



A. Cover Sheet

1. *Project Title, Grant ID Number and Main Collaborators*

Project Title: Addressing Resistance to Pneumococcal Immunization among Rural and Minority Populations in Tennessee Using the Electronic Health Record (EHR)

Grant ID Number: 13165243

Main Collaborators: Qsource, Tennessee Primary Care Association, and Tennessee Department of Health—Immunization Registry

2. *Abstract*

Tennessee is one of the poorest states with a large African American population, a sizable rural population and pneumococcal rates significantly below the U.S. Population. The goal of this research project is to identify sustainable methods for closing this gap by increasing pneumococcal immunizations (PPV) among at-risk rural and urban adults in Tennessee. To reach the designated underserved population, Qsource will work with the Tennessee Primary Care Association (TPCA) to identify 9 FQHCs in counties with the lowest PPV rates who provide access to medical services to the target populations. Through focus groups with patients and comparative effectiveness research, this project will test a system change that includes implementing a clinical decision support (CDS) rule within the Electronic Health Record (EHR) to identify at-risk patients for PPV vaccination during routine clinical care. The addition of a patient reminder notification sent via email through the patient portal will also be evaluated. Important contributions of this study include: 1) establishing a baseline PPV participation rate using EHR practice data among at-risk patients in rural and urban federally qualified health centers (FQHCs) in TN; 2) garnering patient input to develop a communication strategy for healthcare providers that will address and mitigate modifiable barriers to PPV in a clinical setting; 3) identifying sustainable best practices for improving population health that can be adopted by a wide variety of healthcare providers; and 4) improving the process for reporting from the EHR to a state immunization registry.

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C. Main Section of the Proposal

3. Overall Goal and Objectives

The goal of this research project is to test sustainable means for increasing pneumococcal immunizations among rural and minority adult patients in Tennessee (TN). This will be done by testing current strategies that include 1) systematic identification of at-risk patients via a programmed clinical decision support (CDS) rule in the electronic health record (EHR) and 2) a reminder notification sent via email through the patient portal. Specific objectives of this project include:

1. Establish the baseline for Pneumococcal Polysaccharide Vaccine (PPV) participation rate using EHR practice data among at-risk patients in rural and urban federally qualified health centers (FQHCs) in TN.
2. Develop a communication strategy for healthcare providers that will address and mitigate modifiable barriers, including those specific to race and health literacy level, to PPV in a clinical setting.
3. Create a workflow and system change through the incorporation of a CDS rule within the EHR that will alert providers when at-risk patients present to the office for routine care. Then monitor the change monthly with trending data.
4. Evaluate the association of the CDS rule intervention with increased PPV proportions using two-proportion z-test, χ^2 and odds ratios for cases and controls from 10/1/2014 – 9/30/2016.
5. Evaluate the added benefit, above the workflow changes and systematic identification, of patient reminders through the patient portal through attributable risk.

The Tennessee Primary Care Association (TPCA) is an organization that supports Tennessee's federally funded health centers (including FQHCs, rural health centers [RHCs] and FQHC look-alikes) and primary healthcare clinics serving the underserved throughout the state. TPCA is interested in the outcomes of this project and will incorporate the findings into its process for information sharing. Additionally, TPCA will co-host a webinar with Qsource to promote the lessons learned among the larger FQHC provider community.

4. Technical Approach

This research will help identify best practices, using an EHR, for increasing the rates of PPV among rural, African-American (AA) and medically indicated populations in FQHCs by testing two interventions against a control. The interventions are designed in conjunction with healthcare providers with a focus on viability and minimal resource needs to enable ease of integration into clinical practice. Patient focus groups, segmented by target audience, will allow for the mitigation of potential barriers and inform the communication strategies.

a. Current Assessment of Need in Target Area

i. Estimates of Need

Based on 2006-2012 Behavioral Risk Factor Surveillance System (BRFSS) data, many of the FQHCs are located in TN counties with low PPV rates and high proportions of minority populations. This study will be conducted in FQHCs serving the rural and urban counties with the lowest PPV rates (≤ 60 percent). Additionally, all FQHCs will have a fully functional EHR. Demographics of potential FQHC partners are provided in **Table C-1**.

Table C-1. 2010 Population Estimates in Counties with Low PPV Rates						
2006-2012 PPV Rate	County	Rural/Urban	Total Adult Population	African American (%)	65+ (%)	Estimated At-Risk Patients*
48%	Haywood	Rural	23,231	11,615 (50)	3,484 (15)	5,459
50%	Hardeman	Rural	17,578	7,206 (41)	2,636 (15)	4,130
No data	Lake	Rural	19,220	5,381 (28)	2,691 (14)	4,344
56%	Dyer	Rural	11,291	1,693 (15)	1,694 (15)	2,654
68%	Lauderdale	Rural	16,422	2,134 (13)	2,135 (13)	3,564
57%	Hardin	Rural	4,629	879 (19)	926 (20)	1,296
59.2%	Shelby	Urban	588,126	311,706 (53)	64,694 (11)	117,037

ii. Target Audience

The target audience for this study will include all adult patients ages 19 and older who receive care from a participating FQHC, RHC or FQHC look-alike and fall into a medically indicated category based on the recommendations from the Advisory Committee on Immunization Practices (ACIP) for prevention of invasive pneumococcal disease.¹

Possible FQHCs and FQHC look-alikes for this study include rural and minority health clinics in all three of Tennessee's Grand Regions (East, Middle, West). The total FQHC patient population

¹ Source: CDC MMWR. September 3, 2010. Updated Recommendations for Prevention of Invasive Pneumococcal Disease Among Adults Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23). Vol. 59. No. 34. P. 1102-1106.

is 384,109. In 2012, the total racial or ethnic minority was 40.1 percent with 30 percent of these patients self-identifying as African American and less than 10 percent as Hispanic/Latino.²

b. Project Design and Methods

This research is designed to evaluate the comparative effectiveness of the following interventions: 1) **intervention 1** - an intervention that incorporates workflow improvements and systematic identification of patients medically indicated through a programmed CDS rule in the EHR with increased PPV and 2) **intervention 2** - intervention 1 plus patient communication in the form of reminders sent through the patient portal. This will be done by comparing these interventions to matched control sites. Both interventions will be developed with input from providers to ensure they are seamlessly incorporated into routine clinical care. This design will allow for the evaluation of the added benefit of reminders through the patient portal.

Site Selection: TPCA will provide recruitment assistance and information dissemination by co-hosting an informational conference call with Qsource staff for community health center staff in order to promote participation in the initiative.

All nine participating FQHCs will have an established EHR.

Potential Patient and Physician Barriers

Table C-2. Potential Barriers and Mitigating Strategies	
Barrier	Mitigating Strategies
Patients do not take time to seek immunizations.	Identify patients at-risk during regularly scheduled office visits.
Providers are not able to identify medically indicated patients easily.	Educate providers on the guidelines provided in the electronic health record

² Source: Uniform Data Systems <http://bphc.hrsa.gov/healthcenterdatastatistics/>

Table C-2. Potential Barriers and Mitigating Strategies

Barrier	Mitigating Strategies
	(EHR) (clinical decision support rule), and supply other educational materials if necessary.
Cost to patient and provider	Educate patients and providers on the reimbursement process for Medicare Part B, private and employer-sponsored health insurance, and TennCare and patient assistance programs for uninsured patients; provide assistance with the reimbursement process if necessary.
Patients' perceived lack of benefit	Educate healthcare providers to communicate effectively with patients.
Patients' fear of adverse effects	Educate healthcare providers to communicate effectively with patients.
Accurate documentation of immunizations by providers	Promote the use of EHRs as a tool to capture complete health information and not just a means for documenting services provided.
Lack of consistent reminders from providers to patients	Identify and use reminder strategies such as a patient portal and email.

Focus groups will be held among a representative population of FQHC clinics to explore known and unknown barriers to immunization that will be used to inform the mitigation strategy, for provider education, and to construct meaningful messages for provider-patient communications; identify patient barriers, advantages and “meaningful use” of the patient portal from the patient perspective to enable the development of relevant patient portal communication materials for patients.

Interventions

Evidence in the literature indicates that using multiple strategic approaches results in considerably higher vaccination rates, compared with a single strategic approach such as patient education.³ Because less is more in clinical practice, our study is designed to compare the effects of systematic identification of patients in the EHR to a multifaceted approach that includes patient communication.

Provider Education. A 2009 study of 795 primary care practice sites across England published by BMJ⁴ identified clear leadership, effective communication about practice performance, and mailed reminders to eligible patients as independent predictors of higher rates of flu

³ Guide to Community Preventive Services. Increasing appropriate vaccination: health care system-based interventions implemented in combination. www.thecommunityguide.org/vaccines/universally/healthsysteminterventions.html. Last updated: December 2010.

⁴ BMJ Open. Strategies to increase influenza vaccination rates: outcomes of a nationwide cross-sectional survey of UK general practice. <http://bmjopen.bmj.com/content/2/3/e000851.full>. Last updated: May 2012.

vaccination. Specifically, higher vaccination rates were associated with a patient reminder and a regular written evaluation of practice performance. These predicted an 8-percent higher vaccination rate among at-risk patients <65 years and a 7-percent higher rate in patients >65 years old.

Systematic Identification of Medically Indicated Patients. Programs for identifying eligible patients from the practices' EHR are usually issued by the software providers. Modifying the IT supplier's standard search or creating a separate in-house search was associated with significantly higher uptake rates for patients aged 65+ years than using an unmodified IT supplier's search ($p < 0.001$ and 0.027 , respectively).⁴

Qsource has the expertise required to facilitate the programming of a CDS rule in the EHR that will alert providers when medically indicated patients come into the practice. This CDS rule in the EHR will be based upon an algorithm that identifies appropriate patients when they come in for routine care and generates a reminder for the practice administrator. The rule will identify at-risk patients in the system.

Workflow Redesign. The practices participating in the intervention will receive hands-on assistance from the HIT Specialists regarding the use of their EHRs and how to communicate with patients about PPV. For the test practices, we will create a system change by building EHR reminders into their workflows, offering providers an easier method for noting who has or has not had pneumococcal immunization. These reminders can be set to meet certain criteria for patients within the targeted population and can then prompt the physician to ask questions about immunization. Some EHRs can also be configured to send immunization reminders to patients electronically. All of these reminders will be scripted by Qsource for the clinic. Based on the evidence of provider influence, this appears to be a key motivator for patient compliance.

Patient Communication via the Patient Portal (Intervention Group 2). Using personal invitations has been significantly associated with higher rates of influenza vaccination, especially in the 65+ age group ($p = 0.003$).⁴ The same study found a similar association among those less than 65 years of age; however, this association did not reach statistical significance, possibly due to inadequate power.

A patient portal is a secure online website that gives patients convenient 24-hour access to personal health information. Patient portals are designed to enhance patient-provider communication, empower patients, support care between visits, and improve patient outcomes. While portals have been around since the early 1990s, to date, little use has been reported despite studies showing that most patients would like access to online services. Through the collection of information about patient and physician perceptions, motivations and barriers, this study aims to develop effective communication strategies for achieving adoption of the portal among providers and patients in three (intervention 2) FQHCs. Reminders would then be sent to the medically indicated patients via the portal.

FQHCs in the intervention 2 group will be provided patient educational materials on how to access the portal including pamphlets in the waiting rooms. These providers will be given additional technical assistance by the Qsource HIT Specialists with regard to launching the portal and with suggestions/materials on patient content and engagement.

HIT Specialists. Since 2006, Qsource has assisted Tennessee providers with implementation of their EHR systems, improving EHR workflow, conducting risk assessments, data reporting requirements and successfully meeting the meaningful use (MU) objectives. MU is part of the Medicare and Medicaid EHR Incentive Program that provides financial incentives to providers for the “meaningful use” of certified EHR technology to improve patient care.

Qsource HIT Specialists are subject matter experts in this field and have established relationships with FQHCs throughout the three Tennessee Grand Regions. They will play a vital role in the implementation of the interventions, continual monitoring, trouble shooting and data collection and reporting. In all nine FQHCs (intervention 1, intervention 2 and controls), they will establish the reporting process and support the practice-based Information Technology (IT) champions in pulling the data for quarterly deliverables.

In each of the intervention practices, the HIT Specialists will 1) perform an EHR assessment that includes documentation of the EHR vendor and version; 2) conduct a workflow gap analysis; 3) create the EHR reminder rules; 4) run a test report to ensure the rule is working; 5) provide education regarding the intervention and scripting to the practice providers; and 6) contact the practice every month to monitor progress and provide the comparative monthly dashboard report. This report will include PPV rates and missed opportunities by physicians. For those practices in intervention 2, they will assist with the implementation of the patient portal and with establishing the automated reminder emails, and they will provide educational materials for both providers and patients on using the portal.

As part of the mitigation strategy for risks, HIT Specialists will monitor the adoption and consistency of the intervention at the intervention sites and any environmental changes that may affect rates of PPV or potential “contamination” of practices similar to the interventions among the control groups. For example, the practice of systematic identification of patients may occur at one of the control sites during the study. According to our experience, this is not likely; however, Qsource will take this information into consideration during the analyses.

A thorough risk assessment will be conducted to determine potential risks to the program and anticipate solutions to keep the project on track. Regular monitoring will allow for early mitigation to minimize the effect of risk. Risk mitigation strategies are presented in **Table C-3**.

Table C-3. Risk Mitigation		
Risk	Rating	Mitigation Strategies
Internal Project		
Unable to recruit the required number of practices	10	<ul style="list-style-type: none"> • Leverage TPCA partnership. • Offer incentives.

Table C-3. Risk Mitigation		
Risk	Rating	Mitigation Strategies
Competing priorities for providers	8	<ul style="list-style-type: none"> • Make the intervention part of the workflow. • Align necessary reporting with other incentives/requirements (i.e. MU). • Provide regular assistance. • Make the HIT Specialist the third person on the team.
EHR upgrades, downtime and/or data extraction or reporting	9	<ul style="list-style-type: none"> • Make sure there is a paper back-up workflow. • Choose EHRs in which we have expertise. • Good vendor relationships. • Back-up data source. • Improve administration protocols.
Patient refuses the vaccine	10	<ul style="list-style-type: none"> • Listen to the reason for refusal. • Educate.
Vaccine shortage	8	<ul style="list-style-type: none"> • Contact CDC. • Identify other vaccine sources.
Practice dropout rate	10	<ul style="list-style-type: none"> • Keep providers engaged. • Provide value. • Share positive trending data. • Use other providers' success to motivate.
Over budget	10	<ul style="list-style-type: none"> • Regular monitoring. • Feedback reports on hours billed and funding. • Regular communication with staff. • In-control project management.

c. Evaluation Design

This study will be evaluated using mixed qualitative and quantitative methods that include patient focus group reports, provider satisfaction and engagement surveys, ongoing monitoring/risk mitigation and quantitative data from the EHR.

Qsource HIT Specialists will work collaboratively with providers and staff in all nine FQHCs (intervention and control groups) to run data reports by the second week after the end of each

quarter from 1/15/2015-10/15/2016. When possible, this will complement and enhance the reporting requirements for other initiatives such as MU. This will ease the burden of the intervention on the practices and increase the number of providers reporting PPV data. A baseline for comparison will be established including 5 years of PPV data between 10/1/2009 and 9/30/2013 if available. This extended timeframe will allow us to assess whether the impact of the intervention has a greater effect than secular trend.

i. Measures

Control charts of PPV rates and dashboards with practice-specific information by physician, including missed opportunities, will be produced monthly to monitor performance. Quarterly rates of indicated PPV immunization will be tracked and trended through control charts at each of the nine sites. The following study hypotheses will be tested using: 1) Proportions of patients receiving PPV will be compared with two-proportion z-tests and the Pearson χ^2 and Fisher exact test for small samples; odds ratios will be computed with intervention and control groups. The added benefit of the patient portal reminder will be assessed through the assessment of attributable risk and binary logistic regression. Significance will be set at the 95% level, with all P values being 2-sided.

Study hypothesis 1a: Systematic identification of at-risk patients via the EHR is associated with increased proportions of patients receiving PPV among a rural FQHC patient population. 1b: this association differs among those under 65 compared to those 65 and older.

Study hypothesis 2a: Patient reminder emails for PPV sent through the patient portal to at-risk patients is associated with an added increase in proportions of patients receiving PPV. 2b: This association differs among those under 65 compared to those 65 and older.

ii. Amount of Change

We expect a statistically significant increase at year 2 in the proportion of patients at each intervention site (compared to baseline) using a 2-proportions test. Furthermore, we expect the relative increase in proportions to be higher in the 3 FQHCs receiving intervention 2 compared to the 3 FQHCs receiving intervention 1. While it's difficult to estimate the baseline proportion of at-risk patients in each FQHC that receive PPV, based upon the influenza literature, we expect a 7% relative increase in those 65 and older and an 8% relative increase in those under 65 over the two-year period.

Engagement

To assess physician engagement, an annual evaluation tool will be used and the results reviewed and analyzed by the principle investigator (PI). The evaluation tool will include a brief survey among participating providers to determine their satisfaction with the scripting, the office workflow process, patient compliance and their perceptions about involvement and assessment of their data.

Monthly data including missed opportunities will be trended by provider and reported back to the FQHC in the form of a comparison (or dashboard) report.

For providers in the intervention 2 group, an annual satisfaction survey regarding the patient portal will be conducted.

iii. Dissemination Plan

Results from this study will be disseminated in a variety of ways and among varied partners. TPCA is interested in sharing promising practices for increasing PPV among community health center patients and throughout the FQHCs who are TPCA members.

Additionally, the findings from this research will be valuable to a wide variety of audiences including professionals in the fields of HIT, QI, public health, rural health, preventative medicine, patient-centered outcomes research and comparative effectiveness research.

We have a plan in place to share the results via a wide range of modes including professional and academic conferences, publications in peer-reviewed journals, one-on-one meetings with community partners and stakeholders, through press releases and online outlets (websites, blogs and our five-state healthcare provider exchange site) and through patient newsletters.

5. Detailed Workplan and Deliverables Schedule

Detailed deliverables for the entire study period are contained below. To keep the project on target, there will be internal monthly status reviews by the project manager and follow-up with the appropriate parties if necessary. **Table C-4** lists all materials, interim reports, deliverables and major activities with the appropriate timelines.

Table C-4. Workplan and Deliverable Schedule			
Task	Description	Responsible Staff	Duration/ Deliverable Date
Recruitment Practices	Project overview, complete recruitment forms	HIT Specialist, Project Manager (PM)	8/1/2014 – 9/1/2014
Focus Groups	Project overview, conduct interview and gather results	Communications Manager (CM), Principle Investigator (PI)	8/15/2014 – 9/7/2014
Focus Group Report	Analyze and document results, prepare report	CM and PI	9/15/2014
Pull Baseline Data 10/1/2009 – 9/30/2014	Review reporting function in EHR, set report parameters to capture baseline data, run report	HIT Specialist, Analyst	9/15/2014
Orientation/ Education Onsite	Project overview, EHR assessment, education on CDS rule, set CDS rule, test reporting capability	HIT Specialist	9/15/2014 – 9/30/2014
Implement Interventions	Active intervention timeperiod	HIT Specialist, PI	10/1/2014 – 9/30/2016
Monthly	Contact practice, discuss	HIT Specialist and PM	11/2014 –

Table C-4. Workplan and Deliverable Schedule

Task	Description	Responsible Staff	Duration/ Deliverable Date
Follow-Up with Practice	project progression, identify concerns, reiterate goals of the project		ongoing
Quarterly Data Report	Review reporting function in EHR, set report parameters to capture quarterly data, run report	HIT Specialist	1/1/2015 – 10/2016
Interim Report	Detailed report on nine months in the field and listing any changes that may be needed	PM and PI	12/ 2015
Final Report	Detailed report on findings, lessons learned, best practice, conclusions	PI, Analyst, PM	11/2016
Dissemination of Results	Press release; presentations to associations such as TPCA and Pfizer	CM, PI and PM	12/ 2016

D. Qsource Organizational Detail

1. Leadership and Organizational Capability

Qsource is a healthcare quality improvement (QI) and information technology (IT) consultancy dedicated to improving lives through a reduction in chronic disease and the delivery of high-quality healthcare. Established in 1973, Qsource is a designated quality improvement organization (QIO) for the State of Tennessee. Both Qsource and its affiliate, Qsource of Arkansas (QofAR), are registered as International Organization for Standardization (ISO) 9001:2008 certified companies.

We provide a wide range of expert services, including project management, healthcare QI, epidemiology, analytics, and provider and patient communications. Among our client base are the Centers for Medicare & Medicaid Services (CMS), Office of the National Coordinator, departments of Health and Medicaid in Arkansas and Tennessee, and multiple private and nonprofit entities. In addition, as a subcontractor for the Arkansas Data Mining and Program Evaluation since 2010, QofAR has performed immunization research, record procurement and electronic registry analysis throughout Arkansas.

Across the state of Tennessee, Qsource has become a recognized leader in facilitating healthcare QI. As a QIO, Qsource worked with providers and patients to achieve system-level changes to clinical performance measures, including adult immunization rates and assisting providers in screening annual immunization data in their electronic health records (EHRs) and submitting to the state registry.

Qsource has a broad background in working on projects for underserved population groups. We served as CMS's national Underserved Quality Improvement Support Center contractor from its inception in 1999 until the program ended in 2008. In this capacity, Qsource assisted CMS to improve performance measures among underserved populations in three clinical areas: breast cancer, adult immunizations (flu and pneumococcal) and diabetes. We provided leadership to CMS and QIOs on the use of evidence-based interventions to reduce racial and ethnic disparities and influence healthcare quality. We provided cultural competency education and technical assistance to QIOs that worked with practices to implement the Office of Minority Health's National Culturally and Linguistically Appropriate Services Standards, measure Medicare healthcare disparities nationally, and evaluate the effectiveness of state QIO efforts to reduce disparities. In addition, we have been a consultant on recent disparity work regarding diabetes. We also have worked to assist healthcare providers, including federally qualified health centers (FQHCs), to successfully implement EHR systems and ensure they meet government requirements for meaningful use (MU). This work was accomplished through tnREC, the Health Information Technology division of Qsource. tnREC has worked closely during the last four years with approximately half of the 206 FQHC sites across Tennessee to achieve

MU. In this capacity, tnREC also worked with the Tennessee Department of Health immunization registry to facilitate provider EHR submission of the immunization test data required to meet Stage 1 MU requirements.

Furthering Qsource's success in delivering services, our corporate leadership is actively involved in the organization's quality management processes, including the internal quality control and ISO processes that will support all contract activities. Qsource operates under the direction of a chief executive officer who reports to a board of directors. The CEO oversees all federal, state and local contracts. The CEO has more than 20 years of experience in healthcare quality measurement, quality assurance and QI and has co-authored several articles on QI programs, healthcare disparities and the analysis of Medicare data. The CEO recently served on the Institute of Medicine's Committee on Future Directions for the National Healthcare Quality and Disparities Reports.

Key project personnel will have support resources through Qsource staff, a unique mix of experienced clinical, healthcare QI professionals, data analysts and communications specialists, supplemented by a pool of clinical consultants and educational institutions such as The University of Tennessee Health Science Center and The University of Memphis School of Public Health. In addition, we work with a variety of national, state and local associations, including the Tennessee Primary Care Association. Staffing offices are located in Memphis, Nashville and Knoxville and in Little Rock, Arkansas, for easy access to practices and providers.