

IMPROVING VACCINATIONS FOR YOUNG CHILDREN (IVY)

ABSTRACT

The overall goal of the proposed work is to improve Combination 10 vaccination rates for Tennessee children through the development and implementation of a new program, **Improving Vaccination for Young Children (IVY)**. Target participants will include pediatric care providers and clinical staff in pediatric practices. Practices and participants will be recruited from Vanderbilt Pediatric Primary Care Practices and through a collaboration with the Cumberland Pediatrics Foundation, a non-profit company focused on improving health care services for Tennessee's children. The IVY program will include web-based vaccine educational modules individualized for both participant groups (pediatric providers and clinical staff) to educate on important vaccine topics and an in-person QI coaching session incorporating key drivers for improved vaccination rates. Combination 10 vaccination rates for children turning 2 years old will be collected monthly from participating practices and evaluated within the context of a stepped wedge cluster randomized trial. Vaccination rates will be compared between practices monthly and evaluated by practice over time.

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PROPOSAL: IMPROVING VACCINATIONS FOR YOUNG CHILDREN (IVY)

A. GOAL AND OBJECTIVES

A.1. Background: Routine childhood vaccination is a powerful tool to reduce morbidity and mortality.¹ However, vaccination rates in the U.S. remain well below *Healthy People 2020* goals.² Within the U.S., Tennessee had one of the lowest vaccination coverage rates for children aged 19-35 months in 2016, with rates steadily decreasing over the preceding 8 years.³

The reasons for declining vaccination coverage rates in children are numerous and varied.⁴ It is well known that parental concerns about the safety or necessity of vaccines impact vaccine acceptance.⁵⁻⁸ Strong recommendations from healthcare providers have been shown to positively impact vaccination decisions,⁹ however, our earlier work demonstrated that vaccine education for healthcare providers during residency was lacking.¹⁰ Furthermore, some providers and their staff believe that certain vaccines are unnecessary or unsafe, making these individuals less likely to strongly support routine vaccinations for children.¹¹⁻¹⁴ Given that undervaccination due to any reason increases the risk of acquiring vaccine preventable diseases,¹⁵⁻¹⁷ it is imperative for pediatric providers and all clinical team members to fully understand and communicate the safety and importance for all recommended childhood vaccines.

As a Co-investigator, I helped create the Collaboration for Vaccination Education and Research (CoVER) program to improve pediatric and family medicine residents' knowledge, confidence and vaccine communication competency. The CoVER program was then compared to standard training. Residents at CoVER sites had significant improvements in vaccine communication confidence compared to non-CoVER (15.5 vs 5.2, respectively on 100-point scale, $p < .001$ for CoVER pre/post).

A.2. Overall Goal: The proposed work seeks to improve Combination 10 vaccination rates for Tennessee children at 2 years of age through the development and implementation of a new program, **Improving Vaccination for Young Children (IVY)**. Through a collaboration with the Cumberland Pediatrics Foundation (CPF)¹⁸, a non-profit company focused on improving health care services for Tennessee's children, we plan to adapt and disseminate existing CoVER educational materials for community pediatric providers and clinical staff, and develop and implement targeted quality improvement (QI) initiatives.

A.3. Specific Objectives:

1. Design interactive web-based modules individualized for two groups (pediatric providers and pediatric clinical staff) to educate on key vaccine topics. Modules will include information related to 1) diseases vaccines are targeting, including influenza 2) vaccine contraindications, common misconceptions, and vaccine safety, 3) communication techniques, 4) vaccine schedules and catch up rules, and 5) exemptions, school requirements, and practice dismissal.

2. Design an in-person QI coaching session incorporating key drivers for improved vaccination rates. The session will be developed using the 4Pillars™ Practice Transformation Program (4Pillars™) and will include introduction of 1) acute visits for vaccine catch up, 2) team-based care practices, 3) standing vaccination record review and vaccination orders, and 4) reminder/recall systems.

3. Implement educational modules and QI coaching session at specific time points within the context of a stepped wedge cluster randomized trial (SW-CRT). Combination 10 [(Combo 10)(Table1)] vaccine rates will be collected monthly from the Electronic Health Record (EHR) of recruited

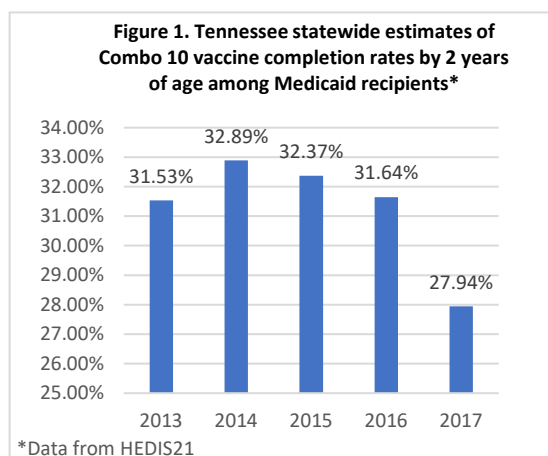
practices for eligible children turning 2 years of age. Vaccine rates will be compared between practices monthly within the SW-CRT design. Rates will also be evaluated by practice over time.

A.4. Goal Alignment:

The proposal goal, objectives and study design align directly with the focus of the grantor through the design, implementation and evaluation of a novel program in a specific population of pediatric practices to improve childhood vaccine rates. Other innovative components of the IVY program include 1) adaption of a proven and theory-based, adult vaccination quality improvement program (4Pillars™) for use in recommended childhood vaccines, 2) evaluating impact of the IVY program on monthly vaccination rates using a rigorous measure for vaccine uptake (Combo 10) within the modern SW-CRT design, and 3) education of both pediatric providers and clinical staff on key vaccine topics. The interests of the primary applicant Vanderbilt University Medical Center (VUMC) Division of General Pediatrics, and collaborator CPF, directly align with the focus of this opportunity: to improve health services and care for Tennessee children. **Dr. Sarah Elizabeth Williams, MD, MPH will serve as the Clinician Leader for IVY.**

B. CURRENT ASSESSMENT OF NEED

Tennessee childhood vaccination rates for children less than 3 years of age are concerning. National Immunization Survey (NIS)²⁰ data for 2016 Combination 7 vaccination coverage for



children aged 19-35 months identify Tennessee as having one of the lowest rates of childhood vaccine coverage in the U.S. (67.4%).³

This is down from 73.6% in 2008. Data

from the current Tennessee Healthcare Effectiveness Data and Information Set (HEDIS)²¹ show that Tennessee childhood vaccination rates are below national Medicaid

average for Combo 10 (27.94% in 2017 compared to 33.24% nationally) and have continued to trend downward over the preceding 5 years (Figure 1). In fact, HEDIS data show that all measures for young child vaccination rates in Tennessee (Combination 5, 6, 7, 8, 9 and 10) have declined from 2016 to 2017.²¹ These data support that the state of Tennessee is a prime recipient for innovative and effective strategies to support and improve childhood vaccination. For this proposal, VUMC will collaborate with CPF¹⁸ to recruit practices with patient populations that are representative of children in Tennessee (See Recruitment, LOS). Currently, CPF serves nearly 700 physicians, 75 practices, and 40 counties and is affiliated with Monroe Carell Jr. Children's Hospital at VUMC. Collectively, CPF's membership serves approximately 500,000 children in the middle Tennessee area across urban, suburban and rural settings. CPF has a strong history for successfully recruiting practices for multiple interventions through their network, most recently including a QI intervention focused on improving HPV vaccine rates in adolescents. Thus, CPF represents an ideal partner for the proposed work.

Table 1. Vaccines included in Combo 10 ¹⁹		
Vaccine	# doses by 2 years	Target Completion(%)*
DTaP	4	90%
IPV	3	90%
MMR	1	90%
Hib	4	90%
Hepatitis A	2	85%
Hepatitis B	3	85%
Varicella	1	90%
Pneumococcal 13	4	90%
Rotavirus	2-3	80%
Influenza	2	80%
*Modified from Healthy People 2020 goals to meet goal by 2 years of age rather than 35 months.		

Practices will also be recruited from Vanderbilt Pediatric Primary Care Practices (VPPCPs) (see LOS's). VPPCP patients are representative of a variety of socioeconomic groups and Combo 10 vaccine rates are routinely measured for all 2-year-old children. Table 2 shows recent data for Combo 10 completion by 2 years of age for 4 VPPCP practices. Vanderbilt's goal for completion of Combo 10 vaccines by age 2 is 80%. Although one VPPCP practice is currently meeting this goal, others have room for improvement and are well-suited to participate in the proposed work. VUMC, the Department of Pediatrics, and the Division of General Pediatrics are focused on improving population health, including childhood vaccination rates, and all are supportive of the proposed work. (See LOS) Given the broad reach of CPF as an organization in the state, and the diverse patient population served by the VPPCPs, the potential impact of IVY on childhood vaccination is significant (see Table 2 for estimates of potential patient impact for VPPCP sites alone).

C. RECRUITMENT

C.1. Targeted

participants:

Targeted participants for IVY will be practicing pediatric care providers and clinical staff (nurses,

Practice	Combo 10 completion by age 2	Combo 10 not completed by age 2	N	% Completion for Combo 10 by age 2	Approx. # Providers per practice	Approx. # Clinical Staff per practice	Approx. # total 2 y.o. pts per year	Approx. # undervaccinated 2 y.o. pts per year
A	17	8	26	65.4%	4	10	100**	35
B	49	41	90	54.4%	11	22	150	68
C	151	37	188	80%	8	15	330	66
D	378	246	624	61%	18	35	1070	417
Total	595	332	927	64.2%	~41	~82	~1600	~590

**Practice is a newer group and expected to grow exponentially over next year

medical assistants (MAs)) in each recruited pediatric group (see Table 2 for estimates of participants at VPPCP sites). Earlier work found that pediatric healthcare providers may not receive adequate education in residency to address parental vaccine concerns^{10, 22, 23} and that clinical staff may have concerning attitudes or beliefs regarding vaccines.²⁴⁻²⁶ Other studies have shown that providers desire additional knowledge and skills to discuss vaccines with patients and families.¹³ Thus, IVY will target both pediatric healthcare providers and pediatric office clinical staff. If awarded, recruitment will take place December 2018 and January 2019 through two systems outlined below.

C.2. Recruitment: Vanderbilt (Goal: 3 Practices):

As a practicing pediatrician at one of Vanderbilt's pediatric academic clinics, Dr. Williams is in a unique position to recruit pediatric groups affiliated with VUMC. Three VPPCP sites have agreed to participate in the study if awarded (see LOS). VPPCP sites care for children from a variety of payers and are representative of diverse socioeconomic groups. Two sites have patient populations primarily insured through Tennessee Medicaid affiliated plans, while one practice's patient population is primarily privately insured. (see Table 2 for estimates of approximate participants and potential lives affected at VPPCP sites).

C.3. Recruitment: CPF (Goal: 5 Practices):

Dr. Williams is collaborating with the largest network for private pediatric practices in the state, the Cumberland Pediatric Foundation (CPF) (see LOS). CPF's primary care practice members are located across urban, suburban, and rural settings, with a geographical range stretching across 40 counties in Tennessee. CPF will recruit five practices for the study with a self-identified need to improve vaccine rates for their young children. Recruited sites will be located across settings (urban, suburban, and rural) and will serve patients from a diverse range of socioeconomic backgrounds. CPF recruits

practices directly through established ongoing relationships and will target practices based on the highest level of provider and patient need for education and strategies to improve vaccine rates. CPF has successfully recruited practices for several VUMC-funded grants, Tennessee Department of Health-funded grants, and private foundation-funded grants. Most recently, CPF successfully recruited and enrolled 26 practices in an NIH-funded R01 grant focused on increasing HPV vaccines rates using quality improvement methodology in private practices in middle Tennessee.

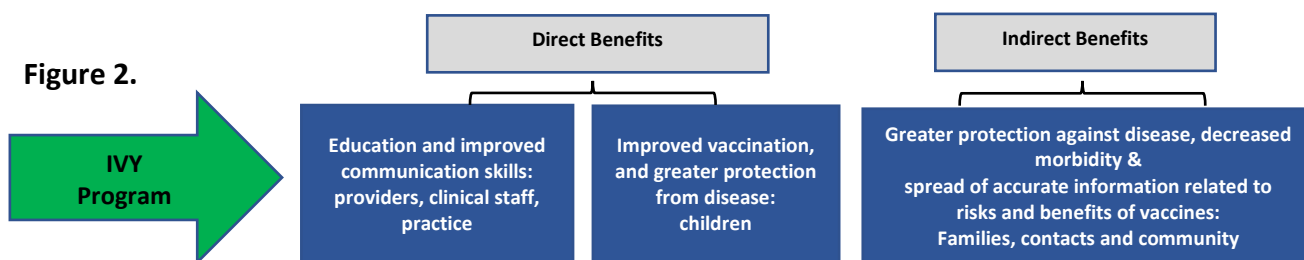
C.4. Incentives for Participants:

Two types of participant incentives will be implemented. For clinical staff, monetary gift cards will be given for completion of educational modules (2 modules during study period, see Project Design). We will apply for MOC4 and AMA PRA Category 1 Credit™ to be awarded to providers upon completion of the IVY program through our institution (see LOS). VUMC has been awarded Accreditation with Commendation as a provider of continuing medical education for physicians by the Accreditation Council for Continuing Medical Education (ACCME).²⁷ Providers will be eligible to receive MOC4 credit upon completion of both educational modules and implementation of at least one QI measure for improving vaccination of young children at the practice level. AMA PRA Category 1 Credit™ will also be available for providers upon module completion.

C.5. Beneficiaries:

The proposed work has both direct and indirect beneficiaries (Figure 2). Direct beneficiaries of project include providers, clinical staff, and young children. Providers and clinical staff will gain knowledge and skills related to vaccines in young children and communication with families. Children at participating practices will benefit by having improved likelihood for complete vaccination by age 2 years, which provides greater protection against morbidity and mortality due to vaccine preventable diseases. Indirect beneficiaries include family members and close contacts of fully vaccinated children as well as greater protection for the surrounding community.

Figure 2.



C.6. Sustainability and Scalability:

Our project design and implementation strategy allow for future scalability. Educational modules will be housed within the CPF website. Dr. Williams will work with CPF to update modules annually. Our collaboration with CPF could allow other CPF member practices to access updated modules in the future (sustainable) and this model could easily be replicated for other states with organizations affiliated with community pediatricians (scalable). Further, we anticipate the QI coaching session could be translated into a video format which could also be available via a website. With additional resources, IVY could be refined after study completion and evaluated on a larger scale.

D. PROJECT DESIGN AND MEASUREMENT STRATEGY

The novel project, Improving Vaccinations for Young Children (IVY), will includes three phases: 1) development of three specific and newly created project components to impact ACIP recommended

vaccination rates in children turning 2 years old, 2) implementation of components, and 3) ongoing and end-of study measurement of project impact on childhood vaccination rates within the modern SW-RCT design. The Community Preventive Services Task Force (CPSTF), established by the U.S. Department of Health and Human Services to develop guidance on community health promotion and disease prevention, conducted a systematic review to evaluate effective measures to improve vaccination rates in targeted populations.²⁸ Evidence from this review supports that incorporating multiple interventions within a health care system has the greatest success in positively impacting vaccination rates. The IVY program incorporates multiple interventions with options to select appropriate QI interventions by practice sites in accordance with these findings. Details of the development, implementation and measurement strategies for IVY are described below.

D.1. Component Development:

Educational modules for both providers and clinical staff will be developed through modification of CoVER materials (see Prior Work). Vaccine education provided through the CoVER modules improved knowledge and confidence in residents who received CoVER training compared to routine training in a recently completed randomized trial. Thus, we believe modification of these tools for practicing providers and staff will be effective in improving knowledge and confidence related to vaccine topics for these groups.

Two modules will be developed for each group (providers and clinical staff): a primary educational module (**Module 1**) and a “booster” module (**Booster**). Module 1 will be robust in providing key educational information for each group.

Although Module 1 will be different for providers (assuming a higher baseline level of immunization knowledge) and clinical staff, the overall educational focus of material will be the same (see Table 3). Planned educational topics to include are

Table 3. Key educational topics identified through the Phase I CQN Immunization Project to be incorporated into IVY Educational Modules
Protection against vaccine preventable diseases
Contraindications
Best practice communication techniques
Influenza vaccine
Vaccine schedule, intervals, catch up, timing
Tennessee immunization regulations (school requirements, practice dismissal, etc.)
Common vaccine concerns and facts to address common misperceptions

those identified through the Phase I Chapter Quality Network (CQN) Immunization Project (will be more specifically identified with receipt of CQN change package upon receipt of award), and through expert input and literature review. Dr. Williams will also query the CPF listserv to identify other potential educational needs from providers upon receipt of award. The Booster module will also include select educational material outlined in Table 3 (as determined by the study team and practice feedback as important for re-emphasis) and focus more specifically on influenza vaccine and communication techniques.

Dr. Williams will lead module development using experience developing four CoVER modules for resident physicians, a vaccine safety module for resident physicians, expertise in vaccines, vaccine safety, and parental vaccine hesitancy, and input from a team of consultant experts (see Prior Work, LOCs). Consultants are experts in vaccines, education and/or QI and were co-investigators with Dr. Williams throughout the CoVER project. The modules will be developed using the same e-Learning software (Articulate RISE²⁹) used for the CoVER modules. Qualitative data support that CoVER modules developed using this software had high usability, visual appeal and could be completed in a timely manner on a variety of platforms (e.g. mobile smart phone, tablet, desktop computer). Dr. Williams has access to all prior CoVER module material and the ability to create new modules using Articulate RISE with minimal additional financial costs. The consultant team will assist in finalizing all modules for appropriateness for target audiences (pediatric providers versus clinical staff) and

information accuracy. Modules will be pilot tested with select volunteer staff at VUMC prior to implementation and revised as needed.

A QI coaching session will be designed by Dr. Williams and the QI Coach (Christine Stroebel, MPH) utilizing the Model for Improvement and the 4Pillars™ Practice Transformation Program. 4Pillars™ was designed specifically to assist adult healthcare providers protect their patients from vaccine preventable diseases through QI initiatives.^{30, 31} The program has, however, been successful in improving childhood influenza vaccination rates^{32, 33} and reducing racial disparities associated with influenza vaccination among children with asthma.³⁴ Because of these successes, we anticipate that modifying the program and applying toward all recommended childhood vaccines will show similar success. Specific QI options to improve vaccination uptake for patients less than 2 years of age will be provided to practices. Table 4 provides examples of proposed changes that practices may select to improve immunization rates in their office. Proposed options are identified from both the 4Pillars™ program and the CQN Immunizations Project. Given that practice capabilities and operations vary greatly, it is important to offer a variety of options so that practices can implement choices that are feasible and achievable. The QI coaching session will also introduce the Model for Improvement as a QI framework³⁵. Incorporation of the Model for Improvement framework will assist in determination of goals for practices, and the selection of QI changes for each practice to reach their goals. Measurement of success after implementation of selected QI changes will be provided to each site monthly from the IVY team leadership. Modifications to QI changes could be incorporated following receipt of these data (i.e., Plan-Do-Study-Act (PDSA) cycles). Use of PDSA cycles to evaluate clinical QI interventions has been shown to be best practice under the Model for Improvement. Dr. Williams will also access and incorporate key elements within the CQN change package (available upon receipt of award) prior to finalizing content for the QI coaching session. Finally, using baseline data obtained at the beginning of the study period, the IVY team will evaluate if any recruited practices are found to be significant outliers for vaccination uptake rates. If outliers are identified, IVY team leaders will investigate why these practices may be more, or less, successful in achieving timely childhood vaccination and incorporate relevant findings into QI coaching session. As an example, if a practice is found to have low completion for rotavirus vaccine dose 3, we could inquire about timeliness of the 6 month well child visit (where the final rotavirus vaccine dose is typically administered). In this example, practices may benefit from incorporation of a targeted reminder/recall system for missed 6 month well visits.

Table 4. Options for QI Process Change Interventions for Childhood Vaccinations, Adapted from the 4Pillars™ Practice Transformation Program.	
Pillar 1: Convenience & Ease of Access	Use every opportunity to vaccinate
	Open access/walk-in for vaccinations/express vaccination opportunities
	Maximize # vaccines/visit to catch up
	Extend influenza vaccination season to keep open if flu still circulating
Pillar 2: Patient Communication Strategies	Discuss serious nature of VPDs** (posters, via MA* or nursing discussion, videos in waiting rooms)
	Train staff to discuss vaccines during routine check-in (front desk), vital signs (MA or nurse)
	Promote 100% staff vaccination rate (posters with visual completion metrics)
	Promote vaccination in clinic (hold music, posters with #'s vaccinated per time interval, special opportunity/gift for patients when vaccinated (gong, coloring book)
	Reach out directly (phone, text, mail, to recommended vaccines that are due)
Pillar 3: Enhanced Vaccination System Strategies	Ensure sufficient inventory
	Assess vaccination eligibility for every patient at every encounter by systematic mechanism
	Review accurate EHR vaccination record keeping
	Update EHR with vaccines from outside, Tenniis***, and as they are administered
	Assess immunizations as part of vital signs
	Establish standing order protocols for patient care staff to vaccinate without an MD order
	Develop systematic process for vaccinating every person with need

Pillar 4: Motivation Strategies	Create a chart to track progress, set improvement goals, & check progress. Post chart in prominent location.
	Provide ongoing feedback to staff on vaccination progress
	Create a competitive challenge for the most vaccinations given among your staff
	Provide rewards for successful results to create a fun-spirited environment

*Medical Assistant, **Vaccine Preventable Diseases, *** Tennessee Immunization Information System

D.2. Implementation of Intervention:

Intervention effectiveness on improving vaccination rates will be evaluated using a SW-CRT. ³⁶

Eight practices (clusters) will eventually be randomized to receive the IVY intervention over a 13-month study period (Feb 19 – Feb 20). Patients are clustered within practices, and outcomes will be assessed on cross-sectional samples of individuals at each practice at 13 discrete, monthly time points. There will be a baseline block of two months where all practices will be in the control group (Figure 3). Following this, two practices will be randomly assigned to receive the intervention (Group 1). Two months after initiation of IVY in Group 1, two practices will be randomly assigned to receive the intervention in Group 2. This will be continued for 4 total Groups. There will be a five-month block after implementing IVY in all practices where data will continue to be collected after all have been assigned to receive the intervention. Continuing to collect data in this manner will allow exploration for potential effects relating to delivery of QI or the Booster module after the initial Module 1. Due to the nature of the intervention, blinding of the centers will not be possible.

Figure 3. Stepped Wedge Cluster Randomized Trial Implementation Plan Over 13 Month Study Period													
Time	Feb-19	Mar-19	Apr-19	May-19	Jun-19	Jul-19	Aug-19	Sep-19	Oct-19	Nov-19	Dec-19	Jan-20	Feb-20
	Baseline Data		Group 1 Intervention Start		Group 2 Intervention Start		Group 3 Intervention Start		Group 4 Intervention Start		All Groups Post-Intervention Start		
Group 1			M1	QI		B							
Group 2					M1	QI		B					
Group 3							M1	QI		B			
Group 4									M1	QI		B	

M1: Module 1, QI: In-person QI Coaching Session, B: Booster Module

Module 1 will be introduced via email to practice leadership with 2 follow up emails to maximize completion over the course of 1 month. Modules will be housed on the CPF website. Participants will be provided unique login to access modules. **The QI coaching session** will be implemented in-person approximately one month after Module 1 is introduced to practices with office leadership and other practice stakeholders in attendance. The QI coaching session will be led by Dr. Williams and the QI Coach. Practices will be instructed to select which option(s) they prefer to implement within 2 weeks following the session. Dr. Williams and the QI Coach will assist in designing and implementing the intervention for the practice. **The Booster** module will be available approximately 2 months after the QI coaching session. This delay will allow for the Booster to surround the start of influenza vaccine season with the intention of maximizing influenza vaccine uptake.

D.3. Measurement and Analysis:

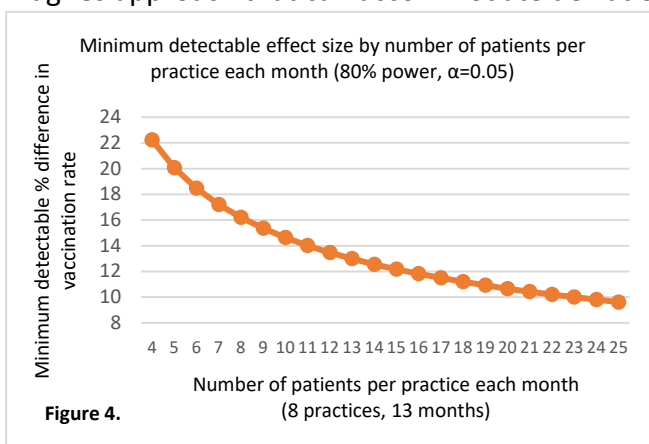
Outcomes: The primary outcome is individual patient-level receipt of all vaccinations [Combo 10 (binary, yes/no)] for children turning 2 years of age, except for influenza due to the seasonal nature of this vaccination. Combo 10 including influenza vaccination will be collected and analyzed in the same manner as a secondary outcome.

Data collection: All vaccination status (yes/no) data by vaccine dose will be collected and stored at the individual patient level, although it will be possible to aggregate and summarize monthly and total vaccination rates at each practice. To protect patient confidentiality, we will not have access to

identifiable patient-level data, including potential covariates of interest (e.g., sex, socio-economic status, parent education level, etc.). Eligible children will include patients who were seen at the participating practice at least once prior to 90 days of life. Combo 10 vaccine data is already collected monthly at all VPPCP sites. For CPF recruited practices, we will utilize a data collection service, Visualize Health³⁷, to interface with EHR systems and extract vaccine data in real-time. The service can also create real-time data visualization dashboards for practices to assess ongoing progress and measures, enable point-of-care functions (e.g., prompt practices on patient who are missing vaccines), and generate aggregated provider and practice-level reports for analysis. Visualize Health is currently collaborating with CPF under an NIH HPV study and successfully collecting HPV vaccine data from 26 practice sites. Aggregated de-identified data from all 8 practice sites will be shared with stakeholders monthly (individual practice data to practice leadership, all aggregated data shared with grantor). Participation, satisfaction, competence, and performance with IVY will be analyzed using Moore's Outcome Framework³⁸ at the end of the study period via survey.

Data Analysis: The primary analysis will determine whether there was an overall effect of IVY on the rate of vaccination for Combo 10 vaccination (less influenza vaccine). An extension of the Hussey and Hughes model-based approach for analyzing data from a cross-sectional SW-CRT will be used to analyze the binary vaccination outcome.³⁹ Intervention effect will be described using an odds ratio regression coefficient and the 95% confidence interval, and model-estimated outcomes will be graphed to facilitate interpretation. Run charts will be created for each practice to visualize overall level and changes in vaccination rates over time. Secondary analyses will explore for potential effects of the QI and Booster components of the intervention by varying the design matrix. In exploratory analyses we will consider using newer (but less well validated) flexible extensions of the Hussey and Hughes approach that can accommodate deviations from the underlying assumptions (e.g., varying

secular trend, varying intervention effects across clusters or time).⁴⁰



Power and Sample Size: Power analyses were conducted to ensure that meaningful intervention effects can be detected with at least 80% power, even with conservative assumptions for important parameters, such as cell size (i.e., the number of eligible patients visiting each practice per month). Power analyses were conducted using the “steppedwedge” Stata command (Stata 14.2), which takes into account

important design features of the SW-CRT methodology that can potentially affect power.⁴¹

Preliminary data from four VPPCP sites was used to inform estimates of the expected average baseline center vaccination rate (65%). Intraclass correlation coefficient (ICC) is expected to be small, but a variety of values were used to examine its potential effects on power (ICC range 0.01-0.05). All analyses assumed a two-tailed significance level of $\alpha=0.05$. The study has 80% power to detect a 10-point rate difference if an average of 23 eligible participants per month visit each center throughout the study. Figure 4 depicts how minimum detectable difference in vaccination rate is affected by the number of patients with 80% power (i.e., the study has 80% power to detect a 15-point rate difference if an average of nine eligible patients per month visit each practice).

Limitations: To protect patient confidentiality we will not have access to identifiable patient-level data, including potential covariates of interest (e.g., sex, socio-economic status, parent education level, etc.). Therefore, our ability to adjust for potential important patient-level covariates is limited.

Ethics: This protocol and any specific modifications will be reviewed and approved by the IRB at VUMC upon receipt of award. The links to modules will go out to potential subjects via practice leadership with an informational introduction and a link to the CPF website to participate. We will request a Waiver of Informed Consent Documentation due to the minimal risk nature of the study. We propose that voluntary participation/completion of the modules will serve as implied consent.

E. PRIOR WORK

E.1. CoVER: As a Co-Investigator, Dr. Williams was awarded a grant from Pfizer Independent Grants for Learning & Change in 2016 to develop the **Collaboration for Vaccination Education and Research (CoVER)**. CoVER was created to augment residents' skill in immunization practices, residents' knowledge and competency in communicating with patients and families about vaccination, and to promote research in the vaccine education field. A pilot CoVER vaccine education curriculum was created and implemented via a randomized controlled trial in 26 residency programs in (2017-2018). The curriculum consisted of 4 modules and one face-to-face training. Pre- and post-curriculum surveys were collected to assess change in residents' knowledge, confidence and beliefs as related to vaccines. Although we did find improvements in knowledge, the most significant improvements we found were related to change in confidence (Table 5). End of year focus group data also support that the curriculum was well received by residents (improved confidence, appropriate for learning needs)

Survey	Coefficient	p-value	95% CI	Predicted Score	Absolute Score Δ^*
Pre, Non-CoVER	-ref-	---	---	56.9	5.2
Post, Non-CoVER	5.20	0.004	1.64-8.75	62.1	
Pre, CoVER	-1.23	0.59	-5.73, 3.26	55.7	15.5
Post, CoVER	14.33	<.001	9.12, 19.55	71.2	

*The difference between pre- and post-survey scores on confidence survey item by arm, 100 pt. scale.

and the E-Learning platform used to develop the modules (Articulate RISE²⁹) had high usability and visual appeal. Given the success with the design, implementation and outcomes with CoVER, we

plan to expand on this model for module development within this proposal, with the target participants being both practicing pediatric providers and clinical office staff. We will also incorporate the expertise of other CoVER co-investigators as consultants.

E.2. Vaccine Safety Curriculum: Dr. Williams solicited U.S. pediatric residency Program Directors to participate in a national collaboration to develop a formal vaccine safety and hesitancy curriculum for pediatric residents. The collaboration developed the curriculum using the six step Kern Approach to Curriculum Development.⁴² Problem identification was determined by review of the literature and prior work.¹⁰ A needs assessment was conducted using a survey to test resident knowledge, skills and attitudes on vaccine safety and hesitancy. The group developed one overarching goal and five objectives for the curriculum. A multimodal educational module, composed of an in-person role-play guide, a take-home job aid, and an interactive web-based training module, was developed through a group-based iterative process. The project was presented at both the Association of Pediatric Program Directors conference and the Pediatric Academic Societies conference in spring 2016.²² The team also developed an 8-question "knowledge score" to assess and compare residents' knowledge

pre- and post- curriculum. The curriculum was piloted in 6 training programs. Table 6 shows improvement in knowledge score pre- and post-pilot.

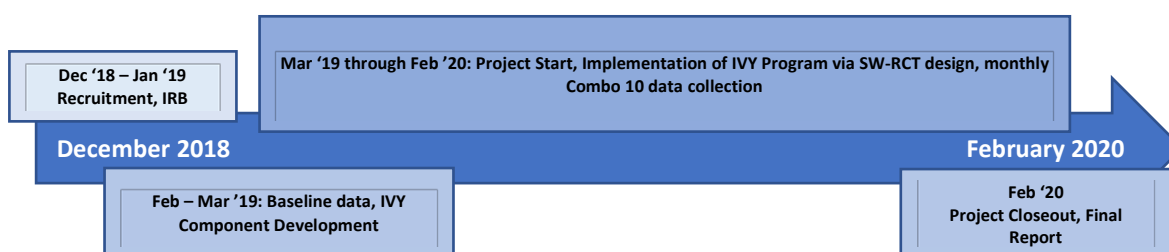
E.3. Flu Study: Prior to the start of influenza vaccine season, clinical staff at one PCPPC practice were provided education on influenza virus, high risk populations for influenza infection, and influenza vaccine. Participants beliefs about the importance of influenza

vaccine, the seriousness of influenza, and common myths about influenza vaccine were evaluated through survey pre- and post-educational session. Results identified that some staff members believed that “the flu vaccine can give you the flu” and/or that “the flu is not that serious”, however, a brief educational session led by the Dr. Williams positively impacted these beliefs. Other data support that medical team members have misconceptions about influenza and/or influenza vaccine and other recommended childhood vaccines.^{24, 26} If funded, our study will directly address clinical staff members who may have similar beliefs for education and quality improvement initiatives.

Table 6. Knowledge score results overall, by year of residency			
	Pre-pilot survey score (N=153) (mean, SD)	Post-pilot survey score (N=64) (mean, SD)	ANOVA
Overall	3.50 (1.46)	4.09 (1.68)	p=0.01
PL1*	3.50 (1.64)	3.91 (2.11)	NS
PL2*	3.52 (1.37)	4.55 (1.60)	p<0.01
PL3*	3.54 (1.34)	3.88 (1.11)	NS
*PL1: first year pediatric residents, PL2: second year pediatric residents, PL3: third year pediatric residents, 8-point scale			

E.4. QI Projects: The Division of General Pediatrics has a strong and active history in implementation of various QI initiatives⁴³⁻⁴⁵ and Dr. Williams has served as an active participant. After completing comprehensive training through the Institute for Healthcare Improvement, her first QI initiative evaluated the impact of translating informational handouts on iron-deficiency anemia from English into Arabic and Spanish on rates of 1) follow-up for hemoglobin rechecks and 2) start of iron prescription. Most recently, she has participated in data collection and implementation of multiple project interventions within the Division of General Pediatrics for the Pediatric Healthcare Improvement Initiative for Tennessee⁴⁶. In 2016, our Division received national recognition for this work (Academic Pediatric Association Health Care Delivery Award).

F. TIMELINE



G. DISSEMINATION OF RESULTS

Results and ideas will be submitted for presentation at the Pediatric Academic Society (PAS) meeting in May 2020, the AAP national conference in November 2020, and the local Tennessee AAP chapter in Fall 2020. Additional presentations or conferences may be added as the project evolves. A manuscript and any other publications determined applicable upon completion will be finalized for submission to peer-reviewed journal 2 months following the end of the funding period (April – May 2020). We will work with grantors and collaborators to determine additional options for local and regional dissemination, such as CPF website or email to CPF membership.

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