FINAL REPORT

Project Title: SINC: Synchronized Immunization Notifications

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ABSTRACT

Purpose: We assessed the impact of electronic health record (EHR) reminders forecasting from a regional Immunization Information System (IIS) on receipt of immunizations in a low-income, urban, pediatric population. We also examined the impact on receipt of immunizations recommended for pediatric patients with chronic medical conditions (CMCs).

Scope: We sought to couple bidirectional exchange of IIS immunization information and forecasting tools with patient level medical history from the EHR to deliver accurate, patient-specific EHR immunization reminders.

Methods: We conducted a randomized cluster-crossover pragmatic clinical trial in four academic-affiliated community health clinics in New York City. We compared captured opportunities at each visit when patients had a vaccine due, as well as under-immunization and over-immunization for all children with visits during the study periods when the alert was “on” versus “off.” The primary immunization series for infants and toddlers (4:3:1:3:3:1:4), school age boosters, and adolescent series (1:1:2/3) were assessed as well as chronic condition-specific vaccines.

Results: Overall, it was possible to build an immunization alert that used centralized immunization rules and synchronized data with the local IIS. The alert had a significant impact on captured opportunities to complete the primary vaccine series in both well-child and sick visits, and among many age groups, but not the adolescent series. It also increased captured opportunities for several different vaccine types, but not for condition-specific vaccines. The alert did not have an effect on under- or overimmunization.

Key Words: electronic health record, clinical decision support, immunization information systems, vaccines

PURPOSE

AIM 1: Assess the impact of EHR reminders integrated with immunization data and forecasting from a regional IIS on receipt of generally recommended immunizations in a low-income, urban, pediatric and adolescent population

AIM 2: Assess the impact of integrated EHR reminders that also incorporate patient's medical conditions on receipt of immunizations specifically recommended for children and adolescents with chronic medical conditions.

SCOPE

Immunization is one of the most effective public health interventions. Yet, coverage has consistently fallen short of national goals, and has remained for the most part stagnant. The continued presence of vaccine-preventable diseases poses a threat to public health. In addition to needed improvement of immunization coverage for the general pediatric/adolescent population, some children with chronic medical conditions need specific additional immunizations, yet many fail to receive them.

Immunization reminders for providers in the electronic health record (EHR) are a type of clinical decision support (CDS) that can reduce missed immunization opportunities. One limitation of these reminders is that they generally depend only on data local to the EHR, which can be incomplete due to record scatter, leading to inaccurate alerts. Another challenge is that pediatric and adolescent immunization schedules are complex, and catch-up doses for children with delayed immunizations are even more challenging as the intervals between and number of immunizations needed changes. Thus, design, testing, and maintenance of forecasting rules- when each vaccine is due- is time-consuming. Thirdly, most immunization CDS systems do not take into account an individual child's medical conditions.

An Immunization Information System (IIS), also known as an immunization registry, is a population-based system that collects immunization data primarily for children and adolescents from providers at a regional or state level. In most cases, access to IIS data and forecasting tools are available only by visiting the IIS's website. However, frontline care providers are most likely to benefit when IIS provide them with data and forecasting at point of patient care in the form of a reminder within their current EHR workflow.

In this grant, we sought to couple bidirectional exchange of IIS immunization information and forecasting tools with patient level medical history from the EHR to deliver accurate, patient-specific EHR immunization reminders. Building on our two previous AHRQ-funded projects, the proposed work will generate empiric knowledge regarding the best practices for implementing immunization reminders and computerized CDS in general, including capitalizing on data-sharing with public health entities like an IIS.

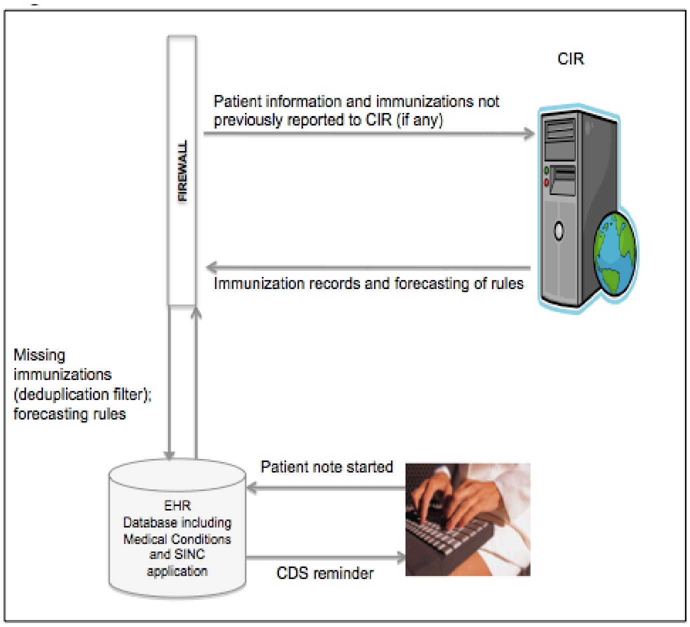
METHODS

ALERT DESIGN AND TESTING

Rules Testing

We designed the SINC alert, acting within the Allscripts/Sunrise SCM Ambulatory application to, upon note opening, retrieve immunization information, via a web service, from EzVac, our hospital immunization registry. At the same time, EzVac synchronizes data with New York City's IIS, the Citywide Immunization Registry (CIR), and queries its forecasting rules to power the clinical decision support (CDS) in the reminder for the general recommended immunizations. This allows the reminder to act on the most up-to-date information available for individual patients (Figure 1). The rules were programmed using the FHIR (Fast Healthcare Interoperable Resources) standard which is the next generation standards framework created by HL7 for formatting data elements in exchanging health related information. Rules have also been updated as needed throughout the study. For example, the CDC recommended a change for human papillomavirus vaccine dosing to a new 2 dose schedule for those who are 11-14 years old at vaccine series initiation. The CIR worked with the vendor who supports their up-to-date rules, and we updated the alert to encompass these rules.

Figure 1: Schematic of SINC alert



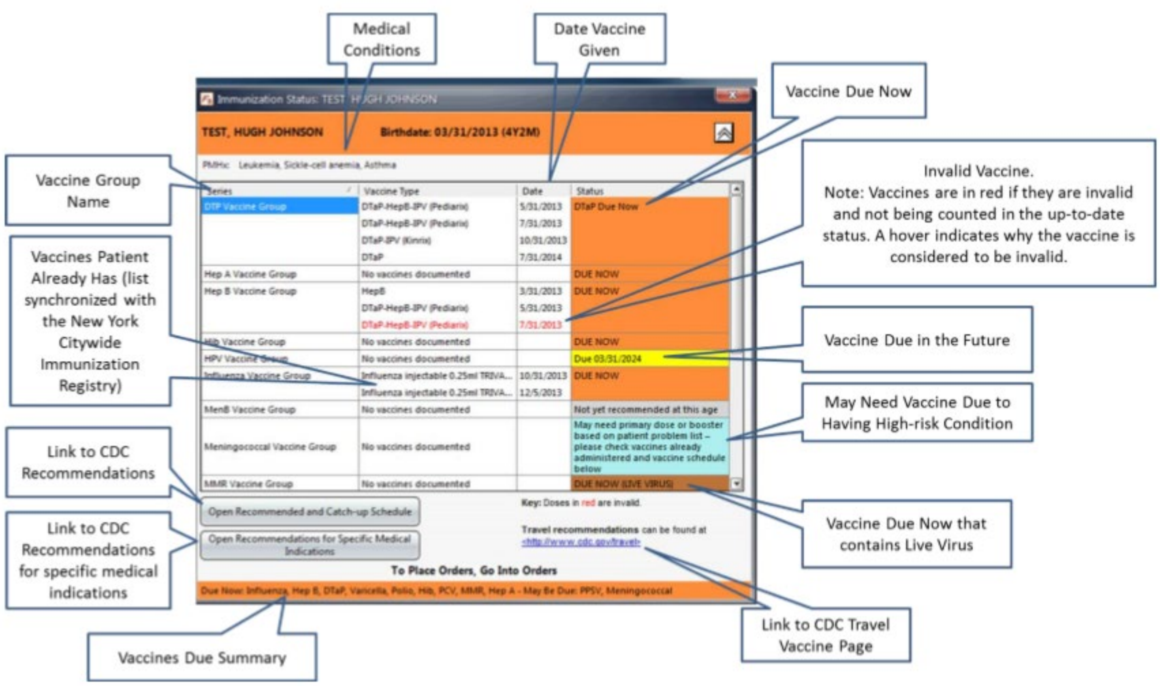
In order to program the reminder for immunizations a given child with a chronic medical condition (CMC) may need, we first had to identify these conditions. These chronic medical conditions were extensively identified based upon Advisory Committee on Immunization Practices (ACIP) recommendations and existing literature, and cross-walked with the International Classification of Diseases (ICD) 9 (legacy) and 10 codes. This logic was incorporated into the reminder. At the same time that the reminder is firing, it additionally queries the patient problem list in the EHR and another set of internal rules using the cross walks provides additional decision support for immunizations a given child with a chronic medical condition (CMC) may need.

Graphical user interface

SINC's graphical user interface (GUI) was designed and revised in order to reflect feedback concerning usability, consistency of data display and efficiency in information assimilation. We also followed the principles of good human-computer interaction. The GUI alerts the provider to the immunization status of the patient with both text and color-coding by vaccine. Based on preferences gathered from provider focus groups in a previous study, the immunization alert appears when the note is opened for patients and shows regardless of immunization status to demonstrate it is working. The alert shows the whole immunization record as well as forecasting for other immunizations. This includes information about immunization series that are already completed, immunizations currently due, and dates when immunizations are next due for immunizations that are currently up-to-date. It also includes relevant medical conditions for each child based on the EHR. (Figure 2)

The alert also includes link to the current immunization recommendations per the CDC, including both the generally recommended immunizations and those given in addition or at an earlier time for children with certain medical conditions.

Figure 2: Screenshot of SINC Alert



Testing

After being fully programmed, the reminder underwent multiple rounds of testing in the development environment with test patients, and changes were made. For example, we needed to change the way that the reminder is linked to the note opening by coupling a shell of the reminder to note opening, but having the web-service call for the immunization and the immunization rules happen in the background so as to not delay note opening. The alert was then tested in production with ten beta testers, who used the alert as they saw patients as a part of their regular clinical work.

Training

In order to best implement the reminder, we created instructional tools to help providers and nurses familiarize themselves with the reminder. This included a Quick Reference Guide, outlining the basic core functionalities of the reminder. We also conducted live in-person trainings on the use of the reminder at each site when the reminder was first deployed there. Any concerns or feedback regarding the reminder were also able to be emailed to our email account, and we provided support.

Trial

This study was approved by the Columbia University Irving Medical Center Institutional Review Board. Using a randomized cluster-crossover design, selection of the intervention groups was made site-wise. The reason behind this particular design was to avoid the carry-over bias of intervention subjects seeing the same provider as the usual care subjects. Using the configuration tools in the EHR, each site had two phases for which the reminder was “on” and two for which it was “off”, allowing each site to act as its own control as well as to account for some seasonal variation (Figure 3). Each phase lasted 3 months. The cluster crossover trial started in June 2017 and ended June 2018. The first crossover occurred in September 2017 and the final crossover occurred in March 2018.

Figure 3: Cluster Cross-Over Design

	Phase 1	**Phase 2**	**Phase 3**	**Phase 4**
Clinic 1	OFF	ON	ON	OFF
Clinic 2	OFF	ON	ON	OFF
Clinic 3	ON	OFF	OFF	ON
Clinic 4	ON	OFF	OFF	ON

Study sites

This trial was conducted in four community health clinics affiliated with the NewYork-Presbyterian Hospital (NYP) Ambulatory Care Network (ACN) and Columbia University. These practices provide ~40,000 visits annually to nearly 19,000 unique patients; 87% for publicly insured patients and 84% for Latino families. The Vaccines for Children (VFC) Program provides the vaccines for free for nearly all patient at the study sites.

ANALYSES

Outcome Variables

Captured opportunities

Captured opportunities are defined as a medical visit in the analytic period during which a child/adolescent was eligible for an immunization, and received it. It includes all children seen during the study period. The denominator includes a child/adolescent in need for a given vaccine at a visit and the numerator includes those who received that needed vaccine at that visit. These analyses were completed both on the individual vaccine level as well as the series level (described below). Individual vaccines included diphtheria, tetanus and pertussis (DTaP)/tetanus, diphtheria, and pertussis (Tdap)/tetanus, diphtheria (Td), polio (IPV), Haemophilus influenzae type b (Hib), hepatitis B (Hep B), 13-valent pneumococcal conjugate (PCV13), measles-mumps-rubella (MMR), Varicella, Meningococcal, and human papillomavirus vaccine (HPV) which are all part of the recommended series described below. In addition, are other recommended vaccines including against Hepatitis A (Hep A) and rotavirus vaccine.

Under-immunization

The outcome variable related to under-immunization is the percent of children and adolescents who are overdue for at least one age appropriate immunization as recommended by the CDC's ACIP. This method is used by the National Immunization Survey.

For the children in the 7-11 months age group, the outcome includes completion of the first set of recommended primary immunizations which includes diphtheria, tetanus and pertussis (DTaP) vaccine, polio vaccine (IPV), Haemophilus influenzae type b (Hib) vaccine, hepatitis B vaccine (Hep B) and 13-valent pneumococcal conjugate vaccine doses (PCV13). The number of doses needed was based on the number of doses a child that age should have been administered, known as the 4:3:1:3:3:1:4 series. For the 19-47 month age group, the outcome included one dose each of the measles-mumps-rubella (MMR) and Varicella immunizations, in addition to age-appropriate DTaP, IPV, Hib, Hep B and PCV13 immunizations as above. For children in the 7-10 years old age group, the outcome was completion of the series as above which for this age also includes receipt of one booster dose each of DTaP, IPV, MMR and Varicella. For adolescents in the 13-17 year old age group, the outcome was receipt of the 4:3:1:3:3:1:4 series as well as the CDC-recommended adolescent immunizations (1:1:2/3 series): one dose of tetanus, diphtheria, and pertussis (Tdap), one dose of Meningococcal vaccine and completion of human papillomavirus vaccine (HPV) series. For adolescents who are 16 years of age, the meningococcal booster dose was included.

For this analysis, the denominator assessed all children in the ages groups as above seen in a given study phase (Figure 3) and included children who were already up to date at their individual visit as well as those who were not yet. The numerator included those who were up to date by the end of that phase. These age groups were selected since they mark the end of when each set of immunizations are due; 7-12 months for the primary series to be completed by 6 months, 19-48 months for the booster series to be completed by 18 months, 7-10 years for the school-age boosters due at 4-6 years, and 13-17 years for the adolescent vaccine due at 11-12 years as well as the meningococcal booster due at 16 years.

Over-immunization

Over-immunization was defined as any invalid dose given in excess of that recommended for an age group. Any child who has received at least one invalid immunization was considered to be over-immunized. We only counted invalid immunizations that were given during the study periods so as not to penalize for previous invalid doses. The denominator for these analyses included any child with a visit occurring during the study period, and numerator included children with an invalid dose.

Children with Chronic Medical Conditions

Children with certain chronic medical conditions (CMCs) require additional vaccinations. CMCs include sickle cell disease, cancers, cochlear implants, chronic liver or kidney disease among others. For children with CMCs, we assessed, as appropriate for their condition, receipt of PPSV23 and/or meningococcal immunizations, which are condition-dependent. This included both as a captured opportunity at a visit in which the denominator included any child with a visit occurring during the study period (either when the reminder was "on" or "off") in a need of the vaccine and the numerator those who received the vaccine at that visit. In addition, we also looked at up-to-date status by the end of each phase, with the denominator were all children with an appropriate condition and the numerator was receipt of the vaccine by the end of the phase.

Analyses

We conducted tests of two proportions to compare the outcomes as delineated above for periods when the reminder was "on" versus "off." As appropriate, we conducted analyses stratified by age and type of visit.

RESULTS

Overall, there were 15,343 unique patients seen over the study period. Half were female, most were publicly insured, and half spoke Spanish (Table 1). There were 26,647 visits for these patients over the study period.

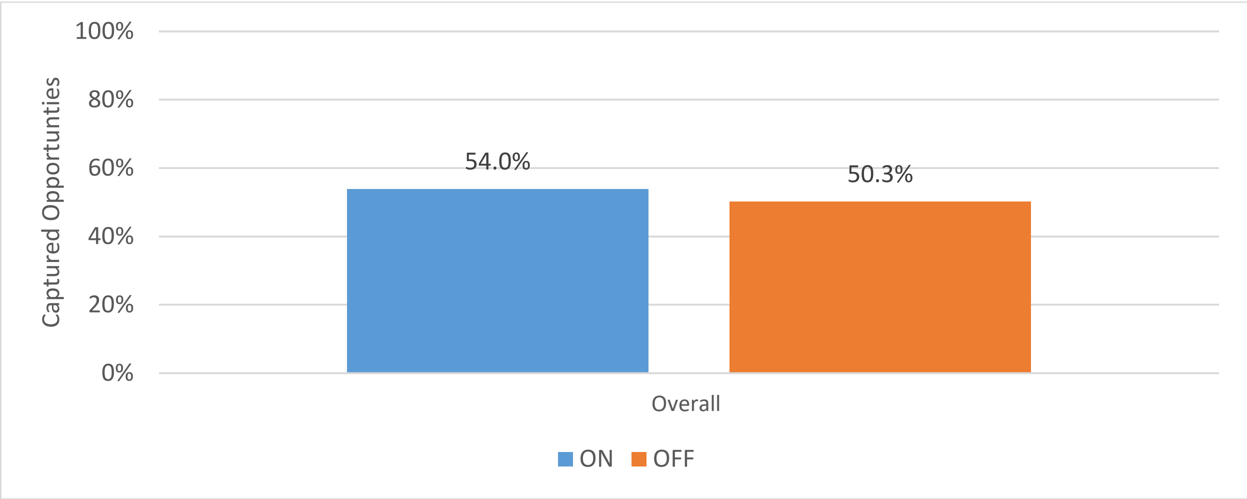
Table 1: Demographic Characteristics of the Study Population

Variable	N	Percent
Gender		
Female	7596	49.5
Male	7747	50.5
Insurance		
Commercial	543	3.5
Public	14532	94.7
Uninsured	265	1.7
Other	8	0.1
Language		
English	6300	41.1
Spanish	8089	52.7
Other Language	959	6.3

Captured opportunities

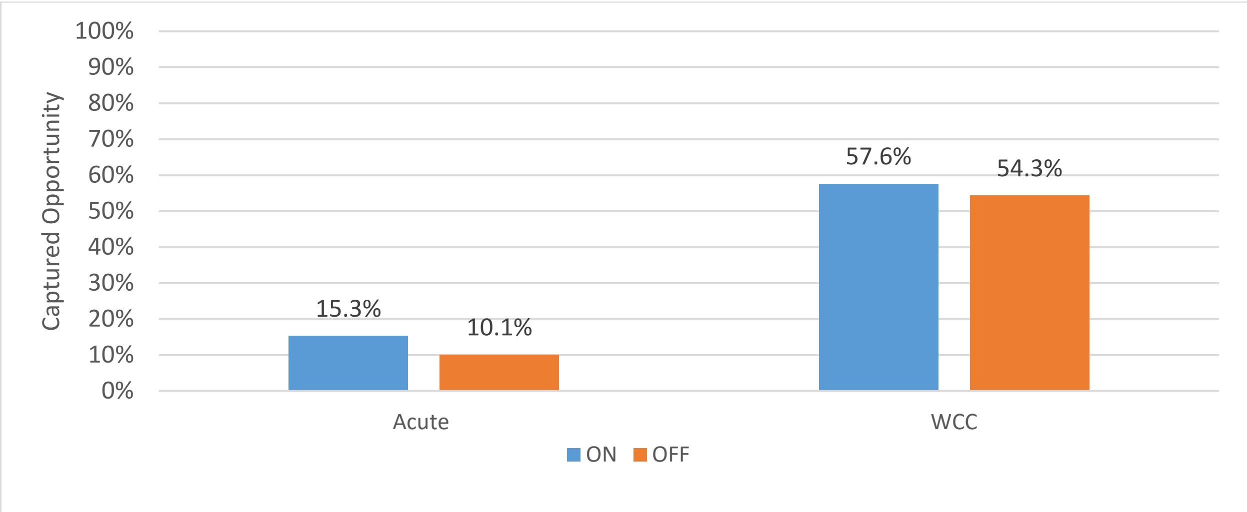
Overall, there were 10,802 visits during the study period in which a child was due for a vaccine in the CDC-recommended 4:3:1:3:3:1 series as described above. There was a small but significant difference in captured opportunities to complete the entire recommended series when the alert was "on" versus when it was "off" (p=0.0001) (Figure 4). There was a significant difference in both acute care (sick) visits as well as for routine well-child care (Figure 5). This relationship also remained significant across many, but not all of the age groups (Figure 6).

Figure 4: Captured Opportunities for the 4:3:1:3:3:1:4 Series



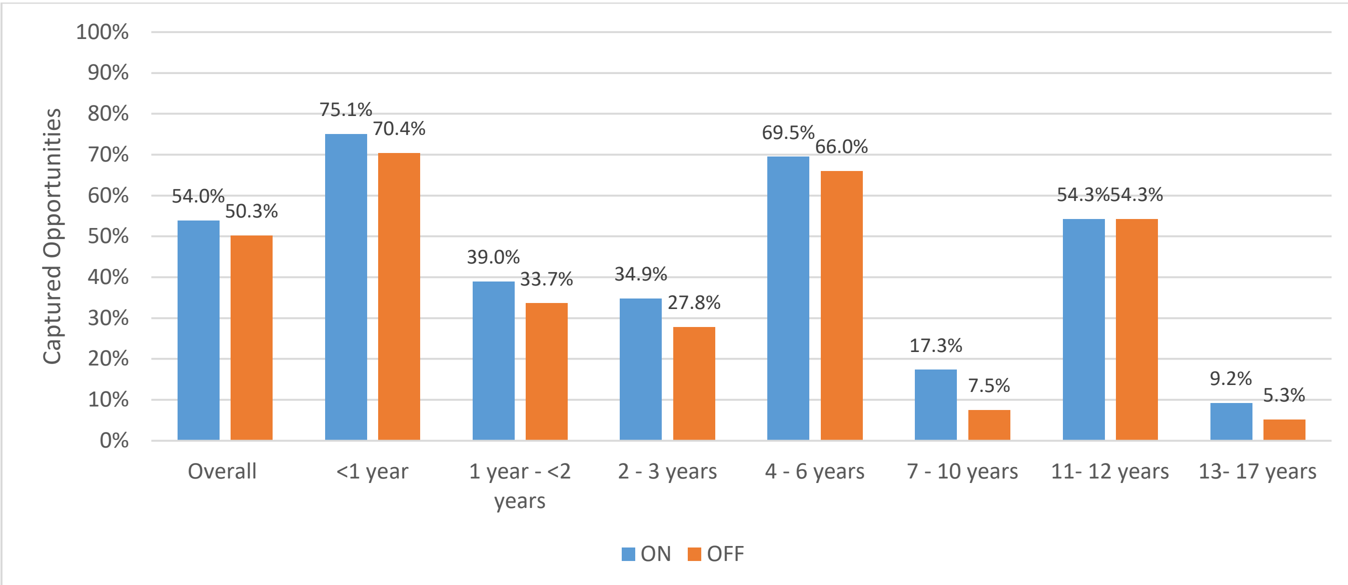
	Overall
p-value	**0.0001**

Figure 5: Captured Opportunities by Visit Type for the 4:3:1:3:3:1:4 Series



	Acute Visit	Well Child Check
p-value	**0.0119**	**0.001**

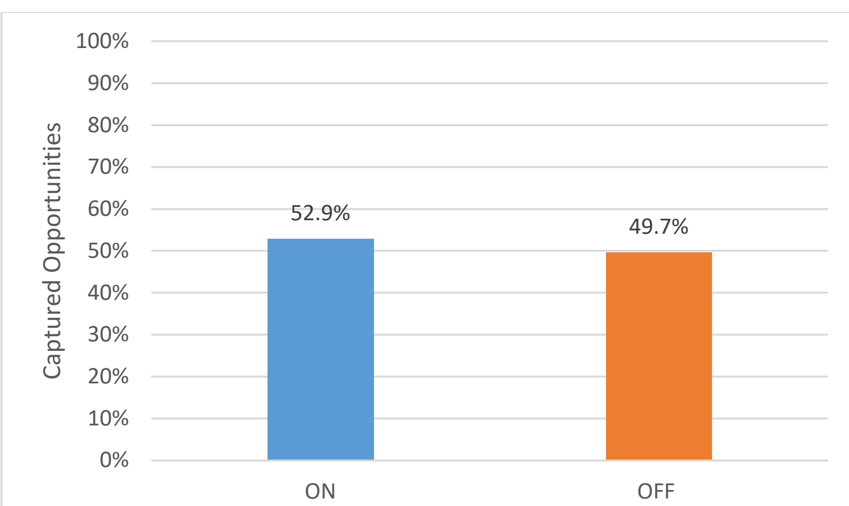
Figure 6: Captured Opportunities by Age for the 4:3:1:3:3:1:4 Series



	Overall	<1 Year	>=1 - <2 years	2 - 3 years	4 – 6 years	7 - 10 years	11 - 12 years	13 - 17 years
p-value	**0.0001**	**0.0006**	**0.0034**	0.10	0.19	**0.0023**	0.998	**0.023**

Overall, there were 2,735 visits during the study period in which an adolescent was due for a vaccine in the CDC-recommended 1:1:2/3 series as described above. There was a not a difference in captured opportunities when the alert was "on" vs. "off" (p=0.1) (Figure 7). There was also no difference when stratified by visit type.

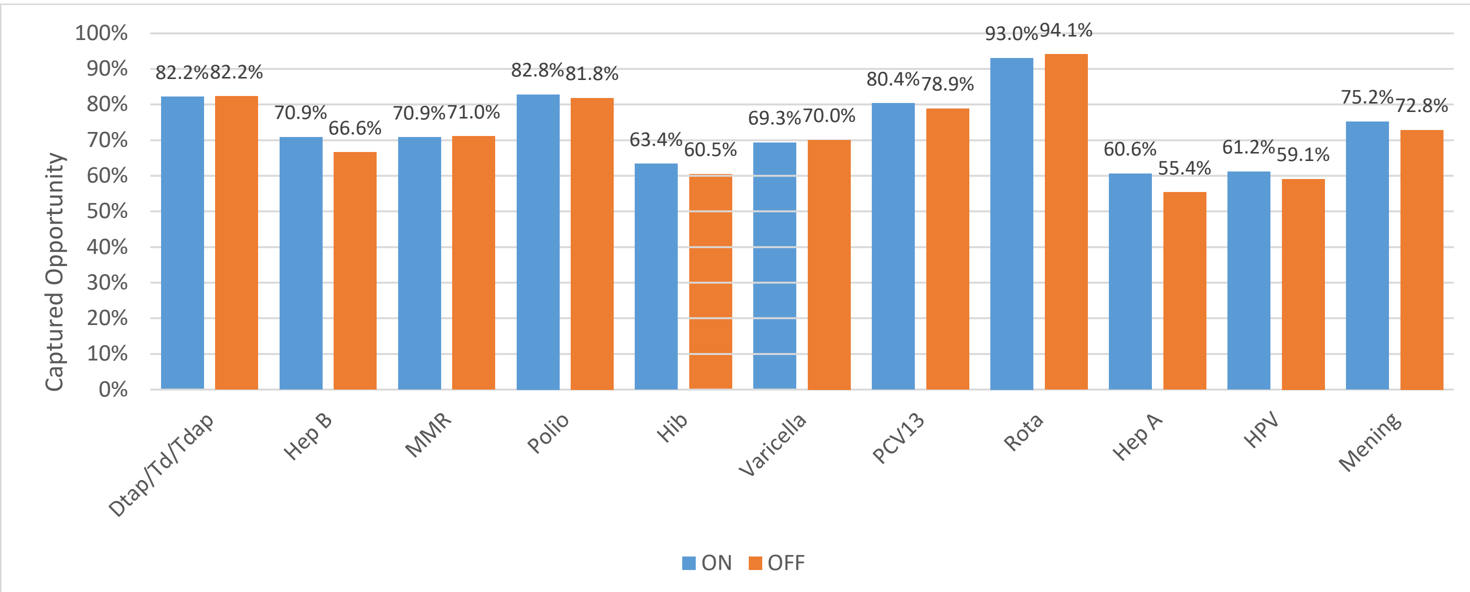
Figure 7: Captured Opportunities by Age for the 1:1:2/3 Series



	Overall
p-value	**0.097**

In addition, we stratified captured opportunities by vaccine type. A few of the vaccine types including Hep B, Hib, and Hep A were more likely to lead to a significant increase in captured opportunity during the "on" periods for alert versus the "off" periods (Figure 8).

Figure 8: Captured Opportunities by Vaccine Type



	DTaP/Td/Tdap	Hep B	MMR	Polio	Hib	Varicella	PCV13	Rota	Hep A	HPV	Meningococcal
p-value	0.98	**0.01**	0.92	0.36	**0.028**	0.68	0.17	0.30	**0.0006**	0.37	0.30

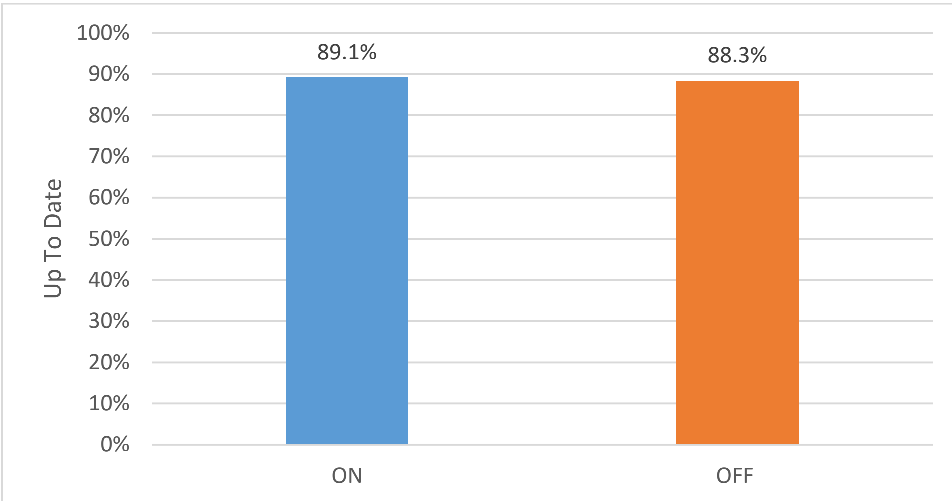
Underimmunization

By the end of each phase, there was no significant difference for all ages combined (Figure 9) (p=0.16) nor when divided by age (Figure 10), with very high immunization rates over all periods.

Over-immunization

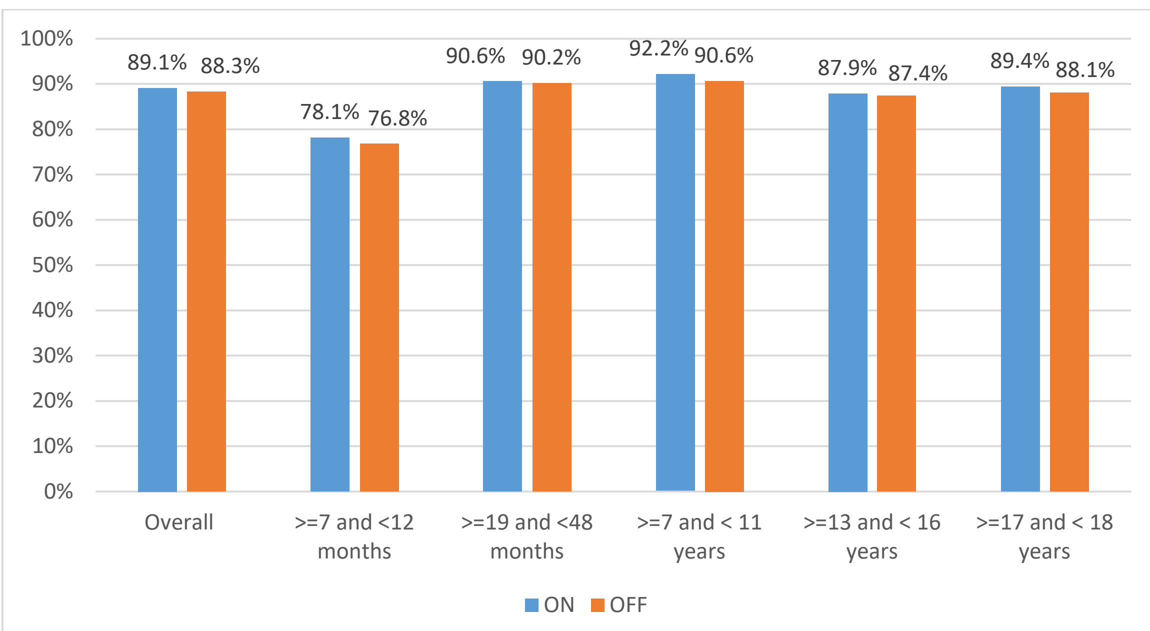
Only a very small n=90 invalid doses were given during the entire study period. There was no effect on the number of invalid doses between children seen during the on versus off periods.

Figure 9: Immunization status for the 4:3:1:3:3:1:4 series by the End of Phase for Study Ages



	Overall
p-value	**0.16**

Figure 10: Immunization status for the 4:3:1:3:3:1:4 by the end of the phase by age



	Overall	>=7 and <12 mo	>=19 and <48 mo	>=7 and <11 years	>=13 and <16 years	>= 17 and < 18 years
p-value	0.16	0.53	0.65	0.07	0.71	0.60

Chronic Medical Conditions (CMCs)

For children with CMCs, we assessed, as appropriate for their condition, receipt of PPSV23 and/or meningococcal immunizations which are condition-dependent. Overall up-to-date status by the end of the phase for pneumococcal vaccine remained low for the 299 children seen during the year with a qualifying condition, when the alert was on (23.7%) and off (24.5%), (p=0.9), and captured opportunities were low (6.6% vs. 2.5%, p=0.13, On vs. Off). Overall up-to-date status for the 35 children who had a qualifying condition for the meningococcal vaccine and were seen during the study period was high both when the alert was on (14 of 19 cases) and off (14 of 16 cases). Captured opportunities during the study period were relatively low (1 of 6 cases vs. 2 of 4 cases On vs. Off) for the 10 children who were due during the study period.

User Survey

We designed a user survey that intended to assess user satisfaction with the SINC alert. The anonymous survey was distributed to providers including residents and attending physicians and nurses via the web platform Qualtrics that users completed online.

Results and comments from the user survey were informative. Overall, 35 providers and 10 nurses completed the survey. Most providers and nurses were either very satisfied or somewhat satisfied with the SINC alert 38/42 providers and 11/11 nurses respectively. Similarly, almost all staff found the alert at least somewhat helpful (39/42 providers and 11/11 nurses). The vast majority of providers said they had ordered a vaccine at least sometimes because of the alert. Many staff commented that the alert helped them elucidate whether or not enough time had elapsed between vaccine doses. Other staff commented that the alert was a good double check of the vaccines they thought were due at the time of the visit. When survey respondents were asked to comment about the benefits of SINC, several staff appreciated the reminder, many noted that it helped make catch-up immunization easier, helped catch errors and/or identify missed vaccine doses. On the other hand, several staff members reported concerns about the accuracy of the alert, concerns that the alert did not synchronize with the city immunization registry, or they had technical difficulties with the alert with reports that sometimes it was blank, incomplete, or did not launch.

DISCUSSION

The SINC alert was associated with improved captured opportunities for patients seen when the alert was on versus when it was off. This was across all visit types, and in many age groups as well as for several specific vaccine types. However, when looking at immunization status by the end of each phase for the recommended series, there was no difference. There was also no impact specifically on immunizations needed for children with chronic medical conditions.

Overall immunization coverage rates were very high across all sites for sites which could have led to the blunted effect of the alert on status by the end of the phase across the population which included children being seen for visits who both needed and did not vaccination. Therefore, on a population level at sites where immunizations are an important part of the workflow and baseline rates are high, such an alert may not have an impact. However, on an individual child level, it may be helpful to aid health care providers in capturing opportunities to vaccinate. Interestingly, the impact on captured opportunities was not only for acute care visits where one might expect that opportunities could be missed, but also for well child checks where health care providers already have an increased attention toward vaccinating. This may be because an individual child was due for a vaccine that was not routinely given at that age because the child had a vaccine delay or a previously administered dose did not count because it was given at too young an age or too short an interval between doses.

However, not all opportunities were captured. Some reasons could be medical such that the health care provider did not want to vaccinate that day, such as when a child has an acute illness or high fever. Some could be logistical such as the family not having time to wait to receive the vaccine that day. Others could be parent-driven such as parents who are vaccine hesitant and ask to delay or refuse vaccinations. There are also technical and trust issues that could have affected the impact of the alert. In the survey, some end users reported frustrations when the alert did not act as expected. For example, for new patients, the alert was not able to find the vaccine record for all patients due to difficulty finding them in the universal patient index table at the time of the visit. This could have led to missed opportunities during these initial visits. In addition, health care providers reported at times not trusting what the alert was telling them. In every case reported to the team, the alert was indeed correct and the patient was in need of immunization. While a concerted effort was made to increase trust in the alert, more education may be needed for the health care providers about the catch up vaccine schedule as well as when doses that have been given previously may be invalid such that when the alert provides them with that information they believe it to be true. It is possible that over time trust would be increased as end users used the alert more.

These limitations above likely also played a role in the lack of effect for children with chronic medical conditions requiring specific immunizations. In addition, there were other reasons that may have led to this negative finding. The alert highlighted for the health care provider that the patient may have a condition that required a condition-specific immunization and directed the provider to the part of the alert where the problem list was located, the vaccine record in the alert and the CDC's overall medical condition-specific recommendations (which was also able to be launched as a pdf from the alert). It is likely the guidance needed to be much more specific, potentially highlighting the exact condition which triggered the alert and including directly in the alert the exact text from the CDC guidance for that specific condition rather than a link to the overall recommendations. In addition, in building the tables that trigged this part of the alert, it proved to be a complicated task to convert the CDC immunization guidelines text into disease specific ICD9 and 10 codes. In addition, because coding in the problem list even for the same condition varies substantially, we had to decide how liberal we would be in identify codes that could possible indicate a condition. We opted to increase the sensitivity of the alert and therefore included parent codes that may be used to code for a condition for which the vaccine would be needed, but that could also code for a condition for which the vaccine may not be needed. We educated the end users as well as noted in the alert that the end user should check the conditions to confirm whether or not the vaccine was needed. This need to confirm may have acted as a barrier. In addition, it could have led to provider alert fatigue if the alert triggered for some patients who were not actually due for the vaccine. It could also enhance provider distrust. It is possible that in an EHR system where billing is more structured such that conditions are more likely to be coded the same way and with more specificity, such an alert could rely on more specific ICD codes which would allow much more specificity in the alert. This would need to be balanced with sensitivity. Another possible explanation for low rates of CMC-related vaccinations could be provider judgement. For example, some CMCs are either present or not such as in the case of sickle cell disease or cochlear implants. However, for other conditions where the patient may be doing clinically well or with mild disease such as mild heart valvular disease, heart surgery in the past, well-controlled kidney or liver disease, or a remote history of cancer, a provider might believe that the vaccine is not necessary. When analyzing CMC results, we used a more conservative approach including patients with mild disease in the denominator for CMC-related vaccinations.

Logistically, we were able to connect to the open-source rules-based engine provided by the New York City's IIS through their vendor. We were also able to synchronize immunizations with the local IIS which aided in the completeness of the immunization record that fed the alert. Using centralized rules are an important way to ensure that EHR vendors are always using the most up to date rules, it also reduces redundancies. Rule updates and changes occurred often during the study. For example, there were 7 updates during the trial itself and 18 over the last three years. This number highlights both the need for centralized rules since a fair amount of work is needed to keep rules up to date again, as well as the need on the EHR side to have a nimble system that can act on these updates as well as a system to make sure the updates are not missed. For chronic conditions specifically, the rules engine was able to highlight when vaccines may be needed for high risk conditions, but did not have a list of ICD 9/10 codes that would constitute conditions that could necessitate that vaccine. That is potentially something that could be useful in the future such that individual sites are not trying to create that themselves. However, the caveats of the sensitivity and specificity balance as discussed above would need to be addressed.

In conclusion, immunization clinical decision support in this population did impact captured opportunities for immunization providing individual children with their needed vaccinations. While we did not see in impact on a population effect due to very high baseline immunization rates, such an alert may be helpful across a population at sites that are not routinely checking for needed immunizations at all visits. The alert did not have an impact on condition-specific immunizations for children with chronic medical conditions, highlighting that more precise coding may be needed to be able to launch sensitive and specific alerts that are more actionable for the end users. Overall, it was possible to build an immunization alert in an EMR that used a centralized immunization rules engine as well as synchronized data with the local IIS.

AHRQ PRIORITY POPULATIONS

This study took place in four urban, academically-affiliated community clinics that serve a primarily low-income, Latino population. Almost all patients have publicly-funded insurance.

LIST OF PUBLICATIONS AND PRODUCTS: NONE