B. MAIN SECTION

1. OVERALL GOAL AND OBJECTIVES

Goal: To revise and implement a practice improvement immunization toolkit to increase vaccinations among adolescents. The 4 Pillars Toolkit www.immunizationed.pitt.edu/4pillarstoolkit, which has been successfully used in adult and pediatric influenza vaccination,[1,2] will be adapted for use with adolescents and tested in a randomized cluster trial in 18-20 pediatric and family medicine practices. Enhancements include electronic messaging to parents/patients and an online practice transformation dashboard for medical practices.

Objective 1

With review by national experts, adapt the 4 Pillars Toolkit to adolescent vaccination, add electronic messaging to Pillar 2, modify an electronic practice transformation dashboard to facilitate office use, and develop online training materials.

Need: National adolescent immunization rates are modest, especially for HPV (53.0% among females ages 13 to 17 years and 29.5% for females ages 19 to 21 years for ≥1 dose with few receiving all three doses[3]), and influenza vaccine (34% for adolescents[4]). Barriers to vaccination can be categorized into system, provider, and patient issues. With the increase in vaccine supply and in coverage by insurance and the Vaccines for Children Program reducing system barriers, provider and patient barriers are the focus of this proposal. While many immunization toolkits have been developed, most are materials based and have not been subjected to rigorous testing, namely a randomized trial and many are not integrated into a package.

Approach: The toolkit's 4 Pillars are 1) Convenient vaccination services, 2) Patient notification/messaging, 3) Standing Orders Programs (SOPs)/Enhanced office systems to reduce missed opportunities,[5] and 4) Motivation/feedback/practice transformation dashboard. The 4 Pillars toolkit has been successful in adult immunizations and will be revised for adolescent immunization. Pillar 2 includes development of culturally appropriate adolescent immunization messages.[6,7] Consequently, electronic delivery methods (e.g., texting) will be used.[8,9] Training on 4 Pillars Toolkit will be provided in-person and online. If CDC/AAP/AAFP change Tdap recommendations for adolescents in 2013 as many expect, this will be incorporated.

Objective 2

Raise adolescent HPV and influenza vaccination rates by an absolute 15% in a randomized controlled cluster trial (RCCT) in which 18-20 primary care practices will be randomized into intervention and control arms. The effect of the intervention will be measured by change in vaccination rates and by using the RE-AIM framework.[10]

Need: Human papillomavirus (HPV) is the most common sexually transmitted infection (STI) in the US with an estimated 39.9 million infections in US females and 39.2 million in males.[11] The consequences include 21,290 HPV-associated cancers in US females and 12,080 cases in males annually.[12] In the pre-vaccine era, about a quarter million cases of genital warts occurred annually in US males. Influenza-like-illness accounted for school-age children missing 1.91 to 4.87 more school days than children with non-influenza-like-illnesses.[13] Despite these

data and the availability of effective vaccines, vaccination rates were modest, as previously mentioned. The US is experiencing a resurgence in pertussis with over 41,000 cases in 2012[14].

Approach:

- Randomize primary care practices treating adolescents in intervention and control practices
- Implement the Toolkit, including automatic and/or electronic office system changes, and motivation from a champion to reduce missed opportunities and increase rates;
- Implement Practice Transformation Dashboards and provide training;
- Evaluate success change in **vaccination rates** and by the **RE-AIM framework**, endorsed by CDC, which focuses on **R**each, **E**ffectiveness, **A**doption, **I**mplementation, and **M**aintenance.

INNOVATION

- The original 4 Pillars Toolkit has been expert peer-reviewed, pilot-tested[1] revised, and re-tested in primary care for adult immunizations.[1,2,15] Its development was funded by CDC and is intellectual property of the University of Pittsburgh. It will be adapted for adolescent immunizations.
- The interventions are ***linked*** in a logical ***chain***. Isolated interventions are unlikely to result in sustained vaccination rate improvements; for instance, purely patient-oriented measures may lead to an accepting patient but no vaccination, due to poor systems; conversely, well equipped providers will not be successful if patients are unavailable. Brief training, provision of and reminders about SOPs are *insufficient* to significantly increase rates.[16] During pilot-testing of our toolkit, we came to the conclusion that **two different approaches** were needed to maximize vaccination rates: (1) reducing missed vaccination opportunities among patients who access office services during influenza season via SOPs, that is, allowing non-physician staff to assess for vaccine eligibility and vaccinate without a specific order (Fig. 1); and (2) notifying patients **not** routinely using office services during influenza season about convenient express vaccination services operating under SOPs (Fig. 2).
- *Culturally competent adolescent messages*,[7] about vaccination will be created and tested.
- Motivation will be fostered by feedback and competition.
- The **multidisciplinary team** includes expertise in statistics, economics, epidemiology, bioethics, preventive medicine, pediatrics, family medicine, and public health.
- Uses UPMC's EpicCare EMR, which can be translated to other EMRs nationally.

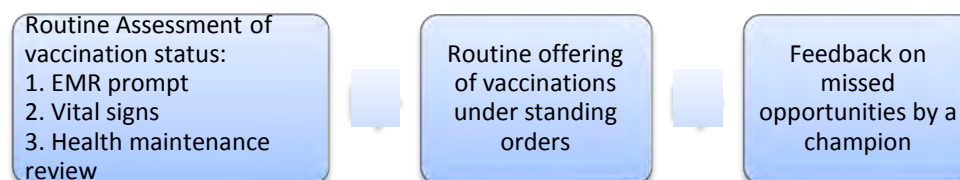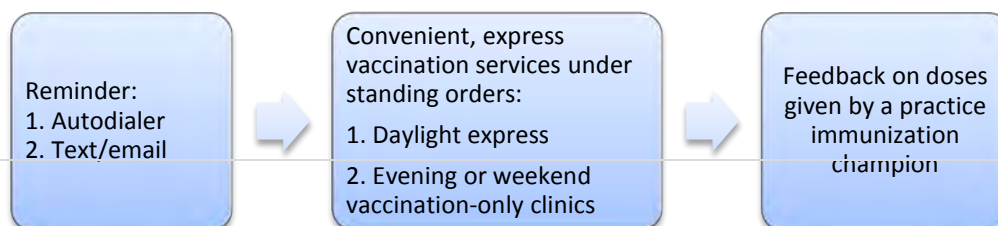Figure 1: Patients Who Access Office During Influenza Vaccination Season

Figure 2: Patients Who Do NOT Access Office Routinely During Influenza Vaccination
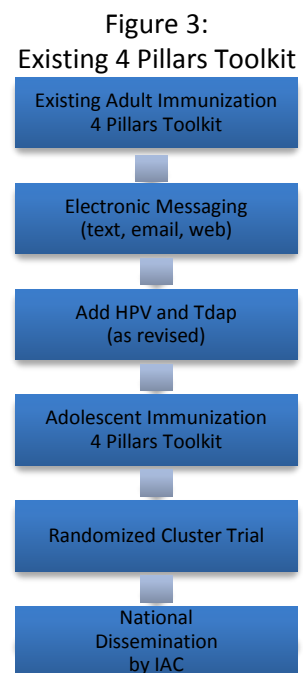
- The Adolescent Practice Transformation Dashboard is the central hub of the 4 Pillars Toolkit and is the master list of all activities. A clinical practice can enroll in the program which initiates an automated guidance process that directs the clinical team through the implementation of evidence-based practices shown to increase immunization rates. Each task on the dashboard is linked to instructions and supplemental resources and is programmatically assigned a due date.

2. TECHNICAL APPROACH

A. CURRENT ASSESSMENT OF NEED IN TARGET AREA.

1. Based on data from EpicCare, the local electronic medical record (EMR). Influenza vaccination rates in 2011-12 ranged from 24% to 63% for children in 10 UPMC-affiliated practices, with a mean of 48.8% among 39,922 children. For HPV vaccination, a network of 7 practices serving urban and mostly disadvantaged sites rates was evaluated. For >1 HPV doses, rates ranged from 1% to 41% and for 3 dose series completion ranged from 0% to 13%. Among 5 mostly pediatric UPMC practices of patients 11-18 years of age with at least 1 visit in the last 2.25 years, HPV vaccination rates for 1, 2, and 3 doses were 33%, 19%, and 1.6%, respectively. Because of our state laws, local adolescent Tdap, meningococcal, MMR, varicella, and hepatitis B vaccination rates are high. For instance, among Medicaid patients in a practice network, among adolescents who turned 13 years of age during 2011, vaccination rates are 89.5% for Tdap and 88.5% for meningococcal conjugate vaccine.

Figure 3:
Existing 4 Pillars Toolkit

Existing Adult Immunization
4 Pillars Toolkit

Electronic Messaging
(text, email, web)

Add HPV and Tdap
(as revised)

Adolescent Immunization
4 Pillars Toolkit

Randomized Cluster Trial

National
Dissemination
by IAC

2. The primary direct audience for the Toolkit is primary care pediatricians and family physicians and their staff. For Pillar 2, patient notification through direct reminders[17] and through clinician recommendation,[18] the audience is adolescents and their parents. In the U.S. in 2012 an estimated 87% of Americans owned cell phones;[19] 92% had personal email accounts;[20] 168 million were on Facebook, and 61% of Americans were on social media.[20] The increase in immunization rates will benefit the practices due to reduced influenza disease burden and higher scores on quality measures. Adolescents will benefit from reduced disease now (reduced school and work absenteeism) and in the future (e.g., reduced orogenital cancer and genital warts). Theoretically, their future children would benefit from reduced laryngeal papillomas. Parents of the adolescents will benefit from not seeing adolescents suffer from influenza and HPV and reduced absenteeism to care for ill children. Siblings, grandparents, and the community will benefit from reduced exposure to influenza due to herd immunity. If the ACIP and AAP change pertussis vaccine recommendations prior to the start of this project as expected, adolescents, their siblings, their families and the community may benefit from reduced pertussis disease and transmission.

B. INTERVENTION DESIGN AND METHODS

1. EXISTING 4 PILLARS TOOLKIT

Objective 1. With review by national experts, adapt the 4 Pillars Toolkit to adolescent vaccination, add electronic messaging to Pillar 2, add an electronic practice transformation dashboard to facilitate office use, and develop online training materials.

The existing 4 Pillars Toolkit was developed from evidence-based strategies, survey research, and practical experience in office practice change on immunizations. As discussed under "Innovation," the toolkit aims to eliminate missed opportunities by SOPs, to reach out to patients, offer convenient express vaccination under SOPs, use influenza vaccination as opportunities to vaccinate against HPV and use electronic reminders for doses 2 and 3. The Adult Toolkit is in the Appendix and follows:

Pillar 1: Convenient vaccination services

Pillar 2: Patient notification about the importance of vaccination and the availability of convenient programs

Pillar 3: Enhanced office vaccination systems based on Standing Order Programs (SOPs)

Pillar 4: Motivation – Office immunization champion tracks progress towards a goal, aided by feedback

For SOPs to be effective, vaccination status should be established using a routine process. Several mechanisms can achieve this, including adding vaccination status as a vital sign, use of EMR prompts, or routine review of the health maintenance or immunization sections of the EMR. While such review may be common during annual routine complete physical examinations, many adolescents do not make such visits. Thus, use of acute and chronic care visits is important as well. We have found higher adult pneumococcal vaccination when it was linked to influenza vaccination. Thus, we believe linking adolescent vaccines will raise rates.

Our experience during the pilot testing showed the importance of identifying a person be responsible for a site's implementation of the toolkit, which we term an immunization champion. This person's training can vary from that of a medical assistant, manager, or physician. The champion is responsible for organizing, implementing the toolkit, monitoring immunization rates and processes, and providing feedback to the clinical teams.

2. Add Electronic Messaging to Parents/Patients IN A HIPAA COMPLIANT AND CULTURALLY SENSITIVE MANNER
RATIONALE FOR ELECTRONIC MESSAGING

Teens have the edge on technology and mobile device use. According to research conducted by Pew Internet Research Center on *Teens and Technology (2013)*, "teens represent the leading edge of mobile connectivity, and the patterns of their technology use often signal future changes in the adult population."[21] Most (93%) of teenagers have access to a computer at home, 78% have cellphones with 47% being smartphone users, and 23% have tablets.[21] Teens have moved to use of mobile devices for accessing the internet with 74% reporting they use their cells phones, tablets or other devices to engage online.[21]

As 85-93% of American adults own a mobile phone and homes are becoming increasingly mobile-only based[22,23] it is likely that reminder-recall systems utilizing text or email messages will be on the rise. Parental views on receipt of text message immunization reminder-recalls from medical providers is overwhelmingly positive, even among parents who are not as competent in texting capabilities.[24,25] One study that found among parents who prefer traditional communication methods, over half were willing to register their cell phones for text based immunization reminder-recalls.[26] A recent systematic review of interventions utilizing text messaging services for promotion of health behaviors found that overall, "text messaging is recognized as a feasible and culturally acceptable way to disseminate health information in pediatric and adolescent populations."[27]

The use of texting and smartphone applications for immunization reminder-recalls have been successfully used with parents of children and youth.[9,23,28-30] Two recent studies were successful in increasing receipt of immunizations among urban low-income and minority pediatric and adolescent populations by sending reminder-recall text messages to parents.[9,30] Text messaging were connected with the medical facilities' EMRs and immunization registries and used texts as a way to both educate parents on the importance of vaccine for their children and as a way to remind them to schedule their teens' vaccination appointment. Another immunization reminder-recall study placed the burden on the parents to self-register for a text reminder service and found that parents who enrolled in this service increased on-time receipt of the second and third dose of HPV vaccine for their children by 13-16%.[23]

Studies have looked specifically at the types of content delivered via text messages that would be deemed acceptable to teens and adults[31-34] similarly conclude that adolescent health related text messages should feature content that is: simple, direct, factual, personal, informative, engaging, positive, sociable (i.e. ability to be able to share with friends), have a credible sign-off (e.g. practice name), and avoid authoritarian language.[31,33,34] For parents immunization reminder-recall text messages should be short, simple and personalized[24,32] including child's name, child's age, type of immunization and due date, doctor's name, clinic phone number, and in one study, clinic address.[24,31,32] Cultural differences should also be taken into account when developing text message content as Hispanic parents preferred an educational component as well.[31]

We will implement a patient-driven mobile marketing approach to stimulate conversation between patients and practitioners, execute timely reminders, and offer resources to patents and parents.

TEXT AND ONLINE MESSAGE DEVELOPMENT

Messages for delivery to patients about adolescent vaccination services will be developed by investigators, reviewed by the consultants, and revised. Subsequently, they will be tested with groups of parents and of teens for clarity, usefulness, and perceived impact. After this review, the messages will be revised again before final use.

TEXT MESSAGING PROCEDURE IN PRIMARY CARE UNDER HIPAA

The point of entry to the process will be through a text message or a web link. To initiate the process, a patient simply texts a keyword to a provided number (e.g., "Text 'vaccine' to 11111 to set up a reminder to schedule your next visit."), enters a URL, or scans a QR code

(Figure 5). Once an individual sends the first message, their number is logged in a database and becomes available for return messaging. The first message will welcome the user to the service, provide a mobile-friendly web page of resources, and offer to collect enough information to provide relevant follow up reminders. For example, we may collect the age of the child, the specific vaccines administered, or other variables that can be used to generate a likely follow up schedule. Automated reminders can be scheduled for distribution based on this information. A participant can unsubscribe from the list, at any time by texting the appropriate message to the service. Because the process is initiated by the patient, any potential HIPAA violations are eliminated, and the burden to clinical staff is minimized.

Figure 4: The process of how patients entering doctors' offices will initiate notifications
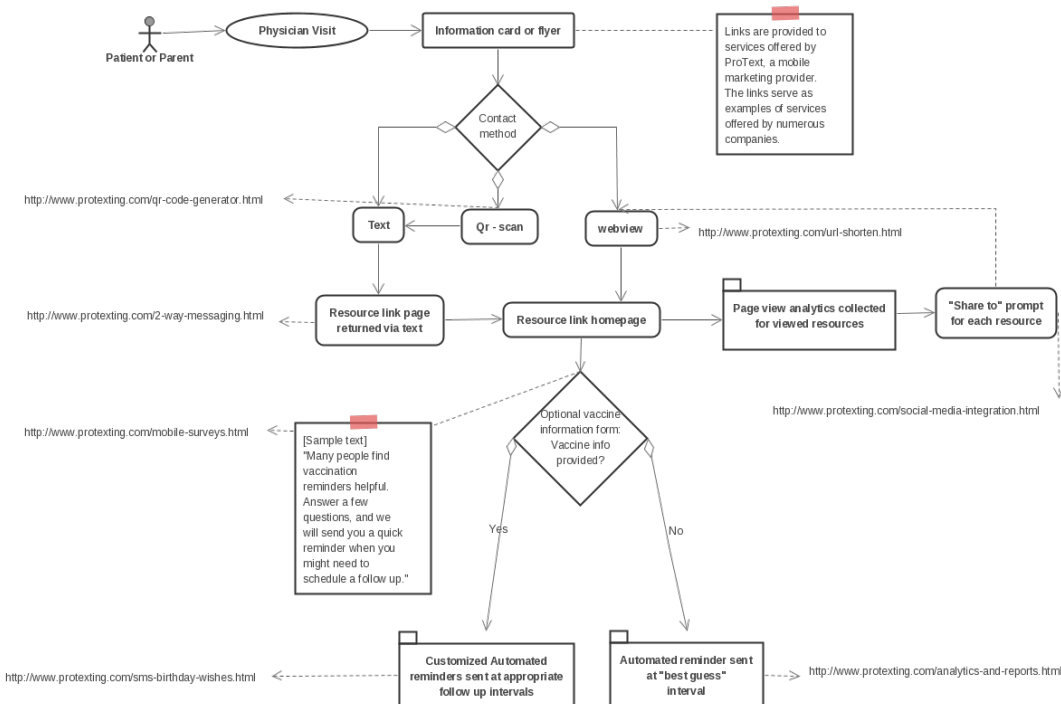
To prompt parents or patients to enroll in an automated reminder system initiating the process, health center staff will be instructed to point out a poster or provide a card to all parents and adolescents at the beginning of the clinical visit. This visual will describe vaccination resources available, instructions for accessing the resources, and a call to action. Resources will be available to any individual with an internet connection (which is available in most practices in our network). This resource page will also provide a second point of entry to the text message reminder service. Individuals who access the resources homepage will find a web form to enroll in the reminder service. This second input will be useful when the resource page is shared through or for those who directly enter the page URL instead of sending the initial text message.

Figure 5: Advertisement in doctors' offices

3. Add content to the 4 Pillars Toolkit and adapt to adolescent vaccination as follows:

- Add HPV, MCV and revised multiple-dose Tdap when released by ACIP, CDC and AAP to the toolkit.

The toolkit does not currently address HPV or MCV. CDC has stated that Tdap recommendations are being revised and will likely go to multiple doses with decisions planned for a 2013 ACIP meeting. The latest Tdap, HPV, and MCV recommendations will be incorporated.

- Add an adolescent Electronic Practice Transformation Dashboard

The Practice Transformation Dashboard is the central hub of the 4 Pillars Toolkit and contains the master list of activities. A practice can enroll in the program online at ImmunizationEd.Pitt.edu. A new enrollment initiates an automated guidance process that directs the clinical team through the implementation of evidence-based practices. Each task on the dashboard is linked to instructions and supplemental resources and is programmatically assigned a due date based on the date of enrollment in the program and delegated to a registered team member. At every step of the process, participating staff can log into the site and view the status of their activities and mark items as complete. Each item is designed to be clear, succinct, and helpful in implementing system change one step at a time.

When an item is completed, the designated clinical team member completes a brief form with the date completed and any relevant information gathered during the task. This information is reported back to the staff when appropriate. For example, task 4, "Choose your immunization measure" asks participants to identify an easily obtained estimate of immunization success. The practice is supplied with a range of options like number of doses per week divided by number of patients seen, or number of immunizations billed. This selection then becomes the ongoing bi-weekly task of reporting the selected measure. The dashboard collects these entries into a table visible to all of that clinic's staff. In addition to the real-time feedback of task completion, and immunization success, the dashboard also features an area for the immunization champion, other staff, and the intervention team to post messages to the team. As a clinic moves through the program, the dashboard sends automated reminders for overdue tasks, reinforcement messages at key milestones, and can be easily programmed to deliver other customized messages from the administrative team. We aim to avoid a "kitchen sink" but to have an organized and thoughtful approach that covers the required information without being overwhelming.

4. EXPAND ONLINE TRAINING

Online training will be expanded, using adult learning theory and interactive feedback features. Learning objectives using the appropriate spectrum of Bloom's taxonomy will be developed as an interactive online format, with PowerPoint-like presentations.[35] Software will be programmed to allow an audiovisual presentation with questions and responses. Based on the learner's response to the questions, various replies will be programmed.

Interactive tutorials will be used for presenting technical information where learner comprehension is tested during the presentation of material (e.g., vaccination guidelines, contraindications, overcoming patient barriers to immunization, and case studies of immunization questions). These tutorials will include video slide presentations with audio voice

over, a case to solve and questions to answer. Links to external references will be provided (e.g., *Shots by STFM* point-of-care immunization information which is co-written by the authors). Progress through the material will be monitored by completion of embedded surveys. Immunization champions will have access to the progress but not the scores of users at their site.

The educational intervention will be administered as an internet web site. The site will be constructed using the open source content management system (CMS), Drupal.

5. CONDUCT A RANDOMIZED CONTROLLED CLUSTER TRIAL OF THE ENHANCED ADOLESCENT 4 PILLARS TOOLKIT.

The fundamental question about an intervention is "**Does it work?**" Thus, it is essential to demonstrate that the adolescent 4 Pillars Toolkit works. We believe that a **randomized controlled cluster trial** (RCCT) is the **strongest methodology** to prove the impact of a toolkit, in large part because randomization will help control for practice level differences in culture and characteristics. Randomization is the design most favored by epidemiologists and is the design most likely to result in positive ratings in formal meta-analyses. This design accounts for changes in immunization rates due to other factors, such as national publicity. Components of a RCCT include recruiting practices, applying inclusion and exclusion criteria, blinded randomization, intervention, and evaluation.

The intervention steps are based on the **evidence-based framework of implementation by Fixsen** et al.[36] and include training of practices, use of the **web-based Practice Transformation Dashboard, feedback on immunization rates** to the practices, and communication with each practice's immunization champion. At each intervention site, investigators will meet with the practice's administrative, medical and support staff to provide "Kick-off" training about the toolkit, culturally sensitive adolescent messaging about immunizations, and the Web-based Practice Transformation Dashboard. Electronic messages will be delivered to adolescents and their parents by the messaging website and by automatic means such as autodialer. Each site will be asked to assign an immunization champion who is tasked with motivating the practice and ensuring implementation. Feedback on doses administered and comparative data from other sites will be provided to the immunization champion on a regular basis to promote competition. The study will be registered in ClinicalTrials.gov.

Inclusion Criteria for practice: The practices are part of Pediatric PittNet, Family Medicine PittNet, and/or UPMC's Community Medicine Inc. Current Pediatric PittNet member practices includes 20 practices with 36 office sites in 6 counties in southwestern Pennsylvania and 170 Pediatric PittNet providers serving over 200,000 patients, aged birth to 21 years. Family Medicine PittNet has 7 practices with over 25,000 patients, split about equally among whites and blacks. Community Medicine Inc. is a group of non-academic practices that were purchased by UPMC, with more than 80 primary care practices, 350 primary care clinicians, and about 250,000 patients. Stratification will occur on important practice characteristics (e.g. specialty location (urban/suburban)).

Exclusion Criteria for the practice: Exclusion criteria include rates of immunization that approach a ceiling (e.g., 80% for influenza) and lack of electronic medical records.

*Patient-level inclusion and exclusion***:** CDC guidelines for patient-level inclusion and exclusion will be used. *Inclusion criteria*: This project will address vaccination of adolescents (aged 11 to 17 years) who are active patients. Active patients are those with a visit within the last 12 months. Exclusion criteria: Those with a true contraindication, following the CDC's Guide to Contraindications, such as prior vaccine anaphylaxis.

C. EVALUATION DESIGN

1. RE-AIM AND VACCINATION DATA TO ADDRESS GAP

As a framework for evaluation, we will use **RE-AIM**, which focuses on Reach, Effectiveness, Adoption, Implementation, and Maintenance and is endorsed by CDC. The **main outcome is change in adolescent immunization rates**, which address both reach and effectiveness. Baseline and end-of-year intervention data will be gathered from UPMC's EHR, EpicCare. To determine whether or not the intervention was successful, **hierarchical linear modeling** (HLM) will be conducted, which accounts for the fact the **patients are clustered within an office**.

All of the practices included will be on the EpicCare EMR and immunization data will come from an honest broker. The UPMC EpicCare system has a bi-directional interface with the Pennsylvania Statewide Immunization Information System.

Statistical Analyses: Due to the clustered nature of the dichotomous immunization data, we will use the Bernoulli distribution in the software package HLM (Lincolnwood, IL) with the full maximum likelihood estimation via the LaPlace approximation algorithm or the Glmmix procedure in SAS.[37] The dichotomous outcome variables are vaccination status for a particular vaccine (e.g., influenza) or for series completion for HPV. Multilevel HLM analyses will be conducted in an incremental fashion, starting with an empty or null model, then adding patient level (Level 1) variables, namely age, sex, and race, and subsequently adding practice level (Level 2) variables, namely intervention site (or not) and fidelity. Co-linearity will be assessed and one member of co-linear variable pairs dropped. We have used similar methods previously to analyze a hierarchical design.[38-40] The model follows:

Level 1 Model:
$$\text{Prob}(\gamma = 1 | \beta) = P$$
$$\log[P/(1-P)] = \beta_0 + \beta_1 * (age) + \beta_2 * (race) + \beta_3 * (sex) + r$$

Level 2 Model
$$\beta_0 = \gamma_{00} + \gamma_{01} * (\text{intervention vs. control site}) + \upsilon_0$$
$$\beta_1 = \gamma_{10} \quad \beta_2 = \gamma_{20} \quad \beta_3 = \gamma_{30}$$

The software automatically calculates 95% confidence intervals for coefficients. To compare change in rates, influenza vaccination status in the baseline year can be added as an independent variable. Fidelity/implementation scores can be added at level 2 to adjust the results. Random effect terms will be added as appropriate for the data.

Table 1: Evaluation components by RE-AIM

RE-AIM component	Methods & data sources	Outcomes
Reach & Effectiveness	-Immunization data from EMR	-Final and change in immunization rates in intervention vs. control sites -Racial disparity in immunization rates
Adoption	-Online survey of immunization champion, lead physicians and head nurses in REDCap	-Reported consistency and degree of use for each pillar of toolkit (i.e., Fidelity) -Assessment of importance of program components -Characteristics of practice
Implementation	-Online survey of immunization champion, lead physicians and head nurses in REDCap -Status of online Practice Transformation Dashboard	-Contextual factors that hinder or facilitate implementation -Progress of each practice in Dashboard
Maintenance	Monthly status of online Practice Transformation Dashboard	-Dates of achievement on each implementation step; qualitative description of efforts and notes made to implement each step
Final Vaccination rates & determinants	-Conduct HLM on influenza rates and HPV series completion rates. -Add fidelity as predictor variable -Evaluate co-linearity -Determine final HLM models	-Odds ratios and 95% CIs for intervention, fidelity, and site level predictors, after checking for co-linearity and controlling for patient mix

To determine reasons for success and contextual perceptions related to the toolkit, we will conduct **surveys of head nurses and physicians and practice champions**. Surveys will be conducted online using the NIH's survey platform called **REDCap**. For comparisons, t-tests will be used for continuous variables and Chi-square or Fisher's exact tests for categorical variables. 95% confidence intervals will be calculated.

The RCCT is a randomized trial which includes a set of **control** practices; the toolkit will be made available to the control practices after the conclusion of the RCCT. By surveying control sites, we will know what methods they used to promote vaccination as we expect some changes at controls sites due to secular trends.

2. QUANTIFY AMOUNT OF CHANGE EXPECTED AND SAMPLE SIZE

Hypotheses: The interventions will increase the vaccination rate by an absolute 15%, comparing intervention versus control sites and the odds ratio based on the coefficient from the intervention versus control group variable in HLM will be statistically significant.

Table 2 shows the output for sample size calculations using Optimal Design software[41] for a randomized cluster trial with a dichotomous outcome, using various expected rates in intervention groups (ϕ_E) and control groups (ϕ_C), an absolute 10% or 15% increase in rates, for an alpha of .05 and for 18 sites (i.e., 9 intervention and 9 control). These data are consistent with the CDC's 2011-12 FluVaxView vaccination coverage rates of 33.7% for children ages 13-17 years.[42] As can be seen, a 10%-15% difference in rates can be determined in a randomized

design with a power of .8 or .9, depending on scenario, for any of these baseline rates with 18 sites. An analysis of patients at 5 of our family medicine sites shows an average of 403 patients per site in the 13-18 year-old age range.

Table 2: Sample Size and Power Calculation

Number of sites	Baseline vaccination rate ϕ_C	Plausible baseline vaccination rate range	Predicted change in rate from intervention	Final vaccination rate in intervention group ϕ_E	Cluster size (number patients)	Power
18	.49	.24 - .63	.15	.64	250	.8
18	.49	.39 - .59	.10	.59	250	.9
18	.40	.30 - .50	.10	.50	250	.89
18	.40	.28 - .52	.10	.50	400	.81
18	.20	.10-.30	.10	.30	250	.81
18	.20	.07-.33	.15	.35	250	.86
18	.10	.03-.20	.10	.20	400	.84
18	.10	.03-.20	.15	.25	250	.91

3. ENGAGEMENT OF TARGET AUDIENCE

Fidelity is a term used in outcome research to **confirm that the intervention actually occurred as intended**.[43] Using a modified Delphi technique,[44] the investigators will develop a fidelity score as others have done [45,46] after review of the head nurse, lead physician, and immunization champion questionnaires. The investigators will be asked to distribute 100 points across the identified measures which will be averaged to create a fidelity point system.   For example, this score could include use of evening or weekend hours for express influenza vaccination services. The score would be applied to selected responses from the head nurse, immunization champion, lead physician surveys that are conducted after implementation to create a fidelity score for each site.

The **Practice Transformation Dashboard** monitors implementation and maintenance. The dashboard collects these entries into a table visible to clinic staff and to the investigators. As a clinic moves through the program, the dashboard sends automated reminders for overdue tasks, reinforcement messages at key milestones, and can be easily programmed to deliver other customized messages from the administrative team. The Project Manager will review each clinic's progress using tables of completion, progress, deadlines, and overdue markers.

4. DISSEMINATION

The toolkit and results will be **disseminated** by a consortium arrangement with the **Immunization Action Coalition** (IAC, www.immunize.org), which is one of the premier immunization dissemination groups in the country. IAC uses email news, 3 well-known websites, mailed newsletters, and conference exhibits to distribute information. In addition, results will be published in peer-reviewed journals and at presentations made at national conferences.

5. LIMITATIONS

Limitations and sustainability

We recognize that control practices might implement some items on their own; thus, we will survey them to determine what strategies are used. We will adjust HLM analyses, by adding level 2 predictors, if needed. Although a study of several arms might clarify better the contribution of each part of a "package," it would require greater support and overlook evidence that multi-component packages raise rates more than single components.[47]

Obviously, testing the revised 4 Pillars toolkit in networks with a common EMR is not generalizable to the country but a mutli-state RCT is beyond the budget. Many of the interventions are sustainable, such as use of SOPs, prompts and use of electronic reminders/notices, especially when integrated into office systems and facilitated by an EMR.

3. DETAILED WORKPLAN AND DELIVERABLES SCHEDULES

The general Project **Timeline** follows:

Quarters 1&2: Institutional review board approval, development and testing of messages to adolescents and parents, refinement of toolkit, recruitment of practices, and randomization.

Quarter 3: Training, practice dashboard and launch of randomized trial.

Quarters 3-6: Implementation of trial, including electronic messaging.

Quarters 7-8: Data collection, analyses of immunizations and RE-AIM evaluation.

Quarters 9-10: Toolkit dissemination, presentations, and manuscripts.

We propose to use online management software, task lists, grant charts, and biweekly team meetings/conference calls as our primary management tools. The team has managed R01s and multiple CDC grants. In addition, the investigator team has worked together and published together previously.

Table 3: Deliverables and Schedule for Completion

Deliverables	Grant Year		Year 1				Year 2				Year 3		Who
	Quarter		1	2	3	4	1	2	3	4	1	2	
Objective 1 – Revise toolkit													
IRB submission			x										RZ, NN
Add HPV, latest Tdap recommendations, and MCV to Toolkit			x										RZ
Adapt toolkit to adolescent vaccination			x										RZ,ER
Develop electronic messages for parents/patients			x										JR
Expert review of the toolkit and subsequent revision			x										Team
Parent and teen testing of electronic messages and revision			x	x									NN JR
Develop interactive online training materials			x	x									RZ ER
Modify electronic practice transformation dashboard			x	x									JR
Produce adolescent vaccination video			x	x									RZ,ER
Program text and electronic messages				x									JR
Stratify and recruit practices				x									RZ,ER
Randomize practices				x									CL
Objective 2 – Conduct RCCT													
Kick-off training & tailoring visits					x		x						MPN
Implement toolkit and dashboard					x	x	x	x					Sites
Periodic online training					x	x	x	x					RZ ER
Use text and electronic messages					x	x	x	x					JR
Regular communication with site's immunization champions					x	x	x	x					JR,NN
Feedback on vaccines administered					x	x	x	x					JR
Monitor toolkit implementation online					x	x	x	x					JR
Surveys of physician, nurses, champions					x		x						NN
Immunization rates, racial disparity in rates, demographics EMR					x		x						CL
Fidelity determination								x	x				CL
Download of data from EMR											x	x	CARe
Statistical analyses									x	x			CL
Manuscripts & abstracts									x	x			Team
Dissemination:													Team
Prepare messages and media with IAC											x		Team
Disseminate toolkit via IAC resources											x	x	IAC
Disseminate via presentation/publication											x	x	RZ,ER

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