

**Improving Immunization Rates for Hepatitis A and Influenza in a Federally Qualified
Health Center**

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Abstract

Vaccination has significantly reduced life-threatening diseases in children. Although the Advisory Committee on Immunization Practices (ACIP) which details when to vaccinate to best prevent illness is standardized throughout the United States, barriers to immunization exist in pediatric healthcare settings. Barriers to vaccination can include a lack of provider awareness of vaccinations resulting in missed opportunities. Computerized electronic alerts may serve to remind providers if vaccination is due, resulting in an increased awareness, and ultimately, increased immunization rates. This project implemented electronic alerts for hepatitis A and influenza vaccines in the electronic record system of an urban Federally Qualified Health Center, within the 6-24 months of age pediatric population in northern New Jersey. The aim of this quality improvement project was to determine if a *clinical decision support system electronic alert can improve immunization rates from baseline rates for hepatitis A and influenza vaccine in the pediatric population 6-24 months of age*. To measure the project outcomes, a pre-and post-implementation design was used where chart audits for hepatitis A and Influenza vaccination rates were conducted prior to implementation of electronic alerts, as well as chart audits at one and two months after implementation. Data analysis results indicate at alpha level $p < .05$, there were no statistically significant differences in hepatitis A ($p = .066$) or Influenza ($p = .841$) pre and post immunization rates. Pre and post immunization rates, however, indicated there was an increase in percentage for hepatitis A immunization rate (11.11%). Further investigation is necessary before a conclusion can be made on the effectiveness of electronic alerts on immunization rates.

Keywords: Immunization rates, clinical decision support system, electronic alerts, medical informatics, quality of care, hepatitis A vaccine, influenza vaccine

Introduction

Immunization by vaccination is one of the most effective ways to prevent disease (Ventola, 2016). The morbidity of diseases such as measles and mumps declined by 99.9%, as well as paralytic poliomyelitis which declined by an astonishing 100% due to vaccination. In addition, other diseases such as diphtheria, tetanus, and pertussis have notably decreased in morbidity, as well as, mortality due to immunization strategies targeting infants and children (Ventola, 2016). Vaccination even led to the eradication of smallpox on a global scale (Oldfield & Stewart, 2016). Approximately 21 million hospitalizations, 322 million illnesses, and 732,000 deaths were prevented among children in the United States (U.S.), born between 1994 and 2014 who were vaccinated, according to the Advisory Committee on Immunization Practices (ACIP) schedule (Whitney et al., 2014). The ACIP provides annual recommendations and guidelines for childhood and adolescent immunizations (Centers for Disease Control and Prevention [CDC], 2019). Financially, immunizations have saved U.S. society an estimated \$1.38 trillion dollars between 1994-2014 (Whitney et al., 2014).

Per Robison et al. (2010), approximately two-thirds of U.S. children under 24 months of age are not fully immunized, mostly due to missed opportunities. In addition, 2010–2013 National Immunization Survey (NIS) data analysis suggests that under-immunization for measles vaccines occurred for causes other than negative vaccine-related beliefs, which included missed opportunities (Smith et al., 2015). Missed opportunities are medical visits in which an individual is eligible to be vaccinated, but for various reasons which will be described later in this paper, are not vaccinated (CDC, 2019a). A factor that may play a role in under-immunization is ineffective or insufficient advice from health care providers. It is also possible that no recommendation is given at all by the provider (CDC, 2018b). Missed opportunities may have

the potential to account for vaccines noted to be missing frequently in children 6-24 months of age, such as hepatitis A and influenza.

A technology-based implementation to maximize immunization opportunities involves the use of the clinical decision system, which activates a prompt or alert within an electronic record system when a child has not received recommended vaccines (Ventola, 2016). Computer-based provider alerts are recommended by the American Academy of Pediatrics (2019) as a strategy to increase immunization rates (Strategies to improve immunization rates, 2019). The alert system can remind the provider that immunizations are due. This project implemented electronic alerts for hepatitis A and influenza in the electronic record system of a Federally Qualified Health Center in northern New Jersey within the 6-24 months of age pediatric population.

Background and Significance

Hepatitis A

In 1971, the largest outbreak of hepatitis A virus (HAV) in the U.S. was reported, which was 59,606 cases (CDC, 2018c). HAV is an enterically-transmitted picornavirus that is easily spread by the fecal-oral route (CDC, 2018c). The virus can also be spread by water, objects contaminated with HAV or food, and subject to certain conditions, can survive for months (Parrón et al., 2017). Once in the body, it replicates in the liver and after about 28 days of incubation clinical signs appear that include malaise, anorexia, fever, nausea, dark urine, abdominal pain, and jaundice (CDC, 2018c). Although not common, fulminant liver, cholestatic hepatitis, relapsing hepatitis, and death are devastating consequences of the disease (Parrón et al., 2017).

Children less than 6 years of age usually do not exhibit signs and symptoms of HAV, but can still spread the disease (CDC, 2018c). Children may also excrete the virus longer than adults (CDC, 2018c). In an effort to reduce the number of cases, in 1996, the ACIP recommended vaccination of persons at risk of HAV infection such as men who have sex with men, drug users (including non-injection), children in communities with increased rates of the disease, and international travelers (CDC, 2018c). In 2006, the ACIP recommended a first dose of hepatitis A vaccine for all children at 12 months of age and administration of a second dose six months later (CDC, 2018c).

From the time that these recommendations were established, the total number of HAV cases has dropped from an average of 31,000 cases of hepatitis yearly to less than 1,500 cases annually in the U.S. (CDC, 2018c). In addition, not only is morbidity and mortality significantly reduced with HAV vaccination, it is also cost-effective when cost analysis is applied by reducing HAV related outpatient visits, hospital admissions, and emergency room visits (Dhankhar et al., 2015). Children play an important role in transmission of HAV, as they mainly do not present with symptoms and infections that are not identified can easily infect others (Byrd et al., 2011). Hospitalization rates for hepatitis A in the U.S. were reduced by an estimated 68% when compared to the pre-vaccination period (prior to 1994), and ambulatory care visits were reduced by 40%. There was an estimated 68% decline in HAV related medical expenditures, which is valued to be approximately \$9.3 to \$29.1 million dollars in savings (CDC, 2018c).

Influenza

The Centers for Disease Control and Prevention estimates that since 2010, there have been 7,000 to 26,000 flu-related hospitalizations of children 5 years and under in the U.S. (CDC, 2018a). Children under two years of age are at high risk for influenza-related complications

which include pneumonia, bronchitis, sinusitis, ear infections, myocarditis, encephalitis, myositis, rhabdomyolysis, and multi-organ failure due to sepsis (CDC, 2019a).

In addition, a CDC study from 2005-2014 estimates that the yearly influenza vaccine has prevented approximately 40,000 influenza-associated deaths in the U.S. (CDC, 2019a). In the 2017-2018 influenza season, the CDC has estimated 11.5 million cases of influenza in children. Children from birth to four years of age had the highest medical visit rates as compared to all other age groups (13,389 per 100,000) (CDC, 2018e). The population that most benefits from the influenza vaccination include children ages six months through four years (CDC, 2019a). This age group is particularly vulnerable because they are more at risk for developing severe influenza related complications (Grohskopf et al., 2018).

Needs Assessment

Global Data

Globally, the vaccination rate was estimated at 85% in 2017 according to the World Health Organization (World Health Organization [WHO], 2018). Immunizations avert 2-3 million deaths every year (WHO, 2018). There are approximately 1.4 million hepatitis A cases a year worldwide (World Health Organization [WHO], 2019). In a modeling study analysis of 92 countries from 1999–2015, among children five years and younger, influenza-associated deaths ranged from 9,243 to 105,690 annually (Iuliano, et al., 2018). In the U.S., the CDC estimated the occurrence of death in and out of the hospital was greater than 600 influenza associated deaths in children for the 2017-2018 influenza season (CDC, 2018e).

National Data

The National Committee for Quality Assurance (NCQA), has separated immunization rates for children 6-24 months of age by type of insurance using the 10 immunization

combination standards, which shows that the U.S. rates in 2017 were 53.4% for healthcare maintenance organization (HMO) commercial insurance, 47.9% for preferred provider organization (PPO) insurance, and 35.4% for Medicaid healthcare maintenance organization. This FQHC project site uses the NCQA 10 immunization combination standards to determine immunization compliance in children 6-24 months of age. In the U.S., the hepatitis A vaccination rate among children 19-35 months of age for at least 1 dose was estimated to be 86% in 2017 (CDC, 2018d). The CDC (2018) estimates that in the 2017-2018 season, 67.8% of children ages six months to four years were vaccinated with the influenza vaccine in the U.S.

Statewide Data

Immunization rates was an estimated 69.3% in 2017 for the state of New Jersey in children ages 19-35 months of age (Healthy New Jersey 2020, 2019b). The CDC (2019), estimates that in New Jersey for the 2017-2018 season, 69.1% of children ages six months to 17 years were vaccinated with the influenza vaccine (CDC, 2018). In the state of New Jersey, the rate for hepatitis A vaccination coverage in 2017 among 19-35 months of age was 82.8% for at least one dose administration (CDC, 2018d).

Local/Project Site Data

At the pediatric primary care clinic setting of an urban Federally Qualified Health Center in northern New Jersey, according to the measure tracking system Mediquire, the immunization rate for ages 6-24 months is 28%, decreasing from the last quarter. However, with a manual chart review of 70 randomized pediatric patients for the same age group (6-24 months of age) the immunization rate is 50%. There are discrepancies that exist with documentation between immunization registries and documentation on the electronic record system that may interfere with the accuracy of the Mediquire system, such as clinical staff incorrectly documenting a

vaccine, or failure of the systems to interface with each other. The quarterly manual chart reviews indicate that the most common trends of vaccines missing or given after 24 months include hepatitis A and the influenza vaccines. Although other vaccines can make a patient non-compliant if they were not given as scheduled by guideline, for the purpose of this project, hepatitis A and the influenza vaccines were the two vaccinations assessed for changes from baseline immunization rate with implementation of alerts. These two specific vaccines were used as a pilot test run mainly because setting parameters is less complex within the EMR system, and this decreases the chances that an alert was triggered incorrectly.

The data from the NQCA (2018) suggests a disparity in immunization rates according to insurance, which suggests that socioeconomic factors can be a barrier to immunizations. No data from NCQA was available for the uninsured using the 10 immunization combination standards for ages 6-24 months. However, data from a 2017 National Immunization Survey-Child report suggested that for uninsured children ages 19-35 months had a lower immunization rate in 2016 for having two doses of Hepatitis A vaccine as compared to insured children (Medicaid commercial, or other insurance) (Hill et al., 2017).

Therefore, it is important to vaccinate at every opportunity and avoid encounters where a patient is eligible to receive vaccines but do not. It may be especially true in a Federally Qualified Healthcare Center where most of the population served are underinsured, have no insurance (2,609), or have Medicaid (10,809) (Metropolitan Family Health Network Annual Report, 2019). The mission statement of the project setting is “to provide high quality, accessible health care to the under-served population in our community, regardless of their ability to pay”. The DNP project setting served approximately 54,620 patients in 2017, and a large proportion (17,082) were pediatric encounters (MFHN Annual Report, 2019). This project aligns with the

mission of the clinic, by increasing immunizations, and simultaneously improve the quality of care.

Problem/Purpose Statement

Child mortality and morbidity are greatly reduced through vaccination. In addition, immunization has also reduced costs to the healthcare system by preventing disease. However, there are barriers to vaccination of children in pediatric primary care settings, including "missed opportunities" (Robison et al., 2010, p. 2). Reasons for missed immunization opportunities include hesitation by parent or provider to give multiple vaccines simultaneously, clinic policies, provider contraindication belief, reimbursement, and lack of awareness of immunization schedule knowledge (CDC, 2019a).

To improve provider awareness, a clinical decision system via automatic electronic prompts, was implemented to ultimately increase the rate of hepatitis A and influenza immunization for children ages 6-24 months. Studies and literature reviews such as Zimet et al. (2018) and Ventola (2016) suggest that immunization rates and compliance by providers can be increased with the use of clinical decision systems. It is also recommended as a strategy by the CDC (2018a), to increase immunization rates and lessen missed vaccination opportunities. This project improved the visibility of hepatitis A and influenza vaccines for the provider to increase immunization rates.

Clinical Question

Among the pediatric population 6-24 months of age, how effective is a clinical decision system alert in increasing immunizations rates for hepatitis A and influenza vaccines over a two-month time span?

Aims and Objectives

The principal aim of this quality improvement project was to increase hepatitis A and influenza immunization rates through the use of clinical decision system (CDS) alerts embedded in the electronic record system. This alert served as a reminder for healthcare providers in a Federally Qualified Health Center.

Objectives for this project were as follows:

- To discuss with stakeholders (Quality Assurance, Information Technology (IT), Chief Medical Officer) the terms, implications, and feasibility of implementation of the project
- To conduct a pre-implementation chart audit to obtain immunization rate baselines for hepatitis A and influenza vaccines for children ages 6-24 months
- To implement activation of clinical support system alerts for pediatric patients in need of hepatitis A and influenza immunization within the electronic record system (Greenway EHS) with the help of IT to:
 - Test functionality of the alert system
- To make providers (Pediatric Physicians and Advanced Practice Nurses) aware of the use of alerts and administration of hepatitis A and influenza vaccines by discussing the project while obtaining consent
- To conduct a post-implementation chart audit to verify the change in immunization rates at one and two months after implementation

Review of the Literature

Search Strategy

Data sources in the search of literature examining electronic alerts and their effectiveness on immunization rate were found by the co-investigator in February 2019 using databases that included Cumulative Index to Nursing and Allied Health (CINHAL), PubMed, ScienceDirect, and Google Scholar. A research librarian did not assist in the development of this search strategy. These databases were used to search for the effect of electronic prompts or alerts on immunizations rates to answer the clinical question “Among the pediatric population 6-24 months of age, how effective is a clinical decision system alert in increasing immunization rate for hepatitis A and the influenza vaccine over a two-month time span?”.

The search on CINHAL was facilitated by using the subject heading function. Subject headings such as “electronic alerts improving immunization rates”, generated 10 results and 2 articles were used and added to the evidence table. PubMed database search included key term classes (“Electronic Alerts” [MeSH] OR electronic alerts...) AND “Improving Immunization Rates in Children” [MeSH]...) which generated 816 results. To refine the search, the subject heading included “alerts to improve immunization rates” and resulted in twelve results. Two of these articles in this database search were added to the evidence table.

The search engine ScienceDirect generated 1,008 results with the terms “electronic alerts to improve immunization rates”. The search was refined by limiting the studies to the last five years and research articles only. This yielded 56 results of which five were chosen for this review as they were the most relevant to the project implementation. In the search on Google Scholar, the advanced search feature was used for the phrase “electronic alerts for needed vaccinations”, which was filtered to be from the last five years (2015-2019). This yielded two results, of which one article was chosen and added to the table of evidence review as they were the most relevant to the project implementation.

The inclusion criteria included English text only, studies limited to the United States, articles that were full text, expert opinion, non-research works, original research studies and systematic reviews in peer-reviewed journals that studied the effects of electronic alerts/prompts on immunization rates. Most searches included the key terms “immunizations”, “vaccination” “rates”, “improving”, “increasing” “children”, “electronic” or “provider”. Due to lack of studies conducted in the past five years, the adult population was also included in all searches at one point.

Benefits of Hepatitis A and Influenza Vaccination

Per Murphy et al. (2016), hepatitis A virus (HAV) outbreaks occur in the U.S. usually due to children that are infected but are asymptomatic and spread the disease to adults such as child caregivers. Worldwide, the incidence of HAV is much greater than in the U.S., the lower U.S. incidence is primarily due to the establishment of recommendations of childhood hepatitis A vaccination (Murphy et al., 2016). In 1996, the annual rate of hepatitis A cases was 11.7 per 100,000 population in comparison to 2003, after the recommendation for hepatitis A vaccine was established by the ACIP for years, the annual rate declined to 2.6 cases per 100, 000 population (Murphy et al., 2016). The successful effectiveness of the hepatitis A vaccine in creating immunity against HAV is one of the important reasons to continue to promote vaccination.

Vaccination is suggested to best protect against influenza in all age groups, as well as for reducing the burdens that follow the disease (Ruf & Knuf, 2014). In a 2010-2014 case cohort analysis of children 6 months to 17 years of age, it is suggested that influenza vaccination was associated with risk reduction of influenza-associated death. Rates for complications were also reduced in those who are vaccinated against influenza and includes respiratory illness in children

with asthma, and markedly reduced the incidence of otitis media (Block et al., 2011; Ruf & Knuf, 2014).

Electronic Alerts in Inpatient Settings

A study that supports the use of electronic alerts to improve immunization rates was conducted by Erst (2017). This retrospective study was intended to determine if the development and implementation of electronic alerts would increase immunization rates in a neonatal intensive care unit. The alert was set up to be activated for patients who were between 56 days of age and 62 days of age when 2-month-old vaccinations were due. Pre- as well as post-implementation chart reviews were conducted and demonstrated a 23% increase in immunization rates in the timespan of 90 days of post-implementation of alert ($p < 0.0001$) (Erst, 2017). Findings of this study are one of the most dramatic increases in immunization rates compared to the many other studies searched and suggests the potential electronic alerts can have upon implementation. However, one of the key differences is that this study was conducted in a hospital setting, which is different from the primary care clinic setting where this DNP project took place.

Electronic Alerts in Outpatient Pediatric Urban Settings

This review of literature also includes a 2007 study which is significantly older than any of the articles presented within the table of evidence in Appendix M. The patient population within the implementation study conducted by Fiks et al., (2007), was ages 6-24 months. The population was also considered an “urban pediatric population” in primary care centers. The implementation consisted of implementing alerts that would appear if immunization was due for children under 2 years. The development of the alert excluded a function that would force provider compliance in order to avoid disruption of current workflows. The study used chi-

square analysis to compare historical control patients ($n=1,548$) and implementation patients ($n=1,669$) with p values ≤ 0.05 considered to be significant. The results were that immunizations had increased from a baseline rate of 80.1% to 90.1% for well-child visits. The immunization rate also increased threefold from the baseline rate (13.2%) to 37.4% for sick visits and other non-well child visit related encounters (Fiks et al., 2007).

Per Bundy et al., (2013), newer recommended immunizations such as hepatitis A are more likely to see a significant increase in immunization rate with electronic medical record clinical decision support (CDS) in an urban pediatric setting. This may be due to its generally low uptake, as well as its narrow margin of time which the vaccine may be given before the age of two. This study uses the Healthcare Effectiveness Data (HEDIS) measures to determine what vaccines are considered full immunization status for children 6-24 months, and are the same requirements as the NCQA, with the exception of the influenza vaccine. Although the CDS prompt to alert providers at the point of care did not significantly increase other vaccine immunization rates which were already historically high to begin with, hepatitis A vaccine was statistically significant for improvement of immunization rate from baseline. This finding may suggest that the implementation of electronic alerts by reminding the provider that vaccination is due, may also reduce missed opportunities, which would allow for any missing vaccinations such as hepatitis A or the influenza vaccine to be administered instead of just focusing on vaccination in well-child visits only.

Electronic Alerts and HPV Vaccination

As mentioned previously, it is suggested from studies such as Bundy et al., (2013), that more novel vaccines may benefit the most from electronic alerts that appear at the point of care. Therefore, many more studies on this electronic medical record feature have been conducted on

vaccines such as the human papilloma vaccine (HPV) which has been recommended more recently (as compared to other vaccines) by the ACIP since 2006 (Ventola, 2016).

A retrospective cohort study conducted by Ruffin et al. (2015), suggested similar results when an electronic medical prompt was implemented in two community-based family practices for HPV vaccination among female patients ages 9 through 26 years of age. The results suggested that the prompted cohort had a significant ($p<0.001$) initiation of HPV vaccination (34.9%) when compared to the unprompted cohort (29.9%). The prompts, however, more actively involved the provider, as the alerts required the outcome to be documented by clicking the course of action taken, which was either “done, ordered, patient declined or not addressed” (Ruffin et al., 2015, p. 326). Although active prompting demonstrated higher initiation rates, it may not support provider workflow as suggested in Fiks et al., (2007).

Studies such as the randomized clinical trial conducted by Zimet et al. (2017), focused on provider reminders for HPV vaccination. In this study, patients 11-13 years of age in five pediatric clinics were randomized and were either given usual practice (control), the implementation of “simple health provider reminder prompt”, or implementation of “elaborated health provider prompt”. These reminder prompts were computer generated, printed out and given to the provider for review at the patient encounter. The simple provider prompt which consisted of reminding of vaccines that may be due such as HPV, the tetanus vaccine (Tdap), and Meningococcal vaccine for strains A, B, C, W-135, and Y (MenACWY). The elaborate prompt was designed to be similar, except that it included the patient's name and suggested an educational message on the beginning that read “Three vaccines are recommended for <first name>, meningococcal to prevent Meningitis, HPV to prevent cancer, and Tdap to prevent tetanus. All three are recommended at this age”. The results suggested that the elaborate prompt

improved HPV rates significantly (17%) as compare to the control and the simple prompts (14%) (Zimet et al., 2017).

Provider Perception of Electronic Alerts

A follow up qualitative study of healthcare provider's perception of electronic alerts in the randomized control trial by Zimet et al., (2017), was conducted by Dixon et al., (2017). One noteworthy theme identified was reasons for non-use of CDS reminders, because it highlighted quotes from providers that described their dissatisfaction with the prompts. An example of this would be that the providers expressed there was an interruption of workflow because they found it to be a hassle to look back and forth between paper and computer. It is suggested in this study that there may be more efficient ways to present alerts to providers and further studies should be conducted to evaluate the effects on vaccination (Zimet et al., 2017).

Another qualitative study conducted by Birmingham et al. (2011) also gave insight to what was desired in electronic alerts for influenza vaccination. The results from thematic analysis of the focus group questions and semi-structured interviews suggested that providers wanted alerts that would allow for reminding of influenza vaccination at the beginning of the medical visit. The alert's accuracy in determining eligibility for vaccination from multiple sources (such as immunization registries), ability to assist with vaccine ordering as well as for the ability for the alert to generate appropriate documentation for refusal of vaccination were also preferences expressed by the providers. In addition, the providers expressed that a barrier to vaccination against influenza is failing to vaccinate during sick visits (Birmingham et al., 2011).

Electronic Alerts and Other Populations

A recent study conducted by Hechter et al., (2019) which implemented electronic alerts for patients 19-59 years of age with diabetes, in need of hepatitis B vaccination, suggests a 70-

fold increase in this vaccine administration over a 12- month time span which was statistically significant (12.3% pre-implementation to 66.6% post-intervention). A control site was included and stayed relatively the same in hepatitis B immunization rate. The alert was designed to appear once a patient's chart was opened and would require action from the provider to dismiss or order the vaccine (Hechter et al., 2019). Although this study was conducted in an adult population with a specific condition, it does support the use of clinical decision support in the form of alerts for a reminder of vaccine administration to ultimately increase immunization rates.

Using Information Technology to Increase Immunization Coverage

In a review of literature compiled by Stockwell and Fiks (2013) the different strategies that can be used from information technology are discussed and includes provider focused clinical decision support systems. Again, the dilemma of missed opportunities for vaccination is stressed, and the literature points out that they occur excessively in children with Medicaid insurance. Stockwell and Fiks (2013) noted that systematic reviews of the literature suggest that electronic alerts are most effective when they provide specific recommendations such as the type of vaccines missed rather than messages that simply state the child is delayed in immunizations. Studies are also cited by Stockwell and Fiks (2013) where electronic alert systems are able to maximize the chances that the provider will immunize at visits other than well-child visits (Stockwell & Fiks, 2013). A review composed by Ventola (2016) examined measures to improve compliance for immunizations, including healthcare-provider interventions such as electronic alert systems. This review cites two studies and one randomized control trial that support the use of electronic alerts to increase immunizations. Maximizing opportunities to vaccinate at all child visits is also a suggestion made in this article (Ventola, 2016).

Synthesis of the Literature

Studies discussed previously have described the negative impact of the influenza virus in the very young children and infants (Allison et al., 2006; Block et al., 2011; Ruf & Knuf, 2014), and the importance of vaccinating for hepatitis A in this population (Murphy et al., 2016). The evidence from various types of studies assessing the use of electronic alerts in improving immunization rates has been considered and examined in detail. The evidence suggests that electronic alerts may be effective in increasing immunization rates (Bundy et al., 2013; Erst, 2017; Fiks et al., 2007; Hechter et al., 2019; Ruffin et al., 2015).

Studies also suggest that the “electronic” nature of this alert may allow for minimal disruption of the current workflow of providers, and may lead to easier acceptance of the implementation (Birmingham et al., 2011; Dixon et al., 2017). In addition, when the implementation of electronic alerts was used for increasing newer vaccines, which fits the description of vaccines such as hepatitis A, studies indicate that this project was appropriate for the purpose of increasing immunization rate in this particular vaccine (Bundy et al., 2013; Ruffin et al., 2015; Zimet et al., 2017).

Theoretical Framework

The Plan-Do-Study-Act (PDSA) framework was initially developed by Walter A. Shewhart as a process of constant and methodical improvement (Donnelly & Kirk, 2015). When used in healthcare, it is ideal for quality improvement projects, as they continue in cycles, and in each cycle, the change/implementation is more refined or adjusted to the needs of the setting. PDSA models have also been studied in research, with positive findings when assessed with models of evaluation (Donnelly & Kirk, 2015).

PDSA is the framework that is selected for this quality improvement DNP project. The planning portion of the cycle included developing an electronic alert for hepatitis A and

influenza vaccines with the aid of information technology staff using evidence-based recommendations and practices. This project was done with the plan of evaluating the effectiveness of electronic alerts on these specific vaccine immunization rates. In planning, annual chart audits were reviewed in order to assess for need and to identify how to develop an efficient alert. Once need was identified, the feasibility of the project was discussed with stakeholders (e.g. information technology, administrators, quality improvement). In the "Do" portion of the cycle, pre-implementation was collected by chart audits of the past three months to obtain baseline data. Introduction and education to pediatric providers (physicians and advanced nurse practitioners) of use of electronic vaccine alert was delivered at the time of obtaining consent for participation in the study. After implementation of alert for one and two months, data was collected by post-implementation chart audit and analysis took place to evaluate the effect of electronic alert on immunization rates of hepatitis A and influenza vaccine in the pediatric population ages 6-24 months. The "Act" portion of the cycle consisted of identifying how the project can be further refined for improvement of the alert in further PDSA cycles, or to decide whether implementation should continue to be sustained. A visual representation of the framework for this project can be found in appendix section (see Appendix B).

Methodology

Project Design

This quality improvement project used a pre-and post-implementation design approach. Chart audits were conducted immediately prior to implementation of electronic alerts for hepatitis A and the influenza vaccine to establish a baseline immunization rate. They were also conducted at one and two months after implementation of the electronic alerts. The framework for this quality improvement project followed a Plan-Do-Study-Act model.

Setting

The project setting was in a Federally Qualified Health Center (FQHC) in northern, New Jersey. Primary care services for adults, pediatrics, gynecology, and obstetrics are available at this site. Pediatrics had approximately 17,082 visits which accounted for the most visits in 2017 out of all visits at the FQHC (MFHN, 2019). The total population of the city in which the clinic is located was 270,753 in 2017 (U.S. Census Bureau, 2018). Racial demographics of the area were 35.4% White, 28.8% Hispanic/Latino, 25.4% Asian, and 24.0% Black/African American (U.S. Census Bureau, 2018). This clinic is also equipped with a laboratory and pharmacy. Patients who do not have insurance or are underinsured are provided services and are charged an income-based fee. This facility is also recognized as a patient centered medical home (PCMH) by the National Committee for Quality Assurance (NCQA). During 2017, approximately 16,670 patients used the medical services at the clinic, in which 35% were male and 65% were female (MFHN, 2019).

Study population

The study populations in this quality improvement project were the pediatric population from 6-24 months of age, and four full-time pediatric physicians. Inclusion criteria for this pediatric population consisted of chart records for 6-24 months of age that were seen for a medical visit by a healthcare provider in the 2-month time span of (10/01/2018-11/30/2018), and the chart records for 6-24-months of age that were seen for a medical visit by a healthcare provider in the 2-month time span of (10/01/2019-11/30/2019). Exclusion Criteria included the chart records for children under 6 months of age or over 24 months of age in the time frames specified above. Patients with documented refusals of all vaccination or out of stock vaccine events were not calculated in the hepatitis A vaccine pre and post immunization rates. Patients

with documented refusals for influenza vaccination and or all vaccines as well as documented out of stock vaccine events were not included in the calculation of influenza vaccine pre and post immunization rates.

Inclusion criteria for Pediatric healthcare providers consisted of pediatric physicians, pediatric nurse practitioners or family nurse practitioners that are employed to work as pediatric healthcare providers at the project site. Exclusion criteria included other healthcare providers not authorized to work with the pediatric population.

Pediatrics had approximately 17,082 visits which account for the most visits in 2017 out of all the types of visits at the FQHC (MFHN, 2019). The total population of the city in which the clinic is located was 270,753 in 2017 (U.S. Census Bureau, 2018). Racial demographics of the area are 35.4% White, 28.8% Hispanic/Latino, 25.4% Asian, and 24.0% Black/African American (U.S. Census Bureau, 2018).

The sample size for chart audit was calculated using Raosoft sample size calculator which determines sample size using a 95% confidence interval, with the estimated known population size of 650 (generated from a project site report indicating the number of patients 6-24 months of age seen for medical visits from October 2018- November 2018) and margin of error of five percent (Sample size calculator, 2004). The pre-implementation baseline chart audit consisted of a calculated sample of 250 charts selected out of 500 patient charts. The same methods which included sample size generation by Raosoft were used to determine the immunization rate for hepatitis A and influenza vaccination in the post-implementation chart audit.

Subject Recruitment

The subjects in this project for recruitment included four full-time pediatric physicians. No other person was involved in the recruitment process except for the co-investigator. The providers were asked if they would agree to participate in the study by the co-investigator.

Consent Procedure

Healthcare provider participation in this project was completely voluntary. Retractable consent was given to participate in the project by having the providers sign a consent form (see Appendix E). They were also provided a copy of the consent form containing information about the project and contact information of the co-investigator, principal investigator, and Rutgers Institutional Review Board. A waiver of consent was obtained and approved by Rutgers Institutional Review Board for the chart audit conducted on the patient charts.

Risks, Harms, and Ethics

This DNP project posed a minimal risk for the study population (pediatric patients 6-24 months of age) and the pediatric healthcare provider participants. Risks included unintended disclosure of patient information during data collection, study burden for providers and interruption of workflow.

Challenges of the clinical decision support system also included that while providers may have agreed that alerts should be implemented for preventative services, they were still having trouble establishing the time the alerts appeared as each provider's workflow varied. This may lead to the question if the bypass or misuse of alerts can have legal implications for clinicians. However, it was possible to minimize these challenges by using a CDS system that was well-developed. As per Greenberg and Ridgely (2011), the use of a well- designed CDS system could reduce overall malpractice risks

Unintended disclosure of patient information was prevented by having any links with patient identifiers destroyed. The chart audit was conducted the same day that the patient medical record numbers were obtained. No recording, coding or storage of the medical record identifiers was needed. This project posed minimal risk for the study population (pediatric patients 6-24 months of age) and the pediatric healthcare provider participants. In this project, there was no immediate, potential or long term physical, psychological, social, financial or reproductive risk for study population (pediatric patients 6-24 months of age) and the pediatric healthcare provider participants.

It is necessary to assess the risks and benefits of this project to weigh in on ethical dilemmas. As legality and ethics are almost always part of translational science, this project does have implications such as to what extent pediatric healthcare providers should rely on these prompts when making decisions on a pediatric patient's health. However, studies such as Zimet et al., (2018) and Ventola,(2016) suggest that immunization rates may be increased with the use of clinical decision systems in place. This quality improvement project also has measures to minimize these risks such as making pediatric healthcare providers aware to not rely only on electronic alerts for vaccination(s) due and to cross check with other sources such as immunization registries. Testing with the aid of information technology staff the electronic alerts to ensure proper functionality and that it target the correct patients also minimized risks. This implementation along with increasing rate of immunization for hepatitis A and influenza, may decrease child morbidity as well as mortality of preventable disease, which may outweigh the risks and ethical implications of this project. In addition, this project was processed by the Rutgers Institutional Review Board and was deemed an exempt minimal risk study.

Subject Costs and Compensation

There were no subject or participant cost or compensation/ incentives in this project.

Study Interventions

Baseline immunization rates (pre-implementation), and post-implementation immunization rates for hepatitis A and the influenza vaccines were obtained by chart audit from the Greenway EHS medical record system with the aid of the generated reports. These were collected on the first data abstraction form in September 2019. The second data abstraction form was used to gather information during the chart audit and only contained de-identified patient information. Baseline immunization rates for hepatitis A and the influenza vaccines were assessed through an audit of the patient chart. The chart audit tool also collected demographic information such as age, gender, and race. Pre-implementation hepatitis A and Influenza rates were taken from the same months the alert was implemented (October and November) of the previous year (2018) for patients ages 6-24 months.

Post implementation data collection (immunization rates for hepatitis A and the influenza vaccine) occurred at one and two months after the implementation of alerts in the EMR. Post implementation immunization rates for hepatitis A and influenza vaccines were obtained by chart audit through the electronic medical record. Compliance was assessed by the same chart audit tool that was used for baseline rates. Demographic data was collected including age, gender, and race for patients ages 6-24 months.

Outcome Measures

The pre-implementation baseline chart audit consisted of a calculated sample of 250 charts selected out of 500 patient charts. The same methods which included sample size generation by Raosoft were used to determine the immunization rate for hepatitis A and

influenza vaccination in the post-implementation chart audit. A chart audit tool created by the co-investigator was used to organize the information as well as select uniform information from the patient chart. This information included age in months, ethnicity, gender, if at least one dose of hepatitis A vaccine was administered, and if the influenza vaccine was given for the current influenza season.

Project outcomes were measured by a pre-and post-implementation chart audits for hepatitis A and Influenza vaccination rates. The measured outcomes for this project were pre-and post-hepatitis A and influenza immunization rates. Chart audits were conducted prior to implementation of electronic alerts, as well as chart audits at one and two months after implementation. The data from these chart audits was de-identified from the initial primary chart audit tool and gathered with the aid of the secondary chart audit tool. The data was analyzed using chi-square tests in SPSS version 26 software to assess for statistical significance between pre-and post-immunization rates. Simple percentage analysis was also conducted to assess for change between pre-and post-immunization rates.

Project Timeline

The project commenced in June 2019 when project proposal took place and was approved. The project was implemented in October of 2019 and continued for two months. Pre-implementation chart audit was conducted in September 2019 for immunization rates and the post-implementation chart audit was conducted after one and two months of implementation. The final post-implementation chart audit was conducted in December 2019. Data was analyzed in January 2020, and evaluation/writing took place in February 2020. Poster presentation, final paper and dissemination occurred in April 2020. A visual representation of the project timeline can be found in the appendix (see Appendix A).

Resources Needed

All costs associated with the project which include dissemination posters were held accountable to the co-investigator alone. The projected expenses and budget can be viewed in the appendix (see Appendix C).

Evaluation Plan

This project was further evaluated by the Plan-Do-Study-Act process. The planning aspect of the process involved recognition for the need of improvement of immunizations rates within the project setting, and further investigation leading to the identification of the specific type of vaccine associated with under-immunization within the 6-24 month pediatric population. Once the need was identified, planning also consisted of searching the literature to develop a strategy to increase immunization rates for specifically hepatitis A and influenza vaccines based on evidenced-based practices. The electronic alert was selected as a strategy due to recommendations by the American Academy of Pediatrics (2019), the CDC (2018b), and per studies that have suggested a positive effect on immunization rates when implemented in a clinical setting (Bundy et al., 2013; Erst, 2017; Fiks et al., 2007; Hechter et al., 2019; Ruffin et al., 2015). Discussion with stakeholders on feasibility of the project was also part of the planning stage of the cycle.

Testing for the functionality of the electronic alert, obtaining baseline immunization rate by chart audit and activation of the alert on the computers of providers were part of the project planning . Analysis of pre- and post implementation chart audits after two months of activation of electronic alerts was the study portion of the PDSA process. Evaluation of the project was the act portion of the PDSA framework. Identification of adjustments to better fit the needs of the project site can serve to improve the implementation in further PDSA cycles. The framework

also assessed for barriers or facilitators and unintended consequences, which are discussed further in the implications section of this paper.

Data Analysis

As pre-implementation and post-implementation chart audit was conducted, a simple percentage analysis was used to calculate the percentages to determine the immunization rates for hepatitis A and the influenza vaccine. To further analyze this data, a chi-square test was used to obtain outcome measures from the population (6-24 months of age) in this project. SPSS version 26 software was used to analyze the data collected and evaluate the effect on immunization rates from baseline. Given that the two groups (pre and post) do not contain the same patients, other factors were not controlled, and the interest was in testing the number of Yes/No cases for each of the 2 types of vaccinations the use of Chi-Square was appropriate. Demographic data was analyzed by simple percent analysis.

Maintenance and Security

Authorized reports were generated by information technology staff from the project site and from Greenway EHS medical record system. Only the medical record identifiers of the 6-24 month population was used to look up patients in the electronic medical record system for chart audit. The chart audit was conducted the same day that the patient medical record numbers were obtained, and were always be in the possession of the co-investigator. They were destroyed immediately after the audit was conducted. No coding or storage of the medical record identifiers was necessary. The de-identified data was kept in a locked office in a password protected computer at the project site. Signed consent forms were kept in a locked office cabinet in a locked office at the project site. Aggregate data and hard copies of the consent forms will be stored at the Rutgers School of Nursing, 11th Floor - Office 1126, 65 Bergen Street, Newark,

New Jersey 07107 as required for record retention by the Rutgers Office of Information Management.

Project Management

The primary investigator, Dr. Sallie Porter, as Rutgers faculty with extensive experience working with infants and young children with special healthcare needs and chair of this Doctor of Nursing Project, oversaw as well as added to the development and execution of this project. Team member Dr. Melanie Percy who also contributed to the development of the project, is a Rutgers faculty member as well and has done research on resilience in low-income children.

Results

Data analysis results including the hepatitis A and influenza immunization rate percentages as well as statistical significance values are presented in this section. In addition to the analysis of immunization rates, the demographic data of the 6-24 month pediatric population such as age, sex, race and ethnicity are also presented. Pre-implementation chart review occurred in September 2019, shortly before the activation of electronic alerts on the computers of four pediatric physicians on October 1st, 2019. A chart review was conducted one month post-electronic alert implementation, and a second chart review occurred after the second month of implementation. The project was implemented October 1st, 2019 through November 30th, 2019. The healthcare providers were given the consent to read and ask questions of the co-investigator. The consent process lasted about 10-15 minutes.

The chart audits were conducted on a total of 477 charts from the 6-24 month pediatric population for both pre- and post-implementation. Approximately 4.1 % ($n = 20$) of the total charts audited had a documented refusal for influenza vaccination. Documented refusal patients

($n = 20$) were excluded when calculating the influenza immunization rates for both pre-implementation and post-implementation. Patients with a documented refusal for all vaccines ($n = 13$) were also excluded from the calculation of all immunization rates (pre and post). For patients with documentation that the hepatitis A and/or influenza vaccines were out of stock, which was approximately 1 % of all charts audited, were excluded from immunization rate calculation (pre and post). Accounting for omission of refusal and out of stock circumstances, a total of 458 patient charts ($n = 458$) were included for the calculation of hepatitis A and influenza vaccine immunization rates (pre-implementation $n = 240$ and post implementation $n = 218$).

Demographics of 6-24-Month Pediatric Population

Collection of demographic data for the sample ($n = 458$) demonstrated that this pediatric population was 48.68% female and 51.31% male when calculating from pre-implementation and post- implementation samples. Demographic information for race and ethnicity for the sample including pre-implementation and post-implementation showed that the population ($n = 458$) was 46.68% Black or African American/ not Hispanic or Latino, 33.40% White/Hispanic or Latino, 12.44% Asian/not Hispanic or Latino, 3.05% were Black or African American/Hispanic or Latino, 2.18% were White/ not Hispanic or Latino, less than 1% were Multiple races/not Hispanic or Latino, and less than 1% of the sample population were American Indian or Alaskan Native/ not Hispanic or Latino. The mean age was 13.7 months.

A patient was considered compliant for hepatitis A vaccination if they had received at least one hepatitis A vaccine after 12 months of age on or before the date of medical visit, (between October 1st, 2018 to November 30th, 2018 in pre-implementation, and October 1st, 2019 to November 30th, 2019 in post-implementation). A total of 129 patients were eligible to receive

the hepatitis A vaccine (12 months and older) and were used for calculation of hepatitis A pre-intervention rates. Post-intervention, 138 patients met the criteria for eligibility to receive hepatitis A (12 months and older) and were used in the calculation for hepatitis A post-intervention rates.

Compliance for the influenza vaccination was confirmed if the if patient had received at least one Influenza vaccine after 6 months of age for the 2018-2019 influenza season on or before the date of medical visit. In this study the medical visits were between October 1, 2018 to November 30, 2018 in pre-implementation, and October 1, 2019 to November 30, 2019 in post-implementation.

Data was analyzed using SPSS v.26 and a chi square test was run to evaluate whether the increase in immunization rates for hepatitis A or the influenza vaccine was significant. At the alpha level of ($p < .05$) to be statistically significant, changes in pre and post immunization rates for hepatitis A were not statistically significant ($p = .066$) (refer to Appendix G). Similarly, the changes between pre- and post-implementation were not statistically significant for the influenza vaccine ($p = .841$) (refer to Appendix H). The calculation of percentages for immunization rates however, demonstrated the hepatitis A vaccine did increase in overall immunization rate from 51.93% (pre-implementation rate) to 63.04 % (post- implementation rate) (see Appendix F, Figure 2). The influenza vaccine did not demonstrate an increase in overall immunization rate post-implementation of electronic alerts (see Appendix F, Figure 3).

Discussion

Results

This two-month long implementation which involved electronic alerts activated on the computers of four pediatric providers as a reminder to vaccinate for hepatitis A or/and influenza

for an eligible child, resulted in no statistically significant differences in hepatitis A or Influenza pre and post immunization rates. An increase in percentage for hepatitis A immunization rate (11.11%) may have been expected as supported by the literature, Bundy et al., (2013) and Ruffin et al. (2015), where newer recommended immunizations such as hepatitis A and HPV were more likely to see an increase in immunization rate with electronic alerts/prompts in similar pediatric primary care settings. This was explained in the literature as possibly due to the vaccine's generally low uptake.

In pre-implementation, children who were 23 months of age were the highest percentage compliant for the hepatitis A vaccine (13%), and children who were nine months of age were the highest percentage complaint for the influenza vaccine (11.76%). In post-implementation, children who were 15 months of age were the highest percentage compliant for the hepatitis A vaccine (14.9%), and children who were also 15 months of age were the highest percentage complaint for the influenza vaccine (12.28%). This may indicate that for the hepatitis A vaccine, the implementation of electronic alerts has allowed for more prompt vaccination.

There was an increase in hepatitis A vaccination given on the date of medical visit, with more than a 50 % increase from baseline percentage. This finding may suggest that the implementation of electronic alerts, reminding the provider that vaccination is due, may reduce missed opportunities, instead of solely focusing on vaccination at well-child visits (Fiks et al., 2007). This is also supported by a month to month data analysis of Hepatitis A rates that demonstrated an increased trend of vaccine compliance from 53.65% in month one of pre-implementation and 48.93% in month two of pre- implementation to 58.82% in month one of post-implementation and 69.81% in month two of post-implementation. This trend was taken from the same data collected for pre-implementation for as well as the data collected one and two

months after implementation. A visual representation of this trend can be viewed in the appendix (see Appendix F, Figure 2).

Influenza vaccine had an overall decrease in percentage of vaccination given on date of medical visits from 50% pre-implementation rate to 47% post-implementation. The data analyzed month by month however, showed a trend of increased uptake for the influenza vaccination given on same day of medical visit in the second month post-implementation, which was 51.16%. Data analyzed month by month for influenza vaccine immunization rates show a decline in rates for pre-implementation rates from 58.50% in month one, to 55.55% in month two.

Post- implementation rates for influenza demonstrated a decreasing trend in month one with a rate of 51%. At the second month, post-implementation, influenza immunization rate had an upward trend (63.95%) (see Figure 3). It was observed that there was an increased frequency of vaccine refusal (both for influenza and for all vaccines) in the first month vs. the second month of post-implementation. There were also more vaccine refusals (both for influenza and for all vaccines) in the post-implementation chart sample overall compared to the pre-implementation chart sample overall. One possibility is that refusals are becoming more frequent, especially for the influenza vaccine during the post-implementation period that may be due to increasing vaccine hesitancy by parents. Vaccine hesitancy is multifactorial (Ventrola, 2016), and will be further discussed in the implications section. Another possibility is that these pediatric providers are documenting in more detail as to why a vaccine was not ordered or given in more recent times as they became more aware of quality improvement chart reviews for immunization rates.

Ultimately, using the alpha $p < .05$, these project findings indicate that there is no statistically significant difference in rates of immunization in the 6-24 month population for hepatitis A or influenza vaccines.

Objectives Accomplished

The objectives of this study included:

- To discuss with stakeholders the terms, implications, and feasibility of implementation of the project.
- To conduct a pre-intervention chart audit on a sample of children 6-24 months for hepatitis A and influenza immunization rates.
- To Implement activation of clinical support system alerts for pediatric patients in need of hepatitis A and influenza immunization within the electronic record system (Greenway EHS) with the help of IT to:
 - Test functionality of the alert system
- To make pediatric providers aware on the use of alerts and vaccine administration of hepatitis A and influenza.
- To conduct a post-intervention chart audit to analyze the effect on immunization rates at one and two months after implementation.

In this study, the objective of discussing the terms, implications, and feasibility of implementation of the project with Quality Assurance, Information Technology, and the Chief Medical Officer was achieved by meeting with each of these stakeholders. These meetings included presentation of the site agreement as well as answering any other questions about the project.

The second objective was to conduct a pre-intervention chart audit to obtain immunization rate baselines for hepatitis A and influenza vaccines for children ages 6-24 months which was attained by EHS reports generated by information technology. Chart audit was successfully conducted and a total of 248 charts were audited. 240 charts met the inclusion criteria, which were ultimately used for calculation of pre-implementation immunization rates for hepatitis A and influenza vaccines.

The implementation of activation of clinical support system alert for pediatric patients in need of hepatitis A and influenza immunization within the electronic record system (Greenway EHS) and testing the functionality of the alert system was achieved with the aid of information technology. Functionality was assessed two weeks before implementation of the electronic alert to ensure that the alert targeted the appropriate patient. Once functionality was established, and consent of all four pediatric providers was obtained, on October 1, 2019, the electronic alerts for hepatitis A and influenza vaccines were activated.

All pediatric providers accepted the terms of the study and consented to having electronic alerts activated on the settings of their computers for the hepatitis A and influenza vaccines by signing a paper consent. The four pediatric providers were made aware on the use of alerts and vaccine administration of hepatitis A and influenza at the time of consent and were encouraged to ask the co-investigator questions about the project.

The objective to conduct a post-intervention chart audit to verify the effect on immunization rates one and two months after implementation was attained by EHS reports generated by information technology. Post- intervention chart audit was successfully conducted and a total of 229 charts were audited. 218 charts met the inclusion criteria which were

ultimately used for calculation of pre-implementation immunization rates for hepatitis A and influenza vaccines.

Lastly, the aim of the study included improving hepatitis A immunization rates, although not statistically significant, did demonstrate an increase of 11.11%. The project may suggest what kind of vaccines electronic alerts would be appropriate to be used for, and seems to benefit more novel, less frequently administered vaccines. It may also decrease missed opportunities, as suggested by the increase in vaccination given on date of visit.

Facilitators

This project was facilitated by support of the site administrators, staff, and the willingness of the provider participants to take part in the study. The Rutgers Institutional Review Board also allowed for the study to be carried out in a timely manner. In addition, the implementation did not cause financial burden and was simple to carry out.

Barriers

Barriers to the project included some alert fatigue, which was expressed by only one pediatric provider. Replacement of the electronic medical record systems was also a barrier, as it had shortened the project length from three months to two months. In addition, the delay of the availability of the influenza vaccine for the 2019-2020 season had also delayed the study from the original start date. Chart audit barriers included lack of detailed documentation for vaccination refusals.

Unintended Consequences

Consequences that were not intended consisted of alerts activation for patients that have received the vaccinations, but did not have the immunizations entered into the chart. This activated the alert erroneously, and this usually happened to new patients. The providers were

advised before the start of the study to cross check with other sources such as immunization cards and immunization registries, as they usually would for verification of immunization with every patient. Two of the four pediatric providers had brought it to the co-investigator's attention for the co-investigator to have knowledge of the unintended consequence.

Additionally, another unintended consequence was that one provider did not like the point in workflow of patient encounter that the alerts had appeared on the computer screen. All alerts were set up to appear when the provider opened the patient's chart. This can be a positive unintended consequence as it may allow for further improvement in the times the alert appears in the workflow of providers, thus adhering with the Plan-Do-Study-Act process described below.

Plan for Process Evaluation

The Plan-Do-Study-Act was the framework used to evaluate this project. The planning aspect of the process involved recognition for the need of improvement of immunizations rates within the project setting, and further investigation leading to the identification of the specific type of vaccine associated with under-immunization within the 6-24 month pediatric population. Once the need was identified, planning also consisted of searching the literature to develop a strategy to increase immunization rates for specifically hepatitis A and influenza vaccines based on evidence-based practices. The electronic alert prompt was selected as a strategy due to recommendations by the American Academy of Pediatrics (2019), the CDC (2018), as well as studies suggesting a positive effect on immunization rates when electronic alerts are implemented in a clinical setting, as noted in the literature review (Bundy et al., 2013; Erst, 2017; Fiks et al., 2007; Hechter et al., 2019; Ruffin et al., 2015).

Discussion with stakeholders on feasibility of the project is also part of the planning stage of the cycle. Testing for the functionality of the electronic alert, obtaining baseline

immunization rate by chart audit and activation of the alert on the computers of providers was the “do” portion of the process. Analysis of pre- and post-intervention chart audits after two months of activation of electronic alerts was the study portion of the PDSA process. Evaluation of the project was the act portion of the PDSA framework and involves the identification of adjustments needed such as when the electronic alert appears to the provider, which can be changed within the computer settings to create a more seamless workflow for the provider based on their preferences. The alerts may also be refined to always target the correct patient. The framework also assessed for barriers or facilitators and unintended consequences mentioned previously to better fit the needs of the project site can serve to improve the implementation in further PDSA cycles.

Implications

Clinical Support Systems can be defined as a tool designed to aid in the clinical decision making process and encourage health care providers to choose the correct assessment, intervention, or recommendation. In this quality improvement project, electronic alerts were set up to prompt the provider if the need for hepatitis A or influenza vaccines were needed in a pediatric primary care setting. This section will further discuss the clinical practice, economic, educational, quality, safety, and policy implications of implementing electronic alerts for hepatitis A as well as influenza vaccines.

Clinical Practice Implications

In this study, electronic alerts served as a reminder of the Advisory Committee on Immunization Practices (ACIP) schedule to pediatric healthcare providers for the hepatitis A and influenza vaccines. Although the electronic alerts did not change clinical practice recommendations of how or when the hepatitis A or influenza vaccines are to be administered, it

helped guide/remind the healthcare providers to vaccinate at the appropriate age and time.

Therefore, electronic alerts are a means to reinforce ACIP recommendations in clinical practice, and not intended to substitute for a healthcare provider's clinical judgment.

The ACIP recommendation for hepatitis A is to have the first dose starting at 12 months of age (Fiore et al., 2006). This electronic alert adhered to the recommendation and appeared for children 12-24 months of age who did not have at least 1 dose of hepatitis A vaccination documentation within the electronic medical record. The recommendation from the ACIP for the influenza vaccination is to have the first dose beginning at 6 months of age "as soon as possible after vaccine becomes available" for the current influenza season (Grohskopf et al., 2018). This clinical alert adhered to the recommendation and appeared for children 6-24 months of age without documentation of at least 1 dose of influenza vaccination in their electronic health record for the current influenza season.

For clinical support systems features such as electronic alerts to be successful in aiding clinical practice decisions, formulation of strategic goals beforehand is crucial as what is practiced may not always be what is regulated by policy (Kendall & Kendall, 2014). These strategic goals include building a CDS team and involving the appropriate stakeholders. For this project, stakeholders included information technology staff, quality improvement and risk assessment staff, as well as healthcare providers who best understood the clinical work flow of vaccination within the facility specifically the pediatric physicians.

Clinical knowledge from providers was as important as information technology skills to set up rules and parameters for the alerts to target the correct patients. Allowing for the electronic alerts to prompt the healthcare provider at the right moment in the workflow was also essential to develop a functional reminder, as it has been noted that although health care providers may agree

that electronic alerts should be used to aid in clinical decision making, they may disagree at what point in workflow process the alerts prompt them in their own workflow (Berner, 2009; Dixon et al., 2017). In this project, the electronic alerts were set to show up when a patient's chart was first opened. Some providers may prefer to have the alert appear at a different point when accessing the chart, for example, when they are in the order set screen. Timing of alerts is an important aspect of clinical practice as it will either interfere or synchronize with a provider's workflow.

Education

Per the Institute of Medicine (2011) report, any development from CDS programs are to be user friendly, with little to no down time, and allow for improvement to workflow that does not increase cognitive or physical workload. Although the electronic alerts are usually simple displays of data that are easy to navigate, education for healthcare providers on what the alert can and cannot do is imperative for correct use of the alert. For example, the alert system could alert health care provider if a hepatitis A vaccination and or an influenza vaccine was due for a patient, but could not input the order for those vaccines. The electronic alerts prompted the healthcare providers only if the code for the order of hepatitis A was not documented in the chart ever in children over 12 months to 24 months of age and/or no code documentation in chart within the past 8 months for the influenza vaccine in children 6 months to 24 months of age. Knowledge of these parameters was important for the providers to acknowledge as they had to be aware that the alert will not trigger for every patient.

Furthermore, education for healthcare providers is beneficial in terms of what the purpose of the alert is, and most importantly that it does not replace clinical sense or judgment, but rather it is a reminder of a due vaccination (i.e., hepatitis A/and or influenza vaccine). The providers

were aware to screen for allergies or contraindications for vaccination as well. It was also relayed to the healthcare providers that cross-checks as routinely done without the electronic alerts with immunization registries, and information in the electronic record system should be executed to verify if the vaccination is actually due. A small demonstration was done for each provider on a test chart at the time of consent so the healthcare provider could visualize the alert and how it would be activated in their workflow. In future implementations of CDS alerts, it would be beneficial for a brief education session to be held for providers to explore its capabilities and limitations.

As immunization recommendations continue to expand and more immunizations become available, the cognitive challenge for health care providers will increase. Therefore, prompts may help lessen the burden.

Observations from this project included lack of vaccination when a child was sick or febrile. Fever is not a contraindication of vaccination, but beliefs of healthcare providers may certainly affect rate of vaccination (Ventola, 2016). Results from the study conducted by Fiks et al., 2007, were that immunizations rates for sick visits and other non-well child visit related encounters were significantly lower than immunization rates for well-child visits, where most likely the child was not ill (Fiks et al., 2007).

This may indicate a need for further education for pediatric healthcare providers such as physicians, advanced practice nurses, and medical and advanced practice nursing students who complete clinical rotations in this community health setting, on what is contraindicated in terms of vaccination. Per ACIP (2006) and the Centers for Control and Prevention (2019b), contraindications for hepatitis A include anaphylaxis after vaccination or to a component of the vaccine, and precautions include “moderate or severe acute illness with or without fever” (Fiore

et al., 2006, page 2). Precautions, however do not mean the vaccine should not be administered, but rather the risks and benefits of vaccination should be assessed. Children with mild illness are able to be vaccinated safely as supported by numerous studies (Cilla et al., 1996; Halsey et al., 1985; Ndikuyeze et al., 1988).

Contraindications for inactivated influenza vaccine (IIV) (which is the only type of influenza vaccine administered in this Federally Qualified Health Center) includes anaphylaxis after vaccination or to a component of the vaccine (which includes severe egg allergy). However, the vaccine may be administered if the benefits of vaccination outweigh the risks and if the patient is in a clinical setting with a healthcare provider capable of managing severe allergic reactions. Precautions for the influenza vaccine include previous Guillain-Barré syndrome within 6 weeks of influenza vaccine administration and “moderate or severe acute illness with or without fever” (Grohskopf et al., 2018, p. 3).

Additionally, influenza vaccine education for parents may also benefit this population, as there was also an observation of increased frequency in refusal for influenza vaccination when conducting the post-intervention chart audit. Per Ventola (2016), a strategy to increase vaccination compliance includes dissemination of educational materials to this population such as brochures and flyers. Another intervention may be to display appropriate health literacy level posters in the waiting area or inside exam rooms, as there were none about the influenza vaccine observed throughout the project time frame.

Potential Implications on Economic and Cost Benefits of Project

Potential economic benefits of the project include the potential minimization of the overall financial burden of hepatitis A and influenza disease. As mentioned previously, immunization has saved society approximately 1 trillion dollars in the time frame of 20 years in

the U.S. (Whitney et al., 2014). In addition, after the establishment of hepatitis A vaccine recommendation in 2006 by the ACIP to have all children vaccinated at the age of 12 months, a decline in hepatitis A related medical visits (both hospital and outpatient) resulted in an estimated \$9.3 to \$29.1 million dollars in savings.

The healthcare system may benefit due to the possibility of decreased hospital visits with uptake of influenza vaccination, as the CDC approximated there have been 7,000 to 26,000 flu-related hospitalizations of children less than five years of age in the U.S. since 2010. Per the NCQA (2018), an estimated 300 children in the U.S. die from diseases preventable by vaccination. A recent study conducted by Willis et al. (2019), compared laboratory confirmed influenza virus to other common respiratory viruses in pre-school children from Western Australia when it came to medication and healthcare use, absence in school as well as the impact on their families. The results indicated that with children infected with influenza virus there was a significant impact on school days missed, work days missed for parents, and the use of the healthcare system as compared to other respiratory viruses.

In addition, children who tested positive for influenza were most likely to not have received influenza vaccination for the current season (86.1% vs 67.6%, $p < .001$). In the U.S., a study on school absence in school age children (5-7 years of age) also indicated that the influenza virus (particularly type B), was associated with prolonged absence in school when compared to other respiratory viruses (Mclean et al., 2017). Influenza vaccination may reduce the duration of illness due to influenza infection and prevent influenza in children which can lead to fewer school days missed. Parents and caregivers would also miss fewer days of work due to influenza illness of children. Ultimately, increased influenza vaccination uptake may reduce the overall socioeconomic burden associated with influenza infection in children.

The project site is a Federally Qualified Health Center (FQHC) and is funded by the Health Resources and Services Administration (HRSA). HRSA also awards Quality Improvement Awards to eligible health centers. This project may aid in further recognition and demonstrate ongoing quality improvement initiatives to improve the quality of care using health information technology (Quality Improvement Awards, 2018). There was no explicit direct monetary cost to the FQHC in the implementation of the electronic alert.

Other potential implications are the recommended CDS teams for successful implementation of electronic alerts. As mentioned previously, for the best designed electronic alerts, time and research is required from stakeholders, which means company time may be spent on the development and implementation of future projects.

Implications on the Impact on Quality/Safety

As a quality improvement project, this implementation strived to improve immunization rates by modifying how recognition of unmet immunization need is delivered. Routinely, within the project site, traditional methods such as immunization records printed out from immunization registries and reviewing immunizations input into the electronic medical record are ways that pediatric health care providers determine the need for immunization. These methods, however, lack the "reminder" prompt aspect if vaccinations are needed. Although not measured in this study, the immunization barrier of missed opportunities may have been, at least partially, addressed with the implementation of electronic alerts for hepatitis A and influenza vaccines.

This electronic alert implementation, while possibly having a positive impact on quality, the providers were aware to not rely solely on the electronic alerts. Cross-checks with traditional methods were performed for safety of the patient, as the alert acts as a "reminder", and as in all computer systems, malfunction may be a possibility where the alert may not be activated or be

activated inappropriately. These implications on safety were reviewed with the healthcare providers before implementation of alerts and as stated previously, functionality testing was also done two weeks before the introduction of alerts into the electronic record system and was continued to be assessed periodically throughout the implementation phase.

The hepatitis A and influenza vaccine electronic alert system was activated with the aid of information technology staff. This alert was set up in the pediatric department, only pediatric healthcare providers who agreed to participate in the study received the electronic alerts. Following the verification of electronic alert functionality within the EMR, the electronic alert was programmed to display on the computer screen during medical visits. The four full-time pediatric providers who participated in this study had their computers set to allow the hepatitis A and influenza vaccine alerts for a period of two months. The co-investigator along with IT staff tested the clinical decision support system (CDS) two weeks before the implementation of alerts to ensure proper functionality. In addition, parameters were set for the alert to target the correct individuals. The influenza vaccine alert was set to target patients ages 6-24 months who did not have evidence of CPT codes for the influenza vaccine in the past 8 months within their electronic medical record. The hepatitis A vaccine alert parameters included patients ages 12 -24 months who did not have evidence of CPT codes for hepatitis A vaccines in their electronic medical record.

Healthcare providers were also aware to check for contraindications/allergies for vaccination in all patients the alert triggered for. It was imperative to make clear these alerts served as simple reminders of if hepatitis A and/ or influenza vaccine was due, and that it did not replace their clinical knowledge, judgment, or expertise. These measures were taken to ensure

the safety of the patient population in this study and to allow the provider to be the best informed about how to use the electronic alerts in their practice.

In addition, children within this community will be better protected from disease and outbreaks (specifically hepatitis A and influenza) as vaccine uptake increases. This is due to improved herd immunity, and even children that have not been immunized will benefit. However, this protection from disease is most effective when most of the population is vaccinated and varies with infectious disease condition (Ventola, 2016). Children are also protected when vaccinated against a disease “the rate of that disease, as well as its associated asymptomatic carrier state, is decreased” (Ventola, 2016, p. 426). The electronic alert reminds the pediatric healthcare provider to vaccinate a child in need of hepatitis A or influenza vaccination, per ACIP recommendations and therefore also reinforces the protection from disease through herd immunity. Ultimately, this leads to a positive impact on population health as the quality of health in children is improved.

Healthcare Policy Implications

The use of electronic alerts may lead to the question if the bypass or misuse of alerts can have ethical or legal implications for providers that may need to change policy within the health center. Some unintended consequences of clinical decision support systems are that providers express concern on how the process sometimes interferes with their workflow. As stated in an article in the *International Journal of Medical Informatics*, excessive alerting often distracts health care providers rather than provides effective clinical decision support and to minimize alert fatigue, only relevant patient data should be included within the alert, allowing health care providers to respond with maximum of one or two clicks (Horsky et al., 2013). New policy can also call for the formation of CDS teams for paramount formulation of electronic alerts to allow

for a seamless process that allows the healthcare provider to make the best and safest clinical decision.

Additionally, the project site does encourage the use of health information technology for the improvement of the quality of care. Use of electronic alerts may be beneficial for improving immunization rates and this tool may be continued to be used at the center. Project site policy may be added or modified to include the use of electronic alerts. It is possible that these new or modified HIT policy(ies) will reflect the recommendations of the National Academy of Medicine (formerly IOM) such as simple navigation and displays of relevant data, no predicted downtime, a system that the healthcare provider would be comfortable interacting with, and implementing CDS electronic alerts if it will allow for improvements to address a clinical problem as well as “leverage multiple data types to bring the most current and relevant evidence and evidence-based practice recommendations to bear on clinical decisions” (IOM 2011; NAM, 2017, p.3). These policy changes or additions may allow for prevention of unintended consequences such as alert fatigue and alert misuse that may cause legal issues.

The healthcare center does not currently have any policy specifically for CDS interventions, but it can be added to their current electronic medical record policy by the chief officer of operations and reviewed by quality assurance. The use of electronic alerts as clinical decision support feature will be further clarified for healthcare providers in terms of how it can aid them in the clinical decision making process as well as how legal consequence can be averted.

Currently the state of New Jersey does have immunization regulations for children participating school. Per the Immunization of Pupils in School rules, New Jersey Administrative Code (N.J.A.C. 8:57-4), includes the vaccines and minimum doses required to enter child care or

preschool in the state of NJ. The regulation includes annual influenza vaccine administration (State of New Jersey Department of Health, 2019). Per N.J.A.C. 8:57-4.3, and (N.J.S.A. 26:1A–9.1) allow for exemptions for medical contraindication and religious exemptions from mandatory vaccination. However, these regulations do not allow for exemption to be based on secular, moral, general or philosophical reasoning. Additionally, medical reasons must be valid as per guidelines from ACIP, or the American Academy of Pediatrics (State of New Jersey Department of Health, 2019).

Sustainability and Translation

In this community clinic delivering healthcare can be improved by the use of clinical decision systems incorporated within the EMR to increase immunization rates in the pediatric population by prompting the healthcare provider. These alerts can be sustained with regular information technology maintenance, and regular update of clinical guidelines by a clinical administrator, if deemed useful for the project site by the QI team after evaluation of the project. Although the results of the project are not statistically significant, they still did show an increased uptake in the hepatitis A vaccination rate, and the alerts may be continued to be implemented with ease as well as possibly be used for other vaccines that may need vaccination rate improvement.

The same process can be implemented to improve other preventative measures such as colonoscopy and mammography in the adult population, where reminders may increase provider compliance. However, as mentioned previously, time for research and testing will be needed from core stakeholders which may distract them from their regular duties and cost the clinic financially. Although the costs are not great, it should be taken into consideration before the implementation of other quality improvement projects. The electronic alert feature comes within

the CDS system which is incorporated within the EMR software and did not cost the clinic to activate.

Plans for Dissemination and Professional Reporting/ Plans for Future Scholarship

The DNP project was disseminated through final presentation, and poster day exhibition at Rutgers University School of Nursing. Upon completion, a manuscript to the Journal of Pediatric Nursing (JPN) will be submitted. Following completion of this project, plans for future scholarship involve other quality improvement projects, and community assessments in order to implement strategies based on evidence-based practice to continue to improve immunization rate/compliance within this specific community.

Conclusion/Summary

Vaccination is one of the most effective public health initiatives, reducing childhood morbidity and mortality as well as reducing the financial burden of disease within the healthcare system (Ventola, 2016). Pediatric primary care settings are where childhood vaccination usually starts, however, challenges such as missed vaccination opportunities can lead to under immunization. This quality project focused on addressing these barriers with the aid of electronic alerts that appeared on the computer screen at every medical child visit and reminded the pediatric healthcare provider if hepatitis A and/ or influenza vaccination was due.

This project was implemented to ultimately increase the rate of immunization for children ages 6-24 months, utilizing electronic alerts supported by the most current evidence-based-practice. The findings of the project did not reflect other studies that demonstrated statistically significant increases in immunization rates, but a small increase (11.11%) in percentage was seen for hepatitis A, which is supported by the literature. Additionally, this study may be helpful in deciding which strategies could be useful in increasing immunization rates for other healthcare

facilities/organizations/clinics. There is a limited number of studies that focus on vaccination among this pediatric population, and more research is needed before a conclusion can be made about the ultimate effectiveness of electronic alerts on immunization rates.

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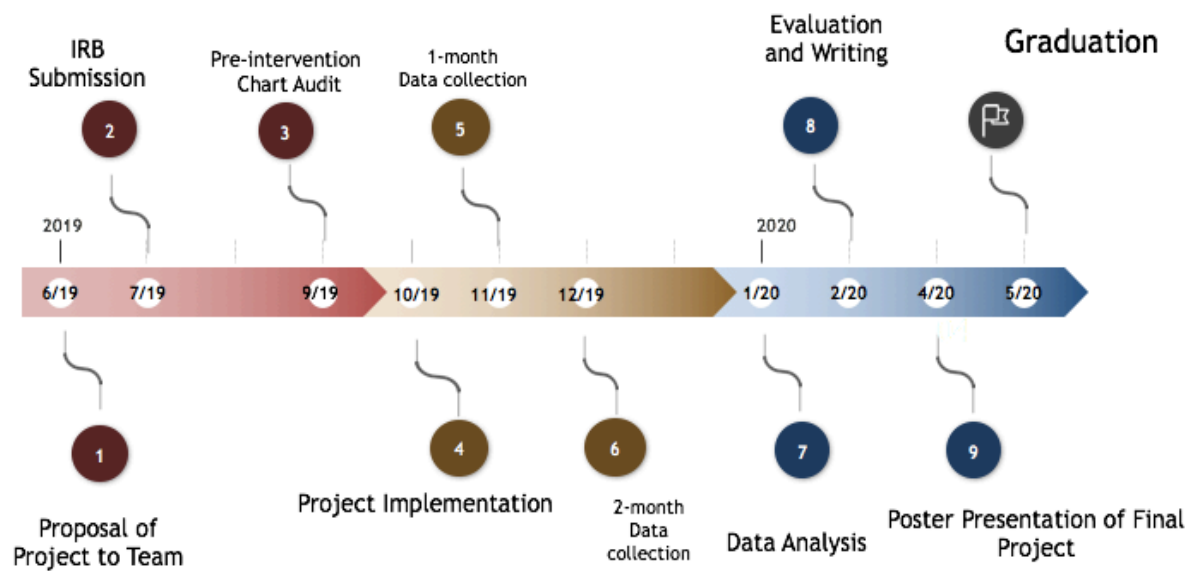
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Appendix A

Project Timeline

Project Timeline



Appendix B

Plan-Do-Study-Act Model for Implementing Electronic Alerts

Act

- Adjust electronic alert per the needs of the clinic
- Decide to continue or not to continue to use alert

**Plan**

- To develop an electronic alert for hepatitis A and influenza vaccines with the aid of information technology staff using evidence-based recommendations
- To evaluate the effectiveness of electronic alert on immunization rates
- To obtain baseline immunization rates with chart audits

Study

- Obtain post-implementation chart audit
- Perform data analysis with pre- and post-implementation chart audits to evaluate effects on immunization rates

Do

- Demonstrate use and introduce alert to pediatric providers
- Implement alert within the clinic's electronic record system

From the Centers for Medicare and Medicaid Services PDSA Cycle Template
Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/downloads/PDSACycledebedits.pdf>

Appendix C**Project Budget and Expenses**

Expense	Cost	<i>Total Cost</i>
Post -QI Dissemination Posters	\$75	\$75.00
TOTAL BUDGET		\$75.00

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Appendix E

Adult Consent Form

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Improving Immunization Rates for Hepatitis A and Influenza in a Federally Qualified Health Center

Co-Investigator: Angie Garcia DNP Student

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not. The purpose of the research is to increase in hepatitis A and influenza immunization rates with the use of clinical decision system (CDS) alerts within in the electronic record system for children 6-24 months of age. If you take part in the research, you will be asked to allow for electronic alerts to be activated as one of your electronic medical record user preferences. You will also be asked to use these alerts as an aid along with other resources such as immunization registries and immunization records to identify patients eligible to receive hepatitis A and/or the influenza vaccine. Your time in the study will be a 2- month time span. Possible harms or burdens of taking part in the study may be Minimal risks to may include study burden, interruption of workflow and alert fatigue. There are no, immediate, potential or long term physical, psychological, social, financial, or reproductive risks with participation in this project and possible benefits of taking part may be your awareness for the need of hepatitis A and influenza vaccination in patients 6-24 months of age may be improved. Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After all of your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research study?

Angie Garcia DNP student is the co-investigator of this research study. A co-investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Angie Garcia co-investigator may be reached at [REDACTED] [REDACTED] [REDACTED]

The co-investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?

The purpose of this study is to increase hepatitis A and influenza immunization rates with the activation of electronic alerts in the electronic record system in a federally qualified health center.

Who may take part in this study and who may not?

Pediatric healthcare providers including physicians and Advanced Nurse Practitioners may take part in this study.

Why have I been asked to take part in this study?

You have been asked to participate in this study because the study aims to increase hepatitis A and influenza immunization rates by having electronic alerts as a reminder for you (the healthcare provider) to administer vaccines if a child is eligible.

How long will the study take and how many subjects will take part?

The study will be implemented for 2 months, and electronic alerts will be seen on your computer screen if a child is eligible for hepatitis A and/or influenza vaccination. An anticipated 4 subjects will take part in this study, as healthcare providers.

What will I be asked to do if I take part in this study?

You will be asked to allow permission for electronic alerts for hepatitis A and the influenza vaccine to be activated within your electronic record system user preferences. Although the functionality of the alerts will be tested before activation of alerts, we encourage a cross-check of other sources of vaccination record such as immunization registries and immunization record input within the electronic medical record to make sure a child is truly eligible to or not eligible to receive vaccines.

What are the risks and/or discomforts I might experience if I take part in this study?

Minimal risks to the participants may include study burden, interruption of workflow and alert fatigue. In this study, there are no immediate, potential or long term physical, psychological, social, financial, or reproductive risks. Your personal information and identifiers will not be collected in this study.

Are there any benefits to me if I choose to take part in this study?

The benefits of taking part in this study may be increased awareness of patients 6-24 months of age who are eligible to receive the hepatitis A and/or influenza vaccine. However, it is possible that you may not receive any direct benefit from taking part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to me to take part in this study?

There is no financial cost in the to you to take part in this study.

Will I be paid to take part in this study?

You will not be paid to take part in this study.

How will information about me be kept private or confidential?

No personal information, or individual information about healthcare providers will be collected or needed in this study. However, all efforts will be made to keep patient information in the research record confidential, but total confidentiality cannot be guaranteed. Data collected will be kept on a desktop in a Rutgers location, which is secured with password only known to the co-investigator, and remains in a locked office at all times. After an analysis of pre- and post-implementation chart audit, all patient and health provider information will be de-identified for use in final project findings. Following Rutgers University Policy, all information will be destroyed once the study has concluded.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled. You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Angie Garcia co-investigator, [REDACTED]

[REDACTED] If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can I call if I have questions?

If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the co- investigator: Angie Garcia DNP student at [REDACTED]

If you have questions about your rights as a research subject, you can call the IRB Director at: Newark HealthSci (973)-972-3608; or the Rutgers Human Subjects Protection Program at (973) 972-1149.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What is the purpose of the research and how will my information be used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

Who may use, share or receive my information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University investigators involved in the study;
- University Hospital or Robert Wood University Hospital personnel to communicate information necessary for health care operations;
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the co-investigator, the person in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of

your information in the research, you must write to the researcher and tell him or her of your decision: Angie Garcia co-investigator, [REDACTED].

How long will my permission last?

Your permission for the use and sharing of your health information will last until the end of the study.

AGREEMENT TO PARTICIPATE**1. Subject consent:**

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name: _____

Subject Signature: _____ Date: _____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (printed name): _____

Signature: _____ Date: _____

Appendix F**Pre- and Post-Implementation Rates by Month****Figure 1**

Pre- and Post-Implementation Rates Month by Month of Hepatitis A and Influenza Vaccines



Figure 2

Pre- and Post-Implementation Rates Month by Month of Hepatitis A

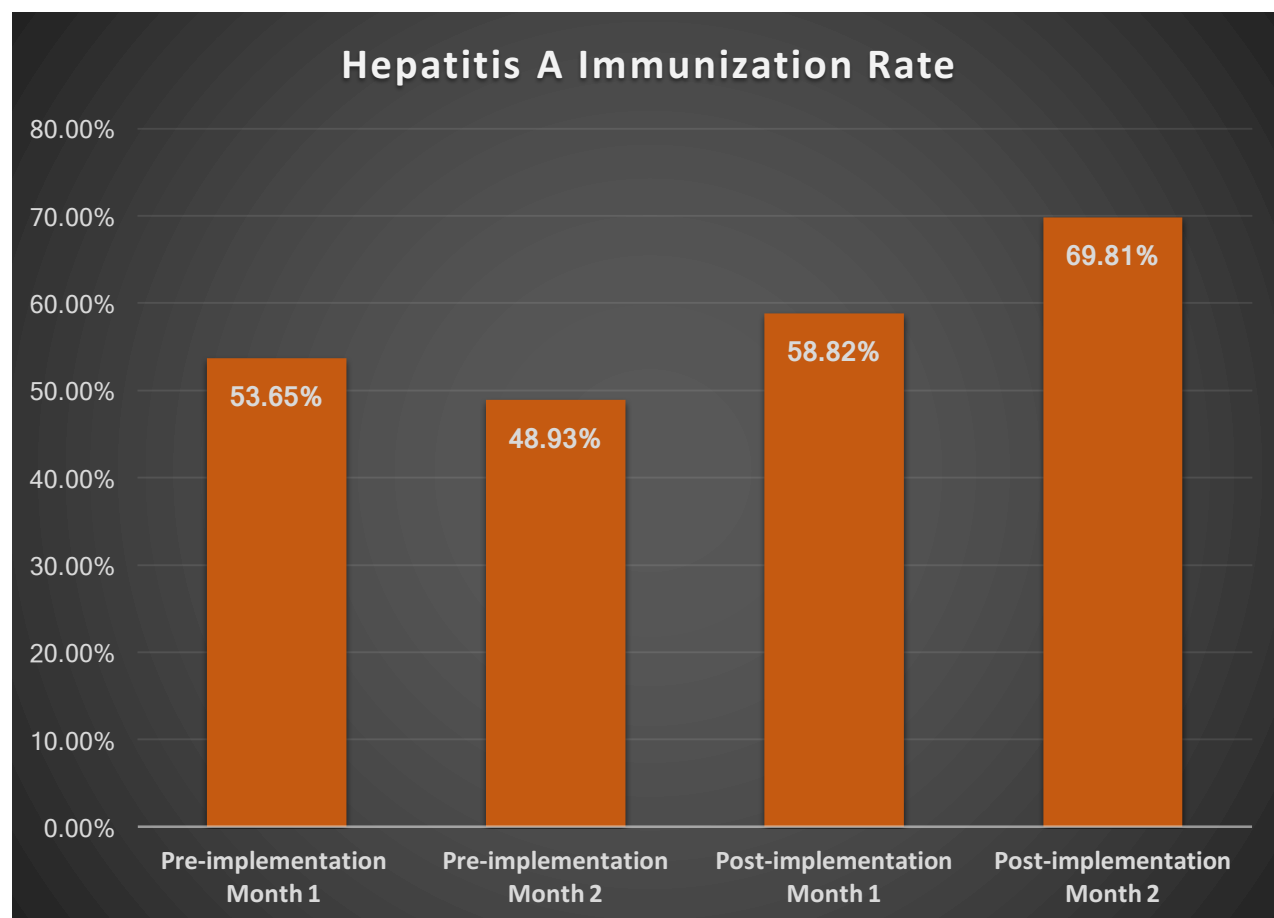
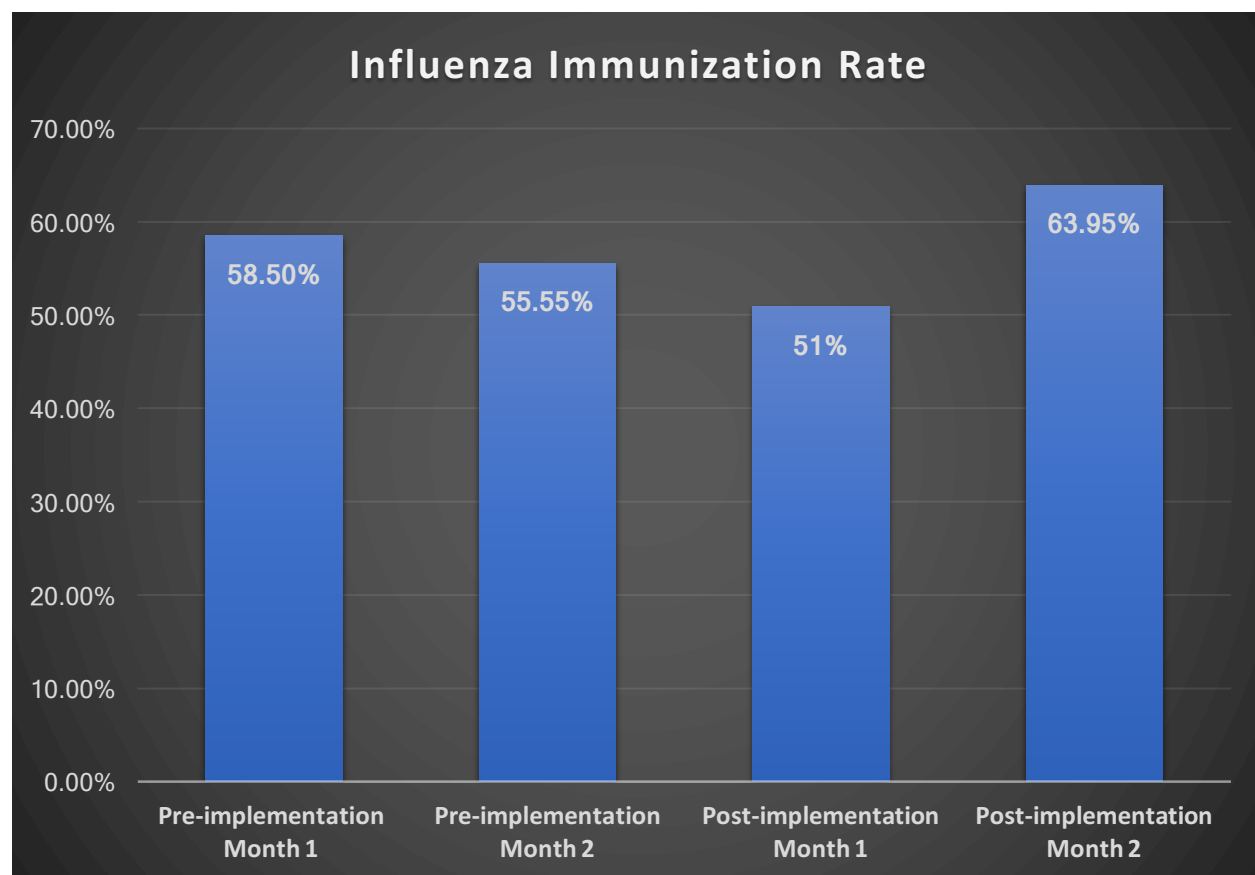


Figure 3

Pre- and Post-Implementation Rates Month by Month of Influenza Vaccines



Appendix G

Hepatitis A Pre-and Post-Implementation Immunization Rate Results

Figure 4

Chi-square results for Pre-and Post-Implementation Hepatitis A Immunization Rates

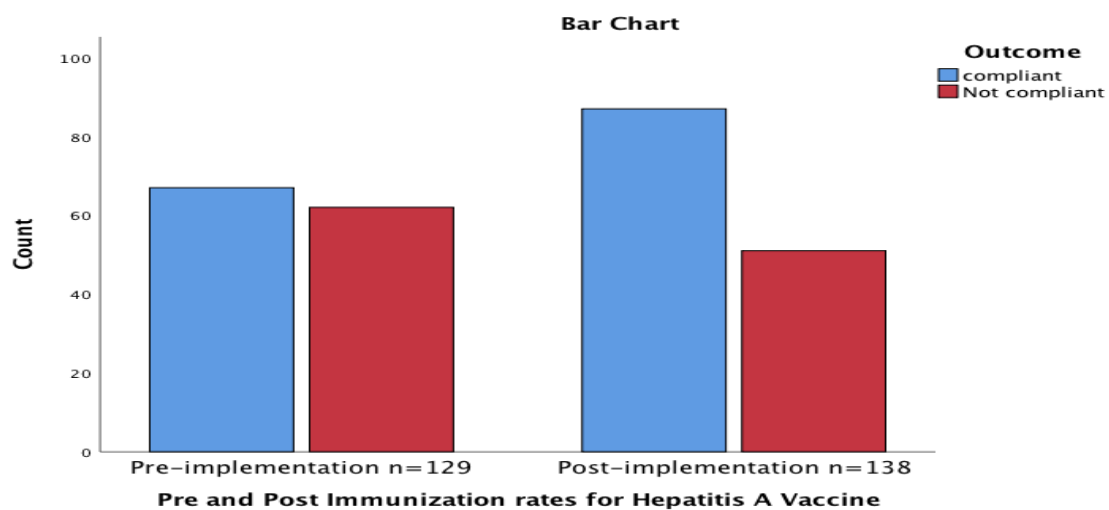
Chi-Square Tests					
	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	3.369 ^a	1	.066		
Continuity Correction ^b	2.929	1	.087		
Likelihood Ratio	3.374	1	.066		
Fisher's Exact Test				.083	.043
Linear-by-Linear Association	3.356	1	.067		
N of Valid Cases	267				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 54.60.

b. Computed only for a 2x2 table

Figure 5

Bar Graph Depicting Pre-and Post-Implementation Hepatitis A Immunization Rates



Appendix H

Influenza Pre-and Post-Implementation Immunization Rate Results

Figure 6

Chi-square results for Pre-and Post-Implementation Influenza Immunization Rates

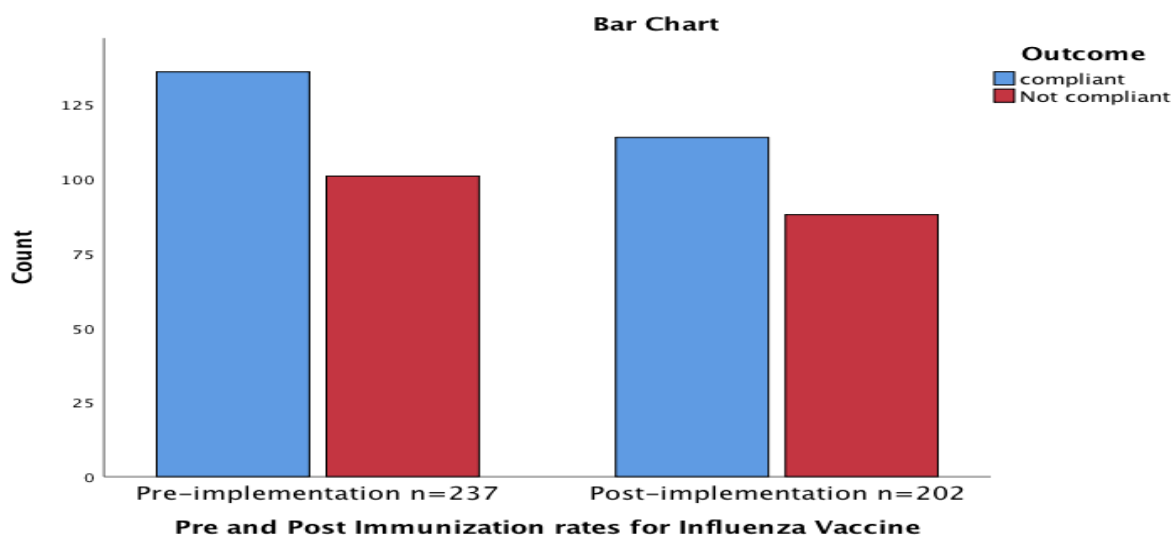
Chi-Square Tests					
	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.040 ^a	1	.841		
Continuity Correction ^b	.011	1	.918		
Likelihood Ratio	.040	1	.841		
Fisher's Exact Test				.847	.459
Linear-by-Linear Association	.040	1	.842		
N of Valid Cases	439				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 86.97.

b. Computed only for a 2x2 table

Figure 7

Bar Graph Depicting Pre-and Post-Implementation Influenza Immunization Rates



Appendix I

Demographics of 6-24-month Pediatric Population

Table 1

Demographic Characteristics of the 6-24 Month Target Population (n=458)

	Pre-Implementation		Post- Implementation		Total	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Gender						
Female	121	50.41	102	46.78	223	48.68
Male	119	49.58	116	53.2	235	51.31
Race/Ethnicity						
Black or AA*/NHOL**	118	49.16	104	47.70	222	48.47
White/Hispanic or Latino	83	34.58	70	32.11	153	33.40
Asian/NHOL **	25	10.41	32	14.67	57	12.44
Black AA*/Hispanic or Latino	5	2.08	9	4.12	14	3.05
White/ NHOL**	7	2.9%	3	<1	10	2.18
American Indian or Alaskan/NHOL**	1	<1	0	0	1	<1
Multiple races/NHOL**	1	<1	0	0	1	<1

*AA=African American

**NHOL=Not Hispanic or Latino

Appendix K

Primary Data Abstraction Tool

	A	B	C	D	E
1	Patient Medical Record Number	Age (6-24 months)	Sex	Race/Ethnicity	Date of Medical Visit
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					

Appendix L

Chart Audit Tool

(Secondary Data Abstraction Tool)

	A	B	C	D	E	F	G	H
	Inclusion criteria: Ages 6-24 months assigned numbers	Age	Gender	Race	Record in compliance for flu? Yes	Record in compliance for flu? No	Record in compliance for hep A? Yes	Record in compliance for hep A? No
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								

Appendix M

Table of Evidence

Article #	Author & Date	Evidence Type	Sample, Sample Size, Setting	Study Findings that help answer the EBP Question	Limitations	Evidence Level & Quality
1	Birmingham et al., 2011	Qualitative study	Four focus groups with providers (n = 21) and practice leaders individual interview (n=5) urban, pediatric primary care network affiliated with an academic medical center in New York City	Through focus group interview, pediatric providers answered questions based on PRECEDE-PRCEDE model as well as semi-structured interviews that included 4 practice leaders and one pediatrician. The discussions were recorded and the analysis of the transcripts was performed by thematic analysis and coding. The results suggested that providers wanted alerts that would allow reminding of influenza vaccination early in the visit, accuracy in determining eligibility for vaccination from multiple sources, assisting with vaccine ordering and the ability for the alert to generate appropriate documentation for refusal of vaccination.	None of the providers or participants had any experience with electronic alerts for vaccination and were all from the same network.	III/B
2	Bundy et al., 2013	Quasi-experimental Design	Children 1.5–3.5, 5.5–7.5, and 12.5–14.5 years Urban hospital-based pediatric primary care clinic	One of two separately studied interventions where electronic medical record clinical decision support systems alerted providers at point of care of vaccines that were due/missing. CDS prompt to alert providers did not significantly increase other vaccine immunization rates, however hepatitis A resulted to be statistically significant for improvement of immunization rate from baseline.	A minor percentage of children received immunizations at other clinical settings which were not captured in the EHR.	II/C
3	Dixon, Kasting, Wilson, Kulkarni., Zimet, & Downs, 2017	Qualitative Study	18 pediatric providers in a publically funded urban health system	This study analyzed interviews conducted on pediatric providers (physicians and Nurse Practitioners) by inductive content analysis and transcripts of the interviews were reviewed by the investigators to identify themes. Data analyzed from the interviews identified five major themes, which were awareness of CDS reminders, utilization of CDS reminders, reasons for non-use of CDS reminders, effect of suggested script and role of nurses in vaccination suggested that although providers mostly stated that these prompts did not influence behavior to vaccinate, they may be effective.	Providers may have strong views or attitudes towards the CHICA system or HPV vaccination that may have influenced the interview answers. This study may also not represent what may occur or be expressed in similar settings.	III/B
4	Ernst, 2017	Retrospective study	261 infants with birth weights less than 2 grams admitted into NICU in [REDACTED]	Electronic pop- up alerts were developed and implemented to remind when 2-month-old vaccinations were due in NICU infants (at 56 days of age). This implementation increased the immunization rate from 71% to 94%.	It is possible pre-implementation NICU infants were not stable enough to receive vaccines or parental consent was missing, and lack of documentation, if these conditions occurred, may have limited the study.	II/B
4	Fiks, Grundmeie, Biggs, Localio, & Alessandrini, 2007	Implementation study	Children 6-24 months of age implementation patients (n=1669) and control patients (n=1548) in 4 urban primary care centers	Electronic alerts appeared if immunization was due at point of care in 15,928 visits to remind provider. This alert was implemented for one year (from 2004-2005). The results of the study suggests that not only were there increases in captured opportunities for vaccinating in the implementation group, but the implementation of the alert also resulted in children being fully immunized at a faster rate than the control group.	Limitations in this study resulted from using historical controls that may have been subject to vaccine supply and demand.	II/B

5	Ruffin, Plegue, Rockwell, Young, Patel, & Yeazel, 2015	Retrospective cohort study	Female patients ages 9-26 Non-prompted cohort ($n=9096$), Prompted cohort ($n=6,019$) in 2 community based family practices	The implementation of an electronic prompt for the reminder of HPV vaccination at point of care for providers suggested that the prompted cohort had a significant ($p<0.001$) initiation of HPV vaccination (34.9%) when compared to the unprompted cohort (29.9%) during the same time frame.	Variables affecting HPV vaccine uptake that were due to the electronic alert such as community acceptance of the vaccine, access to healthcare and clinician attitudes were not taken into consideration in this study. Also, the participants were all female and cannot account for the male population	II/B
7	Hechter et al., 2019	Observational Retrospective cohort study	Ages 19-59 years old with diabetes pre-intervention($n=116,217$)Post-intervention($n=117,305$) in Kaiser Permanente, Northern California	A 12-month implementation of electronic alerts for patients 19-59 years old with diabetes for Hepatitis B where it would appear at point of care and require action from the provider to dismiss or order the vaccine suggested. The results from difference-in-difference analysis was statistically significant (12.3% pre-implementation to 66.6% post-intervention) increase in hepatitis vaccine initiation.	Limitations of this study include records for patients who received hepatitis B vaccination before enrollment into the KPSC health plan or who received vaccination at a different facility during the study time frame may not have been complete	II/A
8	Stockwell, & Fiks, 2013	Literature Review	None	Review of current information on the effectiveness of various strategies used with information technology including electronic clinical alerts to promote immunization.	Use of websites for some information mentioned.	V/B
9	Ventola, 2016	Literature Review	None	Reviews Advisory Committee on Immunization Practices (ACIP) issues annual recommendations and guidelines for childhood and adolescent immunizations as well as barriers to immunization compliance for both healthcare provider and parent. Suggestions for strategies to overcome barriers are mentioned.	Article is directed at pharmacists	V/A
10	Zimet et al., 2017	Randomized Control	Adolescent patients ages 11-13 years. Control group ($n=301$), simple prompt implementation group ($n=124$) and elaborated prompt ($n=223$). 5 Urban Pediatric clinics in Marion County, Indiana	Two electronic prompts were developed (one elaborate and the other simple) and implemented via randomization of patients. The results suggest the simple prompt did not have a significant effect on HPV immunizations when adjusted with generalized estimating equations, although it did show a 14% increase when compared to the control group. The elaborate prompt suggested having a significant effect on HPV vaccine administration (p less than 0.05) and increased HPV immunization rate by 17% as compared to the control group.	Limitations of this study included that the sample size for the simple prompt was smaller, thus may have influenced the nonsignificant results as compared to the elaborate prompts.	I/B

