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Electronic Health Records and Immunization Information Systems Interoperability: Measuring Impact on Immunization Outcomes

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ELECTRONIC HEALTH RECORDS AND IMMUNIZATION
INFORMATION SYSTEMS INTEROPERABILITY: MEASURING
IMPACT ON IMMUNIZATION OUTCOMES

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B.A., Medieval/Renaissance Studies
WELLESLEY COLLEGE

A Thesis Submitted to the Graduate Faculty
of Georgia State University in Partial Fulfillment
of the
Requirements for the Degree

MASTER OF PUBLIC HEALTH

ATLANTA, GEORGIA
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APPROVAL PAGE

ELECTRONIC HEALTH RECORDS AND IMMUNIZATION
INFORMATION SYSTEMS INTEROPERABILITY: MEASURING
IMPACT ON IMMUNIZATION OUTCOMES

By

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ABSTRACT

INTRODUCTION: Immunization is an intervention proven to reduce morbidity and mortality for several infectious diseases, yet coverage remains less than optimal, especially among minorities and the poor. Challenges to adequate coverage are associated with access and consolidated immunization documentation to support clinical immunization decision making. Efforts to improve access and service delivery include Community Guide recommended interventions, the Vaccines for Children (VFC) Program, and electronic data exchange between provider electronic health records (EHR) and state and city immunization information systems (IIS).

AIM: The purpose of this study is to 1) determine if EHR-IIS interoperability improves immunization outcomes and 2) identify how EHR-IIS interoperability may improve the capacity to support activities to increase appropriate immunization.

METHODS: Data reported by state IIS for immunization provider sites both prior to and after the establishment of or the improvement of an existing EHR-IIS interface were analyzed to examine changes in 1) the mean difference in the proportion of 19 to 35 month old children at these sites who were up-to-date for age-appropriate immunizations, and 2) the mean difference in completion of key demographic and vaccine-related fields for 4m to 6 year-old children associated with enhanced sites in the IIS.

RESULTS: Statistical analysis yielded evidence of a positive change in the mean difference in the proportion of children aged 4m to 6 years with key demographic and vaccine data in IIS. A statistically significant change in the mean difference of up-to-date status in 19 to 35 month olds was not detected.

DISCUSSION: Evidence suggests that EHR-IIS interoperability can improve the capacity of IIS in targeting of immunization services to underserved populations and support accountability for the VFC program. Implementation of EHR-IIS interfaces must be performed thoughtfully and with an understanding of the impact of the interface on IIS data used to support immunization program activities. Immunization outcomes for children at provider sites engaging in electronic data exchange with IIS should continue to be monitored. Additional analysis must be done to identify the interoperability factors that are positively and negatively associated with improved immunization outcomes.

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Chapter I

INTRODUCTION

1.1 Background

1.1.1 Immunization in the United States

Considered one of the ten great public health achievements of the 20th century in the United States, immunizations are credited with the substantial reduction in mortality for several infectious diseases (“Achievements in public health,” 1999). Although current vaccination coverage rates indicate the overall success of the United States’ immunization program, coverage remains inadequate in certain segments of the U.S. population, particularly among those in racial and ethnic minorities and those living in poverty (“National,” 2015).

Prior to the development of vaccines, infectious diseases were highly prevalent in the U.S. and caused illness and death in thousands of individuals (“Achievements in public health,” 1999). Since 1900, effective vaccinations against several diseases, including smallpox, diphtheria, pertussis, tetanus, poliomyelitis, measles, mumps, rubella, and *Haemophilus influenzae* type b (Hib) have been developed and systematically implemented by state immunization programs across the country. Vaccines have proven to be an overwhelmingly successful intervention, decreasing deaths caused by these diseases by at least 95%, and in the case of smallpox, by 100% (Orenstein, Rodewald & Hinman, 2004). Failure to sustain adequate vaccination levels, however, can leave the population vulnerable to disease, particularly due to

importation from other countries. This threat manifested when a measles outbreak occurred from 1989 to 1991 (Hinman, Orenstein & Papania, 2004), and most notably again in 2014 and 2015 associated with Disney theme parks in California (“Measles Outbreak,” 2015).

Incidence of vaccine-preventable diseases (VPDs) imposes not only direct health care costs such as those from medical care and hospitalization, but also indirect societal costs such as those stemming from missed work, permanent disability, and premature mortality (Whitney, Zhou, Singleton & Schuchat, 2014). Racial and ethnic minorities and those living in poverty have long experienced lower immunization coverage (“Vaccination coverage,” 1997; “National,” 2015), and the risk of disease and death has therefore been and continues to be disproportionately borne by these populations.

1.1.2. Challenges in Immunization

Although vaccinations are clearly an effective intervention to preventing morbidity and mortality associated with several infectious diseases, challenges remain in the successful delivery of this essential service, such as the increasing complexity of the recommended vaccine schedule. The 2015 Advisory Committee on Immunization Practices (ACIP) recommended vaccination schedule includes 23 to 25 routine vaccinations for all children (“Recommended”, 2015) by 18 months of age, which is an increase from the 15 to 19 vaccinations recommended circa 2000, and the 8 vaccinations recommended roughly 20 years prior to that (Stokley, Rodewald & Maes, 2001). These clinical guidelines are also accompanied by complex specifications for minimum ages and intervals between doses as well as contraindications and precautions (Centers for Disease Control and Prevention [CDC], “IIS - Clinical Decision Support,” 2015). In addition, the increasing use of combination vaccines that contain antigens targeting more than one VPD also requires providers to be aware of which combination vaccine

was administered as well as its individual components (Abramson, Kaushal & Vest, 2014). Making appropriate clinical immunization decisions in the face of evolving and complicated vaccine products and recommendations is not only difficult, but also prone to inconsistency (CDC, “IIS - Clinical Decision Support,” 2015).

Another challenge to reaching and sustaining sufficient coverage against VPDs is incomplete documentation of immunizations. Clinical immunization decision-making is performed by reviewing a child’s immunization history and determining immunizations needed by consulting the recommendations in the ACIP schedule. Lack of a comprehensive record of prior immunizations can therefore contribute to inaccurate immunization recommendations, and in fact has been shown to significantly compromise a provider’s ability to accurately assess immunization status and consequently determine what immunizations are needed when a child presents for care (Stokley et al., 2001). Healthcare providers are required by the *National Childhood Vaccine Injury Act of 1986* to document immunization information in their patients’ medical chart such as vaccine administration date, vaccine manufacturer and lot number, and vaccine provider name and address (National Vaccine Injury Compensation Program [NVICP], 2015), and are generally considered the most reliable source of immunization information. However, children can receive immunizations at locations other than their current medical home such as at the health department or their previous primary care provider. In addition, parents often fail to bring documentation of prior immunization to their child’s initial visit to a new provider office. Immunization records are consequently often scattered across multiple locations, thus putting the provider at risk of making immunization decisions based on incomplete information (Stokley et al., 2001). Such circumstances can also result in the administration of unneeded doses and wasting of valuable resources (Feikema, Klevens, Washington & Barker,

2000). In 2000 Feikema et al. found that an estimated 21.1% of children received at least one extra dose of vaccine, totaling 1.8 million doses and representing \$26.5 million in costs associated with vaccine, administration, and clinic visits. In the aftermath of Hurricane Katrina, record lookup enabled by electronic Health Level 7 (HL7) interfaces saved \$1.6m in vaccine and \$3.04m in vaccine and administration fees for individuals who relocated to other states. (Boom, Dragsbaek & Nelson, 2007) Elementary schools, because they require vaccination records for children prior to enrollment, may have more complete information than a single provider, however, according to federal Family Educational Rights and Privacy Act (FERPA) regulations, immunization records are considered part of the academic record and as such cannot be re-disclosed by schools without parental consent. This regulation thus imposes an additional administrative burden and creates a barrier to sharing of immunization information and the collation of a complete immunization record. (Bobo, Etkind, Martin, Chi, & Coyle, 2013).

1.1.3. Initiatives to Improve Immunization Coverage

1.1.3.1 Vaccines for Children Program

Research on the aforementioned measles outbreak in the late 1980s and early 1990s revealed that a disproportionate number of cases were among poorer, inner-city pre-school aged children of black, Hispanic, or American Indian heritage. These findings led to the inception of the Childhood Immunization Initiative 1993, which sought to reduce disparities in immunization coverage among U.S. children. Part of this initiative was the establishment of the Vaccines for Children (VFC) program in 1994. This program, administered by the CDC, purchases vaccines and distributes them to participating providers at no cost for administration to children under 18 years of age who meet specified eligibility criteria. Children are eligible to receive VFC vaccine if they are uninsured, underinsured, Medicaid-eligible, or of American Indian/Alaska Native

race/ethnicity (Smith, Lindley & Rodewald, 2011). The program is the largest administered by the CDC with almost \$1 billion spent in fiscal year 2004 alone (Ching, 2007) and, due to the growing number of recommended immunizations and increasing costs, to nearly \$3 billion in 2007 (Metroka, Hansen, Papadouka & Zucker, 2009), with the majority of the VFC budget, approximately 90%, used to purchase vaccine (Ching, 2007). Although vaccine is provided at no cost to participating providers through this program, there are a number of administrative tasks associated with its implementation in provider offices (Bartlett, Washington, Bryant, Thurston & Perfili, 2007). Data required by VFC state policies for accountability include the vaccine recipient's race and ethnicity in order to assure they meet the eligibility requirements of the program, as well as data related to the vaccine itself in order to support vaccine ordering and inventory management (Office of the Inspector General, 2012), such as vaccine manufacturer and lot number of the dose administered, and to document that VFC vaccine was administered only to VFC-eligible children (Office of the Inspector General, 2012). Although necessary for accountability purposes, these administrative and reporting requirements were, according to a 1999 provider satisfaction survey, the least popular aspect of an otherwise well-received program (Zimmerman et al., 2001). A recent economic evaluation of this program found that an estimated \$402 billion in direct and \$1.5 trillion in societal costs have been saved by vaccination since the inception of this program (Whitney, Zhou, Singleton & Schuchat, 2014).

1.1.3.2 The Guide to Community Preventive Services' Recommended Interventions to Increase Appropriate Immunization

The Guide to Community Preventive Services (“the Community Guide”) researches interventions for improving health and preventing disease to identify those that, on the basis of systematic review of the scientific literature, have been proven effective. The Community Guide

therefore serves as a resource for public health programs, including immunization, by providing information about interventions proven to be effective. The Community Guide has researched several vaccination interventions and since 2008 has identified thirteen different effective interventions for improving immunization coverage. These interventions are grouped within three categories: those that improve access to vaccination, those that increase community demand for vaccinations, and those that are provider- or system-based. The interventions proven to improve access are home visits, reducing out-of-pocket costs, school- or child care center-based programs, and programs conducted in Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) clinics. Interventions recommended that increase community demand for vaccination are: monetary incentives, reminder/recall, community-wide interventions used in combination, and vaccination requirements for day care, school or college. Provider- or systems-based interventions recommended by the Community Guide are: health care system-based interventions implemented in combination, provider assessment and feedback, provider reminders, and standing orders. In 2010, on the basis of their ability to support both public health and private provider immunization activities, the Community Guide added immunization information systems to their list of recommended provider- or systems-based interventions (The Community Guide, 2010).

1.1.3.3. Immunization Information Systems

As defined by the Community Guide, immunization information systems (IIS) are “confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area” (Groom et al, 2014, p.2).

With high levels of participation by providers within its jurisdiction:

“At the *point of clinical care*, an IIS can provide consolidated immunization histories for use by a vaccination provider in determining appropriate client vaccinations. At the *population level*, an IIS provides aggregate data on vaccinations for use in surveillance and program operations, and in guiding public health action with the goals of improving vaccination rates and reducing vaccine-preventable disease.” (Groom et al, 2014, p.2).

IIS facilitate the delivery of immunizations by performing several functions that support evaluation of immunization status on both an aggregate and individual basis. Public health officials and state and city immunization programs can use IIS data to evaluate immunization coverage at multiple levels such as county, zip code, vaccine type, or even by individual provider or provider organization. With such information, programs can identify pockets of need in their communities or identify provider education needs should it appear that a provider’s coverage rate for a specific antigen is inconsistent with other vaccines. Public health can also use IIS data to support outbreak response, vaccine recalls, evaluate trends in immunization coverage, and partner with other stakeholders to perform other immunization–related research (Groom et al, 2014).

In the clinical setting, participating providers can access the immunization record at the time of service for a child in their state or local IIS who presents for care. If the provider has not treated that child previously, the provider or his staff may access their record in the IIS if the child’s previous provider reported the immunizations they administered to the IIS. After enrollment in an IIS, the system will, based on computerized algorithms, recommend vaccinations due based on the ACIP recommended schedule and the child’s previous immunization history. Any contraindications to vaccination can be recorded, or, should any exist during the encounter, the provider may document them. When immunizations are administered,

the provider can document information related to VFC eligibility status, such as the child's race and ethnicity, as well as record information such as manufacturer, lot number, dosage, and administration site for the vaccines given. If a provider uses the IIS's vaccine inventory management system, doses will be decremented from their inventory, streamlining the ordering and replenishment process. If a parent requests a copy of their child's record, one can be printed directly from the IIS and given to the parent. A provider may also query the IIS for their practice's immunization coverage rate, and even produce a list of patients that are due or overdue for vaccination to perform reminder/recall. If a provider uses an Electronic Health Record (EHR), then depending on the functionality of the EHR and its capacity to support Health Level 7 (HL7), the established data exchange format for immunizations, these data can be entered into the EHR instead of into the IIS and then extracted and reported to the IIS, eliminating any duplicate data entry (Linkins & Feikema, 1998).

1.1.3.4 National Health Information Technology Policies

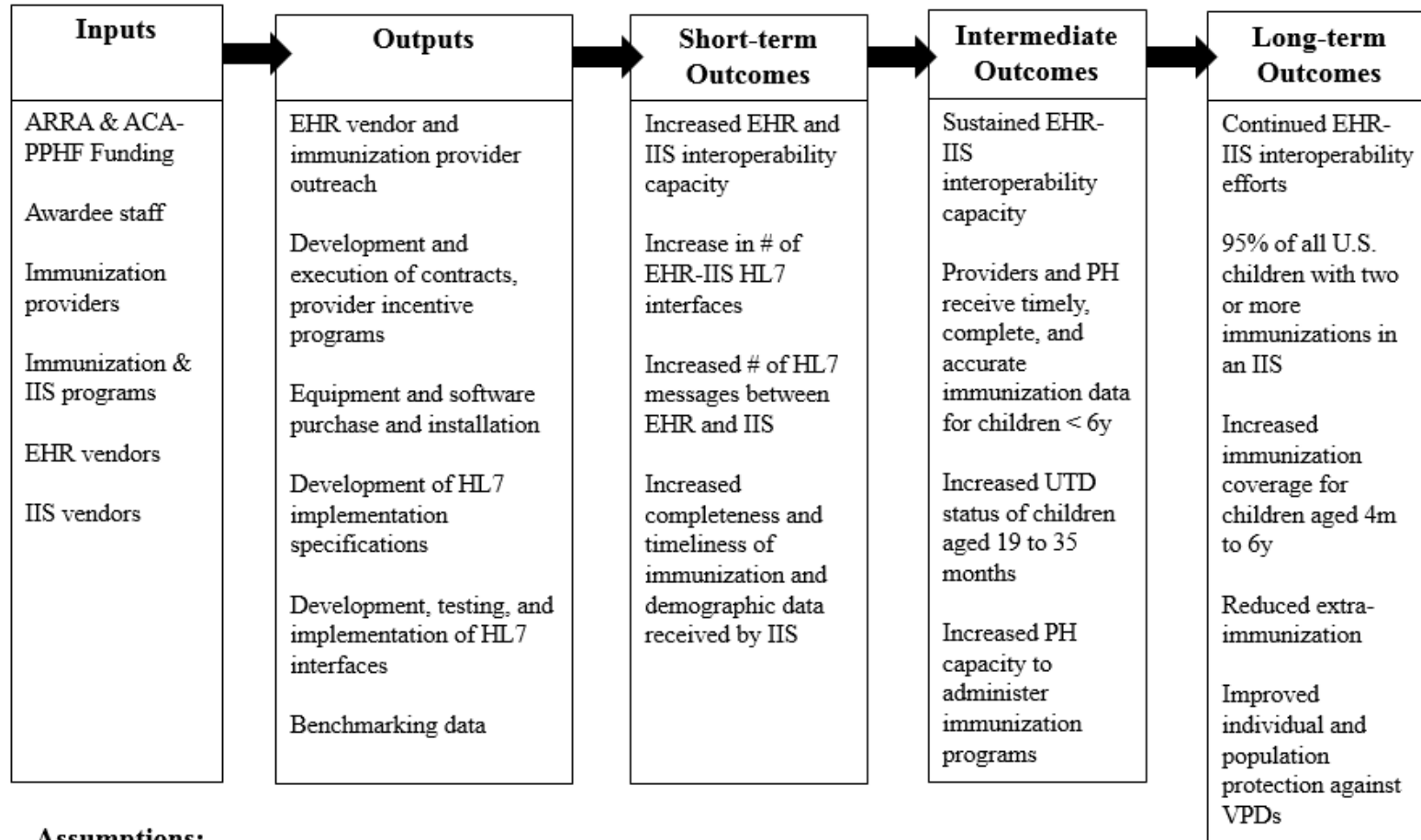
Recently enacted national policies aiming to improve health care quality in the U.S. have resulted in the creation of programs that impact IIS and have provided large amounts of funding to implement them. The American Recovery and Reinvestment (ARRA) and the Health Information Technology for Economic and Clinical Health (HITECH) Acts of 2009 (Blumenthal, 2009), the Patient Protection and Affordable Care Act (ACA) (Office of the Legislative Counsel, 2010) and the Prevention and Public Health Fund (PPHF) (Department of Health and Human Services [DHHS], 2015), and the Centers for Medicare and Medicaid Services (CMS) Meaningful Use Program enacted in 2010 (CDC, "IIS – Meaningful Use," 2012) all promote the use of health information technology as a means to improve the quality of health services. The overarching vision of these initiatives is to bridge the gap between the private and

public sectors to contribute to the creation of a unified health information network. The Meaningful Use initiative in particular seeks to drive the adoption of Electronic Health Record Systems (EHR) by private providers and promote the exchange of data between these systems and public health (CDC, “IIS – Meaningful Use,” 2012). In addition, ARRA and ACA-PPHF funding has been provided to develop and implement programs to support the creation of interfaces between EHR and IIS (Blumenthal, 2009; DHHS, 2015). The interfacing of EHR to IIS, or EHR-IIS interoperability through these funding opportunities, will increase the quantity of immunization data in IIS, and, it is believed, improve immunization outcomes and the capacity of IIS to improve population health (American Recovery and Reinvestment Act [ARRA], 2015; DHHS, 2015).

Funding for EHR-IIS Interoperability was made available to immunization programs through competitive funding process with ARRA funds in 2010, again with ACA-PPHF funds in 2012, and still continue. The purpose of these programs was to provide support for vaccination data exchange between provider site EHRs and their state or local IIS with a specific focus of reducing the duplicate data entry burden on providers. The program rationale was that by supplanting other less rigorous IIS reporting methods, the implementation of standardized electronic data exchange using the HL7 standard between EHR and IIS would yield the following benefits: improved completeness of client demographic information and immunization histories available to clinicians and public health, improved timeliness of immunization data submission to an IIS, improved quality of IIS coverage assessments, and an increase in the data available to other public health systems (e.g. vaccine preventable disease surveillance units). In addition, it was reasoned that improved interoperability would also reduce extra immunization, thereby saving time and resources (ARRA, 2015; DHHS, 2015).

Required activities under these programs included the identification of large, high-volume provider practice sites that immunize children less than six years of age that use EHR products and collaborate with them to implement interoperable interfaces between their EHR products and their IIS. Collaborative activities consisted of upgrading their IIS to support HL7 data exchange, supporting the upgrade of provider site EHRs to support HL7, HL7 message formatting and testing, data quality evaluation and the implementation and ongoing monitoring of HL7 electronic data submission to IIS (ARRA, 2015; DHHS, 2015). Figure 1 presents a logic model of the interoperability of EHR with IIS in terms of Inputs, Outputs, and expected Short-, Intermediate- and Long-Term Outcomes.

Figure 1: Logic Model for ARRA and ACA-PPHF Electronic Health Record and Immunization Information Systems Interoperability Cooperative Agreements



Assumptions:

- 1) EHR vendors have capacity for HL7 immunization data exchange with IIS
- 2) EHR vendor products can capture and transmit IIS core data elements to IIS
- 3) Providers and EHR are willing to work with IIS to establish HL7 immunization data exchange with IIS
- 4) Awardees have capacity to execute cooperative agreement activities

1.2 Purpose of Study

The purpose of this study is to examine the impact of EHR-IIS interoperability on immunization outcomes and on the completeness of data in IIS, as measured by up-to-date status of 19 to 35 month old children at provider sites reporting immunization data to IIS from their EHR, and by the population of key data fields in IIS for children less than six years of age, respectively. This study will also examine the potential for EHR-IIS interoperability to impact the capacity of IIS to support activities to increase appropriate immunization.

1.3 Research Questions

This study set out to examine these issues by asking the following two research questions:

- 1) Does interoperability between EHR and IIS improve immunization outcomes?
- 2) How can EHR-IIS Interoperability improve the capacity of IIS to support activities to increase appropriate immunization?

These questions will be answered by analyzing data on immunization and demographic information reported to IIS by providers to selected state and city immunization program recipients of ARRA and ACA-PPHF funds for EHR-IIS interoperability programs. These data include multiple metrics at the provider site level collected both prior to and after the implementation of electronic immunization reporting from their EHR to their statewide IIS. The metrics used for this study are the up-to-date status for children aged 19 to 35 months, and completeness of the following immunization and demographic data fields: vaccine manufacturer, vaccine lot number, mother's first name, mother's last name, child race, and child ethnicity.

Chapter II

REVIEW OF THE LITERATURE

A literature search was conducted to catalogue evidence for IIS support of Community Guide-recommended immunization promotion activities for U.S. children less than six years of age and the use of population-based IIS to support and evaluate aspects of immunization delivery. Supplemental searches were also conducted to characterize the functional capacity of IIS across the nation, the level of adoption of EHR in the United States, and to identify other studies that have been conducted to evaluate the impact of EHR and also of EHR-IIS interoperability.

2.1 Use of Population-Based IIS for Immunization Promotion Activities for U.S. Children Less than Six Years of Age and for Evaluating Immunization Delivery – Method

First, the Community Guide's findings from their systematic review of the literature on IIS in 2014 (Groom et al., 2014) were consulted. Their review included literature on IIS published from 1994 through 2011 as well as study findings presented at conferences. It included IIS studies in non-U.S. countries involving populations of all ages, and also on non-population-based IIS (e.g., IIS not populated using birth records). Studies that were included as evidence in the review were retrieved, and because this current study is concerned with only the IIS and population impacted by ARRA and ACA-PPHF EHR-IIS interoperability IIS in the United States, additional inclusion criteria were applied.

Of the 246 Community Guide studies, only studies were included that:

- were published in a peer-reviewed journal,
- were conducted in the United States,
- used data from a population-based IIS, or merged data with that from a population-based IIS;
- were done on study populations of children under 6 years of age, and
- reported one or more quantitative outcomes.

Second, in addition to those studies from in the Community Guide review, a subsequent search was conducted to identify relevant studies published after 2011. Using the same search criteria within the same library databases used for the Community Guide review, 248 studies were identified. After application of the inclusion criteria and deduplication, a total of 30 journal articles remained.

Data were abstracted from the studies to identify the following:

- Evidence for IIS support of immunization promotion activities targeting children <6
- How IIS supported Community Guide evidence-based recommended interventions
- Use of IIS to evaluate immunization coverage for specific age groups
- Use of IIS to research and evaluate immunization delivery

2.1.1 Evidence for IIS support of immunization promotion activities for children less than 6 years of age

Dombkowski, Harrington, Dong and Clark (2012) and Kempe et al. (2013) both documented the use of a statewide IIS in guiding immunization outreach using reminder recall. Dombkowski et al. assessed the feasibility of specialized use of the Michigan Care Improvement Registry (MCIR), Michigan's statewide IIS, for vaccine reminders for seasonal influenza, an annual immunization promotion activity. They used MCIR to target reminder notices to high-risk children aged 24 to 60 months, and found that receipt of a reminder was positively linked to flu vaccination for the target population (2012). Kempe et al. also examined the use of an IIS for immunization reminder recall activities, but compared the efficacy and cost-effectiveness of population-based recall performed by public health to practice-based recall done by private

providers in increasing immunization rates for preschool children (2013). They found that recall notices sent to households from provider offices were more effective at raising immunization rates yet were more costly, but that only 5% of practices in the intervention actually did so, citing lack of time (2013). Both studies also cited a high rate of returned notices due incorrect addresses and highlighted the importance of updated contact information in the IIS (Dombkowski et al., 2012; Kempe et al., 2013).

Researchers in Kansas used the Kansas statewide IIS to evaluate a pilot test of a childhood immunization intervention program, Text Reminders for Immunization Compliance in Kids (TRICKs). They found that a higher proportion of children whose parents received text message reminders had received their immunizations, and received them on time (Ahlers-Schmidt et al., 2012). As with Dombkowski et al. and Kempe et al., this study experienced issues with contact information, reporting that approximately 40% of the parents enrolled lost mobile phone service seven months into the study and recommended that supplemental contact information should be collected from parents upon enrollment. Post-intervention interviews with parents yielded additional suggestions to send reminders to more than one number, and also to include specific information about their child's appointment in the message (2012).

Feemster, Spain, Everhart, Pati and Watson (2009) used data in the Philadelphia IIS to identify the maternal and provider characteristics of children at risk for late initiation of immunization. They found that younger maternal age, fewer prenatal care visits, increased number of older siblings, and use public health clinic services were the predictors most strongly associated with a child being a late starter. One outcome of this research is that this information is being used by the Philadelphia Immunization Program to inform immunization promotion activities, such as partnering with maternal and child health services and obstetricians. The

author also suggests introducing vaccine education prenatally (Feemster et al., 2009). In a simpler study, Stille & Cristison-Lagay (2000) used the Connecticut statewide IIS to inform chart reviews for inner-city infants, and found that up-to-date status for the study cohort increased by 5% after consulting CIRTSS. The IIS data contributed to a more complete understanding of immunization status, thereby reducing extraimmunization and allowing redirection of promotion efforts to those children who were truly behind (Stille & Cristison-Lagay, 2000).

Similar to Feemster et al., Weston and Enger (2010) leveraged the MCIR system to identify factors associated with the receipt of hepatitis A vaccine in Michigan one-year-olds, and also assess overall hepatitis A coverage among this group. Authors cited using a number of variables from the MCIR system: gender, race/ethnicity, mother's age, provider type, Medicaid and WIC status, and zip code. They found that 55.8% of their age group of interest received at least one dose of hepatitis A vaccine by 24 months of age. They also found that black and Hispanic children enrolled in WIC, Medicaid or both programs had higher odds of vaccine receipt. Additional characteristics associated with vaccine receipt were residing in a non-rural area and receiving care from a public provider. These findings prompted recommendations to examine the nature of who and how this particular vaccine is promoted and if it was different than promotion methods for other immunizations (2010).

Daskalaki, Spain, Long, and Watson (2008) also performed a study to examine aspects of coverage with respect to one vaccination. Their study examined rotavirus vaccination and the impact of the strict age limits for initiation for this vaccine series on coverage for other vaccinations, and how many providers complied with the age recommendation and how many did not. Using demographic and vaccination data from the Philadelphia IIS, the authors found that children served by public health clinics initiated the DTaP vaccine series too late, leaving them at

risk and vulnerable to VPDs. The authors emphasize that adherence to timeliness recommendations has been observed to be increasingly important in protection against vaccine-preventable diseases. Consequently, the capacity to perform this type of study is valuable to determine the prevalence of vaccine delay and identify ways to address this issue. On the basis of their findings, the study authors recommend changing the age at which promotion initiatives are triggered from ten months to three months, and also consider conducting these activities at the birth hospital in order to facilitate identification of mothers with other risk factors that may put their newborn at risk (2008).

Livingood and colleagues (2013) described the use of the Florida IIS to assist in the evaluation of a quality improvement (QI) initiative to improve immunization rates for two year-olds conducted within the state's immunization program. The statewide IIS, Florida SHOTS, was used as the primary data source for measuring immunization rates during the project, which used QI methods to improve implementation of evidence-based approaches for improving immunization. Staff generated coverage reports for 19 to 35 month old children throughout the project, and revealed consistent and steady improvement in coverage rates (Livingood et al., 2013).

2.1.2 Use of IIS to Support Community Guide Recommended Interventions to Increase Appropriate Immunization

Several studies from the literature review documented the use of Community Guide-recommended evidence-based interventions. The studies performed by Dombkowski et al., Kempe et al., and Ahlers-Schmidt et al. described above, all used IIS to perform reminder/recall, one of the Community Guide's recommended interventions for increasing community demand for immunization. Findley et al. also documents the use of reminder recall, but as one piece of a

larger evaluation of a multi-component, coalition-led immunization intervention program, or as the Community Guide would characterize the effort, a community-based intervention implemented in combination, another of the Community Guide's recommended activities for increasing demand. Using the population-based New York Citywide Immunization Registry (NYCIR) as their immunization data source, the Start Right coalition performed multiple activities in this campaign to target the Latino, low-income community, which was understood to have coverage lower than both city and national rates. These activities included the development of promotional materials, training health educators, performing outreach, education, and parent reminders (2012). As the sole source of immunization data used for the population, NYCIR helped document and track immunization rates for the children targeted by the intervention, and the program found that children receiving coalition services were 53% more likely to be up to date than children in the control group (2012).

Kattan, Kudish, Cadwell, Soto and Hadler (2014) also describes the implementation of a multi-pronged immunization intervention in Connecticut, where Immunization Action Plan (IAP) coordinators to target immunization promotion activities for a provider- and systems-based intervention in areas of low socioeconomic status (2014). These coordinators used CIRTS data to identify the children within their assigned area who were behind schedule at seven months of age, and then carried out a number of actions to get them caught up. Among those activities were home visits, returning the child to care by assigning them to a medical home, supporting implementation of reminder recall at the provider site, and performing evaluation and feedback to the provider. Study authors emphasized that the implementation of coordinators in combination with the information in the IIS was key to minimizing the disparities in immunization coverage

within the population and helping them achieve full protection by twenty-four months of age (2014).

2.1.3 Use of IIS to Evaluate Immunization Coverage for Specific Age Groups

As described above, IIS can be effectively used to isolate immunization status of different segments of the population based upon health risk (Dombkowski et al., 2012) and even create risk profiles for children based upon a number of characteristics (Feemster et al., 2009), such as census tract (Kattan et al., 2014). IIS that are population-based and enroll children in their systems using birth certificate data, due to having data on almost the entire child population their jurisdiction, therefore have the potential to perform analysis on the entire IIS jurisdiction for any number of age groups. This literature review alone identified studies examining twenty different age groups. Four studies examined the six month to five year old population (CDC, 2006; CDC, 2007; CDC, 2008; Ma, 2006), three examined the 19 to 35 month-old population (Findley et al., 2008; Kempe et al., 2013; Khare et al., 2013), and two studies examined the nine month population and the 24 month-old population (Robison et al., 2012; White et al., 2011). All other studies looked at unique groups, ranging from very young populations such as newborns less than three days old (White, Anderson, Stanley & Ehresmann, 2009) to a one-year cohort for which coverage was calculated at milestone ages (Robison, Kurosky, Young, Gallia & Arbor, 2010).

2.1.4 IIS Use of IIS to Research and Evaluate Immunization Delivery

In addition to the studies described above, other studies included in this literature described a number of applications of IIS data for the research and evaluation of immunization delivery. Two studies used IIS data to evaluate vaccine effectiveness or safety (Cortese et al., 2011; Guh & Hadler, 2011) and two evaluated the impact of vaccine shortages on immunization coverage levels (Allred et al., 2006; White, Pabst & Cullen, 2011). One described the use of a

city-wide IIS in notifying providers of a vaccine recall (Papadouka, Metroka & Zucker, 2011), and another described the use of the Delaware IIS to support public health response in a pertussis outbreak in an Amish population (CDC, 2006). Other studies assessed provider compliance with vaccine recommendations (Allred et al., 2006; Bronson-Lowe & Anderson, 2009); two specifically examined the use of alternative vaccination schedules (Nadeau et al., 2015; Robison, Groom & Young, 2012). One researcher evaluated the effect of media coverage on flu vaccination in 2003 (Ma et al., 2006) and another the impact of the medical home on immunization rates (Ortega, Stewart, Dowshen & Katz, 2000). IIS have also partnered with Managed Care Organizations in conducting research as well, evidenced by Happe, Lunacsek, Marshal, Lewis and Spencer in 2007, which examined the impact of the use of a combination vaccine on timeliness of vaccination and coverage rates for their enrollees.

IIS, which operate at state and city levels, are also being increasingly examined for how they may support national-level vaccination surveillance. Khare, Piccinino, Barker and Linkins in 2006 described the use of IIS as supplemental data sources for the National Immunization Survey, which is a survey conducted annually by CDC to develop estimates of immunization coverage for states and large metropolitan areas (CDC “National,” 2015).

One of the strengths of IIS for evaluating immunization coverage and delivery is their capacity to use their data to perform geographical analysis, stratifying immunization coverage by using certain variables with geographic data in the IIS and enabling the identification of geographic pockets of need that have lower immunization rates and may need special attention. Analysis of IIS data by address information, including street address, county, or zip code was described in thirteen studies (Allred et al., 2006; Cortese et al., 2011; Daskalaki et al., 2008; Dombkowski et al., 2012; Feemster et al., 2009; Guh & Hadler, 2011; Kattan et al., 2014; Kempe

et al., 2013; Livingood, et al., 2013; Nadeau et al., 2015; Robison et al., 2010; Robison et al., 2012; and Weston & Enger, 2010). Six of these studies recounted leveraging the data fields that are of interest in this study. Two studies used vaccine manufacturer and four used race and ethnicity in conjunction with their geographic data analysis. Robison et al. used vaccine manufacturer in his analysis of a one-year cohort's progress through early immunization milestones (2010), and Cortese et al. (2011) used vaccine manufacturer and lot number in her rotavirus vaccine effectiveness study. Race and ethnicity data were used in combination with geographical analysis to evaluate the effect of late initiation of rotavirus vaccine (Daskalaki et al., 2008), characterize geographic distribution and sociodemographic characteristics of children who are "late starters" (Feemster et al., 2009), evaluate the effect of immunization coordinators on socioeconomic disparities in immunization (Kattan et al., 2014), and identify the factors associated with hepatitis A vaccination receipt in one-year-olds in the IIS jurisdiction (Weston & Enger, 2010).

Similar to the Community Guide review, this review found few studies that addressed provider consultation of the data in the IIS. As described above, Kempe et al. compared provider-based reminder recall with population-based recall done by public health (2013). Zeretke et al. (2012) described a study that evaluated the effect of consulting an IIS for documentation of immunization for children presenting with fever in the emergency room, found that consulting the IIS for vaccine histories resulted in a 58% reduction in the ordering of blood work.

2.2 Functional Capacity of IIS in the United States

Since 1994, the Centers for Disease Control and Prevention (CDC) has allocated funds annually to its immunization program awardees for the development and implementation of IIS under Section 317(b) of the Public Health Service Act. Throughout this process, CDC has

assisted in developing functional standards, setting performance goals and monitoring IIS progress. As of the end of calendar year 2012, 86% of children less than six years of age had at least two immunizations in an IIS (“Progress in Immunization Information Systems,” 2013).

Table 1 lists Functional Standards for IIS and the percentage that reported compliance with them in the Calendar Year 2012 Immunization Information Systems Annual Report (IISAR). These Functional Standards were developed with input from a variety of immunization program managers and IIS developers across the U.S., endorsed by the National Vaccine Advisory Committee (NVAC), and represent fundamental capabilities that IIS should possess in order to fulfill their purpose of supporting immunization providers and public health programs in the delivery of immunizations and assuring appropriate levels of population protection from vaccine preventable diseases (CDC, “IIS – Functional Standards,” 2012).

As shown in Table 1, all IIS reported the capacity to enable access to a child’s immunization history at the time of the clinical encounter and 96% reported the ability to forecast

Table 1: Percentage of IIS Meeting CDC Functional Standards, Immunization Information Systems Annual Report, 2012 (Cardemil, Ng & Pabst, 2013).

IIS Functional Standard	% IIS
Stores all core data elements	65%
Establishes newborn record within 6 weeks of birth	83%
Enable real-time access to and retrieval of immunization information	100%
Receive and process immunization information <i>within 1 month</i> of vaccine administration	78%
Protect the confidentiality of health care information	100%
Ensure security of health care information	100%
Exchange immunization records using Health Level Seven (HL7) standards	77%
Forecast immunizations needed according to ACIP schedule	96%
Identify individuals due or late to support reminder/recall	98%
Generate coverage reports by providers, age groups, and geographic areas	92%
Produce official immunization records	100%
Promote accuracy and completeness of registry data	98%

immunizations needed, based upon the child’s immunization history in the IIS and the vaccines needed according to ACIP recommendations. These functionalities are key to supporting clinical

decision-making for immunization providers. Most IIS (92%) reported the capacity to generate immunization coverage reports by various criteria, such as county, zip code, age groups, and even race/ethnicity, a function key to identifying areas or populations with low coverage, thus supporting the planning of targeted immunization interventions. One such intervention, reminder/recall notices, could be supported by 98% of IIS. Eighty-three percent of IIS reported that they could enroll a newborn in their geographic jurisdiction within six weeks of birth, and 78% reported the capacity to receive and incorporate immunizations into a child's record within one month of administration. Because a child's first dose of most vaccines in the childhood immunization schedule are due at two months of age ("Recommended," 2015), the availability of a demographic record in the IIS at the time of that visit is key to supporting immunization providers in immunization decision-making and documentation for that visit, and for every other visit thereafter. In addition, because the child's next immunization visit is at four months of age ("Recommended," 2015), it is critical that the immunizations administered at the two-month visit be included in the child's IIS record to support clinical decision-making at that next encounter. Seventy-seven IIS reported the ability to receive and process immunization data transmitted to their system electronically following Health Level 7 (HL7) standards. Health Level 7 is an international data exchange standard, and is also standard required by CMS for meeting the Meaningful Use immunization measure. This capacity, therefore, is essential for EHR-IIS Interoperability and for receiving updates to child immunization records in the IIS via electronic transmission. Finally, only approximately two-thirds of IIS reported that they could capture all of the core data elements for IIS. A complete list of these data elements is provided in Appendix A, but a list of selected core data elements is listed in Table 2, along with the percentage of IIS reporting these fields as being populated within their system. As made evident by these data,

patient race and ethnicity were populated in only approximately one half to two-thirds of demographic records in IIS for children less than six years of age. Along with vaccine manufacturer and lot number, which were populated in 66% and 70% of IIS records respectively, these fields are not only key in the documentation of immunizations, but also in documentation requirements for the Vaccines for Children program.

Table 2: Percentage of IIS records with select core data elements populated for children <6 years of age, U.S. National Average, Immunization Information Systems Annual Report, 2013 (Cardemil, 2014).

IIS Core Data Element	% Populated in IIS
Mother's first name	77%
Mother's last name	67%
*Patient race	65%
*Patient ethnicity	54%
*Vaccine manufacturer	66%
*Vaccine lot number	70%

*Required by NVICP to be recorded in patient record

2.3 Adoption of EHR in the United States

A supplemental search was conducted to identify what was known in the literature about the adoption of EHR in the United States, both overall and among the specialties who deliver immunizations.

In a January 2014 National Center for Health Statistics (NCHS) data brief, Hsiao and Hing reported results and trends found in the National Ambulatory Medical Care Survey (NAMCS), a nationally representative annual survey of office-based physicians. The data collected from 2001 through 2013 show that approximately 18% of office-based physicians in 2001 used any type of either partial or fully electronic medical or health record system. Use increased steadily by 39 percentage points to 57% in 2011, then over two years rose over twenty percentage points to 78.4% in 2013. Adoption of "basic" systems meeting selected criteria rose from 10.5% in 2006 to 21.8% in 2009, when incentive payments for EHR adoption were authorized by the HITECH Act.

From 2010 to 2013, this adoption rate increased another 26.3 percentage points, reaching 48.1%. The adoption of EHRs that supported reporting to IIS increased from 26.9% in 2010 to 39.1% in 2013 (Hsiao & Hing, 2014).

When evaluating the adoption of EHR by family physicians, Xierali et al. found that 68% of practices in this specialty had implemented EHR by 2011, and that this medical specialty is adopting EHR at a faster rate than other specialties (2013). Although there were variations in the level of adoption across the country, the rate of adoption doubled from 2005 and was projected to reach 80% by 2013.

Leu et al. surveyed a sample of members of the American Academy of Pediatrics (AAP) in 2009, seeking to characterize the adoption of EHR by pediatricians, who deliver the bulk of childhood immunizations (2012). The authors found that self-reported EHR use was 41%, lower than the general level of adoption, but only 25% of this group used systems that met the definition of having “basic” functionality. They also found that an even lower proportion, just 3%, used systems the authors considered to be “pediatric supportive.” To be termed “pediatric supportive,” an EHR had to support five fundamental features for pediatric practice, including immunization tracking. The authors found that barriers to EHR adoption were primarily financial in nature, but also were related to concerns as to how implementation and use of the software would impact office productivity, and also how well it would meet their practice’s needs (Leu et al., 2012).

Lehmann, O’Connor, Shorte, and Johnson conducted a similar follow-up survey of AAP members in 2012. They found that the number of office-based pediatricians using EHR had risen to almost 80%. In addition, the percent of pediatricians using EHRs increased from 58% in 2009 survey to 79% in 2012. Thirty-one percent of pediatricians used “basic” EHRs, and only 8% used “pediatric supportive” EHRs. As with the previous survey, the authors found that costs associated

with implementing EHR remained a concern, as did the potential negative effect on productivity. The authors also state that while the benefits of EHR use to improve quality of care have been widely promoted, they believe that EHRs that support pediatric practice may be less than desired, and point out that pediatricians' voices must be heard in the development and certification process for EHR to improve functionality, efficiency, and data exchange capability (Lehmann et al., 2015).

2.4 EHRs and EHR-IIS Interoperability

A supplemental search was conducted to identify what was known in the literature about EHR–IIS interfaces and the status of EHR adoption by pediatric providers in the United States.

Bundy et al. (2013) evaluated EHR-derived immunization prompts in a urban hospital-based pediatric and primary care clinic, meant to call provider's attention to overdue vaccinations and reduced missed opportunities for immunization (when a child presents in the office and could receive a vaccination, but does not). EHR-delivered immunization prompting was found to be insufficient to improve immunization rates among the study population that already had baseline coverage (Bundy et al., 2013).

Merrill, Phillips, Keeling, Kaushal and Senathirajah (2013) evaluated the impact that EHR-based HL7 reporting had on their routine reporting of immunizations to the New York Citywide Immunization Registry (NYCIR) compared to their legacy reporting format. Comparing median pre-implementation and post-implementation timeliness and completeness measures, the authors found that the proportion of new immunizations reported to the NYCIR rose by 18%, and historical immunizations (those reported more than one year since administration) rose 98%. They also found that the number of immunizations reported in less than two days rose by 17% and that the median time from reporting to receipt in the NYCIR

decreased from 13 days to 10 days. Despite the overall positive impact, the authors did find that documentation of VFC eligibility decreased by 8%. Upon further investigation, this decrease was attributed to EHR workflow. They found that the EHR did not have a field to capture Medicaid ID, which was a means by which the practice determined VFC eligibility. Rather than capture Medicaid ID, the EHR's immunization reporting module had more than one field where VFC eligibility status could be documented, however the data extraction process pulled eligibility information from only one of these fields. Unless entered in the field included in the download and batch submission, status was not captured and sent to the NYCIR (Merrill et al., 2013).

Hills, Revere, Altamore, Abernethy and Lober (2012) compared the quality of data submitted to the Washington State IIS from provider site EHR using HL7 format to a flat file, non-standard format. They examined several demographic and vaccination data fields, however none of these data elements were the same as those examined in this study. The authors found that data received via HL7 were more timely but that flat file data were more complete (Hills et al., 2012). Schauer, Maerz, Verdon, Hopfensberger and Davis (2014) also compared timeliness and completeness of data received within a state IIS submitted via HL7 and flat file formats. They evaluated data from provider site EHR to the Wisconsin Immunization Registry (WIR) using the HL7 standard format compared to a flat file, non-standard, format. Three of the data elements they evaluated were vaccine manufacturer, vaccine lot number, and VFC eligibility. Overall, they found that data submitted via HL7 interfaces were more timely and complete than via flat file. Specifically, vaccine manufacturer data reporting increased from 42% to 62%, lot number reporting increased from 26% to 63%, and VFC eligibility reporting increased from 0% to 95% (Schauer et al., 2014).

2.5 Summary

Overall, the use of IIS to support Community-Guide recommended interventions to increase immunization is well-documented, not only within the original scope of the Task Force's systematic review, but also for children less than six years old in population-based IIS in the United States. The literature also documents the capacity of IIS to support a wide array of evaluation studies, both for immunization coverage and delivery. The use of race/ethnicity and vaccine manufacturer and lot number fields is documented in multiple studies, illustrating that these fields are key not only to VFC program accountability, but also to public health research in immunization. A review of IIS functional status in 2012 indicate that almost all IIS could support immunization forecasting as well as reminder recall, but also that about two thirds of IIS could capture all core data elements, and approximately three-quarters of IIS could exchange immunization records using HL7 standards in 2012.

Findings regarding use of EHR in the United States indicate that providers are responding to the CMS Meaningful Use incentive program and implementing EHR in their practices, but that pediatric practices are adopting EHR at a slower rate. Also documented is that many EHR do not have the functionality to appropriately support pediatric practice, and that only a small percentage of EHR implemented among pediatric practices can support immunization tracking. Studies examining the effect of EHR-IIS interoperability on completeness of data in IIS are few, and those available reported contrasting results regarding the timeliness and completeness when comparing HL7 versus non-standard data exchange formats. The study that did find HL7 to provide more complete data also found increased completion in some of the fields of interest in this study. Both of these studies examined data within only one IIS; this study is the first to examine data collected at the provider site level across multiple states.

Chapter III

METHODS AND PROCEDURES

3.1 Data

A cross-sectional design was used to conduct this study. Data used for the study was provided by fifteen IIS who received both ARRA-HITECH and PPHF 2012 funding for EHR-IIS interoperability projects. As part of their project requirements, these IIS queried their system data to produce benchmarking metrics on immunization and demographic data reported to them by provider sites with which they had implemented HL7 interfaces (ARRA, 2015; DHHS, 2015). Data were collected prior to HL7 implementation (“pre-enhancement”) and after HL7 implementation (“post-enhancement”). Post-enhancement queries were conducted every 90 days after implementation until the end of the given project period. Once queries were completed, IIS recorded the benchmarking metrics for each provider site in a secure website. Benchmarking data for the ARRA-HITECH projects were collected from September 1, 2010 through November 30, 2012. Benchmarking data for PPHF 2012 projects were collected from September 30, 2012 through November 30, 2014. Provider sites selected for inclusion in the study were those that collaborated on HL7 interface development with IIS during both the ARRA-HITECH and PPHF 2012 interoperability projects, and for whom benchmarking data was collected and reported. No individually-identifiable data were collected as a part of this project; only aggregate data were used. The data were from a non-public CDC data set, and author was given permission to use

these data by CDC. The benchmarking data set fields selected for analysis captured data related to up-to-date immunization status for 19 to 35 month-old children, population of selected demographic data fields, and population of selected vaccine fields. The variables collected by IIS for provider sites at pre-enhancement and post-enhancement and their use in the study are identified and listed in Table 3.

Table 3: EHR-IIS Interoperability Benchmarking Dataset Field Codes, Description and Use in Study Analysis

Dataset Field Codes	Description of Key Study Variables	Use in Analysis
series431331Prop	Proportion of children aged 19 to 35 months for 4:3:1:3:3:1, (4 or more DTaP/DTP/DT, 3 or more Polio, 1 or more MMR, 3 or more Hepatitis B, ≥ 3 or ≥ 4 of Hib, and 1 or more Varicella) at the provider sites as of the benchmarking date	Up-to-Date Status
iis435	Number of children aged four months to six years at the provider site as of the benchmarking date	Demographic Data Completeness
numNVAC4	Number of children aged 4 months to six years at the provider site with mother's first name, mother's last name, and patient race and ethnicity populated in their demographic record in the IIS as of the benchmarking date	Demographic Data Completeness
iis435NumVac	Number of vaccinations reported to the IIS by the provider site for children aged four months to six years at pre-enhancement as of the benchmarking date	Vaccine Data Completeness
iis4m6yNumVac	Number of vaccinations reported to the IIS by the provider site for children aged four months to six years at post-enhancement as of the benchmarking date	Vaccine Data completeness
numNVAC2	Number of vaccinations reported to the IIS by the provider site for children aged four months to six years with vaccine manufacturer and lot number populated in the IIS as of the benchmarking date	Vaccine Data Completeness

3.2 Data Analysis Plan and Methods

This study analyzed benchmarking metrics from provider sites participating with these 15 IIS to examine the change in up-to-date immunization status of 19 to 35 month-olds and the completion of demographic and vaccine fields in IIS from prior to HL7 interface implementation (pre-enhancement) to after HL7 interface implementation (post-enhancement).

Reported pre-enhancement and post-enhancement data sets for that collaborated on HL7 interface development with IIS during both the ARRA-HITECH and PPHF 2012 interoperability projects were matched by provider site ID, and analyses were performed on the matched pairs of metrics reported for each site. Because IIS provided several sets of post-enhancement measurements at 90-day intervals for each provider site after HL7 implementation, the most recent post-enhancement measurement at each provider site was selected in order to allow the greatest possible elapsed time after enhancement, and consequently to allow the greatest possible time for the intervention's intended effect.

Because the number of children in the age groups of interest varied widely across the provider sites included in the analyses, proportions were calculated and compared rather than the actual number of children up-to-date or demographic or vaccination records. After matching the pre-enhancement and post-enhancement data sets for each provider site, the proportion of demographic and vaccine records considered complete at pre-enhancement and at post-enhancement were calculated. To be considered complete, the IIS had to have both vaccine data fields and all four demographic data fields populated in the IIS, for the vaccine data completeness and demographic data completeness analysis, respectively. Proportions for the analysis were calculated as follows:

Demographic Data Completeness, Pre-enhancement: $\frac{iis435}{numNVAC4}$

Demographic Data Completeness, Post-enhancement: $\frac{iis435}{numNVAC4}$

Vaccine Data Completeness, Pre-enhancement: $\frac{iis435NumVac}{numNVAC2}$

Vaccine Data Completeness, Post-enhancement: $\frac{iis4m6yNumVac}{numNVAC2}$

As seen in Table 3, the proportion of children up-to-date for the 4:3:1:3:3:1 vaccination series at pre- and post-enhancement had already been calculated and no further calculation for this analysis was needed.

Test statistics were performed on the dependent pairs to determine if the mean difference in the proportion of children in up-to-date status or the proportion of demographic or vaccine data fields populated in IIS from pre-enhancement to post-enhancement for these measures was statistically significant. Because the sample sizes for each analysis were greater than 30, the Central Limit Theorem applied and the following test statistic was used with an accompanying hypotheses and decision rule:

Test Statistic:	$Z = \frac{\bar{X}_d - \mu_d}{\frac{s_d}{\sqrt{n}}}$
Null and Alternate Hypotheses:	<p>H₀: $\mu_d = 0$</p> <p>H₁: $\mu_d > 0$ $\alpha = 0.05$</p>
Decision Rule:	<p>Reject H₀ if $Z \geq 1.96$ or if $Z \leq -1.96$</p> <p>Do not reject H₀ if $-1.96 < Z < 1.96$</p>

Chapter IV

RESULTS

The following section will describe the findings of this evaluation study and address the following research questions:

- 1) Does interoperability between EHR and IIS improve immunization outcomes?
- 2) How can EHR-IIS Interoperability improve the capacity of IIS to support activities to increase appropriate immunization?

4.1 Results

Sixty-three state- and city-level IIS are currently operating in the U.S. Twenty of these IIS (31.7%) received ARRA funding to perform EHR-IIS interoperability projects in 2010, and fifteen of these twenty, roughly a quarter of all operational IIS, were funded a second time in 2012 with ACA-PPHF funds. From these fifteen IIS, provider sites were identified that had been included in both ARRA and PPHF projects. After data cleaning, of those provider sites, forty-eight were identified for the 4:3:1:3:3:1 up-to-date analysis from six statewide and one citywide IIS, and 47 provider sites were identified for the demographic and vaccination record completeness analysis from five statewide and one city-wide IIS. Table 4 lists the number of provider sites included from each IIS.

Table 4: Number of Provider Sites Enhanced, ARRA-HITECH and PPHF 2012, and Number of Provider Sites Included in UTD and Completeness Analyses, by IIS

IIS	Number of Sites Enhanced - ARRA	Number of Sites Enhanced - PPHF	Sites Included in UTD Analysis	Sites Included in Completeness Analyses
A	76	60	4	4
B	237	149	26	26
C	25	222	1	1
D	210	200	3	3
E*	7	45	5	5
F	56	16	1	0
G	90	268	8	8
TOTAL	701	960	48	47

*indicates city-wide IIS

For the provider sites included in the 4:3:1:3:3:1 up-to-date analysis, the HL7 interface had been established an average of 927 days (30.8 months) prior to the most recent post-enhancement measurement used, with a range of 270 (9.0 months) days to 1,346 days (44.9 months). For the provider sites included in the demographic and vaccination record completeness analysis, the HL7 interface had been established an average of 919 days (30.6 months) prior, with a range of 181 days (6.0 months) to 1,346 days (44.9 months).

Results of the statistical analysis are displayed in Table 5.

Table 5: Comparison of Mean Differences in Proportion of Children UTD and Field Completeness for Selected EHR-IIS Interoperability Measures

Interoperability Benchmarking Measure	Sample Mean \bar{X}_d	Std Dev Difference s_d	Z-statistic	C.I.
<i>Up-to-Date Status</i>				
UTD for 4:3:1:3:3:1 19-35 month-olds	3.61	18.64	1.34	3.61 ± 5.29 (-1.72,8.94)
<i>Completeness</i>				
Mother's First Name & Last Name, Child's Race & Ethnicity 4 month to 6 year olds	16.09	25.31	4.36	16.09 ± 7.2 (8.86,23.33)
Vaccine Manufacturer & Lot Number 4 month to 6 year olds	17.33	32.17	3.69	17.33 ± 9.2 (8.13,26.73)

4.2 UTD Status for 19-35 month olds

The analysis of benchmarking data for the up-to-date status for 19 to 35 month olds confirmed the null hypothesis. The Z-statistic of 1.34 failed to demonstrate sufficient evidence at .05 alpha to show that the mean difference in the proportion of children UTD for the 4:3:1:3:3:1 series in this age group at enhanced provider sites after EHR-IIS enhancement was greater than zero. The confidence interval for this statistic showed 95% confidence that the a mean change in up-to-date status for 19 to 35 month-olds at enhanced provider sites was between -1.73% and 8.61%.

4.3 Completeness of Demographic Data

The results of the analysis for the completion of the four selected demographic data elements (Mother's First Name, Mother's Last Name, Child Race and Child Ethnicity) in IIS for children aged four months to six years supported the study's hypothesis. The Z-statistic of 4.36

demonstrated sufficient evidence at .05 alpha to show that the mean difference in the proportion of children in this age group at provider sites with completed demographic data in the IIS after enhancement was greater than zero. The confidence interval for this statistic showed 95% confidence that the mean change in completeness for the selected demographic data elements for children aged four months to six years at enhanced provider sites was between 8.86% and 23.33%.

4.4 Completeness of Vaccine Data

The results of the data analysis for the completion of the two selected vaccine data elements (Vaccine Manufacturer and Vaccine Lot Number) in IIS for children aged four months to six years supported the study hypothesis. The Z-statistic of 3.69 demonstrated sufficient evidence at .05 alpha to show that the mean difference in the proportion of children in this age group at provider sites with completed vaccination data in the IIS after enhancement was greater than zero. The confidence interval for this statistic showed 95% confidence that the mean change in completeness for the selected vaccine data elements for children aged four months to six years at enhanced provider sites was between 8.13% and 26.73%.

Chapter V

DISCUSSION AND CONCLUSION

5.1 Discussion of Research Questions

The purpose of this research study was to answer the question of whether interoperability between EHR and IIS improve immunization outcomes.

The first immunization outcome of interest in this study is the up-to-date status for 19 to 35 month old children. Findings indicated that, at the provider sites included in this study, this outcome did not improve. The EHR-IIS interfaces may have contributed to some initial increase in up-to-date status simply by consolidating immunization records, as was found in Stille et al.'s 2000 study, however any change in the mean difference in the proportion of 19 to 35 month-old up-to-date children was not statistically significant. There are several factors that could explain this outcome, such as the nature of the metric used for evaluation. During the course of each provider site's involvement in the EHR-IIS interoperability project with the IIS, the up-to-date status for children aged 19 to 35 months was being evaluated every 90 days. Because the children selected for inclusion in the age group being evaluated for up-to-date status were identified by date of birth relative to the date of evaluation, children would age in and out of the group over time, and so the same group of children was more than likely never assessed more than once. New patients who were behind on immunizations could have also joined the practice during the project period and included in any given up-to-date evaluation, thereby lowering the coverage rate

for the practice. In addition, if any new patient's previous immunizations were either not reported to the IIS by their previous provider, or if records of prior immunization were not provided by the parent, then the child could truly be up-to-date yet lack the documentation to prove it.

Other factors related to human behavior or to the interface itself may also have been at play. It is possible that immunizations administered at the provider practice were not being consistently entered into the EHR for reporting to the IIS, or also that immunizations in the EHR were not being consistently captured during data extraction for transmission to the IIS. In addition, providers may not be either consulting the IIS for recommended immunizations during each patient visit, thereby missing opportunities to catch the child up to schedule. Also, the interface between the EHR and IIS may not have been bi-directional, which could have harmonized the data in the EHR and IIS and also delivered immunization recommendations to be displayed in the provider's EHR. Providers could also have been following parental desires to follow alternative immunization schedules and intentionally delay immunizations; children of these parents would therefore appear to be behind on immunizations according to the ACIP recommended schedule.

This study yielded more favorable findings regarding the outcomes of interest related to IIS data completeness. The results for both vaccine data and demographic data completeness demonstrated that EHR-IIS interoperability favorably impacted these measures, similar to the findings of Shauer et al. (2014).

The mean difference in vaccination records with both vaccine manufacturer and lot number and demographic records with mother's first name, last name, and child's race and ethnicity populated in the IIS was shown to have a statistically significant increase. An important consideration in the completion of vaccine manufacturer and lot number completeness outcome is that these data are key to vaccine ordering and inventory management, and in the case of

providers participating in the VFC program, they are required and therefore crucial to provider business. Vaccine manufacturer and lot number, along with child race and ethnicity, are also required by the VFC program for eligibility tracking purposes. IIS can support documentation of vaccine manufacturer and lot number by pre-populating these fields with known inventory on hand, avert documentation errors by employing edit checks, thereby simplifying vaccine documentation and improving accuracy. Also at play is that immunization programs are increasingly requiring IIS reporting as a part of VFC program participation and relying on their IIS to support VFC accountability activities (Use of IIS as a VFC Requirement, 2015).

As seen in the calendar year 2013 IISAR data, data completeness for individual fields is variable. To be included in the count of records considered “complete” for this study, data needed to be in both or all four of the vaccination or demographic fields, respectively. If completeness of each field were queried individually, completion rates might have varied and potentially revealed a greater increase in completeness than was yielded in this study. Another important consideration is that although this study yielded positive findings with regard to data element completeness, the quality of those data was not evaluated. Though it was found that data fields were more complete, it is unknown if the data contained in these fields were valid. Data completeness could also be affected by the capacity of EHR to capture these data elements; there are thousands of EHR products in the marketplace, (Office of the National Coordinator for Health Information Technology, 2015), the capacity of each one of these products is challenging to catalogue and the criteria by which these products are certified may not be fully in alignment with pediatric needs (Spooner, 2012). In addition, it is unknown to what extent EHR users at provider sites have been trained to enter these data, or even if entering data in these fields is required. Both

user training and data entry requirements could therefore play a role in completion of demographic and vaccination records.

Also under consideration as a part of this study is the broader question of how EHR-IIS interoperability can support activities to increase appropriate immunization. IIS capacity to perform coverage analysis as well as completion of the data elements of interest in this study are central to answering this question.

Although in this study EHR-IIS interoperability was not shown to increase up-to-date status for 19 to 35 month old children, other studies have shown IIS to be useful in conducting coverage analysis for this as well as any number of other age groups. By supporting the consolidation and availability of immunization status for children within the jurisdiction of an immunization program, IIS are a powerful tool for identifying factors contributing to suboptimal coverage among specific subgroups. Because IIS can also support coverage analysis at the provider level, they support evaluation of immunization provider performance and adherence to the ACIP recommended vaccination schedule. Providers who are not following recommended immunization guidelines or taking every opportunity to assess immunization status can then be contacted by the program for education. By evaluating coverage at numerous levels, IIS can provide valuable information to programs to support addressing barriers to appropriate immunization among all components of the immunization delivery system. Using that information, programs can then develop new approaches to reach underimmunized groups and ensure that levels of protection against VPDs are consistent throughout the population.

The specific demographic and vaccine data of interest in this study and their inclusion in IIS are key to supporting initiatives to increase appropriate immunization. Although most IIS can capture child race, child ethnicity, vaccine manufacturer, and vaccine lot number, according to

2013 IISAR data, IIS have room to improve in the completeness of these fields. These fields are key to VFC program administration, and because EHR-IIS interfaces can automate the documentation and reporting process for VFC providers, EHR-IIS interoperability can yield improved field completion rates, eligibility documentation and vaccine management in IIS and for immunization programs. When documentation and accountability improve, the program's capacity to efficiently manage its publicly-purchased vaccine stock improves as well. Additionally, with more complete data and immunization decision support, extraimmunization can be reduced. When considered in the context of averted extra doses for VFC-eligible children, these efficiencies can translate into dollars saved for the VFC program, which over time could become substantial.

Increased completion of these key data elements also translates to increased capacity of IIS to evaluate immunization delivery and develop more effective promotion strategies to reach underimmunized children. As described above, improved ability to evaluate coverage can support program efforts to target interventions to those understood to be chronically at risk for delayed immunization or underimmunization. The improved completion of race and ethnicity only increases IIS capacity even more to support Community Guide recommended strategies such as reminder-recall, home visits, and coordination of outreach with other health programs and physician specialties through consolidation of records, surveillance, and sharing of immunization information can strengthen the public health safety net and close gaps in coverage.

5.2 Study Strengths and Limitations

This study had key strengths and several limitations. One substantial strength of this study is that it used provider site-specific data. Because these data were queried and calculated by provider site, they allow more precise identification of the practice-level factors influencing data the completeness of data received in IIS via interoperable interfaces at the clinic level. With

further analysis, these data will continue to support the evaluation of the effects of EHR-IIS interoperability on immunization outcomes.

There are several limitations in this study. This study had a very small and non-random sample. The IIS selected, although not identified here, are ones that have high rates of child and provider participation compared to most IIS in the U.S. These results therefore are not generalizable, having been produced using data from IIS and provider sites that are more likely to experience positive change. Another limitation is that the quality of the data in the fields measured in this study was not assessed, only the completion of the fields. It is unknown whether or not the data in these fields was valid or not. This study is also limited by the extent to which the IIS followed the benchmarking logic guidance provided to them. The accuracy of the benchmarking data is dependent on IIS following the guidance correctly. And finally, these data were queried and reported by IIS, and as such were self-reported.

5.3 Implications of Findings

Data exchange between EHR and IIS, because of its potential to impact immunization decision-making for individuals and interventions for populations, has business and clinical implications for both providers and public health. This study, along with Schauer et al (2014), shows that EHR-IIS data exchange can yield an increase in IIS data critical for VFC program management and accountability and immunization program coverage analysis and evaluation. Provider office staff and EHR vendors play a key role in the success of EHR-IIS interfaces; providers are responding to the Meaningful Use incentive program, yet evidence suggests that simply implementing EHR is not enough to yield the intended benefits. Appropriate and accurate capture of demographic data to support outreach, reminder recall, and other analysis to help target immunization interventions to under-immunized populations is critical to closing gaps in

coverage and increasing overall population protection against vaccine-preventable disease. Lack of accurate address or other contact information was documented in the literature to be a barrier to receipt of reminder recall notices; although this study examined only four demographic data elements, other demographic data, such as address and phone number, may be positively impacted as well.

5.4 Recommendations for Future Research

EHR-IIS interfaces must be carefully tested to assure accurate immunization, demographic, and VFC-related data are captured in EHR and extracted appropriately for upload into IIS. Providers should be educated about the functionality of EHR and their capacity to support all aspects of their clinical practice, including immunization. IIS and immunization programs must communicate with provider office staff to assure key data are captured in EHR for transmission to IIS. Because little is known about provider attitudes concerning IIS, their confidence in IIS data and their immunization recommendations, research on provider opinions is critically needed. The capacity of EHR to support immunization data capture, as well as bi-directional capability and receipt and display of IIS-generated immunization recommendations should be examined. Other methods for examining the impact of EHR-IIS Interoperability on up-to-date status, such as evaluation of a static group of children, should be explored. Due to the value and importance of the VFC program, research must be conducted to determine the impact of IIS-based VFC eligibility and inventory tracking on the VFC program, and the additional impact of EHR-IIS interoperability on these crucial activities.

Additional analysis of EHR-IIS interoperability benchmarking data should be conducted. Potential analyses of these data include looking at outcomes by enhancement type, by IIS, by

EHR vendor, by HL7 version, by length of time since the implementation of an HL7 interface, and by prior IIS reporting method.

5.5 Conclusion

Immunization is an intervention proven to reduce illness save lives, yet challenges to achieving and sustaining adequate coverage remain. Lack of access, scattered documentation of immunization and constantly evolving vaccines and associated recommendations contribute substantially to suboptimal coverage. The VFC program, by eliminating financial barriers to immunization, seeks to improve protection in minority and poorer populations, yet participation entails many administrative tasks. As documented in the literature, immunization information systems can lower these barriers by supporting documentation, coverage analysis, and proven interventions to increase coverage. National health information technology policy is simultaneously driving the adoption of EHR by health care providers and supporting the exchange of immunization data between EHR and IIS, but the literature shows that simply implementing an EHR is insufficient to yield the desired benefits. These systems must be selected with careful thought to practice needs and implemented to ensure appropriate data capture both on the provider site and during extraction for transmission through an electronic interface. Little is documented about the effects of EHR-IIS interoperability on the data in IIS, but this study produced results that are consistent with published findings, specifically the increase in the completion of data fields key to VFC program management and coverage analysis for vulnerable populations. Additional research should be conducted to identify the factors contributing to successful EHR-IIS interfaces. IIS have the capacity to coordinate and harmonize the multiple components of immunization delivery in the United States, and by streamlining reporting to IIS, EHR-IIS

interoperability can accelerate the growth of IIS and, in turn, empower public health to assure equal protection against disease and disability associated with vaccine preventable disease.

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Appendix A

Table 6: IIS Core Data Elements (CDC, “IIS – Functional Standards - Vaccines,” 2012).

Patient ID (previously listed as “Medicaid Number”)	Patient Telephone Number Type (e.g., home, cell)
Patient ID: Assigning Authority ID (i.e., owning source)	Patient E-mail Address
Patient ID: Type (e.g., medical record number, IIS ID)	Patient status indicator—Provider facility level
Patient Name: First	Patient status indicator—IIS level
Patient Name: Middle	Vaccine Product Type Administered
Patient Name: Last	Vaccination Administration Date
Patient Alias Name: First	Vaccine Manufacturer Name
Patient Alias Name: Middle	Vaccine Lot Number
Patient Alias Name: Last	Vaccine Expiration Date
Patient Date of Birth	Vaccine dose volume and unit
Patient Gender	Vaccine Site of Administration
Patient Multiple Birth Indicator	Vaccine Route of Administration
Patient Birth Order	Vaccine Ordering Provider Name
Responsible Person Name: First	Vaccine Administering Provider Name
Responsible Person Name: Middle	Vaccine Administering Provider Suffix (e.g., MD, RN, LPN)
Responsible Person Name: Last	Vaccination Event Information Source (i.e., administered or historical)
Responsible Person Name: Relationship to Patient	VFC/grantee program vaccine eligibility at dose level
Mother’s Name: First	VIS Type & Publication Date
Mother’s Name: Middle	VIS Date given to patient
Mother’s Name: Last	Contraindication/Precaution(s)
Mother’s Name: Maiden Last	Contraindication/Precaution(s)Observation Date
Patient Address: Street	Exemption(s)/Parent Refusal(s) of Vaccine
Patient Address: City	Date of Exemption(s)/Parent Refusal(s) of Vaccine
Patient Address: State	Vaccine Reaction(s)
Patient Address: Country	History of vaccine preventable disease (e.g., varicella)
Patient Address: Zipcode	Date of History of Vaccine Preventable Disease
Patient Address: County of Residence	
Race	
Ethnicity	
Birth Facility Name	
Patient Birth State	
Patient Primary Language	
Patient Telephone Number	