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Practice, Protocols and Innovation of Public Health Decision Support Systems that
Advance Automated Disease Reporting

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M.P.H., Emory University, 2016

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An abstract of

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Abstract

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Denisha N. Abrams

Public health reporting is the cornerstone of disease surveillance and is a “requisite for managing disease burden in a community”. In the United States, selected diseases and conditions must be reported to public health authorities by physicians, hospitals, laboratories and other reporters to control disease and outbreaks. The current process of disease reporting is a manual process, prone to human error and lack of knowledge of what is reportable. Each jurisdiction determines the “who, what, when, where and how” of disease reporting, which is resource-intensive and scattered across documents and websites. The specifications associated with reportable events also vary by condition, which contributes to the complexity and management of changes that occur in reporting guidelines or clinical terminology standards. There is a need for national collaboration that looks towards interoperable standards and system development that can move disease reporting beyond its current state. Standard terminologies such as *Logical Observation Identifiers Names and Codes (LOINC®)* provide a building block to the data exchange between clinical care and public health. The development of public health decision systems that support automated disease reporting has some notable early adopters. The population of study includes three systems: Massachusetts Department of Health (MDPH) - Electronic Support for Public Health (ESP); Regenstrief Institute - Notifiable Condition Detector (NCD); and the Council of State and Territorial Epidemiologists (CSTE) - Reportable Conditions Knowledge Management System (RCKMS). The purpose of this research is to examine the practice of two locally developed public health decision support systems and compare their development protocols to a national prototype. A content analysis of the existing models will inform national efforts of how these systems work and the innovation behind their development. The reusability of what currently works shows that progress has been made but the associated gaps between local implementations and a national platform to automate disease reporting reveals a journey fraught with barriers to widespread adoption.

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1 INTRODUCTION

1.1 INTRODUCTION AND RATIONALE

Public health reporting is the cornerstone of disease surveillance and is a “requisite for managing disease burden in a community” [1]. In the United States, selected diseases and conditions must be reported to public health authorities by physicians, hospitals, laboratories and other public health personnel to control disease and outbreaks. Since 1951, the Council of State and Territorial Epidemiologists (CSTE) has been providing reporting specification recommendations, in *consultation* with the Centers for Disease Control and Prevention (CDC), that describes how diseases should be reported [2]. Surveillance case definitions provide not only disease reporting content but instruction to state health officials of how to classify disease information that is voluntarily reported to the CDC. Nationally notifiable disease condition lists are governed by the CDC and are included in some jurisdiction’s reportable condition lists. Jurisdictional laws and regulations govern the reportable conditions list for each state and specify those that are mandated to be reported [3]. These “lists” do not automatically include nationally notifiable conditions that are requested to be reported to the CDC from state health departments. Public health case reporting information is commonly thought of as beginning with the identification of a disease that is deemed reportable. What is often overlooked is the *definition, publishing and access* to reporting specifications which are fundamental steps that precede the detection of a reportable event [4]. Publication to the clinician is often through several channels, such as agency websites and via listservs. Few states actually enforce penalties for non-compliance with reporting regulations, which can lead to a physician’s license being suspended or in some cases being placed on probation for failing to notify health officials [2]. Public health reporting should be dually reported by both clinicians and laboratories, but often times a clinician assumes the laboratory has reported which causes underreporting with missed cases. Positive electronic laboratory reporting (ELR) to the state is not sufficient alone to investigate disease cases, which requires supporting clinical details that are recorded in the electronic health record. The Council of State and Territorial Epidemiologists (CSTE) suggests that nationally notifiable conditions (NNCs) be included as reportable conditions across all state jurisdictions. State sovereignty over what is

reportable and to whom, often results in a lag of reporting, due to reporters lacking direct access to succinct reporting information about what is reportable and to which jurisdiction.

The power of public health informatics includes the innovative use of information science and technology that improves efficiency and effectiveness of “traditional public health practice” [5]. Public health informatics has been defined as the combined efforts of information science, computer science and technology [5]. The field of informatics takes on many faces depending on the domain, such as those in biomedical informatics, clinical informatics or health informatics. Regardless of the discipline, *informatics* in general can be associated with three core principles that connect *data* and *information* that translates to *knowledge*, commonly referred to as the informatics pyramid [6]. Leveraging technology such as clinical decision support systems, which have long provided physicians with alerts to avoid adverse medical events, can be used to advance areas of public health, including disease reporting. The expansion and growth of electronic health records provides an abundance of reusable structured and unstructured data, that is a “*major focus of public health informatics*” interoperability [5]. The proliferation of technology in health care has increased the need for public health to focus on existing data streams that can be leveraged to improve disease surveillance. The application of an informatics perspective to solving problems that are interdependent helps mitigate public health reporting challenges, and results in benefits that addresses the needs of the entire public health community [5].

1.2 PROBLEM STATEMENT

The timeliness and completeness of reporting is of public health concern and importance. Passive surveillance is the most common type of public health surveillance method and relies on laboratories and health care providers recognizing and taking the initiative to notify public health jurisdictions of a potential case. The current process of disease reporting is largely manual, prone to error and reporters lack central knowledge of what is reportable. Each jurisdiction determines the “who, what, when, where and how” of disease reporting, and posts that information in documents on websites (*Fig. 1*).



(Figure 1. Snapshot of sample reporting guidelines and summary of the problem.)

CSTE maintains an archive of position statements that “represent the documentation and analysis of policy issues affecting public health” [7]. These documents provide definition to the reporting specifications for notifiable conditions, and contain condition-specific reporting specifications and case classification information that some states follow to create or revise their laws for reportable condition lists. Position statements are structured as human readable documents that are developed from CSTE templates that are divided into thirteen sections. Each position statement begins with narrative sections that describe the problem, background, actions to be taken and the surveillance goals intended to be achieved, followed by subsequent sections that lists reporting criteria in tables, an effort to standardize surveillance information for diseases and conditions [8]. The reporting criteria that is listed in section six of a particular position statement is the area where reporters should draw from to determine reportability. In many cases, case classification information in section seven is referenced for case reporting, which is an inaccurate interpretation of the information referenced in the position statement, and is another example of the problems associated with determining reportability. The key difference is that section six in the position statement is directed towards state and local reporters and section seven is more focused on what the CDC is requesting to be sent from the states. The healthcare terms found within these documents vary depending on the condition, which creates inconsistencies in how reporting

criteria is represented across clinical, laboratory, epidemiologic and demographic sections [9]. A common source of contention with disease reporters is that there is ambiguity with interpreting reporting criteria, which impacts not only the timeframe in which a report is sent, but also the accuracy and completeness of reporting. A determination of reportability can take anywhere from seconds to over eight minutes to search agency websites [9] and varies in reporting on conditional elements such as patient residence, laboratory location and where clinical care was provided. National changes in clinical coding (such as with the recent transition from ICD-9 to ICD-10), further demonstrates the complexity with determining reportability and the need for a centralized source of knowledge that can provide guidance to reporters. CSTE has recently led several discussions and initiated an assessment of jurisdictional reporting differences and the need for automation through collaborative partnerships [10]. Although, position statements provide guidance of what is reportable, they lack the standardization and structure to be automatically adjudicated by an electronic system. No system provides a single point of access for reporters that aid in the decision-making process associated with determining reportability, making it labor-intensive and time-consuming for reporters to know when to report a potential case, and to which jurisdiction(s) it should be reported.

1.3 PURPOSE STATEMENT

The purpose of this research is to examine the practice of two locally developed public health decision support systems (PHDSS) and compare their development protocols to a national prototype. Additionally, the practice of these developed systems, the protocols that surround how they function, and the innovation behind their development will be evaluated. There is a need to look towards automated solutions on a national level and move beyond the current scattered efforts of determining the logistics of disease reporting.

1.4 RESEARCH OBJECTIVES

The primary objectives are to:

- **Objective 1:** Review the practice of two locally developed public health decision support systems and compare their development protocols to a national prototype
- **Objective 2:** Assess strengths and limitations of existing local PHDS solutions
- **Objective 3:** Identify components of local solutions that can be reused for a national solution

1.5 SIGNIFICANCE STATEMENT

There is a need for public health stakeholder collaboration that looks towards interoperable standards and components of existing public health decision support systems that can be used to move disease reporting beyond its current state. Automated disease reporting supports the Case Reporting Meaningful Use Stage 3 objective that is part of the Health Information Technology for Economic and Clinical Health (HITECH) act, enacted as part of the American Recovery and Reinvestment Act (ARRA). There is opportunity to improve the exchange of information between clinical care and public health through the support of regulatory initiatives. The significance of these regulatory initiatives speaks to the interest of public health in increasing use of technology to enable interoperability and promote standardization of approaches. Examining the lessons learned from existing systems can help inform national efforts.

1.6 DEFINITION OF TERMS

Key terms and acronyms used are defined here.

Algorithm	Logic derived from rules
Architecture	“A fundamental underlying design of computer hardware, software, or both”. [11]
Case definition	“A set of uniform criteria used to define a disease for public health surveillance”. [12]
CDS	Clinical Decision Support
CSTE	Council of State and Territorial Epidemiologists
ELR	Electronic Laboratory Reporting
ESP	Electronic Support for Public Health

HL7	Health Level Seven
ICD	International Classification of Diseases
IHIE	Indiana Health Information Exchange
JPHIT	Joint Public Health Informatics Taskforce
LIMS	Laboratory Information System
LOINC®	Logical Observation Identifiers Names and Codes
NNC	Nationally Notifiable Condition – voluntary reporting from state health departments
NCD	Notifiable Condition Detector
Open-source	License free programming source code
PHDS	Public Health Decision Support
PHDSC	Public Health Data Standards Consortium
Reportable Condition	Mandatory reporting of disease conditions of public health importance to states
RCKMS	Reportable Condition Knowledge Management System
RX-Norm	“Normalized names for clinical drugs and links its names to many of the drug vocabularies...”[13]
SNOMED-CT®	Systematized Nomenclature of Medicine--Clinical Terms
Trigger	“The clinical event that causes a rule to be invoked.”[14]
Web-service	Electronic communication from one system to another via the Internet in support of interoperable interaction.

2 LITERATURE REVIEW

2.1 INTRODUCTION

This chapter reviews the emerging themes discussed in the literature as it pertains to the practice, protocols and innovation of three public health decision support systems that currently support automated disease reporting or are in development to support such an achievement on a national scale. The literature describes the growth of the use of electronic health data and its reusability to support public health disease reporting surveillance. The central elements that impact the development of these systems revolve around clinical data standards and decision support components that have the ability to

transfer knowledge back to a user or in some cases directly to public health. Clinical terminology standards combined with a knowledge source and information technology provide an architecture in support of automated disease detection, as described in the literature. This review will provide an organizational overview of the PHDS systems included in this research, their practice with using electronic health records or laboratory information systems, and the subcomponents that help advance electronic disease reporting to public health agencies. The functional process, technical framework, and contextual elements of each system will be further discussed in the findings.

What is a public health decision support system?

Clinical decision support systems are associated with clinical practice, providing alerts to physicians to assist with medical aversion and in patient care decision-making. Decision support is not a frequent term used within the public health domain. These systems run off algorithms that enable strategic decision-making, by providing predictive insight that can enhance organizational activities and clinical workflows. The adoption of clinical decision support concepts coupled with an interface to support electronic messaging and public health knowledge that leverages clinical data, such as those recorded in an EHR, is an example of a public health decision support system. It is the knowledge resource that these advanced systems provide that transforms their usability across both clinical and public health milieus. In essence, public health knowledge that intersects with clinical data to generate a decision can also be described as a public health decision support tool. These systems can be quite sophisticated and have advanced the use of EHR systems, creating a bidirectional exchange of information “between public health and clinicians” [15]. There is growing evidence that supports the use of clinical criteria found within electronic health records that can provide early detection of reportable and notifiable disease conditions. The evolution of web technology services and federal IT initiatives demands a closer look at the development of advanced clinical decision support systems, their architecture and network sharing platforms.

Early Adopters and Innovation

The early adopters identified were systems developed by two local jurisdictions. The Indiana Health Information Exchange (IHIE) and the Massachusetts Department of Health (MDPH) have been electronically detecting notifiable, and in some cases reportable diseases derived from clinical settings and automatically transferring data to their respective state health agencies [16] [1]. The organizations behind the innovation and development of these systems are described below, in addition to the development of RCKMS a national PHDS prototype that is envisioned to provide a central knowledge base of reportable conditions, reporting criteria, reporting actions and jurisdictional rules [17].

Electronic Support for Public Health (ESP)

Electronic Support for Public Health (ESP) was developed from a pilot project funded by the CDC's National Center for Public Health Informatics (NCPHI) and was created by the Massachusetts Department of Health (MDPH). ESP is a core component of the ESPnet project, which is a combination of two-open source software systems developed by the Harvard Medical School's Department of Population Medicine at the Harvard Pilgrim Health Care Institute [18]. ESP is the disease surveillance software and PopMedNet provides governance of disparate health data that is received from and stored in different locations. ESP enables medical practices and hospitals to provide automated, timely reports to public health departments about notifiable conditions, influenza-like illness and chronic diseases by using information in electronic health records.

Notifiable Condition Detector (NCD)

The Notifiable Condition Detector (NCD) was developed by the Regenstrief Institute over a decade ago. Their centers for research include the Indiana University Center for Aging Research (IUACR), the center for biomedical informatics (CBMI) and their health services research (HSR) center. This organization leads

informatics and health care research efforts throughout the U.S. and is an internationally recognized organization that is affiliated with Indiana University[19]. The NCD operates in the Indiana Health Information Exchange (IHIE), which is a network of providers in Indiana that participate in the Indiana Network for Patient Care (INPC). The system enhances their disease surveillance and reporting workflow by automatically notifying providers of potentially reportable conditions.

Reportable Condition Knowledge Management System (RCKMS)

The Council for State and Territorial Epidemiologists (CSTE) has partnered with the CDC and HLN Consulting, LLC. to develop of the Reportable Condition Knowledge Management System (RCKMS). HLN is the lead technical developer of RCKMS and is currently developing an authoring framework that translates human-readable reporting specifications into computable rules logic. The innovation behind RCKMS builds off existing work that has been developed with the *Reportable Condition Mapping Table* (RCMT), a mapping table between reportable conditions and laboratory tests and results. RCMT was another joint effort with the CDC and CSTE that served as a first step to reducing the burden of reporters in determining which laboratory test and result codes that apply to reportable conditions.

Table 1. An overview of the population and their development organizations.

System	1	2	3
Organization Name	Massachusetts Department of Public Health (MDPH)	Regenstrief Institute	Council of State Territorial & Epidemiologists (CSTE)
Organization Type	State Health Department	Informatics and health care research organization	National
System Name	Electronic Support for Public Health (ESP)	Notifiable Condition Detector (NCD)	Reportable Condition Knowledge Management System (RCKMS)
System Status	Production (2007) ^[20]	Production (10+ years) ^[21]	Prototype/Pilot (Phase I / 2013-2014; Phase II / 2014-2015)

Major components of a public health decision support system

The key components to operationalizing a PHDS system that determines the reportability to public health of a potential case includes the secondary use of clinical data elements found within the electronic health record and within electronic laboratory information systems. These systems include the demographic

detail, clinical and laboratory results that are often necessary to investigate case reports. The literature revealed the use of these systems in support of electronic case reporting in two very different primary settings, one through a distributed network and the other within a centralized HIE. Additionally, there were several key concepts revealed that are relevant to how PHDS enhances automated disease reporting. The emerging themes are framed around the use of EHR/ELR information technologies, clinical data standards, and the general flow of information among varying architectural frameworks. The major components of a CDS are that it includes programmatic logic that is a combination of clinical data and a knowledge repository that results in additional information being transferred back to an end-user or to generate a report. It is these components that can be recalibrated for public health consumption on a broad scale. The use of a PHDS system is largely dependent on electronic health record data and the clinical data standards that govern health care delivery.

2.1.1 Electronic Health Record/Laboratory Information Systems

The emergence of electronic health record systems is ubiquitous and continues to grow to meet the needs of clinical providers. As defined by the Centers for Medicare and Medicaid (CMS), an EHR “is an electronic version of a patient’s medical history” [22], that may include structured or unstructured data elements. Those structured elements, such as biomedical ontologies and vocabularies are those which provide the linkage to how health care data can strengthen public health disease reporting. Repurposing the information that flows within clinical care settings has been operationalized with the NCD and ESP surveillance systems [19, 23]. The NCD, an ELR and automated case detection application used within the IHIE, uses secondary data to pre-populate case reporting forms [24] that are sent to the reporter for manual completion and submission to public health. NCD electronically identifies reportable conditions, which enhances a traditionally paper-based reporting structure to an advanced disease reporting workflow [19]. The IHIE is comprised of data collected from participating providers on clinical events and NCD acts as a filter to assess laboratory results and their association with notifiable conditions. ESP takes electronic detection of potentially infectious and communicable disease a step further than NCD, by not

only incorporating test results, but includes diagnosis codes and medication history that is stored in the medical record to detect notifiable conditions. Their approach increases the sensitivity and automatic identification of suspected cases that public health wants to know about in lieu of a confirmed diagnosis, such as with tuberculosis [25]. The alternate use of EHR data has an impact on not just healthcare outcomes but also extends to benefit public health surveillance. Studies on EHR surveillance is limited, yet systems such as ESP and NCD demonstrate the use of clinical and laboratory data in support of automated disease reporting [23, 26]. EHR data provides an optimal opportunity to automate disease reporting and increase the completeness and timeliness of information that is sent to public health agencies.

2.1.2 *Data Standards*

The building blocks to the data exchange between clinical care and public health include the use of standardized terminologies, such as Logical Observation Identifiers Names and Codes (LOINC®), International Classification of Diseases (ICD), and Systematized Nomenclature of Medicine--Clinical Terms (SNOMED-CT®). These common coding standards provide a gateway to semantic exchange of clinical data across health information systems. The literature discusses the integration of clinical terminologies and their usefulness in detecting communicable and infectious diseases. The previous section discussed the benefits and growth of EHRs, but the ways in which the clinical and laboratory data standards have been applied were also mentioned in the literature.

LOINC codes provide a common terminology of laboratory tests, results and other observations.

Developed and maintained by the Regenstrief Institute since 1994, LOINC is a universal set of codes, identifiers and names for clinical and laboratory observations [27]. The main aspect of LOINC codes is that they provide a standardized method for identification of clinical observations within an electronic message. The structure of a LOINC code is based on a fixed number string that ranges from 3-7 characters, that ends with a number that is preceded by a hyphen. The specific numbers that identify a particular LOINC code contains six attributes; component, property, time aspect, system type, scale and method. These attributes provide details about the laboratory test or clinical observation associated with

the LOINC code. The NCD system is described as an automated disease detection and an electronic laboratory reporting (ELR) system that screens the observation identifier (OBX3) segment field from HL7 messages received from INPC stakeholders, to determine if there is a match to a notifiable condition [28]. The NCD exclusively uses LOINC code mapping database tables to capture laboratory results from inpatient and outpatient settings to evaluate if they match a notifiable disease and determine its associated LOINC code [29]. Researcher's at Regenstrief have conducted several studies to determine the implications of various LOINC code mapping strategies based on the frequency of codes used or "all-inclusive" mapping that can be further defined with "rule-based processing" [29] [30]. Their research revealed that combining both methods significantly reduces the burden of local code mapping to all LOINC codes and a focus should be placed on those values that are linked to reportable conditions [29]. Currently, NCD leverages both internal code mapping and linkages to national registries, such as the reportable conditions mapping table (RCMT) that filters LOINC® and SNOMED-CT® codes based on reportable conditions [29]. The acceptance of LOINC® codes as a universal clinical data standard continues to grow, although by themselves they lack the demographic and clinical details for complete case reporting.

2.1.3 *Software Architecture and Message Standards*

Software application architecture is based on a broad set of factors that should "*consider the user, the system and the goals of the business*" that envelop "structural elements and their interfaces by which the system is composed" [31]. The ESP application is designed to function within a distributed network model that supports independent installations at multiple host sites [20]. ESP's open-access framework is supported by various sub-systems, such as those that process incoming data to validate notifiable condition logic [16]. This approach differs from the "community-wide" infrastructure of the IHIE, which utilizes a centralized repository that is managed and operated by Regenstrief Institute staff [32]. The NCD application resides within the IHIE network which can pull information from shared databases to coordinate knowledge about the patient in conjunction with business intelligence tools that can detect

notifiable conditions. The ESP and NCD applications model the structure of clinical decision support systems, requiring a knowledge and a logic source which are foundational to the decision-making process that these systems produce. The modular architecture that both systems utilize, allows for the ease of connection to component systems and applications, which reduces functional dependencies on one application or system. *How* information technology can help automate antiquated reported practices requires innovative approaches to system development and the utilization of established standards [33]. The HL7 clinical decision support workgroup envisions the adoption of a single model standard that could be applied to CDS implementations [34]. The architecture of these systems have evolved from the early standalone design to more integrated platforms that seek to formalize the syntactical structure of machine-executable clinical rules and logic [14]. The current movement towards advancing clinical decision support models is through service-oriented architecture (SOA) which enables the exchange of information via web technology services. The RCKMS proposed architecture is anticipated to be a centralized repository of public health reporting knowledge expressed as rules through an open-source clinical decision support interface engine.

2.2 SUMMARY OF THE CURRENT PROBLEM

The efforts to move automated disease reporting forward on a national scale include many stakeholders. The capabilities of clinical decision support systems (CDSS) are significant in their ability to transform “real-time, event-driven logic to aid clinical decision-making” [35] in support of public health action. Local systems that have been developed are siloed efforts that remain functional to meet the needs of their jurisdictions, but how do they translate to broader efforts? The core standards and architecture described above are key to the structure and development of systems that can automate disease reporting. Contextual analysis of existing systems to support collaborative solutions will move the nation to a unified front for automated disease reporting. There has been limited research on the practice of automated disease reporting largely because there are not many systems that exist to support these efforts. A standards-based approach to automating disease reporting increases the reliability of data and reduces

human error. Stand-alone systems that are segmented by state jurisdictional lines, work well in their respective space, however it is the combined functions of these systems and a harmonization of efforts that will move disease reporting forward into the future.

3 METHODS

3.1 INTRODUCTION

This chapter describes the research methods and the population of study. The previous chapter discussed the emerging themes found in the literature. A review of the literature was conducted using bibliographic peer-reviewed databases, such as Medline and PubMed. The search was confined to literature published from 2005 to 2015 to capture the most recent development efforts that pertained to the current practice of the systems selected for review. The review of the literature was not exhaustive and was limited to articles that mentioned the *name* of the systems that were included in the comparative analysis. The inclusion criteria was narrowed to articles that included the full system name; (1) Electronic Support for Public Health; (2) Notifiable Condition Detector and; (3) Reportable Condition Knowledge Management System and/or their acronyms (ESP, NCD, RCKMS). The search strategy was extended to include specific terms such as “public health decision support” and “electronic health record (EHR, EMR) AND “surveillance” and slight variations of other closely related terms to gather further details about the organization, define terms and related practices found within the system focused literature search. Articles were excluded that did include the system name or associated terms described above. Other sources included non-published materials (with permission from source), abstracts, posters, and presentations that were synthesized and reviewed according to the themes that unfolded.

3.2 POPULATION

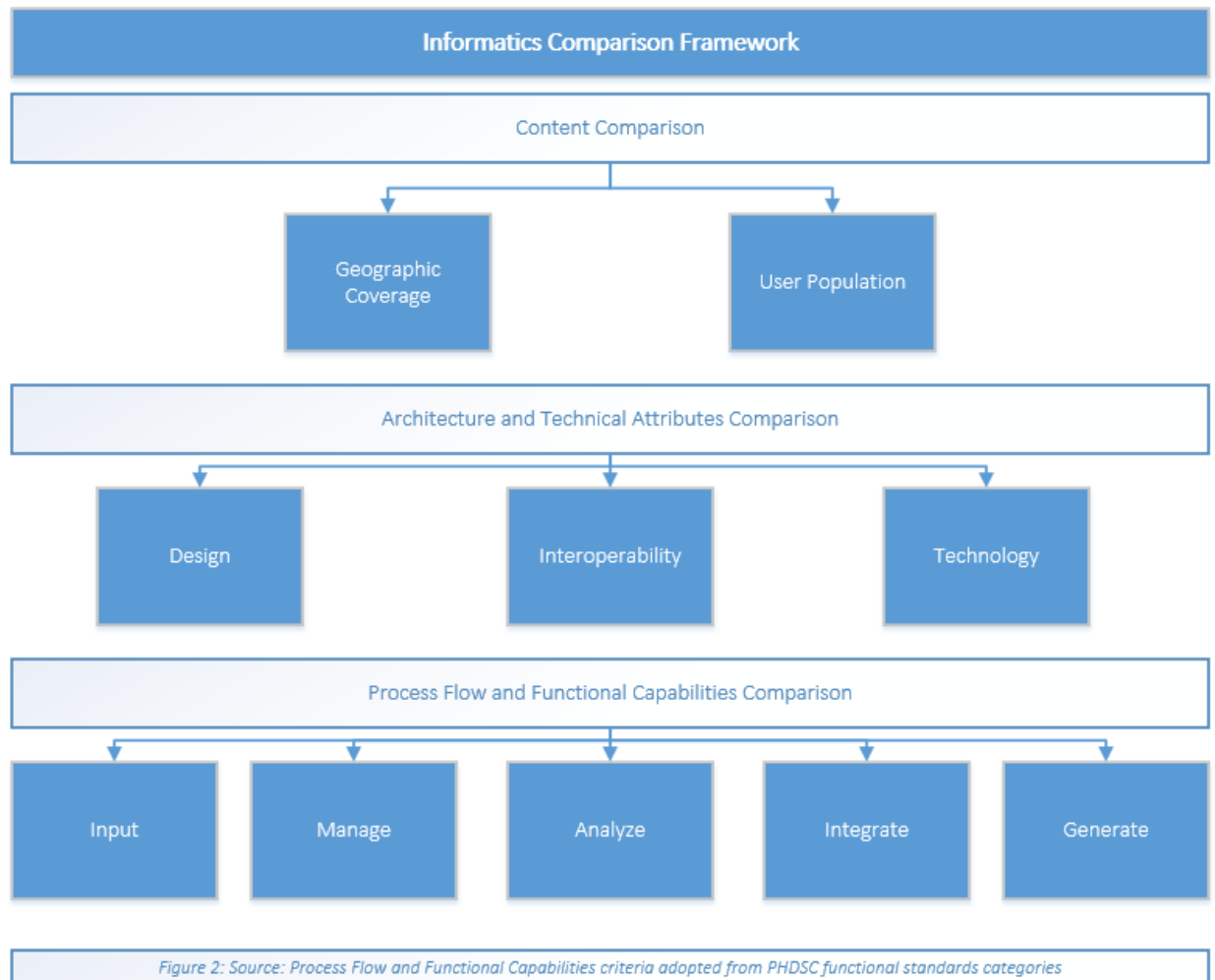
The population included three systems: Massachusetts’ Electronic Support for Public Health (ESP); Regenstrief’s Notifiable Condition Detector (NCD); and CSTE’s Reportable Conditions Knowledge Management System (RCKMS). Overall, there is limited literature on systems that have been developed to electronically detect infectious and communicable diseases in support of automated case reporting. The

systems included in this research were selected based off the knowledge of existence by the author, whose primary research focus was on PHDS systems that included automated assessments of EHR data elements to trigger the detection of a reportable disease event. Two of the systems selected are currently in production, while the third system, in contrast, is in a prototype/pilot phase. A general overview of the population and their systems are summarized in *Table 1*.

3.3 RESEARCH DESIGN

This research was conducted using comparison – descriptive methods. Comparative research methodologies aims to make comparisons and describe similarities and/or differences across unique subjects or variables. An informatics driven comparison framework (*Fig.2*) was developed to assess key informatics system capabilities and development trends across the various systems [36]. The framework includes three overarching categories that are further decomposed to specific criteria to compare system details. The Joint Public Health Informatics Taskforce (JPHIT) and the Public Health Data Standards Consortium (PHDSC) have done considerable work in support of public health informatics research and standards promotion through partnerships and collaborations with public health associations [36, 37]. The categories were selected based on the emerging themes revealed in the literature and their connection to the previously mentioned public health informatics organizations that support system development and business process standards. The first category was *content comparison*, which was based on two criteria: (1) geographic coverage, and (2) user population. It was important to determine the goals and scope of each system from a development perspective as foundational elements that further analysis could be built upon. The second category was *architecture and technical attributes*, which was based on three criteria: (1) system design, (2) interoperability, and (3) technology. The third category was *process flow and functional capabilities*, which were based on five criteria: (1) *Input*: which describes the elements that creates an initial system notification; (2) *Manage*: which describes how data is received and stored; (3) *Analyze*: which describes how information is being assessed; (4) *Integrate*:

which describes the various systems' that may be involved or other associated sources of validation, and;
(5) *Generate*: which describes the types of alerts or notifications that is generated from each system.



3.4 PLANS FOR DATA ANALYSIS

A comparative – descriptive analysis was performed using the three overarching categories previously described in section 3.3. A synthesis of the data collected for each system was analyzed based on the categories described in the methods section 3.3. The extraction of the details for each criteria was collected from primary, secondary and key informant sources, and maintained in Excel spreadsheets. A graphical representation of each comparison group was developed to further illustrate the key findings

and comparison details. A descriptive analysis method was applied to characterize each system, the associated categories and subsequent criteria.

3.5 LIMITATIONS AND DELIMITATIONS

The selection criteria was focused specifically on three systems and in addition to peer-reviewed articles, gray literature was included from conference proceedings, webinars, websites and abstracts. Additional sources of information were gathered by convenience sample.

4 RESULTS

4.1 INTRODUCTION

This chapter describes the findings that relate to the primary research questions. The aim was to answer two key questions; (1) what is the architecture, functional process and scope of each system?; and (2) what are the reusable components from two local systems (NCD & ESP) that should be considered with the development of a national system? The organization of the findings begins broadly with a characterization of each system describing the scope of their development. The results progress to categorical comparisons of the selected criteria, sectioned in comparison groups for the architectural and functional process of each system, with a focus on answering the main objectives of this research.

4.2 FINDINGS

4.2.1 *Content Comparison*

The comparison of content criteria were, (1) geographic coverage and (2) user population. Based on the specificity of the population of study it was evident from onset that there were differences in the organizational structure of each organization that developed and implemented these systems, as summarized in *Table 1*. It was further revealed that the geographic coverage at a local level differed for NCD versus ESP, as did their user population and conditions of coverage (*Table 2*).

The initial deployment of ESP has grown from providing coverage to large ambulatory care practices in Massachusetts, to current operations in both Ohio and Texas [38], reaching over two million people across multiple jurisdictions. The growth and expansion of ESP into other geographic regions

demonstrates the flexibility of the software to be used at other sites. ESP is currently reporting cases of selected notifiable diseases, which include gonorrhea, syphilis, Lyme disease, Chlamydia, pelvic inflammatory disease, pertussis, active Tuberculosis, and acute Hepatitis A, B, and C [39]. In comparison, the NCD module operates through the Indiana Health Information Exchange (IHIE) that “connects over 100 hospitals, long-term care facilities, rehab centers, community health clinics and other healthcare providers” in the state of Indiana [40]. Over half of the state of Indiana’s providers participate in the Indiana Network for Patient Care (INPC) and can receive electronic notifications of notifiable diseases [24]. In contrast, the RCKMS is intended to be an authoritative source for all public health reporters to access jurisdiction-specific *reportable* condition information from a centralized system. The RCKMS prototype was piloted in 2015 as a clinical decision support demonstration project, designed to determine reportability for four conditions: Chlamydia, lead, pertussis and Tuberculosis. The test population included eleven state jurisdictions, as well as Intermountain Healthcare, a multi-specialty healthcare organization [41]. The system is currently being extended from the pilot to provide default reporting criteria and decision rules logic for all reportable conditions that possess a CSTE position statement. A RCKMS authoring interface is under development to allow all jurisdictions to manage their reportable conditions list, and accompanying reporting specifications in this centralized knowledge repository, that can be queried by reporters, providing a public health decision support service on *what* is reportable and to *which* jurisdiction(s).

Table 2. Summary of content comparison (scope, geographic coverage, & user population)			
	Scope	Geographic Coverage	User population
ESP	Select notifiable conditions	Massachusetts (expansion into Ohio & Texas)	Large ambulatory groups
NCD	Laboratory confirmed notifiable conditions	State of Indiana	Indiana Network for Patient Care (INPC), (hospitals, long-term care facilities, rehab centers, community health clinics and other healthcare providers)
RCKMS	Reportable conditions	All tribal, state & local jurisdictions	All reporters types (laboratories, physicians, hospitals)

4.2.2 *Architecture and Technical Framework Comparison*

To compare the architecture across the three systems we focused on three criteria, (1) system design (2) interoperability, and (3) technology. These criteria have been selected as key factors that support trends in public health informatics and contribute to the success of future systems development [36]. The context of the criteria was influenced by a series of informational briefs developed by the Joint Public Health Informatics Taskforce (JPHIT) in partnership with HLN Consulting, LLC. [36]. The JPHIT coordinates health information technology (IT) standards and policies with national public health associations that contribute to the development of public health information systems.

System Design

Each local system was developed with a modular design, which follows a component-based architectural pattern which enables interactions with other data streams. The ESP software includes a “core logic” component that is framed around a relational database model, where information from several different databases are stored independently, such as code mapping and case detection rule engines [20]. ESP’s extensibility to multiple independent installations of the software, is designed to be accessed through a “pluggable interface” that connects at the host EHR [20]. Each practice that connects to an ESP server retains control over their data which enhances adherence to patient privacy data laws. Similarly, the NCD functions as a module, however it is situated within the IHIE and can access stored INPC data from their clinical repository that is organized by practice and then by patient [32]. NCD was developed to interface with the central repository, to detect notifiable conditions and analyze LOINC® codes within the HL7 lab result message stored from INPC stakeholders. After NCD detects a reportable event, the application records the information in a reportable conditions database and then pushes data back to stakeholders via the EHR, with a partially completed case report form.

The key difference between all three systems included in this study is that the architecture is unique to the scope of the solution. ESP is designed to operate within a distributed network, which requires

significant installation and configuration at each site [20], while NCD operates out of a centralized local HIE, that can present challenges in long term sustainability and scalability to other states. The innovation behind RCKMS' design is that not only does it intend to provide an authoring framework to support content authoring, but the translation of reporting specifications into decision rules would be sharable via both a centralized web service as well as in a human-readable report format. Additionally, RCKMS will provide a decision support service for local deployment inside an organization's firewall. The rules generated, are consumable and implementable within an independent EHR.

Interoperability (Semantics)

Health Level 7 (HL7), provides the format standard for clinical information to be exchanged between systems. Currently, there are several HL7-based standards that support the structure of information in either in a message or a document, which are HL7 v2.x - v3, Continuity of Care Document (CCD), Clinical Document Architecture (CDA), and Fast Healthcare Interoperability Resources (FHIR). There is no agreed upon global standard for data exchange, which depends on the needs of the organization(s) who are exchanging data. The hierarchical message structure of HL7 standards are defined by message type, segment and code values. ESP models their case reporting from existing CDC ELR HL7 specifications used by the MDPH [20], while NCD uses both HL7 case reporting in combination with their proprietary clinical messaging service, Doc 4 Docs®. In contrast, RCKMS will be able to receive a HL7 clinical document standard, consolidated clinical data architecture (C-CDA), adhering to electronic initial case report (eICR) templates. EHR vendors are already able to generate other C-CDA documents making the eICR less of an effort to implement in the future. LOINC®, a vocabulary standard, was adopted across all three systems as a common standard for coding laboratory data, although their use of HL7 standards slightly differed. What was common among the three systems was that the triggering of reportable events was based on a match to an associated LOINC® code. The results of a triggered event were similarly validated with rules

algorithms or analyzed against code maps and created an alert or notification that was sent back to the provider or authoring source.

Technology (Platform)

Standardized semantics increase information sharing between systems, yet syntactical agreement can be a challenge with proprietary and legacy systems converging to a common universal language. Although there has been a strong surge towards the use code of LOINC® codes, with ELR, there is still a need to map local codes to standardized vocabularies. What helps speed this process along is the use of “low-cost” open-source software that reduces the need for “high-cost” proprietary systems development and licensing. Open-source technology enables the use of web services to serve as an interface between legacy systems and code mapping tools to standardized vocabularies. ESP’s source code is available for use via *esphealth.org*, where you can find the complete technical details and dependencies specific to the setup of an ESP server. ESP also uses a HL7 interface engine that enables bi-directional communication between systems that load ETL file extracts from the host site for further adjudication [20]. The NCD, since 2009, also operates a component of their systems using an open-source format with Open Medical Record System (OpenMRS®) modules [42] in conjunction with a previous virtual address eXtension (VAX) system [21] .

The pilot phase of the RCKMS included the use of open-source programming with Open Clinical Decision Support (OpenCDS), which incorporates the use a clinical decision support administration tool (CAT) that provides an interface to manage code groups, commonly referred to as value sets. OpenCDS uses a “standards-based and service-oriented” approach that supports scalability and knowledge representation that is reusable [43]. Clinical concepts are grouped by LOINC®, SNOMED-CT®, RX-Norm and ICD-10 codes, and assigned a value set name that is used to generate decision support algorithms. These if –

then – else rules form the decision logic that integrates both clinical and laboratory findings, supported by reporting specifications in the CSTE position statements.

4.2.3 *Process Flow and Functional Capabilities Comparison*

Organizations such as the Public Health Data Standards Consortium (PHDSC) seeks to “empower the healthcare and public health communities with health information technology standards”[37]. Although they are not a standards development organization, their major activities provide additional support and expertise with the current movement to link public health and clinical care through an EHR. They also advocate for the harmonization of business processes and functional standards. PHDSC describes five elements of functional standards that can be broadly applied to ‘how’ a software application should work [37]. These five categories were used as criteria to compare the functional capabilities of each system included in this research. The criteria used were: (1) Input, (2) Manage, (3) Analyze, (4) Integrate, and (5) Generate [37]. The definition of how these criteria were applied is described in section 3.3 of this paper and will be further discussed below.

Input could generally be described as the type of data that is being loaded into the software. It was evident from the literature that each system (ESP, NCD and RCKMS) included the use of codified standard clinical terminologies which provide linkages to either laboratory or clinical information found within the electronic health record or laboratory information system (LIMS). There were differences with what type of information was pushed or extracted, for example, the ESP server receives patient encounter information that includes demographics, diagnostic, laboratory orders and results, vaccine and social history that are transmitted in real-time or nightly [39], via a customizable interface for any EHR installation site [20]. The NCD module operates as an electronic laboratory information system and pulls positive final laboratory result data from the IHIE [29], which can then pull in provider details that are stored in their INPC repository to pre-populate communicable disease reports. RCKMS is being designed

to process clinical and laboratory findings within an organization's firewall or provided as Drools rules for integration in local EHR/LIMS systems.

The *inputs* described above provide the initial triggering components of the automatic detection of reportable diseases. The information that is captured must then go through a validation process and be verified to be true. But before the data is analyzed, how is it stored? Centralized versus decentralized networks provide different advantages and/or disadvantages, which essentially relates to how information is being stored and *managed*. The ESP distributed network reduces the movement of patient data, while their server extracts detectable diseases for further analysis against condition specific algorithms developed by investigators [44]. Their use of “an extract, transform, load (ETL) process, results into carat delimited text files”, that are then processed by the application [20]. *Manage and analyze data* criteria are major components to the development of each system that often have blurred lines of distinction, and deal with how data is stored and how it is being accessed. The core functionality of the ESP application logic is that the rules engine automatically processes information about the patient and case definition criteria that is stored in a “relational database schema” [20]. ESP algorithms can distinguish the differences between acute and chronic communicable diseases, such as with hepatitis B or active or latent tuberculosis [25, 45]. Their validation process includes the use of CDC case surveillance definitions, which provide the knowledge and structure to case reporting requirements. This application has demonstrated that the use of laboratory and clinical information coupled with medication information and diagnosis codes, increases the “positive predictive value (PPV) and reduces false positives” [25] in reporting.

The NCD algorithms rely on code mapping and translation of local codes to LOINC® code concepts that are published in RCMT [28]. RCMT provides a list of value sets comprised of clinical concepts that are linked to reportable conditions. RCKMS is proposed to function similarly with a two-step process of first

identifying codes that can trigger a reportable event and then analyzing a received payload through a series of clinical rules that forms the basis of the decision logic, which includes the use of clinical elements, such as symptoms, diagnoses, medications, demographic and epidemiologic related criteria. This approach increases the sensitivity of case detection by combining both clinical and laboratory findings. For example, clinical indicators such as a *cough of any duration* in combination with an inspiratory whoop, paroxysmal cough or posttussive vomiting could trigger suspicion for a new pertussis case, prompting public health to take action sooner on a potentially fatal condition.

The *integration and translation* of local proprietary data is a function that both the ESP and NCD include in their software validation process, while leveraging the use of standardized vocabularies. The same infrastructure that was built for INPC stakeholders within the IHIE, supports the NCD application, and its ability to extract additional provider details prior to transmitting information to public health agencies [46]. These supporting elements can be attached to positive laboratory findings, which increases the completeness of their case reports. ESP's decoupled design [16] is envisioned to be integrated within the EHR product itself, with more of a focus on collaboration with EHR vendors, than with individual sites [47].

RCKMS is within its second phase of development which includes defining reporting specifications for all reportable conditions with CSTE position statements that will be pre-loaded into the RCKMS system to serve as defaults for adoption by jurisdictions as is, or can be refined for local differences as needed. The tool will *translate* the default reporting specifications into executable decision support logic to be used to determine reportability. The two-pronged approach involves short development sprints using an agile/scrum methodology for both the curation of the content and technical specifications. The content development process includes diverse stakeholders who provide input via workgroup meetings where

reporting criteria is proposed, vetted and updated, creating a continuous feedback loop that informs the specifications that will serve as default knowledge within the system.

The systems discussed above *generate* varying levels of notification that range from HL7 case reports (ESP)[20], to email summaries or daily batches to infection control or public health agencies (NCD), as illustrated in *Fig 2*. The NCD uses a proprietary clinical messaging system (Doc 4 Docs®) that not only acts as a filter and transmits messages to the state, the system generates pre-populated forms as a part of their clinical messaging service to ordering providers, who can complete the form and forward it to the state health department [24].

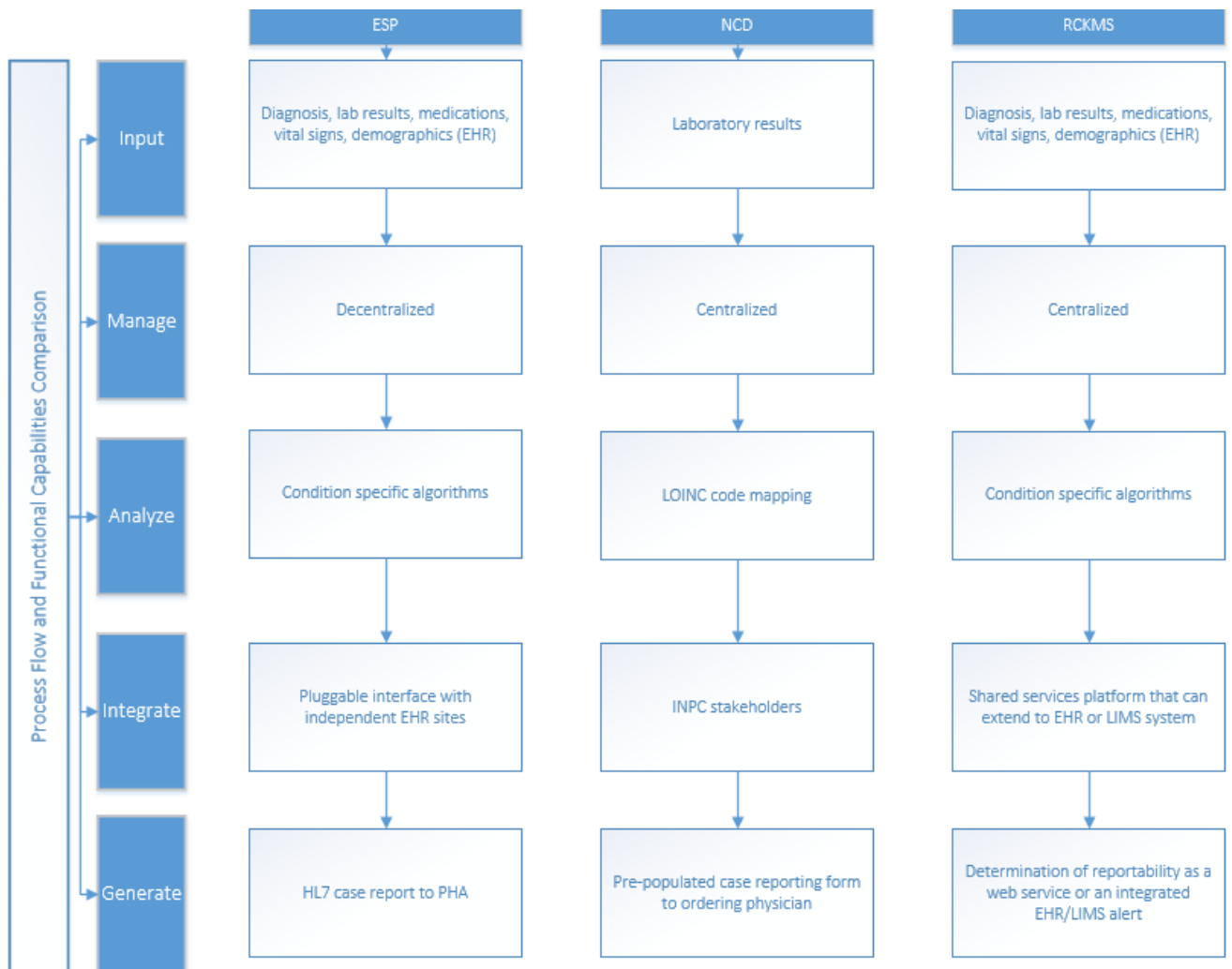


Figure 3: Process flow and functional capabilities comparison criteria (Source: Adopted from PHDSC functional standards categories)

4.3 SUMMARY

In summary, ESP and NCD offer two very different solutions that demonstrate the reusability of secondary data produced in clinical and laboratory settings. The common thread revealed in the findings surrounds the standardization of semantic, syntactic and transport standards that are key to the success of truly interoperable systems that receive, understand and process sharable information. The structure of exchangeable messages transmitted between entities continues to evolve with HL7 standards. The adoption of these standards are supported by national programs which seek to standardize the way systems communicate. The content of those messages will inherently be strengthened by the continued use of vocabulary standards such as LOINC®, SNOMED-CT®, ICD-10, Rx-Norm and clinical vaccine formulation (CVX). The transport mechanisms have evolved from closed private networks to cloud-based approaches with open programming concepts and the use of application programming interfaces (API) to connect systems and share information. The RCKMS shows promising signs of taking steps in the right direction, and should continue down the path of inclusion and consideration of existing PHDS components that can be reused for a national system.

Table 3. Summary of key attributes.

	Natural Language Processor	Aggregate summary reports to PH	PH access to query data	Local code mapping to LOINC	Open-Source Component	Case report form	Reporting Specifications	Clinical Messaging
ESP	X	X	X	X	X		X	HL7
NCD	X	X	X	X	X	X		Doc4Docs
RCKMS					X		X	C-CDA

5 DISCUSSION

5.1 INTRODUCTION

This chapter summarizes the major findings and advantages of local PHDS systems and their applicability to the development of a national system.

5.2 SUMMARY OF STUDY

This study offered a glimpse of the practice, protocols and innovation behind select existing and emerging public health decision support systems that support automated disease reporting. The review of the literature showed that secondary use of clinical data can improve the current landscape of disease detection, with an emphasis on messaging structure and content. While the differences between the scope and functional processes of ESP and NCD are salient, the apparent use of semantic standards are what makes them similar and their systems interoperable. The reusability of secondary data streams are the backbone to standards-based development and strengthens their usability and expansion to other regions. The RCKMS incorporates some of the existing elements (*Table 3*) discussed with the local systems that were reviewed. Although, local mapping, such as with NCD and ESP was not included in the RCKMS findings, their knowledge authoring component adds a much needed element that promotes jurisdiction involvement and subsequent provisioning of their local reporting needs. Additionally, the inclusion of a natural language processor [47] that can parse strings of text into computable knowledge, is an added valuable component that was considered with ESP and NCD development. If the idea is to reduce the burden on reporters, and improve accuracy and timeliness, then components more focused on the jurisdictional needs should be key to an ongoing development strategy with a national system. Additionally, RCKMS is envisioned to provide a determination of reportability, but should also look to extending a service that includes the formation of a case report, such as with NCD. Electronic case reporting would inherently reduce variability in reporting and eliminate traditionally paper-based methods, decreasing the need for manual intervention. This feature is significant, as the nation looks towards the broad development and support of end to end case reporting that starts with clinical care and ends with public health.

National efforts by CSTE support the need for standardized reporting protocols, although it is important that the local needs of a jurisdiction remain available as needed. Local mapping to standardized systems may continue to prove challenging, however with the shift of national incentives and support, local health systems may be more willing to adopt a standardized coding language. There is great potential in the broader scope of development with a public health decision support system that supports automated disease reporting, however, the findings above reveal challenges that are deeply embedded in policy and governance constraints.

5.3 CONCLUSION

Leveraging clinical vocabulary standards that are used in electronic health records and laboratory information systems provides a mechanism to coordinate and reuse existing data that can be interpreted across clinical and public health milieus. The modernization of electronic health records continues to grow, as well as the use of public health and healthcare standards. Through collaborative efforts and support from multidisciplinary organizations such as the PHDSC and JPHIT, standards based development could be achieved more broadly. Technical, semantic and organizational processes, serve to enhance interoperability measures between healthcare and public health. Determining if a national solution could eliminate the need for localized mechanisms is a large scale endeavor, however this effort could be realized with a closer look at PHDS capabilities and trends that includes the voice of all public health stakeholders, particularly those that support a standards based approach to development. The reusability of what currently works shows that progress has been made but the associated gaps between local implementations and a national platform to automate disease reporting reveals a journey fraught with barriers to widespread adoption. Additional barriers include those surrounding governance and policy issues that deal with how and where information is managed and stored.

5.4 IMPLICATIONS

The growth of EHR data reuse is contingent on many factors that involve policy, various stakeholder engagement and a continuum of efforts that link healthcare and public health domains. National policies, such as Meaningful Use can drive the adoption of interoperable standards that promote the exchange of clinical information from system to system. An extension of this study would further evaluate the design needs and capabilities of information systems, which can strengthen an informatics agenda. Additional assessments should include design requirements and integration components that bridge public health and clinical care. Long-term funding will need to be assessed, in addition to the expertise of staff that will be able to sustain the growth and development of these systems.

5.5 RECOMMENDATIONS

There are systems that utilize clinical data in support of public health disease reporting, however, more research is needed on information architectures and platforms that connect public health and clinical domains. It is not clear if a national solution will eliminate the need for localized mechanisms, however what is clear is that a central source of knowledge can be extremely useful in moving the nation towards a norm of automated disease detection, starting with healthcare to public health. CDC should look to harmonize funding efforts that are spread across programs and cooperative agreements to develop a more resource focused approach to achieving automated disease reporting. A framework that is supported by informatics theory and standardized concepts, such as those used in evaluating the systems in this paper, should be used in the long term analysis of system development approaches and overall feasibility of a national system.

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