.14: XML FHIR Resource structure as an example for a patient [68].

The concept of resources and their layers have been explained earlier and references has been mentioned. Now, let's show a very basic example on how resources reference each other. Using Unified Modeling Language (UML) diagram, Patient resource will cover data on a patient or animal with attributes to support demographic, administrative, financial and logistic data. The Patient resource could be used to referenced by other resources such as Account, Appointment, CarePlan, CareTeam resources and many others. The domain resource of the patient contains data such as name, gender, birthday, marital status and other demographic data, also it includes data on practitioner and healthcare facility. The patient in the Patient resource could be linked a related person such as a family member and linked to contact person with their relationship to the patient, see Figure 2.15.

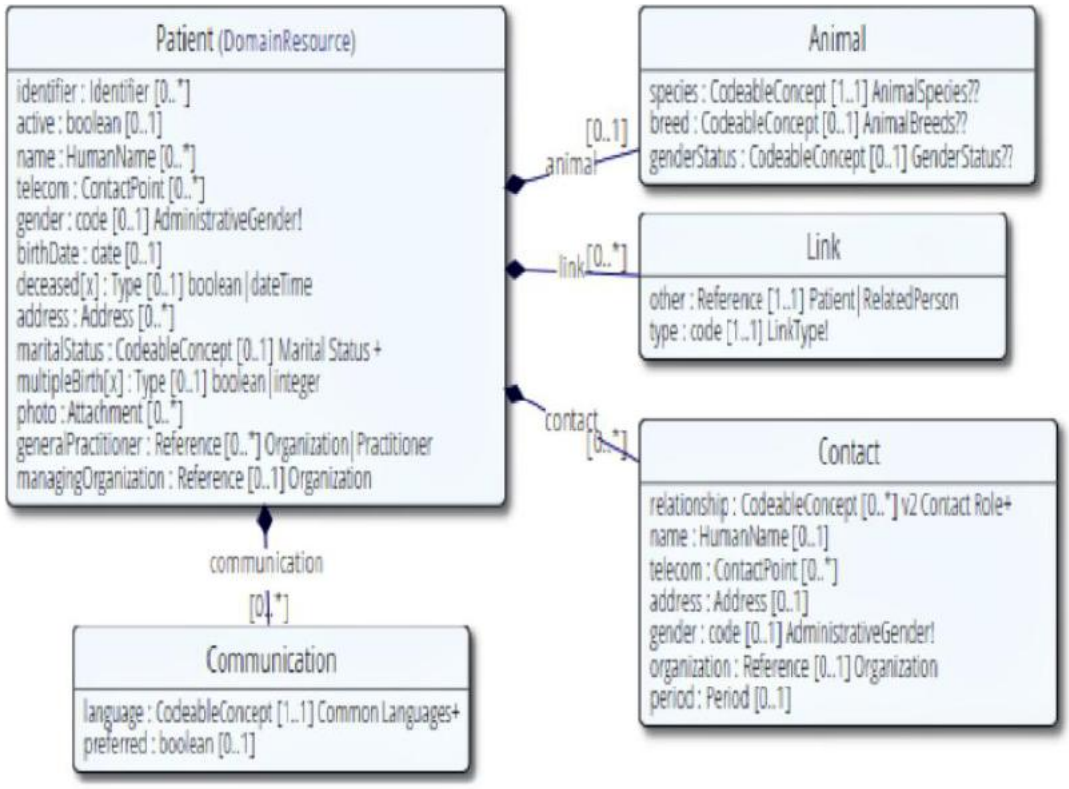


Figure 2.15: A FHIR Patient Resource definition with example in UML diagram [37]

2.9.1.2 FHIR Resources and Extensions: Reusability and Composability

The FHIR resources do not attempt to include all medical data that could be possibly used in the medical field. Instead, FHIR resources are designed with the 80/20 rule to reflect reusability and composability [37]. Resources are developed to include core common data requirements of many medical use cases to avoid any overlapped or redundant medical data, which will be the 80% [37]. Extension will allow to use the remaining 20% to customize resources through FHIR profiling to allow generic resources to be adopted as needed for medical use cases to meet specific needs into a healthcare system [37]. Extensions will be considered as optional additional fields within the pre-defined fields or units to be added

to resources. Extensions contains references to definitions, so the straightforward way for a developer to interact with extensions is to add them into a resource that the developer creates or to read them from resources that the developer consuming.

FHIR Resources supports composability by referring other resources or bundle them through a referral request [37]. When a user request data on a patient through a referral request, composition will get the requested data from one single request through searching multiple resources and bundle them into one single logical document instead of multiple pages. A composition could contain results from observation, patient, medication, progress and other data from many resources. The composition resource organizes requested clinical data and administrative content into sections and provides narrative description and references to the included resources within the request [75].

2.9.2 FHIR Profiles

Profiling in FHIR is an important concept for potential users. FHIR has a per-defined resources such as patient and observations with very generic definitions. FHIR profiles allows users to author new customized resource definitions, by specifying a set of constrains and relationships to the pre-defined resources. As mentioned earlier, resources are designed to contain the most commonly used data in a resource based on the 80/20 rule. Let's assume that there is a healthcare system wants to use a patient resource and this resource contains fields such as name, date of birth, gender and other fields. However, an implementation requires to include a field that is not included in the base resource such as a religion. Profiling allows users to add this new field (religion) to the supported base resource and link it to the patient pre-defined resource, which allows the healthcare system to fit users' needs in a way that human and computer can understand [74]. FHIR profiling has the flexibility to add a new field (religion) by implementing few rules such as defying the new term, specify cardinality(1-1, 1 to many, many to many) and either give the new field a unique code or using one of the existed codes.

2.9.3 FHIR Scenarios

The FHIR is about exchanging clinical and administrative data, which means it needs to meet healthcare providers and technical users. The ideas of FHIR scenarios is to help applications developers to design medical applications supports medical scenarios and understands the purpose or resources, how to link them and build a FHIR document. The FHIR scenarios are developed to test if FHIR resources can support the needed data in a medical scenario. If the medical scenario is not fully supported by the FHIR resources, then developers can use extensions/profiles or request to develop new FHIR resources.

2.9.4 FHIR Back-end Technology and Standards

The FHIR is built on previous HL7 standards format, HL7, Hl7 v.2 & 3. The FHIR is designed to be used for the web and provides resources and foundations based on may protocols. The FHIR is built for easy implementation due to the use of Application Programming Interface (API) technology including Hypertext Transfer Protocol (HTTP) protocols and Hypertext Markup Language (HTML). API is a collection of well-defined interfaces between 2 applications [37]. The FHIR provides a choice of using Extensible Markup Language (XML) or JavaScript Object Notation (JSON) for data representation in the resources.

The FHIR uses RESTful web services to deliver requested healthcare data to its destination. REpresentational State Transfer (REST) is an architectural style for networked application used to be applied with web services for networked applications, so any service based on REST using web services is called a RESTful service. The REST design architecture is used in many applications on the web such as Facebook, Amazon, Google and Twitter [72].

The FHIR uses the open standard for authorization (OAuth 2.0) to provide users with the ability to access FHIR resources as a third party without storing users' credentials data such as username and password inside the application's or website's server. OAuth 2.0 web standard allows users (healthcare providers or patients) to access specific and well-defined set

of data from a healthcare service provider such as EHRs. The FHIR uses Atom Syndication Format (Atom) for aggregation to return the results of any search into a single package regardless how many resources matched the search by linking the searched words.

2.9.4.1 FHIR – OAuth2.0

OAuth has been mentioned earlier as a standard for authorization to provide a user with ability to access health data from EHRs, so let's talk about how it works in general. OAuth2.0 will be responsible of authentication and authorization to access data on a third-party application. Let's assume that there is a user wants to view certain data form an EHR. The authentication step in this scenario is to know that the user who is trying to access the EHR is the same person who claims to be. In most cases, it would be done through a username and password. The authorization step in this scenario is to know what kind of data the user can access. It could be a medication list or a lab results. The authorization server in the following Figure, Figure 2.16, is a separate component has the users' credentials. The authorization server is a trusted component, which identifies the users and specifies what kind of data the user can access. As mentioned earlier, authorization server used in Facebook, Amazon, Google and Twitter.

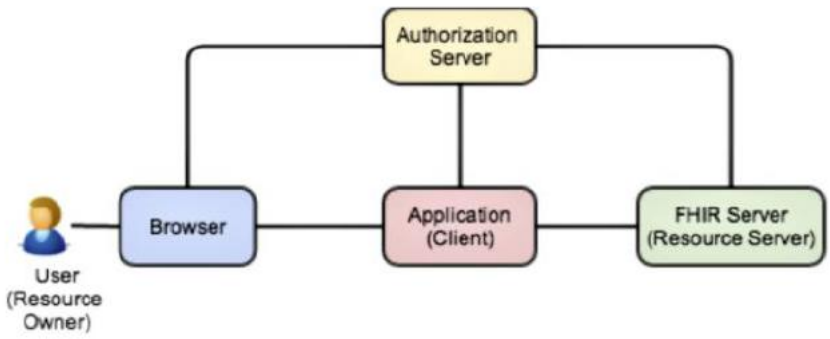


Figure 2.16: FHIR and OAuth2.0 framework to access a user data on another server [75].

Having the authorization server as a separate component will avoid the application of saving user's credentials in the application server, which will increase the security level and reduce the chances of losing credentials in a security attack. To break down a high-level of flow when a user sends a request to access certain data in an EHR until the user get the requested data, let's follow this figure, Figure 2.17.

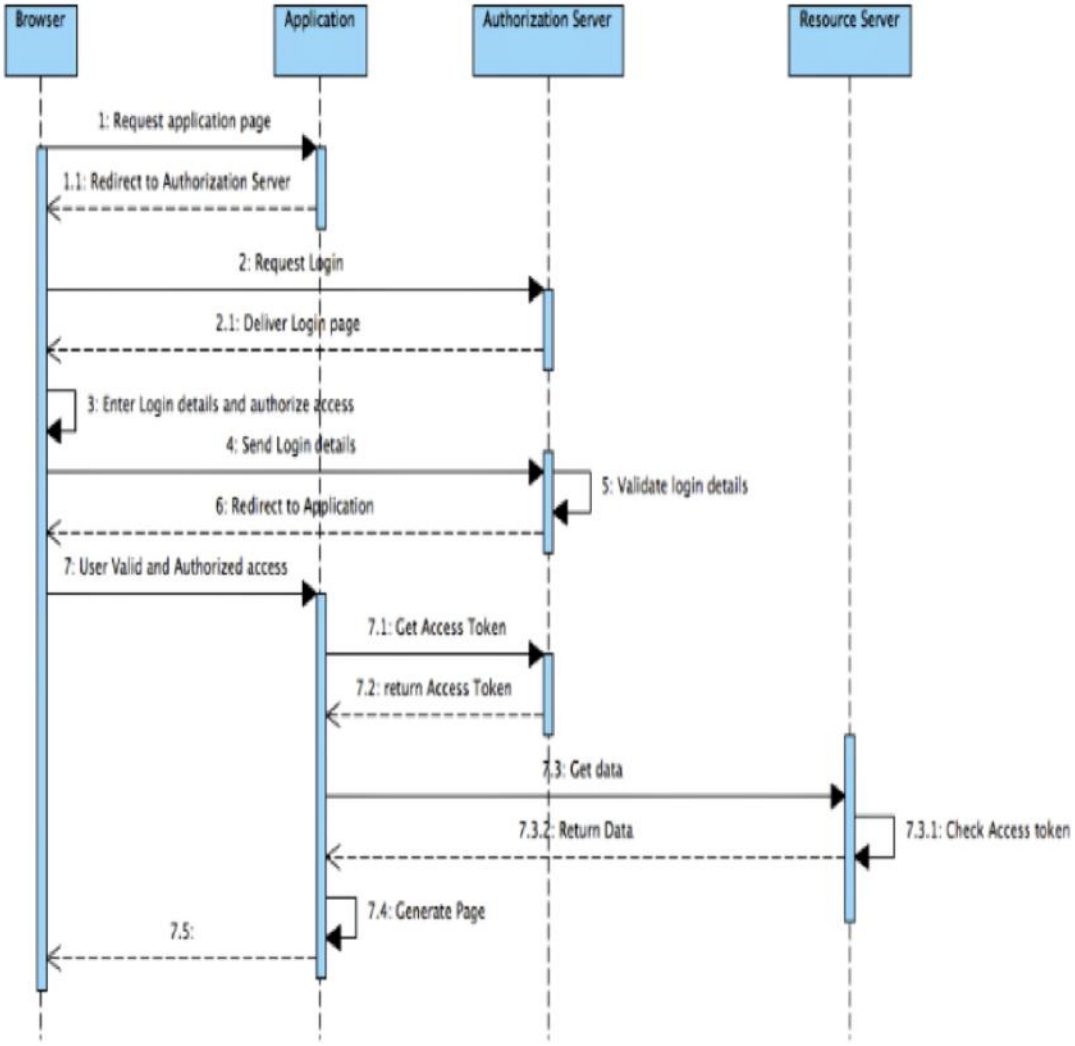


Figure 2.17: High-level flow of OAuth2.0 from user to FHIR resources [76].

1. The user will send a request to access an application (client) through a browser. The application needs to access specific data from the FHIR server (Resource Server).

2. The authorization server sends a login in page to the user to enter their credential data such as username and password.

3. The user enters the log in information.

4. The log in information will be send to the authorization server

5. The authorization will validate the log in information. Hint, the user already has an account to be validated.

6. The authorization server will re-direct the user to the browser to navigate through the application. The authorization server will specify the authentication code, which has the access permissions to certain data or functions.

7. The application will use the authorization server with the authentication code to get an access token. Then, the application will send a FHIR query to the resource server to access the requested data along with the access token. The resource server will check the validity of the access token, then send the requested FHIR data to the application. The application will generate the data and view it in the user's browser [76].

2.9.4.2 The FHIR RESTful web services

As mentioned earlier, REST stands for Representational State Transfer and used for architectural style for networked applications using HTTP standard for interface. REST is an architectural style that defines a set of rules used to build web services to provide interoperability between computer systems on the internet. REST was first introduced by Roy Fielding in the year 2000 [77]. In REST architecture, REST enables REST client to access and present resources through a REST server. REST identifies resources through URL and

presentation using XML and JSON. REST uses many HTTP methods, but the most used ones are GET, PUT, DELETE, POST [78].

GET: Read only access to a resource from a server PUT: create a new resource DELETE: remove a resource POST: Update an existing resource or create a new one in a server. There is a small difference between PUT and POST methods. PUT mostly used to create a new resource at a specific URL know by the client while POST could be used to create a new resource when the client does not know the specific URL.

As mentioned earlier, any service based on REST using web services is called a RESTful service. A web service is assembly of open protocols and standards used for exchanging data between applications using the World Wide Web. RESTful uses many web services such as the RESTful messages. RESTful uses HTTP protocols as a standard of messages between client and server. The client sends request message in HTTP request format and the server sends a response message in an HTTP response format. Figure 2.18 demonstrate the HTTP request while Figure 2.19 demonstrate HTTP response. The HTTP request has five main components [79].

1. Request Body: Contains the message content or resource representation.

2. Requested Header: Contains metadata of the requested HTTP message.

3. HTTP Version: Specifies the used HTTP version.

4. URI: Contains the Uniform Resource Identifier (URL) of a specific resource on the resource server.

5. Verb: Specifies the used HTTP method (GET, POST, DELETE, PUT, and others)

The HTTP response has four main components [79].

1. Response Body: Contains the response message or resource representation.

2. Response Header: Contains metadata of the responded HTTP message.

3. HTTP Version: Specifies the used HTTP version.

4. Response Code: Specifies the server status for the requested source. For example, 204 for no content, 400 for bad request, 401 for not authorized, 404 for not found and other status codes [78].

Figure 2.18: HTTP Request [79] .

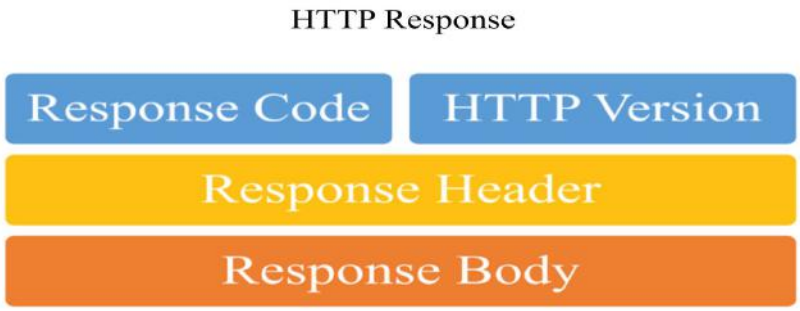


Figure 2.19: HTTP Response [79] .

2.9.5 HL7 v2, v3 and FHIR brief comparison

The HL7 standards was created and maintained by Health Leven Seven. HL7 v2 is a well-established messaging standard for the HL7 standards family, it is the most widely implemented standard for the HL7 standards family. The HL7 v2 was created under the influence of clinical interface specialists and designed to provide a framework where clinical date could be exchanged among healthcare systems [80]. The HL7 v2 is designed to target healthcare providers and IT venders [81].

HL7 v3 is a messaging standard for the HL7 standards family, it is not as widely implemented as the HL7 v2. The HL7 v3 was developed to be the next generation of HL7's messaging standard. The HL7 v3 was created under the influence of governmental and medical information users [80]. The HL7 v3 standard is developed not only for messaging, but for documents as well. The HL7 v3 standard allows healthcare systems to exchange clinical data among healthcare stakeholders. The HL7 v2 is not compatible with HL7 v3 and designed to target healthcare industry organizations and companies [82]. For HL7 v2, v3 and FHIR time line, see Figure 2.20.

Fast Health Interoperable Resources (FHIR) is the latest standard in the HL7 standards family, recently started to be recognized and adopted in many projects. The following table will introduce brief comparisons between HL7 standards; v2, v3 and FHIR and, see Table 2.5.

2.9.6 FHIR Benefits

The HL7 FHIR standard is designed to be flexible, faster implementation, lower cost, scalable, and free to use. One of the challenges for healthcare standards is how to be flexible in handling variability and expansion of healthcare data and processes, which leads to implementation challenges. The FHIR solves flexibility challenge by designing a framework able to read or extend current well-defined resources. The FHIR framework provides a human-readable format for every resource using HTML as a display format, which enables

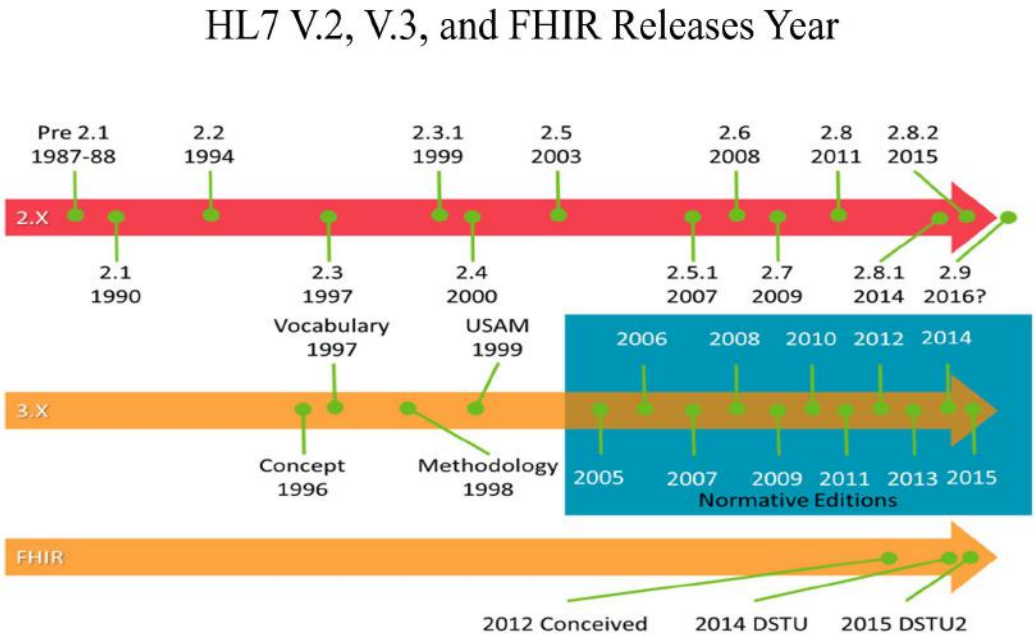


Figure 2.20: HL7 v2, v3 and FHIR release timeline [80].

applications and systems to easily read the current or extended base resources in human or machine-readable formats, which will lead to an easier implementation. FHIR standard and its specifications are publicly available on the internet and free to use with online community support and many examples. The online support community created and posted on the internet open source libraries and validation tests, which will help to reduce the burden of application developers to join the field.

The FHIR standard have many promises and brings benefits on many stakeholders such as Healthcare providers, healthcare organizations, patients and applications developers or implementers. The HL7 FHIR has the promise to improve interoperability where it defines away to represent information to be shared and describe how to share resources, documents and messages between healthcare systems. This will lead to improve data access and encourage applications developments. Patients will be targeted by application developers as

Table 2.5: HL7 v2, v3 and FHIR brief comparison table [83]

Field	**HL7 v2**	**HL7 v3**	**HL7 FHIR**
Year introduced	1987	2005	2011
Architectural Paradigm	Messages, Fields and records	Messages oriented	RESTful
Semantic Ontology	No	Yes	Yes
Learning Curve	Weeks	Months	Weeks
Specialized Tools	Yes	Yes	No
Specifications	Hundreds of Pages	Thousands of Pages	Hundreds of Pages
Implementation Examples	Yes	Minimum	Yes
Reference Implementations by HL7	No	No	Yes
Industry and Community Support	Strong	Weak	Too Now
Suitable for Mobile Devices	No	No	Yes
Cost	Fees	Fees	Free
Human Readable	No	Yes	Yes

potential users and try to develop applications to serve their needs, which lead for more patients' engagements. The FHIR has the promise to help patients who see multiple providers in different healthcare systems and facilities not to worry about having multiple portals to access their healthcare data. All personal health data could be presented into one personal health record using FHIR. This one personal health record could integrate personal health data when requested from different healthcare providers and different format to represent it

into a single personal healthcare portal to improve care coordination.

Healthcare providers might be able to customize their tools using FHIR to meet their professionals and specialty needs. They will be able to pull data from different healthcare systems to feed their healthcare systems with data to have more complete clinical picture to help in making decisions. This will help healthcare providers to save time and improve the quality of healthcare outcomes. Application developers and implementers can benefit from using trusted and familiar standardizing access, authentication, authorization, communication, exchanging and security tools, which help them to focus on core functions to make the field more attractive.

For healthcare organizations, it increases the areas for application developments and lower cost of interoperability and implementation, which gives the freedom for healthcare organizations to design specific applications to serve specific functions or use already developed applications in the market. Also, it gives healthcare organizations the freedom to develop and share applications to serve their needs. It also allows healthcare organizations to reduce the risk of vendor lock-in, which makes it easier to replace non- performing tools or systems with an alternative tools or systems.

2.9.7 FHIR Challenges

The promises of the FHIR HL7 standards comes with many challenges. As mentioned earlier, the FHIR framework is built around the concept of resources. Resources has a maturity levels ranging from 0 to 5 where 0 is lowest maturity level and 5 is the heights maturity level [73]. There are only 12 resources out of 119 with maturity levels 4 and 5. The remaining resources range from maturity level 3 to 0, see Table 2.6. This tells us that there is a long way to develop all resources to be in maturity level 5.

The FHIR needs a big support from stakeholders in healthcare industry to be developed, implemented, tested and used. The used protocols and standards in FHIR need to be mature, well-documented and supported specially when it comes to security, authentication and authorization. On the other hand; stakeholders need to agree on common value sets

Table 2.6: Number of resources based on the resources maturity levels [73]

Number of Resources Based on the Resources Maturity Levels	
Maturity Level	**Number of Resources as of June 2019**
Maturity Level 5	13
Maturity Level 4	1
Maturity Level 3	24
Maturity Level 2	42
Maturity Level 1	19
Maturity Level 0	49

to be used with the clinical data. Having multiple used value set will cause interpretation issues. One of the gaps in FHIR, it is not a real-time protocol unlike other HL7 real-time protocols.

FHIR is still a request based protocols, a user can get data only when it is requested. Electronic Health Record (EHR) vendors need to make changes to their current EHRs to adopt the use of FHIE, which might affect the workflow in healthcare organizations. Healthcare organizations will face many challenges when it comes to the issues of legality, laws, policies and privacy. They might need to create or modify current practices according to HIPPA and other laws.

What about Mapping Challenge? Specially with data stored on multiple sources and de-normalized data.

2.9.8 SMART on FIHR

Exchanging healthcare data among healthcare systems have many problems such as interpretations, communications and inflexible Electronic Health Records (EHR) architectures. Kenneth Mandl and Isaac Kohane from Harvard Medical School inspired by the big success

of applications developments in the smart phones industry based on well-defined platform using Application Programming Interfaces (API) [68]. Mandl and Kohane reasoned for EHRs systems to be able to run third-party applications with easy interpretations and implementations. In 2010, Harvard Medical School and Boston Children's Hospital started an interoperability project called Substitutable Medical Applications and Reusable Technologies (SMART) to develop a platform capable of running third-parties' medical applications able to run on many Electronic Health Records (EHRs). The project is funded by the Office of National Coordinator for Health Information Technology (ONC) and operated independently from other ONC's interoperability initiatives [68].

The vision of SMART on FIHR is to develop a platform capable of running third-party applications without expensive and complicated custom integration that allows adoption of common and interoperable data specifications as a key requirement. FHIR focuses on implementers to make implementations easy and fast to be adopted, managed and used. FHIR designed to support multiple paradigms and architectures such as mobile, tablet, PC devices to work on different web browsers and operating systems supported by different EHRs. SMART development team got an agreement with HL7 to publish FHIR as an open license agreement, so any one can access and use FHIR [68].

2.9.8.1 SMART App Gallery

Healthcare providers are limited to the available functions and tools that are offered by the EHRs used in their healthcare facilities. It is not economically practical to develop standalone tools that only runs on certain EHRs. The vision of SMART on FHIR allows healthcare providers to go beyond the limitation of their EHRs by developing tools run or multiple EHRs or choose tools from a pool of available tools by their liking. This will provide healthcare providers with the ability to search, install and run applications in a comparable situation of searching an application on Google Play store or Apple store. The SMART project developed their own application store and called it "SMART App Gallery" [84]. As of 2014, there was about 4 applications in the SMART App Gallery, while the number

increased in 2017 to 44 freely available applications to be downloaded and used. The App Gallery divides the applications into sections by their features such care coordination, data visualization, medication and other sections [84], see Figure 2.21.

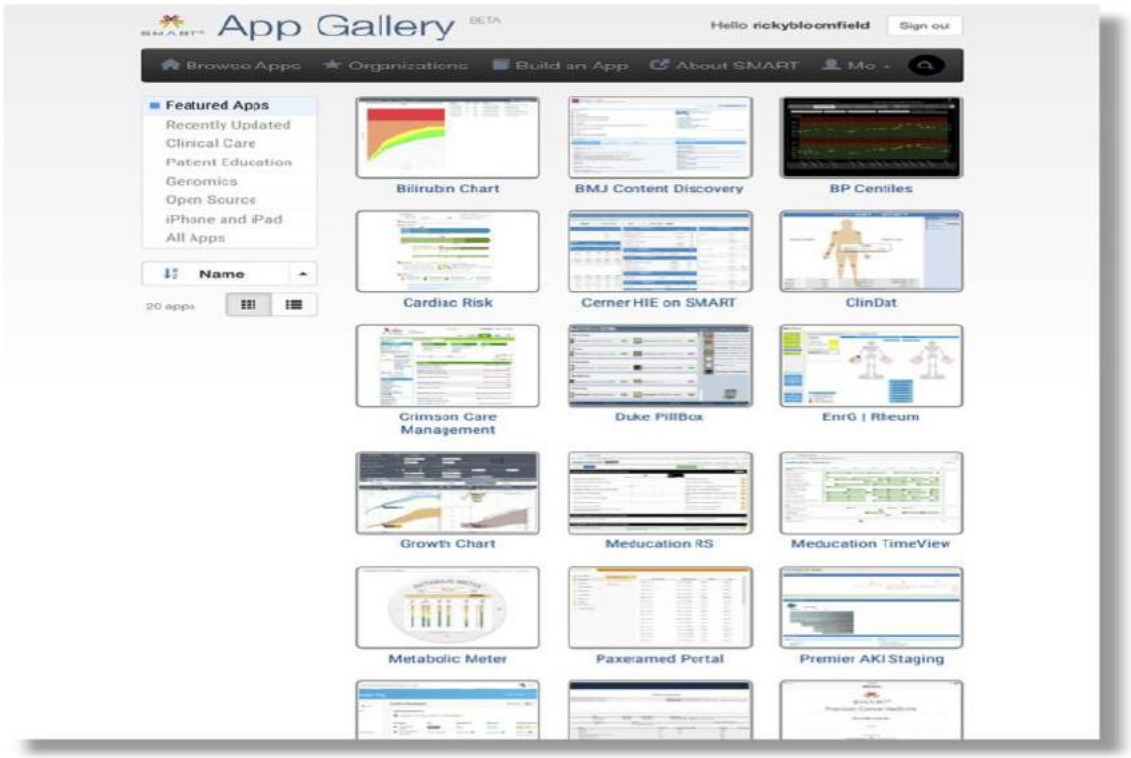


Figure 2.21: The SMART App Gallery [68].

2.9.8.2 SMART Sandbox

The Health Platform Services Consortium and iSalus Solution funded by SMART Health IT Project to develop SMART Sandbox as a free testing service to the community of medical applications developers [85]. The Sandbox is a virtual testing environment mimics a live EHR environment. The sandbox includes multiple sample datasets that could be used for application testing. Also, it has multiple application client libraries in Java Scripts, Pythons

and iOS to be used on SMART on FHIR to integrate tested applications to EHRs. The SMART Sandbox helps application developers with tutorials on how to provide reliable and secure authorization for applications access to EHRs using OAuth2.0 standard [85].

2.9.8.3 The SMART on FHIR Reference Implementation

The SMART on FHIR reference implementation is an open-source stack to reference demonstration and implementation SMART on FHIR specifications. SMART on FHIR development team has created a reference implementation of 3 components to ease and explain implementations to developers, the 3 components are:

1. Reference API Server: The server supports functions to create, read, update delete AND search FHIR sources. Also, the server supports access control of web services such as HTTP and OAuth2.0.

2. Reference Authorization Server: The server supports functions to use OAuth2.0 web authorization standard to authorize an access of a third-party web application to an EHR system.

3. Reference Apps Server: The server supports functions to allow web application to query well-specified data on a specific patient and present it in a structured way.

2.9.8.4 Challenges of SMART on FHIR

SMART on FHIR gains growing interest in the healthcare information technology and more stakeholders are showing interest to create applications that can run on any EHR supports FHIR standard, but FHIR comes with many challenges. FHIR faces many challenges on many levels like how to attract implementers, use of technology, provide common medical scenarios and security.

Focus on implementers: More specification needs to be written for target audience by providing terminology definitions, structure and implementer support for services. Expansion

on Sandbox to include more simple and complicated examples and tutorials on testing and validation methods on how to work with specifications and how to connect client servers with EHR servers is a challenge. Also, SMART on FHIR needs to provide more publicly data sets and test servers to cover more simple and complicated scenarios on medical cases to fit developers needs to include more functionality in medical applications.

Leverage existing technologies: Creating a comprehensive framework based on many web services and standards to exchange, integrate and share electronic health information among stakeholders in an elegant and uncomplicated way would be a challenge. Having many standards and technologies to make it work within one framework will make interoperability more complicated. SMART on FHIR still has a long way to pass its trail period and expand to cover more complicated medical scenario cases and needs [86].

Make content freely available: Make access, testing and tutorials free to everyone to expand the base of participants and attract more stakeholders and potential application developers to work on SMART on FHIR to increase the variety and number of medical web applications is a challenge. For now, FHIR and the used technology for web services are free to use, but when expanded on the SMART App Gallery and supported services would make it difficult to keep it 100% free in the future.

Demonstrate best practices governance: FHIR Work Group works on core infrastructure artifacts and setting objectives. FHIR Work Group created sub groups like methodology and management groups to coordinate work activities, resource creation and maintenance, work content and responsibilities [87]. Meeting the set objectives by the FHIR Work Group and keeping harmonization on multiple sub groups would be a challenge.

Keep common scenario simple: FHIR faces a challenge with keeping medical scenarios easy to be figured it out over short-time to potential users then to grow into the specifications for more complex scenario's. On the other hand, FHIR faces the challenge on how to go into more complex medical scenario in a way that potential users can get.

Provide documents readability: FHIR is designed to provide readability to machine and human. Based on web services, XML and JSON are used to provide machine readability.

Provide human readability format in a structured document would be a challenge when it comes to complicated medical scenarios.

Malware applications: The used web services and technologies used in SMART on FHIR provides the opportunity for plug-and-play platform like mobile application store; Google Play and Apple Store. This will raise the issue of malware applications and malicious code and how to block attackers from accessing or stealing information. The SMART App Gallery would face the challenge of developing control monitoring, create a team to test applications before approval and learn from other industries who faces similar challenges

Bigger community involvement and participations: SMART on FHIR needs to gain more support from stakeholders and attract application developers to produce more medical applications using FHIR to meet potential users' expectations and needs. SMART on FHIR needs support from stakeholders to involve with supporting workflow, interoperability and allow FHIR to be integrated by different EHRs.

2.10 Usability

Usability is recognizable as a trusted evaluation method during the design and development stages in the Human-Computer Interaction field. Usability is a way to measure how well a design fits the goal for potential end-users. The usability method helps developers achieve specific design qualities such as efficiency, effectiveness, and satisfaction.

There are many definitions to the term usability; the International Organization for Standards (ISO 9241-210) defines usability as "extent to which a system, product or service can be used by specified users to achieve specific goals with effectiveness, efficiency, and satisfaction in a specified context of use" [88]. This definition focuses on three usability measures, which are effectiveness, efficiency, and satisfaction. The effectiveness refers to the accuracy and completeness when potential users complete specific tasks and goals [88]. The efficiency relates to the used resources about the accuracy and completeness when potential users complete particular tasks and goals. Satisfaction refers to the freedom from discomfort and positive attitudes towards the use of the system, product or service [88], see Figure 2.22.

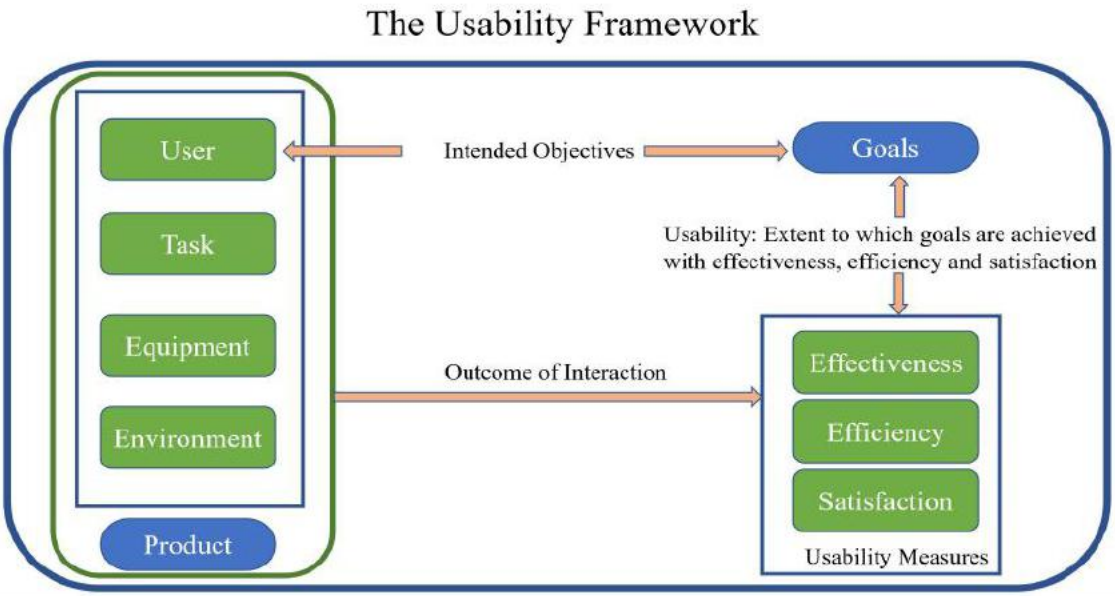


Figure 2.22: Usability Framework by ISO 9241-11 [89]

Nielsen defined usability as a quality attribute, where it measures how easily the users can interact with the interface [90]. Nielsen introduced five quality components, refer to Figure 2.23 for the five usability quality components:

1. Learnability: How easy for users to complete basic tasks by the first time?

2. Efficiency: After the users learn the design, how fast they could perform tasks?

3. Memorability: When users go back to the design after a time of not using it, how quickly can they memorize navigation to achieve proficiency?

4. Errors: There few factors to measure such as how many errors do users make when using the design? What is the severity of the error? How easy can they recover from the error?

5. Satisfaction: How pleasant are potential users with the use of the design?

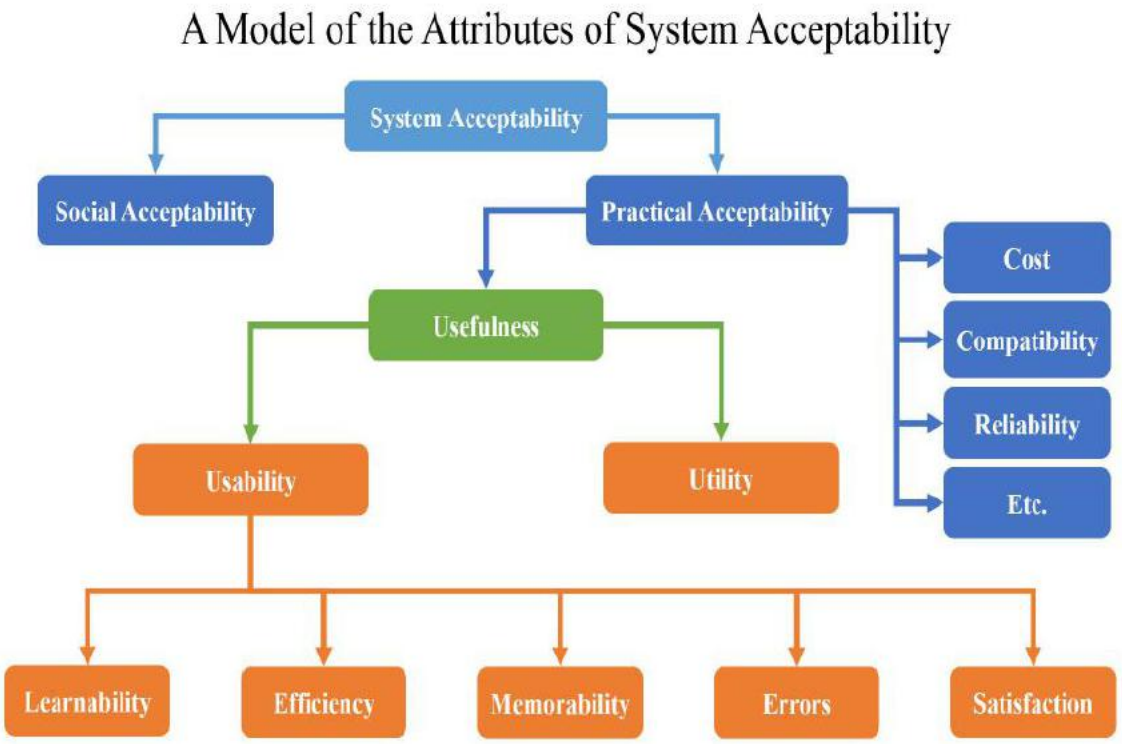


Figure 2.23: System acceptability model attributes [91] .

Shneiderman provided a similar definition to Nielsen's in 1998, but used different terminologies [92]. Shneiderman's definition focuses on five usability measures. The five usability measures are time to learn, the speed of performance, the rate of errors by users, retention over time, and subjective satisfaction. For a comparison between ISO, Nielsen and Shneiderman definitions of usability, see Table 2.7.

2.10.1 Benefits of Usability Testing

Usability testing provides an assessment of how easy it is to use the design by potential end-users. Usability testing helps developers to identify design problems or design expectation. Usability offers many benefits for the development team and potential end users. ISO-9241 standard from the International Organization for Standards (ISO) listed a variety of benefits

Table 2.7: Usability definitions by ISO 9241-210, Nielsen, and Shneiderman

ISO 9241-210	**Nielsen**	**Shneiderman**
	Learnability	Time to learn
Efficiency	Efficiency	Speed of performance
Effectiveness	Memorability	Retention over time
	Errors	A rate of errors by users
Satisfaction	Satisfaction	Subjective satisfaction

from utilizing usability such as improved productivity, enhanced user's well-being, avoidance of stress, improved accessibility, and reduction in user's risk of harm [88]. Although performing usability during the development stages adds more cost, it demonstrates a plethora of benefits as a return of investment, such as:

1. Improve user productivity by making the design easy to use [93].

2. Reduce user errors by fixing problems that potential users may face before releasing the design [93].

3. Reduce training costs by having an accepted design by potential end-users [93].

4. Improve savings by making changes in the preliminary stages during the developments process to achieve a better-quality design [93].

5. Reduce users support and help by providing friendly interface design and natural functions to use [93].

2.10.2 Usability Evaluation Methods

Usability evaluation methods are a set of methods employed to evaluate a design, prototype, or a system against usability criteria [94]. The usability evaluation method is a general term

used to refer to any evaluation method or technique used to perform usability evaluation during any development stage. The usability evaluation method is a set of precise steps and actions designed to collect data on users' activities while they interact with a design or a product to help developers to reach a certain level of usability.

A systematic mapping study on usability evaluation methods showed a significant increase of 766% in the use of usability evaluation methods between the years of 1997 and 2009 [95]. The result of this study act as a reliable indicator of how usability evaluation methods have gained an essential role in the previous decades.

There are many usability evaluation methods and many factors to classify said usability evaluation methods. There are some classifications which depend on the objective of the testing, and some that rely on the type of evaluation. The usability methods could be classified based on the evaluator type or source. The source could be a potential user, an expert in the usability field or usability models. The next section introduces a method of classifying usability evaluation methods.

2.10.3 Usability Methods Classifications

Usability evaluation focuses on how well potential users can learn and use a product to accomplish specific tasks. The focus extends to measure the satisfaction level of potential users when using a product. Usability evaluation methods are potentially divided or classified into two ways. One approach is to classify usability evaluation methods into expert-based methods, model-based methods and user-based methods, see Figure 2.24. In this dissertation; the focus is on the Think-Aloud evaluation method under the User-based method.

2.10.3.1 Expert-based Methods

The expert-based methodology includes methods that involve having experts evaluate and assess the usability of the interface to identify interface problems while also providing suggestions for interface improvement. There are many evaluation methods based on the Expert-based, but this dissertation will mention briefly only two expert-based evaluation methods.

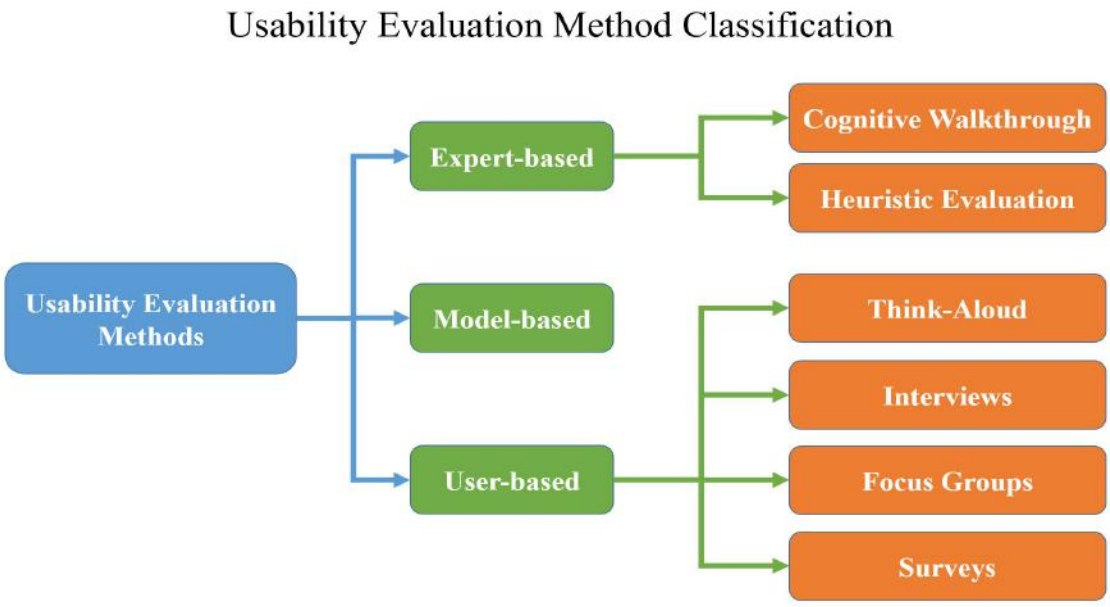


Figure 2.24: A usability evaluation methods classification.

1. Cognitive Walkthrough Method: Wharton and Rieman developed this method in 1994 [96]. The focus of this inspection method is understanding the design's learnability for either potential or new users [91]. In this method, experts simulate a user's goals by performing a set of tasks. This method requires at least usability or domain expert to walk through a series of tasks trying to mimic potential users and their way of thinking. Developers can apply this method in preliminary stages of the design process, and it is less popular than Heuristic evaluation [91].

2. Heuristic Evaluation: Nielsen and Molich developed this method in 1990 [97]. The focus of this popular inspection method is to identify the interface problems by usability domain experts [91]. This method requires expert reviewers to identify interface problems against a list of design principles (pre-defined set of heuristics) that does not follow the design principles [91]. Developers can apply this method in preliminary stages of the design process, and it is more popular than Cognitive Walkthrough.

2.10.3.2 Model-Based Evaluation Method

The Model-based evaluation method uses many models on how potential users would use a product or a design to perform predicted usability measures. The measures convey useful information about the relationship between completed tasks during the design and the tested design regarding time and task completion [98]. Many developers observe this method as an alternative way to implement an iterative process for developing a usable system and predict certain features of user performances [98]. Developers can apply this method in preliminary stages of the design process, but it is less popular than Heuristic and Cognitive Walkthrough evaluation methods.

Card, Moran, and Newell presented GOMS in 1983 [98, 99]. GOMS (Goal, Operators, Methods, and Selection Rules) model is an example of many Model-based evaluation methods. GOMS model is an information processing model that predicts how potential users perform specific tasks. This model attempts to capture user behavior and measure the procedural knowledge that a user must have to perform tasks on a product or a design [98, 99]. The tasks during the evaluation session is presented in a sequence, which evaluates the time for task completion; then the results verified against an agreed upon performance requirements.

2.10.3.3 User-based Evaluation Methods

User-based evaluation methods involve users for the designs targeted audience. There are many evaluation methods based on users such as Surveys, Interviews, Focus Groups, and Think-Aloud. Think-Aloud is the evaluation method used in this dissertation and is an evaluation method under the User-based evaluation method.

The design of the survey method centers around asking participants closed-ended questions constructed based on what the participant thinks of a specific task during the evaluation session, however this method is not meant for more in-depth questions. The purpose of surveys is to target large groups of participants at a low cost while also receiving feedback

quickly, however a disadvantage is that surveys result in limited answer clarifications.

The design of the interview method includes asking participants open-ended questions to collect more in-depth feedback on what participants think of a specific task. The interview method fosters an interactive setting between the interviewer and participant, which provides more space for the participant to express their opinions and feelings. The interview method provides rich and in-depth answers, which allows for follow-up questions. The interview method faces challenges such as interviewer training and participants recruitment in comparison to surveys.

The focus groups method is designed to ask participants open-ended questions in order to collect in-depth and diverse feedback and views on a specific topic which, in turn, helps uncover ideas and issues. In the focus group evaluation session, multiple potential users participate in a discussion session which centers around reflecting on the evaluated product or design. The focus group is an interactive group setting between the interviewer and participants, which provides more space for the participant to express their opinions and feelings among peers. The focus group method is useful to collect information on a specific subject over a brief period. Some of the challenges of focus groups are training moderators, note takers, and coding.

Surveys, interviews, and focus groups are all useful tools in system development, and aids in getting specific answers to questions such as how to get users' feedback. However, all three evaluation methods have a narrow view on how to discover what users want from a design or a system and as Nielsen stated this is unlike the Think-Aloud Method [91].

2.10.4 A high-level comparison of the usability evaluation methods

For high-level advantages and disadvantages of the three main Usability methods (User-based, Expert-based, and Model-based), see Table 2.8. Many of the user-based evaluation methods mentioned earlier such as surveys, interviews, focus groups, and Think-aloud. Table 2.9 provides a short comparison of the survey, focus group and interview methods. The Think-aloud evaluation method is covered in more details in the few coming sections.

Table 2.8: Advantages and disadvantages of the user, expert and model-based usability evaluation methods by Dillon [100].

Usability Method	**Advantages**	**Disadvantages**
User-based	Provides realistic usability estimation Provides a clear list of essential problems	Time-consuming Expensive with larger users' sample Requires prototype to perform a test
Expert-based	Cheap Fast	Expert skills and opinions affect the findings of the study
Model-based	Can be applied on interface specifications Provides a rigorous estimate of usability measures	Measures one component of usability Limited task applicability

2.10.5 Think-Aloud Evaluation Method

Lewis introduced the Think-Aloud method in the usability field in 1982 [101, 102]. This evaluation method was developed and based on the techniques and protocol analysis by Ericsson and Simon [103]. Figures in the usability field such as Nielsen and others improved the think-aloud evaluation method by making the usability evaluation a highly effective and cost-efficient way to test usability.

Think-Aloud is a method where participants articulate their thoughts, actions, and feelings while they are working on every specific task during the evaluation session. During an evaluation session, a single participant performs a single task at a time. The evaluator sits

Table 2.9: Comparison of some of the User-based evaluation methods

	Survey	**Focus Group**	**Interview**
Type of data	Quantitative	Qualitative	Qualitative
Cost	Cheap	More expensive than a survey	More expensive than a survey
Sample Size	Easy to increase the sample size	Harder to increase the sample size than surveys	Harder to increase the sample size than surveys
Type of Questions	Closed-ended questions	Open-ended questions	Open-ended questions
Follow-Up Questions	No	Yes	Yes
Depth of answers	Not deep	Deep	Deep
Type of answers	Objective	Subjective	Subjective
Number of Participants per evaluation session	Solo	groups	Solo
Feedback Diversity	Focused feedback	Diverse feedback	Diverse feedback

next to a computer with a participant; then asks the participant to complete a series of tasks by using the tested product or design.

A task in the Think-Aloud model is any task a potential user would perform by using the tested product or design. In the case of the prototype system the key tasks necessary for reporting a case of influenza using the EHR. The Think-Aloud evaluator instructs participants to think aloud while he/she performs a task and tell how they go, what are they trying to do, what are participants looking for, what is the decision participants going to take, why they decided on these decisions. The participants should verbalize their thoughts, actions,

and feelings while performing critical tasks. The Think-Aloud evaluator should encourage the participants to speak aloud when they go silent and to keep the focus on verbalizing the tested task itself.

2.10.6 Think-Aloud Benefits

The Think-Aloud has many benefits, for example effectiveness, because it reveals the hidden thoughts of the participant's internal planning and reactions to performing a task. Think-Aloud also expresses the reasoning behind the participants decision, which helps the evaluators with observations and analysis. Usability evaluators often identify problems with the usability design. Think-Aloud helps evaluators create a link between the participants thought process and decision making while performing a task and how the tested product or design is interacting with participants.

Another benefit of Think-Aloud is bringing potential users face to face with developers while they perform tasks, which convinces developers to make decisions faster. Every individual has their way of thinking; the diversity of participants' thinking benefits the evaluators by allowing them to reach a decision or to solve a usability problem. It helps evaluators reflect on the users' thinking and how they can learn from thinking aloud, what participants think about, and how they express themselves.

The Think-Aloud evaluation method is relatively fast because it requires a sample size between 5 and 9 participants and results in fast turn out. Also, it is a cheap evaluation method since there is not specific equipment required. The Think-Aloud evaluation method is easy to learn by potential evaluators. It is a flexible method because evaluators can apply this method in many stages of the development cycle such as prototypes, implementation, or a fully running system.

2.10.7 Think-Aloud Challenges

The Think-Aloud evaluation method has its challenges. Think-Aloud slows down the participants thought process because they need to speak out loud while performing a task, which

potentially leads to longer thinking times when performing a critical task. The slow thought process might prevent errors from happening in a standard work setting. The Think-Aloud might seem unnatural and distracting to many participants, which may affect the participants learning curve. Evaluators observe participants while they interact with unfamiliar design and verbalizing their thoughts, feelings, and actions during the evaluation session make the evaluation session unnatural environment for participants. This combination of factors might reduce the validity of the evaluation session finding.

Many participants might filter statements while they perform a task before saying it aloud and share it with evaluators. The filtered statements or comments defeat the purpose of the participants verabally relaying their thoughts.The Think-Aloud might be tiring to many participants since they must verbalize their thoughts, actions, and feelings while performing tasks.

Moderating a Think-Aloud evaluation session requires proper training in this technique to achieve the best results. Moderators might negatively affect the evaluation sessions flow if they try too hard to meet lab-style testing objective standards while they perform the session therefore, proper moderators training is required [104]. Finally, there is a chance that an evaluator is biasing user behavior. Answering and clarifying questions to participants might change users' behavior, so there is a need for proper evaluator training.

2.10.8 High-level Comparisons between some of the expert-based and user-based usability evaluation methods

Previously, a high-level comparison in Table 2.8 was introduced to compare different usability evaluation methods such as Expert-based, User-based, and Model-based. Then Table 2.9 compared several of the User-based evaluation methods such as interview, survey, and focus group. The following sections introduces the Think-Aloud evaluation method and some of the benefits and challenges. The following table, Table 2.10, compares a few of the popular evaluation methods by usability practitioners. It covers the Heuristic evaluation method and cognitive walkthrough from the Expert-based and compares it to the Think-Aloud evaluation

method from the User-based evaluation method.

Table 2.10: Comparison of some of the expert-based evaluation methods (Heuristic and Cognitive Walk-through) and a user-based evaluation method (Think-Aloud).

Heuristic Evaluation Method	
Type	Inspection [105, 106]
Stages	Design, testing, and release of application [105, 107]
When	The early stage of system design [105, 107]
Popularity	Most Popular [105–108]
Cost	Cheap [107]
Targeted Evaluators	Expert-based testing method [105, 107]
Aim of testing	Uncover potential usability problems [105, 106]
How	Expert-based evaluators inspect an interface against a list of pre-defined heuristic principles [105–107]
Sample size	Number of usability experts 3-5 experts or 2-3 double experts [107, 109]
User's background characteristics	The research team does not consider the user's background during the evaluation process [105, 107]
Input	List of predefined heuristics principles [105–107]
Output	1- List of violated heuristic principles [105–107] 2- Severity rating per usability flaw [107, 110]
Benefits	1- Quik [106] 2- Requires minimum memory load on evaluators [107] 3- Promotes comparability between alternative system designs [107] 4- Useful when time and resources are limited [107]

	5- Provides an estimate on the severity of usability problems [107] 6- No need to involve potential end-users [105, 107] 7- Detects many usability flaws [105, 107]
Limits	1- Unstructured approach [107] 2- Defined general heuristics [107] 3- Results affected by the number of evaluators, evaluator's perspectives and skills [107] 4- Hard to decide which guidelines hold in a particular context [106, 107] 5- Find less severe problems than more severe problems [107] 6- Evaluators are not the potential end users; evaluators only emulate potential end-users [107]
Cognitive walkthrough Evaluation Method	
Type	Inspection [106, 108, 111]
Stages	Design, testing, and release of application [107]
When	The early stage of system design [107]
Popularity	Less famous than heuristic evaluation [106, 107]
Cost	More expensive than Heuristic evaluation [107, 108, 111]
Targeted Evaluators	Expert-based testing method [107, 108, 111]
Aim of testing	Uncover potential usability problems through learnability by exploration [108, 111]
How	Experts simulate potential end user's tasks through structured and explicit guideline with no guidelines on how to navigate the system to simulate a novice user [107, 108, 111]

Sample size	2-4 evaluators [107, 111]
User's background characteristics	The research team considers the user's background during the evaluation process [107, 111, 112]
Input	List of representative tasks [107, 108, 111]
Output	List of potential usability problems at different user interaction stages [107, 108, 111, 112]
Benefits [107]	1- Structured approach [108, 111] 2- A rich analysis of usability flaws [108, 111, 112] 3- Finds more severe problems than less severe problems [111] 4- No need to involve potential end-users [111, 112]
Limits	[107]1- Long and tiresome [108] 2- Discourage explorations [111] 3- Requires more memory load on evaluators than heuristic evaluations [107] 4- Results affected by task specified descriptions, evaluator's perspectives and skills [111, 112] 5- No estimate on the severity of usability problems [108, 112] 6- Find fewer flaws than heuristic evaluation [111] 7- Evaluators are not the potential end users; evaluators only emulate potential end-users [106] [111, 112]
Think aloud Evaluation Method	
Type	Testing [106, 109, 110, 113]
Stages	Design, testing, and release of application [107]
When	Implementation stage[107, 109, 110, 113]

Popularity	Less famous than heuristic evaluation and cognitive walkthrough methods [106, 107]
Cost	More expensive than cognitive walkthrough [107, 113]
Targeted Evaluators	User-based testing method[107, 109, 110, 113]
Aim of testing	Developed to gather information on the cognitive behavior of individual performing tasks through: 1- Measure users' performances to do specific tasks [107, 109, 113] 2- Measure users' satisfaction through surveys and interviews [107]
How	End users perform a series of tasks while thinking out loud then evaluators would collect the thought in systematic ways then perform analyses to obtain a model of the cognitive processes when a user challenges a problem [107, 109]
Sample size	5-8 users [107, 113]
User's background characteristics	The research team considers the user's background during the evaluation process [107]
Input	1- Human factors of user's thoughts [107, 109, 110] 2- Clear pre-defined set of scenarios with specific tasks [107, 109, 110]
Output	1- Usability problems at distinct stages during the user interaction with the system [107, 109, 110] 2- Verbal protocols [107]
Benefits [107]	1- Vibrant source of data [106, 109, 110] 2- Very rich feedback on the usability problems [107, 109]

	3- Helps evaluators to identify and understands the source of problems [107] 4- Finds more severe problems than heuristic and cognitive walkthrough evaluation methods [107] 5- Provides a larger understanding of the user's mental model [107, 109]
Limits [107]	1- It should include potential end-users [107, 113] 2- Very expensive [107, 113] 3- Time-consuming [107, 113] 4- Subjective outputs [107, 109, 113] 5- Identify fewer usability problems than the Heuristic and Cognitive Walkthrough evaluations [107] 6- Results affected by evaluators' perspectives, skills, user group and task selections [107] 7- Evaluator interfere only when the user stops talking during the evaluation session, which makes it hard to maintain the session [107, 113] 8- To avoid bias; a minimum of 2 independent coders is required [107]

2.10.9 The popularity of Think-Aloud evaluation method in the usability field

Think-Aloud is gaining more interest among usability practitioners. In the usability field, the Think-Aloud method seems to be one of the most popular evaluation methods [114]. A survey conducted in Denmark in 2002 by 120 usability specialists. The results among the usability specialists in the survey study showed 100% of participants have at least a weak interest in using one or more theories in the usability field while no one has no interest in the use of theories in the usability field. Further results showed 75% of participants have

one or two favorite methods to use in the usability field. Results showed the Think-Aloud evaluation method as the most used evaluation method in a pool of 25 evaluation methods [115], see Figure 2.25 [115].

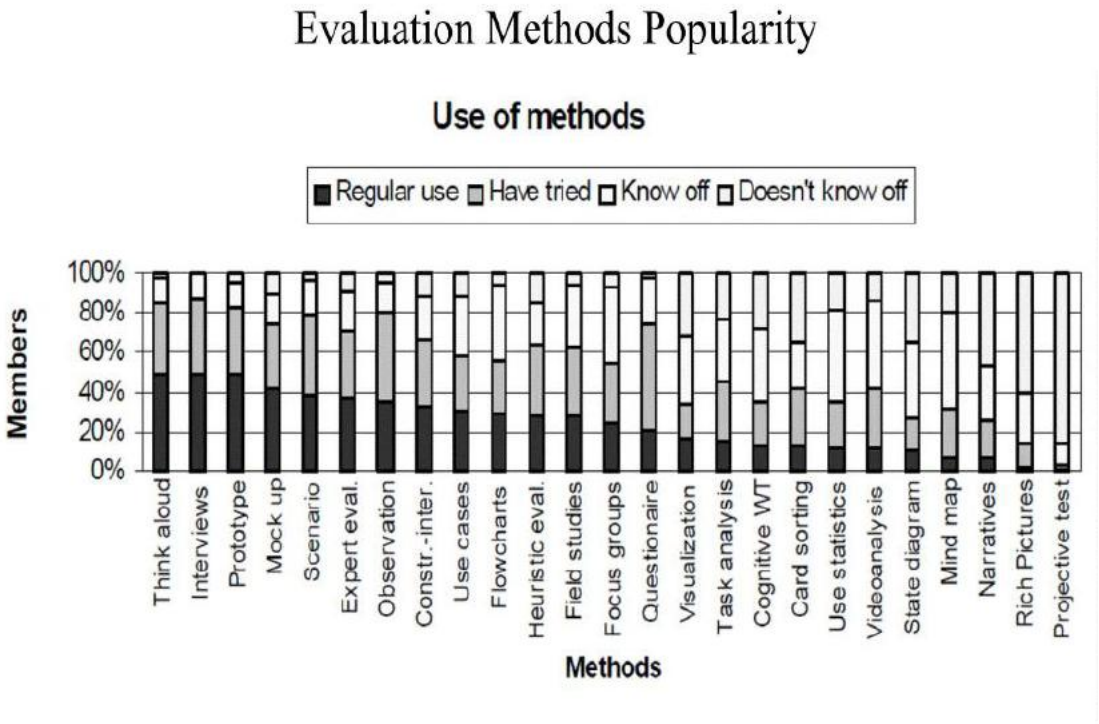


Figure 2.25: Usability specialists usage of evaluation methods (N=120) [115].

Another study published in 2012 exploring the Think-Aloud in usability testing. The study was based on an international survey with a sample size of 120 participants in the usability field [116]. The sample consisted of individuals who worked in the usability testing field from 1-2 years (5%) to more than ten years (37%) from a diverse range of background disciplines. The results showed 98% of participants use the Think-Aloud method at least sometimes and 71% on common bases. These findings supports another study, which ranked the Think-Aloud to be in the top three used evaluation methods by usability professionals in Sweden in 2004 [117].

2.10.10 Types of the Think-Aloud Method

As mentioned earlier in this chapter, the Think-Aloud evaluation method was developed based on the techniques and protocol analysis by Ericsson and Simon [118]. Scholars criticized the Think-Aloud approach by pointing out that thinking aloud is an unnatural process, and the act of thinking aloud might change the cognitive demands of the task [116]. In response to the criticism, Ericsson and Simon expanded on the Think-Aloud method to distinguish between two types of thinking aloud, concurrent Think-Aloud and retrospective Think-Aloud. There are other types of Think-Aloud such as Constructive Interaction method, but briefly will cover the concurrent and retrospective Think-Aloud methods.

The Concurrent Think-Aloud is the used usability evaluation testing method in this dissertation. There are other types of Think-Aloud in the usability field, but the next sections introduce only three types of Think-Aloud. The next sections also provides a graph that shows the popularity of Concurrent Think-Aloud type among usability practitioners.

The Concurrent Think-Aloud type requires participants to verbalize their thoughts, actions, and feeling while performing a task in real time. The moderator's goal is to encourage participants to think aloud in order to keep the flow of verbalization as they perform tasks. Many usability practitioners are attracted to the Concurrent Think-Aloud for many reasons [119]. It is easy and fast to implement where participants provide real-time responses during the evaluation session.

The Retrospective Think-Aloud type requires participants to verbalize their thoughts, actions, and feelings after performing a task, in contrast to the Concurrent Think-Aloud where participants verbalize their thoughts, actions, and feeling while performing a task in real time. This method is less popular among usability practitioners in comparison to the Concurrent Think-Aloud [119]. The Retrospective Think-Aloud type has some benefits, for example, participants can perform a task at their own pace. Retrospective Think-Aloud does not slow the process of performing a task since they do not need to verbalize anything while performing a task. Verbalizing thought, feelings, and actions after performing a task provide

an opportunity for participants to reflect on their experience, which provides clear feedback to the evaluators.

2.11 Participants satisfaction measurement tools

Participants satisfaction is an important way to measure the usability of a product or design. Two questionnaires are used to measure participants satisfaction in this study. The first questionnaire called After Scenario Questionnaire (ASQ), (see Appendix A.1), and the second questionnaire called System Usability Scale (SUS) Questionnaire, (see Appendix A.2). The ASQ questionnaire is used to measure the satisfaction per task while the SUS questionnaire is to measure the users satisfaction with the tool [120, 121].

The ASQ was first introduced by Lewis in 1991 [120]. This questionnaire is to measure the satisfaction level on each task on a numbered scale from Strongly Disagree to Strongly Agree. The 3 questions are:

1. I am satisfied with the ease of completing the tasks in the scenario.

2. I am satisfied with the amount of time it took to complete the tasks in this scenario.

3. I am satisfied with the support information (online help, messages, documentation) when completing the tasks.

The three questions are developed to cover three fundamental areas of usability. The first question was developed to touch on the effectiveness, while the second question was developed to touch on efficiency. All the three questions were developed to touch on the users satisfaction per task.

The SUS questionnaire was developed by Brooke in1986, and it consists of ten questions [121]. Half of the 10 questions are worded positively, and the other half of the questions are worded negatively. The SUS questionnaire helps to measure the ease of use of the tool on a numbered scale ranged from strongly disagree to strongly agree [121–124] , see Figure 2.26 . The SUS questionnaire has been tried and tested throughout decades; usability

practitioners consider the SUS a reliable method for products usability evaluations [125]. The SUS questionnaire used in many related health evaluation studies to measure users satisfactions [126–128].

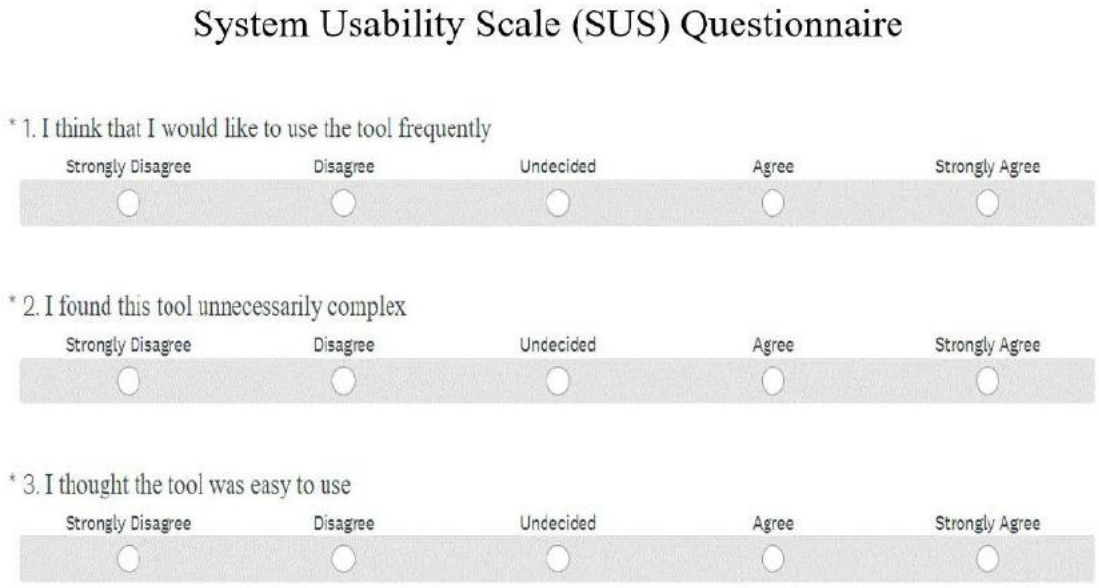


Figure 2.26: Some questions of the System Usability Scale (SUS) questionnaire .

The SUS questionnaire is quick, easy to use, easy to understand and provides a single score on a fixed scale for analysis [129]. A five-point scale of agreement are used to rate each question by participants. The SUS questionnaire used by the usability practitioners to assess the usability of a product easily for several reasons. The SUS questionnaire focuses on areas of participants experience while performing tasks such as attractiveness (Is the product or design attractive?), expectations (Does the product or design meet the users expectation). All the ten questions were developed to touch on the users satisfaction with the tool.

2.12 Summary

This Chapter provided an overview of the Influenza types and subtypes, then provided an overview of the Novel Influenza and history of pandemic novel influenza mortality in the last 120 years. Also, the Chapter provided data categories and sources of influenza surveillance. The Chapter provided distinct types of documentations used in communicable diseases reporting process. The purposes of case report forms and reporting guidelines, benefits and challenges of reporting Novel Influenza cases were covered in this Chapter. Then, detailed challenges on healthcare provider level, reporting process level, and reporting recipient level were covered to give a better picture of the general challenges with communicable disease reporting process.

Surveillance system quality indicators such as completeness and timeliness were covered in detail. Many studies were introduced to discuss the importance of these two indicators and how they can impact the quality of reporting process. Continuous evaluation of quality indicators such as completeness and timeliness can improve any surveillance system quality and outcomes.

The Chapter covered the purpose and main objectives of the Meaningful Use Program. The objective of this program aligns with the objective of the work of this dissertation by providing and developing ways to exchange case report form on communicable disease and the use of HL7 standard. Also, the Chapter covered many on-going projects that shares the same objectives of the Meaningful Use Program and the work of this dissertation.

The Chapter covered the Clinical Document Architecture (CDA) standard, which is an HL7 standard. The CDA standard designed to make the exchange of medical documents such case report forms between healthcare stakeholders easier. The Meaningful Use Program requires the use of the CDA standard to exchange medical documents and the Centers for Disease Control and Prevention (CDC) recommends the use of the CDA standard. The Chapter introduced the CDA structure and hierarchy and a high level example of developing a CDA template.

The Chapter covered the Fast Health Interoperability Resources (FHIR) standard, which developed by HL7. This standard is still under development but comes with many promises to overcome many of the challenges in interpretation and integration. The Chapter covered many topics on FHIR included main components, framework, resources structure, used technology, brief comparisons to few HL7 standards, SMART on FHIR. Also, The Chapter covered benefits and challenges of using FHIR and it needs more improvements to help developers and stakeholders to widely accept the FHIR standard.

Finally, the Chapter covered many aspects on the usability and how it could benefit the work of this dissertation. Many definitions of the usability were introduced to help understanding the scope and depth of the usability definition. The usability framework introduced the five quality components in detail. Then, the usability benefits were introduced along with different usability evaluation methods and classifications. The classification method covered a way to classify different usability evaluation methods. The Think-Aloud evaluation method was introduced in detail. Benefits and challenges of the Think-Aloud method discussed. The popularity of the Think-Aloud method in the usability field and types of the Think-Aloud method was discussed in this Chapter and will be the method used in Chapter 5 (Aim 3).

Chapter 3

AIM 1 – PROBLEM FORMULATION – RESULTS AND ANALYSIS

This chapter defines the used methods to collect and code data to part of Aim 1 in this dissertation. Also, this chapter defines the coding instruments, data sources, data collections and analyzes techniques. The targeted sample in this study is to include all case report forms and reporting guidelines that are used in all the 50 states, see Section 2.2 , along with the CDC to report novel influenza type A viruses from section 2.1 .

Mixed of qualitative and quantitative techniques are used to code and analyze the collected documents to identify the similarities and differences between the required data to be collected in reporting guideline and the actual data collected by a case report form within one state. The same principle is applied to compare the similarities and differences between all the states that are included in this study to cover a part of Aim 1 to identify gaps in novel influenza reporting process. Identifying the similarities and differences between states to report novel influenza helps us to understand the process and required data in reporting novel influenza cases from healthcare providers to healthcare authorities. This chapter is to summarize the collected data, analysis and present selected tables and figures to present the findings.

3.1 Document Collection

A search was conducted on the U.S. states public health departments websites to collect official contact information. The researcher crafted an invitation email to be sent out to all potential participants on individual levels. All 50 states have been contacted via email, where I used informative subject for the invitation email, introduced myself and supervisor with

clickable links, project, importance of the project, make clear what is being requested, asked participants to participate voluntarily and ensure confidentiality, explained how participants can fulfill the request, provided full contact information to clarify any issues before or after participating and finally expressed his appreciation.

Some states use a disease-specific case report form to report novel influenza cases while others use a general diseases case report form such as Disease Case Report or Report Card. The states health departments have been asked to provide the official case report form whether it is a specific case report form along with the used reporting guideline for novel influenza reporting or a general case report form and reporting guideline if the state has no specific case report form for novel influenza reporting. Some states have outdated or multiple documents in their websites related to novel influenza case reporting and to avoid any confusion or the use of wrong documents, the inclusion and exclusion criteria were developed.

3.1.1 Inclusion and Exclusion Criteria

To cover the document collection for Aim 1, criteria have been created to include and exclude states in this study. Any state matches the inclusion criteria included in this study while any state matches the exclusion criteria was removed from this study. The inclusion criteria are the following:

1. Have both documents; the official case report form, and the reporting guideline for novel influenza reporting.

2. The case report form could be specific to a novel influenza case or a general notifiable condition case reporting form. A notifiable condition is a disease that is required to be reported to governmental authority by law.

3. The used documents must be provided by the state's department of health

The exclusion criteria are the following:

1. The state's health department provided no response to the invitation and follow-up emails to participate in the study

2. The state's health department provided no or only one of the requested documents, either case report form or reporting guideline

3. Any state uses only phone calls to report novel influenza will be excluded from the study

4. Any redundant document is being excluded from this study

All the 50 states have been contacted to participate in this study to represent the population of the study and to limit the influence of outliers. In the initial invitation email, participants received information regards the researcher and the purpose of the study. Different methods of contact such as email address, mail address and fax number were provided to the states' departments of health.

In the case of no response to the initial invitation email, a reminder email within 3-4 weeks of the initial invitation email was sent. In the case of no response to the reminder email, that state was not included in this study, see Figure 3.1 for the primary documents collection flowchart.

After many rounds of contacting and follow-ups, only 33 states provide the required documents to be included in this study based on the inclusion and exclusion criteria. Out of the 33 states, there were five states uses the CDCs case report form and the reporting guideline. This makes the number of unique states 28 different states with unique case report forms or reporting guidelines plus the states that uses the CDC case report form and reporting guideline. This makes the number of comparison 28 states plus the CDC when counting the other five states as one state since they use the same documents as the CDCs documents use for reporting with no other requirements for reporting, see Figure 3.2 for the PRISMA flowchart of the included and excluded states in this study.

Based on the inclusion and exclusion criteria, 17 states were excluded from the study. There are many reasons to exclude the 17 states. Some of the excluded states provided no documents and some states provided only one of the two required documents. Having the required documents serves the purpose of comparing the two documents to identify gaps. Some of the excluded states have their required documents posted online with multiple documents for the same purpose of reporting which were internally inconsistent. To avoid any confusion, the states were contacted and asked to provide their single set of most updated and current required documents, Section 3.5 covers more limitations. To see a map of the included and excluded states in this study, see Figure 3.3 . The population in the 33 included states in this study covers about 82 % of the U.S. population based on the US Census Bureau as of July 2017 [130].

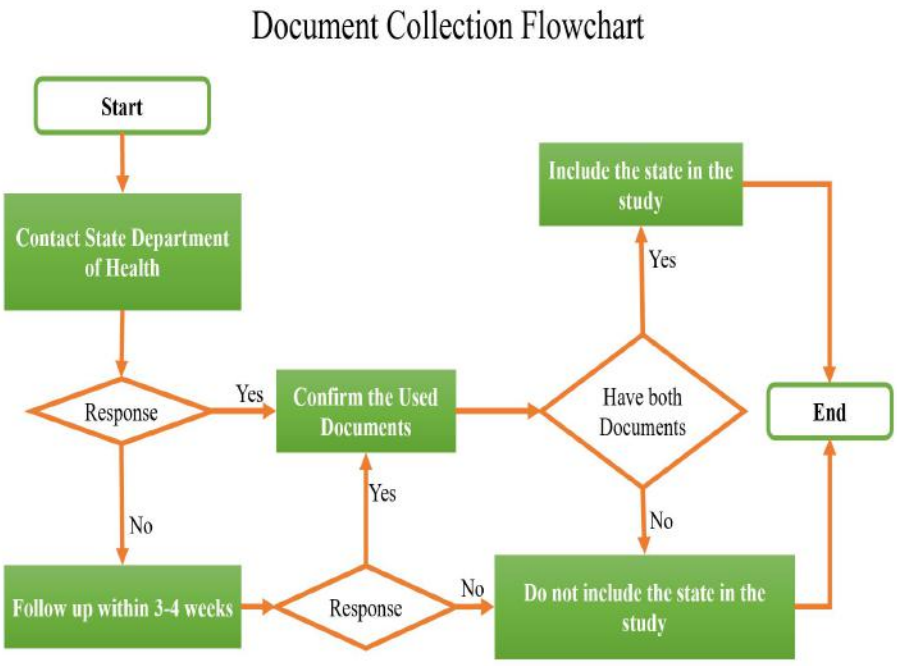


Figure 3.1: States' document collection flowchart.

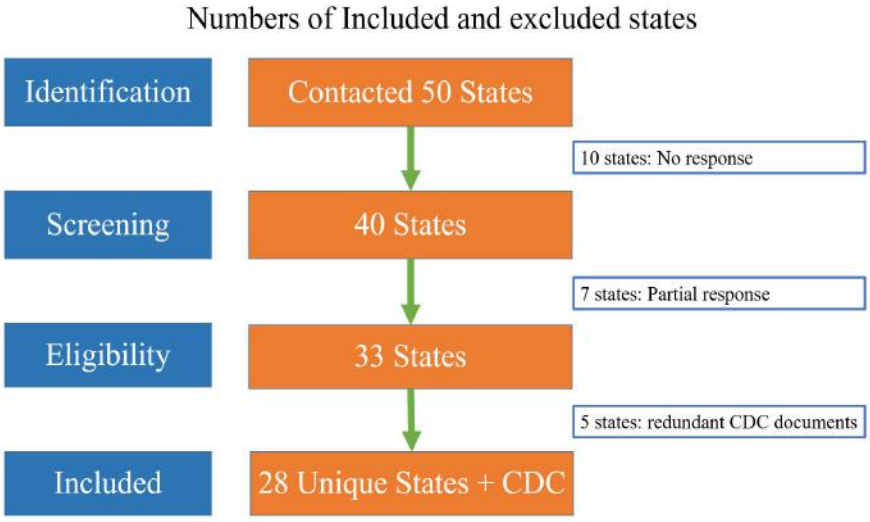


Figure 3.2: PRISMA flowchart for the included and excluded states.

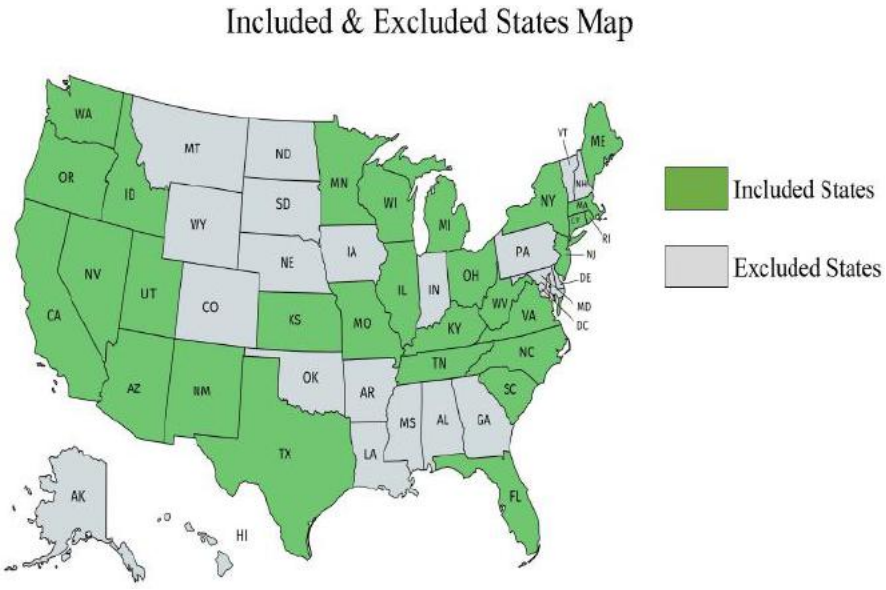


Figure 3.3: Map of the included and excluded states.

3.2 Data Coding

The collected case report forms and the reporting guidelines in each state were coded and compared to identify the gaps between the case report forms and reporting guidelines through capturing the presence or absence of data fields in the coded documents. An example of a gap could be a data field that is included in the reporting guideline to be collected such as patient's contact number, where there is no such data field in the case report form to be collected for the patients contact number. Another example could be a data field in the case report form for a medication dosage and no corresponding mention in the reporting guideline for the medication dosage. The similarities and differences (gaps) across the coded documents (case report forms and reporting guidelines) of all the included states are highlighted in this study.

ATLAS.ti (Version 7) was used to mark-up and organize data fields in the case report forms and reporting guidelines. Microsoft Excel (Version 2011) and RStudio (Version 0.99) were used for the quantitative data analysis. Atlas.ti provides tools to capture and analyze structured and unstructured data systemically. Atlas.ti is used to identify data elements in the blank case report forms and the text in the reporting guidelines from the primary data materials, case report forms and reporting guidelines. Although Atlas.ti is typically used for qualitative research, it has been utilized to link descriptive codes to the specific text and form regions. We further utilized code families to group codes representing data fields into semantically similar collections.

3.2.1 Hermeneutic Unit and Primary Documents

By using Atlas.ti version 7, the Hermeneutic Unit has been created where all the project's documents, codes and any associated file saved. The Hermeneutic Unit is the main workspace area and main editing tools for the documents to be analyzed in the Atlas.ti, see Figure 3.4 for the Hermeneutic Unit (HU). All the case report forms and reporting documents to be analyzed were uploaded into the primary document manager. These documents are called

the primary documents, see Figure 3.5 for primary document manager.

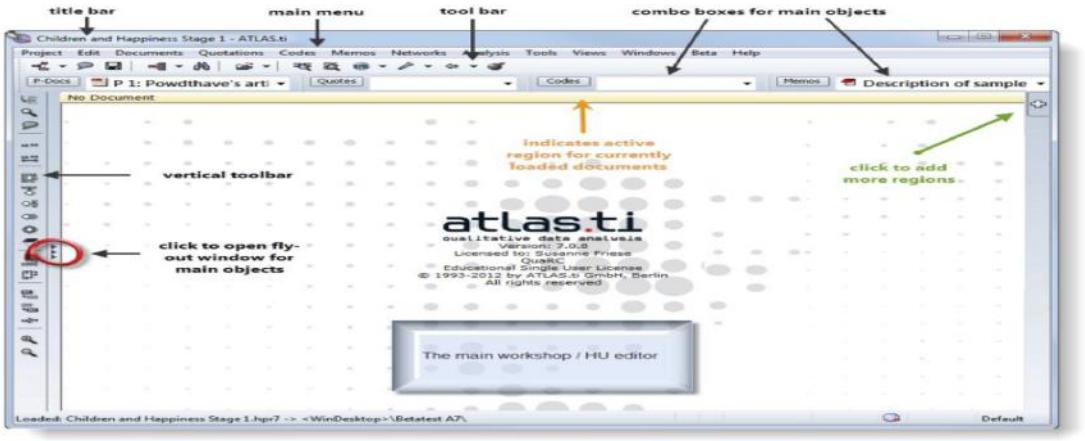


Figure 3.4: The Hermeneutic Unit (HU) [131].

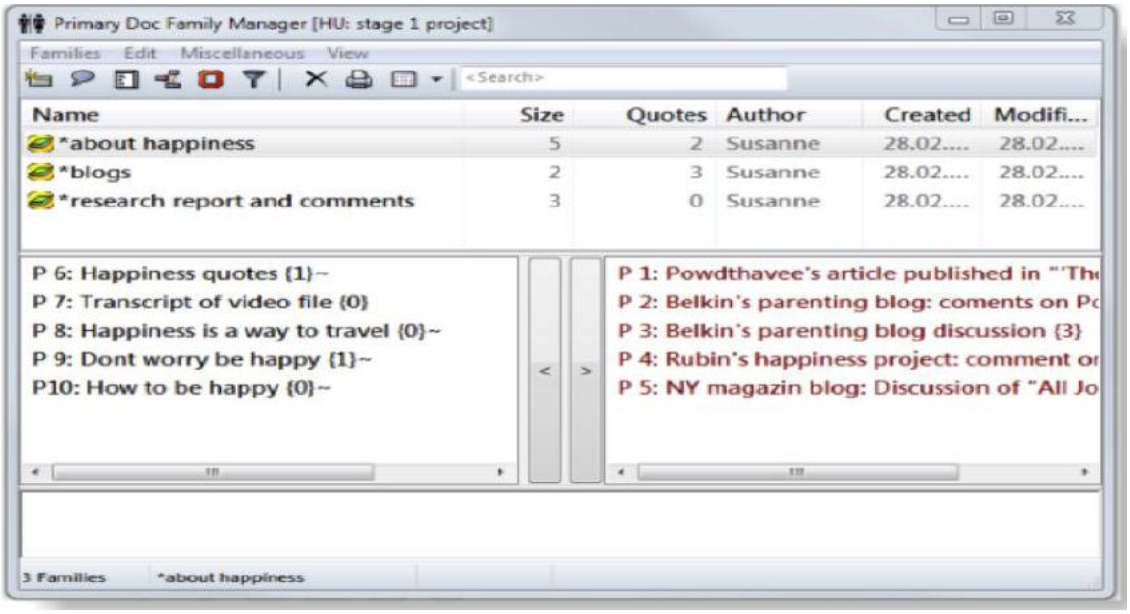


Figure 3.5: The Primary Documents Manager [131].

3.2.2 Code Families

All the documents were uploaded into Atlas.ti as primary documents. Each document was reviewed and coded into a set of code families. The code families were developed during the preliminary coding process by the primary researcher in the first few rounds of coding. Then, the developed code families were discussed with several researchers to develop a final set of agreed on code families. The final set of code families consist of 12 Code families where data fields were reviewed by the primary researcher for any error, such as similar or duplicate codes, see Figure 3.6 for all the code families.

The unique coded elements or data fields in all documents from all the included states are 257 unique data fields distributed in 12 code families. Demographic code family contains data fields relevant to the case such as patient's name, address, age, date of birth. Prognosis code family contains data fields relevant to the case's outcomes such as death and hospitalization data. Reporting code family contains data fields relevant to the person who is required to fill out the case report and send it to the public health authorities such as name and address. The results chapter will cover more details on the unique data fields in each code family.

3.2.3 Creating Code and Code Manager

The two primary data fields sources for this study are case report forms and reporting guidelines. Most case report forms and reporting guidelines are broken into sections where the sections could be structured similarly or varied from a state to another. A demographic information section usually appears in all case report forms. On the same perspective, not all the case report form requires traveling information section. Data fields such as diagnosis, treatment, lab test results and the date of onset of illness could be required to be collected by guidelines and case report forms. Some guidelines and case report forms require data on patient hospitalization admission (when occurring) and data on facility and healthcare providers.

To code a primary document, select the data section to be coded then a code name would

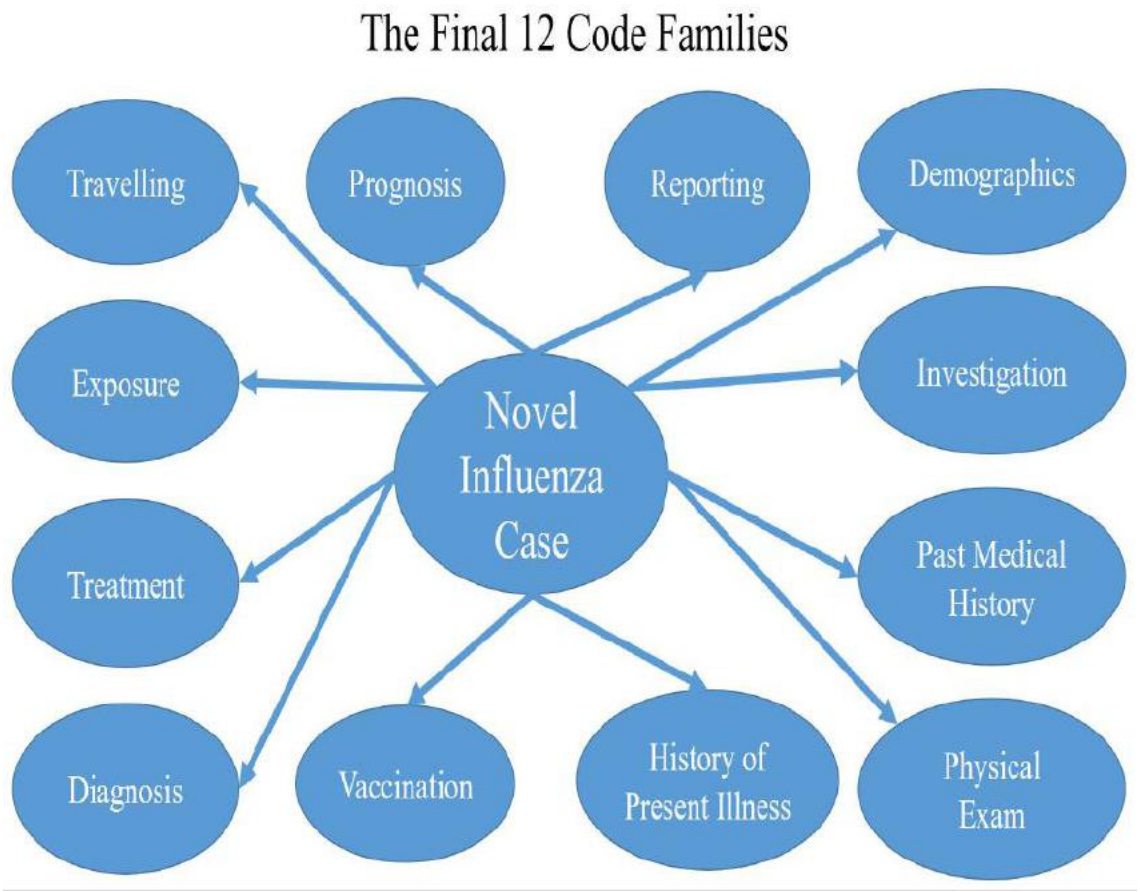


Figure 3.6: The final 12 code families.

be entered. The new code would be saved in the code manager. See Figure 3.7 for the coding menu and Figure 3.8 for the code manager. The same principle has been applied to code all the primary documents. Figure 3.9 shows multiple codes from one primary document.

3.2.4 Query & Co-occurrence Tools and Files Exports

The query tool is used for complex search requests, this tool is used to retrieve codes and build new results based on combinations of codes using one or many operators (AND, OR, NOT, etc.) that define condition(s) that a code must meet to be retrieved, see Figure 3.10.

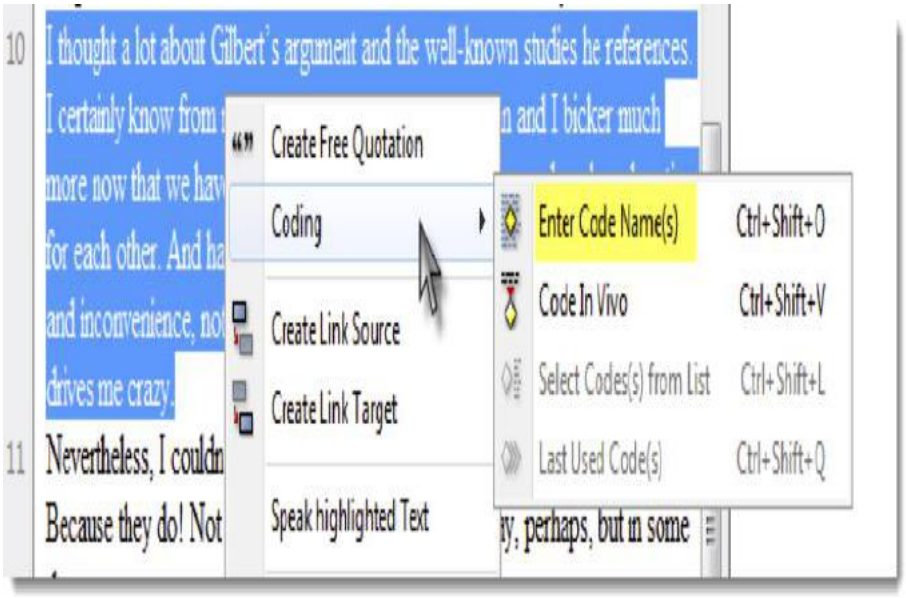


Figure 3.7: Coding menu to create new codes [131].

Figure 3.8: The code manager [131].

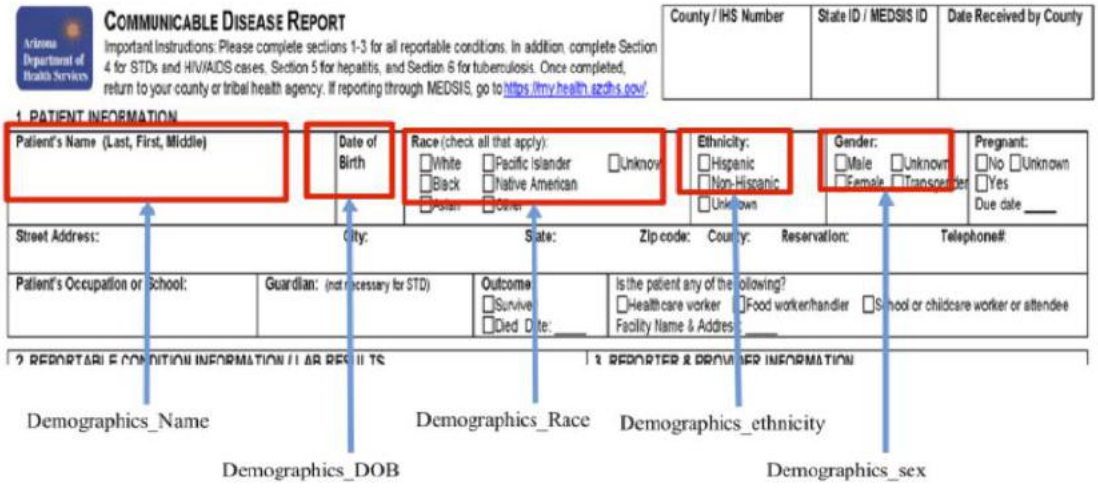


Figure 3.9: A primary document coding example.

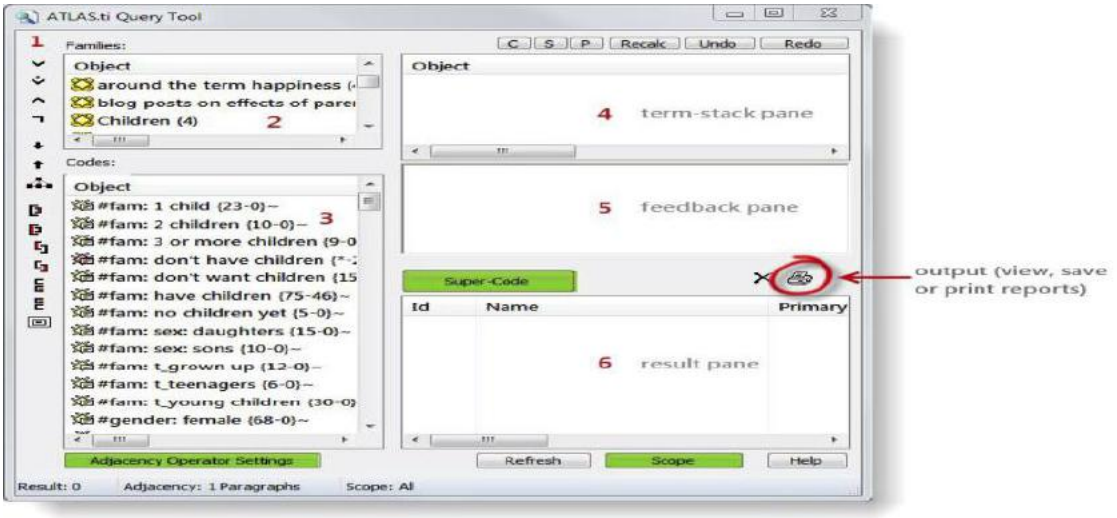


Figure 3.10: The query tool manager [131].

The co-occurrence explorer tool in this study is used to produce outputs in a table view. Data fields or codes are extracted from the primary documents into tables of rows and columns. The extracted data fields were arranged into rows (code families) and columns (states' names). The co-occurrence explorer tool is used to calculate the frequency of co-occurrence of codes across documents and provides aggregated counts based on code and the primary documents, see Figure 3.11.

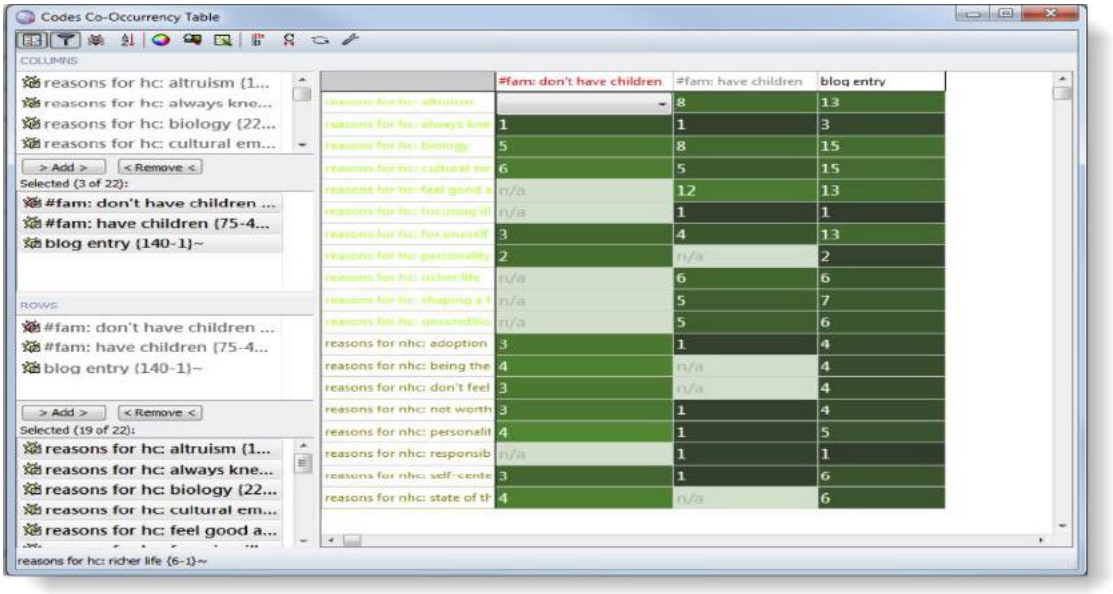


Figure 3.11: Results of a co-occurrence query [131].

The lists of the queried data and the co-occurrence frequency have been exported in excel using Comma-Separated Values (CSV) format. Then the data has been exported to into CSV format to run standard statistical tests using RStudio and EXCEL and plotting to determine possible categorical outcomes. The analyzes help to specify a list of gaps between case report forms and reporting guideline within and across all the included states in this study. Also, it helps to specify the most used data fields and most intersected data fields in case report forms and reporting guidelines, for more details go to the results chapter.

3.3 Results and Analysis

As mentioned earlier, the generated Co-occurrence tables contains the coded data fields for the included documents in this study. Across the included 28 states in this study, there were 257 unique coded data fields distributed in 12 code families. Each code family contains relevant data fields covers similar data. Each co-occurrence table contains selected interesting combinations of data fields and states.

A comparison among the coded 257 data field shows 4 possible categorical outcomes. The possible categorical outcomes are given numbers from 0 to 3 for each unique coded data field. The possible 4 outcomes are

0. Data field is absent in both documents, the case report form and reporting guideline

1. Data field is present in only the case report form

2. Data field is present in only the reporting guideline

3. Data field is present in both documents, the case report form and reporting guideline

For more information on the 4 possible distribution outcomes (0 to 3) of the 257 coded data fields, see Figure 3.12 and Table 3.1 .

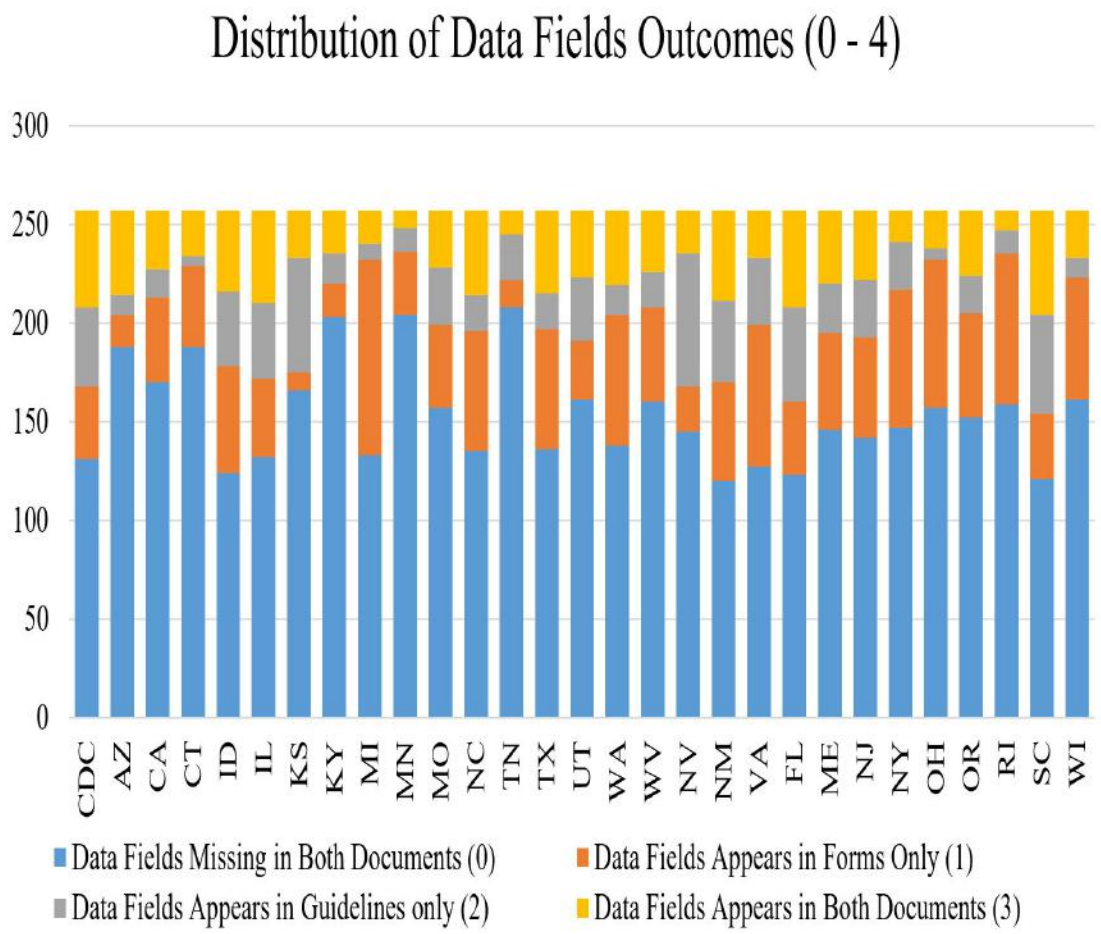


Figure 3.12: The 4 possible outcomes of the coded data fields per state.

Table 3.1: Distribution of the 4 possible outcomes (0 to 3) on the 257 coded data fields within case reports form and reporting guideline per state.

Data Fields Occurrences

Index	**State**	**Data Fields Missing in Both Documents (0)**	**Data Fields Appears in Forms Only (1)**	**Data Fields Appears in Guidelines only (2)**	**Data Fields Appears in Both Documents (3)**	**Total**
1	CDC	131	37	40	49	257
2	AZ	188	16	10	43	257
3	CA	170	43	14	30	257
4	CT	188	41	5	23	257
5	ID	124	54	38	41	257
6	IL	132	40	38	47	257
7	KS	166	9	58	24	257
8	KY	203	17	15	22	257
9	MI	133	99	8	17	257
10	MN	204	32	12	9	257
11	MO	157	42	29	29	257
12	NC	135	61	18	43	257
13	TN	208	14	23	12	257
14	TX	136	61	18	42	257
15	UT	161	30	32	34	257
16	WA	138	66	15	38	257
17	WV	160	48	18	31	257
18	NV	145	23	67	22	257

19	NM	120	50	41	46	257
20	VA	127	72	34	24	257
21	FL	123	37	48	49	257
22	ME	146	49	25	37	257
23	NJ	142	51	29	35	257
24	NY	147	70	24	16	257
25	OH	157	75	6	19	257
26	OR	152	53	19	33	257
27	RI	159	76	12	10	257
28	SC	121	33	50	53	257
29	WI	161	62	10	24	257

The Demographic code family contains 33 unique coded data fields relevant to the case demographic information (name, address, age, date of birth, sex, etc.). The Diagnosis code family contains 15 unique coded data fields relevant to diagnosis name and date (diagnosis name, influenza type, diagnosis date). The Exposure code family contains 30 unique coded data fields relevant to case's physical contacts to, infected or suspected people, animal and public venues (exposure to ill person, exposure to suspected ill person, exposure to an animal).

The History of Present Illness code family contains 6 unique coded data fields relevant to the symptoms and signs that related to the reported novel influenza (symptom name, sign name, onset date). The Investigation code family contains 30 unique coded data fields contains lab test and X-rays data (lab name, specimen collection data, lab test results, imaging date). The Past Medical History code family contains 49 coded unique data fields relevant to the case general health and risk factors (Allergies, history of chronic diseases, pregnancy risks). The Physical Exam code family contains 3 unique coded data fields relevant to the Body Max Index (weight, height, BMI). The Prognosis code family contains 39 unique

coded data fields relevant to the case's outcomes (status and hospitalization data).

The Reporting code family contains 35 unique coded data fields relevant to the person who is required to fill out the case report and send it to the public health authorities (name, address, facility name, contact information). The Traveling code family contains 2 unique coded data fields describing travel movement data (if relevant). The Treatment code family contains 6 unique coded data fields describing prescriptions data (medication name, frequency, start and finish date). The Vaccination code family contains of 10 unique coded data fields relevant to the history of patient's vaccination (vaccine name, date, type), see Figure 3.13.

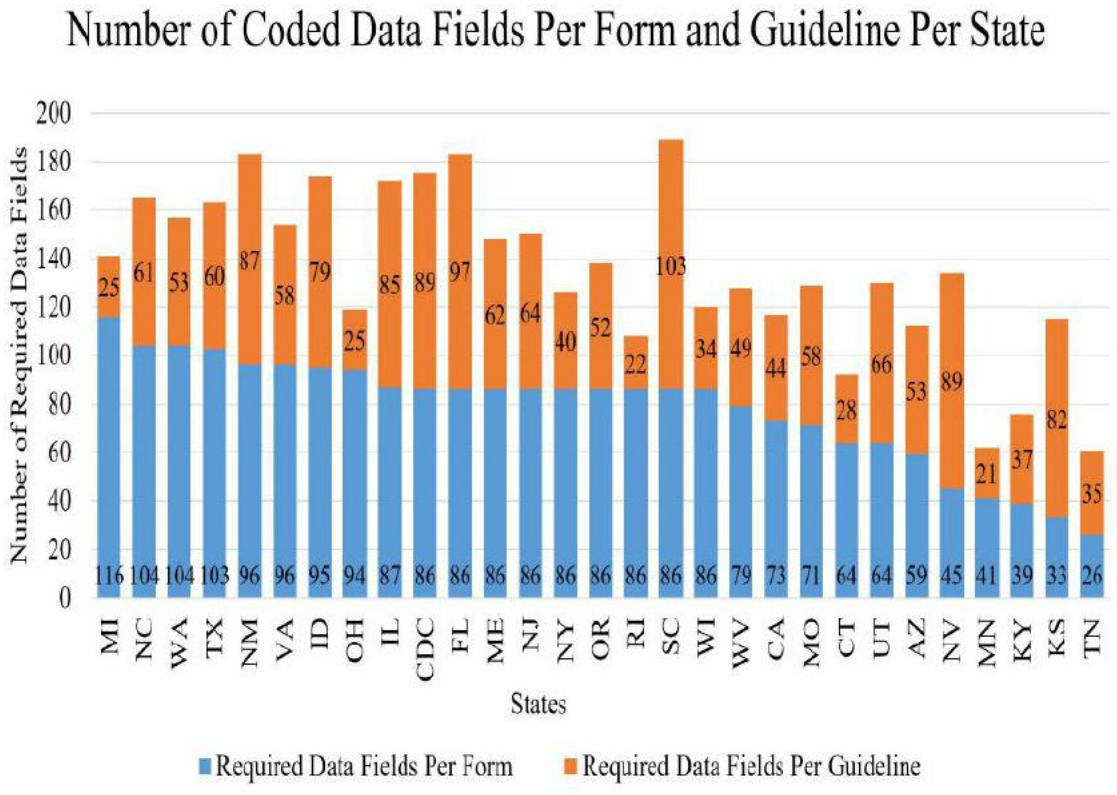


Figure 3.13: Number of unique coded data fields per family in all the included states.

Most of the required data fields by reporting guidelines are required to be collected by case report forms, but with more details by case report forms. Michigan (MI) state has the highest number of required data fields to be collected in a case report form with 116 data fields distributed in 11 code families while MI state's reporting guideline requires only 25 data fields distributed on 6 code families. The 116 data fields were focused mostly on the Past Medical History, Prognosis, and demographics code families. North Carolina (NC) and Washington (WA) states have the second highest number of required data fields to be collected in a case report form with 104 data fields distributed in 11 code families in NC and 12 code families in WA. NC state's reporting guideline requires 61 data fields distributed on 11 code families while WA state's reporting guideline requires 53 data fields distributed on 10 code families. The 104 data fields in NC and WA states were focused mostly on the exposure and prognosis code families, see Table 3.2.

On the other hand, South Carolina (SC) state has the highest number of required data fields to be collected in a reporting guideline with 103 data fields distributed in 11 code families while MI state's reporting guideline requires 86 data fields distributed on 12 code families. The 103 data fields were focused mostly on the Exposure and Prognosis code families. Florida (FL) has the second highest number of required data fields to be collected in a reporting guideline with 97 data fields distributed in 12 code families while case report form requires 86 data fields distributed on 12 code families. The 103 data fields in SC and FL states were focused mostly on the exposure and prognosis code families, see Table 3.2.

As mentioned earlier, most states collect more data fields in case report forms than reporting guidelines. Past Medical History code family in case report forms in Rhode Island (RI), Ohio (OH) and Michigan (MI) states require data fields on the Past Medical History to be collected while the corresponding reporting guidelines requires no data fields to be collected on the Past Medical History. The same examples apply on the Exposure code family, where Connecticut (CT) and Rhode Island (RI) states require data fields to be collected on the Exposure code family while the corresponding reporting guidelines requires no data fields to be collected on the Exposure code family, see Table 3.2.

Table 3.2: Total coded data fields per code family for case report form and reporting guideline per state.

Code Family Name														
Index	**State Name & Document**	**Demographics**	**Diagnosis**	**Exposure**	**History of Present Illness**	**Investigation**	**Past Medical History**	**Physical Exam**	**Prognosis**	**Reporting**	**Travelling**	**Treatment**	**Vaccination**	**Total**
1	CDC Form	6	7	23	3	6	14	0	16	2	1	5	3	86
2	CDC Guideline	3	7	19	4	13	11	2	14	6	1	6	3	89
3	AZ Form	14	6	6	1	13	2	0	3	14	0	0	0	59
4	AZ Guideline	14	6	6	3	10	1	0	2	11	0	0	0	53
5	CA Form	8	4	10	3	7	12	3	14	5	1	4	2	73
6	CA Guideline	1	5	12	2	5	5	0	8	0	1	5	0	44
7	CT Form	15	5	8	1	13	2	0	9	8	1	0	2	64
8	CT Guideline	10	3	0	1	3	0	0	0	11	0	0	0	28
9	ID Form	12	5	14	3	8	23	0	4	16	1	5	4	95
10	ID Guideline	4	11	12	4	9	10	1	18	2	1	5	2	79
11	IL Form	15	4	19	3	10	7	0	11	10	1	4	3	87
12	IL Guideline	13	9	11	3	14	8	0	13	12	1	1	0	85
13	KS Form	9	3	4	2	4	0	0	2	5	0	4	0	33
14	KS Guideline	4	11	12	2	11	7	1	17	12	1	3	1	82
15	KY Form	9	3	3	3	5	2	0	6	8	0	0	0	39
16	KY Guideline	9	5	0	0	4	0	0	3	16	0	0	0	37

17	MI Form	19	10	11	3	17	21	0	19	7	1	4	4	116
18	MI Guideline	9	5	6	1	1	0	0	0	3	0	0	0	25
19	MN Form	12	2	2	1	6	4	0	7	7	0	0	0	41
20	MN Guideline	0	6	0	1	6	0	0	7	1	0	0	0	21
21	MO Form	15	3	9	4	8	7	0	7	9	1	5	3	71
22	MO Guideline	2	10	14	2	5	5	0	6	7	0	3	4	58
23	NC Form	14	5	22	5	11	7	0	20	13	1	4	2	104
24	NC Guideline	6	5	10	3	17	2	0	6	2	1	4	5	61
25	TN Form	8	1	0	1	4	1	0	4	7	0	0	0	26
26	TN Guideline	5	7	4	2	9	0	0	1	3	1	2	1	35
27	TX Form	9	4	22	3	10	16	2	16	8	1	4	8	103
28	TX Guideline	4	9	16	3	7	4	0	2	9	1	2	3	60
29	UT Form	11	4	6	1	5	5	3	11	11	1	0	6	64
30	UT Guideline	11	9	13	2	8	6	0	11	2	1	3	0	66
31	WA Form	15	8	17	3	8	9	3	17	14	1	5	4	104
32	WA Guideline	2	5	16	2	6	2	0	8	0	1	6	5	53
33	WV Form	14	8	8	2	9	6	0	13	13	1	2	3	79
34	WV Guideline	9	4	1	4	8	1	0	1	11	1	2	7	49
35	NV Form	16	2	4	2	2	2	0	4	8	1	4	0	45
36	NV Guideline	3	7	19	4	13	11	2	14	6	1	6	3	89
37	NM Form	9	7	23	3	9	14	0	16	6	1	5	3	96
38	NM Guideline	10	8	15	4	11	5	0	9	16	1	6	2	87
39	VA Form	9	7	23	3	9	14	0	16	6	1	5	3	96
40	VA Guideline	5	7	9	1	6	2	0	16	8	0	0	4	58
41	FL Form	6	7	23	3	6	14	0	16	2	1	5	3	86
42	FL Guideline	5	10	20	4	13	9	1	15	11	1	6	2	97

43	ME Form	6	7	23	3	6	14	0	16	2	1	5	3	86
44	ME Guideline	2	7	16	2	5	6	1	8	9	0	3	3	62
45	NJ Form	6	7	23	3	6	14	0	16	2	1	5	3	86
46	NJ Guideline	5	7	12	3	14	4	0	11	4	1	3	0	64
47	NY Form	6	7	23	3	6	14	0	16	2	1	5	3	86
48	NY Guideline	10	3	2	1	10	4	0	1	8	0	1	0	40
49	OH Form	9	6	23	3	7	14	0	16	7	1	5	3	94
50	OH Guideline	2	2	5	2	6	0	0	4	1	0	3	0	25
51	OR Form	6	7	23	3	6	14	0	16	2	1	5	3	86
52	OR Guideline	0	5	15	2	7	3	0	9	3	1	6	1	52
53	RI Form	6	7	23	3	6	14	0	16	2	1	5	3	86
54	RI Guideline	7	4	0	1	5	0	0	0	5	0	0	0	22
55	SC Form	6	7	23	3	6	14	0	16	2	1	5	3	86
56	SC Guideline	8	9	20	4	13	11	2	15	11	1	6	3	103
57	WI Form	6	7	23	3	6	14	0	16	2	1	5	3	86
58	WI Guideline	2	4	9	2	5	3	0	4	0	0	5	0	34

Each coded data field in this study had either 0 for absence or 1 for presence at the stage of coding for every single document. The included states in this study utilize different data fields to be collected in the case report forms and guidelines. A comparison of the presence/absence of code families and data fields in guidelines and case report forms for individual states shows misalignment. Most case report forms require more data to be collected than guidelines in the included states, see Figure 3.13.

Overlap between the collected data fields in case report forms and the required data fields to be collected by reporting guideline vary from a state to another. Not every required data field by a reporting guideline is always collected by a case reporting form in the included states in this study. Arizona (AZ) state has the heights percentage of overlapped data fields

with 62% data fields of total coded data fields and a 43 data fields from a total of 69 coded data fields. South Carolina (SC) state has the heights number of overlapped data fields and the second largest percentage of overlapped coded data fields. It has with 53 data field from a total of 135 coded fields and a percentage of 39%, see Table 3.3 and Figure 3.14.

On the other hand, Rhode Island (RI) state has the lowest number and percentage of overlapped data fields with 10 data fields from a total of 98 coded data fields and a percentage of almost 10%. Minnesota (MN) state has an equal number to Rhode Island (RI) state as the least overlapped data fields with 10 data field from a total number of 53 coded data fields and a percentage of 19%. For more information, see Table 3.3 and Figure 3.14.

Numbers of collected coded fields in only case report forms are high in many states. Michigan (MI) state has the highest percentage and number of coded data fields in form only with 80% of total coded data fields and a 99 data fields from a total of 124 coded data fields. Rhode Island (RI) state has the second highest percentage and number of coded data fields in form only with 78% of total coded data fields and a 76 data fields from a total of 98 coded data fields, see Table 3.3 and Figure 3.14.

On the other hand, Kansas (KS) state has the lowest percentage and number of coded data fields in form only with 10% of total coded data fields and a 9 data fields from a total of 91 coded data fields. Nevada (NV) state has the second lowest percentage of coded data fields in form only with 21% of total coded data fields and a 23 data fields from a total of 112 coded data fields, see Table 3.3 and Figure 3.14.

Numbers of collected coded fields in only reporting guidelines are high in many states. Kansas (KS) state has the highest percentage and number of coded data fields in reporting guideline only with 64% of total coded data fields and a 58 data fields from a total of 91 coded data fields. Nevada (Nv) state has the second highest percentage of coded data fields in reporting guideline only with 60% of total coded data fields and a 67 data fields from a total of 112 coded data fields, see Table 3.3 and Figure 3.14. On the other hand, Ohio (OH) state has the lowest percentage and number of coded data fields in reporting guideline only with 6% of total coded data fields and a 6 data fields from a total of 100 coded data

fields. Michigan (MI) state has the second lowest percentage of coded data fields in reporting guideline only with 6% of total coded data fields and a 8 data fields from a total of 124 coded data fields, see Table 3.3 and Figure 3.14.

Table 3.3: The total number and percentage of coded overlapped data fields per state .

Index	**State**	**Total Number of Coded Data Fields**	**Number of Data Fields Shows Only in Form (1) and %**	**Number of Data Fields Shows Only in Guideline (2) and %**	**Number of Data Fields Overlap in Both Documents (3) and %**
1	AZ	69	(16) 23%	(10) 14%	(43) 62%
2	SC	135	(33) 24%	(49) 36%	(53) 39%
3	CDC	126	(37) 29%	(40) 32%	(49) 39%
4	KY	55	(18) 33%	(16) 29%	(21) 38%
5	IL	125	(40) 32%	(38) 30%	(47) 38%
6	FL	134	(37) 28%	(48) 36%	(49) 37%
7	NC	122	(61) 50%	(18) 15%	(43) 35%
8	TX	121	(61) 50%	(18) 15%	(42) 35%
9	CA	87	(43) 49%	(14) 16%	(30) 34%
10	UT	97	(31) 32%	(33) 34%	(33) 34%
11	NM	137	(50) 36%	(41) 30%	(46) 34%
12	CT	69	(41) 59%	(5) 7%	(23) 33%
13	ME	111	(49) 44%	(25) 23%	(37) 33%
14	WV	96	(47) 49%	(18) 19%	(31) 32%
15	WA	119	(66) 55%	(15) 13%	(38) 32%
16	OR	105	(53) 50%	(19) 18%	(33) 31%

17	ID	133	(54) 41%	(38) 29%	(41) 31%
18	NJ	115	(51) 44%	(29) 25%	(35) 30%
19	MO	100	(42) 42%	(29) 29%	(29) 29%
20	KS	91	(9) 10%	(58) 64%	(24) 26%
21	WI	96	(62) 65%	(10) 10%	(24) 25%
22	TN	49	(14) 29%	(23) 47%	(12) 24%
23	NV	112	(23) 21%	(67) 60%	(22) 20%
24	OH	100	(75) 75%	(6) 6%	(19) 19%
25	MN	53	(31) 58%	(12) 23%	(10) 19%
26	VA	130	(72) 26%	(34) 55%	(24) 18%
27	NY	109	(70) 64%	(23) 21%	(16) 15%
28	MI	124	(99) 80%	(8) 6%	(17) 14%
29	RI	98	(76) 78%	(12) 12%	(10) 10%

Not every code family is required to be collected in both case report forms and reporting guidelines in all included states. For more information on the code families distribution across states, see Figure 3.15 .Investigation code family has the highest number of appearance among case report forms and reporting guidelines in all the included states with 53 times. It is only missing in 5 positions, 4 states' guidelines (AZ, CA, CT and MI) and 1 states' case report form (KS). Reporting code family has the second highest number of appearance among case report forms and reporting guidelines in all the included states with 52 times. It is only missing in 6 positions, 4 states' guidelines (CA, WA, OH and WI) and 2 states' case report form (CT and FL), see Table 3.4.

On the other hand; travelling and Physical Exam code families has the highest number of absence among case report forms and reporting guidelines in all the included states with 47 times. Travelling code family only mentioned in 11 positions, 2 states' guidelines (KS and TN) and 9 states' case report form (CT, MI, MO, VA, ME, NY, OH, RI and WI). Physical

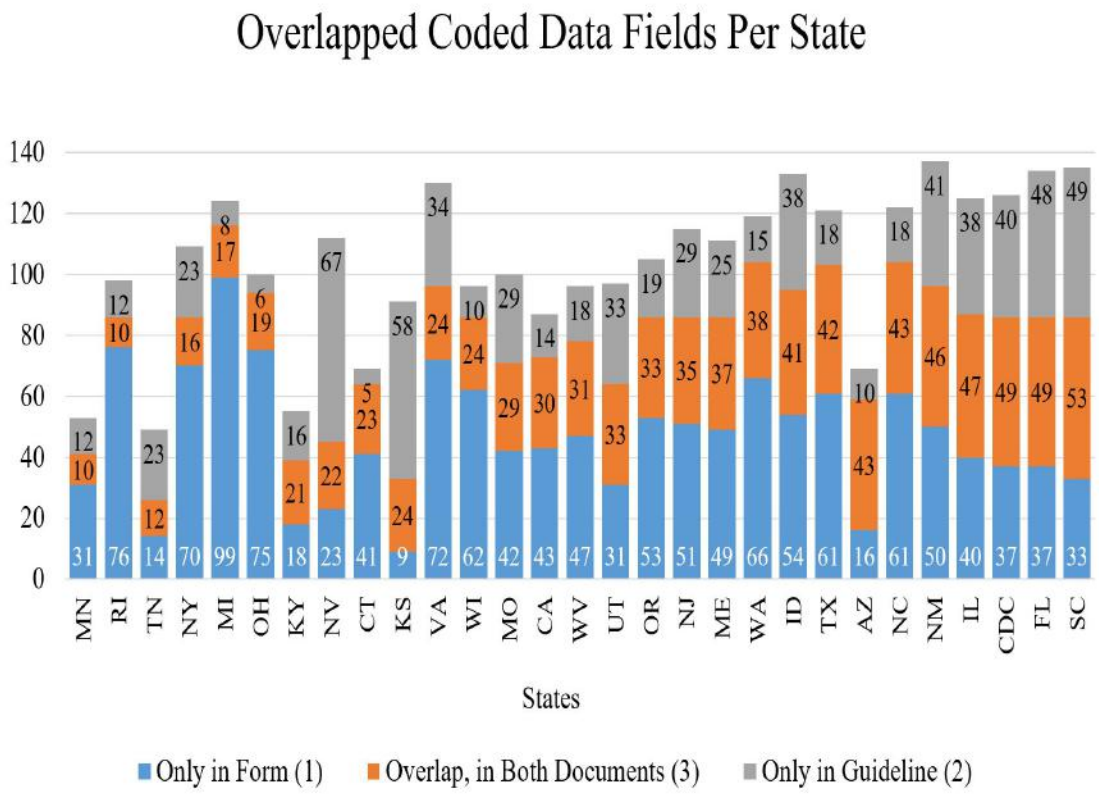


Figure 3.14: Numbers of overlapped coded data fields by guideline and case report form per state.

Exam code family only mentioned in 11 positions, 7 states' guidelines (CDC, ID, KS, NV, FL, ME and SC) and 4 states' case report form (CA, TX, UT and WA), see Table 3.4.

When it comes to code families within one state, no case report form or reporting guidelines includes all the 12 code families. There are many states miss only 1 code family in their case report form. 7 states (MI, VA, ME, NY, OH, RI, and WI) miss only the physical exam code family while cover the rest of code families in different extend. Travelling code family is missed in CA's case report form and SC's reporting guideline, see Table 3.4.

On the other hand; there are 3 states (CT, KS, OH) with the highest number of 9 missing

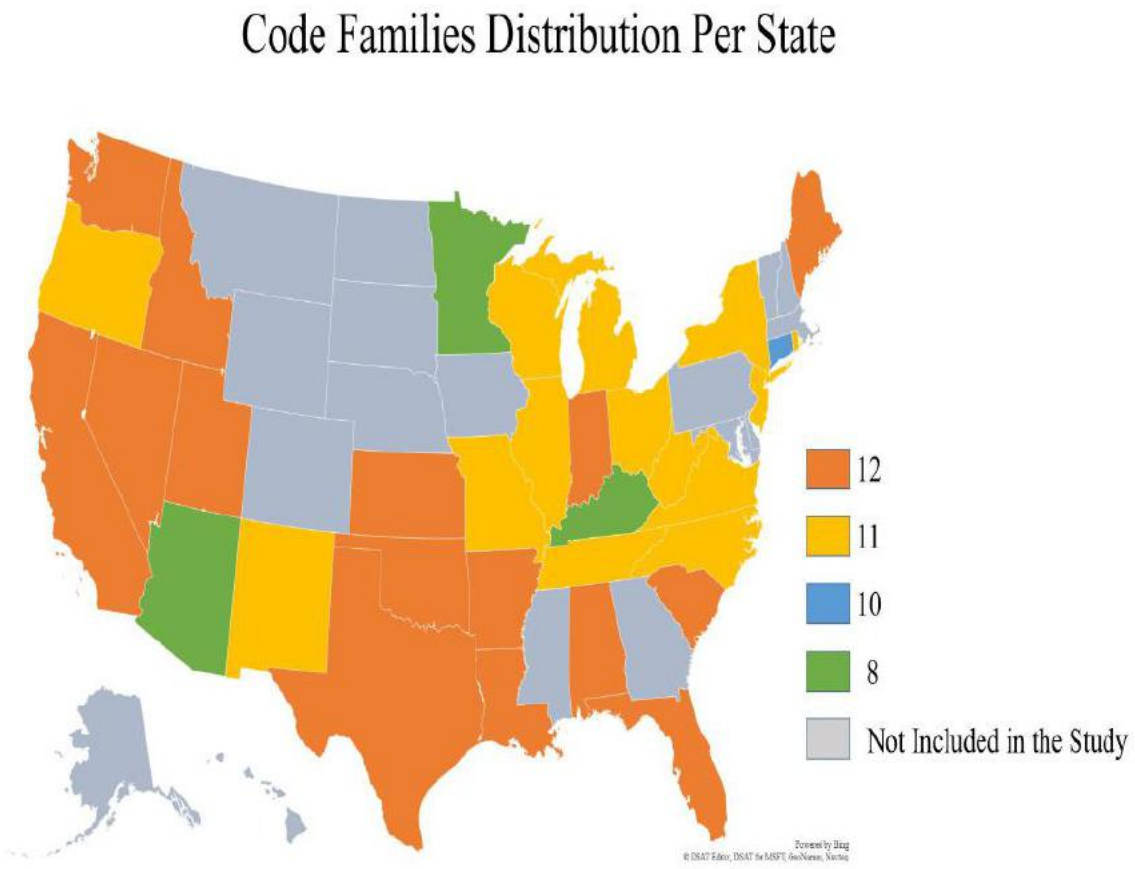


Figure 3.15: Numbers of code families distribution per state.

code families in either case report form or reporting guideline. CT state is missing 9 code families in their guideline and only 4 in their case report form. OH state is missing 9 code families in their guideline and only 1 in their case report form. KS state is missing 2 code families in their guideline and 9 in their case report form, see Table 3.4.

Table 3.4: Number of coded data fields per code family per state.

Code Family Name														
Index	**State Name & Document**	**Demographics**	**Diagnosis**	**Exposure**	**History of Present Illness**	**Investigation**	**Past Medical History**	**Physical Exam**	**Prognosis**	**Reporting**	**Travelling**	**Treatment**	**Vaccination**	**Total**	**Total Number of 0's**
1	CDC Form	3	3	8	1	4	10	0	6	1	0	0	1	37	3
2	CDC Guideline	0	3	4	2	11	7	2	4	5	0	1	1	40	2
3	AZ Form	2	3	0	0	3	1	0	2	5	0	0	0	16	6
4	AZ Guideline	2	3	0	2	0	0	0	1	2	0	0	0	10	7
5	CA Form	7	3	1	1	2	8	3	10	5	0	1	2	43	1
6	CA Guideline	0	4	3	0	0	1	0	4	0	0	2	0	14	7
7	CT Form	6	3	8	0	10	2	0	9	0	1	0	2	41	4
8	CT Guideline	1	1	0	0	0	0	0	0	3	0	0	0	5	9
9	ID Form	10	0	4	0	4	19	0	0	15	0	0	2	54	6
10	ID Guideline	2	6	2	1	5	6	1	14	1	0	0	0	38	3
11	IL Form	5	1	8	1	5	4	0	4	6	0	3	3	40	2
12	IL Guideline	3	6	0	1	9	5	0	6	8	0	0	0	38	5
13	KS Form	6	0	0	0	0	0	0	0	2	0	1	0	9	9
14	KS Guideline	1	8	8	0	7	7	1	15	9	1	0	1	58	2
15	KY Form	1	0	3	3	3	2	0	4	1	0	0	0	17	5
16	KY Guideline	1	2	0	0	2	0	0	1	9	0	0	0	15	7
17	MI Form	11	7	9	2	16	21	0	19	5	1	4	4	99	1

18	MI Guideline	1	2	4	0	0	0	0	0	1	0	0	0	8	8
19	MN Form	12	0	2	1	3	4	0	3	7	0	0	0	32	5
20	MN Guideline	0	4	0	1	3	0	0	3	1	0	0	0	12	7
21	MO Form	13	0	2	2	4	6	0	4	7	1	2	1	42	2
22	MO Guideline	0	7	7	0	1	4	0	3	5	0	0	2	29	5
23	NC Form	10	2	12	2	3	5	0	14	12	0	1	0	61	3
24	NC Guideline	2	2	0	0	9	0	0	0	1	0	1	3	18	6
25	TN Form	3	0	0	0	1	1	0	4	5	0	0	0	14	7
26	TN Guideline	0	6	4	1	6	0	0	1	1	1	2	1	23	3
27	TX Form	7	0	6	0	5	12	2	14	8	0	2	5	61	3
28	TX Guideline	2	5	0	0	2	0	0	0	9	0	0	0	18	8
29	UT Form	1	0	2	0	2	1	3	5	10	0	0	6	30	4
30	UT Guideline	1	5	9	1	5	2	0	5	1	0	3	0	32	3
31	WA Form	13	3	4	1	6	9	3	13	14	0	0	0	66	3
32	WA Guideline	0	0	3	0	4	2	0	4	0	0	1	1	15	6
33	WV Form	8	4	7	0	5	5	0	12	7	0	0	0	48	5
34	WV Guideline	3	0	0	2	4	0	0	0	5	0	0	4	18	7
35	NV Form	13	0	0	0	1	1	0	1	7	0	0	0	23	7
36	NV Guideline	0	5	15	2	12	10	2	11	5	0	2	3	67	2
37	NM Form	3	2	9	0	5	12	0	13	4	0	0	2	50	4
38	NM Guideline	4	3	1	1	7	3	0	6	14	0	1	1	41	2
39	VA Form	5	2	16	2	7	12	0	15	5	1	5	2	72	1
40	VA Guideline	1	2	2	0	4	0	0	15	7	0	0	3	34	5
41	FL Form	3	2	7	0	4	12	0	8	0	0	0	1	37	5
42	FL Guideline	2	5	4	2	11	7	1	7	9	0	1	0	49	2
43	ME Form	4	2	9	1	5	12	0	12	9	1	2	1	58	1

44	ME Guideline	0	2	2	0	4	4	1	4	7	0	0	1	25	4
45	NJ Form	4	2	11	1	2	14	0	10	2	0	2	3	51	2
46	NJ Guideline	3	2	0	1	10	4	0	5	4	0	0	0	29	5
47	NY Form	1	5	21	2	4	12	0	15	2	1	4	3	70	1
48	NY Guideline	5	1	0	0	8	2	0	0	8	0	0	0	24	7
49	OH Form	7	4	19	1	4	14	0	14	6	1	2	3	75	1
50	OH Guideline	0	0	1	0	3	0	0	2	0	0	0	0	6	9
51	OR Form	6	2	10	1	5	14	0	11	2	0	0	2	53	3
52	OR Guideline	0	0	2	0	6	3	0	4	3	0	1	0	19	6
53	RI Form	2	4	23	2	5	14	0	16	1	1	5	3	76	1
54	RI Guideline	3	1	0	0	4	0	0	0	4	0	0	0	12	8
55	SC Form	2	2	7	1	4	10	0	5	1	0	0	1	33	3
56	SC Guideline	4	4	4	2	11	7	2	4	10	0	1	1	50	1
57	WI Form	5	4	14	1	6	13	0	12	2	1	1	3	62	1
58	WI Guideline	1	1	0	0	5	2	0	0	0	0	1	0	10	7
	Total Number 0f 0's	10	13	16	27	5	13	47	10	6	47	32	26		

The *Investigation* code family in another guideline requires data on lab test results while the corresponding case report form includes data on specimen type, collection site, and date. The Medical History code family in one guideline requires data on symptoms onset date while the corresponding case report form includes data on symptoms' names, vaccination history, and patient's current chronic diseases. The Exposure code family in one guideline requires data on exposure to animals while the corresponding case report form requires data on exposure to animals, public places, household members, and co-workers.

A list of the topmost missing used data fields among guidelines and forms shows data fields from many code families. The Demographic, Reporting, Diagnosis, Medical History,

and Investigation code families have data fields among the most missing used data fields, see Table 3.5 and Figures 3.16 and 3.17 .

Table 3.5: The top 50 used data fields in case report forms and reporting guidelines in all included states.

Index	**The Top 50 Most Used Data Fields in Case Report Forms**	**Total Number of Apperance in Case Report Forms**	**The Top 50 Most Used Data Fields in Reporting Guidelines**	**Total Number of Apperance in Reporting Guidelines**
1	Demographics_Age / DOB	29	Diagnosis_Name	28
2	Demographics_Sex	29	Demographics_Age / DOB	26
3	Diagnosis_Name	29	History of Present Illness_Symptoms_Onset Date	25
4	History of Present Illness_Symptoms_Onset Date	29	Investigation_Lab Test_Type	25
5	Prognosis_Death	29	Diagnosis_Classification	24
6	Demographics_County Name	27	Diagnosis_Influenza Type	24
7	Demographics_Ethnicity	27	History of Present Illness_Symptoms_Name	23

8	Demographics_Race	27	Investigation_Lab Test_Results	23
9	Investigation_Lab Test_Type	27	Exposure_Direct_Ill Person	21
10	Prognosis_Hospitalized	27	Investigation_Lab Specimen_Collection Date	21
11	Reporting_Reporting Date	27	Investigation_Lab Specimen_Sample Sent to State Lab	21
12	Investigation_Lab Specimen_Collection Date	26	Investigation_Lab Specimen_Type	21
13	Past Medical History_Pregnancy	26	Treatment_Name	21
14	Prognosis_Hospitalized_ Admission Date	25	Diagnosis_Influenza Subtype	20
15	Prognosis_Hospitalized_ Discharge Date	25	Diagnosis_Part of An Outbreak/ Epi	20
16	History of Present Illness_Symptoms_Name	24	Demographics_Name	19
17	Prognosis_Death_Date	24	Diagnosis_Date	19
18	Travelling_Details	24	Exposure_Direct_Agricultural / Animal	19
19	Treatment_Name	23	Reporting_Reporting Date	19
20	Vaccination_Influenza Vaccine Name	23	Exposure_Direct_Healthcare Workers / Facility	18

21	Exposure_Direct_Facility	22	Exposure_Direct_Agricultural_Type of Animal	17
22	Exposure_Direct_Healthcare Workers/Facility	22	Exposure_Direct_Household Members	17
23	Past Medical History_Pregnancy_Duration	22	Prognosis_Complications_Name	17
24	Treatment_Start Date	22	Prognosis_Death	17
25	Treatment_Type	22	Treatment_Type	17
26	Vaccination_Influenza Vaccine_Date	22	Demographics_Race	16
27	Diagnosis_Influenza Type	21	Exposure_Direct_Group Setting	16
28	Exposure_Direct_Children Facility	21	Exposure_Direct_Suspected Ill Person	16
29	Exposure_Direct_Group Setting	21	Investigation_Lab Specimen_Source/Site	16
30	Exposure_Direct_Household Members	21	Past Medical History_Complications_Name	16
31	Demographics_Name	20	Prognosis_Complications	16
32	Exposure_Direct_Children Facility_Info	20	Reporting_Provider_Name	16
33	Exposure_Direct_Healthcare Workers/Facility_Info	20	Reporting_Reporting_To State Health Department	16
34	Exposure_Direct_Suspected Ill Person	20	Reporting_Reporting_To State Health Department_Date	16

35	Investigation_Diagnostic Imaging	20	Travelling_Details	16
36	Investigation_Diagnostic Imaging_Results	20	Treatment_Start Date	16
37	Past Medical History_Chronic Condition_Name	20	Demographics_Sex	15
38	Prognosis_Complications	20	Exposure_Direct_Facility	15
39	Prognosis_Complications_ Name	20	Exposure_Direct_Household Members_Info	15
40	Prognosis_Death_Reason of Death	20	Exposure_Direct_Ill Person_Info	15
41	Demographics_Contact Info	19	Prognosis_Hospital Isolation	15
42	Exposure_Direct_Agricultural / Animal	19	Prognosis_Hospitalized	15
43	Exposure_Direct_Agricultural / Animal_Info	19	Vaccination_Influenza Vaccine Name	15
44	Exposure_Direct_ Agricultural_Type of Animal	19	Demographics_Address	14
45	Exposure_Direct_Ill Person	19	Exposure_Direct_Healthcare Workers / Facility_Info	14
46	Exposure_Direct_Ill Person_Info	19	Past Medical History_Complications	14
47	Exposure_Direct_Suspected Ill Person_Info	19	Prognosis_Death_Reason of Death	14

48	Prognosis_Mechanical Ventilation Use	19	Prognosis_Non-Hospital Isolation	14
49	Treatment_Finish Date	19	Demographics_County Name	13
50	Diagnosis_Classification	18	Diagnosis_Linked to Suspected or Confirmed Case	13

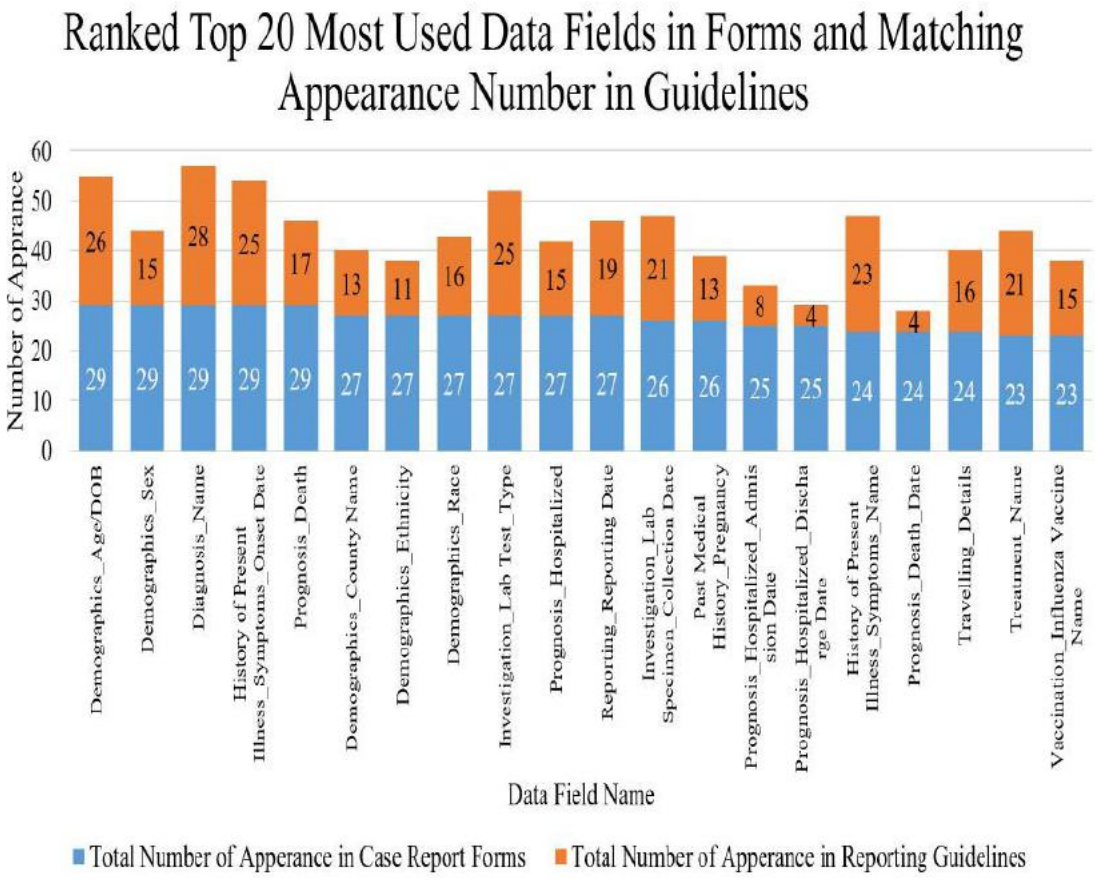


Figure 3.16: The 20 topmost used data fields in case report forms and matching appearances number of the data field in reporting guideline.

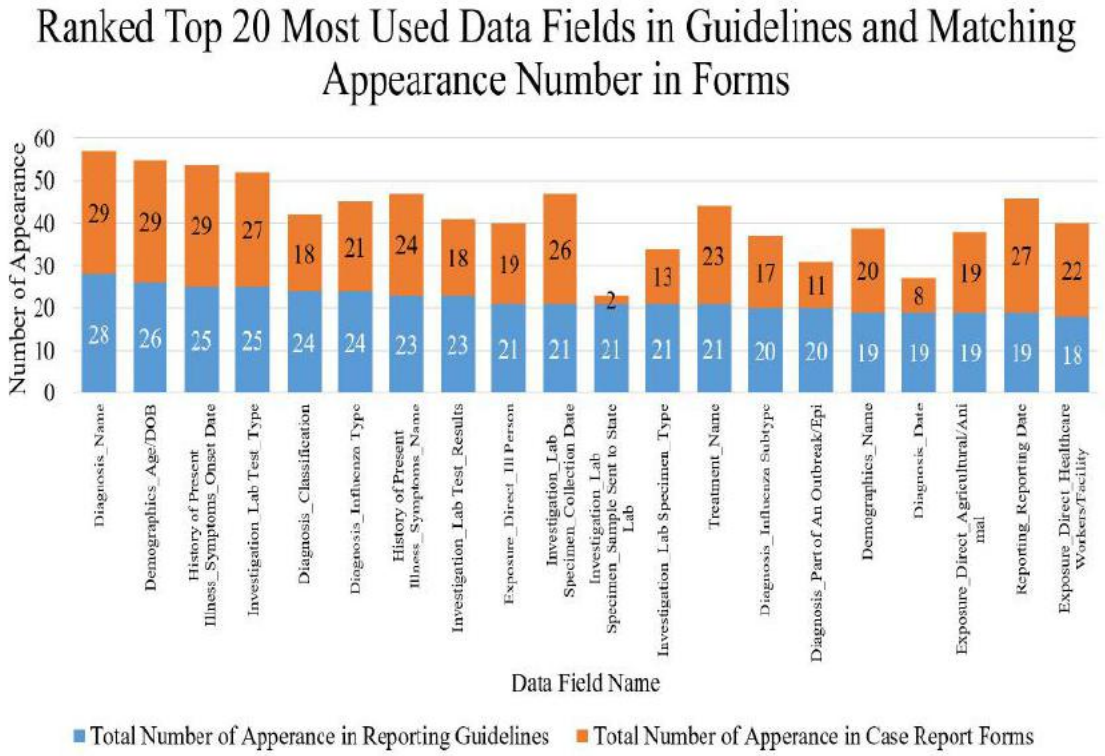


Figure 3.17: The 20 topmost used data fields in guidelines and matching appearances number of the data field in case report forms.

The Demographic code family appears with eight unique missing data fields followed by Reporting and Medical History code families with six unique missing data fields. For more details on the most commonly missing data fields occurring in both guidelines and case report form.

At the level of guidelines among the six states, many code families were used by the all guidelines. The Demographic code family had the most commonly used data fields by all guidelines with 11 unique coded data fields followed by the Reporting code family with six unique coded data fields. The Diagnosis, Medical History, and Investigation code families appear with one unique coded data fields among all guidelines.

The Demographic code family has the most commonly used data fields among all nine code families. Figure 3.18 shows clustering represent data fields (rows) among the six states (columns) to illustrate the four possible outcomes of data fields in guidelines and forms. Data fields such as date of birth (DOB), address, gender, name, and race are the most commonly collected fields in guidelines and forms; while SSN, marital status, country of origin, reservation name, age unit, and parent/guardian address are the least commonly collected data fields in guidelines and forms among the six states. Arizona state has the most matched required data fields (12 data fields) between form and guideline.

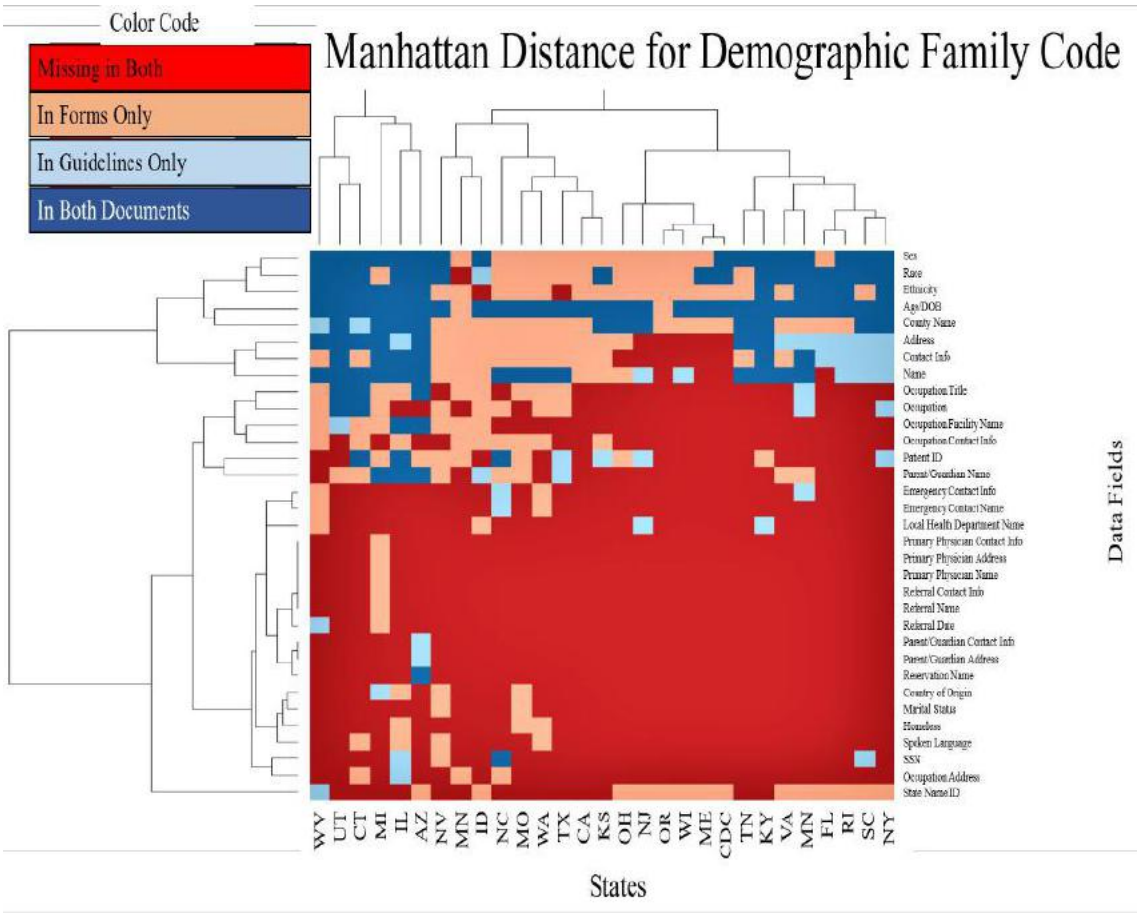


Figure 3.18: Manhattan Distance for Demographic code family per state.

For the Investigation code family clustering, Figure 3.19 shows a different clustering of data fields. Lab test results is the most commonly collected data field in guidelines and forms while information on the collected specimen, and lab contact phone number are the least commonly collected data fields in forms and guidelines in the Investigation code family among 6 states. Arizona has the most matched required data fields (6 data fields) between guideline and form in Investigation family code among six states.

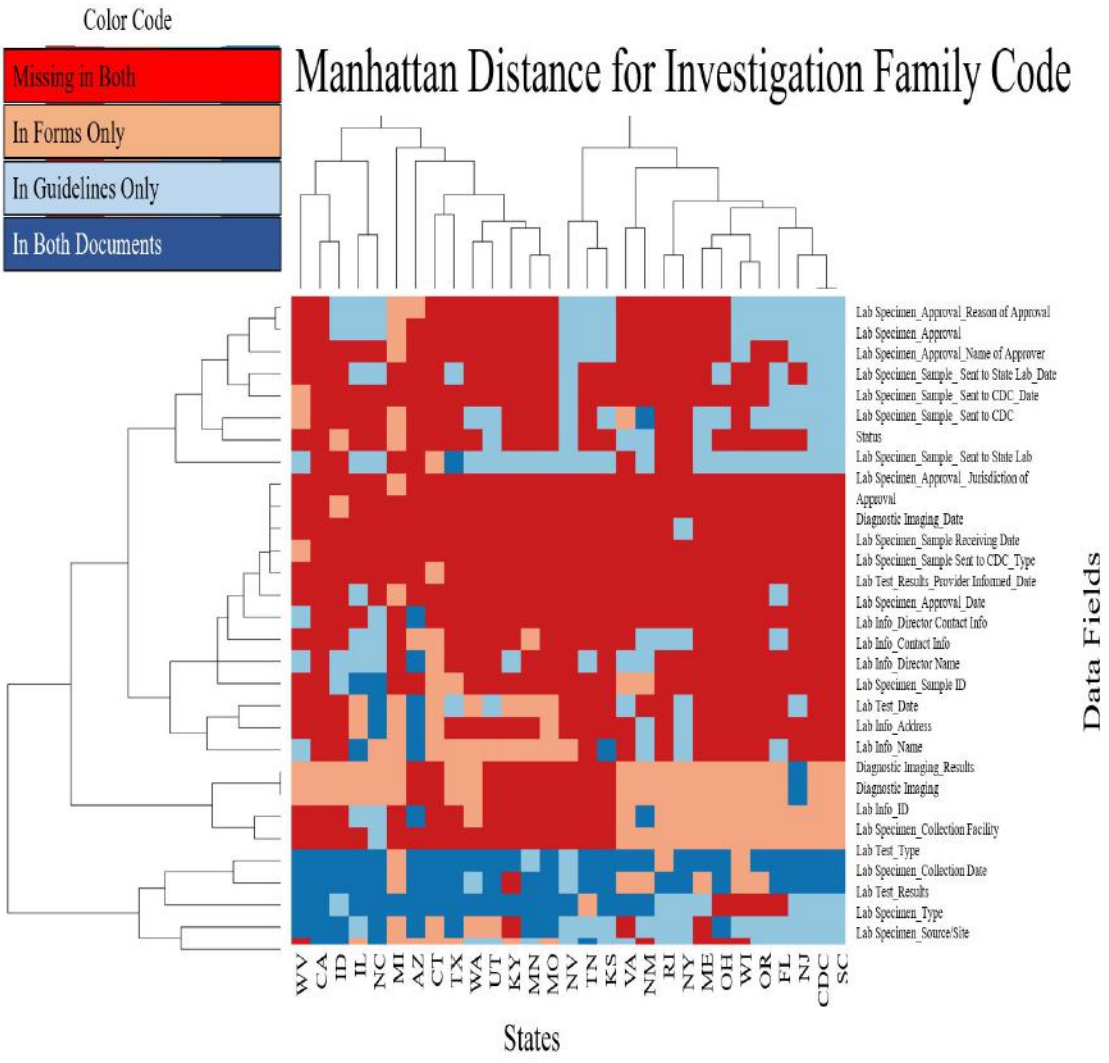


Figure 3.19: Manhattan Distance for Investigation code family per state.

For the Reporting code family clustering, Figure 3.20 shows different patterns of required data fields by different states. This figure shows information on patient's provider such as provider name, address as the most commonly collected data fields while provider's National Provider ID (NPI), provider email address, provider county name and contact information are the least commonly collected data fields in guidelines and forms in Reporting code family among the 6 states. Connecticut state has the most matched required data fields (7 data fields) between guideline and form in Reporting code family among six states.

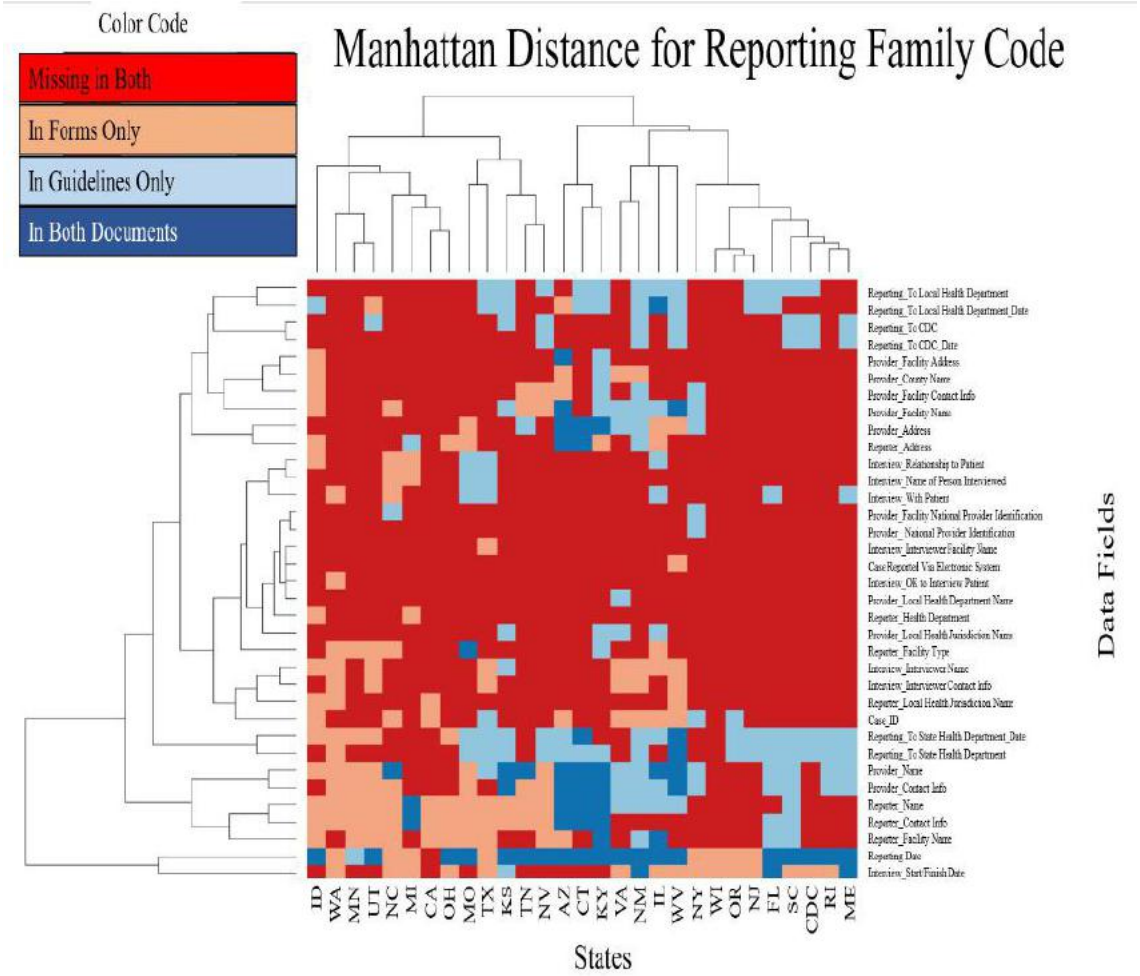


Figure 3.20: Manhattan Distance for Reporting code family per state.

3.4 Discussion

The code families grouped the identified data fields related to demographics, past medical history, treatments, exposure, and other code families. The included states varied in the total number of code families per state. The range of code families in stated ranged from 8 to 12 code families where most of the states have 11 or 12 code families covered in their official documents.

The total number of the identified data fields used in Novel Influenza reporting were 257 different data fields. The past medical history code families grouped the highest number of related data fields with 49 data fields and prognosis grouped 39 related data fields, while demographic code family grouped 33 related data fields. Demographic code family grouped related data fields on patients information such as name, address, date of birth, ethnicity, race, and other related data fields. Past medical history code family grouped related data fields on patients such as allergies, chronic diseases, medications to diseases other than novel influenza, previous hospitalizations and other related data fields to patients past medical history.

Identifying gaps on states level went through a process of coding official case report form and reporting guideline of each state. The data fields in both official documents were compared for presence/absence. Data fields were extracted from the official documents into tables of rows and columns using the co-concurrency tool in Atlas.ti 7. The extracted data fields were arranged into rows (data fields) and columns (documents). A comparison of the extracted data fields based on the presence/absence of data fields (denoted as 1 for presence and 0 for absence) was performed. This process provided three possible categorical outcomes per state:

- (1)The extracted data field shows only in the case report form.
- (2) The extracted data field shows only in the reporting guideline.
- (3) The extracted data field shows in both documents, the case report form and re-

porting guideline.

Identifying gaps across all the included states went through a process of combining and comparing the possible outcomes from all induvial states. The extracted data fields were grouped into rows (data fields) and columns (states names). A comparison of the extracted data fields based on the presence/absence of data fields was performed. This process provided four possible categorical outcomes per data field:

- (0) The extracted data field is not in neither the case report form nor the reporting guideline.
- (1) The extracted data field shows only in the case report form.
- (2) The extracted data field shows only in the reporting guideline.
- (3) The extracted data field shows in both documents, the case report form and reporting guideline.

There were key findings from the document collection, coding, and analysis. One of the key findings was that the ranked data fields were identified based on the number of appearances per data fields based on the states case report forms and reporting guidelines. The ranked data fields in case report forms were ranked based on the appearances of the 28 states plus the CDC case report form. The ranked data fields showed collected data fields in 29 case report forms out of 29 case report forms such as patients date of birth, gender and diagnosis name, and other data fields. The ranked data fields from the reporting guidelines applied the same principle as the case report forms where the data fields were ranked based on the number of appearances in states reporting guidelines.

Other key findings were identifying the gaps on the individual state level and across included states in the study. The gaps showed misalignments between the reporting guidelines and case report forms on both individuals and across states. Also, the gaps showed different

required data fields among the included states where some states required more details than other states.

3.5 Limitations

There were some limitations in document collection and analysis. Seventeen states were excluded from the study due to no or partial responses from the 50 states. One of the inclusion criteria specified the use of both documents, case report form, and reporting guideline, for each state to identify gaps. The excluded states only provided one of the required documents or no documents.

Some of the seventeen excluded states have the novel influenza case report forms and reporting guidelines documents available on their websites but decided not to be include the documents in this study. The reason behind this that some states websites have multiple case report forms and reporting guidelines for novel influenza case reporting. After following up with multiple states, I found that some of the posted case report forms and guidelines were outdated case report forms and they are not in use anymore. For this specific reason, I decided not to include any state does not confirm the current novel influenza case report form and reporting guidelines that are used for reporting.

Another limitation was that the identified gaps were based on the Novel Influenza disease only. Applying the same study on other communicable diseases would help to identify more gaps, which leads to identifying more areas of improvements in the reporting process. Including other communicable diseases will expand the knowledge of communicable diseases reporting process requirements.

3.6 Summary

Chapter 3 covered the research mythology to collect official states documents for novel influenza reporting process. Also, the chapter covered document coding and the process to identify gaps between case report forms and reporting guidelines within a state and across states. The Chapter defined the primary documents used in this study for novel influenza

reporting.

Chapter 3 listed the inclusion and exclusion criteria to include states in this study. The chapter listed the and compared the results and finding among the 28 unique states plus the CDC novel influenza reporting documents. Also, the chapter provided the process of states contacting and document collection. The document collection showed the excluded states in each step and the reason behind it.

Chapter 3 showed the final number of unique identified data fields, 257 data fields, used in novel influenza case reporting across states in this study. Also, the chapter introduced the unique 12 code families to group all the identified 257 fields. The code families covered many code families such as demographics, past medical history and other code families.

The process of identifying gaps between the case report forms and reporting guideline in each state provided a table of data fields that showed only in case report form, data fields showed only in reporting guideline, and data fields showed in both documents (case report form and reporting guideline). After performing the same process of identifying gaps among individual states, a comparison across the included states performed to compare the identified gaps. The results and findings produced a ranked list from the most used data fields to the least used data fields of case report forms and reporting guidelines across all the included states.

These findings among and across states showed the differences in data requirements to report novel influenza from healthcare providers to healthcare authorities These findings highlight the needs to improve case report forms and /or reporting guidelines to improve the process of reporting novel influenza.

There is a need to provide a tool to help healthcare providers with novel influenza reporting process challenges as identified in sections 2.1 and 2.2 . The tool should use target quality indicators and aligns with the Meaningful Use Program as discussed in sections 2.3 and 2.4. Also, the tool should implement the Clinical Document Architecture (CDA) standard to comply with the Meaningful Use Program requirements and CDC recommendation in communicable disease reporting. Chapter 4 covers the proposed prototype communicable

disease Web-based clinical reporting tool.

Chapter 4

AIM 2 –DEVELOPING A PROTOTYPE COMMUNICABLE DISEASE WEB-BASED CLINICAL REPORTING TOOL

Many agencies and organizations have scars from projects that did not meet the expectations or goals; and disease surveillance or diseases reporting is no exception. With the recent technologies and advancements, the Centers for Disease Control and Preventions (CDC) and other agencies are pushing to focus on applying new technologies and standards in diseases reporting. As we explained earlier in Chapter 2 , many new ongoing projects such as the Public Health Community Platform (PHCP), see Section 2.5 , and the Digital Bridge (DB), see Section 2.6, are focusing on using electronic reporting and standardization.

As explained earlier in Chapter 2 , there were misalignments between reporting guidelines and case report forms for Novel Influenza reporting. Also, there were different required documents, data fields and reporting process. The findings of Chapters 2 and 3 highlights the needs for an electronic reporting tool that links and gets data from EHRs based on standardized reporting process and format. Aim 2 of this dissertation proposed developing a prototype communicable disease Web-based clinical reporting tool to report Novel Influenza from healthcare provider to healthcare authorities using as use case report forms from states where reporting guidelines and case report forms were aligned.

The development process of this proof of concept tool aligns with the mentioned ongoing projects earlier, PHCP and DB, and the Meaningful Use program, see Section 2.4 . This tool is designed to use the Clinical Document Architecture (CDA) standard, see Section 2.8 , to enable clinical documents exchange and reporting between stakeholders. The tool designed to use medical terminologies such as LOINC and SNOMED-CT to overcome the challenges of interpretation and understanding the exchanged medical documents in com-

municable diseases case reporting. Also, this tool was designed to provide electronic novel influenza case reporting from healthcare providers to healthcare authorities to help improving communicable disease reporting process.

Health Informatics is the intersection of technology, standardization, and policies to provide modern innovations to benefit the healthcare field; reporting communicable diseases is an example. Following the directions of applying electronic reporting and standardization, this proposed prototype communicable disease Web-based clinical reporting tool is developed to help healthcare providers in reporting infectious or communicable diseases. The proposed tool is designed to help healthcare providers to report diseases from the providers end to the health authority end using electronic reporting features and applying the Clinical Document Architecture (CDA) standard.

To link this proposed tool to the novel influenza cases, the tool used a few examples of the official case report forms from Minnesota and Washington states. The proposed prototype communicable disease Web-based clinical reporting tool has a front end as user interface and backend where the technology is applied to do the reporting. The following sections covers the tools model design, hierarchy, layers and the front and back end flow.

As mentioned earlier in Section 2.2 , there are many benefits and challenges with reporting communicable diseases from healthcare providers to healthcare authorities. The prototype tool developed to overcome some of the challenges on many levels. On the healthcare provider level, the tool designed to provide reporting standard such as the CDA and provide an electronic method of reporting. On the reporting process level, the tool provided a unified case report within one state. Also, the tool provided a proof of concept to link the tool to an EHR. On the reporting recipient level, the tool provided a tool that has the potential to improve the reporting process, which helps the recipient level to obtain data from healthcare providers in a timely manner if applied well.

4.1 Web-based Reporting Tool front end

This tool works with the assumption that it is connected and compatible with an Electronic Health Record. The tool's front end or user interface go into a sequence of steps to report a case from a healthcare provider end to an authority ends. The reporting scenario starts with the healthcare provider starting the reporting process as the following:

1. The authorized user requests an event (search, view, update) after logging in the Web-based reporting tool using a username and password. The authorized user goes through a series of steps to generate a specified case report form on a specific patient. The steps sequence to generate a case report form on a specific patient are:

   (a) Search a patient by using the tool's search function.

   (b) Select a specific patient for case reporting.

   (c) Select a specific case report form as a part of the reporting process.

2. The back end of the tool provides the requested data back to the authorized user.

3. The tool pre-populates the selected case report form filled with the required data fields on a specific case.

4. The authorized user has the option to double check the generated case report form to see if needs more actions such as filling in the missing data field before sending the generated case report to the authority.

5. The authorized user sends the generated case report form to the healthcare authorities in a CDA format, see Figure 4.1.

In the first step in Figure 4.1,after successful login the authorized user will need to request specific data fields that are required by the case report form. To do that, the authorized user requests an event such as sending a query request that includes the patient's Medical

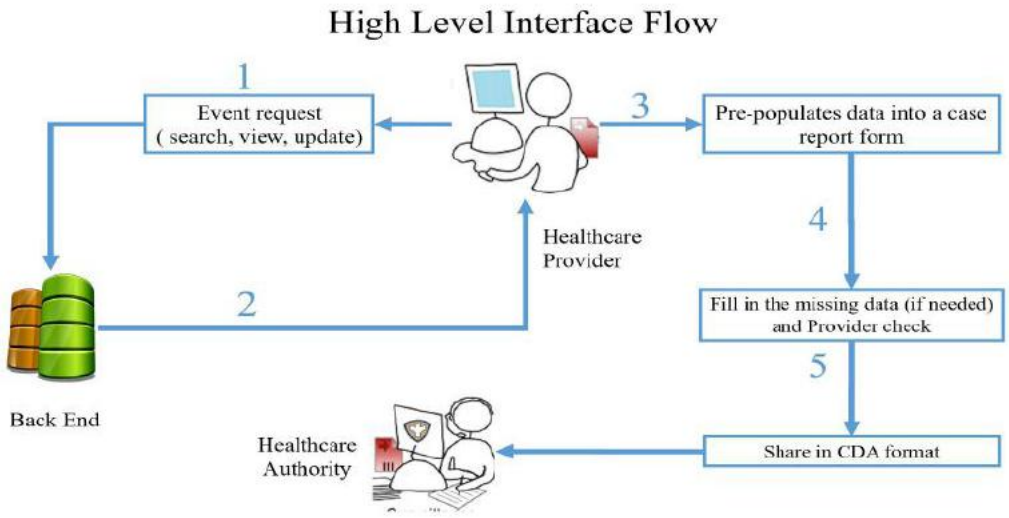


Figure 4.1: The web-based reporting tool front end.

Record Number to an Electronic Health Record (EHR) to be reported. Also, the authorized user specifies a case report form to be used in the reporting process.

In the second step in Figure 4.1, the tool searches for the requested data in the EHR to provide results to the authorized users. Then, the tool sends back the results of the query request, which is the medical record information for a specific case in this scenario.

In the third step in Figure 4.1, the tool pre-populates the selected case report form filled with the patient's medical data into the required fields. In this step, the authorized user will be able to view all the pre-populated data into the specified case report form.

In the fourth step in Figure 4.1,the authorized user has the option to fill in any missing data in the case report form if needed.At this point; the provider can check the case report form to perform a check on the case report form before sharing it.

In the fifth step in Figure 4.1, the authorized user sends the case report form to healthcare authority in the CDA format. The authorized user can send the generated case report form to multiple healthcare authorities if needed.

4.2 The web-based reporting tool graphical interface

This section presents the graphical user interface of the Web-based reporting tool. This section is not intended to describe every single feasible way of interacting with the tool, but to give the primary flow from login page until sending the case report form to healthcare authority and viewing the reporting history. The following figures and sub-sections cover mock-up views of the most critical aspects of the graphical user interfaces along with textual descriptions of their purposes and contents.

4.2.1 Log in

This sub-section describes the "Login" page, which is a common way to access the reporting tool. In this component, the user needs to provide the credentials to be authorized to log in the tool and be able to use the tool. The purpose of the login page is to be the starting point of using the Web-based reporting tool. The login page contains a welcome message that identifies the purpose of the tool and a login area, see Figure 4.2.

Box number 1 in the figure contains a logo for the tool to familiarize and ensure the users that they are in the right place. Box number 2 provides a brief welcome sentence that explains the purpose of the tool. Box number 3 provides the login area while box number 4 to provides the login button. The valid credentials will direct the user to the home page or the main page in the tool.

4.2.2 Home page

After the successful login, the tool directs the user to the "Home" page. This sub-section describes the "Home" page or the main search page, which is the only page to search for a patient. The "Home" page contains five main components, see Figure 4.3.

Box number 1 contains a welcome banner to confirm the login for an authorized provider. Box number 2 contains the basic search box where a user can search for a patient by using a Medical Record Numbers or a name. Box number 3 contains the advance search box where

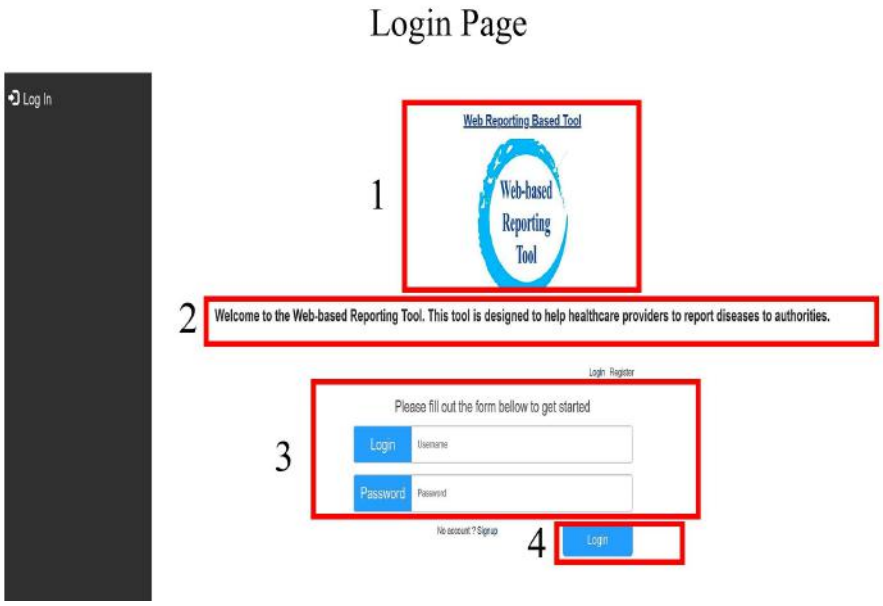


Figure 4.2: The tool's Login Page.

Figure 4.3: The tool's Home Page.

a user can search by a specific piece of data such as Medical Record Number, first name, last name, and date of birth. Box number 4 contains the drop-down menu for a list of available case report form to be used in the reporting process. Box number 5 contains the "Generate Form" button. Box number 6 contains the tool's sidebar menu for easy navigations. Also, this subsection describes the process to generate a case report form, which is the purpose of this page. To generate a case report form, a user needs to apply a sequence of steps, see Figure 4.4. The steps are:

1. Search a patient either through a basic or advanced search.

2. Select a patient from the query result.

3. Specify the required case report form.

4. Click on the "Generate Form" button.

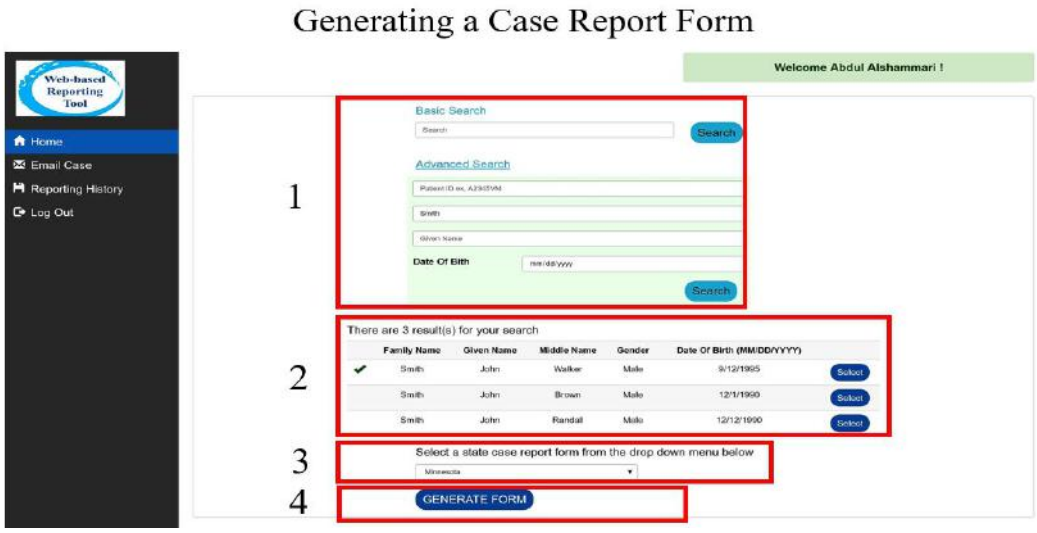


Figure 4.4: The steps to generate a specific case report form for a specific patient.

4.2.3 Data fields Pre-population into a case report form

After selecting a patient and a case report form and clicking on the "Generate Form" button, the tool directs the user to the "Pre-populated Case Report Form" page. This page is the only place where a user can view the patient's information. The "Pre-populated Case Report Form" page contains seven main components, see Figure 4.5. The components in Figure 4.5 are divided into three main sections. One section is covering the layout of the generated case report form (Box 1). Another section is covering the missing data fields in the populated case report form (Boxes 2, 3, and 4), and the last section is covering the tool's buttons (Boxes 5, 6, and 7).

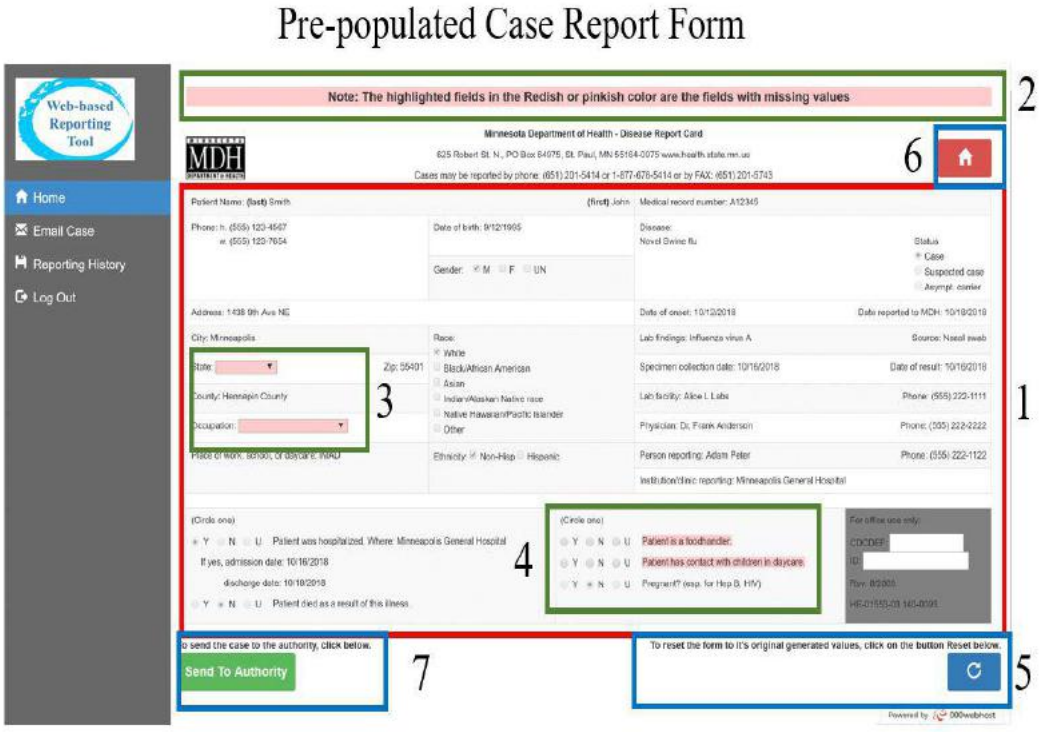


Figure 4.5: The pre-populated case report form by searching a specific patient and selecting a specific case report form.

Box number 1 contains the populated case report form. This form is the official case report form to report novel influenza and other diseases. Boxes 2, 3, and 4 are related. Box number 2 contains a message to the user that the highlighted fields in the pinkish/reddish color are the missing data fields. Missing data fields could happen for some reasons; the first reason that the values of the data fields are missing in the EHR or the data fields does not exist in the EHR. Boxes number 3 and 4 contain the missing data fields in the case report form. The purpose of highlighted missing data fields is to ease the process of finding the missing data fields to the user. In box number 3, a drop-down menu helps the user to pick an option to be used. In box number 4, a user can click on one of the options in the form to be selected.

Boxes number 5, 6, and 7 are related. Box number 5 contains the "Reset" button where this button allows the user to reset all the pre-populated data to its original generated values. For example, when a user wants to correct some of the entered values after entering some values in the missing data fields, then the user can click on the "Reset" button to reset the case report form to its original pre-populated status. Box number 6 contains the "Home" button, which navigates the user to the "Home" page. Box number 7 contains the "Send To Authority" button. This button sends the case report form to healthcare authorities. When clicking on the "Send To Authority" button, the tool generates a message after sending a case report form to healthcare authority to confirm the sending step, see Figure 4.6. The healthcare authority could be a local health authority, public health agency or a state department of health. The sent case report form contains the pre-populated data fields and the manually entered options by the users.

4.2.4 Reporting History Table

After the successful case reporting to authority, a user can navigate to the "Reporting History" tab on the side menu in the left side of the tool. This sub-section describes the "Reporting History" tab, which is the only page to search the reporting history. The "Reporting History" tab contains two main components, see Figure 4.7. Box number 1 contains

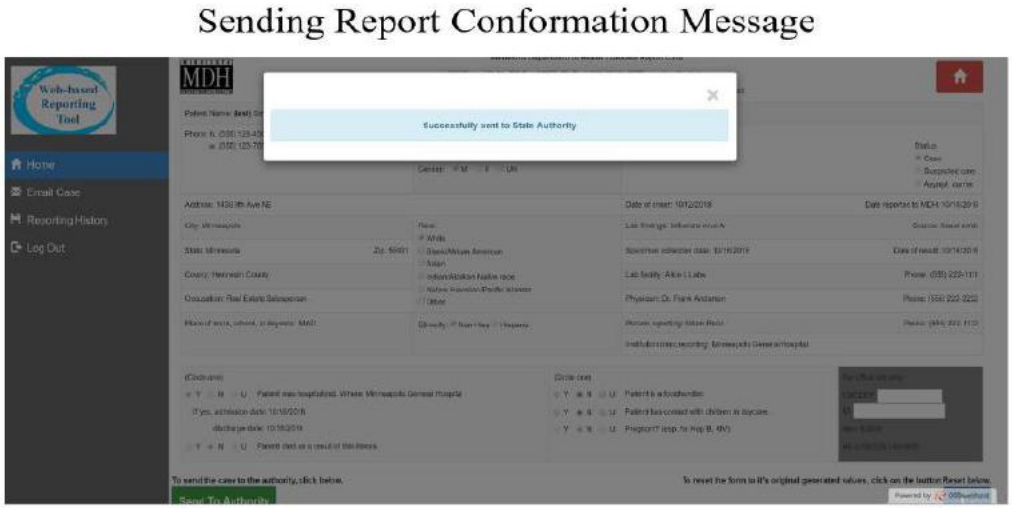


Figure 4.6: The report submission confirmation message.

a table on about the sender information and the reported cases. In box number 1, there is a table header that contains the index of the reported case along with a file name. Also, the reporting history table contains the date and time of the sent report along with the title to the reported healthcare authority. Finally, the table provides the name of the sender. Box number 2 contains the basic search box where a user can search for a reported case using any of the tables' header such as the sender name, date of sending or a file name.

4.3 The tool design model

The tool's design followed the Model View Controller (MVC) model. The MVC contains three main components. The three main components are:

1. Model: The model represents the data. In the Web-based reporting tool, the model represents the patient's data and the case report forms.

2. View: The view displays data to the user. It is responsible for displaying the model's data and user's actions such as button clicks to perform required actions. In the tool's

Figure 4.7: The reporting History table.

model, the view represents elements in the tool's interface based on the user's actions.

3. Controller: The controller represents the interactions between the model and the view components. In the Web-based reporting tool, the controller interprets users' actions such as performing a search click and view it in the tool's interface so that the user can see the results of an action.

To explain the flow of the web-based reporting tool high-level flow, see Figure 4.8 to follow the flow steps.

1. A User interacts with the Web-based reporting tool such as clicking on a button.

2. The Controller component is responsible for responding to the user's input or interaction. The controller component receives the input or request then send it to the Model component.

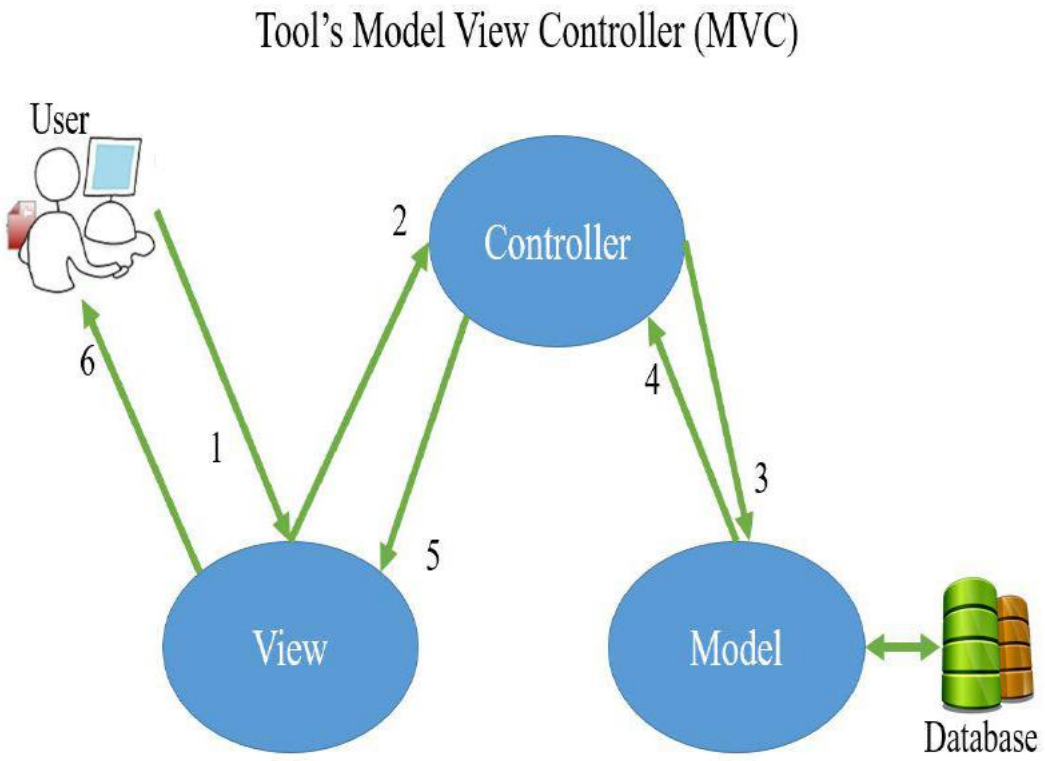


Figure 4.8: The Tool's Model View Controller (MVC).

3. The Model component response to the instruction from the Controller component requested query.

4. The Model component sends the result of the requested query to the Controller component.

5. After receiving the result of the requested query, the Controller component inputs the query result to the View component.

6. The View component displays the requested input on the Web-based reporting tool interface so that the user can see the results of the input request.

4.4 The Tool hierarchy

To achieve the goal of Aim 2 and following the MVC model, I developed the Web-based reporting tool based on a hierarchy of four levels. In each hierarchy level, there are different components. This section explains the use of the different technologies and standards used to develop the Web-based reporting tool, see Figure 4.9. This figure provides a high-level description of the four layers.

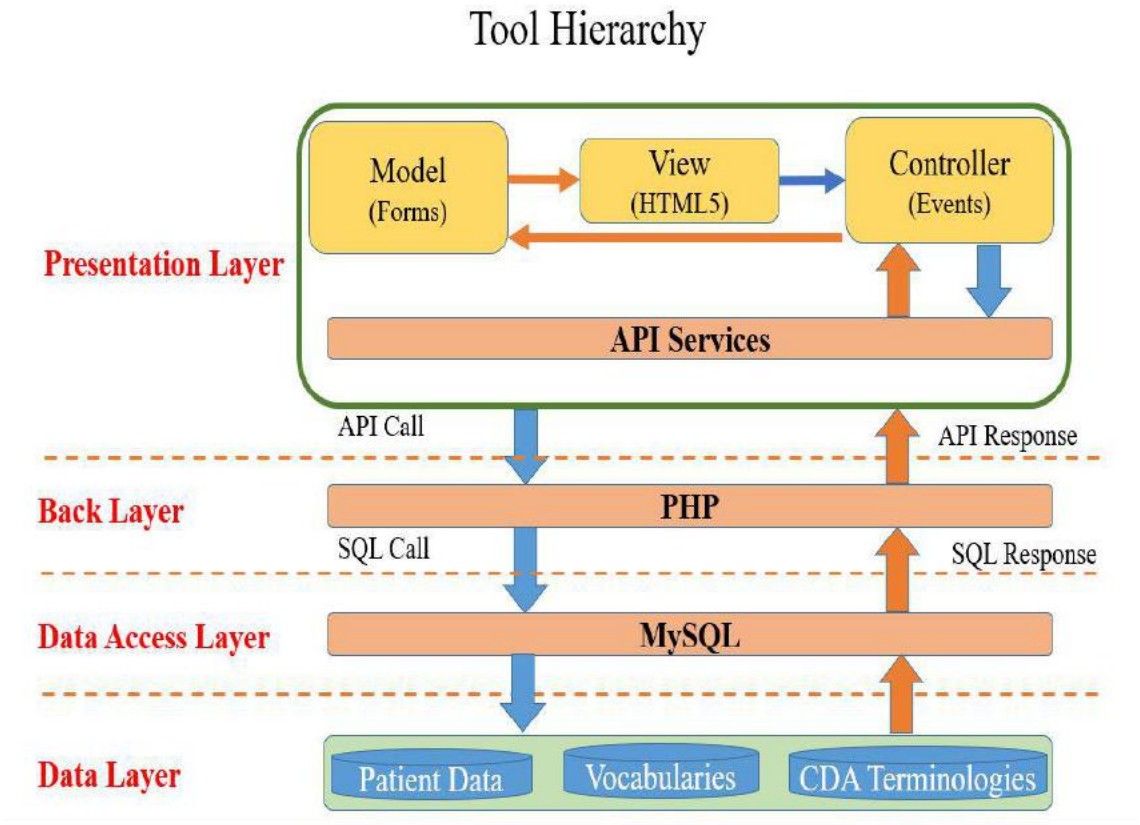


Figure 4.9: Web-based Reporting Tool hierarchy.

The Web-based reporting tool's four layers covers the client and server l sides. The server side includes the data layer, data access layer and back layer. The client side includes the presentation layer. The layers are as the following:

1. Data Layer:

   (a) Patient Data: It includes the patients' database used in the Web-based reporting tool to populate data such as demographics and clinical data.

   (b) Vocabularies: Medical vocabularies include the used vocabularies in the Web-based reporting tool such as ICD-9 and LOINC.

   (c) CDA Terminologies: It covers the CDA's terminologies used the Web-based reporting tool such as "guardian" or the definition of "Legal Name"

2. Data Access Layer:

   (a) MySQL: It is an open source Relational Database Management System used to access the data in the Data Layer and to write SQL queries.

3. Back Layer:

   (a) PHP: PHP is an open source scripting language used for web development and can be embedded into HTML5.

4. Presentation Layer:

   (a) API: Application Program Interface (API) is a set of routines and protocols that help developers in web developments. Examples of the web API are REpresentational State Transfer (REST) Simple Object Access Protocol (SOAP) and JavaScript..

   (b) HTML5: Hypertext Markup Language (HTML5) is a language used to create electronic documents or pages to be displayed on the World Wide Web.

   (c) Controller: It is part of the Model View Controller (MVC). It handles incoming HTTP requests and sends a response back to the user.

(d) Model: It represents the logic and structure of the tool in the tool's interface. The model works with the view component, which displays the requested query results to the user.

4.5 User interaction flow

A user's interaction with the Web-based reporting tool goes in a sequence of logical steps based the tools' design model and hierarchy. To follow a user's interaction with the tool, see Figure 4.10 flow steps.

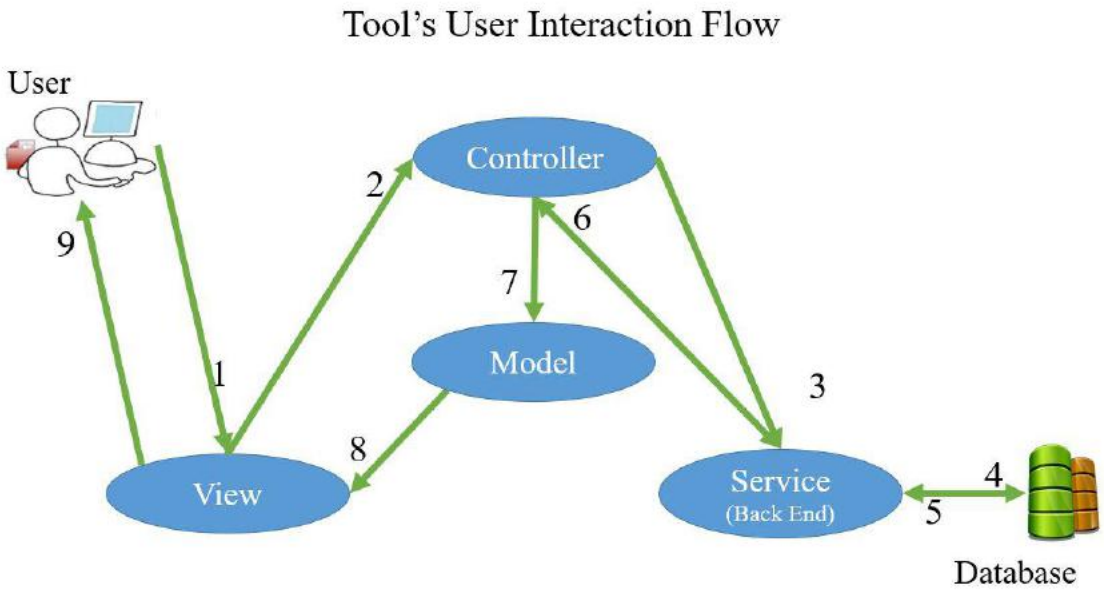


Figure 4.10: User's interaction flow with the Web-based reporting tool.

1. A user interacts with the tool through the View component through a click in the tool's interface.

2. The Controller component intercept the interaction between the user and the View component.

3. The Controller component sends the requested interaction query to the Service (back end) component.

4. The Service component interacts with the tool's database to perform an action (delete, update, interest, view)

5. The Service component gets the result of the requested interaction query from the database

6. The Service component send the results of the requested interaction query to the Controller component.

7. The Controller component send the result of the requested interaction query to the Model component.

8. The Model component includes the results of the requested query once it has been pulled from the backend. The Model component push the result of the requested interaction query to the View component.

9. The user sees the result of the requested query through the tool's interface.

4.6 CDA Template

Sending data from healthcare providers to healthcare authorities can be done by different methods such as electronic methods. There are many electronic methods taht could be used, Clinical Document Architecture (CDA) is one of the newer ways that gaining interest, see Section 2.8 , and required by the Meaningful Use Program, see Section 2.4 as a reporting standard. The CDA document is required to be used as standard templates to exchange clinical data among healthcare providers and healthcare authorities.

Medical documents have been structured differently from one medical specialty to another and varied in the required medical fields based on the medical specialty. There are

guidelines and standards that impose some structures to follow and imply. Clinical Document Architecture (CDA) is one of the frameworks that give a great flexibility in exchanging medical documents and supports the meaningful use of health information exchange and it is recommended by the HL7.

Clinical Document Architecture (CDA) is an electronic standard developed by the Health Level 7 (HL7) and approved in the year 2000. It has 2 releases (HL7 CDA Release 1 and Release 2). CDA is based on HL7 Reference Information Model (RIM), the documents are encoded in Extensible Markup Language (XML) language and specify the structure and semantics of "Clinical Documents" [132, 133]. CDA supports different contents that could be included in any "Clinical Documents" such as: imaging reports, admission and discharge summaries, history or physical examinations, diagnostic reports, referral, prescriptions, pathology reports, multimedia content and so on [132–134].

One of the advantages of the CDA is the complexity level. The CDA complexity level can support simple documents to more complex documents based on the document's contents. This advantage needs support from the healthcare providers and organization who use the CDA documents.

4.6.1 General Requirements of the CDA template

This sub-section covers the general requirements for the CDA templates that used in generating the Web-based reporting tool output. This sub-section covers only a portion of the coded CDA template's header.

As mentioned earlier in Chapter 2 , a CDA can be a discharge summary, referral, case report or other medical document types. A CDA document consists of a header and a body. The CDA header contains metadata for document management and retrieval while the CDA body consists of clinical report data such as discharge summary, referral, case report or other documents.

The CDA header describes the document itself such as the document unique number or document version. Also, the CDA header describes the participants in the document such

as the healthcare provider, the author of the document, the patient and other components. Figure 4.11 shows an example of a generated CDA document. The figure shows only a part of the CDA header. The purpose of this figure is not to explain the CDA header line by line, but to show a few examples of required components in the CDA header. Box number 1 covers the patient's name while Box 2 covers the patient's name and type of the name, which is Legal name. Box 3 covers the patient's race and ethnicity.

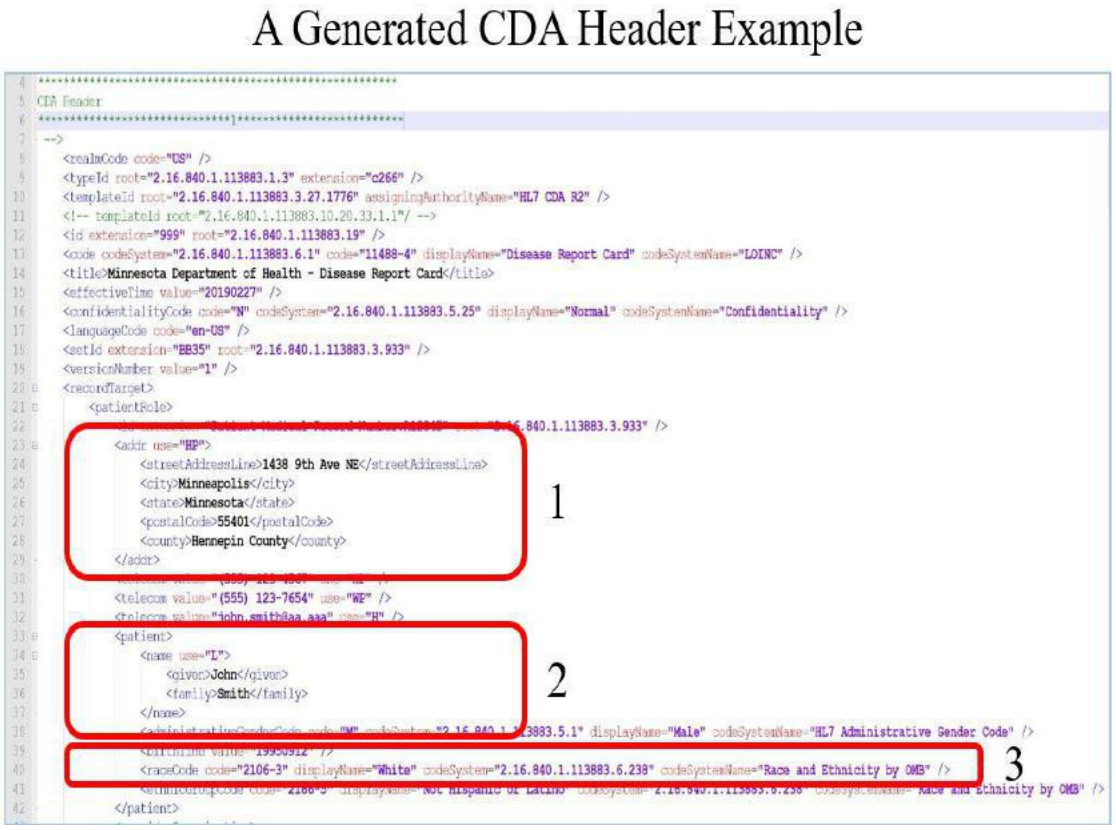


Figure 4.11: CDA template header code example.

Every CDA document must contain a header to help identifying and classifying the CDA document. The CDA header consists of many elements, but it must have minimum required elements. The minimum required elements are in the following table, Table 4.1

Table 4.1: The minimum required CDA header elements

Index	Element Name	Description
1	“Id”	Unique identifier for the CDA document
2	“typeId”	An id for the document type such as discharge summary or other medical documents
3	“code”	To specify the medical coding language such LOINC
4	“effectiveTime”	To provide the time stamp when the documents was created
5	“confidentialyCode”	To classify the document confidentiality level such as normal or restricted
6	“recordTarget”	To refer to a patient in the CDA document
7	“author”	To specify the creator of the CDA document such as a person or a machine
8	“custodian”	To specify the name of the organization that maintains the CDA document

4.6.2 CDA Header

The purpose of the CDA header is to enable the clinical document exchange across and within healthcare providers, patients, and healthcare authorities. The CDA header contains metadata to identify the document type, patient, provider, and other relevant information. As an example, the XML elements in CDA uses languagecode attribute to present language element. The language element is used to provide information on the used language of the CDA document.

The languagecode attribute uses ISO 639 codes to represent the used language in this document such as ”en-US” for US English, see Table 4.2 and Figure 4.12 . The ISO 639 is an international standard for language codes used for the for the representing languages or

languages families and maintained by the Library of Congress of language codes [135] .

Table 4.2: Languages codes attribute used by the CDA and maintained by ISO 639 international code

Language codes by ISO 639 Codes(CDA Code System: 2.16.840.1.113883.6.121)			
Index	**Code**	**Code System**	**Description**
1	En	Internet Society Language	English
2	Fr	Internet Society Language	French
3	AR	Internet Society Language	Arabic
4	en-US	Internet Society Language	US English
5	es-US	Internet Society Language	Spanish
6	SO	Internet Society Language	Somali
...	...	...	...

```
1 <!-- This example represnts language coding-->
2 <languageCommunication>
3  <languageCode code="en-US"/>
```

Figure 4.12: Document's Language code in the CDA format.

4.6.3 RecordTarget and PatientRole

The XML elements in the CDA uses "recordTarget" attribute to present the patient as the focus of the CDA document. The recordTarget records the demographics, administrative and

clinical data of the patient who is represented within the clinical document. The recordTarget must contain at least one patientRole, see Figure 4.13.

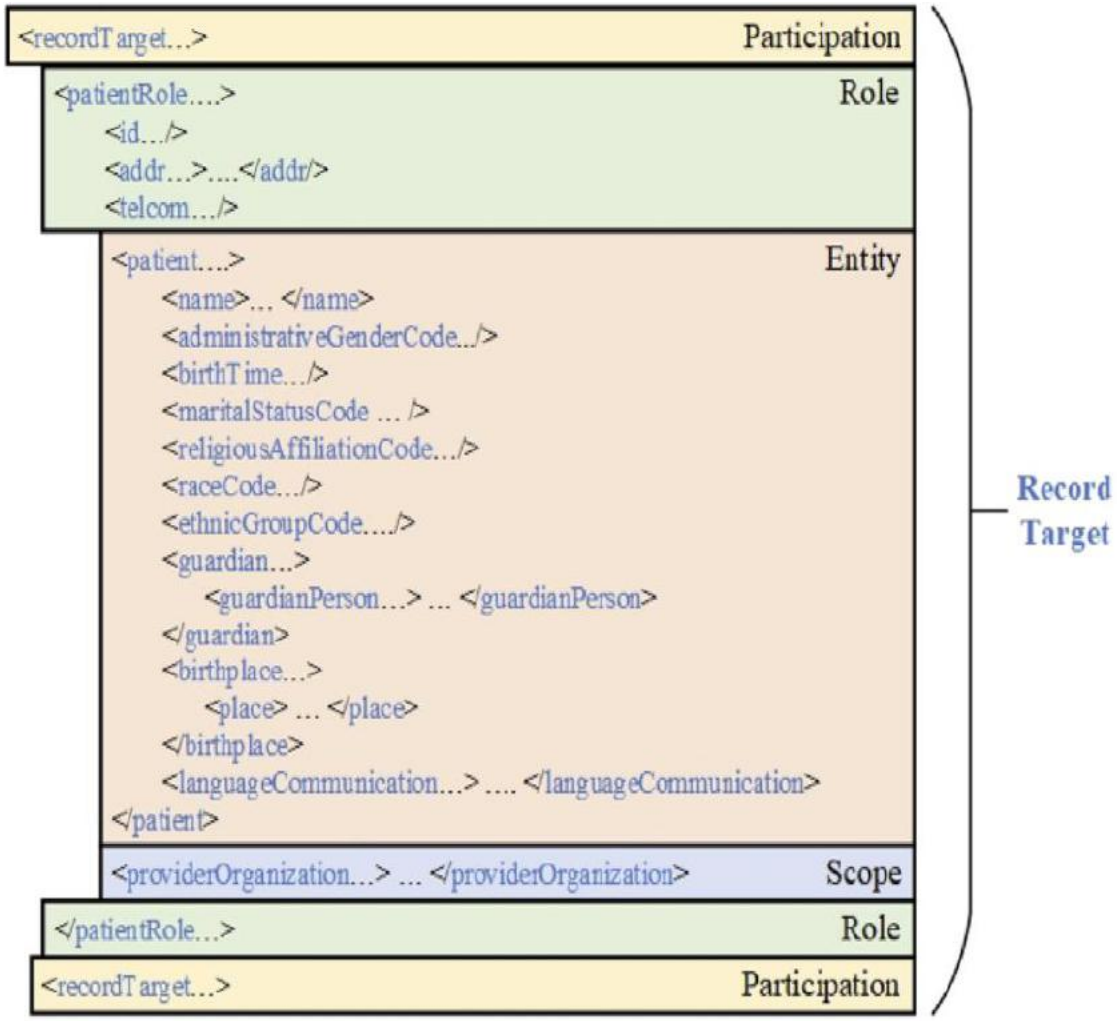


Figure 4.13: The Record Target

The XML elements in CDA uses "addr" attribute to present address element. The address element is used to provide address information on a patient or an organization. CDA provides a way to represent the type of address along with separate fields on the address details. Also CDA provides information on the type of address or number, see Table 4.3.

Table 4.3: Address attribute elements used for address types specifications in the CDA format.

Address Type Used by CDA (CDA Code System OID: 2.16.840.1.113883.5.1119)				
Index	**Code**	**Code System**	**Cardinality**	**Description**
1	H	HL7 AddressUse	[1..*]	Home
2	HP	HL7 AddressUse	[1..*]	Primary home
3	HV	HL7 AddressUse	[1..*]	Vacation home
4	WP	HL7 AddressUse	[1..*]	Work Place
5	DIR	HL7 AddressUse	[1..*]	Direct or Private number
6	PUB	HL7 AddressUse	[1..*]	Public (switchboard, operator)
7	BAD	HL7 AddressUse	[1..*]	Bad/wrong number/address
8	TMP	HL7 AddressUse	[1..*]	Temporary number/address
9	AS	HL7 AddressUse	[1..*]	Answering service
10	EC	HL7 AddressUse	[1..*]	Emergency contact
11	MC	HL7 AddressUse	[1..*]	Mobile contact
...	..	..	..	..

The CDA helps to differentiate between distinct types of communication addresses by using value attributes. The value attribute must contain a prefix to provide a meaning for the attribute, e.g., tel or fax, see Figure 4.14 and Table 4.4. When the telecom element is required, but the value is missing the nullFlavor attribute code be used to indicate that the required attribute is missing, see Figure 4.14.

4.6.4 Patient (Record Target)

The XML elements in the CDA uses "name'' attribute to present names such as a person, organization, and places. Name attribute is used as a sub-element , where it consists of

```
<!-- This example represnts different ways of communication methods coding-->
<!-- Home Telephone number -->
<telecom use="HP" value="tel:+1555-123-4567"/>
<!-- Workplace= Fax number -->
<telecom use="WP" value="fax:+1555-123-4567"/>
<!-- Workplace E-mail -->
<telecom use="WP" value="mailto:John.smaith@aaa.com"/>
<!-- http -->
<telecom value="http://www.google.com"/>
<!-- Missing Required Telephone number -->
<telecom nullFlavor="UNK" value="tel:"/>
```

Figure 4.14: Communications' elements coding in the CDA Format.

Table 4.4: Telecommunication attribute elements specifications in the CDA Format.

Telecommunications Addresses Specifications			
Index	**Code**	**Cardinality**	**Description**
1	tel	[1..*]	Telephone
2	fax	[1..*]	Fax
3	mailto	[1..*]	Email address
4	http	[1..*]	Web address
5	ftp	[1..*]	File Transfer Protocol address
6	sftp	[1..*]	Secure File Transfer Protocol address
7	MC	[1..*]	Mobile contact
8	PG	[1..*]	Pager

different elements to represent different parts of a name, see Table 4.5 and Figure 4.15. for more details on the name attribute. The name attribute uses many name types to be specified by the CDA document, see Table 4.6. for different name types

Table 4.5: Name attribute elements used for name specifications in the CDA format.

Name Specifications			
Index	**Code**	**Cardinality**	**Description**
1	Use=	[0..1]	Provides information on the person's name
2	Prefix	[0..*]	Provides information on the prefixes for the person's name
3	family	[1..1]	Provides information on the person's family name
4	given	[1..*]	Provides information on the person's first name
5	suffix	[0..1]	Provides information on the person's suffix

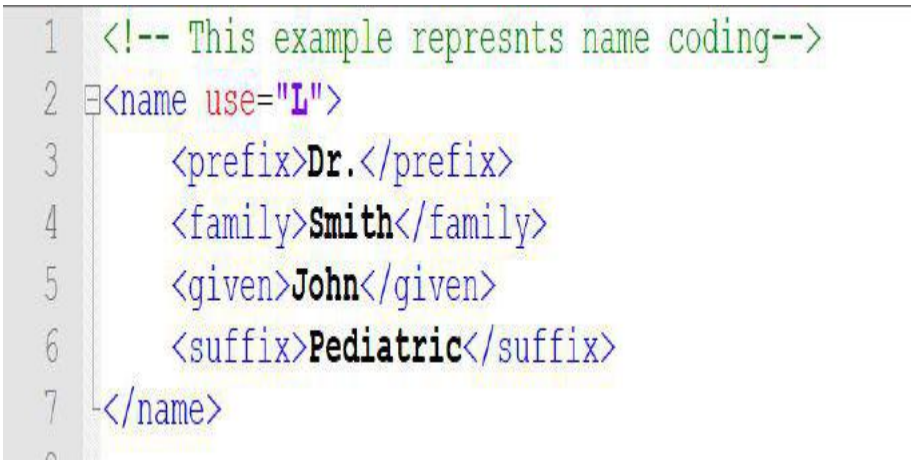


Figure 4.15: Persons or organization name in the CDA format.

The XML elements in CDA uses "adminstrativeGenderCode" attribute to present a person's gender. It is used as a sub-element of the patient element, it contains only three values, see Figure 4.16 and Table 4.7 for more details.

The XML elements in the CDA uses "maritalStatus" attribute to present a person's marital status. This attribute allows medical documents to capture the marital status of a patient at the time of creating the document, see Figure 4.17 and Table 4.8 for more details.

Table 4.6: Entity name elements specification the in CDA format.

Name Type by CDA (CDA Code System OID: 2.16.840.1.113883.5.45)			
Index	**Code**	**Code System**	**Description**
1	C	HL7 EntityNameUse Code	License or a name that differs from legal name
2	I	HL7 EntityNameUse Code	Indigenous/Tribal
3	L	HL7 EntityNameUse Code	Legal name
4	P	HL7 EntityNameUse Code	Pseudonym – another name that is not the legal name and not the primary name by which the person is called
5	A	HL7 EntityNameUse Code	Artist/stage name
6	R	HL7 EntityNameUse Code	Religious name
7	SRCH	HL7 EntityNameUse Code	Name used for searching
8	PHON	HL7 EntityNameUse Code	Phonetic spelling of name
9	ASGN	HL7 EntityNameUse Code	Assigned name
10	ABC	HL7 EntityNameUse Code	Alphabetic
...	...	...	...

Table 4.7: Gender attribute elements specifications in the CDA format.

Gender (Sex) by CDA (CDA Code System OID: 2.16.840.1.113883.5.1)			
Index	**Code**	**Code System**	**Description**
1	M	HL7 Administrative Gender Code	Male
2	F	HL7 Administrative Gender Code	Female
3	UN	HL7 Administrative Gender Code	Undifferentiated

```
<!-- This example represnts gender coding-->
<administrativeGenderCode
code="M"
displayName="Male"
codeSystem="2.16.840.1.113883.5.1"
codeSystemName="HL7 AdministrativeGenderCode"/>
```

Figure 4.16: Persons gender in the CDA format.

```
<!-- This example represnts marital status coding-->
<maritalStatusCode
code="S"
displayName="Single"
CodeSystem="2.16.840.1.113883.5.1"
codeSystemName="MaritalStatusCode" />
```

Figure 4.17: Persons marital status in the CDA format.

The XML elements in the CDA uses "religiousAffliliationCode" to present a person's spiritual faith or religion. The religiousAffliliationCode is a sub-element of the patient elements. The religiousAffliliationCode is a value set contains 80+ concepts, where code attribute consists of 4 digits to represent a spiritual faith or religion, see Figure 4.18 and Table 4.9 for more information .

The XML elements in the CDA uses "raceCode" and "ethnicGroupCode" attributes to present a person's race and ethnicity categories. Both the raceCode and ethnicGroupCode are sub-elements of the patient elements. The Office of Management and Budget (OMB)

Table 4.8: Marital status attribute elements specifications for marital status in the CDA format.

Marital Status By CDA (CDA Code System OID: 2.16.840.1.113883.5.2)			
Index	**Code**	**Code System**	**Description**
1	A	HL7 Administrative Marital Status Code	Annulled
2	D	HL7 Administrative Marital Status Code	Divorced
3	I	HL7 Administrative Marital Status Code	Interlocutory
4	L	HL7 Administrative Marital Status Code	Legally Separated
5	M	HL7 Administrative Marital Status Code	Married
6	P	HL7 Administrative Marital Status Code	Polygamous
7	S	HL7 Administrative Marital Status Code	Never Married
8	T	HL7 Administrative Marital Status Code	Domestic Partner
9	W	HL7 Administrative Marital Status Code	Widowed
...	...	...	...

```
1  <!--This example represntsReligion coding-->
2  <religiousAffiliationCode
3  code="1013"
4  displayName="Christian (non-Catholic, non-specific)"
5  codeSystem="2.16.840.1.113883.5.1076"
6  codeSystemName="HL7 Religious Affiliation"/>
```

Figure 4.18: Persons religious affiliation specifications in the CDA format.

issued the Race and Ethnic Standards for Federal Statistics and Administrative Reporting. This code set is used by CDC to code race and ethnicity, see Figure 4.19 and Tables 4.10 , 4.11 .

Table 4.9: Religion affiliation attribute elements specifications in the CDA format.

Religious Affiliation Code by HL7 Religious Affiliation Code (CDA Code System OID: 2.16.840.1.113883.5.1076)			
Index	**Code**	**Code System**	**Description**
1	1009	HL7 Religious Affiliation Code	Baptist
2	1013	HL7 Religious Affiliation Code	Christian (non-Catholic, non-specific)
3	1020	HL7 Religious Affiliation Code	Hinduism
4	1023	HL7 Religious Affiliation Code	Islam
5	1036	HL7 Religious Affiliation Code	Orthodox
6	1077	HL7 Religious Affiliation Code	Protestant
...	...	...	...

```
<!-- This example represnts race and ethnicity coding-->
<raceCode
code="2106-3"
displayName="White"
codeSystem="2.16.840.1.113883.6.238"
codeSystemName="OMB Standards for Race and Ethnicity"/>
<ethnicGroupCode
code="2186-5"
displayName="Not Hispanic or Latino"
codeSystem="2.16.840.1.113883.6.238"
codeSystemName="OMB Standards for Race and Ethnicity"/>
```

Figure 4.19: Persons race and ethnicity specifications in the CDA format.

4.7 Tool Testing

In this section, I will talk about the validity of the generated CDA file along with testing the tools functions in different web pages. The CDC recommend validate the CDA output file by using the Lantana Groups Schematron Validator [136] . Testing the generated output CDA file by the developed prototype Web-based reporting tool in the CDA validator; produced

Table 4.10: Race attribute elements specifications used in the CDA format.

Race by OMB Standards for Race and Ethnicity (CDA Code System OID: 2.16.840.1.113883.6.238)			
Index	**Code**	**Code System**	**Description**
1	2106-3	Race and Ethnicity by OMB	White
2	2054-5	Race and Ethnicity by OMB	Black/African American
3	2028-9	Race and Ethnicity by OMB	Asian
4	1002-5	Race and Ethnicity by OMB	Indian/Alaskan Native race
5	2076-8	Race and Ethnicity by OMB	Native Hawaiian/Pacific Islander
6	2131-1	Race and Ethnicity by OMB	Other
...	...	...	...

Table 4.11: Ethnicity attribute elements specifications used in the CDA format.

Ethnicity by OMB Standards for Race and Ethnicity (CDA Code System OID: 2.16.840.1.113883.6.238)			
Index	**Code**	**Code System**	**Description**
1	2186-5	Race and Ethnicity by OMB	Not Hispanic or Latino
2	2135-2	Race and Ethnicity by OMB	Hispanic or Latino ethnicity
3	2131-1	Race and Ethnicity by OMB	Other
...	...	...	...

a valid CDA file, see Figure 4.20 . The testing process covered more elements that covered earlier in the CDAs header, see Table 4.1 in Section 4.6.2 .

The testing process covered many functions and navigations on the following web pages of the tool:

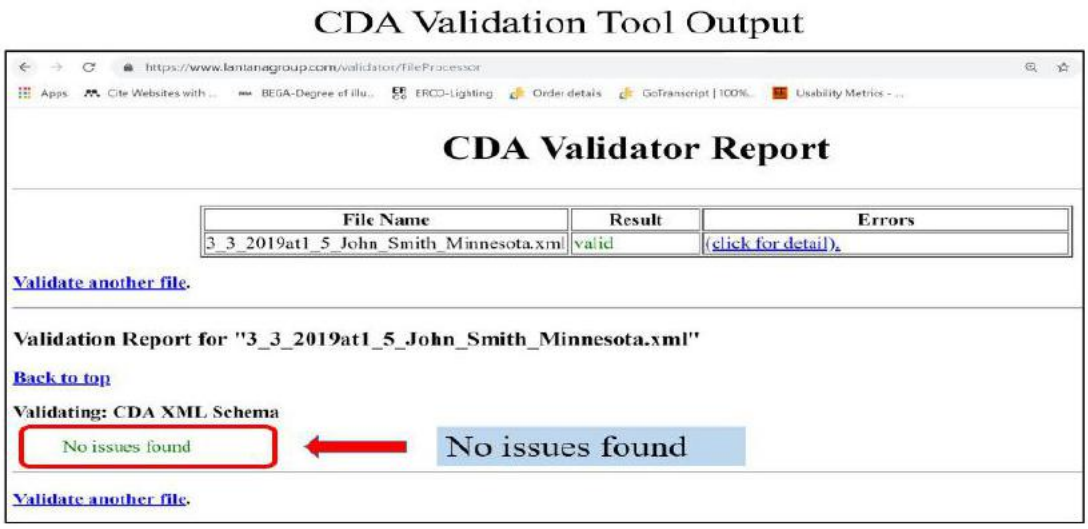


Figure 4.20: The result of the validated CDA output file by the recommended CDC validator.

1. Login page
2. Home page
   (a) Search a patient
   (b) Select a patient
   (c) Retrieve data values from the database
   (d) Mapping data values from the database to the case report form
   (e) Generate a case report form
3. Fill in the missing data fields
4. Generate and send the populated case report form
5. Organize and search the reporting history table

4.8 Limitations and Challenges

The prototype communicable disease Web-based clinical reporting tool was developed as a proof of concept prototype informatics solution to address challenges and barriers discussed in section 2.2 . The tool demonstrated feasibility to pull data fields from the multiple simulated EHRs and send data fields to multiple case report forms, but the tool was not linked to real EHRs, which affects the results of functionality testing. Testing the tool on a real EHR would increase the level and knowledge of challenges of security, authorizations, authentications, database base access and use, and interpretation.

Another limitation was data mapping between databases and case report forms in the prototype tool was a challenge. Data mapping is the process of creating data elements that maps the data from a source database to a destination. Many different techniques could use data mapping; this prototype communicable disease Web-based clinical reporting tool used hand-coded technique and the data were stored in local relational databases. The hand-coded technique is lengthy and has a higher chance of making mistakes. There are other mapping techniques such as using FHIR standard as mentioned in section 2.9 . The FHIR standard wasnt implemented for the challenges and barriers discussed in section 2.9 .

The CDA template development process that used to generate the CDA file into the developed Web-based reporting tool was a challenge. The CDA document has a large scope and purpose; it covers many medical documents trying to accommodate many medical document types. This scope gives more support to developers by providing many CDA templates, but in the same time the CDA templates face challenges to fit other medical document types that are not in the example templates. For example, the patients occupation was required in the states case report form, but the CDA templates did not provide occupation example and did not specify coding system to be used. This limitation in the templates might lead developers to use different coding system, which would raise interoperability issues.

In implementation level; CDA does not provide implementation guide for level 3 (content level) , its only provides implement guide to the level 2 (constrains sections). Another CDA

templates issue is the document readability of the CDA document. It is possible to generate a CDA document with entries only, without textual representation, which makes the document hard to read by human.

4.8.1 Mapping data values between the database and the case report form

Most of the data are currently stored in relational databases; mapping the data from the databases to the case report forms requires specialized technical skills and the knowledge of data schemas. Data mapping is the process of creating data elements that maps the data from a source database to a destination. Data mapping could be used by many different techniques; this Web-based reporting tool used hand-coded. The hand-coded technique is lengthy and has a higher chance of making mistakes. There are other mapping techniques such as semantic mapping or using FHIR standard as mentioned in section 2.9.

4.8.2 CDA templates development

The CDA document has a large scope and purpose; it covers many medical documents trying to accommodate many medical document types. This scope gives more support to developers by providing many CDA "templates", but in the same time it is CDA templates face challenges to fit other medical document types that are not in the templates. In implementation level; CDA doesn't provide implementation guide for level 3(content level) , it's only provides implement guide to the level 2 (constrains sections). Another CDA templates issue is the document readability of the CDA document. It is possible to generate a CDA document with entries only, without textual representation, which makes the document hard to read by human.

4.9 Discussion

The developed prototype communicable disease Web-based clinical reporting tool is designed and built to use the CDA standard format. The tool is built for easy and flexible creation

of case report forms due to the use of the flexible CDA standard. The prototype Web-based reporting tool provides a CDA output file, human and machine-readable formats, which enables applications, systems, and human to easily read CDA files. The easy interpretation and understanding of the exchanged CDA files lead to easier implementation. The use of the CDA standard in communicable disease reporting process have many promises to improve interoperability and medical documents exchange between healthcare providers and systems by using many medical terminologies such as LOINC and SNOMED-CT.

The developed prototype Web-based reporting tool can customize case report forms by using the CDA standard to meet healthcare providers professional and specialty needs. The tool provides a mapping engine to map and pre-populate data from EHRs to specific data fields in the case report form. The per-populating step helps healthcare providers to speed up the reporting process and reduce the manual work. Also, it helps to save time, avoid human errors and improve the quality of the reporting process. The developed prototype Web-based reporting tool is a flexible tool to design many case report forms to serve the purpose of reporting communicable diseases from healthcare providers to healthcare authorities.

The CDA standard is designed to be flexible and covers many medical documents to serve the medical documents exchange, but flexibility might lead to implementation and interpretation challenges with different healthcare systems design and usage. As mentioned earlier, the CDA standard is a flexible standard to use many controlled vocabularies, but stakeholders need to agree on common value sets to improve the interpretation and adaption.

4.10 Summary

The tool designed to overcome many communicable disease reporting challenges discussed in section 2.2 on healthcare providers level, reporting process level, and reporting recipients level. The developed prototype communicable disease Web-based reporting tool focused on the use electronic reporting based on standardization and following reporting guidelines to use official states novel influenza case report forms. The tool was designed to help healthcare providers to report communicable disease cases from healthcare providers level to healthcare

authorities level by applying the Clinical Document Architecture (CDA) standard, see section 2.8 . The use of CDA standard allows the tool to implement and use of medical terminologies such as LOINC and SNOMED-CT to overcome the challenges of interpretation in communicable disease case reporting.

The tools interfaced offered many functions such as log in, basic and advanced search to search a patient for reporting issues. Also, the tool allows to select a specific patient for reporting, allows the option to choose a specific case report form to be used in the reporting process. The tools have an important feature to electronically map and pre-populate data fields from EHRs to into a case report form. Also, the tool allows users to manually enter missing data fields in the case report form that did not electronically populated in the case report form. Another important feature was converting the generated case report form with the pre-populated data and manually entered data into Clinical Document Architecture (CDA) standard format. The tool allows the converted CDA file to be exchanged with a third party into CDA format.

The tool development was based on four a hierarchy of four levels. The first level was data layer level to cover patient data, clinical vocabularies such as LOINC and SNOMED-CT, and CDA standard terminologies. The second layer covered data access layer through MySQL. The third level covered the backend layer which included the PHP. The fourth and last level covered the presentation level, which covers and explained the use of Application Program Interface (API), Hypertext Markup Language (HTML5), controller and model components.

The tool development faced many challenges with mapping specific data from databases to specific data fields in case report form and creation of SQL queries. Also, the development of CDA templates was a challenge to modify templates to fit the case report form required data fields. The developed tool needs evaluation with potential users to measure acceptance level and to identify usability problems. The Usability problems identifications process helps to identify the tools challenges and identify areas and functions for improvements. The tool evaluation is discussed in Chapter 5.

Chapter 5

AIM 3 –PROTOTYPE COMMUNICABLE DISEASE WEB-BASED CLINICAL REPORTING TOOL EVALUATION METHOD

This chapter introduces the reader to the evaluation methodology used to assess the prototype communicable disease Web-based clinical reporting tool introduced in Chapter 4 . As mentioned in section 2.10, the evaluation methodology is a tool to help developers and stakeholders better understand the needs of the potential users while simultaneously providing a product of excellent quality. The evaluation method is essential in identifying areas for improvement and helps developers in making decisions which helps to achieve the projects objectives and goals. The primary objective of this chapter is to introduce the actions and activities regarding values, principles, and standards to enhance the usability of the evaluated prototype communicable disease Web-based clinical reporting tool.

Firstly this chapter introduces the evaluation methods search process. Secondly, it focuses on the applied evaluation methods to perform the prototype communicable disease Web-based clinical reporting tool evaluation, which is the Think-Aloud evaluation method (see Section 2.10.5) . Furthermore, this segment also introduces the reasoning and logic behind the choice of evaluation method as the selected evaluation tool for this dissertation. This chapter continues by explaining the evaluation methodology processes. Lastly, this chapter provides some of the results and findings of applying the evaluation method to the tested Web-based reporting tool.

5.1 Evaluation Methods Search

I conducted a review of the evaluation methods used in the healthcare field. Based on prior knowledge gained via literature reviews and the provided search key terms in the peer-reviewed articles, I used the following words in Table 5.1

Table 5.1: The used search key terms

Term	**Alternative Terms & Synonyms**
Usability	Usability OR usable
Evaluation	Evaluate OR Evaluation OR Measure OR Measurement OR Test OR Testing OR Method OR Methodology
Tool	Tool OR software OR Application OR Website OR Web

I explored the key terms using two digital libraries to search for published articles. The two digital libraries were PubMed and The Association for Computing Machinery (ACM) database, which identified some of the performed evaluation methods in the healthcare fields. The investigation used the applied key search terms, inclusion, and exclusion criteria.

The inclusion criteria are:

- Has any of the search key terms in the title or abstract
- Articles published in the last ten years
- Articles use the English language
- Peer-reviewed articles in the PubMed and ACM search engines
- Retrievable peer-reviewed articles
- Applicable evaluation methods to this tested tool

The exclusion criteria are:

- Abstracts only
- Papers with no focus on the evaluation domain
- Articles older than ten years old
- Articles cannot be fully retrieved
- Duplicate articles
- Papers not written in English
- Papers are not peer-reviewed

5.1.1 Evaluation Research Question

The goal of this evaluation method is to evaluate the usability of the prototype Web-based reporting tool from the perspective of the evaluation research question: Is the tool usable? . This research question will help developers to summarize and categorize evaluation findings and identify areas for improvement. Table 5.2 shows the details and motivation of the evaluation research question.

5.1.2 Retrieved Results

The PubMed search engine retrieved 1760 articles based on the search key terms. There were only 179 articles have the search key terms in titles or abstracts. In the following step; there were 151 excluded articles because we specified the time duration to 10 years, which further reduced the remaining articles results to 28 . In the next step; 22 articles did not meet inclusion criteria because there was no applicability of the evaluation methods to the

Table 5.2: Evaluation research question and motivation

Research Questions	**Motivation**
Is the tool usable for healthcare providers who either used or never used a reporting system for reporting communicable diseases such as Novel Influenza?	To discover whether the evaluated tool meets potential users needs and expectations to overcome novel influenza reporting process challenges . To help evaluators to identify potential usability problems to improve the tools acceptance for potential users.

tested tool in this dissertation. This process further reduced the remaining final articles to 28, see Figure 5.1.

The advanced search features in the ACM search engine is different from the PubMed advanced search design, which makes the search steps in the ACM and PubMed different. The advanced search engine in the ACM set to retrieve publication that has the search key terms in the title or abstract only. The ACM search engine retrieved 1759 articles based on the search key terms. There were 592 excluded articles because of the specified time duration (10 years). This time specification reduced the number of articles to 1167 relevant articles. In the next step; there were 1050 excluded articles due to publication type (only peer-reviewed articles), which left 117 articles which met search criteria. In the next step; there were 102 excluded articles due to the lack of applicability of the evaluation method to the tested tool in this dissertation, which left 15 remaining final articles, see Figure 5.2.

5.1.3 Retrieved evaluation methods

The PubMed search included only six peer-reviewed articles based on the inclusion and exclusion criteria while ACM included fifteen peer-reviewed articles. I reviewed all the 21

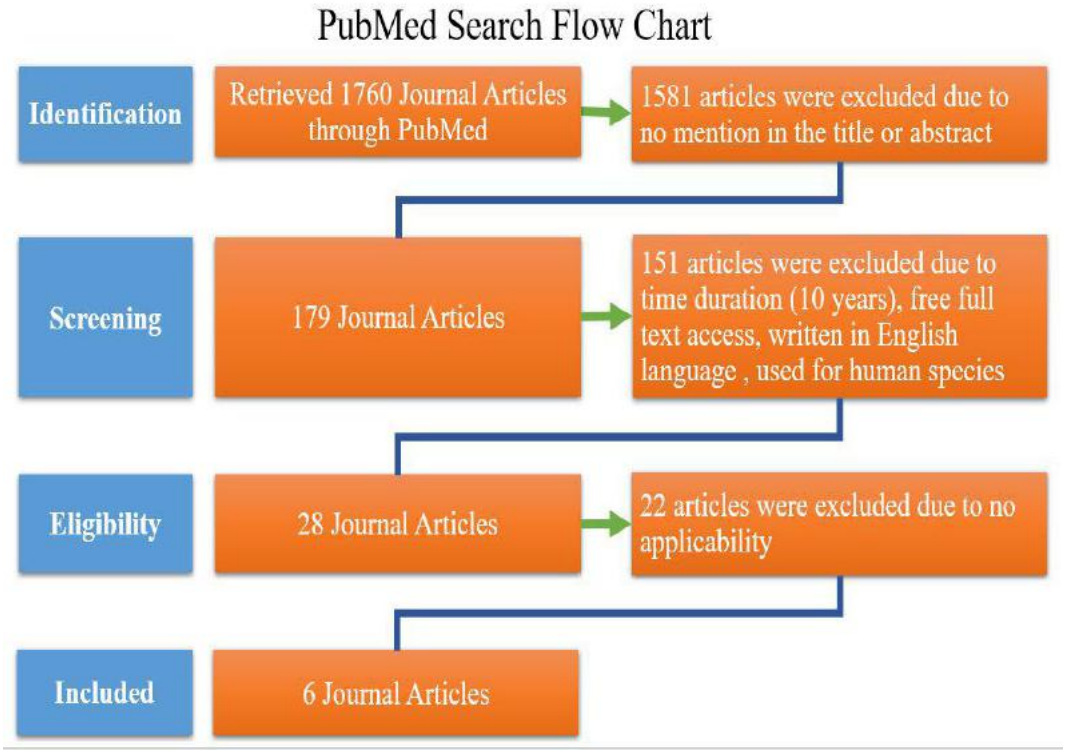


Figure 5.1: The PubMed PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart.

peer-reviewed articles and compiled a list of the applied evaluation methods. There are diverse ways to classify evaluation methods such as qualitative, quantitative, and mixed methods. For simplicity, I used qualitative and quantitative categories.

The evaluation methods under the qualitative methods are open-ended interviews, usability, observation, focus groups, and online expert discussion. The evaluation methods under the quantitative methods are survey and testing with a special tool used for testing purposes only. Refer to Figure 5.3 to find the detailed qualitative and quantitative evaluation methods and how many times each evaluation method applied in the final 21 peer-reviewed articles.

Ensuing discussions with the Ph.D. committee members based on the benefits of each evaluation method led to the joint decision in utilizing the Usability evaluation method as

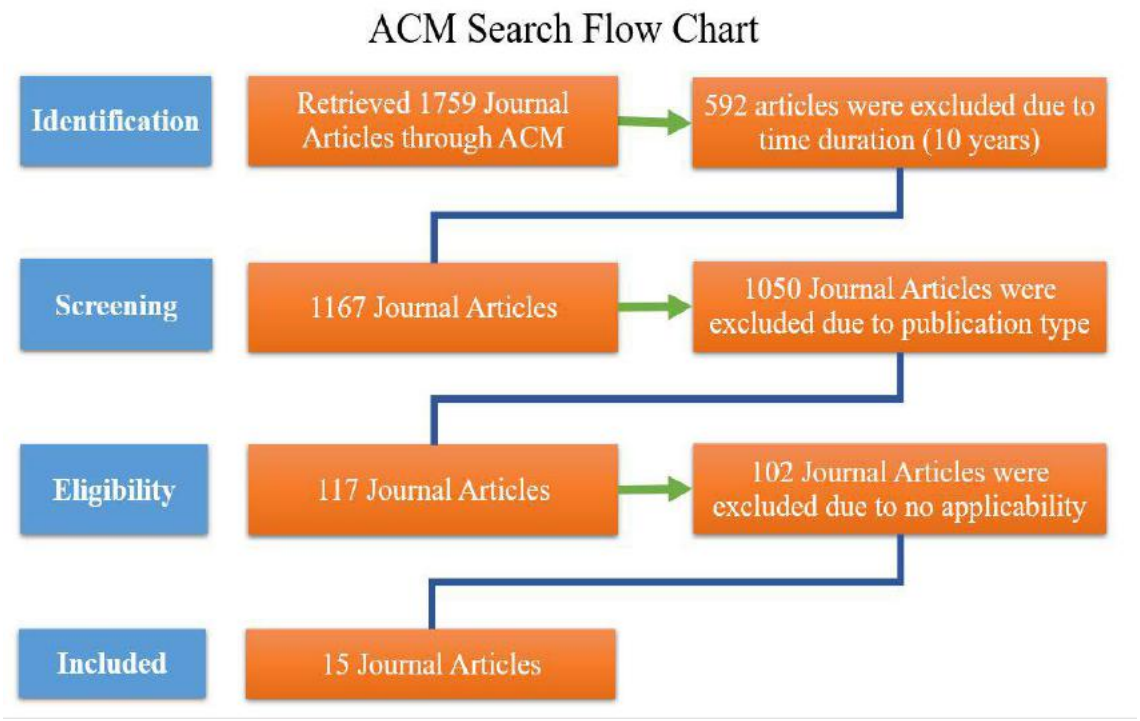


Figure 5.2: The ACM PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart.

the evaluation method for this dissertation. Later in this chapter, some of the benefits of employing the Usability evaluation method are mentioned.

5.2 The Used Usability Evaluation Methods to Evaluate the Prototype Communicable Disease Web-based Clinical Reporting Tool

The success or failure of a product design depends on the ease or difficulties when the potential users interact with the design. Therefore, designing a usability evaluation method process became critical for improving the tool . The main purpose of the usability testing is to improve the design. Usability testing helps developers to better understand how real users interact with the tool. Also, usability testing helps improving the tool by identifying areas for improvements. The challenge to develop a more usable design led to the emergence

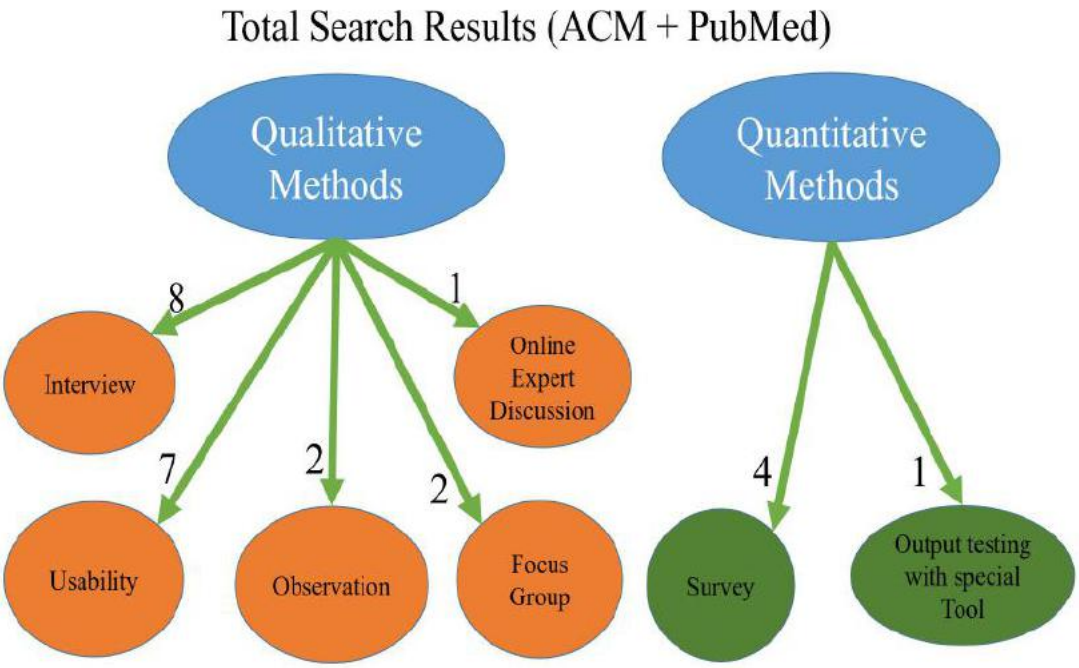


Figure 5.3: The numbers of times each evaluation method appeared in the final 21 peer-reviewed articles for the qualitative and quantitative methods.

of several evaluation methods to address users expectations and needs. There is no single evaluation method suitable for all types of evaluations goals and objectives.

Evaluators are constantly modifying usability evaluation methods to support the goals and objectives of the evaluation sessions better. A combination of evaluation methods shows better results than a single evaluation method [95, 137]. Therefore, the PhD dissertation committee members and I agreed to use a mixture of evaluation methods. The used evaluation methods are Concurrent Think-Aloud and Surveys methods to achieve a better understanding of the evaluated design to help to improve the usability of the design to increase the users acceptance and meet their expectations. The chosen evaluation methods for this dissertation provide qualitative and quantitative data.

5.3 The Concurrent Think-Aloud evaluation study

This section covers the evaluation session process, tasks, equipment, location settings of the evaluation session, data collection sources, evaluation study procedure and finally presents the results and findings of evaluating the prototype communicable disease Web-based clinical reporting tool.

Every usability evaluation session for all the participants followed the same process from the start to the end of the evaluation session. When a participant arrived at the usability testing location, the participant was greeted and asked to review the consent form (See Appendix B.1). The consent form provided an overview of the study and the evaluation process. After singing the consent form and answering any question from a participant, tasks were performed in the same order as other participants. After finishing all tasks, the participant filled surveys related to the usability session evaluation. After finishing all the surveys, the usability evaluation session comes to an end. For a general usability evaluation session see Figure 5.4 and section 5.5 will cover the usability evaluation session in detail.

5.3.1 Tasks

The evaluation study involved looking for information on the prototype communicable disease Web-based clinical reporting tool. Evaluators provide participants with a list of tasks to perform by using the tool. The list of tasks designed to test what potential users would perform in real settings. Tasks are developed to target different areas of the tested tool to avoid learning curves. Tasks are designed entirely independent of each other to avoid affecting another. Failure on completing a task does not affect the overall process.

The tasks utilized in this evaluation study are presented in a scenario format. Scenarios are widely accepted and are used by usability practitioners as a familiar way to present tasks in the usability field. Each task has a clear description of what participants are supposed to achieve by performing a task. Each task has no instruction on how to perform a task, only the goal of task (See Appendixes B.2 and B.3 for a complete list of tasks). All tasks are

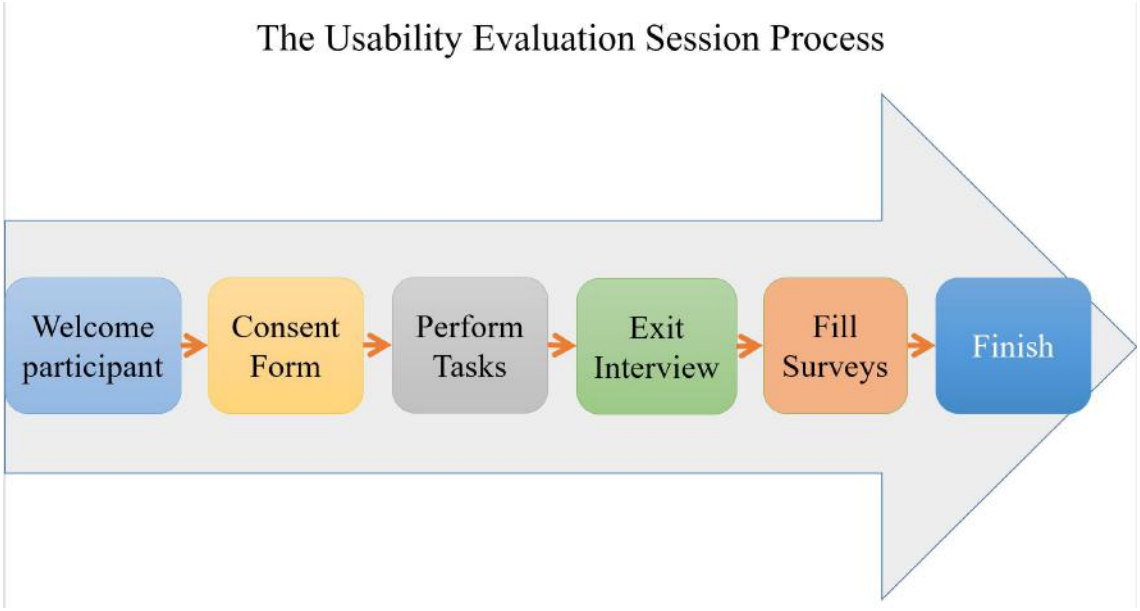


Figure 5.4: Order of evaluation session process.

designed to be short and to not extend the evaluation session time or tax the participants memory. Each task has one correct answer to enable evaluators to find whether participants accomplished the tasks or not.

Tasks are designed to cover the Web-based reporting tool key features and functions while also predicting usability problems. Tasks are designed to not be difficult to accomplish nor too easy to accomplish. Avoiding too hard or too easy tasks makes the participants verbalizing flow normal to avoid affecting the findings which will then not affect the findings.

The five Tasks were designed to cover key features of the tool interaction and functionalities. The five tasks are:

- Task 1: Log in to the tool
- Task 2: Generate a specific case report form
    1. Search a patient

2. Select a patient
3. Specify a case report form
4. Generate a specific case report form

- Task 3: Fill in the missing data
- Task 4: Send the generated case report form to a healthcare authority
- Task 5: Search the reporting history for a specific user

All tasked were reviewed by many PhD candidates with usability testing experiences. All tasks went through pilot tests before finalizing the list which ensured the wording of tasks was clear and used familiar terms to the participants. The tasks were designed to evaluate the key features in the tested tool. Then an initial developed list of tasks went through the pilot testing. After the pilot testing, the evaluator improved on the list of tasks based on the feedback from the pilot testing and the discussion with the PhD candidates with usability testing experience, see Figure 5.5 . An example of one of the final tasks is listed below(See Appendixes B.2 and B.3 for more details) :

"The generated Novel Influenza state's case report form might have some missing data fields. You want to have a case report form with no missing data fields. Using the tool and the provided patient card, can you fill in the missing data fields in the Minnesota case report form?"

Another reason for the pilot tests was to estimate the average time it took to accomplish the tasks. After finalizing the tasks list, the next section covers the process of recruitment participants.

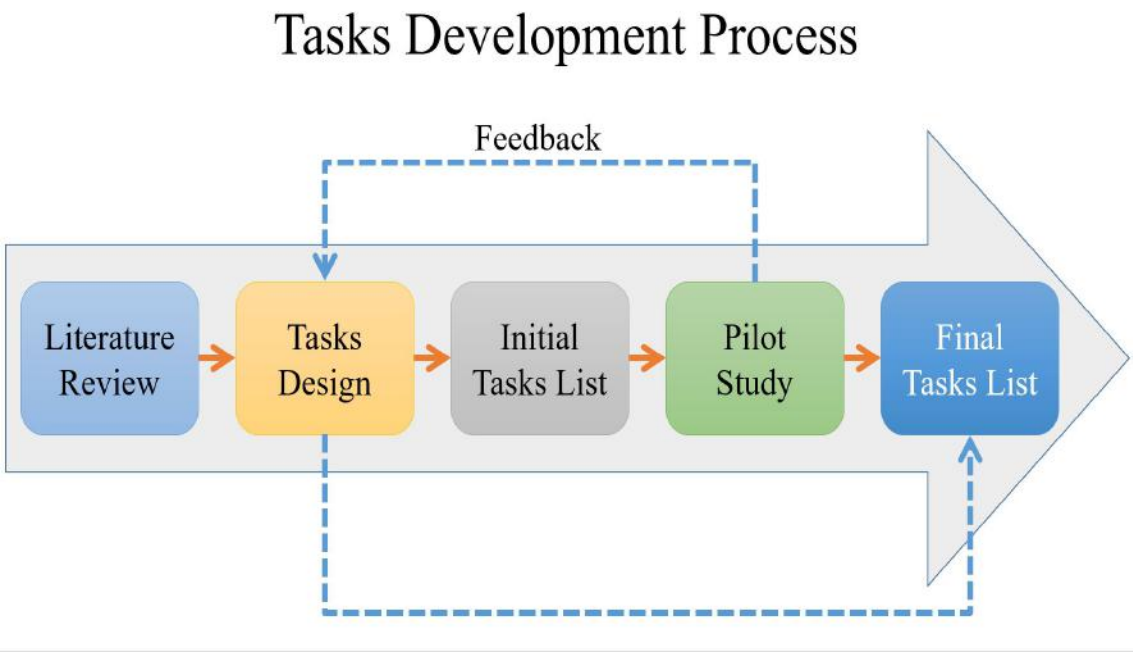


Figure 5.5: The final tasks development process.

5.3.2 Participants Recruitment

Recruiting participants is a significant and essential step in the evaluation process. It requires careful planning to target the potential participants and to collect quality data to help developers improve the design. Hinderer and Nielsen provided over 200 tips and tricks to recruit participants in usability studies [138]. In regards recruiting participants, they mentioned many essential factors to collect better quality during the evaluation sessions. They focused on the following:

1. Decide on how many participants to recruit as a sample size

2. Learn about potential users to target specific participants

3. Develop recruitment criteria

4. Specify the recruitment method

The listed above four bullets are the main factors to recruit participants for this study. The recommended participants sample size for this study is covered in section 5.3.3 . Methods to target potential participants covered in section 5.3.4 . Potential participants recruitment criteria is covered in section 5.3.5 while the recruitment methods is covered in section 5.3.6 .

5.3.3 Participants Sample Size:

The reality is that most usability evaluation studies cannot identify all usability problems [114, 139]. The goal of this evaluation is to identify the major usability problems. A multitude of studies argue different sample sizes, but Hinderer and Nielsen's recommendation is to have five to nine participants in a usability study where five participants can identify 85% of usability problems, see Figure 5.6 [138].

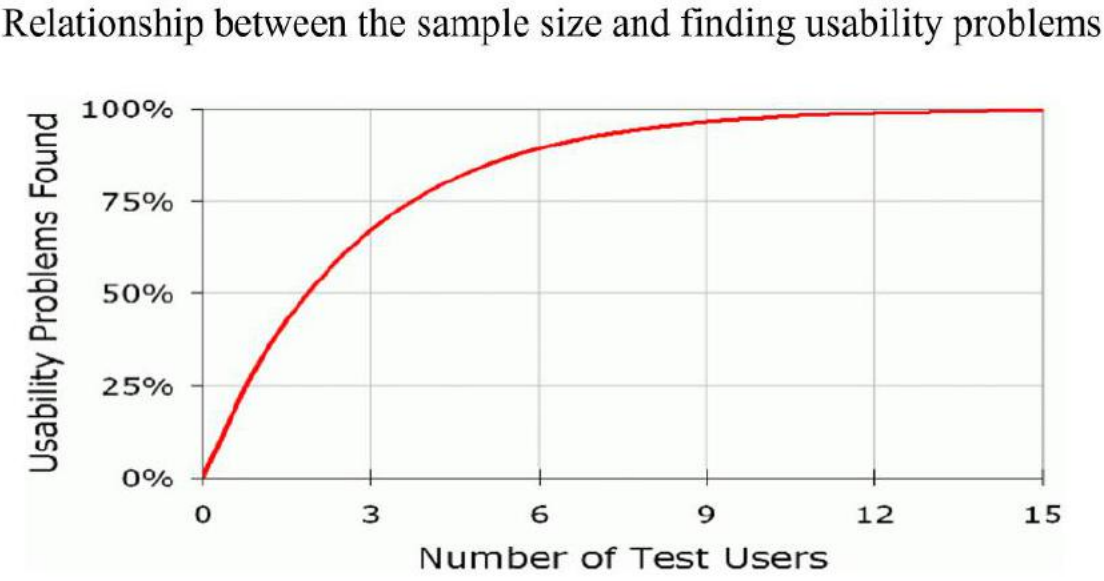


Figure 5.6: Relationship between the identified usability problems and the number of participants [140].

Another recommendation is to consider recruiting more than nine participants as a back-up to cover cases of no-shows and pilot tests. The purpose of backup recruitment is to cover the cases of no-shows because the average no-show rate is about 10% [138]. In this evaluation study, the goal is to have two backup participants to cover for no-show cases since the sample size is not large.

The purpose of the pilot study is to conduct an evaluative session as a real session in order to understand session timing and tasks feasibility. For smaller studies, the recommendation is to target one pilot user [138]. In this evaluation study, the goal is to have two pilot testing sessions to improve session timing and tasks feasibility. Based on these recommendations, the total number of participants size is 11, see Table 5.3

Table 5.3: The total targeted number of participants in the usability sessions

Participant Type	**Number**
Pilot sessions with Ph.D. students with Usability background	2
Pilot from the final sample size	1
Max number of participants for the study	9
Backup	4
Total	16

5.3.4 Targeting Potential Participants

As mentioned in the sample size section, the goal of this evaluation is to identify the major usability problems. The primary factor is to collect valuable feedback from participants in order to target representative potential users which will serve the goal of improving the evaluated tool. Non-representative potential users generate inaccurate feedback, which affects the outcomes of the evaluation sessions.

To learn more about the potential users for this evaluation method, I budgeted time

to meet on a one-to-one informal meeting with healthcare providers and state department health to know more about the potential users. The next paragraph identifies some of the potential participants. The potential users of this tool are healthcare providers. Mostly, the ones who are responsible for reporting suspected novel influenza cases from the healthcare providers point to an authority point. This kind of potential participants includes many healthcare providers such as physicians, nurses and medical assistance. The potential participants are located in hospitals, primary care facilities, emergency departments, labs, or other healthcare facilities. Ideally is to target different healthcare providers from many specialties who are mostly in charge for reporting novel influenza cases, but for this study I only targeted physicians and nurses from healthcare facilities located in Seattle, WA.

5.3.5 Recruitment Criteria

Identifying the potential users and what they do and how the tool is intended to help them report communicable or infectious diseases helps to prepare recruitment criteria. Healthcare providers consist of a substantial number of practitioners with diverse specialties. Having only five to nine participants in the usability evaluation would be a challenge to represent all potential participants. After discussing the sample size and diversity of potential users with the PhD dissertation committee members; the decision was to target participants from Seattle, WA. Targeting potential users from Washington state was expected to facilitate the process to sample representative potential users. The developed inclusion and exclusion criteria are listed below.

The research study team recruits potential participants based on the following inclusion Criteria:

1. The age of participants must be 18 years or older.

2. The participants must be fluent in the English language to be able to share their feedback with the research team and be able to understand the tasks.

3. Participants must have any experience of using Electronic Health Record (EHR) or patient's paper-based chart to be able to extract information on patients. This decision would help the research team to understand potential users needs regardless if they ever used reporting tool or not.

4. Participants must have any experience in dealing with a patient who had an infectious or communicable disease such as Influenza. This decision would help participants to understand the importance of reporting certain cases and understand the importance of having a reporting tool.

5. Due to the nature of the study, participants should have no severe conditions (mental or physical disabilities) or injury prevent from participation. Conditions such as speech, sight, hearing disabilities do limit the finding of the usability evaluation study.

6. Participants must be willing to participate in the evaluation session and have their voice and screen interaction recorded for analysis purposes only. In the usability evaluation study, voice recording and screen interaction would be an essential outcome for statistical purposes.

The research study team excludes any potential participants based on the following inclusion Criteria:

1. The research team excludes any participant who is younger than 18 years.

2. The research team excludes any participant who is not fluent in the English language.

3. The research team excludes any participant who has no experience in the healthcare field.

4. The research team excludes any participant who has prior familiarity with the evaluated web-based reporting tool to avoid any bias.

5. The research team excludes any participant who is not willing to have his/her voice and screen interaction recorded during the evaluation session for analysis purposes only.

After developing the inclusion criteria, I developed a screening questionnaire which was approved by the dissertation committee to target qualified potential participants. All the screening questions were designed to target the inclusion criteria. For example, for the inclusion criteria regarding the targeted healthcare providers, one question was designed to specify the participant's healthcare service type (e.g., Primary Care, Nursing Care, Specialty Care, Public Health Services, Administrative staff).

The screening questionnaire used online-based survey tool called SurveyMonkey [141]. This tool is free, user-friendly, and provides real-time access to potential participants and research team. It also provides real-time analysis and charts on the number of participants and about each question in the screening questionnaire. The introduction page of the screening survey highlighted some of the critical points such participants rights, incentive, confidentiality, risk level, duration of the evaluation session, and location. Also, the screening questionnaire mentioned that filling the questionnaire does not mean that the potential participant is enrolled in the study. The next section talks about recruitment methods.

5.3.6 Recruitment Methods

I used three recruiting methods in this usability evaluation study: email listservs, flyers and snowball sampling. The following sub sections provides more details on each recruitment method.

5.3.6.1 Emailing

I asked facilities permission under the School of Medicine at the University of Washington through official channels to forward the recruitment invitation email to the appropriate staff and senior students. Furthermore, I contacted Washington State Department of Health to forward the recruitment invitation email to their appropriate staff. The invitation email

extended to contact hospitals such as the University of Washington Medical Center and Seattle Childrens Hospital to forward the recruitment invitation email to the appropriate staff, a full list of contacted places for recruitments is discussed in section 5.3.8 .

5.3.6.2 Flyers

I asked permission through official channels to post flyers in the public spaces of the Health Sciences Building at the University of Washington and other public places on the campus such as the School of Medicine, School of Nursing, School of Public Health, Libraries, such as Suzzallo, Allen Libraries, and the Health Science Library. I also received permission to post flyers at the clipboards at the shared places at the University of Washington.

5.3.6.3 Snowballing

I used snowball sampling, where potential participants recruit other participants for the evaluation study [142]. The snowball recruitment method started with identifying potential participants using the research team, and the potential participants help in recruiting other potential participants. Regardless of the advantages and disadvantages of snowball sampling, this method can help in to recruit more potential participants. Also, snowball sampling where participants help to recruit and target other potential participants with specific inclusion criteria from their network or practice community would increase credibility to research and reassure other potential participants of confidentiality [143].

5.3.7 The script

The script of the flyers and invitation emails used for the recruitment clearly outlined the information that potential users needed to know to decide to participate in the evaluation sessions or not. The beginning of the script had an introduction to the research team and the purpose of the evaluation study, and what would be tested in the evaluation session. Also, stated what would a potential participant be doing during the evaluation session and

the location of the evaluation session. The script stated the amount of financial reward a potential participant would collect by the end of the evaluation session and the level of risk, if any, to participate in the evaluation session.

5.3.8 Targeted Facilities and Locations

In this evaluation study, I targeted many healthcare facilities for recruitment such as the University of Washington Medical Center, which is the largest healthcare facility in Washington State. The reach out included School of Nursing and School of Public Health at the University of Washington-Seattle. Also, contact Seattle Children's Hospital and Washington State Department of Health, see Table 5.4 for a full list of targeted places to recruit potential participants. About 50 flyers have been posted in the indoor advertisement boards in the mentioned locations in Table 5.4.

5.3.9 Pilot testing

As mentioned earlier, there are many reasons to perform pilot testing before starting the usability evaluation sessions. One reason is to finalize the list of tasks to ensure the wording of tasks is clear and uses familiar terms with the participants. Another reason to go through pilot tests is to estimate the time to accomplish every task. The pilot study was scheduled to run through one week, and the main study was scheduled to run through seven weeks period. Each participant was scheduled for only 60 minutes evaluation session. All evaluation sessions were arranged to run through weekdays to avoid any conflicts with weekends plans. A reminder email was sent a few days before the evaluation session's scheduled date and time to remind potential participants with the details of the evaluation session.

5.4 Usability Testing Location Setup and Equipment

All evaluation sessions were performed in the agreed location between the research team and the participants. For the participant's convenience, the University of Washington was

Table 5.4: A full list of targeted places to recruit potential participants

Index	**Location**	**Recruitment Method**
1	University of Washington Medical Center-Seattle, WA	Email
2	School of Medicine, University of Washington-Seattle, WA	Flyer and Email
3	School of Nursing, University of Washington-Seattle, WA	Flyer and Email
4	School of Public Health, University of Washington-Seattle, WA	Flyer
5	Seattle Children's Hospital, Seattle, WA	Email
6	Washington State Department of Health, Seattle, WA	Email
7	Harborview Medical Center, Seattle, WA	Email
8	Institute of Translational Health Sciences (ITHS), University of Washington-Seattle, WA	Flyer and Email
9	Department of Family Medicine Student Program, University of Washington-Seattle, WA	Flyer
10	Health Sciences Library, UW-Seattle	Flyer
11	Suzzallo and Allen Libraries, UW-Seattle	Flyer
12	South Lake Union Building- Building C	Flyer

chosen as the default location to host the evaluation sessions unless the research team and the participants agreed to meet somewhere else. Invitation emails were sent to all the included participants in the evaluation study included the address and map location of the evaluation session. Also, the invitation email included the phone number of the Primary Investigator to avoid any ambiguity of the location and to coordinate with the potential participants.

The evaluation session location consisted of a waiting area outside of the room where the

evaluation session was held. The room has a table and chairs belongs to the University of Washington, and a laptop belongs to the research team. The research team made sure that the room was comfortable and with a minimum level of noise. The session evaluator was seated beside the participant to observe the participant's interaction with the evaluated tool and to avoid any distraction, see Figure 5.7.

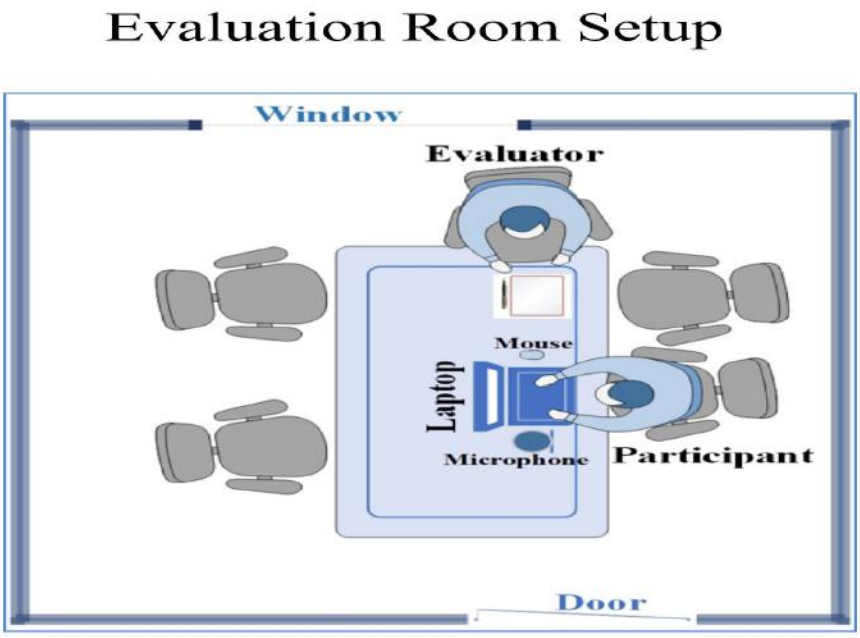


Figure 5.7: The setup of the evaluation study room .

The testing machine (laptop) was equipped with Microsoft Windows 10 Home (x64-based PC operating system), 2.70GHz Intel processor, 2904 Mhz, 2 Cores, 4 Logical Processors, 16 GB of RAM. Google Chrome (Version 71.0.3578.98) was the default web browser. Camtasia software was used for the voice recording during the session and to record participants' screen interactions. Also, there was a wireless mouse for the ease of navigation and a microphone to increase the voice quality recording.

5.5 The evaluation session phases

The evaluation session was planned to go through well-defined and clear steps to perform the usability testing. There are four main phases planned for the evaluation session. The first phase called Before performing the tasks; this phase starts by the participants arrival at the usability testing locations and ends before performing the actual tasks. The second phase called While performing the tasks; this phase starts by performing a task and ends by performing all the listed tasks. The third phase called After performing all the tasks; this phase starts after performing all the listed tasks and ends by filling all the required questionnaires. The fourth phase called By the end of the evaluation session; this phase is the closing phase of the session and ends by walking the participant out of the evaluation room, see Figure 5.8.

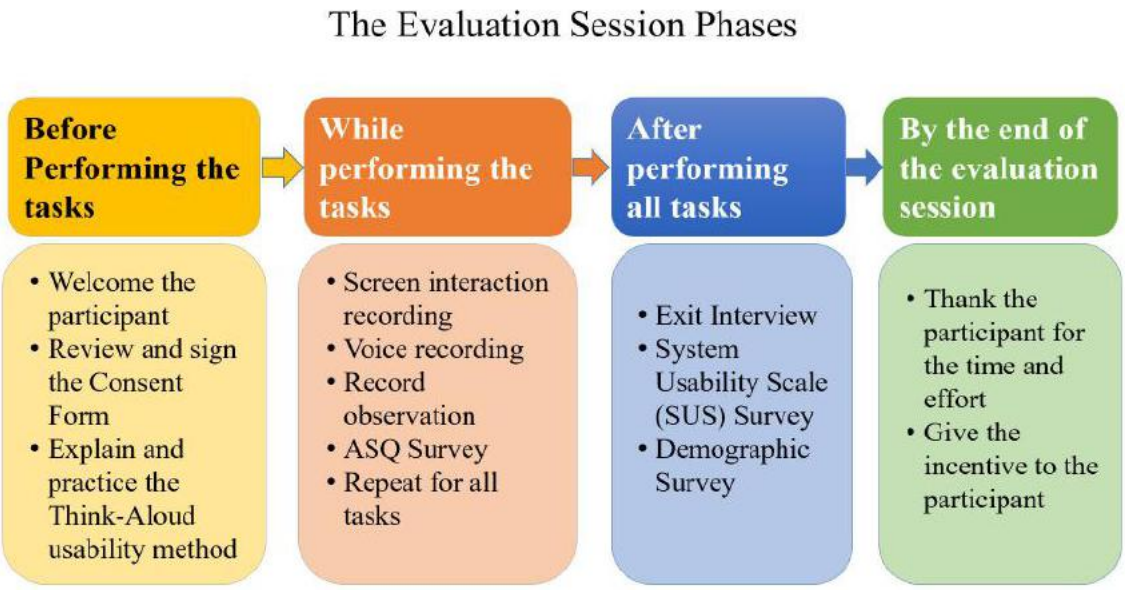


Figure 5.8: The evaluation session phases during each evaluation session.

5.5.1 Before performing the tasks

At the arrival of the participant to the evaluation session location, they were welcomed by the evaluator. The evaluator asked the participants not to discuss the evaluation session or the tool with other potential participants to avoid bias or affect the evaluation sessions findings. Also, the evaluator told the potential participant that they could withdraw from the study at any time with no consequences. The evaluator asked the participants to review and sign the approved consent form by the University of Washington Human Subjects Division (HSD), see (Appendix B.1). The evaluator introduced the concept of the Think-aloud method to the participants, and they were instructed to think aloud while performing the tasks.

5.5.2 While performing the tasks

After making sure that participants understood the think-aloud method itself, roll in the evaluation session, and fully understood the tasks instructions; the evaluator turned on the screen capture recording software and voice recording. The evaluator presented the tasks in the same order for all participants. While performing each task; the evaluator took observation notes while participants were performing each task using the Observation Evaluation Matrix Sheet (see Appendix B.4). This sheet contains fields to record the participants ID where participants names were replaced with participant ID. The sheet contains fields to record the start and finish time of the session and each task. Also, the sheet contains fields to record the task status (completed or failed) and notes space for observations.

After performing each task, the evaluator asked the participant to fill in the first questionnaire, which is the After Scenario Questionnaire (ASQ), see Appendix A.1. This questionnaire consists on three questions to measure the participants satisfaction with the performed tasks. The same process was repeated until performing all the tasks.

5.5.3 After performing all the tasks

After the performing all the assigned tasks, the participants were asked to fill the second questionnaire, which called System Usability Scale (SUS) Questionnaire (see Appendix A.2). The SUS questionnaire consists on ten questioned to measure the participants satisfaction with the tool. When the participants finished the SUS questionnaire, there were asked to fill the last questionnaire. The last questionnaire called Demographic Questionnaire, see (Appendix B.5). The demographic questionnaire is designed to collect demographic data such as age, gender, education level, years of experience in the healthcare field. The participants demographic information is collected for the purpose to determine whether the individuals who participated in the evaluation study are a representative sample of the targeted population for generalization purposes.

5.5.4 By the end of the evaluation session

After the session concluded and each participant filled all the required questionnaires, the evaluator thanked the participant for their contribution, time and effort. After that, the evaluator gave the participant the agreed-on incentive in an envelope labeled with their name, which means the end of the evaluation session. The evaluator collected all the evaluation session materials (notes and questionnaires) in a file assigned with the participants ID. The screen interaction and voice recording were collected into a folder assigned with the participants ID. Finally, the location of the evaluation session was restored to its original setting before the evaluation session.

5.6 Usability Evaluation Method Results

This section addresses the findings of the Concurrent Think-Aloud evaluation method. The results section covers many findings such as the participants demographics, tasks completion (success and failure rates), time spent on tasks, and satisfaction. Also, this section includes the results and findings of the used three questionnaires of this evaluation study (SUS, ASQ,

Demographics Surveys).

5.6.1 Usability Testing Participants

48 completed screening questionnaires were filled by Potential participants through the online questionnaire. The answers in the screening questionnaire were checked to make sure that only potential participants who meet the inclusion criteria are recruited. Out of the 48 candidates who participated in the screening questionnaire, only 14 candidates met the inclusion criteria. The 14 candidates were contacted and invited through invitation email to participate in the usability evaluation study, see Table 5.5 . The other participants were excluded because they did not meet all the inclusion criteria. Another reason to exclude other candidates from the evaluation study was the recruited candidates reached the proposed maximum sample size of the study. As mentioned earlier, some of the candidates who met the inclusion criteria were located for the pilot study and backups potential participants.

Table 5.5: The candidates distribution in the evaluation study.

Distribution of Participants	**Number**
Total number of participants in the screening questionnaire	48
Excluded	34
Included	14
Potential Participants (sample size)	5–9
Pilot	1
Backup	4
Final Participants without Pilot Testing	8

Before going through the results and findings, it is worth to mention that all the recruited participants are fluent in the English language and have experience in the healthcare field. All the included participants never worked on the evaluated tool before. All the

included participants have en experience in reporting communicable or infectious diseases either electronically or on paper. The following sub-sections cover more detailed results about participants and the findings of the Think-Aloud usability evaluation method.

5.6.2 Participants demographics

All the included participants are fluent in the English language and older than 18 years old. All participants are from both genders, do work in the healthcare field, and have some experience in using both Electronic Health Record (EHR) and patients paper-based charts. Also, all the participants have had experience in reporting communicable or infectious diseases. The participants education level varies from bachelors degrees holders to Ph.D. holders. All the participants have between 5 and 14 years of experience in the healthcare field. For more information on the participants demographic information and other characteristics, see Figure 5.9 . For more information on the participants characteristics, see Appendix B.6 .

5.6.3 Task Performance

As discussed in section 5.3.1 , the five Tasks were designed to cover key features of the tool interaction and functionalities. Task performance measured by measuring task completion rate and the time on tasks to perform the assigned tasks. The following two sub-sections covers the tasks completion rate and time spent to perform every task for all the participants.

5.6.3.1 Tasks Completion rate

The task completion rate is a widely used measurement to quantify the task completion rate [144]. The task completion rate or the success rate was measured based on the numbers of either task completed, or tasks failed. If the user or participant cannot completely perform a task, then this provide an evidence to the developing team that there was something wrong with the design.

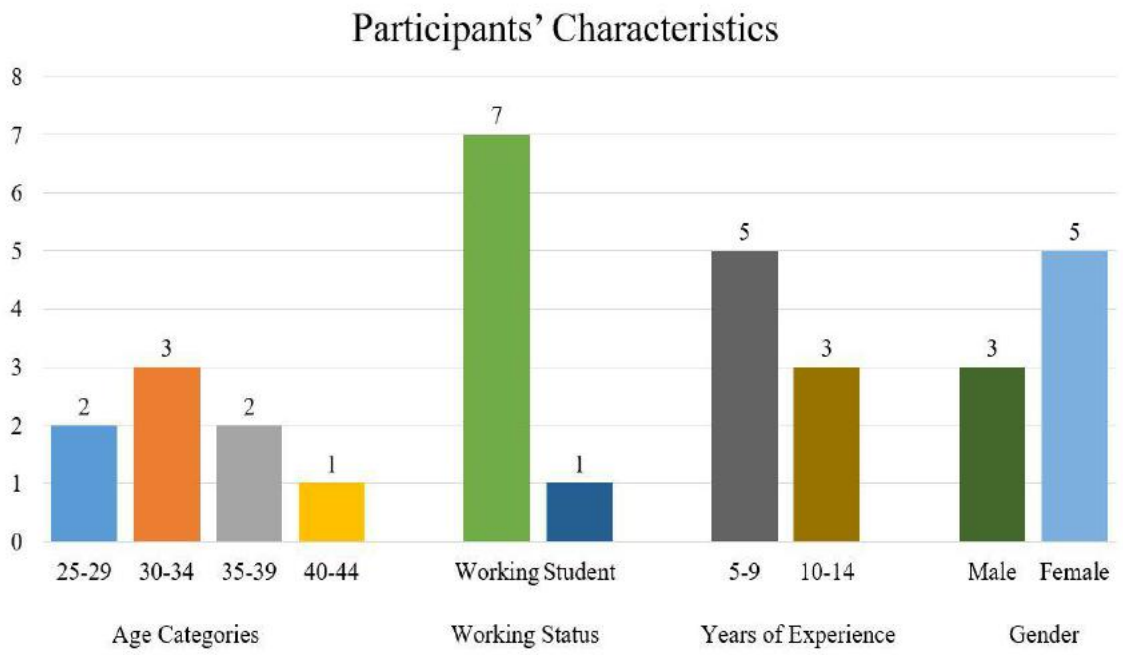


Figure 5.9: Some of the participants characteristics.

Each successful task was given a score of 1, and each failed task was given a score of 0. There were 8 participants where each participant asked to perform 5 tasks, which gives a total of 40 tasks for all the 8 participants. Task 1 covered login into the tool, Task 2 covered generating a specific case report form, Task 3 covered filling in any missing data, Task 4 covered sending the generated case report form to a healthcare authority, and Task 5 covered searching the reporting history for a specific user. For a list of tasks, see Section 5.3.1 and Appendixes B.2 and B.3. The participants completed 40 tasks (97.5% success rate) while they failed 1 task (2.5% failure rate). Each participant completed 5 tasks out of 5 tasks. For more information on the completion and failure of the tasks, see Table 5.6 and and Figure 5.10.

Table 5.6: Tasks' completion average per participant.

Participant ID	T1	T2	T3	T4	T5	Average
1	1	0	1	1	1	80%
2	1	1	1	1	1	100%
3	1	1	1	1	1	100%
4	1	1	1	1	1	100%
5	1	1	1	1	1	100%
6	1	1	1	1	1	100%
7	1	1	1	1	1	100%
8	1	1	1	1	1	100%
Total	100%	88%	100%	100%	100%	

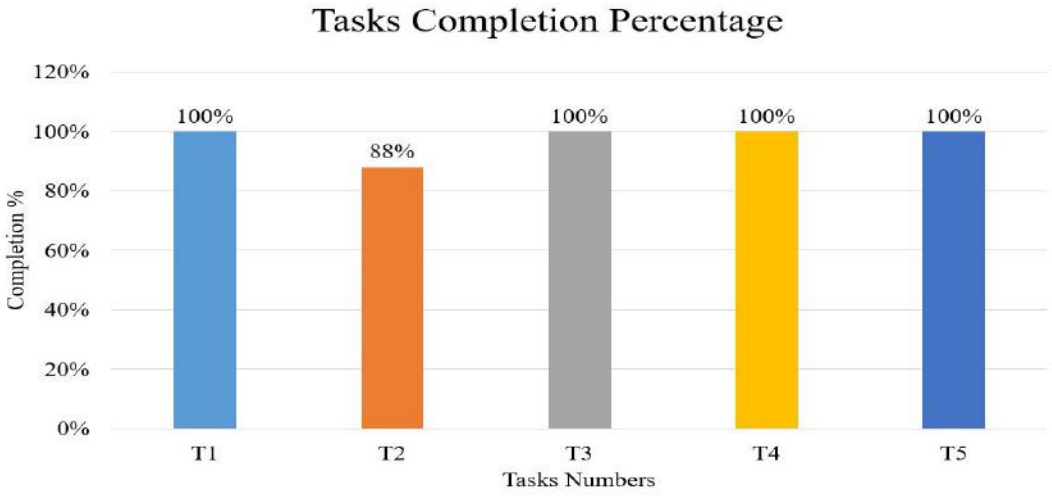


Figure 5.10: Percentage of the completed tasks for all the participants.

5.6.3.2 Time on Tasks

Time on task or task completion time is defined as a way to measure the efficiency of a product or design. The purpose of this measurement is not to measure how fast a user can perform a task, the purpose is to measure the experience itself [144]. Time on task is the time of the start of a task until the time of finishing a task. By using the Camtasia software used in this evaluation study, the moderator calculated the elapsed time [145]. Table 5.7 shows the results of the median and average time it took each participant of the eight participants to perform the 5 tasks, which gives a total of 40 performed tasks. Section 5.3.1 provided a description on the tasks and Appendixes B.2 and B.3 provided the tasks and scenario used in the usability evaluation sessions.

Table 5.7 shows that Tasks 1 and 5 took the shortest average time to perform while Task 3 took the longest average time to perform. Task 5 took the shortest median time to perform while Task 3 took the longest median time to perform. For more information on the lower bound times, upper bound times, average times, and median times per task, see Table 5.7 and Figure 5.11.

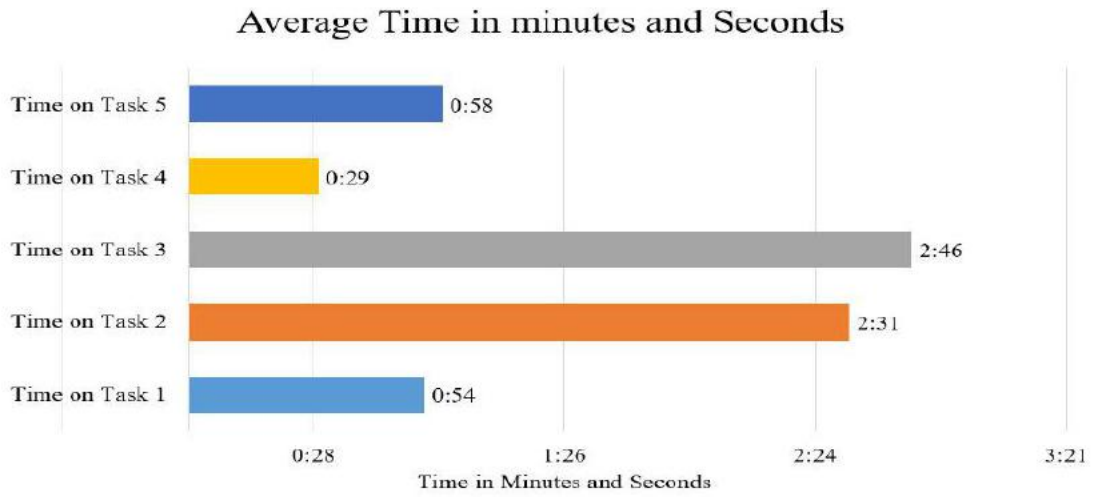


Figure 5.11: The average time per task for all the participants.

Table 5.7: Summary of the time on each task per participant per task.

Participant ID	**Time on Task 1**	**Time on Task 2**	**Time on Task 3**	**Time on Task 4**	**Time on Task 5**
Participant 1	1:01	5:00	3:49	1:06	1:50
Participant 2	0:18	1:28	3:21	0:13	1:07
Participant 3	0:42	2:27	2:29	0:31	0:34
Participant 4	0:54	2:12	2:48	0:35	0:45
Participant 5	0:32	1:35	2:24	0:18	0:36
Participant 6	1:28	1:37	2:50	0:03	0:26
Participant 7	1:04	1:22	1:52	0:26	1:02
Participant 8	1:08	1:33	2:27	0:22	0:44
Median Time in minutes	0:57	1:36	2:38	0:24	0:44
Average Time in minutes	0:53	2:09	2:45	0:26	0:53
Lower bound	0:18	1:22	1:52	0:03	0:26
Upper bound	1:28	5:00	3:49	1:06	1:50

5.6.4 Participants Satisfaction results

As mentioned in Section 2.11 , participants satisfaction is an important way to measure the usability of a product or design. To measure participants satisfaction, two questionnaires were used in this study. The used questionnaires are After Scenario Questionnaire (ASQ), (see Appendix A.1), and System Usability Scale (SUS) Questionnaire, (see Appendix A.2). The ASQ questionnaire, see Section 2.11 , was applied to measure the users satisfaction per task while the SUS questionnaire, see Section 2.11 , was applied to measure the users satisfaction with the tool.

5.6.4.1 Satisfaction Per Task

To quantify the post-tasks satisfaction by using the ASQ, overall of the three questions for each task was calculated. Further, overall ASQ score for the Web-based reporting tool was calculated by averaging the scores obtained for each of the five tasks for all the participants. For more results, see Table 5.8 and Figure 5.12.

Table 5.8: The rating of the ASQs questionnaires for all the participants.

Participant ID	**P1**	**P2**	**P3**	**P4**	**P5**	**P6**	**P7**	**P8**	**Average**
T1:Ease	5	5	5	5	5	5	5	5	5
T1:Time	5	5	5	5	5	5	5	5	5
T1:Suppor	4	5	2	5	5	5	5	5	4.5
T2:Ease	4	4	2	3	2	4	4	4	3.4
T2:Time	4	5	3	5	2	4	5	5	4.1
T2:Suppor	4	4	1	3	2	3	5	4	3.3
T3:Ease	5	4	4	4	4	5	5	5	4.5
T3:Time	5	5	3	5	4	5	5	5	4.6
T3:Suppor	5	5	4	5	3	4	5	5	4.5
T4:Ease	5	5	5	5	5	5	5	5	5
T4:Time	5	5	5	5	5	5	5	5	5
T4:Suppor	5	5	2	4	5	5	5	5	4.5
T5:Ease	5	5	5	5	4	5	5	5	4.9
T5:Time	5	5	5	5	5	5	5	5	5
T5:Suppor	4	5	2	5	4	5	5	3	4.1

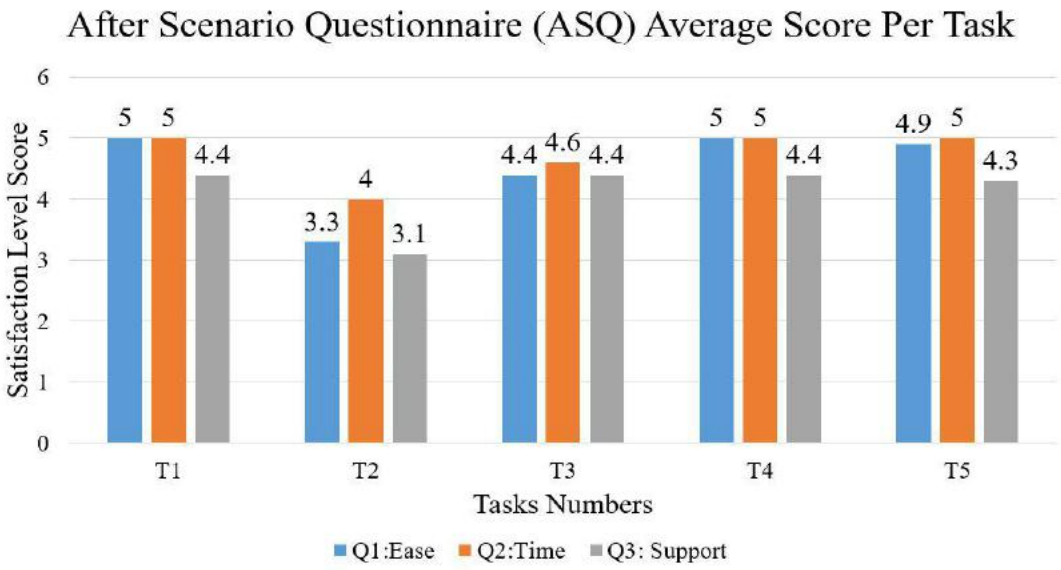


Figure 5.12: The overall average of the 3 ASQ questions.

5.6.4.2 Tool Satisfaction

Participants ranked all the ten questions from one to five based on how much they agree with each statement of the SUS questionnaire. The scores of the ten questions in the questionnaire are not meaningful on their own, but when combined they could present a useful measurement.

Thomas provided three simple rules to calculate the usability score using the SUS questionnaire [125]. Thomas stated that the participants rank the ten questions based on the participants' level of agreement with every question. Each question has a score ranges from zero to four. The three simple rules according to Thomas are:

1. For each odd-numbered question (1, 3, 5, 7, 9), subtract one from the score.

2. For each even-numbered question (2, 4, 6, 8, 10), subtract their value from 5.

3. Take the new-found values and add up the total score, then multiply the number by 2.5.

The overall score based on the previous rules has a range from 0 to 100 where the higher rating reflects a more top participant's satisfaction with the product or design. The result of applying the three rules by Thomas produce a score out of 100. This score is not a percentage; it is only an easy way of seeing the score. The free online spreadsheet by Thomas was used to do the calculation of the SUS score [125]. Based on Figure 5.13 and Table 5.9, the overall SUS score of evaluation testing was X, which fits in the excellent range in the scale and the acceptable range in the acceptability ranges. This score shows that there is some area of improvement for future work.

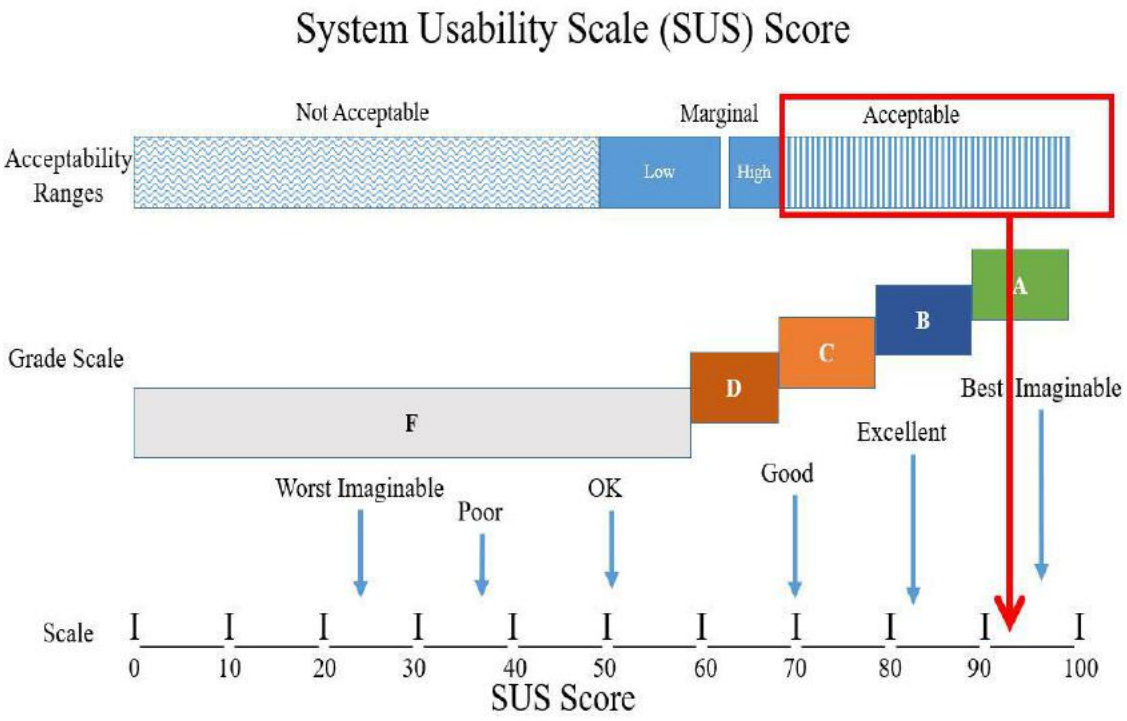


Figure 5.13: The SUS questionnaire score ranking [146] .

Table 5.9: SUS calculation steps based on the applied 3 rules developed by Thomas [125] .

For each odd-numbered question (1, 3, 5, 7, 9), subtract one from the score. For each even-numbered question (2, 4, 6, 8, 10), subtract their value from 5. Take the new-found values and add up the total score, then multiply the number by 2.5.

P. ID	**Q1**	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**	**Q8**	**Q9**	**Q10**	**Sum**	**SUS Score (Sum*2.5)**
P1	4	4	4	4	4	3	4	4	4	4	39.0	97.5
P2	3	4	3	4	4	2	4	4	4	4	36.0	90
P3	3	4	4	4	4	4	4	4	3	4	38.0	95
P4	2	2	3	4	3	3	3	3	3	3	29.0	72.5
P5	4	4	4	4	4	4	4	4	3	4	39.0	97.5
P6	4	4	3	4	4	3	4	4	4	4	38.0	95
P7	4	4	4	4	4	4	4	4	3	4	39.0	97.5
P8	4	4	4	4	4	4	4	3	4	4	39.0	97.5
											Average	92.8

5.7 Usability Problems Extraction

Usability problems or issues are typically qualitative data where usability problems include the identification and description or problems. This section covers the results regards the individual usability problems types, frequency, sources, and severity. Howarth and other researchers state that there is no universal standard guideline for the usability problems extraction process [122–124]. There are many usability problems definitions in the usability field. In this usability evaluation study, I used the definition of Lavery "A usability problem is an aspect of the system and/ or a demand on the user which makes it unpleasant, inefficient, onerous or impossible for the user to achieve their goals in typical usage situations" [147].

5.7.1 Usability problems extraction process

In this evaluation method process, many recommendations were considered in the usability problems extraction based on the literature to increase the validity of the usability problems findings. It is important to mention that the criteria used to identify usability problems can range from short lists to very detailed lists [124]. The structured usability problem extraction process used in this evaluation method was based on the developed process by Howarth and similar to other extraction processes [122] [148] , see Figure 5.14 .

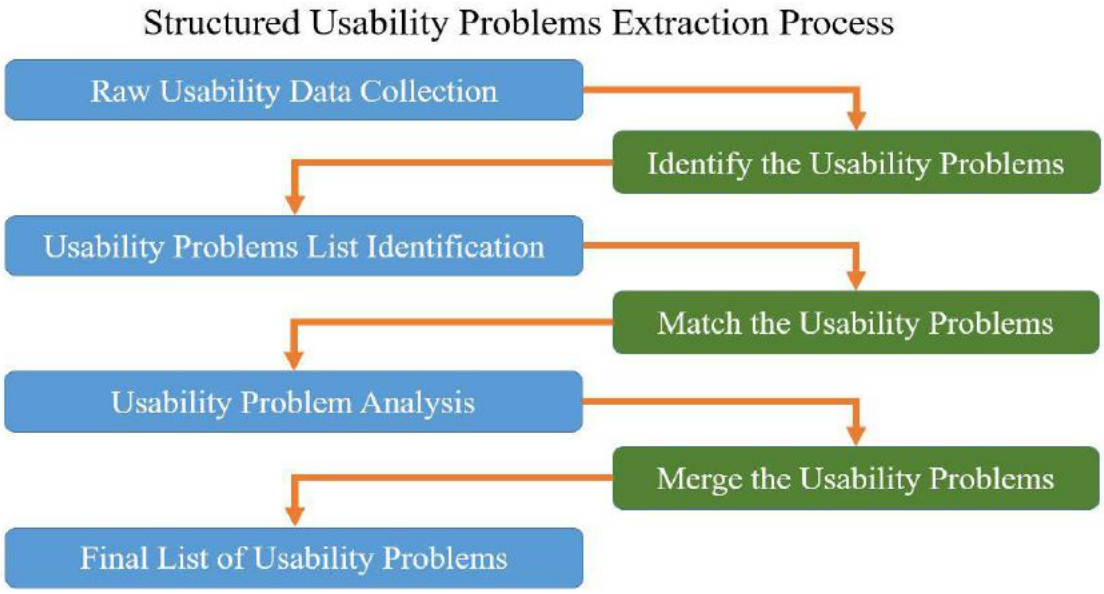


Figure 5.14: The used structured of usability problem extraction method.

In the raw usability data collection level, I identified the usability problems based on the individual usability evaluation sessions. Then, I went through the iterative process to produce a checklist of usability problems indicators. I used the DEVAN problem indicators checklist (See Appendix B.7) to guide the the usability problems extraction, which is used in the usability field to indicate usability problems [148–150]. The DEVAN checklist was developed by Vermeeren to detect usability problem in task-based products or designs [149].

The reason for choosing the DEVAN problem indicators checklist is to have clear and explicit checklist criteria to run it through all the identified usability problems by the evaluation sessions.

In the usability problems list identification level; all the identified usability problems from the previous level were listed to find similarities between the usability problems. Matching usability problems is not a straightforward process, and it requires iterative process [123]. Every discovered usability problem was assigned a unique number for easy references. Matching usability problems were easier based on matched and similar identified usability problems.

In the usability problem analysis level, individual usability problems were merged from all participants to provide a list of usability problems. The provided list of usability problems has merged usability problems based on the description and context of usability problems. At this stage, every usability problem was assigned a unique number and got ready for the analysis stage. The usability problem analysis level produced the final list of usability problems.

5.7.2 Usability Problems Results

As mentioned earlier, one of the primary goals of usability evaluation testing is to identify, prioritize and address usability problems. The usability problems were determined by using the DEVAN problem indicators checklist mentioned in section 5.7.1 . In this sub-section, I will cover the following four main findings:

1. Number of individual usability problems

2. Types of usability Problems

3. Source and frequency of the usability problems

4. The severity of the usability problems

5.7.2.1 Number of individual usability problems

The most common way to measure usability problems is to count the number of identified usability problems per participant. Table 5.10 shows the total number of identified usability problem per participant and the total number of the identified usability problems for all participants. There were 66 identified usability problems by all participants with only 20 unique usability problems after removing duplicated usability problems.

Table 5.10: The number and percentages of identified usability problems per participant.

Participants ID	**No. of Usability Problems**	**% of Problems**
P1	11	17%
P2	9	14%
P3	8	12%
P4	9	14%
P5	7	11%
P6	5	8%
P7	8	12%
P8	9	14%
Total	66	100%

5.7.2.2 Usability problems types

The identified usability problems were extracted from the initial review of the data. Then, the usability problems types were identified based on the related literature on classifying and categorization usability problems [144, 148]. Table 5.11 has the definitions of the usability problems types. Table 5.12 shows the numbers and percentages of the different types of the identified usability problems and the related usability problems types.

Table 5.11: Types of usability problems

Usability Problem Type	**Definition**
Navigation	Participants have problems in navigation the tool's pages
Layout	Participants have difficulties with the tool layout such as web elements, display content, and structure
Content	Participants have difficulties with understanding the content of the tool such as terminology or choice of words
Functionality	Participants have difficulties with the tool functions, either absence of needed functions or difficulties with normal functions

Table 5.12: The distribution of the number and percentage of the usability problems types

Usability Problem Type	**P1 (n)**	**P2 (n)**	**P3 (n)**	**P4 (n)**	**P5 (n)**	**P6 (n)**	**P7 (n)**	**P8 (n)**	**Total**	**%**
Navigation	0	0	0	0	0	0	0	0	0	0%
Layout	6	4	1	4	2	2	3	4	26	39%
Content	4	4	3	2	5	3	3	5	29	44%
Functionality	1	1	4	3	0	0	2	0	11	17%
Total	11	9	8	9	7	5	8	9	66	100%

5.7.2.3 Sources and Frequency of Usability Problems

Problem frequency (counting) is a common way to measure usability problems; it is a straightforward process. Problem frequency is merely counting the number of times each usability problem was identified. I used two ways to identify the usability problems sources.

The first and easiest way to trace the usability problem source is from the participants verbal data during the evaluation session. The second way to identify the usability problem sources depends on the evaluators observations of the participants during performing the tasks, for more results on the frequency of the usability problems and sources, see Table 5.13.

Table 5.13: Number of individual usability problems sources.

Usability Problem Source	**P1 (n)**	**P2 (n)**	**P3 (n)**	**P4 (n)**	**P5 (n)**	**P6 (n)**	**P7 (n)**	**P8 (n)**	**Total**	**%**
Verbalized	7	8	4	5	7	5	7	8	51	77%
Observed	4	1	4	4	0	0	1	1	15	23%
Total	11	9	8	9	7	5	8	9	66	100%

5.7.2.4 Individual usability problems and severity

Usability problems severity scale is an indication of the usability problem severity. The primary objective of problem severity is to identify usability problems with higher severity problems than to identify usability problems with lower severity problems. The Usability problems severity scale helps designers with priorities; it provides a relationship between the priority and severity of usability problems.

There are many usability problems severity scales in the usability field [151–153][154] . Most of the usability problems severity scales rate the severity into many levels. Some severity scales use three levels, other use fours levels and some use five levels severity scale. Jakob Nielsen proposed five levels severity scale in 1993 [151]. Wilson proposed five severity scale level then he changed it to four severity scale level in 2001[152]. Dumas proposed four severity scale levels in his book in 1999 [154]. Also, Rubin proposed four severity scale levels in his book in 1994 [153]. Dumas proposed four severity scale levels for usability problems

in 1994 [154]. Molich and Virzi, each proposed three severity scale levels [155, 156].

In general, there is a lack of consistency among usability practitioners when it comes to usability problems scale. All the mentioned usability problems scales are similar in meaning and provide similar scales and levels with different wordings, so I decided to choose Dumas severity scale levels for simplicity and clearness. For more details on the Dumas scale levels, see Table 5.14 below. Table 5.15 shows the numbers and percentages of the identified usability problems according to the severity scale levels.

Table 5.14: Usability problems severity rating by Dumas [154].

Scale	**Definition**
Level 1 – Critical	Problems prevent completion of a task
Level 2 – Major	Problems create significant delay and frustration
Level 3 – Minor	Problems have a minor effect on usability
Level 4 – Enhancement	Problems are more subtle and often point to enhancements that can be added in the future

Table 5.15: The distribution of the frequency and percentage of the identified usability problems according to the severity scale levels

Severity Level	**P1 (n)**	**P2 (n)**	**P3 (n)**	**P4 (n)**	**P5 (n)**	**P6 (n)**	**P7 (n)**	**P8 (n)**	**Total**	**%**
Level 1	2	0	0	0	0	0	0	0	2	3%
Level 2	4	0	0	0	0	0	0	0	4	6%
Level 3	5	7	4	3	3	5	6	5	38	58%
Level 4	1	2	4	5	4	0	2	4	22	33%
Total	12	9	8	8	7	5	8	9	66	100%

5.7.2.5 Final usability problem list

As mentioned in section 5.7.2.1 and earlier in the tables, there were 66 identified usability problems with only 20 unique usability problems. Tasks 2 to 5 identified many usability problems and areas for improvements. Task 2 identified 10 out of the 20 unique usability problems where Tasks 3 and 5 identified each 5 usability problems, and Tasks 1 and 4 identified no usability problems. Table 5.16 shows the 20 unique identified usability problems with the severity level and usability problem type, see Appendix B.8 for more details on the unique 20 identified usability problems.

Table 5.16: The final list of the 20 unique identified usability problems.

Index	**Task No.**	**Severity Level**	**Usability Problem Type**
1	T2	Level 2	Layout
2	T2	Level 3	Content
3	T2	Level 3	Content
4	T2	Level 3	Content
5	T2	Level 3	Content
6	T2	Level 2	Functionality
7	T2	Level 2	Functionality
8	T2	Level 4	Layout
9	T2	Level 4	Layout
10	T2	Level 1	Functionality
11	T3	Level 3	Layout
12	T3	Level 3	Layout
13	T3	Level 3	Layout
14	T3	Level 4	Layout
15	T3	Level 3	Layout
16	T5	Level 3	Layout

17	T5	Level 3	Content
18	T5	Level 3	Functionality
19	T5	Level 4	Layout
20	T5	Level 4	Functionality

5.7.3 Solving usability problems

As mentioned earlier there were 20 identified unique usability problems. Most of the identified usability problems are layout and content problems. Figure 5.15 shows five usability problems examples and Figures 5.16 and 5.17 shows each a usability problem. For more information on some of the usability problems see Table 5.17 and for a full list of the usability problems see Appendix B.8 .

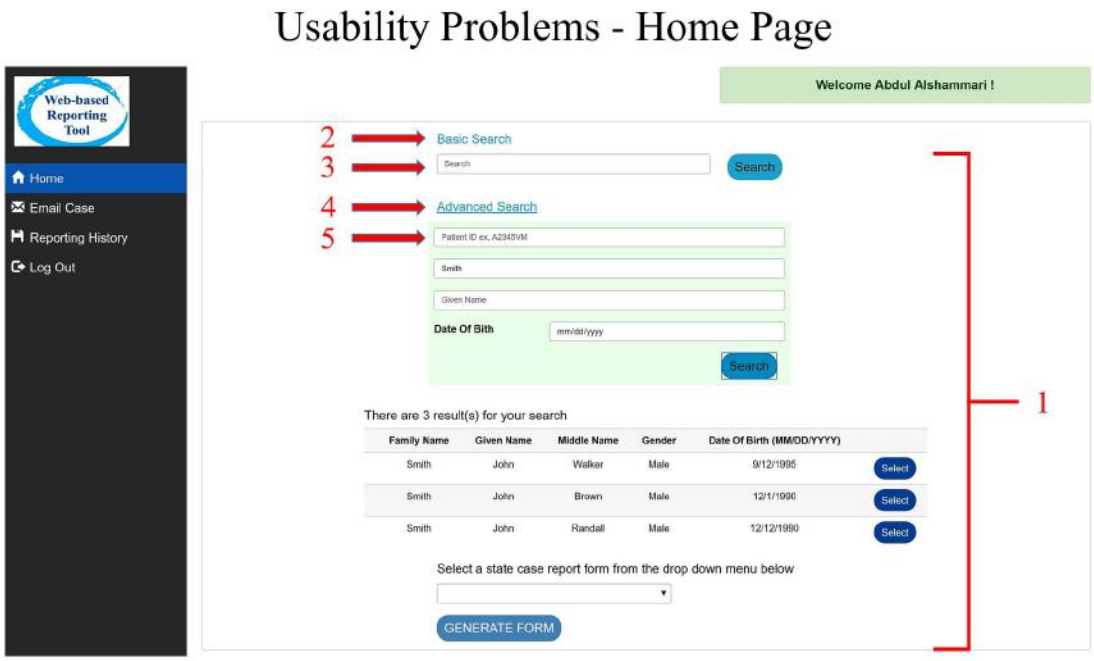


Figure 5.15: Some of the the tool's Home page usability problems examples.

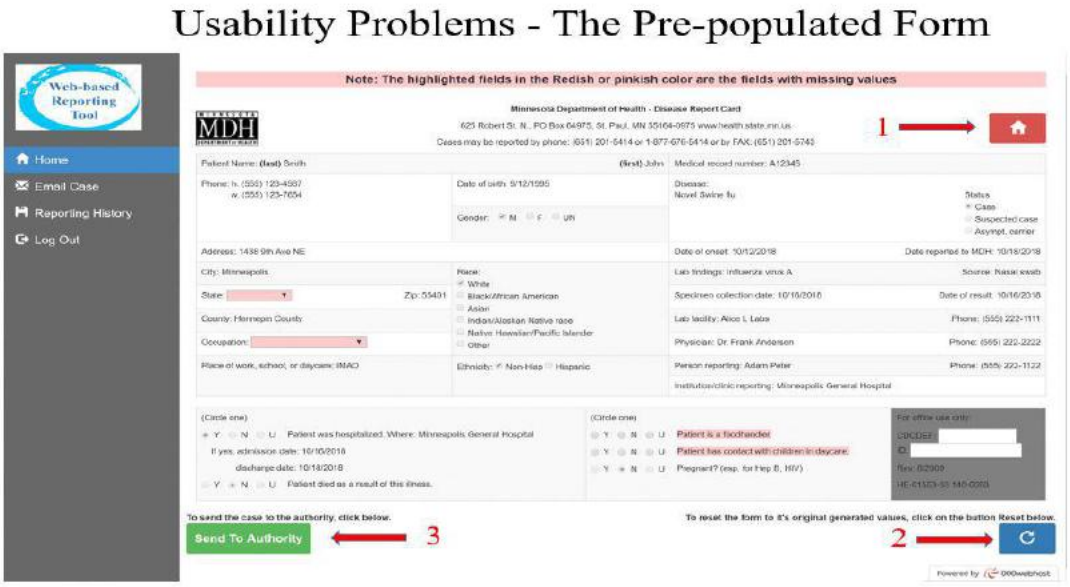


Figure 5.16: Some of the the tool's Pre-population page usability problems examples.

Figure 5.17: A usability problem example of the tool's Reporting History page.

Table 5.17: Some of the final usability problems list.

Index	**Task No.**	**Usability Problem and Related Figure**	**Usability Problem Description**
1	T2	Label 1 in Figure 5.14	The layout of the page does not tell the sequence of steps a user should follow to generate a specific case report form for a specific patient.
2	T2	Label 2 in Figure 5.14	The Basic Search title does not tell users what to search.
3	T2	Label 3 in Figure 5.14	The prompt inside the basic search box does not provide a search example.
4	T2	Label 4 in Figure 5.14	The Advanced Search title does not tell users what to search.
5	T2	Label 5 in Figure 5.14	The prompt inside the advanced search box does not provide a search example.
6	T3	Label 1 in Figure 5.15	The Home button is inside the space for the pre-populated case report form. The Home button should outside the case report form space.
7	T5	Labels 1–4 in Figure 5.15	The files name is crowded. There is no need for a date to be included in the files name specially that there is a specific column for a date and time.

There are many techniques and methods to identify usability problem, but finding solutions to usability problems takes more than one design opinion. Finding solutions to usability problems requires input from design practitioners. There is no universal standard technique on how to fix all usability problems. Designers can brainstorm to make changes to a design to improve the design and solve some of the usability problems.

Some techniques could be applied to the prototype communicable disease Web-based clinical reporting tool to improve the design and solve some of the usability issues. One technique is modifying interface elements like making them bigger, smaller, or to use distinct colors. Another technique is combining elements together. Another technique that could be applied is rearranging things in the design. Another way to improve the design is to eliminating things from the design. the following paragraphs are specific examples of applying these techniques that could be used to improve the usability of the tool.

Modification technique could be applied in this usability problem. My Home page design has two search boxes for patients, basic and advanced (Labels 2 and 4 in Figure 5.15). Based on my observations and the identified usability problems, the labels and prompts of the search boxes are not informative (Labels 2 to 5 in Figure 5.15). The new design could modify the elements to include more informative words in the search box labels and prompts. To improve on the new design, the search box label could include more words to clarify the purpose of the search box. Also, the search box prompt could include more informative text such as an example of what a user can search by using the search box.

Modification technique could be applied in this usability problem. The case report form page has a Home and Reset buttons to enable users to go to the Home page or to reset the form to its original pre-populated status (Labels 1and 2 in Figure 5.16). Based on my observation and the identified usability problems, some participants missed the button or could not see it right away. The new design could consider making the button larger or with a different color to create more attention. The same idea could be applied to improve all the buttons in the design (Label 3 in Figure 5.16).

Combing technique could be applied in this usability problem. As stated earlier, the Home

page has two search boxes, basic and advanced (Labels 2 and 4 in Figure 5.15). Based on the feedback and the usability problems, some participants were confused to decide on using one of the two search boxes. The new design could combine the two search boxes into one search box to avoid any confusion in the interface and make browsing the interface easier.

Rearranging technique could be applied in this usability problem. The Home page in my design requires four steps to generate a specific case form on a specific patient (Label 1 in Figure 5.15). The four steps are:

1. Search a patient by using any of the following: Medical Record Number, First name, Last name, or Date of birth.

2. Select a patient from the result section.

3. Specify a states case report form from a drop down menu.

4. Click on generate the form button.

Based on my observations and the identified usability problems, these four steps and the order of them confused the participants. The new design could rearrange the sequence of the steps to make the flow easier. Another solution could be numbering the steps to guide potential participants on how to generate a case report form.

Eliminating technique could be applied in this usability problem. The Reporting History page in my design has a table of many columns, which provides information on the reported cases and reporters (Labels 1 to 4 in Figure 5.17). Based on my observations and the identified usability problems, the page is crowded with a bigger number of columns than needed. The new design could reduce the number of columns to make browsing the interface easier.

5.8 Limitations with the Usability Evaluation Sessions

Usability practitioners face many challenges during any usability testing, and this study is no exception. The location of testing in a formal testing room might lead the participants to some behavior changes than their standard working settings, which might affect the findings of the usability testing. Another challenge was the demographic characteristics; the research team could not control the equal distribution of the gender, age categories, level of education, years of experience, which might affect the findings. Another challenge was the number of tested case report forms (two official case report forms), and the number of states (Washington and Minnesota) included in the usability testing. A bigger number of tested case report forms and states would provide more reliable findings.

Timing the start and end of each task was a challenge because it was the evaluators responsibility to start and stop the timer per task. To avoid this limitation, I went back to the recorded sessions to double check the time spent to perform each task for all participants. There is some professional usability testing software such as Morae. This software cost about $2,000 U.S. dollar. This software can help with solving some of the challenges such as time spent on tasks and success rate.

All the participants were healthcare providers from the same city (Seattle, WA), which means targeting one group of participants with equivalent way of reporting practice and requirements. Including other groups such quality control participants, health insurance agencies and state department of health staff and other practitioners from different states would make the findings richer.

Another limitation with this usability testing was human resources. It was only one evaluator who managed all the usability sessions. Working solo means that the same person who designed and built the tool was the same person who physically attended and performed all the usability evaluation sessions. This might lead to bias from the developer/evaluator and friendliness bias from the participants when evaluating the tool and knowing that the developer is the same person as the evaluator. As an evaluator trying to avoid bias, I

discussed the evaluation method, evaluated my review tools and process with multiple Ph.D. candidates who have experience with evaluation methods before performing the sessions.

As an evaluator, I explained to the participants many things that might reduce the bias. I stated that the purpose of the evaluation was to assess the tool and to identify areas of improvements to encourage participants speak frankly. Also, I mentioned that there will be further work to improve the tool by getting the participants feedback and comments. Also, I encouraged participants to provide their critic to the tested tool by having specific an open-ended questions of the things they did not like in the tool and to provide suggestions for improvements. Also, I did not specify that the evaluator and developer is the same person.

5.9 Discussion

The primary goal of Aim 3 was to evaluate the developed prototype communicable disease Web-based clinical reporting tool usability. To accomplish Aim 3, the usability evaluation study applied well-known usability evaluation methods . The usability evaluation results revealed that the participants were satisfied with the usability of the tool. Even though responses from participants revealed some usability problems for generating the case report form (Task 2), they indicated a willingness to use the tool in the future. The identified usability problems revealed areas of improvements such as generating the case report form task (Task 2) and searching the reporting history (Task 5).

This usability evaluation study identified the usability problems severity levels. The usability problems severity levels help developers to identify priorities when resolving usability problems. Also, It helps developers to focus on the usability problems that prevent participants from completing tasks (Level 1) then target usability problems that create significant delay and frustration (Level 2). After resolving usability problems related to levels 1 and 2, developers can target minor usability problems with Levels 3 and 4.

This evaluation study focused on healthcare providers who reported communicable or infectious diseases before. As a result, the usability evaluation study was able to identify the participants needs and expectations. As discussed in section 5.8.4, Level 1 severity

level indicates a critical usability problem and Level 4 indicates an enhancement usability problem. The identified usability problems ranged from Level 1 to Level 4, where most of the usability problems ranged between Level 3 and 4. Levels 3 and 4 indicates less severity usability problems.

As discussed in section 5.7.2.4 , there were four types of usability problems, Navigation, Layout, Functionality, and Content. Half of the identified usability problems were Layout usability problems and the other half divided equally between Functionality and Content usability problems with no Navigation usability problem. Layout and Content usability problems are easier than Functionality usability problems to fix.

Task 2 identified half of the usability problems, which needs more attention than other Tasks, but this is not the only reason to focus on Task 2. Severity Level is the most important indicator to prioritize which usability problem to fix first and which one to dedicate more time and energy for it. There was only one usability problem with severity of Level 1 and three usability problems with severity of Level 2, so the focus should start from Level 1 severity level then move to the next severity level until reaching severity of Level 4.

5.10 Summary

This Chapter introduced the importance of usability testing and findings to improve the potential users acceptance of the tool. Also, explained how the testing could help developers to understand better how real users interact with the tool and to set certain expectations by the users. The Chapter introduced the Think-Aloud were covered the list of tasks, equipment, location settings, evaluation session phases, and presented the findings of the usability evaluation sessions. The Chapter introduced the usability evaluation session phases starting from the beginning of the evaluation session until the end of the evaluation session. The phases went from welcoming the participant, sign consent form, explain and practice the Think-Aloud method, perform tasks, have the exit interview, fill in surveys until the finish of the evaluation session.

Tasks list development and improvement explained in this Chapter. All the developed

tasks were short and easy to understand with one correct answer to enable the evaluator to find whether the participant accomplished the task or not. The developed five tasks were designed to target key features of the tool. All the tasks went through multiple rounds of revisions by multiple Ph.D. candidates to improve the wording, flow of the tasks, and to target the essential key features of the tool.

Participants recruitment process and sample size covered in this chapter. This Chapter introduced the process of identifying and targeting potential participants in this study, where inclusion and exclusion criteria developed. Also, the chapter covered the used recruitment methods to target potential users (emails, flyers, and snowball sampling). This Chapter provided a list of the targeted locations and facilities names to post flyers or to distribute invitation emails. The Chapter identified the used sample size based on recommendations in the literature by figures in the usability field. The Chapter covered the location of the usability sessions and a description of all the equipment and software used in usability testing.

The Chapter described the four steps of each evaluation session. The four steps are

1. Before Performing the Tasks

2. While Performing the Tasks

3. After Performing the Tasks, and

4. By the end of the Evaluation Session.

The Before Performing the Tasks step consist of welcome the participant, review and sign the consent form, and explain and practice the Think-Aloud method before starting the actual session. The While Performing the Tasks steps consist of screen interaction recording, voice recording, record observation by the evaluator and fill in the After Scenario Questionnaire. The After Performing all Tasks step consist of performing short Exit Interview, fill in the System Usability Scale (SUS) survey and Demographic Surveys. The Exit Interview was a semi-structured interview to collect qualitative data while the two surveys were to

collect quantitative data. The By the End of the Evaluation Session step consist of ending the evaluation session and provide the incentives to the participant.

The results of the usability evaluation session provided many findings of the total number of candidates who filled the screening questionnaire to identify the eligibility of the candidate to participate in this evaluation study. The results provided participants demographics, which covered many findings on their age categories, years of experience in the healthcare field, gender, and other demographic information.

The results covered many indicators on the performed five tasks for all the participants. The results covered the performance of the tasks, which consist of tasks completion rate and time spent on each task to perform. The results showed the completion rate per task per participant and identified the tasks with the highest and lowest rates. The results covered the time spent per participant to perform each task and showed the tasks with the highest and lowest median and the average time to accomplish each task.

The results covered the participants satisfaction, which consists of satisfaction per task and satisfaction on the tool. The After Scenario Questionnaire (ASQ) was used to calculate the users satisfaction per task. The System Usability Scale (SUS) survey was used to calculate the users satisfaction with the tool. The ASQ showed that Tasks 1 and 4 had the highest satisfaction level, while Tasks 2 and 3 had the lowest satisfaction level. The SUS showed that participants were satisfied with the tool, and the SUS calculation algorithm showed that the tool fits in the acceptable level.

The results covered the used structure of usability problem extraction method. The extraction method showed the steps from collecting the raw usability data collection until the process of identifying the final list of usability problems. The identified usability problems results covered the identified list into details. The details covered the number of the usability problems, types of usability problems, and sources and frequency of the usability problems. Also, the results identified the final list of identified usability problems after removing the duplicated usability problems.

Each participant of the eight participants performed five tasks, which helped to identify

66 usability problems in total. Participants helped in identifying usability problems where they identify a range of 5 to 11 usability problem per participant. The identified 66 usability problems were classified based on the usability problem type. The usability problem types where Navigation, Layout, Content, and Functionality usability problems types. Also, the usability problems were identified based on the source, which based on the verbalized or observed actions. The usability problems were classified based on the severity levels. The four severity levels are Level 1(Critical), Level 2 (Major), Level 3 (Minor), and Level 4 (Enhancement). The levels vary in definitions and importance where Level 1 severity level related to problems prevent completion of a task Level 4 severity level related to problems often point to enhancements that can be fixed in the future.

Finally, the results section in this chapter identified the final 20 usability problems out of the identified 66 usability problems. The 20 usability problems were classified based on the related task where Task 2 identified 10 out the 20 usability problems. Then they were classified based on the severity level where 11 usability problems were related to Level 3. Also, the identified 20 usability problems were classified based on the usability problems types where 10 of the usability problems were related to Layout usability problems.

Chapter 6

CONCLUSION

The overall of this research investigation is to help in improving the communicable diseases reporting cycle and introduced the Novel Influenza as a classic reportable disease. As described in Chapter 2 , Novel Influenza is a highly pathogenic and communicable disease and associated with high mortality. Chapter 2 provided an overview of the background on the literature review and significance in related work to communicable diseases reporting.

Chapter 2 covered a part of Aim 1 for this dissertation to understand the challenges of the novel influenza reporting process. Chapter 2 first defined the Novel Influenza types, and subtypes then provided the threat of novel influenza spread to the community were introduced some of the mortality of pandemic novel influenza history. The chapter introduced current tools and systems of data categories and sources of influenza surveillance from healthcare providers level to healthcare authorities level.

Chapter 2 covered the benefits and challenges of reporting communicable diseases from healthcare providers to healthcare authorities. The challenges covered challenges on the healthcare providers level, reporting process level, and reporting recipient levels. Also, the chapter introduced surveillance systems quality indicators in general and more specifically on completeness and timeliness indicators. The chapter presented many studies showed the importance of completeness and timeliness in reporting communicable diseases.

Chapter 2 covered the Meaningful Use Program and how the program would help to overcome the problems of health information exchange between healthcare stakeholders. The Meaningful Use Program stages were introduced to ensure and enable Electronic Health Records to have the capabilities to exchange data and use the clinical data in meaningful use ways. The chapter introduced multiple ongoing projects to improve the process or report-

ing communicable diseases such as Public Health Community Platform (PHCP) in Section 2.5, Digital Bridge of Electronic Case Reporting in Section 2.6, and Reporting Conditions Knowledge Management System (RCKMS) in Section 2.7.

Chapter 2 covered the Clinical Document Architecture (CDA) standard in Section 2.8, which a flexible HL7 standard to enable contents on clinical medical documents such as discharge summaries and medical notes to be read by humans or processed by machines. CDA has the flexibility to allow controlled terminologies to be included and used, such as LOINC, SNOMED-CT, and other standards. Also, the chapter covered the CDA document hierarchy, structure, and characteristics.

Chapter 2 introduced a new standard in the HL7 family, which is the Fast Health Interoperability Resources (FHIR) in Section 2.9. HL7 claims that the FHIR standard is simple, easy to understand, and used, and has the potential for more acceptance in the future. Chapter 2 introduced FHIR, FHIRs main components, framework, resources structure, FHIR reusability and composability, FHIR profiles, FHIR scenarios. Also, the chapter covered some of the backend technologies and standards used by FHIR standard and listed many of FHIR benefits and challenges. SMART on FHIR, SMART applications gallery, and SMART Sandbox.

Chapter 2 covered the usability definitions in Section 2.10. Usability evaluation methods and classifications (Expert-based, Model-based, and User-based) were introduced in chapter 2 along with benefits and challenges for each usability methods. Chapter 2 covered the applied usability evaluation method, Think-Aloud Usability Method, benefits, and challenges. Chapter 2 introduced the popularity of the Think-Aloud method usage among usability specialists.

Chapter 3 looked at the research methodologies used to contact states health departments, document collection, document coding, identifying gaps, contribution, and limitations of Aim 1. The official novel influenza case report forms or any general case report forms along with the reporting guidelines were the primary documents used in this study if there is no specific novel influenza case report form or reporting guideline. The inclusion and exclusion criteria

were used to include or exclude any state in this study. The included states that using unique case report forms and reporting guidelines are 28 states along with other five states using the CDCs case report form and reporting guideline. Data coding and analysis applied both qualitative and quantitative analysis methods.

The document collection process went through multiple stages of contacting official officers in states health departments asking to participate in the study by providing official and updated documents, case report forms, and reporting guidelines. The document collection process showed how many states were included or excluded in every step during the document collection process. The final included number of states were 33 states where there were 28 individual states plus CDC documents. There were many states included in the study, such as California, Texas, Florida, New York, Illinois, Ohio, Washington, and other states.

Chapter 3 covered documents coding process from the 28 states plus CDC , which identified 257 data fields. The identified 257 data fields were grouped into 12 code families (demographics, past medical history, treatment and other code families). The number of grouped data fields per code family ranged in numbers where the past medical history family group has the highest number while the travelling code family has the least number of identified data fields.

The collected documents (case report forms and reporting guidelines) went through multiple rounds of coding with multiple coders to compare the presence and absence of each required data field between the states case report form and the states reporting guideline. This process provided the results into tables where each state has a table of outcome of each data field. The possible outcomes are as the following:

- (1)The data field show only in case report form
- (2)The data fields show only in reporting guideline
- (3) The data field show in both documents (case report form and reporting guideline)

After performing the same process to all included states and having a table for each state, a compassion between the data fields was applied across all the states. This process provided four outcomes per data felid:

- (1) The extracted data field is not in neither the case report form nor the reporting guideline.
- (2) The extracted data field shows only in the case report form.
- (3) The extracted data field shows only in the reporting guideline.
- (4) The extracted data field shows in both documents, the case report form and reporting guideline.

After performing this step, a comparison between the collected data fields based on the most used data fields in the case report forms to rank the data fields based on the number of the appearances of the case report forms. This step identified the most used data fields across all states in the novel influenza cases reporting. The same process was applied on the reporting guidelines to identify a ranked list of data fields based on the most used data fields.

These findings produced key findings in identifying the gaps on the state level and across states levels in this dissertation work. The gaps showed misalignments between the reporting guidelines and case report forms on both individuals and across states. Also, the gaps showed different data fields requirements across states and they differ from the CDC requirements. These findings highlight the needs to improve case report forms and /or reporting guidelines to narrow the gaps to help healthcare providers to reach best practices.

Chapter 4 covered the process of developing the prototype communicable disease Web-based clinical reporting tool. The tool was designed and developed to help healthcare providers reporting novel influenza to healthcare authorities. The tool provided few benefits by providing an electronic reporting method and applying required reporting standard.

Also, the tool provided a flexible method to generate a pre-populate data field into case report forms.

Chapter 4 covered a high level of the interface flow where explained a users process to interact with the tool to generate a case report form, fill in any missing data if needed, provide a check, convert the generated case report form into Clinical Document Architecture (CDA) standard format, and share the generated case report form with healthcare authorities.

Chapter 4 covered the steps of log in to the tool until submission of the generated case report form into CDA format. The steps covered the log in, basic and advanced search, select a specific patient from the search result, select a specific states case report form, pre-populate data into a case report form, fill in data if needed and submission of the case report form into CDA format to a healthcare authority.

Chapter 4 covered the tools design model. The designed followed the Model View Controller (MVC) model. The chapter explained the relationship and flow between the Model, View, and Controller components and rolls. Then the chapter provided more details of the tools user interaction flow. The details covered the sequences of logical steps based on the design model.

Chapter 4 covered the tools hierarchy, which consists of four levels. The four levels covers and explain the relationship between the tools front end and back end. Each hierarchy level covered different components and different technologies and standards used to develop the prototype communicable Web-based clinical reporting tool. The covered four layers are the data layer, data access layer, back end, and presentation layer.

Finally, Chapter 4 covered CDA templated development and challenges to fit the case report forms used within the reporting tool. Also covered CDA templates (discharge summary, referral, case report form) and the structure of the CDA template. Also, the chapter covered the tool testing and discussed some of the limitations and challenges with the tool development.

Chapter 5 covered Aim 3 for this dissertation to evaluate the prototype communicable disease Web-based clinical reporting tool from Aim. Chapter 5 covered the importance of

evaluation, evaluation method, tasks, and sample size, recruitment methods and participants, results, contributions, and limitations. The focus of chapter 5 was to evaluate the satisfaction of the participants by using the tool and to identify usability problems to improve the tools design, functionality, and acceptance in future rounds of improvements.

Chapter 5 introduced the process of how to decide on a suitable evaluation method for the prototype Web-based clinical reporting tool. This process covered many factors such as the purpose of the evaluation method, key search terms, inclusion and exclusion criteria, digital libraries, and the retrieved results on the types of the evaluation method. This process led to the usability method was used in this dissertation, which is the Think-Aloud evaluation method.

Then the chapter defined the usability method and listed some of the benefits of using it. Also, it provides a way to classify the usability methods. The usability method classification introduced three ways of classifications, Expert-based, Model-based, and User-based evaluation methods. Then the chapter provided a high-level comparison between the classified usability method, which led to the decision of choosing the Think-Aloud method as the applied evaluation method in this dissertation.

The chapter introduced the Think-Aloud evaluation method and listed some of the benefits and challenges with the Think-Aloud. Then, introduced the popularity of the Think-Aloud in the usability field. After that, the chapter introduced the different types of Think-Aloud. The comparison of the different types of Think-Aloud led to the decision of using Concurrent Think-Aloud type. After deciding on the evaluation method, Concurrent Think-Aloud evaluation method, the chapter introduced the evaluation study plan. The study plan showed the process of developing the final list of tasks; then it showed the process of deciding on the sample size. After that, it showed the list of the participants recruitment criteria and how to target potential participants and the method of communicating with potential participants. Finally, the plan talked about the location of the evaluation test and the equipment used in the evaluation testing.

After that, the chapter introduced the actual evaluation procedure. It showed the steps

when a participant walked into the evaluation session room until the end of the evaluation session. The evaluation procedure showed the steps of the before the evaluation session, during the evaluation session, after finishing all the tasks and the steps by the end of the evaluation session. Finally, the chapter introduced the findings and results of the evaluation session. The findings included some demographic information about the included participants in the study, such as age, gender, years of experience in the healthcare field, level of education, and other demographic information. The results covered the tasks completion time, success, and failure rate for all the tasks. Also, I covered the participants satisfaction level through the SUS questionnaire. Also, the results section covered and explained the process of classifying the identified usability problem into types (navigation, layout, content, and functionality).

10 out of the 20 identified usability problems were layout usability problems ranged from Level 2 to Level 4(Major, Minor, and Enhancement Levels). The new design needs to focus on the tools interface to improve the users experience while interacting with the tool. There was one usability problem with Level 1 (Critical Level) which needs mire attention to solve in comparison to other usability problem. Critical Level usability problem can prevent a user from completing a task.

In brief, the findings from chapter 5 demonstrated findings of Aim 3 regards the usability testing. The findings showed an acceptable tool to report influenza cases with areas for improvements by the participants. The identified areas for improvement will be addressed in future work.

6.1 Limitations and Contributions

There are many limitations of this study that will need to be addressed in future work. Aim 1 had few limitations regards the final number of included states in this dissertation work. There were 17 missing states due to no or partial response for invitation emails to participate in this study. Only Novel Influenza as a communicable and reportable disease was covered in this dissertation. Covering other communicable and reportable diseases would expand the knowledge of reporting communicable diseases reporting process and identify

other challenges.

Aim 2 limitations were technical challenges with developing the prototype communicable disease Web-based clinical reporting tool. The tool was not linked to a life EHR, which limits the possible findings of usability problems and identifying more areas for improvements. Another technical challenge was mapping the required data fields from the case report form to the database. All data fields mapping was manual mapping through writing queries to map each data field in the case report form to a data field in the database. There were many data fields in the case report form would not be existed or limited in EHRs, such as exposure or traveling information. Another technical problem was deciding on different clinical vocabularies to implement in the tool such as ICD-9 Vs. ICD-10 or the use of other vocabularies.

Aim 3 limitations were usability testing limitations. The results out of the usability testing have no benchmark results to compare it to other results. Participants were from one geographical location (Seattle, WA), which limits the way of reporting practice in one way, and that might limit the findings. There was a bias limitation to the findings since the designer and developer of this tool was the same person who designed and performed the usability testing. The present of the evaluator during the usability testing might affect the findings of the usability testing, which called friendliness bias.

Aim 1 contribution was identifying list of data fields used in novel influenza reporting process. Then, developing a comprehensive ranked list of the data fields across all included states from those used by all states to those used by only one state. Also, Aim 1 identified gaps between case report forms and reporting guidelines in data reported at state levels and across states.

Aim 2 contribution was demonstrating the feasibility of a tool that pulls data fields from multiple simulated EHRs and sends data fields to multiple state reporting case report form using CDA standard. The tool showed a proof of concept informatics solution to address barriers and challenges in the communicable disease reporting process from the healthcare providers to healthcare authorities.

Aim 3 contribution was identifying usability problems by testing the tool with the required size of participants and applying the Think-Aloud method. The evaluation process and findings showed the validation of the tools utility and acceptability level to potential end users. Also, the usability testing identified areas for improvements to increase the levels of functionalities, acceptance and satisfaction to potential end users.

6.2 Future Work

During the past years, developers focused on exchanging documents contain data among healthcare providers and organizations. They used many ways to exchange data and documents using fax, email, or electronic methods; where providers choose a set of data on a specific case then generates a message contains the chosen data to be sent out. This approach makes it possible for healthcare stakeholders to communicate and exchange data. On the other hand, it is limited when it comes to meaningful use 2.4 and decision making because the exchanged data is static and needs extra effort to extract the data and feed it to another system to be usable.

FHIR 2.9 allows application developers to use the standardized Application Programming Interface (API) to develop applications. Developed standardized applications using FHIR plugged to basic EHR systems can feed healthcare providers with information fits with their workflow. This will eliminate the steps of missing specific data when exchanging documents and save the healthcare providers time between searching multiple exchanged documents and look into their EHR system to come to a decision.

The FHIR resource contains individual units of information on some certain elements such as a name, address, gender of a patient. Also, for the same patient, it contains data on many common data elements such as medication list, observations, vaccination, and others. These FHIR resources could be bundled into one clinical document, which saves the healthcare providers time and makes it more comfortable and faster to read. Also, the bundled clinical document could be extended to include additional data elements in the same case. When comparing this approach of bundling multiple documents into one document for a specific

case to the approach of HL7-CDA standard when sending multiple documents on a specific case; FHIR will be more comfortable and faster to use.

FHIR is a specification that includes formats in XML, JSON, and RESTful API to query and present clinical data. The RESTful framework allows transactions such as read, update, delete, and other interactions to be performed directly on the resources server using HTTP operations to simplify healthcare information exchange. REST does not require the client to know anything about the structure of API and can communicate multiple resources into a single exchange, which makes applications easier to develop and use. RESTful services, including OAuth, which has well-supported tools where applications developers can benefit from standards and tools used across many industries.

Many stakeholders and researchers recognize the potential for FHIR interoperability, where they started to collaborate to advance the adoption of FHIR as an open interoperability standard. There are many projects under developments such as Argonaut project [157] . The Argonaut project is a collaboration of venders and providers such as Epic, Cerner, MEDITECH, Mayo Clinic, and others to enhance the adoption of FHIR standard into EHR core services by providing tested implementation guides and make it accessible to developers.

OpenMRS is an open source EHR platform that is implemented and used internationally [158] . A team integrated FHIR for OpenMRS to demonstrate how third-party applications could interact with the OpenMRS platform using FHIR for interpretation [159] . By applying modifications to the OpenMRS system architecture, the team was able to integrate the OpenMRS platform with a third-party application via FHIR to enable interoperability. The work of this dissertation could align with the ongoing projects of using FHIR to use the potential and advancements of FHIR potential interoperability, but FHIR faces many challenges, as discussed in the sub-Section FHIRChallenges .

FHIR uses many challenges in the meantime. The FHIR needs big support from stakeholders in the healthcare industry to be implemented, tested, and used in life EHRS. Also, FHIR needs security, authentication, and authorization improvements when connecting to real EHRs. Stakeholders need to agree on standard value sets to be used with the clinical

data to avoid interpretation issues.

Electronic Health Records vendors need to make changes to their current EHRs to adopt the use of FHIR, which is a significant challenge with FHIR. Healthcare organizations and providers need to create or modify current practices according to HIPPA and other laws to use FHIR in healthcare practices.

The evaluation process needs some future work as well. Applying other evaluation methods such as Heuristic Evaluation method helps to improve the tools interface by providing a feedback from design experts. In the heuristic evaluation method, usability experts would review the tools interface and compare against ten know principles to identify a list of potential usability problems. The Heuristic Evaluation is a fast and inexpensive method for early design process, but finding expert evaluators is relatively hard and can be expensive.

Also, applying focus group methods would help to collect more qualitative data and in-depth information on potential users perceptions, insights, experiences, needs and beliefs. Focus group method is easy to set up but recruiting the right candidates could be a challenge. Analyzing the collected qualitative data is time consuming and needs to be well planned.

Expanding on the participants sample size and including more stakeholders might lead more discoveries. Including participants beside healthcare providers such as states or local health departments users, policy makers, quality and management officers will lead to more findings to improve the functionality of the developed reporting tool.

Having multiple teams of developers and usability testing evaluators would help to improve the results and avoid any bias in the usability results and findings. Also, the usability evaluation team should include multiple evaluators and coders to improve the usability testing results. Finally, solving the identified usability problems will improve the functionality, acceptance level, utility, value and usefulness of the tool.

BIBLIOGRAPHY

[1] Rumi Chunara, Clark C Freifeld, and John S Brownstein. New technologies for reporting real-time emergent infections. *Parasitology*, 139(14):1843–1851, 2012.

[2] Centers for Diseases Control and Prevention (CDC). Disease Burden of Influenza, 2019 last accessed March, 2019. https://www.cdc.gov/flu/about/burden/index.html.

[3] World Health Organization (WHO). Influenza – WHO – Regional Office for Africa, 2017 last accessed March, 2019. https://www.afro.who.int/health-topics/influenza.

[4] Matthew Lozier. Incidence of zika virus disease by age and sex?puerto rico, november 1, 2015–october 20, 2016. *MMWR. Morbidity and mortality weekly report*, 65, 2016.

[5] National Notifiable Diseases Surveillance System (NNDSS). Novel Influenza a Virus Infections, 2019 last accessed Feb, 2019. https://wwwn.cdc.gov/nndss/conditions/novel-influenza-a-virus-infections/.

[6] Centers for Diseases Control and Prevention (CDC). Overview of Influenza Surveillance in the United States – Seasonal Influenza (Flu), 2015 last accessed March, 2015. http://www.cdc.gov/flu/weekly/overview.htm.

[7] Centers for Disease Control and Prevention (CDC). Principles of Epidemiology in Public Health Practice, 2012. [Internet]. 3rd ed. Atlanta, http://www.cdc.gov/ophss/csels/dsepd/ss1978/.

[8] The Office of the National Coordinator for Health Information Technology. Health IT Quick Stats- Office-based Physician Electronic Health Record Adoption, 2019 last accessed Feb, 2019. https://dashboard.healthit.gov/quickstats/quickstats.php.

[9] Elaine C Jong and Dennis L Stevens. *Netter's Infectious Diseases E-Book*. Elsevier Health Sciences, 2011.

[10] Control and Prevention CDC. Types of Influenza Viruses, 2017 last accessed Feb, 2019. https://www.cdc.gov/flu/about/viruses/types.htm.

[11] Centers for Diseases Control and Prevention (CDC). Types of Influenza Viruses, 2014 last accessed March, 2015. http://www.cdc.gov/flu/about/viruses/types.htm.

[12] Virginia Department of Health. Novel, Variant, and Pandemic Influenza – Epidemiology, 2015 last accessed November, 2017. http://www.vdh.virginia.gov/epidemiology/influenza-flu-in-virginia/novel-variant-and-pandemic-influenza/.

[13] European Centre for Disease Control and Prevention (ECDC). Likely Scenarios for Influenza in 2010 and the 2010/2011 Influenza Season in Europe and the Consequent Work Priorities, 2011. Stockholm, http://www.bepast.org/docs/globalbiodefense/2010-3-9_RA_forward_look_influenza_ECDC.pdf.

[14] Yoshihiro Kawaoka and Gabriele Neumann. *Influenza virus: methods and protocols*. Humana Press, 2012.

[15] ECDC Forward Look Risk Assessment. Likely Scenarios for Influenza in 2010 and the 2010/2011 Influenza Season in Europe and the Consequent Work Priorities. *Stockholm: European Centre for Disease Prevention and Control*, 2010 last accessed March, 2015.

[16] World Health Organization (WHO). Global INfluenza Virological Surveillance, 2015 last accessed March, 2015. http://www.who.int/gho/epidemic_diseases/influenza/virological_surveillance/en/.

[17] The Center for Diseases Control and Prevention. National Respiratory and Enteric Virus Surveillance System (NREVSS), 2015 last accessed March, 2015. http://www.cdc.gov/surveillance/nrevss/.

[18] Centers for Diseases Control and Prevention (CDC). Overview of Influenza Surveillance in the United States | Seasonal Influenza (Flu) | CDC, 2015 last accessed March, 2015. http://www.cdc.gov/flu/weekly/overview.htm.

[19] The Center for Diseases Control and Prevention. Iinfluenza (FLU) (2016) FluView Interactive | Seasonal Influenza (Flu) | CDC, 2016 last accessed March, 2016. http://www.cdc.gov/flu/weekly/fluviewinteractive.htm.

[20] Centers for Diseases Control and Prevention (CDC). CDC - 122 Cities Mortality Reporting system, last accessed Mar, 2016. [Internet]. http://www.cdc.gov/epo/dphsi/121hist.htm.

[21] The Center for Diseases Control and Prevention. Tthe US Influenza Hospitalization Surveillance Network (FluSurv-NET), 2015 last accessed March, 2016. http://wwwnc.cdc.gov/eid/article/21/9/14-1912_article.

[22] Digital Media Branch D of PA Office of the Associate Director for Communication. CDC Yearly Lab Work on Flu Viruses Infographic, 2017 last accessed November, 2017. https://www.cdc.gov/flu/resource-center/freeresources/graphics/infographic-lab-work.htm.

[23] Information Technology Services Home SLU. Policies, Standards, Guidelines, Procedures/Processes?: Saint Louis University Information Technology, 2017 last accessed October, 2017. https://www.slu.edu/its/policies.

[24] T-Y Leong, Katharina Kaiser, and Silvia Miksch. Free and open source enabling technologies for patient-centric, guideline-based clinical decision support: a survey. *Yearbook of medical informatics*, page 74, 2007.

[25] Mary E Kingston, Joanne M Krumberger, and William T Peruzzi. Enhancing outcomes: guidelines, standards, and protocols. *AACN Advanced Critical Care*, 11(3):363–374, 2000.

[26] Steven H Woolf, Richard Grol, Allen Hutchinson, Martin Eccles, and Jeremy Grimshaw. Potential benefits, limitations, and harms of clinical guidelines. *Bmj*, 318(7182):527–530, 1999.

[27] R Thomson and M Sordo. Openclinical: Knowledge management for medical care.". *Introduction to Neural Networks in Healthcare". Harvard*, 2002.

[28] Brian K Cooke, Elizabeth Worsham, and Gary M Reisfield. The elusive standard of care. *The journal of the American Academy of Psychiatry and the Law*, 45(3):358–364, 2017.

[29] Linan Zeng, Youping Li, Lingli Zhang, Guanjian Liu, Yang Zhang, Shangwei Zhen, Honghao Li, Xue Song, Yanjun Duan, Jiajie Yu, et al. Guideline use behaviours and needs of primary care practitioners in china: a cross-sectional survey. *BMJ open*, 7(9):e015379, 2017.

[30] Marieke L van Engelenburg-van Lonkhuyzen, Esther MJ Bols, Marc A Benninga, Wim A Verwijs, and Rob A de Bie. Effectiveness of pelvic physiotherapy in children with functional constipation compared with standard medical care. *Gastroenterology*, 152(1):82–91, 2017.

[31] Bethesda MD : National Library of Medicine, National Institutes of Health. Ccollection development manual of the National Library of Medicine, 4th ed, 2004 last accessed October, 2017. https://www.nlm.nih.gov/tsd/acquisitions/cdm/formats46.html.

[32] WHO. Hhealth policy. in: Who, 2013 last accessed October, 2017. http://www.who.int/topics/health_policy/en/.

[33] K Casey Lion, Davene R Wright, Suzanne Spencer, Chuan Zhou, Mark Del Beccaro, and Rita Mangione-Smith. Standardized clinical pathways for hospitalized children and outcomes. *Pediatrics*, pages peds–2015, 2016.

[34] Leigh Kinsman, Thomas Rotter, Erica James, Pamela Snow, and Jon Willis. What is a clinical pathway? development of a definition to inform the debate. *BMC medicine*, 8(1):31, 2010.

[35] Open Clinical. Clinical Pathway, 2006 last accessed October, 2017. http://www.openclinical.org/clinicalpathways.html.

[36] Center for Disease Control and Prevention. Novel Influenza a Virus Infections Overview of Influenza Surveillance in the United States, 2015 last accessed Feb 2019. https://www.cdc.gov/flu/weekly/overview.htm.

[37] HL7 FHIR. Overview - Architects, 2017 last accessed Nov, 2017. https://www.hl7.org/fhir/overview-arch.html.

[38] Team WHO Epidemiological Surveillance Strengthening. Communicable disease surveillance and response systems, 2006.

[39] Ruth Ann Jajosky and Samuel L Groseclose. Evaluation of reporting timeliness of public health surveillance systems for infectious diseases. *BMC public health*, 4(1):29, 2004.

[40] Debra Revere, Rebecca H Hills, Brian E Dixon, P Joseph Gibson, and Shaun J Grannis. Notifiable condition reporting practices: implications for public health agency participation in a health information exchange. *BMC public health*, 17(1):247, 2017.

[41] Brian E Dixon, Zuoyi Zhang, Patrick TS Lai, Uzay Kirbiyik, Jennifer Williams, Rebecca Hills, Debra Revere, P Joseph Gibson, and Shaun J Grannis. Completeness and timeliness of notifiable disease reporting: a comparison of laboratory and provider

reports submitted to a large county health department. *BMC medical informatics and decision making*, 17(1):87, 2017.

[42] Nagla Sahal, Ralf Reintjes, and Arja R Aro. Communicable diseases surveillance lessons learned from developed and developing countries: Literature review. *Scandinavian journal of public health*, 37(2):187–200, 2009.

[43] Hyo-Soon Yoo, Ok Park, Hye-Kyung Park, Eun-Gyu Lee, Eun-Kyeong Jeong, Jong-Koo Lee, and Sung-Il Cho. Timeliness of national notifiable diseases surveillance system in korea: a cross-sectional study. *BMC public health*, 9(1):93, 2009.

[44] Elisabeth Reijn, Corien M Swaan, Mirjam EE Kretzschmar, and Jim E van Steenbergen. Analysis of timeliness of infectious disease reporting in the netherlands. *BMC Public Health*, 11(1):409, 2011.

[45] Center for Disease Control and Prevention. Public Health and Promoting Interoperability Programs, 2017 last accessed May 2019. https://www.cdc.gov/ehrmeaningfuluse/introduction.html.

[46] HealthIT.gov. Meaningful Use Definition and Meaningful Use Objectives of EHRs, last accessed Feb, 2016. [Internet]. https://www.healthit.gov/providers-professionals/meaningful-use-definition-objectives.

[47] Health Resources and Services Administration. What is "Meaningful Use"?, last accessed Feb, 2016. [Internet]. http://www.hrsa.gov/healthit/meaningfuluse/MUStage1CQM/whatis.html.

[48] The Office of the National Coordinator for Health Information Technology. Office-based Physician Electronic Health Record Adoption, 2017 last accessed Feb 2019. https://dashboard.healthit.gov/quickstats/quickstats.php.

[49] HealthIT.gov. Meaningful Use Criteria and How to Attain Meaningful Use of EHRs, last accessed Feb, 2016. [Internet]. https://www.healthit.gov/providers-professionals/how- attain-meaningful-use.

[50] The Public Health Community Platform. Public Health Community Platform, 2016 last accessed Nov, 2017. http://www.thephcp.org/about-PHCP/background.

[51] Paul Jarris, Paula Soper, G Scott Gordon, Monica Huang, and Marcus Rennick. Shared technology infrastructure for the public health enterprise: the time is now. *Journal of Public Health Management and Practice*, 21(3):308–309, 2015.

[52] The Public Health Community Platform. Platform factsheet Factsheet, last accessed Nov, 2017. http://astho.org/Programs/Informatics/Public-Health-Community-Platform/Factsheet/.

[53] Alan C. O?Connor JP Kyle Clark-Sutton. Economic analysis of electronic case reporting Final Report. North Carolina, last accessed Nov, 2017.

[54] The Public Health Community Platform Committees. Case Reporting - Public Health Community Platform (PHCP), 2016 last accessed Nov, 2017. http://www.thephcp.org/committees/case-reporting.

[55] The Public Health Community Platform (PHCP). Association of State and Territorial Health Officials (ASTHO) year 1 summary, last accessed Nov, 2017.

[56] Digital Bridge. About | Digital Bridge, 2017 last accessed Nov, 2017. http://www.digitalbridge.us/about/.

[57] Digital Bridge. Transforming Health through a Digital Bridge, 2017 last accessed Nov, 2017. http://www.digitalbridge.us/db/wp-content/uploads/2017/10/DigitalBridge_flow-diagram-update-20170412.pptx.pdf.

[58] Noam Arzt, Jhon Loonsk, Catherine Staes, and Kathryn Turner PZ. Advancing Electronic Case Reporting (eCR) to Enable Public Health Disease Control and Emergency Response: Getting into the Technical Weeds, 2017 last accessed Nov, 2017. AMIA 2017 Annual Symposium - https://amia2017.zerista.com/event/member/389075.

[59] Center for Disease Control and Prevention(CDC). Reportable Conditions Kknowledge Management System - Meaningful Use, 2019 last accessed Apr 2019. https://www.cdc.gov/ehrmeaningfuluse/reportable-conditions-knowledge-management-system.html.

[60] Council of State and Territorial Epidemiologists (CSTE). SURVEILLANCE / INFORMATICS: REPORTABLE CONDITION KNOWLEDGE MANAGEMENT SYSTEM, 2017 last accessed Nov, 2017. http://www.cste.org/members/group.aspx?id=154895&hhSearchTerms=%22Reportable+and+Conditions+and+Knowledge+and+Management+and+System%22.

[61] Centers for Disease Control and Prevention (CDC). Reportable Conditions Knowledge Management System | Meaningful Use | CDC, 2015 last accessed Nov, 2017. https://www.cdc.gov/ehrmeaningfuluse/reportable-conditions-knowledge-management-system.html.

[62] Karen L Eilbeck, Julie Lipstein, Sunanda McGarvey, and Catherine J Staes. Evaluation of need for ontologies to manage domain content for the reportable conditions knowledge management system. In *AMIA Annual Symposium Proceedings*, volume 2014, page 496. American Medical Informatics Association, 2014.

[63] Robert H Dolin, Liora Alschuler, Sandy Boyer, Calvin Beebe, Fred M Behlen, Paul V Biron, and Amnon Shabo. Hl7 clinical document architecture, release 2. *Journal of the American Medical Informatics Association*, 13(1):30–39, 2006.

[64] Ross Lazarus, Michael Klompas, Francis X. Campion, Scott J. N. McNabb, Xuan-

lin Hou, James Daniel, Gillian Haney, Alfred DeMaria, Leslie Lenert, and Richard Platt. Electronic Support for Public Health: Validated Case Finding and Reporting for Notifiable Diseases Using Electronic Medical Data. *Journal of the American Medical Informatics Association*, 16(1):18–24, 01 2009. URL: https://doi.org/10.1197/jamia.M2848, arXiv:http://oup.prod.sis.lan/jamia/article-pdf/16/1/18/2571073/16-1-18.pdf, doi:10.1197/jamia.M2848.

[65] Health Level Seven International. CDA Release 2, last accessed Feb, 2016. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7.

[66] The Office of the National Coordinator for Health Information Technology. Clinical Document Architecture (cda), 2013 last accessed Oct 2018. https://www.healthit.gov/sites/default/files/resources/cda_ccda_theirrole_in_mu.pdf.

[67] The Office of the National Coordinator for Health Information Technology. Hospital Health IT Developers, 2017 last accessed Nov, 2017. https://dashboard.healthit.gov/quickstats/pages/FIG-Vendors-of-EHRs-to-Participating-Hospitals.php.

[68] Joshua C Mandel, David A Kreda, Kenneth D Mandl, Isaac S Kohane, and Rachel B Ramoni. Smart on fhir: a standards-based, interoperable apps platform for electronic health records. *Journal of the American Medical Informatics Association*, 23(5):899–908, 2016.

[69] The Office of the National Coordinator for Health Information Technology. Hospital Health I T Developers, 2017 last accessed March 2019. https://dashboard.healthit.gov/quickstats/quickstats.php.

[70] FHIR-HL7. All Published Versions of FHIR, 2017 last accessed Nov, 2017. http://hl7.org/fhir/directory.html.

[71] FHIR-HL7. Introducing HL7 FHIR, 2017 last accessed Nov, 2017. http://www.hl7.org/fhir/summary.html.

[72] Brian Ahier-Healthcare IT News. FHIR and the future of interoperability, 2015 last accessed Nov, 2017. http://www.healthcareitnews.com/news/fhir-and-future-interoperability.

[73] HL7 Work Groups. Resource index – FHIR, 2017 last accessed Nov, 2017. http://hl7.org/fhir/resourcelist.html.

[74] Hay E. FHIR – Sparking Innovation In Health Information Sharing, 2015 last accessed Nov, 2017. https://orionhealth.com/us/knowledge-hub/blogs/fhir-is-sparking-innovation-in-health-information-sharing-how-do-you-become-a-part-of-the-fhir-phenomenon/.

[75] HL7. FHIR Release 3 Resource Composition - Content - FHIR, 2017 last accessed Nov, 2017. http://www.hl7.org/implement/standards/fhir/composition.html.

[76] David Hay. SMART on FHIR – adding OAuth2, 2014 last accessed Nov, 2017. Orion Health - https://fhirblog.com/category/oauth2-2/.

[77] Roy T Fielding and Richard N Taylor. *Architectural styles and the design of network-based software architectures*, volume 7. University of California, Irvine Doctoral dissertation, 2000.

[78] HL7-FHIR. RESTful API, 2017 last accessed Nov, 2017. https://www.hl7.org/fhir/http.html.

[79] Tutorials Point. Simply Easy Learning RESTful Web Services Messages, last accessed Nov, 2017. https://www.tutorialspoint.com/restful/restful_messages.htm.

[80] Corepoint Health. Corepoint Health Versions of the HL7 Standard, last accessed

Jan, 2018. https://corepointhealth.com/resource-center/hl7-resources/hl7-standard-versions.

[81] HL7. HL7 Standards Product Brief - HL7 Version 2 Product Suite, last accessed Jan, 2018. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=185.

[82] HL7. HL7 Standards Product Brief - HL7 Version 3 Product Suite, last accessed Jan, 2018. https://www.hl7.org/implement/standards/product_brief.cfm?product_id=186.

[83] Duane Bender and Kamran Sartipi. Hl7 fhir: An agile and restful approach to healthcare information exchange. In *Computer-Based Medical Systems (CBMS), 2013 IEEE 26th International Symposium on*, pages 326–331. IEEE, 2013.

[84] SMART Health IT. Project SMART App Gallery, last accessed Nov, 2017. https://apps.smarthealthit.org/.

[85] SMART Health IT. SMART Sandbox, 2017 last accessed Nov, 2017. http://docs.smarthealthit.org/.

[86] George Morris. Five Challenges to Interoperability that FHIR can Extinguish, 2017 last accessed Nov, 2017. https://www.transcendinsights.com/five-challenges-to-interoperability-that-fhir-can-extinguish/.

[87] HL7 Wiki. MnM Minutes WGM 201501 SanAntonio, 2015 last accessed Nov, 2017. http://wiki.hl7.org/index.php?title=MnM_Minutes_WGM_201501_SanAntonio.

[88] International Organization for Standardization. *Ergonomics of Human-system Interaction: Part 210: Human-centred Design for Interactive Systems*. ISO, 2010.

[89] E Din. 9241-11. ergonomic requirements for office work with visual display terminals (vdts)–part 11: Guidance on usability. *International Organization for Standardization*, 1998.

[90] Nielsen J. Usability 101: Introduction to Usability, 2012 last accessed Oct 2018. https://dashboard.healthit.gov/quickstats/quickstats.php.

[91] Jakob Nielsen. *Usability Engineering*. Morgan Kaufmann Publishers Inc., San Francisco, CA, USA, 1993.

[92] Ben Shneiderman. *Designing the user interface: strategies for effective human-computer interaction*. Pearson Education India, 2010.

[93] Aaron Marcus. User interface design's return on investment: Examples and statistics. In *Cost-justifying usability*, pages 17–39. Elsevier, 2005.

[94] H Rex Hartson, Terence S Andre, and Robert C Williges. Criteria for evaluating usability evaluation methods. *International Journal of Human-Computer Interaction*, 15(1):145–181, 2003.

[95] Adrian Fernandez, Emilio Insfran, and Silvia Abrahão. Usability evaluation methods for the web: A systematic mapping study. *Information and software Technology*, 53(8):789–817, 2011.

[96] Cathleen Wharton. The cognitive walkthrough method: A practitioner's guide. *Usability inspection methods*, 1994.

[97] Jakob Nielsen and Rolf Molich. Heuristic evaluation of user interfaces. In *Proceedings of the SIGCHI conference on Human factors in computing systems*, pages 249–256. ACM, 1990.

[98] Julie A Jacko. *Human computer interaction handbook: Fundamentals, evolving technologies, and emerging applications*. CRC press, 2012.

[99] David Kieras. Goms models for task analysis. *The handbook of task analysis for human-computer interaction*, pages 83–116, 2004.

[100] Andrew Dillon. The evaluation of software usability, 2001.

[101] Clayton Lewis. Using the'thinking-aloud'method in cognitive interface design. *Research Report RC9265, IBM TJ Watson Research Center*, 1982.

[102] Clayton Lewis and John Rieman. Task-centered user interface design. *A practical introduction*, 1993.

[103] Anders Ericsson. K and ha simon. *Verbal Reports as Data, Psychological Review*, 87(3):215–250, 1980.

[104] Mie Nørgaard and Kasper Hornbæk. What do usability evaluators do in practice?: an explorative study of think-aloud testing. In *Proceedings of the 6th conference on Designing Interactive systems*, pages 209–218. ACM, 2006.

[105] Freddy Paz, José Antonio Pow-Sang, and César Collazos. Validation of a usability evaluation protocol based on the heuristic inspection method: an experimental case study in the web domain. *Adv. Sci. Technol. Lett*, 142:63–68, 2016.

[106] Jonathan Lazar, Jinjuan Heidi Feng, and Harry Hochheiser. *Research methods in human-computer interaction*. Morgan Kaufmann, 2017.

[107] Monique WM Jaspers. A comparison of usability methods for testing interactive health technologies: methodological aspects and empirical evidence. *International journal of medical informatics*, 78(5):340–353, 2009.

[108] Julien Huart, Christophe Kolski, and Mouldi Sagar. Evaluation of multimedia applications using inspection methods: the cognitive walkthrough case. *Interacting with computers*, 16(2):183–215, 2004.

[109] JM Christian Bastien. Usability testing: a review of some methodological and technical aspects of the method. *International journal of medical informatics*, 79(4):e18–e23, 2010.

[110] Mariëtte M van Engen-Verheul, Linda WP Peute, Nicolette F de Keizer, Niels Peek, and Monique WM Jaspers. Optimizing the user interface of a data entry module for an electronic patient record for cardiac rehabilitation: A mixed method usability approach. *International journal of medical informatics*, 87:15–26, 2016.

[111] Clara Schaarup, Stine Hangaard, and Ole K Hejlesen. Cognitive walkthrough: an element in system development and evaluation–experiences from the ewall telehealth system. *Procedia Computer Science*, 100:539–546, 2016.

[112] Yuanhua Liu, Anna-Lisa Osvalder, and Sven Dahlman. Exploring user background settings in cognitive walkthrough evaluation of medical prototype interfaces: a case study. *International Journal of Industrial Ergonomics*, 35(4):379–390, 2005.

[113] Mattias Georgsson and Nancy Staggers. An evaluation of patients? experienced usability of a diabetes mhealth system using a multi-method approach. *Journal of biomedical informatics*, 59:115–129, 2016.

[114] Janni Nielsen, Torkil Clemmensen, and Carsten Yssing. Getting access to what goes on in people's heads?: reflections on the think-aloud technique. In *Proceedings of the second Nordic conference on Human-computer interaction*, pages 101–110. ACM, 2002.

[115] Torkil Clemmensen and Pelle Leisner. Community knowledge in an emerging online professional community: the interest in theory among danish usability professionals. *tc*, 45(3815):2389, 2002.

[116] Sharon McDonald, Helen M Edwards, and Tingting Zhao. Exploring think-alouds in usability testing: An international survey. *IEEE Transactions on Professional Communication*, 55(1):2–19, 2012.

[117] Jan Gulliksen, Inger Boivie, Jenny Persson, Anders Hektor, and Lena Herulf. Making a difference: a survey of the usability profession in sweden. In *Proceedings of the third Nordic conference on Human-computer interaction*, pages 207–215. ACM, 2004.

[118] K Ericsson and H Simon. Verbal reports as data psychological review, 87, 215-251. *Ericsson21587Psychological Review1980*, 1980.

[119] Linda W Peute, MW Jaspers, et al. Cognitive evaluation of a physician data query tool for a national icu registry: comparing two think aloud variants and their application in redesign. *Studies in health technology and informatics*, 160(Pt 1):309–313, 2010.

[120] James R Lewis. Psychometric evaluation of an after-scenario questionnaire for computer usability studies: the asq. *ACM Sigchi Bulletin*, 23(1):78–81, 1991.

[121] John Brooke et al. Sus-a quick and dirty usability scale. *Usability evaluation in industry*, 189(194):4–7, 1996.

[122] Jonathan Howarth, Terence S Andre, and Rex Hartson. A structured process for transforming usability data into usability information. *Journal of usability studies*, 3(1):7–23, 2007.

[123] Asbjørn Følstad and Kasper Hornbæk. Work-domain knowledge in usability evaluation: Experiences with cooperative usability testing. *Journal of systems and software*, 83(11):2019–2030, 2010.

[124] Céline Mariage, Jean Vanderdonckt, and Costin Pribeanu. State of the art of web usability guidelines. *The handbook of human factors in web design*, pages 688–700, 2005.

[125] Nathan Thomas. How to use the system usability scale (sus) to evaluate the usability of your website. *Usability Geek*, 4, 2015.

[126] Setiawan M. Zhou L., Bao J. et al. The mhealth app usability questionnaire (mauq): Development and validation study. *JMIR Mhealth Uhealth*, 7(4):e11500, 2019.

[127] Newman C Maramba I, Chatterjee A. Methods of usability testing in the development

of ehealth applications: A scoping review. *International Journal of Medical Informatics*, 126(6):95–104, 2019.

[128] Fleur Fritz, Sebastian Balhorn, Markus Riek, Bernhard Breil, and Martin Dugas. Qualitative and quantitative evaluation of ehr-integrated mobile patient questionnaires regarding usability and cost-efficiency. *International Journal of Medical Informatics*, 81(5):303–313, 2012.

[129] Aaron Bangor, Philip T Kortum, and James T Miller. An empirical evaluation of the system usability scale. *Intl. Journal of Human–Computer Interaction*, 24(6):574–594, 2008.

[130] Enchanted Learning. US States: Population and Ranking, 2019 last accessed May 2019. https://www.enchantedlearning.com/usa/states/population.shtml.

[131] ATLAS.ti7. ATLAS.ti 7 User Guide and Reference Manual, 2013 last accessed Jan, 2018. http://atlasti.com/wp-content/uploads/2014/05/atlasti_v7_manual_201312.pdf?q=/uploads/media/atlasti_v7_manual_201312.pdf.

[132] Robert H Dolin, Liora Alschuler, Calvin Beebe, Paul V Biron, Sandra Lee Boyer, Daniel Essin, Elliot Kimber, Tom Lincoln, and John E Mattison. The hl7 clinical document architecture. *Journal of the American Medical Informatics Association*, 8(6):552–569, 2001.

[133] Robert H Dolin, Liora Alschuler, Sandy Boyer, Calvin Beebe, Fred M Behlen, Paul V Biron, and Amnon Shabo. Hl7 clinical document architecture, release 2. *Journal of the American Medical Informatics Association*, 13(1):30–39, 2006.

[134] Jeffrey M Ferranti, R Clayton Musser, Kensaku Kawamoto, and W Ed Hammond. The clinical document architecture and the continuity of care record: a critical analysis. *Journal of the American Medical Informatics Association*, 13(3):245–252, 2006.

[135] Enchanted Learning. Code for the Represtation of Names of Languages, 2017 last accessed Feb 2019. https://www.loc.gov/standards/iso639-2/php/code_list.php.

[136] Center for Disease Control and Prevention(CDC). Validation Tools and Test Sites - Shematron Validator, 2015 last accessed Mar 2019. https://www.cdc.gov/nhsn/cdaportal/datavalidation/toolsandtestsites.html.

[137] Po-Yin Yen and Suzanne Bakken. A comparison of usability evaluation methods: heuristic evaluation versus end-user think-aloud protocol–an example from a web-based communication tool for nurse scheduling. In *AMIA annual symposium proceedings*, volume 2009, page 714. American Medical Informatics Association, 2009.

[138] Deborah Hinderer Sova and Jakob Nielsen. *234 tips and tricks for recruiting users as participants in usability studies*. Nielsen Norman Group, 2010.

[139] Jakob Nielsen. *Usability Engineering*. Morgan Kaufmann Publishers Inc., San Francisco, CA, USA, 1993.

[140] Jakob Nielsen. Why you only need to test with 5 users, 2000.

[141] SurveyMonkey. The world?s most popular free online survey tool, Dec 2018. https://www.surveymonkey.com/.

[142] Chaim Noy. Sampling knowledge: The hermeneutics of snowball sampling in qualitative research. *International Journal of Social Research Methodology*, 11(4):327–344, 2008.

[143] Rowland Atkinson and John Flint. Accessing hidden and hard-to-reach populations: Snowball research strategies. *Social research update*, 33(1):1–4, 2001.

[144] William Albert and Thomas Tullis. *Measuring the user experience: collecting, analyzing, and presenting usability metrics*. Newnes, 2013.

[145] TechSmith. Screen Recorder and Video Editor, 2019 last accessed Feb 2019. https://www.techsmith.com/video-editor.html.

[146] Aaron Bangor, Philip Kortum, and James Miller. Determining what individual sus scores mean: Adding an adjective rating scale. *Journal of usability studies*, 4(3):114–123, 2009.

[147] Darryn Lavery, Gilbert Cockton, and Malcolm P Atkinson. Comparison of evaluation methods using structured usability problem reports. *Behaviour & Information Technology*, 16(4-5):246–266, 1997.

[148] Obead Alhadreti and Pam Mayhew. Thinking about thinking aloud: an investigation of think-aloud methods in usability testing. In *Proceedings of the 30th International BCS Human Computer Interaction Conference: Companion Volume*, page 41. BCS Learning & Development Ltd., 2016.

[149] Arnold POS Vermeeren, Karin den Bouwmeester, Jans Aasman, and Huib de Ridder. Devan: A tool for detailed video analysis of user test data. *Behaviour & Information Technology*, 21(6):403–423, 2002.

[150] Tingting Zhao, Sharon McDonald, and Helen M Edwards. The impact of two different think-aloud instructions in a usability test: a case of just following orders? *Behaviour & Information Technology*, 33(2):163–183, 2014.

[151] Jakob Nielsen. Severity ratings for usability problems. *Papers and Essays*, 54:1–2, 1995.

[152] Chauncey Wilson and Kara Pernice Coyne. The whiteboard: Tracking usability issues: to bug or not to bug? *interactions*, 8(3):15–19, 2001.

[153] Jeffrey Rubin and Henrietta Nickels Shirk. Handbook of usability testing: How to plan, design, and conduct effective tests. *Journal of Technical Writing and Communication*, 26(1):97–106, 1996.

[154] Joseph S Dumas, Joseph S Dumas, and Janice Redish. *A practical guide to usability testing*. Intellect books, 1999.

[155] Jeff Sauro. Rating the severity of usability problems. *Measuring Usability*, 2013.

[156] Morten Hertzum. Problem prioritization in usability evaluation: From severity assessments toward impact on design. *International Journal of Human-Computer Interaction*, 21(2):125–146, 2006.

[157] HL7. The Argonaut Project, 2015 last accessed Jan 2019. https://www.hl7.org/implement/standards/fhir/2015Jan/argonauts.html.

[158] HL7. Who is Openmrs ?, 2016 last accessed Jan 2019. https://openmrs.org/about/.

[159] Suranga N. Kasthurirathne, Burke Mamlin, Harsha Kumara, Grahame Grieve, and Paul Biondich. Enabling better interoperability for healthcare: Lessons in developing a standards based application programing interface for electronic medical record systems. *Journal of Medical Systems*, 39(11):182, 2015. URL: `https://app.dimensions.ai/details/publication/pub.1012558663`, `doi:10.1007/s10916-015-0356-6`.

Appendices

Appendix A

APPENDIX A

A.1 After Scenario Questionnaire (ASQ)

Using the rating sheet below, please circle the number nearest the term that most closely matches your feelings about the web-based Reporting Tool, where 1 for Strongly disagree and 5 for strongly agree.

Table A.1: After Scenario Questionnaire (ASQ)

After finishing each task, please indicate your opinion accordingly.					
Task Number: 1					
	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
Overall, I am satisfied with the ease of completing this task	1	2	3	4	5
Overall, I am satisfied with the ease of completing this task	1	2	3	4	5

Overall, I am satisfied with the support information (interface messages) when completing this task	1	2	3	4	5
Task Number: 2					
	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
Overall, I am satisfied with the ease of completing this task	1	2	3	4	5
Overall, I am satisfied with the ease of completing this task	1	2	3	4	5
Overall, I am satisfied with the support information (interface messages) when completing this task	1	2	3	4	5
Task Number: 3					
	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
Overall, I am satisfied with the ease of completing this task	1	2	3	4	5

Overall, I am satisfied with the ease of completing this task	1	2	3	4	5
Overall, I am satisfied with the support information (interface messages) when completing this task	1	2	3	4	5
Task Number: 4					
	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
Overall, I am satisfied with the ease of completing this task	1	2	3	4	5
Overall, I am satisfied with the ease of completing this task	1	2	3	4	5
Overall, I am satisfied with the support information (interface messages) when completing this task	1	2	3	4	5
Task Number: 5					
	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree

Overall, I am satisfied with the ease of completing this task	1	2	3	4	5
Overall, I am satisfied with the ease of completing this task	1	2	3	4	5
Overall, I am satisfied with the support information (interface messages) when completing this task	1	2	3	4	5

A.2 System Usability Scale (SUS) Questionnaire

Using the rating sheet below, please circle the number nearest the term that most closely matches your feelings about the web-based Reporting Tool, where 1 for Strongly disagree and 5 for strongly agree.

Table A.2: System Usability Scale (SUS) Questionnaire

After using the tool, please indicate your opinion accordingly.					
	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1- I think that I would like to use the tool frequently	1	2	3	4	5
2- I found this tool unnecessarily complex	1	2	3	4	5
3- I thought the tool was easy to use	1	2	3	4	5
4- I think that I would need the support of a technical person to be able to use this tool	1	2	3	4	5

5- I found that the various functions in this tool were well integrated	1	2	3	4	5
6- I thought that there was too much inconsistency in the tool	1	2	3	4	5
7- I would imagine that most people would learn to use this tool very quickly	1	2	3	4	5
8- I found the tool very awkward to use	1	2	3	4	5
9- I felt confident using the tool	1	2	3	4	5
10- I needed to learn many things before I could get going with this tool	1	2	3	4	5

Appendix B

APPENDIX B

B.1 Consent Form

UNIVERSITY OF WASHINGTON

CONSENT FORM

Web-based Reporting Tool Usability Testing

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We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

PURPOSE OF THE STUDY

Healthcare providers are aware of the requirements to report a communicable or infectious disease such as Influenza to the authorities such as the state department of health, but compliance is a challenge. Advances in technology can help in complying with the reporting requirement, and electronic reporting tools can help in increasing the reporting rate.

Reporting communicable or infectious diseases to public health authorities is a keystone for events management on local, national and international levels. It helps public health authorities to gather data to assist any public health event. Reporting the collected data on an event from healthcare providers to local/public health authorities and share received data to national healthcare authorities will benefit other healthcare authorities. Therefore, it is going to improve the reporting process on a larger scale.

The purpose of this study to assess the usability and explore the feasibility of using the Web-based reporting tool to help healthcare providers to report communicable or infectious diseases from healthcare provider end to public health authorities end. The results of this study will help inform future work to continue the development of this tool to support the future of reporting tools.

STUDY PROCEDURES

This study will consist of three components. First, we will collect information from you using a survey. Specifically, we will ask for your demographic information such as your age, gender and your experience in dealing with infectious or communicable diseases such as Influenza. Second, we will then conduct usability evaluation session of a web-based reporting tool designed to help healthcare providers to report Novel Influenza cases to public health authorities. During the usability evaluation session, participants will be asked to complete tasks such as using the tool to identify patient to be reported to an authority or specify a case report form to be used for the reporting process. During or after each task, participants will be asked to verbally explain their thought process, goals, and steps taken aloud. After each task, participants will complete the After Scenario Questionnaire (ASQ), which is a three questions survey to assess participant satisfaction after each task. During the session,

we will record quantitative usability session data (e.g. time required to complete a task, task completion) and qualitative data (observation) using the Observation Evaluation Matrix Sheet. The researcher conducting the usability evaluation session will also take notes during the session as part of the observation. Third, After tasks completion, evaluator will conduct a brief exit interview with the participant to better understand the participants perceived utility of the web-based reporting tool, their willingness to use the tool to report novel influenza cases and to receive general feedback from the participants about the web-based reporting tool (i.e. best/worst features, major obstacles).

At the end of the usability evaluation session; the participants will complete two questionnaires:

1. Demographics Questionnaire to collect data such as ages, gender, English language proficiency, number of experience years in the healthcare field, any experience in dealing with an infectious or communicable disease such as Influenza.

2. System Usability Scale (SUS) questionnaire to collect data on the ease of using the tool.

The usability session will be audio recorded, and the screen interaction of the web-based reporting tool will be recorded. We may also take photos, without the inclusion of any identifying features such as faces or tattoos, during the usability testing. The usability testing session will last no longer than one hour. You are under no obligation to participate in any activity during the evaulation session or share information you wish to keep private. Additionally, you may ask questions or withdraw from the study at any time.

RISKS, STRESS, OR DISCOMFORT

There is a small risk of discomfort by participating in this study because you will be asked to complete a series of tasks using an unfamiliar tool within a specific period. You may decline to answer any question or choose not to share any confidential information. If

you become uncomfortable during the study and do not wish to continue, you have the right to withdraw from this evaluation session at any time. This evaluation session is evaluating the tool and not the participants knowledge or skills. There is a minimal risk of a breach of confidentiality. To minimize this risk of a confidentiality breach; only the research team will have access to direct participant identifiers. These direct participant identifiers will be stored according to UW laws and regulations. Direct patient identifiers links will be retained according to federal, state, and local laws. Any excerpts or photos used in publications or presentations will be anonymized using indirect patient identifiers (e.g. P01) and the omission of identifying features (e.g. faces, tattoos).

BENEFITS OF THE STUDY

By participating in this study, you will help identify how the Web-based reporting tool can be used to support reporting communicable or infectious diseases such as Influenza. There is no direct benefit for you by participating in this study.

CONFIDENTIALITY OF RESEARCH INFORMATION

The data collected in this study will be confidential and linked to direct participant identifiers. Direct participant identifiers links will be retained according to federal, state, and local laws. The link between your identifiers and the research data will be destroyed after the records retention period required by state and/or federal law. Any excerpts used in publications or presentations will be anonymized with indirect participant identifiers (e.g. P01). However, if we learn that you intend to harm yourself or others, we must report that to the authorities. Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

OTHER INFORMATION

You may refuse to participate; you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. You will be compensated with a $40 gift card for successful participation in this study.

RESEARCH-RELATED INJURY

If you think you have a medical problem or illness related to this research, contact Abdulwahhab Alshammari at Email address: wahhab@uw.edu, or you can call or leave a voice message at this number (206) 488-5000. Also, you contact Peter Tarczy-Hornoch at pth@uw.edu.

It is important that you promptly tell the researchers If you believe that you have been harmed because of taking part in this study, you can tell the researcher in person or call him at Email address: wahhab@uw.edu or you can call or leave a voice message at this number (206) 488-5000. This number will be monitored 24 hours a day.

If you have questions, complaints or concerns about this study, you can contact Abdulwahhab Alshammari at Email address: wahhab@uw.edu, or you can call or leave a voice message at this number (206) 488-5000. Also, you contact Peter Tarczy-Hornoch at pth@uw.edu, the contact information are listed at the top of this form.

The UW does not normally provide compensation for harm except through its discretionary program for medical injury. However, the law may allow you to seek other compensation if the harm is the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

Subjects statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I will receive a copy of this consent form.

Printed name of subject:

Signature of subject:

Date:

Please mark the box if you would like to be contacted regarding future research opportunities

- ( ) Yes
- ( )No

B.2 Tasks List- Male Participant

Task 1:

Lets assume that your name is Nate Williams. You are a new employee in a healthcare facility where your job requires you to report novel influenza cases based on the states law. You have been assigning a temporary user name and password to log in in the tool.

Using the tool, can you use the provided below to log in?

Username: test-2

Password: 2222

- Remember to think aloud while performing the task.
- Please, say readystart when you are ready to perform the task.
- Say Finished when you finish the task.

Task 2:

You want to report a case for a patient diagnosed with a novel Influenza virus, the patients information is below.

Using the tool, can you search and select the patient then generate the Minnesota case report form?

Medical Record Number: A12345

Patient name: Smith, John Walker

Date of birth: 09/12/1995

Gender: Male

- Remember to think aloud while performing the task.
- Please, say readystart when you are ready to perform the task.

- Say Finished when you finish the task.

Task 3: The generated states novel influenza case report form might have some missing data fields. You want to have a case report form with no missing data fields.
Using the tool and the Case 1 Discharge Summary Report, can you identify and fill in the missing data fields in the generated Minnesota case report form?

- Remember to think aloud while performing the task.
- Please, say readystart when you are ready to perform the task.
- Say Finished when you finish the task.

Task 4: You want to report the generated novel influenza case to the authority.
Using the tool, can you send the generated case report to authority?

- Remember to think aloud while performing the task.
- Please, say readystart when you are ready to perform the task.
- Say Finished when you finish the task.

Task 5: You want to view the reporting history of the tool.

Using the reporting tool, how many reports are sent by the following user?
Sender: Nate Williams

- Remember to think aloud while performing the task.

- Please, say readystart when you are ready to perform the task.

- Say Finished when you finish the task.

B.3 Tasks List- Female Participant

Task 1:

Lets assume that your name is Nancy Oliver. You are a new employee in a healthcare facility where your job requires you to report novel influenza cases based on the states law. You have been assigning a temporary username and password to log in in the tool.

Using the tool, can you use the provided information below to log in?

Username: test-1

Password: 1111

- Remember to think aloud while performing the task.
- Please, say readystart when you are ready to perform the task.
- Say Finished when you finish the task.

Task 2:

You want to report a case for a patient diagnosed with a novel Influenza virus, the patients information is below.

Using the tool, can you search and select the patient then generate the Minnesota case report form?

Medical Record Number: A12345

Patient name: Smith, John Walker

Date of birth: 09/12/1995

Gender: Male

- Remember to think aloud while performing the task.
- Please, say readystart when you are ready to perform the task.

- Say Finished when you finish the task.

Task 3:

The generated states novel influenza case report form might have some missing data fields. You want to have a case report form with no missing data fields.
Using the tool and the Case 1 Discharge Summary Report, can you identify and fill in the missing data fields in the generated Minnesota case report form?

- Remember to think aloud while performing the task.
- Please, say readystart when you are ready to perform the task.
- Say Finished when you finish the task.

Task 4:

You want to report the generated novel influenza case to the authority.
Using the tool, can you send the generated case report to authority?

- Remember to think aloud while performing the task.
- Please, say readystart when you are ready to perform the task.
- Say Finished when you finish the task.

Task 5:

You want to view the reporting history of the tool.

Using the reporting tool, how many reports are sent by the following user?

Sender: Nancy Oliver

- Remember to think aloud while performing the task.
- Please, say readystart when you are ready to perform the task.
- Say Finished when you finish the task.

B.4 Observation Evaluation Matrix Sheet

Table B.1: Observation Evaluation Matrix Sheet

Task 1	**Time duration to complete:**
• ( ) Task completed • ( ) Task completed, but it took too long	• ( ) Participant gave up • ( ) Moderator stops the task because the participant is making no progress or frustrated • ( ) Participant performed the task incorrectly • ( ) Participant believed the task was complete even though it was not
Notes	_____ _____ _____ _____ _____
Task 2	**Time duration to complete:**
• ( ) Task completed • ( ) Task completed, but it took too long	• ( ) Participant gave up • ( ) Moderator stops the task because the participant is making no progress or frustrated • ( ) Participant performed the task incorrectly • ( ) Participant believed the task was complete even though it was not

Notes	_____ _____ _____ _____ _____
Task 3	**Time duration to complete:**
• ( ) Task completed • ( ) Task completed, but it took too long	• ( ) Participant gave up • ( ) Moderator stops the task because the participant is making no progress or frustrated • ( ) Participant performed the task incorrectly • ( ) Participant believed the task was complete even though it was not
Notes	_____ _____ _____ _____ _____
Task 4	**Time duration to complete:**
• ( ) Task completed • ( ) Task completed, but it took too long	• ( ) Participant gave up • ( ) Moderator stops the task because the participant is making no progress or frustrated • ( ) Participant performed the task incorrectly • ( ) Participant believed the task was complete even though it was not

Notes	_____ _____ _____ _____ _____
Task 5	**Time duration to complete:**
• ( ) Task completed • ( ) Task completed, but it took too long	• ( ) Participant gave up • ( ) Moderator stops the task because the participant is making no progress or frustrated • ( ) Participant performed the task incorrectly • ( ) Participant believed the task was complete even though it was not
Notes	_____ _____ _____ _____ _____

B.5 Demographic Questionnaire

After using the tool, please indicate your opinion accordingly.

Participant ID:

The testing process covered many functions and navigations on the following web pages of the tool:

1. Which category below includes your age?

   (a) ( ) 18 24

   (b) ( ) 25 29

   (c) ( ) 30 34

   (d) ( ) 35 39

   (e) ( ) 40 44

   (f) ( ) 45 49

   (g) ( ) 50 54

   (h) ( ) 55 59

   (i) ( ) 60 64

   (j) ( ) 65 or greater

2. Which gender do you identify yourself with most (select one)?

   (a) ( ) Male

   (b) ( ) Female

   (c) ( ) Other

3. Are you fluent in the English language?

   (a) ( ) Yes

(b) ( ) No

4. Please check your completed educational level below:

   (a) ( ) Undergraduate student

   (b) ( ) Bachelors degree

   (c) ( ) Masters degree

   (d) ( ) Ph.D. degree

   (e) ( ) Postgraduate student (Master, Ph.D., Post Ph.D.)

   (f) ( ) Other (Please specify):

5. Do you work in the healthcare field?

   (a) ( ) Yes, currently

   (b) ( ) Yes, before

   (c) ( ) No

6. If you answer question 5 with (Yes, currently) or (Yes, before), please specify the health care service type (e.g., Primary Care, Nursing Care, Drug Therapy, Specialty Care, Public Health Services, Healthcare Insurance Agency, Administrative)

   (a) ( ) Please specify:

7. What is your professional status?

   (a) ( ) Student

   (b) ( ) Working

   (c) ( ) Retired

   (d) ( ) Other (Please specify):

8. Please check your years of expertise in the healthcare field below.

   (a) ( ) Less than a year

   (b) ( ) 1 4 years

   (c) ( ) 5 9 years

   (d) ( ) 10 14 years

   (e) ( ) 15 19 years

   (f) ( ) 20 24 years

   (g) ( ) 25 29 years

   (h) ( ) 30 years or greater

   (i) ( ) I would prefer not to say

9. Did you interact with a patient before?

   (a) ( ) Yes

   (b) ( ) No

10. Did you use any patients paper-based chart before?

    (a) ( ) Yes

    (b) ( ) No

11. Did you use any Electronic Health Record (EHR) before?

    (a) ( ) Yes

    (b) ( ) No

12. Did you interact with any patient with an infectious or communicable disease such as Influenza before?

(a) ( ) Yes

(b) ( ) No

13. Approximately; how many communicable or infectious diseases cases have you reported before either manually or electronically?

(a) ( ) Less than 10

(b) ( ) Between 10 and 20

(c) ( ) More than 20

Thank You.

B.6 Participants Characteristics Survey Results

1. Which gender do you identify yourself with most?

   (a) (3) Male

   (b) (5) Female

   (c) (0) I would prefer not to say

2. Age

   (a) (0) 18 24

   (b) (2) 25 29

   (c) (4) 30 34

   (d) (2) 35 39

   (e) (1) 40 44

   (f) (0) 45 49

   (g) (0) 50 54

   (h) (0) 55 59

   (i) (0) 60 64

   (j) (0) 65 or greater

3. Are you fluent in the English language?

   (a) (8) Yes

   (b) (0) No

4. Please check your completed educational level below:

   (a) (0) Undergraduate student

(b) (1) Bachelors degree

(c) (2) Masters degree

(d) (1) Ph.D. degree

(e) (1) Postgraduate student (Master, Ph.D., Post Ph.D.)

(f) (3) Other: (Physicians (MD)s):

5. Do you work in the healthcare field?

(a) (8) Yes, currently

(b) (0) Yes, before

(c) (0) No

6. What is your professional status?

(a) (1) Student

(b) (7) Working

(c) (0) Retired

7. Please check your years of expertise in the healthcare field below.

(a) (0) Less than a year

(b) (0) 1 4 years

(c) (5) 5 9 years

(d) (3) 10 14 years

(e) (0) 15 19 years

(f) (0) 20 24 years

(g) (0) 25 29 years

(h) (0) 30 years or greater

(i) (0) I would prefer not to say

8. Did you interact with any patient with an infectious or communicable disease such as Influenza before?

   (a) (8) Yes

   (b) (0) No

9. Have you had any experience in using Electronic Health Record (EHR)?

   (a) (8) Yes

   (b) (0) No

10. Have you had any experience in using a paper-based chart?

    (a) (8) Yes

    (b) (0) No

11. Approximately, how many cases of communicable or infectious have you reported before either manually or electronically?

    (a) (3) Less than 10

    (b) (5) Between 10 and 20

    (c) (0) More than 20

B.7 Problem Indicators Checklist- DEVAN

Indications types based on verbal and/or non-verbal behavior:

- **Puzzled:**
  1. Uncertainty about what actions to take.
  2. To be sure whether a specific action is needed or not.
  3. Not being able to understand something on the system (e.g. informative text, a link name, terminology, or a function).
- **Wrong explanation or Understanding:**
  1. The user gives an explanation of something that has happened but this explanation is incorrect.
  2. User verbalizes an incorrect understanding of something on the system (e.g. informative text, a link name or functionality).
- **Recognition:**
  1. User indicates they recognize a preceding error.
  2. User indicates that they now understand something previously not understood.
- **Quit Task:**
  1. The user declares that they are abandoning a task.
  2. The user recognizes that the current task was not finished successfully, but continues with a subsequent task.
- **Doubt, Surprise, Frustration:**
  1. They are unsure as to where they have and have not been on the system.

2. They are unsure as to whether an action has executed properly.
3. Do not understand an actions effect.
4. To be surprised by an action's effect.
5. That something did not meet their expectations.
6. The effect of an action was unsatisfactory or frustrated the user.
7. They dislike or disapprove of something

- **Random Actions:**

1. The user indicates verbally or non-verbally that they are performing random actions.

- **Impatience:**

1. The user shows impatience by clicking repeatedly on objects that respond.
2. Slowly or the user expressed impatience verbally.

- **Wrong goal:**

1. User formulates a goal that cannot be achieved.

- **Search for function:**

1. Not being able to locate a specific functional link or piece of information.
2. They are searching for a function the evaluator knows does not exist.

Indication types based on observed actions:

- **Wrong Action:**

1. User points at a correct function/object but does not execute the action.

2. Execution of an action not done correctly or optimally.
3. User stops executing a correct action before it is finished.
4. An action does not belong to the correct sequence of actions.
5. An action is omitted from the sequence.
6. An action within a sequence is replaced by another action.
7. Actions within a sequence are performed in reverse order.

- **Repeated Action:**

1. User has to re-do certain actions (e.g. re-enter form data due to it not being saved).
2. User repeats an action with the same effect.

- **Technical Issues:**

1. System crashes, broken links, slow response system.

B.8 The Final list of the 20 identified usability problems

To match the tools final list of usability problems to the tools interface and assigned tasks, see the numbers on Figures B.1 , Figure B.2 , and Figure B.3 . The numbers on the figures shows the derived usability problems from the evaluation usability study in Aim3.

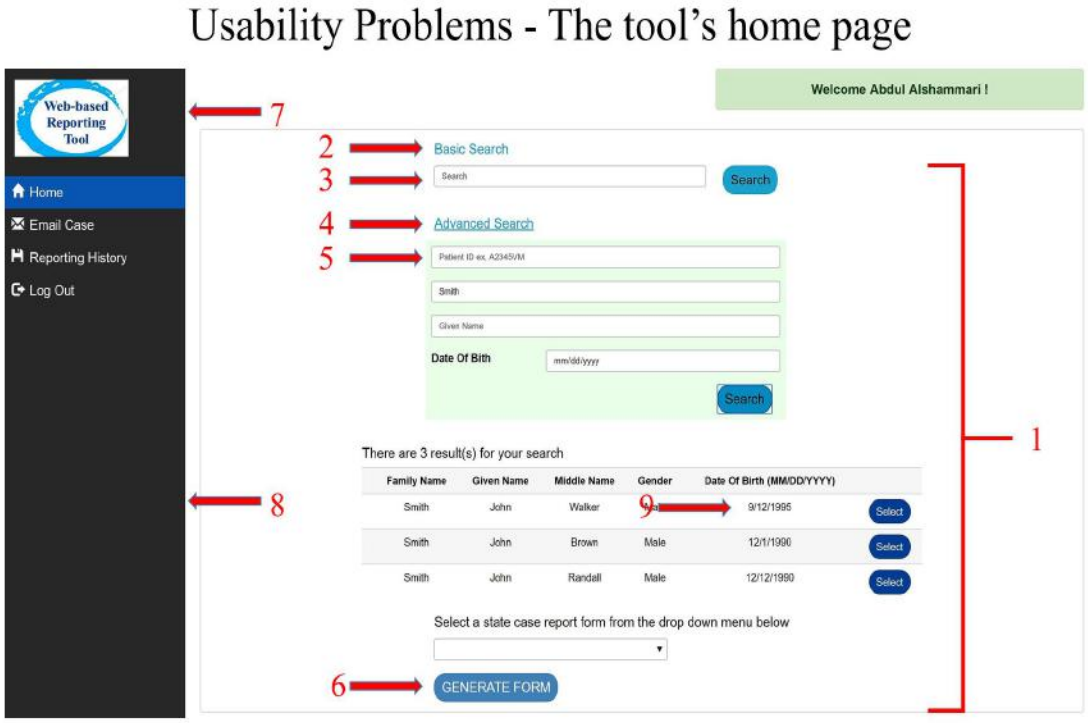

Figure B.1: The tools home page.

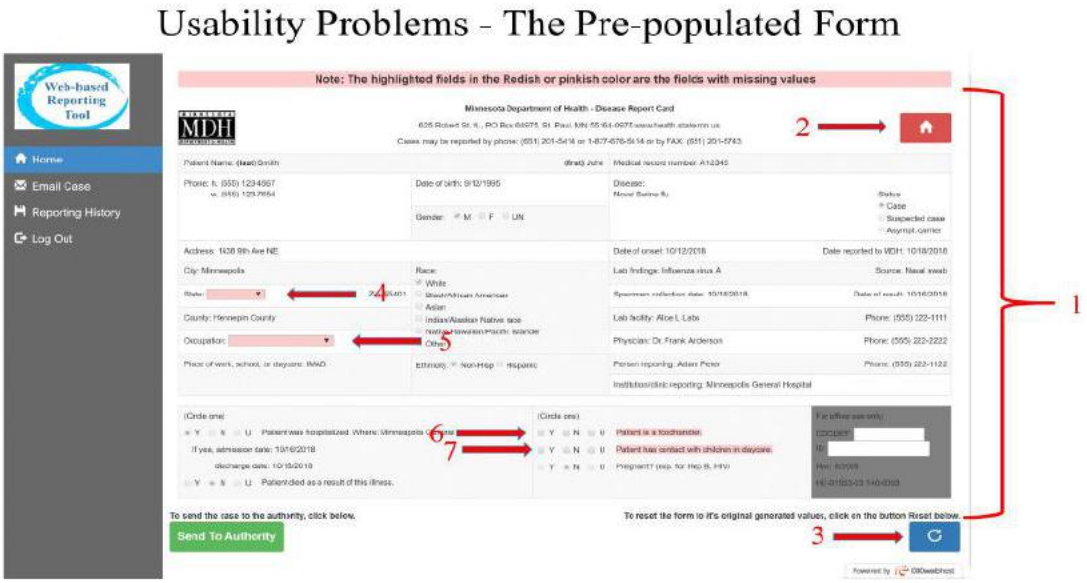

Figure B.2: The Pre-populated form.

Figure B.3: The reporting History Table.

Table B.2: The final list of usability problems.

Index	Task No.	Usability Problem and Related Figure	Usability Problem Description	Severity Level [*]	Usability Problem Type [**]
1	T2	No.1 in Figure B.1	The layout of the page does not tell the sequence of steps a user should follow to generate a specific case report form for a specific patient.	Level 2	Layout
2	T2	No. 2 in Figure B.1	The Basic Search title does not tell users what to search.	Level 3	Content
3	T2	No. 3 in Figure B.1	The prompt inside the basic search box does not provide a search example.	Level 3	Content
4	T2	No. 4 in Figure B.1	The Advanced Search title does not tell users what to search.	Level 3	Content
5	T2	No. 5 in Figure B.1	The prompt inside the advanced search box does not provide a search example.	Level 3	Content
6	T2	No. 6 in Figure B.1	The Generate Form button in clickable even though a user selects no patient. It should not be clickable unless a user selects a patient and specify a case report form to the reporting process.	Level 2	Functionality

7	T2	No. 6 in Figure B.1	In the case when a user selects a case report form without selecting a patient for the reporting process and click on the Generate Form button, the tool does not prompt a message to tell the user to select a patient to complete the process.	Level 2	Functionality
8	T2	No. 7 in Figure B.1	The tools logo is outdated, and the logos dimensions do not match the sidebar spaces.	Level 4	Layout
9	T2	No. 8 in Figure B.1	The tools colors combination needs improvement.	Level 4	Layout
10	T2	No. 9 in Figure B.1	Technical problem when the tool returned a mismatched patients date of birth.	Level 1	Functionality
11	T3	No. 1 in Figure B.2	The pre-populated case report form edges are not clear to distinguish what inside the form from what is related to the tool.	Level 3	Layout
12	T3	No. 2 in Figure B.2	The Home button is inside the space for the pre-populated case report form. The Home button should outside the case report form space.	Level 3	Layout
13	T3	No. 2 in Figure B.2	The Home button color distracts the user because it attracts users attention. The Home button should use a different color.	Level 3	Layout
14	T3	No. 3 in Figure B.2	This usability problem is related to usability problem number 10, the edges between the generated case report form and the Reset button are not clear.	Level 4	Layout

15	T3	No. 4, 5, 6, and 7 in Figure B.10.2	After selecting values for the highlighted data fields, the background color goes to white, which some of the users didnt like. Users preferred to see the missing fields all the time to double check the reporting process.	Level 3	Layout
16	T5	No. 1 in Figure B.3	The search box background color does not attract users attention; the search box was easy to miss.	Level 3	Layout
17	T5	No. 1 in Figure B.3	The prompt inside the search box does not provide a search example.	Level 3	Content
18	T5	No. 2 in Figure B.3	Users tried to sort Sender column by clicking on the header title. This function is not in the tools functions. The same principle applies on other tables headers.	Level 3	Functionality
19	T5	No. 3 in Figure B.3	The files name is crowded. There is no need for a date to be included in the files name specially that there is a specific column for a date and time.	Level 4	Layout
20	T5	No. 4 in Figure B.3	Users suggested to have an extra column for a PDF version of the reported case.	Level 4	Functionality

Note: Note: There were no identified usability problems with tasks T1 and T4.

[*] Severity Level: Level 1- Critical (Problems prevent completion of a task). Level 2-Major (Problems create significant delay and frustration). Level 3-Minor (Problems have a minor effect on usability). Level 4-Enhancement (Problems are more subtle and often point to enhancements that can be added in the future).

[**] Usability problem Type: Navigation (Participants have problems in navigation the tools pages). Layout (Participants have difficulties with the tool layout such as web elements, display content, and structure). Content (Participants have difficulties with understanding the content of the tool such as terminology or choice of words). Functionality (Participants have difficulties with the tool functions, either absence of needed functions or difficulties with normal functions).