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ELECTRONIC LABORATORY REPORTING (ELR) OF REPORTABLE CONDITIONS AND DISEASES:

A LITERATURE REVIEW ON ELR IMPLEMENTATION AND THE USE OF DATA STANDARDS

BY
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M.P.H., Emory University, 2014
B.S., San Francisco State University, 2009

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An abstract of
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Abstract

ELECTRONIC LABORATORY REPORTING (ELR) OF REPORTABLE CONDITIONS AND DISEASES: A LITERATURE REVIEW ON ELR IMPLEMENTATION AND THE USE OF DATA STANDARDS

By
Makena Muchunku

Electronic records have been in use for a long time in various business settings apart from healthcare. Capturing information electronically affords digital formats of data, capable of being shared across various organizations. Amidst technology innovations that have occurred in the last decade, healthcare has leveraged the use of digital technology for electronic data exchange by facilitating the adoption of Electronic Health Records (EHR) and Electronic Laboratory Reporting (ELR) among other technology innovations. EHR and ELR adoption is an effort led in part by the American Reinvestment & Recovery Act (ARRA) Meaningful Use objective and financial incentives. However, despite ARRA incentive efforts, ELR adoption has not kept pace with other electronic data exchanges among healthcare entities.

Electronic Laboratory Reporting, the automated transmission of laboratory related reportable disease data from various laboratories to State Public Health Departments utilizes Laboratory Information Management Systems (LIMS) and is presumed to alleviate problems related to data timeliness and accuracy that are associated with conventional reporting methods. While electronic exchange of health information is critical to timely implementation of disease prevention and control measures, it is imperative that claims about the timeliness and accuracy of ELR data are evaluated. This research therefore seeks to examine various literatures on ELR:

- To analyze empirical evidence related to "claims" that ELR implementation increases the timeliness and accuracy of available data,
- To describe ELR adoption trends among healthcare entities,
- To identify barriers associated with ELR adoption, and
- To highlight gaps in ELR literature, as well as offer insight on future topics for study.

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ABBREVIATIONS

AARA	American Reinvestment & Recovery Act
APHL	Association of Public Health Laboratories
ELC	Epidemiology and Laboratory Capacity
ELR	Electronic Laboratory Reporting
ELRTA	Electronic Laboratory Reporting Technical Assistance program
EHR	Electronic Health Records
CDC	Centers for Disease Control and Prevention
CDPH	California Department of Public Health
CMS	Centers for Medicare & Medicaid Services
CRF	Code of Federal Regulations
CSTE	Council of State and Territorial Epidemiologists
DOH	Department of Health
DOHMH	Department of Health and Mental Hygiene
EP	Eligible Professionals
EH	Eligible Hospitals
FTP	File Transfer Protocol
GAO	Government Accountability Office
GWU	George Washington University
HITECH	Health Information Technology for Economic and Clinical Health
HRSA	Health Resources and Services Administration
IOM	Institute of Medicine
LHD	Local Health Department
HL7	Health Level Seven (7)

LIMS	Laboratory Information Management Systems
LOINC	Logical Observation Identifiers Names and Codes
NCDPH	North Carolina Department of Public health
NEDSS	National Electronic Disease Surveillance System
MDPH	Massachusetts Department of Public Health
MMWR	Morbidity and Mortality Weekly Report
MU	Meaningful Use
OSDH	Oklahoma State Department of Health
PHA	Public health agencies
PHL	Public health laboratories
PHINMS	Public Health Information Network Messaging System
SAMSHSA	Substance Abuse and Mental Health Services Administration
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
STD	Sexually Transmitted Diseases

CHAPTER ONE

INTRODUCTION

Electronic records use and technology advancements have continued to thrive in various business settings except in healthcare. The year 1991 was an overdue watershed moment, as both the Institute of Medicine (IOM) and the Federal government sounded the call for healthcare to transition to paperless records (Ford, Menachemi, & Phillips, 2006). Since then, the transition to electronic data in the healthcare industry, including both electronic health records (EHR) and electronic laboratory reporting (ELR) has steadily increased. However, ELR adoption is slow among health care entities. This slow adoption, despite the strong promotion of ELR by the Federal government, warrants an analysis to determine the factors that contribute to ELR adoption. This study therefore seeks to explore available literature to determine factors that influence ELR adoption, as well as empirical evidence to claims that ELR increases timeliness and accuracy of state-mandated reportable diseases data.

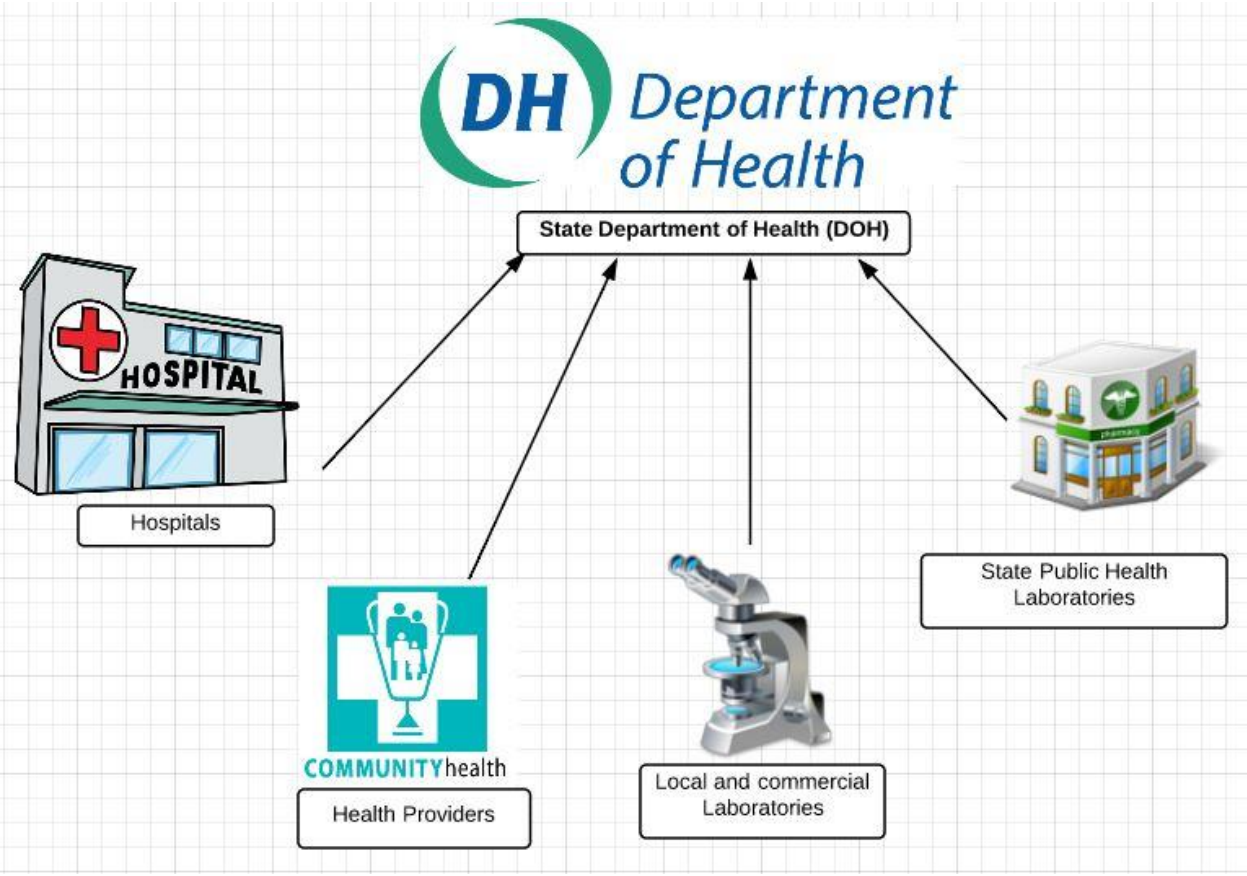
EXAMINATION OF CONTENT AND BACKGROUND

Reportable Conditions and Disease history

Electronic Laboratory Reporting is the automated transmission of laboratory related reportable disease data from local, public health, hospital and commercial laboratories to State Health Departments (Figure 1)(Centers for Disease Control Prevention, 2014a). Reportable disease data includes communicable and non-communicable diseases and conditions deemed to be of great public health importance by each state and territorial government. As such, ELR contributes data that aids in tracking disease outbreaks, and supports implementation of

control and prevention measures in public health (Zarcone et al., 2010). Defining reportable diseases and conditions requirements hence remains fundamental to ELR within each state.

Figure 1: Electronic Laboratory Reporting (ELR) to the State Department of Health



Reporting of disease cases originated in 1878. At the time, Congress authorized the collection of disease data from local occurrences of cholera, smallpox, plague and yellow fever from United States consuls overseas, in an attempt to institute quarantine measures and prevent these diseases from spreading to the United States (Centers for Disease Control Prevention, 2014a). Subsequent measures by state and territorial health authorities in 1912 followed suit. In 1951, state and territorial epidemiologists documented a list of nationally notifiable diseases, reportable by telegraph or by letter. The Council of State and Territorial

Epidemiologists (CSTE), was latter convened and charged with the "responsibility for defining and recommending which diseases and conditions are reportable within states and which of these diseases and conditions will be voluntarily reported to CDC"(Centers for Disease Control Prevention, 2014a). CSTE continues to uphold this responsibility by reviewing infectious disease needs among state and local health departments, while updating recommendations for state reportable conditions.

ELR is an important source of information that provides a bridge for engagement among multiple public health agencies, while enabling states to efficiently implement disease control measures in response to public health events. This is especially true as 60-70% of reportable disease data in some states are now reported by ELR to the State Department of Health (Council of State and Territorial Epidemiologists, 2014). ELR also plays a significant role in disease surveillance by contributing a proportion of reportable disease data (also known as notifiable diseases) to the National Electronic Disease Surveillance System (NEDSS). Other benefits of ELR include the surveillance of environmental diseases, which is supported by the diverse testing capabilities of public health laboratories on both human and non-human specimens (Zarcone et al., 2010).

Reporting Methods: Conventional vs. Electronic laboratory Reporting (ELR)

Reportable conditions allow for the collection of statistics on disease incidence, evaluation of resulting control measures, and tracing of fluctuations in disease incidence and changing behavioral patterns, which can influence disease occurrence (Doyle, Glynn, & Groseclose, 2002). In the past, health entities reported state mandated reportable diseases via telegraph,

postal mail, telephone and fax, also known as conventional reporting methods. However, data from conventional paper-based reports were often delayed for days if not weeks due to manual data entry, leading to delays in the implementation of disease control measures (Centers for Disease Control Prevention, 1998). Effler and Samoff have asserted that ELR has the potential to increase the volume of reportable disease data (Effler et al., 1999) and improve timeliness and accuracy of laboratory reports (E. Samoff, M. T. Fangman, A. T. Fleischauer, A. E. Waller, & P. D. Macdonald, 2013) compared to conventional reporting methods. The CDC Morbidity and Mortality Weekly Report (MMWR) definition of a reportable condition stresses the importance of frequent and timely information regarding individual disease reports for prompt prevention and control of disease (CDC-Morbidity and Mortality Weekly Report, 1999). Manual data entry delays and human errors introduced by conventional reporting methods impede timeliness, accuracy and frequency of reporting laboratory test results data.

The evolution of technology has modernized data exchange from conventional methods such as telegraphic and letter reporting used in 1912, to the current use of information systems and adoption of data standards in electronic data exchange (Centers for Disease Control Prevention, 2014b). The utility of information systems such as laboratory information management systems (LIMS), among laboratories is gradually replacing conventional reporting methods, as conventional reporting has been blamed for incomplete, untimely and error-prone reports (Dixon, Grannis, & Revere, 2013). LIMS are projected to improve sample management, data accuracy by directly capturing data from laboratory instruments, and data access by the use of in-built query tools to search data, therefore minimizing the human effort required for these processes.

ELR that utilizes LIMS data in an automated and standard fashion is of particular interest to state and local laboratories for the promise ELR holds in fostering better communication among stakeholders, specifically in electronic reporting of state-mandated reportable conditions. Moreover, laboratories and providers utilizing ELR for reporting state-mandated reportable conditions can also retrieve the same data they submitted by ELR, and obtain close to real-time aggregated and geographically mapped data on reportable diseases (Wurtz & Cameron, 2005). This access to more accurate data is attractive to health care entities in considering ELR adoption.

ELR Legislation and Adoption

According to the *2011 National Electronic Laboratory Reporting (ELR) Snapshot Survey* (Magnuson, 2012), most of the 54 participants interviewed responded that they had no 'ELR legislation' in place before the year 2000. Nevertheless, the survey approximately reports a ten-fold increase in the number of participants with ELR legislation in their jurisdictions between 2005 and 2010. This increase has led to ELR adoption and is driven in part by the American Reinvestment & Recovery Act (ARRA) Meaningful Use objective and financial incentives.

Enacted in 2009 to stimulate economic spending, ARRA is made up of a variety of investment programs, including the Health Information Technology for Economic and Clinical Health (HITECH). The HITECH Act created incentive plans to spur adoption of Electronic Health Records (EHR) and related functionalities. Through HITECH, the Centers for Medicare & Medicaid Services (CMS) coordinate adoption of EHRs, and grants financial incentives to Eligible

Professionals (EP) and Eligible Hospitals (EH) (United States Department of Health & Human Services, 2013). Public health laboratories (PHL) and public health agencies (PHA), however, do not qualify for the HITECH Act financial incentives. As such, PHL and PHA bear an extra (and unfunded) financial burden for ELR adoption, often choosing to fund other competing laboratory priorities instead of ELR due to lack of sufficient funds. Financial incentives that support ELR adoption among all health entities are in essence fundamental to ELR adoption.

Funding eligibility for HITECH financial incentives requires that EP and EH achieve specific Meaningful Use (MU) capabilities such as the use of certified EHR and related Information Technology (IT) tools to enhance patient care (Centers for Medicare & Medicaid Services, 2014). Implementation and use of ELR for laboratory related reportable disease data fulfills one of many MU objectives. The use of Logical Observation Identifiers Names and Codes (LOINC®) and Health Level Seven (HL7®) v2.5.1 messaging format in the electronic submission of reportable laboratory test results are also cited as MU certification criteria and are necessary for EHR use (National Institute of Standards and Technology, 2010). Collectively, HITECH financial incentive requirements are influencing ELR adoption progress and the standardization of Health IT tools in use among eligible healthcare entities.

ELR adoption proponents assert that a transition from conventional reporting to ELR eliminates the need for data entry staff (Nguyen, Thorpe, Makki, & Mostashari, 2007), increases timeliness and accuracy of disease reporting from clinical laboratories to state health departments, and improves communicable disease surveillance (National Institute of Standards and Technology, 2010). Yet challenges to electronic laboratory reporting are linked to the

"widespread reliance on idiosyncratic local codes and other variations" (Wu, Finnell, & Vreeman, 2013). While local codes may be easily updated or changed within an institution, they make data sharing between other institutions laborious. In an effort to solve this dilemma, Meaningful Use EHR technology requirements assert that data be standardized in both format and content at submission (Magnuson, Merrick, & Case, 2014). Standardized data employ the use of data or content standards which fall into three categories: vocabulary, format and transmission/messaging standards. HL7®, a format standard, and vocabulary standards, LOINC® and Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT®) are the most widely adopted and commonly used content standards in ELR (Magnuson et al., 2014). Prompt implementation and use of content standards among healthcare entities is anticipated to ease laborious ELR data sharing beget by use of local laboratory codes.

Implementation and utility of ELR content standards is nonetheless slow due to limitations such as:

1. Varying ELR reporting criteria and requirements across various jurisdictions
2. Availability of multiple ELR report formats (HL7 2.3.1, HL7 2.5.1) acceptable for reporting state-mandated diseases
3. The need to educate users on various content standards
4. The need to map local codes to acceptable data standards
5. The time and resources spent on complying with jurisdiction-specific requirements (CSTE-CDC ELR Task Force, 2012)

Despite these obstructions to adoption of data standards, the CDC reports that ELR adoption progress among Public Health Laboratories has tremendously increased since the year 2000 to include 54 out of 57 jurisdictions in 2013, composed of 48 states and six large local health departments, capable of receiving some laboratory reports through ELR (CDC-Morbidity and Mortality Weekly Report, 2013). Though these results may imply that nearly all laboratories are onboard with ELR adoption, data only includes public health agencies (PHA) (state laboratories and local health department laboratories), while excluding ELR adoption among commercial and other privately owned laboratories. However, among PHAs, approximately 62% of 20 million laboratory reports were received electronically in 2013 compared to 54% of laboratory reports in 2012. Technology advancements that incorporate messaging syntax standards in LIMS and the provision of software and hardware resources by the NEDSS program in collaboration with CDC have been monumental to ELR adoption by local and State departments (Gluskin, Mavinkurve, & Varma, 2014). Overall, states' ELR implementation and adoption guidelines, presidential executive orders (Code of Federal Regulations, 2004), and Federal grants (Centers for Medicare & Medicaid Services, 2014) to name just a few factors, have been instrumental to ELR adoption.

Over the past ten years since ELR initial implementation around 2000, the public health community has seen an exponential increase in the number of ELR journal articles (Gluskin et al., 2014; Overhage, Suico, & McDonald, 2001; Pinner, Jernigan, & Sutliff, 2000). This thesis therefore seeks to examine various available literatures on ELR adoption to:

- Determine trends in ELR adoption

- Assess the empirical evidence about claims that ELR implementation increases the timeliness and accuracy of available data
- Identify ELR implementation barriers
- Highlight gaps in literature
- Offer insights to future research

CHAPTER TWO

PROBLEM STATEMENT AND PURPOSE

Communication of laboratory results to local and public health entities remains fundamental to public health surveillance. Standardized Electronic Laboratory Reporting (ELR) has been the presumed and recommended solution to the problems associated with conventional methods. Conventional methods compromise data quality, decrease accuracy, and reporting timeliness (Zarcone et al., 2010) and may lead to increased costs due to delayed case management of disease outbreaks (Dixon, McGowan, & Grannis, 2011). Despite ELR perceived accuracy and timeliness in reporting state mandated reportable conditions, ELR adoption among healthcare entities is not universal.

The purpose of this study is to review available literature on Electronic Laboratory Reporting adoption to gauge progress on ELR implementation and establish if the acclaimed ELR benefits, i.e. timely and accurate transmission of laboratory data, are well founded. This study also aims to review literature on available funding options and barriers to ELR adoption, including unintended consequences that arise due to ELR adoption among laboratories. Accomplishing these objectives will enhance the ability of health care systems to prioritize and respond to similar public health Information Technology (IT) challenges, by enabling data exchange among varying information systems across multiple organizations.

RESEARCH QUESTIONS

Adoption of information technology in health care has lagged behind that of other industries such as the banking and automotive industries. Some have argued that the

complexity of healthcare IT, as compared to other industries, explains the delayed adoption and use of health technology (May et al., 2011; Plsek, 2003). The following research questions were developed to better understand the health IT adoption processes that are critical to policy makers and the role health IT plays in laboratory reporting of state-mandated reportable conditions.

Influences to ELR Implementation

- What are the barriers to implementation and use of data standards in clinical and public health laboratories?
- Who is funding ELR adoption?
- Does ELR implementation and use of data standards enhance timely and accurate reporting of state-mandated reportable conditions?
- What struggles/unintended consequences arise with ELR use?

An Overview to ELR and Data Standards Implementation

- Which laboratories are implementing ELR and what progress have they made?
- When should we anticipate universal use of ELR among clinical entities?
- What is the future of electronic laboratory reporting?

CHAPTER THREE

METHODOLOGY

Literature Overview

A Literature search was conducted to identify relevant literature about ELR adoption, timeliness, accuracy and the use of content standards in ELR. The search prioritized premier academic databases such as PubMed, Embase and Web of Science. Key search words included, but were not limited to:

Table 1: Key Search words

Electronic laboratory systems*
Clinical laboratory information systems*
Communicable diseases*
Reportable diseases *
Notifiable diseases
Health information standards*
Data collection methods*
Comparative study*
Time factors *
Incentives*
* including variations and combinations of these words.

PubMed, the United States National Library of Medicine's search service that provides access to peer reviewed literature, citations and abstracts, was initially utilized for this thesis literature search. Key words found in Table 1 were used in the PubMed search, yielding 82 publications. However, subsequent literature searches on both Embase and Web of Science

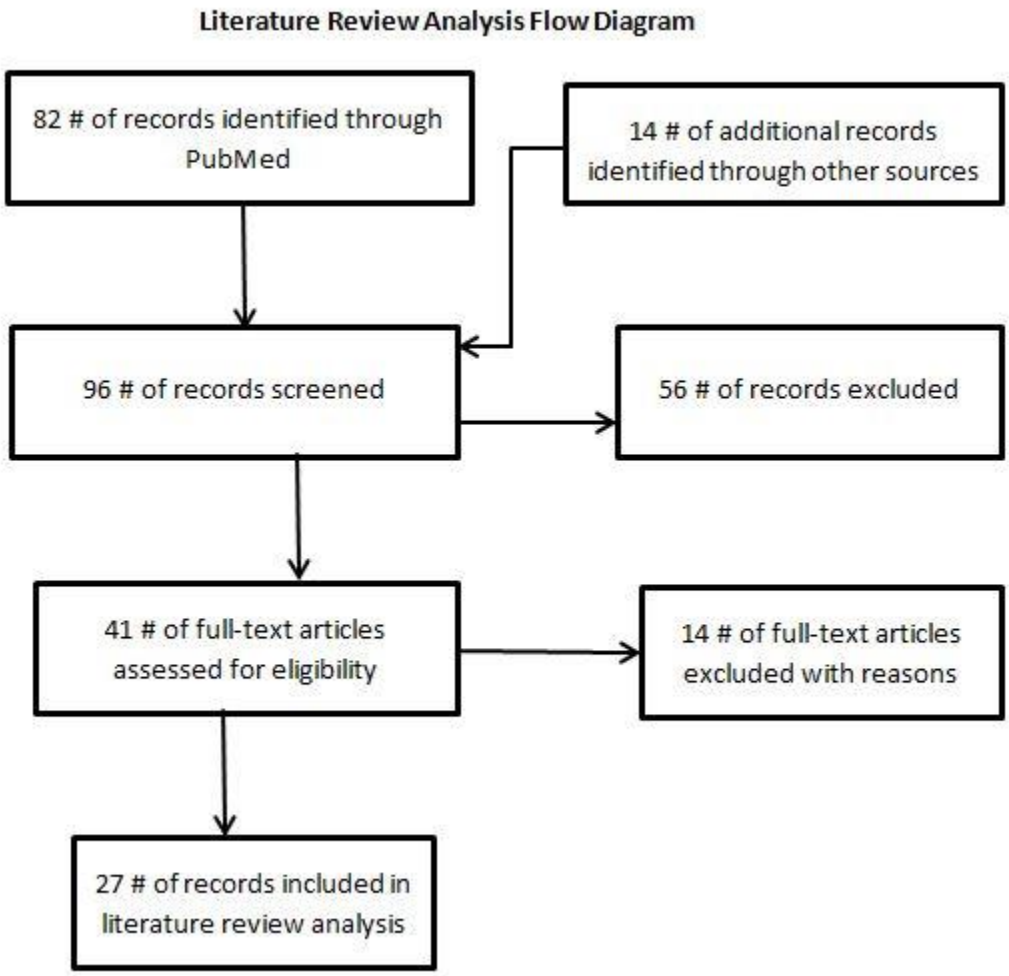
databases produced over 4,000 publications. The scope of this study comprises factors that influence ELR adoption, ELR adoption progress and empirical evidence to claims that ELR increases timeliness and accuracy of state-mandated reportable diseases data. Relevant publications from Embase and Web of Science search results were compared to PubMed search results (82 publications), and unique articles relevant to the scope of this literature review added to PubMed search results.

Although electronic laboratory reporting has been implemented and is in use in other regions of the world such as Europe (Johansen & Rasmussen, 2012), and literature on those ELR is extensive, this thesis study was limited to ELR adoption within the United States. As such, publications were eliminated if they did not meet this and subsequent criteria. Additional literature search limitations used for PubMed searches included publication dates within the last twenty years (1994 - 2014) and papers published in English.

Other non-peer reviewed literature, such as white papers, charts, presentations and posters that addressed this study's research questions were considered. Most non-peer reviewed material were found by performing searches on Google, meeting abstracts, footnotes and reference lists of both peer reviewed and non-peer reviewed articles, including the Association of Public Health Laboratories website. Publications were then screened and abstracts assessed for relevance as shown on Figure 2. All articles were placed in chronological order according to the publication date, beginning with the earliest (1994) to the most current (2014) with the intention of sketching out ELR progressive adoption. Once in chronological order, articles were then placed in two research question categories: Influences to ELR Implementation and An

Overview to ELR and Data Standards Implementation. This organization trickled down, therefore identifying specific articles that addressed each of the questions the investigator sought to ascertain through this literature review.

Figure 2: PubMed Literature Search



While most publications addressed barriers related to ELR adoption (15 publications), few addressed ELR timeliness and accuracy (5 publications) in reporting state mandated reportable conditions. The investigator observed that there were twice as many ELR timeliness and

accuracy publications eliminated (at least 10 publications) due to their reference to notifiable diseases (voluntary reporting to CDC) as opposed to reportable diseases (mandatory reporting to a state department of health), since the latter is the focus of this thesis study.

Chronological ordering of publications also revealed an incremental difference in the number of ELR publications from 2008-2014 compared to ELR publications from 1994-2007. Similarly, publications on ELR funding, the anticipated universal use of ELR or speculations on future ELR adoption progresses were scarce.

CHAPTER FOUR

LITERATURE REVIEW RESULTS/ANALYSIS

Publications/articles utilized in this thesis literature analysis include:

- Fifteen (15) articles on ELR implementation barriers; eight (8) peer reviewed, seven (7) non-peer reviewed.
- Four (4) articles evaluating ELR timeliness and accuracy; all peer reviewed.
- Four (4) articles on ELR adoption progress and participants surveyed; all non-peer reviewed.
- Four (4) articles reviewing ELR funding sources; all non-peer reviewed.
- Four (4) articles outlining struggles and unintended consequences that arise with ELR adoption; three (3) peer reviewed, (1) non-peer reviewed.

INFLUENCES TO ELR IMPLEMENTATION

Table 2 below offers a synopsis of key literature findings on ELR adoption barriers, enablers and unintended consequences that result from ELR adoption. Subsequent sections discuss these findings at length.

Table 2: Literature Analysis on ELR Adoption Barriers, Enablers & Unintended Consequences

Barriers	Enablers/Accelerators	Unintended Consequences
Funding	HITECH financial incentives Indirect financial support: •Health IT loans •Health IT grants •ELRTA program	•ELR slow adoption by public health labs, agencies & small labs •Increase in reportable disease case volumes •Backlog of disease reports
Lack of electronic LIMS	Software & hardware resources by CDC, NEDSS	•Varied ELR jurisdiction reporting of state mandated reportable diseases
Lack of sufficient IT staff	Health IT loans	•Decreased laboratory data quality
Varied electronic messaging and	ELR-TA program	•Varied ELR jurisdiction reporting of state mandated

vocabulary standards		reportable diseases
Time and resources required for education & training	Can be improved by continued learning programs	•Slow ELR adoption

I. Barriers to ELR Implementation

Funding was the underlying barrier to ELR adoption (Council of State and Territorial Epidemiologists, n.d.; CSTE-CDC ELR Task Force, 2012; Moore, Reddy, Kapell, & Balter, 2008). The ELR Task Force (CSTE-CDC ELR Task Force, 2012) identified the lack of sufficient funding among health department laboratories as the highest ranked ELR implementation barrier. Small clinical laboratories with limited resources were less likely to implement ELR, as the quantity of reportable diseases among these laboratories was significantly lower compared to commercial laboratories (Pinner et al., 2000). Additionally, costs associated with building and maintaining functional ELR systems were estimated between $1 million to greater than $5 million (Council of State and Territorial Epidemiologists, n.d.), sums too great for small laboratories to meet in light of other competing priorities (Magnuson, 2012). Consequently, the lack of financial incentives for large commercial laboratories and public health agencies inhibits ELR adoption.

The lack of electronic LIMS among clinical/local health departments reduced the capability for laboratories to adopt ELR (Magnuson, 2012; Wurtz & Cameron, 2005). Compared to other competing information technology priorities, such as the replacement of traditional laboratory tests by molecular testing, ELR implementation was less of a priority considering that reportable disease test results constituted a small proportion of outgoing laboratory test

reports and seldom generated revenue for laboratories. Above all, competing health department priorities were evident among jurisdictions surveyed by the CSTE study and ranked second (20%) as the most prevalent ELR adoption barrier (Council of State and Territorial Epidemiologists, n.d.).

Ranked third (16%) was the lack of sufficient information technology staff (Council of State and Territorial Epidemiologists, n.d.; Magnuson, 2012). Additional staff was increasingly required for development of ELR system prototypes (Effler et al., 1999), in certification and monitoring of laboratory data quality (Nguyen et al., 2007; Samoff et al., 2013) and in mapping of local laboratory test codes to those of LOINC and SNOMED (Overhage et al., 2001; Wurtz & Cameron, 2005). The latter was especially true for new reportable disease tests that needed to be mapped to LOINC and SNOMED codes. An increase in the number of IT staff therefore resulted in higher staffing expenses, and was ranked highest (52%) compared to other ELR information technology expenses such as software (23%) (Council of State and Territorial Epidemiologists, n.d.). Strained ongoing communications and collaboration between information technology and laboratory staff also contributed to ELR slow implementation (Council of State and Territorial Epidemiologists, n.d. ; Moore et al., 2008).

Varied electronic messaging and vocabulary standards, and continued use of local laboratory codes have been documented to limit ELR test result reporting and ELR adoption (Overhage et al., 2001; Wu, Finnell, & Vreeman, 2013; Wurtz & Cameron, 2005). This includes the use of multiple HL7 ELR message reporting formats, e.g., HL7 2.3.1, HL7 2.5.1. ELR staff training needs, including time and resources required by labs to educate clients on reportable

diseases and the use of appropriate LOINC & SNOMED were significant barriers to ELR adoption (Council of State and Territorial Epidemiologists, n.d.; CSTE-CDC ELR Task Force, 2012; Magnuson, 2012). Other ELR adoption challenges include the lack of knowledge among clients on nationwide standardized ELR transmission protocols, such as Public Health Information Network Messaging System (PHINMS).

II. Who is Funding ELR Adoption?

Under the HITECH Health Act of 2009, incentive programs provide financial support to Eligible Professionals (EP) and Eligible Hospitals (EP) that demonstrate meaningful use of certified EHR technology (GAO, 2013). Financial support for ELR adoption among laboratories is embedded within the EHR MU objective, and is payable to EP and EH from CMS Medicare and Medicaid EHR incentive programs. It is estimated that between 2014 and 2019, over $15 billion HITECH incentive payments will be available for the adoption of MU technologies (HHS, 2013).

While HITECH incentives are not available to public health agencies, several programs (Dougherty, Williams, Millenson, & Harvell, 2013) support health IT adoption for ineligible entities. However, these programs financial support varies by total appropriations, eligible healthcare entities and participating states. They include the technical assistance resources and toolkits for EHR implementation provided by Health Resources & Services Administration (HRSA) and health IT resources such as those provided by Substance Abuse & Mental Health Services Administration (SAMHSA). Health IT loans available for both eligible and non-eligible providers are provided by a few states (North Dakota, Minnesota and Maine); this includes

loans provided to states by grant programs permitted by Title XIII of HITECH to support the purchase of EHRs and training of personnel (Dougherty et al., 2013). Other programs include the Electronic Lab Reporting Technical Assistance (ELRTA) program funded by HITECH Act's Epidemiology and Laboratory Capacity (ELC) grants (Assosication of Public Health Laboratories, n.d.).

III. What Struggles/Unintended Consequences Arise with ELR Use?

Four studies reported unanticipated consequences experienced by implementation of ELR among clinical laboratories. In the North Carolina study, the volume of reportable disease laboratory results increased within the state. The end result was a backlog of approximately 18,000 laboratory results that encroached on the agency's limited workforce to process reportable disease data (Samoff et al., 2013). New Jersey's local health departments experienced similar increases in the number of ELR reports, perhaps because ELR reporting improved and/or shortened processing time of reportable diseases. As a result, additional time required to handle ELR data began to impede the New Jersey's Department of Health's ability to address other public health priorities, and gave rise to an increase in resources needed to address public health problems (CDC-Morbidity and Mortality Weekly Report, 2008). The New York Department of Health and Mental Hygiene (DOHMH) was faced with ELR reporting inconsistencies. While most laboratories were consistent in providing information mandated by New York State Public Health Law 2102 such as patient name, test type and provider name, some laboratories sent electronic reports lacking these required elements (Nguyen et al., 2007).

As a result, verification of data elements resulted in longer processing time and staffing resources increased proportionately.

Dixon et al. (2014) further discusses the anticipated increase in laboratory results data with increased use of ELR among healthcare entities. According to the Dixon study, approximately 20 unique laboratory reports were reported per 1000 persons per year, an estimate double the national average (Dixon, Gibson, & Grannis, 2014). While this estimate could vary depending on the burden of reportable diseases among states as well as state reporting laws, the public health workforce could adversely be impacted by the volume of laboratory reports further requiring additional staff to process laboratory result data.

AN OVERVIEW TO ELR AND DATA STANDARDS IMPLEMENTATION

ELR Adoption Population

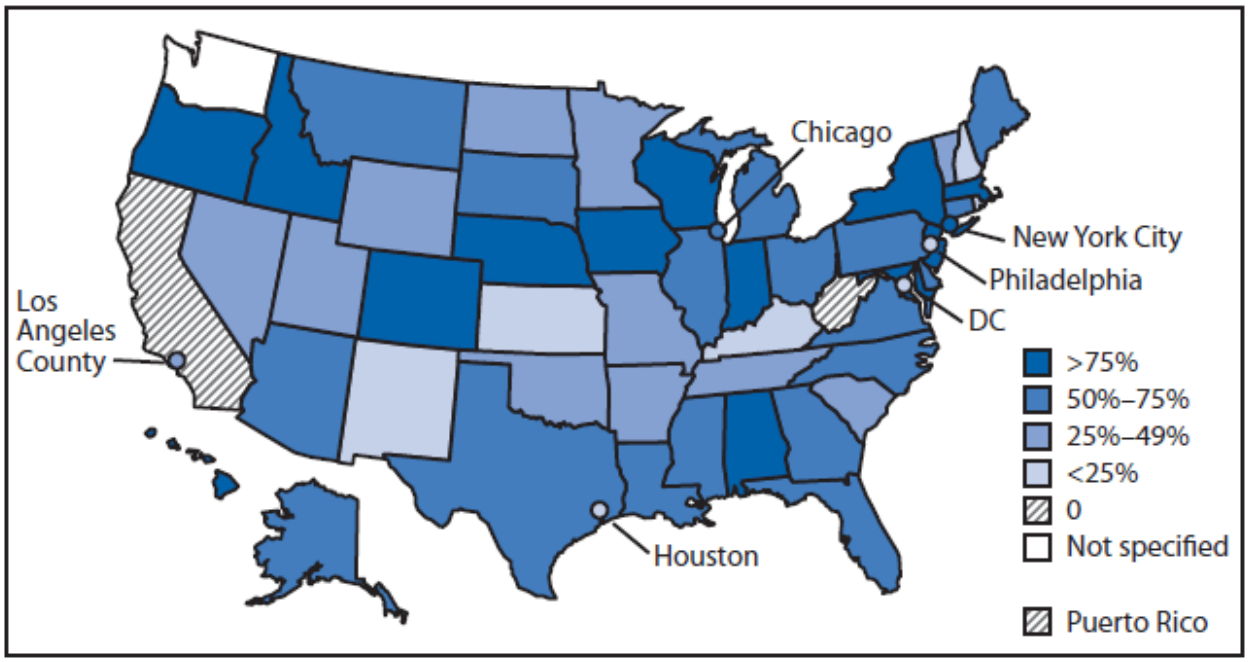
Various incentive programs previously discussed in this study have contributed to ELR implementation advancements by local and state laboratories. The California Department of Public Health (CDPH) process guide (California Department of Public Health, 2014) identifies laboratories that perform the largest quantities of reportable disease conditions as priority targets for ELR adoption.

The CDC identifies the current ELR adoption population as 5,400 of 10,400 laboratories engaged in sending reportable test results data to public health agencies nationwide (CDC-Morbidity and Mortality Weekly Report, 2013). However, it is evident from this study that

electronic receipt of laboratory reports varies by jurisdiction. To illustrate these electronic report variances among the ELR target population is Figure 3.

Figure 3 represents 12-month estimates of the proportion of electronic laboratory reports received by 54 out of 57 jurisdictions monitored in 2013 (CDC-Morbidity and Mortality Weekly Report, 2008). The variation is evidenced by 14 jurisdictions capable of receiving 75% of laboratory results electronically, while nine jurisdictions receive less than 25% of laboratory reports electronically. Moreover, 40% of laboratory reports received electronically were from one of four large commercial laboratories, 30% from public health laboratories and 14% from hospital laboratories.

Figure 3: Percentage of Laboratory Reports Received by Public Health Agencies Through Electronic Laboratory Reporting — United States, 2013*



* N = 57 jurisdictions, including 50 states, one territory, and six cities (for this report, Los Angeles County and the District of Columbia are categorized as cities). Data for Los Angeles County, which has a separate health jurisdiction, are not included in the data for California, which is expecting its first electronic laboratory report in October. Source: Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR). Progress in

Increasing Electronic Reporting of Laboratory Results to Public Health Agencies — United States, 2013. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6238a5.htm

What Laboratories are Implementing ELR and what Progress has Been Made?

Four studies that addressed ELR implementation progress and laboratories involved in ELR implementation were identified through a Google search and reference lists of other literature used in this thesis. Table 3 summarizes each publication utilized in assessing ELR adoption progress, participants and ELR utility among participants.

Table 3: ELR Adoption Progress

Publication	Attribute	Year	Year
Magnuson		**2010**	**2012**
	Participants	Labs in 39 states (45 participants)	Labs in 49 states (54 participants)
	ELR with 1-49% operational capability	23 states	40 states
	ELR with 50-100% operational capability	14 states	46 states
	ELR utility in public health laboratories	29 participants	42 participants
	LOINC & SNOMED utility in ELR messaging	NA	29 participants
	Manual web data entry	19 participants	3 participants
Regenstein (GWU)		**NA**	**2012**
	Participants	NA	Privately owned clinical labs Over 22 states (77 labs)
	ELR utility	NA	68% of lab reports by ELR
CDC MMWR		**NA**	**2013**
	Participants	NA	57 state, local and territorial health department labs
	Laboratory reports via ELR	54% of lab reports (2012)	62% of 20 million Lab reports
	ELR utility variability > 75% lab reports via ELR <25% lab reports via ELR	 NA NA	 14 jurisdictions 9 jurisdictions

Magnuson published results from two surveys, one in 2010 and another in 2012 (Magnuson, 2010; Magnuson, 2012). The 2012 survey reflected some of the original survey questions examined in the 2010 survey, therefore providing comparisons on ELR adoption progress. Although neither Magnuson survey distinguished participants as either public health laboratories or commercial laboratories, participants were laboratories from 39 states (Magnuson, 2010) and 49 states (Magnuson, 2012), including laboratories in the Federated States of Micronesia and select United States metropolitan areas. The CDC published a progress report on ELR implementation among 57 state, local and territorial health department laboratories funded by CDC (CDC-Morbidity and Mortality Weekly Report, 2013). Authors at George Washington University (GWU) also published survey results from a study that included independent clinical and regional laboratories from 22 states (Regenstein & Andres, 2012). While the GWU study was not primarily focused on ELR adoption, it provided insight on electronic laboratory reporting among privately owned laboratories, which on average had been in business for 22 years. Collectively, these publications exemplify the diversity of laboratories implementing electronic laboratory reporting.

A comparison on Magnuson survey results data from the 2010 and 2012 articles provide an overview on ELR adoption progress. There appears to be an increase in the number of participants: from 45 participants to a total of 54 participants in the 2010 and 2012 articles respectively (Magnuson, 2010; Magnuson, 2012). While both posed similar survey queries to

participants, the following analysis only include survey data results indicative of ELR progressive adoption and ELR use in participating laboratories:

- While none of the participants surveyed (n=54) in the 2012 publication indicated having 'ELR legislation' in place before 2000, the number of participants with 'ELR legislation' steadily increased from one participant by the end of 2005, to 13 participants by the end of 2010 (Magnuson, 2012).

- In response to "what is the current stage of ELR for your jurisdiction" responses indicated varying levels of ELR operation capabilities: in 23 states, ELR were 1-49% operational and in 14 states, ELR were 50-100% operational (Magnuson, 2010). The number of participants within each ELR operational level doubled and tripled respectively during the next three years of the Magnuson survey: 40 states reported 1-49% ELR operational capabilities and 46 states reported 50-100% ELR operational capabilities (Magnuson, 2012).

- The number of participants in receipt of electronic data for state reportable diseases remained unchanged (25 participants) in both Magnuson surveys.

- ELR reporting among public health laboratories increased from 29 participants (Magnuson, 2010) to 42 participants (Magnuson, 2012).

- Among public health laboratories utilizing ELR for test result reporting, 22 laboratories used HL7 version 2.3.1 and 29 laboratories utilized LOINC and SNOMED codes (n=42) (Magnuson, 2010).

- The use of manual web data entry to upload ELR data greatly decreased from 19 participants (n=45) (Magnuson, 2010) to three participants (n=51) (Magnuson, 2012). ELR data was either directly uploaded from LIMS (19 Participants) or fed into centralized data systems (24 participants) (Magnuson, 2012).

The GWU study (Regenstein & Andres, 2012) observed low ELR adoption among independent privately owned clinical laboratories serving urban, suburban and rural markets. While participants indicated that on average 68% of laboratory results were reported electronically, utility of ELR was highly variable.

The CDC study documents approximately 62% of 20 million laboratory reports in 2013 as having been reported via ELR compared to 54% of reports in 2012 (CDC, 2013). However, only 14 jurisdictions received greater than 75% of laboratory reports electronically while nine jurisdictions received less than 25% of laboratory reports electronically (Figure 3). The survey (CDC-Morbidity and Mortality Weekly Report, 2013) also indicates variability in the proportion of reportable conditions test reports submitted by ELR. ELR was extensively used for reporting general communicable diseases (76%); variability is evident in reportable laboratory results for sexually transmitted diseases (STD) and human immunodeficiency virus at 63% and 54% respectively. The inequities in ELR utility observed by various publications are not only indicators to where ELR future implementation efforts should be employed but also an indicator that future surveillance of reportable diseases may be impacted by these inequities.

Does ELR Enhance Timeliness and Accuracy?

Four papers met the inclusion criteria for timeliness and accuracy of state mandated reportable conditions and diseases (Heisey-Grove, Church, Haney, & DeMaria Jr, 2011; Johnson, Williams, Lee, & Bradley, 2014; Moore et al., 2008; E. Samoff, M. T. Fangman, A. T. Fleischauer, A. E. Waller, & P. D. M. MacDonald, 2013). The four papers assessed timeliness by comparing laboratory result data received in both paper and ELR formats. The author identifies the data analysis period for each study as the select time period for which laboratory test reports transmitted by ELR and conventional methods were compared (in months or years). The average data analysis period for all four papers included in the timeliness analysis was 2.6 years (min 6 months, max 6 years). ELR timeliness findings were based on the following:

1. How was timeliness reported? Contingent on ELR timeliness as a difference in the number of reporting days observed between ELR and conventional reporting methods or as a percent (%) of total records evaluated by the study.
2. How timeliness was assessed? Contingent on if studies assessed timeliness based on the date when a positive test report was recorded in a laboratory system and when test results were reported to state department of health (DOH), or if the study assessed ELR timeliness based on transit time of reports (from reporting health facility to DOH).

Moore (2008) and Heisey-Grove (2011) studied the timeliness of laboratory reports originating from clinical laboratories to the state DOH for more than 2.6 years. Both papers evaluated ELR timeliness in reporting a single reportable condition: hepatitis A (Moore et al., 2008) and hepatitis C (Heisey-Grove et al., 2011). In both papers, timeliness was based on when a laboratory record of the disease was created and when test results were received by the state DOH (for both electronically and non-electronically reported hepatitis A and C cases).

The median reporting time for hepatitis A cases received by the New York Department of Health and Mental Hygiene (DOHMH) between 2000 and 2006 significantly decreased from 27 days to 6 days (77% decrease, P<.001) (Moore et al., 2008), while hepatitis C reports received by the Massachusetts Department of Public Health (MDPH) between 2004 and 2008 median reporting time decreased from 454 days to 26 days (94% decrease) (Heisey-Grove et al., 2011). Hepatitis C reports could be received at MDPH through electronic messaging formats such as HL7. Comparative analysis of these data can be found on Table 4 below.

Table 4: Literature Analysis on ELR Timeliness and Accuracy

Publication	Disease	Reporting Time
Moore et al., (2008) NYDOH	Hepatitis A	↓ 27 days to 6 days (77%)
Heisey-Grove et al., (2011) MDOH	Hepatitis C	↓454 days to 26 days (94%)
Johnson et al., (2014). ODOH	18 of 61 reportable diseases	Based on Lab reports reported in ≤ 1 day; •ELR: 91% reports (399/440) •Non-ELR: 87% reports (995/1138)
Samoff et al., (2013). NCDOH	Not identified Excluded :TB, Syphilis, HIV	Median reporting time; •ELR: ↓9 days to 7 days (22%) •Non-ELR: ↓14 days to 8 days (42%)
	Chlamydia & gonorrhea overall processing time:	2010: •ELR= 40 days •Non-ELR =56 days 2012: •ELR= 20 days •Non-ELR = 25
	vaccine preventable reportable diseases	No significant difference in processing time difference between ELR or non-ELR reports

In the other two papers that met the inclusion criteria for this study, Johnson (2014) and Samoff (2013) evaluated ELR timeliness for less than 2.6 years (Johnson et al., 2014; Samoff et

al., 2013). Johnson (2014) evaluated ELR timeliness in reporting 18 out of 61 reportable diseases in the state of Oklahoma. The 18 reportable diseases included: anaplasmosis, brucellosis, campylobacteriosis, cryptosporidiosis, ehrlichiosis; Escherichia coli (E. coli) O157, O157:H7, or a non-O157 Shiga toxin-producing E. coli infection, legionellosis, listeriosis, Lyme disease, malaria, mumps, pertussis, Q fever, spotted fever rickettsioses, salmonellosis, shigellosis, Streptococcus pneumoniae invasive disease among children 5 years of age, and vibriosis. The data analysis period began January 1, 2011 and ended December 31, 2011. Johnson et al. compared the time from which positive test reports were recorded at any of the 18 participating laboratories to when test reports were reported to the Oklahoma State Department of Health (OSDH). However, only cases reported within one business day were considered timely. The Johnson et al. study reported (399) of 440 (91%) ELR reports met the criteria for being timely, compared to (995) of 1138 (87%) of conventional reports (Johnson et al., 2014).

Samoff (2013) studied ELR trends in North Carolina over two data analysis periods: May – August 2010 and January – March 2012 (Samoff et al., 2013). While Samoff et al. did not specifically identify reportable diseases utilized in the ELR timeliness assessment, tuberculosis, syphilis and human immunodeficiency virus results data were excluded by the study. ELR timeliness was established as the time difference between receipt of a reportable condition case report at the local health department (LHD) and reporting of the case report to the North Carolina Department of Public health (NCDPH), referred to as processing time by the researchers. The processing time for the data analysis period May – August 2010 was a median of nine days for ELR cases reports, compared to 14 days for non-ELR case reports (*P=0.*08),

while the January – March 2012 data processing period median was seven days for ELR and eight days for non-ELR case reports (*P=0.31*) (Samoff et al., 2013).

Samoff et al. calculated ELR accuracy as the proportion of cases returned from the NCDPH to the LHD due to incorrect or missing data or the need for additional information. Reportable diseases included in the accuracy computation were required to meet two criteria: a) reportable by both ELR and non-ELR methods and b) more than 10 cases of the disease were reported. For the 2010 data processing period, 2% of ELR records compared to 8% of non-ELR records were returned, while in 2012, 2% of ELR records compared to 6% of non-ELR records were returned (Samoff et al., 2013).

Key findings pointed out by (Samoff et al., 2013a) include: first, major gains in ELR timeliness in reporting Chlamydia and gonorrhea STD test results. ELR processing time for Chlamydia and gonorrhea STDs decreased from 40 days in 2010 to 20 days (50% decrease) in 2012, compared to non-ELR reporting processing time which decreased from 56 days in 2010 to 25 days (55% decrease) in 2012. Second, a) there was not a significant processing time difference between ELR or non-ELR reports for vaccine preventable reportable diseases, and b) processing times for ELR reports were significantly longer in reporting *Haemophilus influenza* infection case reports (*P*=0.05 and Lyme disease case reports (*P*=0.007). These preliminary findings merit further research into disease-specific variances.

When Should we Anticipate Universal Use of ELR among Clinical Entities?

While the universal use of electronic reporting among clinical laboratories has not yet been realized, ELR future adoption is dependent on addressing factors that contribute to ELR

adoption: implementation costs incentives, interoperability and ELR usability, particularly as these factors relate to the MU objective (Hamilton, 2012). Market structure and innovations (the number of hospitals or providers in the market using electronic reporting, product innovations by vendors and presence of active electronic data exchange) (Blavin, 2013), are also predicted as forces that will drive MU compliance rates, therefore ELR adoption.

Conclusion:

ELR universal adoption and use among clinical laboratories is unpredictable and its progress is highly dependent on provision of funding. However, with technology advancements and the emphasis on electronic reporting gaining ground in healthcare, it is expected that conventional reporting methods will soon be replaced by electronic laboratory reporting methods. Besides funding, other barriers that influence ELR adoption include interoperability of systems and standardization of vocabulary and messaging standards. Managing these barriers will facilitate widespread adoption of electronic laboratory reporting.

CHAPTER FIVE

DISCUSSION, IMPLICATIONS and RECOMMENDATIONS

KEY POINTS

I. Barriers to Implementation

The evidence generated from this literature review suggests that financial incentives for ELR adoption are inadequate and / or lacking among clinical laboratories (CSTE-CDC ELR Task Force, 2012; Magnuson, 2012). Based on the CSTE report (CSTE-CDC ELR Task Force, 2012), ELR estimated implementation and maintenance costs are $1 million or higher. These are substantial costs for laboratories ineligible for MU incentives, including small laboratories and other laboratories that do not consider ELR adoption a priority due to competing priorities. In addition, reportable disease test results constitute a small proportion of outgoing laboratory test reports and seldom generate revenue for laboratories. Competing priorities and the inability of ELR reporting to generate a return on investment among health care entities is proposed as a factor that leads to varied ELR adoption rates among jurisdictions (CDC-Morbidity and Mortality Weekly Report, 2008). While this could be true, literature on ELR adoption has gaps and does not provide sufficient evidence on the ELR adoption progress from inception (the year 2000) to 2007. Bias on author affiliation is also presumed as two out of the three papers that met the inclusion criterion for assessing ELR adoption progress were from the same author (Magnuson, 2010; Magnuson, 2012). Future ELR literature should therefore consider evaluating ELR timeliness

and accuracy for state-mandated reportable diseases, competing laboratory priorities and their effect on ELR adoption, as well as funding options that reduce ELR adoption variability.

Interoperability of laboratory management systems and use of vocabulary and messaging standards can promote the exchange of electronic laboratory data. Currently, the use of SNOMED, LOINC and HL7 messaging standards in ELR is inhibited by several factors such as use of local codes in reporting laboratory test results (Wu et al., 2013), use of multiple HL7 messaging standards and varying ELR reporting criteria and requirements across various jurisdictions (CSTE-CDC ELR Task force, (2012). Efforts to alleviate some of these concerns include mapping of local laboratory test codes to LOINC and SNOMED, an effort facilitated by APHL's ELR TA program (Assosication of Public Health Laboratories, n.d.). The use of varying ELR reporting criteria across jurisdictions suggest collaborations between various governing authorities to enable discussions that support the use of similar content standards in ELR of reportable conditions data.

II. ELR Timeliness and Accuracy

It is difficult to establish the impact of ELR on timeliness and accuracy of state mandated reportable diseases because assessments on timeliness greatly vary across studies included in this literature review and only one study met the inclusion criteria for the accuracy assessment. As noted in this analysis, there is lack of consistency in calculating the timeliness of ELR systems. While some studies assessed timeliness based on the date a reportable disease positive laboratory test was recorded in a laboratory system to when it was reported to the state DOH (Heisey-Grove et al., 2011), other studies assessed timeliness

based on the time difference between receipt of a reportable condition case report (laboratory test report) at the LHD and reporting of the case report to the state DOH (Samoff et al., 2013).

Each study's measure for reporting timeliness and data analysis period (select time period for which laboratory test reports transmitted by ELR and conventional methods were compared) differed greatly. While some studies reported timeliness as the difference in the number of reporting days observed between ELR and conventional reporting methods (Heisey-Grove et al., 2011; Moore et al., 2008), other studies reported timeliness as a percent of the total records evaluated (Johnson et al., 2014). The average data analysis period was 2.6 years (range 6 months to 6 years) (Moore et al., 2008). Evaluating timeliness based on the Heisey-Grove et al. and Moore et al. studies provided more cogent results, therefore future studies should consider modeling the evaluation methods of these studies.

While this literature review suggests an overall decrease in reporting time of laboratory data when ELR is utilized, the small number of studies that address ELR accuracy and timeliness in reporting state mandated reportable diseases warrant further research. Without more studies of this nature or a more consistent approach to evaluate timeliness and accuracy of reportable disease data reported via ELR systems, the data presented can only suggest trends and highlight the need for further studies.

III. ELR Unintended consequences

The literature reviewed reveals several unintended consequences with the adoption and use of electronic laboratory reporting. Laboratories utilizing ELR reported increases in the

volume of reportable diseases, therefore resulting in backlogs of reportable disease data (Samoff et al., 2013). Consequently, backlogs necessitated additional staff to process reportable disease reports and impeded the ability of health departments to address other public health priorities (CDC-Morbidity and Mortality Weekly Report, 2008; Dixon, Gibson, & Grannis, 2014). ELR also introduced inconsistencies in required data elements (Nguyen et al., 2007).

Conclusion

Although this literature review has its limitations, it is a first step in highlighting some of the factors that influence the adoption of electronic laboratory reporting among clinical laboratories, namely: financial incentives, interoperability of ELR systems, the use of data standards, and competing priorities among others. It is clear that the three studies that met the inclusion criterion for assessing ELR adoption progress are too few to determine the overall ELR adoption progress within the United States. Therefore, this merits further study of ELR adoption as well as studies on efficiencies afforded by ELR utility in reporting state-mandated reportable diseases.

Implications and Recommendations

ELR adoption has revealed unintended consequences, such as increased volume of reportable diseases case reports, backlogs of cases reports and the need for additional staff to process these case reports and to efficiently address other public health problems. However, it is evident the number of studies and results considered in this in this literature review is fairly small and cannot be generalized to all laboratories currently implementing

ELR or laboratories that hope to adopt ELR in the future. For this reason, more evidence based research should be conducted on the effect of electronic laboratory reporting. The following are recommendations for future studies:

- Evaluation studies should consider standardizing the data analysis period and employ consistency in assessing timeliness and reporting timeliness as seen with the Heisey-Grove et al. and Moore et al. studies.
- Studies should consider if the use of data standards in electronic reporting of reportable condition affects timeliness and accuracy of reportable disease data.
- While only one study categorized ELR participating laboratories based on their affiliations: commercial labs, hospital labs and public health labs (CDC-Morbidity and Mortality Weekly Report, 2013), future studies should consider this criteria to highlight ELR adoption progress.

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