National Immunization Project with the APA (NIPA)

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Abstract

This is part of a project with a focus on adolescent populations within primary care clinics, our project goals are to: 1) Implement evidence-based strategies to improve adolescent immunization delivery (AID), and specifically human papillomavirus vaccine, through quality improvement (QI) activities; 2) Provide an opportunity for primary care providers to participate in a national QI project, including faculty and residents in academic institutions and clinicians in public and private settings.

Protocol

Overview and Objectives

National Immunization Survey-Teen data show that vaccination rates for adolescents for HPV vaccine in the United States are far from the Healthy People 2020 targets in contrast to both Tdap and MenACWY. Human papillomavirus (HPV) vaccine rates are increasing at a slower pace than other vaccines recommended for adolescents. Data suggest that lack of awareness among parents and/or lack of health care provider recommendation are associated with under-immunization among adolescents in the United States, including HPV vaccine. Other research specific to HPV vaccine suggests that practitioners may be reluctant to enter into in-depth discussions about HPV vaccine with questioning parents, and may be facilitating the delay of this vaccine past the recommended age of administration. HPV requires a 3-dose series; thus, a successful immunization delivery strategy also includes the need to have adolescents return for subsequent doses, at an age when preventive health visits occur less frequently.

This project addresses Healthy People 2020 objective IID-11 (Increase routine vaccination coverage levels for adolescents) by identifying and testing strategies to improve health care provider vaccine communication and recommendations and immunization delivery for adolescents. Lessons learned in this project will also be used to help health care practitioners improve communication with adolescents and their parents regarding the importance of timely vaccination and completion of a 3-dose series. Increased vaccination coverage among adolescents will help reduce morbidity and mortality from infectious diseases and may reduce health disparities associated with these diseases, particularly HPV. It will also give information needed for the effective dissemination of these strategies through distance methods. (See Project References).

This project capitalizes on the collaborating strengths of the Academic Pediatric Association (APA) and the National Improvement Partnership Network (NIPN), two leading national pediatric membership organizations. APA is a national organization of academically-based primary care providers, child health experts, adolescent and emergency department specialists, and health care education experts. This project will be disseminated using the Continuity Research Network (CORNET), the primary care research network of the APA. NIPN is a network of over 20 states that have formed Improvement Partnerships (IPs), which are
collaborations of public and private partners that use measurement-based efforts and a systems approach to improve child health outcomes and the quality of their healthcare.

The overarching project goal is to implement evidence-based strategies to improve AID through QI activities and practice changes.

The project will implement a rigorous QI program within the CORNET and NIPN networks and engage multidisciplinary teams to improve HPV vaccination rates in their clinics and train pediatric providers about QI in AID. Standard QI methodology will be employed throughout the intervention including: training in QI methods, setting goals, data collection and feedback, ongoing coaching and support by QI facilitators, and access to relevant tools and resources.

During the learning collaborative stages of this project, participating practices will be asked to implement at least one of three strategies to improve their HPV vaccine immunization rates: standing orders, provider prompts, or a reminder-recall system. They may also choose to select additional interventions from a list of proven strategies to implement in their practice. All sites will receive training to enhance their strong provider recommendations. The selected strategies will be implemented in the practice for 6 months, during which clinic champions will participate in monthly learning collaborative calls.

The global aim for this project is to improve HPV vaccine initiation and series completion rates in the participating clinics from baseline to the end of the study by 10 percentage points.

**Consent**

We are seeking a waiver of informed consent for chart reviews of patients.

The visits of adolescent patients (11-17 years of age) will be chosen for retrospective chart reviews, using a randomization scheme, to provide a valid estimate of missed opportunities for HPV vaccination in each participating practice. No PHI will be collected by the data coordinating center. Charts will be entered in an electronic entry form via REDCap. Sites will track the patient charts they enter into REDCap in a log which is retained on site and is not contained in the REDCap dataset (See Appendix K and L). The REDCap data contains no PHI. This log will be kept at each participating site and will be used for reference by the site study team if there are any clarification questions that may occur during data collection and cleaning. This log will be destroyed upon completing the de-identification of the final data set.

**Project Design**

All practices will receive training in QI methods and strong provider recommendations. Each site will be required to review educational materials related to the fundamentals of QI techniques and giving strong HPV vaccine recommendations. A short “Practice Readiness Assessment” (See Appendix A) will be administered to faculty at each practice to determine relative exposure to Quality Improvement through training or participation in QI projects, and will help the project team recommend training materials for each site.
In addition, an Office Systems Inventory to explore practice systems for immunization delivery of HPV vaccine will be completed by providers at each participating practice. (See Appendix B and C) Respondents will be asked to complete the survey once prior to the implementation of the QI phase and again after the QI phase has concluded.

Each practice will select at least one of the following three evidence-based strategies, and adapt the general intervention to their clinic. Strategy selection will be guided by practice-specific process flow mapping and feasibility considerations. These interventions were selected since they are widely proven to be most effective in increasing immunization rates:

1. **Prompts to healthcare providers**: reminders to give vaccine at the time of the visit; specifically prompts by nurse/staff (e.g., flag charts) at all visits. In situations where an electronic health record (EHR) is utilized but no specific EHR prompt exists, nurse or staff may add the prompt to the EHR record.

2. **Standing orders**: protocols that authorize office personnel to vaccinate, if due, without direct doctor involvement at the time of patient care.

3. **Reminder-recall systems**: notifications to members of the target population that vaccinations are due or overdue.

Sites may also choose to select additional interventions from a list of proven strategies to implement in their practice, including practice-based changes for reducing missed opportunities, implementing active immunization tracking, communicating with vaccine-hesitant parents, and ensuring adolescent-friendly office policies. Supplemental, strategy-specific tools focusing on HPV immunization will be provided to practices based on their specific selections.

Practices will be grouped into Learning Collaboratives (LCs) and meet monthly by conference call. Each practice will develop a specific plan (goals, aim statements, timelines), implement the plan, measure defined metrics, modify the interventions, and report monthly to the LC about barriers and successes. For the Learning Collaborative phase, all practices will conduct monthly missed opportunity assessments (using a centralized data system, REDCap) and receive feedback in order to track progress against their stated aim(s).

The calls will be co-led by designated NIPA project leaders who will provide feedback on practice and overall progress, facilitate group discussion of the process measures, respond to obstacles that arise and brainstorm ways to ensure standardization of the intervention and maximize implementation of the intervention at each site. Content experts will provide practices with specific strategies to aid in achieving their improvement goals.

**Project Population/Inclusion and Exclusion Criteria**

**Target Population:** Adolescent patients 11-17 years old who have not completed the three-dose series of HPV vaccine

**Practice inclusion:** CORNET and NIPN will use current lists of primary care practices serving adolescents to elicit interest in this quality improvement project. Criteria include willingness and
commitment to participate with practice teams and make improvements in the delivery of the HPV immunization, identification of a site champion and practice team to include pediatric residents, Medical Assistants, Physician’s Assistants and/or nursing staff.

- CORNET: Primary care practices that participate in the Continuity Clinic Research Network (CORNET) and care for adolescents aged 11 through 17 years. Ten programs will be targeted in this wave of the project.

- NIPN: Primary care practices recruited through the existing network of state-based Improvement Partnerships that care for adolescent patients 11 through 17 years of age. Five states will be targeted in this cohort of the project.

Practice exclusion: None.

Patient inclusion: All adolescent patients age 11 through 17 who are eligible for HPV vaccine

Patient exclusion: Inability to obtain parental consent, anaphylaxis to previous HPV vaccine

Project Expectations

Team Expectations: Each primary care practice is expected to establish a multidisciplinary team to participate in the QI initiative. CORNET programs are expected to identify at least one faculty member to serve as QI site leader and 2-3 residents to serve as study team members, in addition to other faculty and office staff. NIPN practices will require 2-3 medical staff.

Each Participating Site will be expected to:
- Identify and encourage participation of a multidisciplinary team as the site’s core improvement team.
- Implement strategy ideas discussed during the LC conference calls at the site and prepare for monthly discussions/reporting on progress.
- For CORNET programs, physician must precept residents in continuity clinic at least once per week

Each QI Site Team will be expected to:
- Complete educational modules related to QI and strong provider recommendations
- Complete a Practice Readiness Assessment prior to the project (Appendix A)
- Complete an office systems inventory regarding processes for HPV immunization delivery, once before intervention and once after (Appendix B and C)
- Submit baseline chart review data (96 charts) prior to QI phase (Appendix D)
- Submit monthly chart review data during the QI phase (16 charts/month for 6 months) (Appendix E and H)
- Submit a tally of charts reviewed during both the baseline and monthly chart review (Appendix F and G)
- Submit PDSA Self-Assessment, and report on progress made and barriers faced during the QI phase (Appendix I)
• Complete a balancing measure on time effort, once at midpoint and once after (Appendix J)
• Discuss with QI Leader(s) progress made on the monthly Learning Collaborative (LC) conference calls
• Have regular access to email and the Internet for communication with the project team for ongoing support, information and communication

Each **QI Site Leader** will be expected to:
• Serve as leader of site-specific team and identify multidisciplinary team members
• Participate and oversee chart reviews (pre-intervention and monthly)
• Participate in monthly Learning Collaborative (LC) phone calls with other site leaders
  o Attend at least 5 of the 7 LC sessions
  o Discuss with other participating sites the baseline chart run results on the first LC conference call.
  o Discuss with other participating sites the monthly chart run in addition to site progress during each monthly LC conference call.
• Discuss site-specific month-to-month and overall progress throughout duration of the intervention
• Ensure site-specific education and adherence to protocol for clinical site
• Have regular access to email and the Internet for communication with the project team for ongoing support, information, and communication

**Measurement**

**Measures:**
1. Missed Opportunities: among patients 11-17 years of age, the proportion of patient visits where HPV vaccine was **due at the beginning of the visit but not given** during the visit among all visits where HPV vaccine is due (captured opportunities is the converse, the proportion of patient visits where HPV vaccine was due and given among all visits where HPV vaccine was due).
2. HPV vaccine initiation rate: among patients 11-17 years of age, the proportion of patients who receive the first dose of HPV vaccine at **the visit** among all patient visits with no doses of HPV vaccine reviewed.
3. HPV vaccine completion rate: Among patients 11-17, the proportion of patients with 3 doses of HPV vaccine received among all patient visits reviewed.
4. HPV vaccine up-to-date rate: Among patients 13-17, the proportion of patients with 3 doses of HPV vaccine received prior to the **beginning of the visit** among all patient visits reviewed.

Data collection process is described below for the following:
• **Baseline chart review (retrospective):** review 96 consecutive patient visits (16 per month, 6-month period prior to intervention) due for vaccine, missed opportunity (captured opportunity), 1st vaccine and vaccine completion
• **Monthly chart review** for the QI phase: 16 charts from each month (6 months) due for vaccine, missed opportunity (captured opportunity), 1st vaccine and vaccine completion
• **Pre and Post-Vaccine Completion Rate (if possible):** Measured through
  1) State registry
  2) Practice EMR

**PRE-WORK:**

**Baseline Chart Review:** Review 96 consecutive patient visits due for vaccine, missed opportunity (captured opportunity), 1st vaccine and vaccine completion. The pre-intervention measurement of missed opportunities will consist of a chart review of 8 patient visits in each 1/2 month period for 6 months (96 charts total) who are due for HPV vaccination at the start of the visit. Sites will also collect a small amount of data on the patient visits that are not due to allow calculation of an initiation, completion, up-to-date as well as a missed opportunity rate (see Tally Chart Form explanation below). The selection will be random. Randomization will be achieved by providing a random date and session (AM or PM) for the start of the chart review. The chart review will examine consecutive charts until the 8 patients due for HPV vaccination in that period have been captured.

Objective: To measure missed opportunities for HPV vaccination for 11 to 17 year olds seen for care over the 6 months prior to the intervention period in ½ month increments. This will allow the construction of a 6-month baseline control chart.

**Tally Chart Form:** Sites will tally and enter a count for all patient charts reviewed during the baseline chart review, both those NOT DUE for HPV vaccine at the start of the visits as well as those patients who are DUE for HPV vaccine. *(See Appendix F and G)*

Obtaining vaccine completion rates: Sites that are able to pull vaccination rates for their patient population-base through their EMRs or immunization registries will be asked to do so. The sites will write up a brief description of the process to obtain vaccine completion rates and send to the NIPA Project Team. This will also be done at the end of the study. All sites will collect vaccine initiation, completion, up-to-date and missed opportunity rates as part of the Baseline Chart Review (above) and the bi-monthly chart review (below).

**IMPLEMENTATION:**

**Monthly process measure chart review:** Each month from the onset of the intervention, participating sites will review the charts of patients seen in the practice (patient visit) who were due for HPV vaccine at the time of the visit. The sites will receive a randomization chart defining the date and session to begin the review (see Baseline Chart Review above). They will review patient visits in consecutive order to locate 16 patient visits per month due for HPV vaccine, with 8 in the 1st half of the month and 8 in the 2nd half of the month, in real time, for the 6-month data collection period to assess programs. In order to have a functional p-chart with the control limits above 0%, we will need 16 charts per clinic per month of adolescent patients, 11 through 17 years of age who are eligible for the HPV vaccine at that visit. *(See Appendix E and H)* Sites will tally and enter a count for all patient charts reviewed during the bi-monthly chart review using the same tally chart form as in baseline chart review. *(See Appendix F and G)*

**MEASURES**

Primary **Outcome** Measures:
- Missed Opportunity rate: Proportion of visits by adolescent patients 11 through 17 years of age who are due for an HPV vaccine dose at the time of the visit and do not receive a dose of HPV vaccine at that visit.
- Initiation of HPV series: Proportion of visits by adolescent patients 11 through 17 years of age who are due for the first HPV vaccine dose and receive that first dose.

Primary Process Measures:
- For sites implementing reminder-recall: Proportion of patients 11 through 17 years of age who are eligible for an HPV vaccine dose, are contacted via the reminder-recall system, and receive an HPV vaccine dose within 30 days of contact. (See Appendix H)

Balancing Measures (each practice will select one):
- Impact on staff (benefit to time ratio): to assess whether the time and effort required to implement office systems interventions benefits staff in planning, scheduling and conducting visits for adolescents who are due/overdue for HPV vaccine. A Likert scale score will be calculated from 2 polls of participating practitioners at the practice, collected at the midpoint and endpoint of the intervention. (See Appendix J)
- Impact of intervention on adolescent well care visits: to assess whether adolescent well care visits decrease because patients may be seen for “immunization-only” visits. Proportion of adolescent visits to the practice that are well care visits, calculated pre- and post- intervention.

POST-WORK:
Post-Intervention Process: If possible sites will have two options to obtain HPV vaccine completion rate. They can use 1) state registry, or, 2) practice EMR.

SUMMARY:
The NIPA team will train each participating clinician in the chart review and data entry process. The NIPA staff is available by phone for questions over the course of their reviews and data entry completion. Clinicians will conduct chart reviews at each site.

Overall, this project has been designed to monitor and collect high quality data. Multiple data sources will be triangulated, such as qualitative data, quantitative process and impact data. Verification of the data will ensure program fidelity. Data will be closely monitored and monthly conference calls will compare qualitative responses with the quantitative survey results. All data will be aggregated and questions of data reliability will be addressed back to pediatric teams to resolve missing and inconsistent data.

A medical record/chart review training document will be developed and provided to all participating teams; phone calls will be held to orient the teams to the data collection process and answer any team questions. In addition, individual coaching and support will be provided on an as needed basis to teams to ensure accurate baseline, monthly and post project data collection. Monthly phone calls will take place and clinical sites will participate in calls with other practices in the project. The calls will allow group discussion of the process measures and brainstorm ways to ensure standardization of the intervention and maximize implementation of the intervention at each site.
Process data will be submitted monthly by each group and that information fed back to the
groups in SPC charts. Each local clinic will be expected to look at their performance in their
process measures and work towards 90% adherence with their intervention. We will be able to
assess different interventions in different clinics and share in a collaborative way what is
working in the monthly QI Learning Collaborative calls.

The NIPA team will assist each clinical team in tracking progress towards goals for each
measure. Progress towards these goals may be reported by the clinical teams on the Learning
Collaborative calls, but for aggregate patient data, not individual patient or practitioner data.

**Potential Risks/Benefits**

We anticipate benefits of participating in the intensive quality improvement intervention to
include: receiving feedback on practice behaviors; credit towards the QI requirement for
pediatric maintenance of certification through the American Board of Pediatrics; and tools,
strategies and educational materials to promote AID.

For any residents involved in the project, ACGME Resident Learning Requirements may be
fulfilled. Residents must demonstrate the ability to investigate and evaluate their care of patients,
to appraise and assimilate scientific evidence, and to continuously improve patient care based on
constant self-evaluation and life-long learning. This project addresses the following resident
ACGME Milestones:
- Practice based learning and improvement
- Systematically analyze practice using quality improvement methods, and implement
  changes with the goal of practice improvement

For faculty, this project may fulfill requirements for Maintenance of Certification (MOC) which
includes a QI project within their practices.

As compensation for time, CORNET practices will receive $2000 ($1000 after the completion of
the baseline chart reviews and $1000 after the completion of the post-intervention chart reviews).
NIPN IPs will receive $5000 for assistance with local practice recruitment and project support.

Participation poses minimal risks to the participating practices. Since this study involves medical
chart reviews, the greatest risk posed is the possible loss of confidentiality. To minimize this risk,
information such as child name and medical record number will be kept only at the individual
site and will not be sent to the coordinating center. Each site will keep their own file that links
the participants to a study ID. *(Appendix K and L)*

**Alternatives to Research**

Participation in this project is completely voluntary. Practice team members may refuse to
participate or may stop participating at any time and for any reason without any penalty.

**Research Related Costs**
Practice team member time to participate in project.

**Confidentiality of Data**

Comprehensive measures will be implemented to maintain patient confidentiality and anonymity. All data collection materials for the study will be identified by a study identification number only. For baseline and monthly data collection, the individual practice sites will maintain the master list linking medical record numbers to study identification numbers. *(See Appendix K and L).*

Each site will do manual chart review and submit their data via an online data entry source (REDCap) housed at University of Rochester. All data will be aggregated and questions of data reliability will be addressed back to pediatric teams to resolve missing and inconsistent data. The REDCap database is protected by Gazzang's zNcrypt product. zNcrypt transparently encrypts and secures data at rest without any changes to your applications or database and ensures there is minimal performance lag in the encryption or decryption process. Advanced key management and process-based access controls enable organizations to meet compliance regulations and ensure that unauthorized parties or malicious actors never gain access to the encrypted data. zNcrypt meets compliance for HIPAA, PCI-DSS, FISMA, EU Data Protection, and others.

**Funding/Sponsors**

Center for Disease Control (CDC)

**Project References**

Coverage and Safety


Missed Opportunities

**Interventions Overall**

**Provider Recommendation**

**Prompting Intervention**

**Standing Orders**


**Reminder/Recall Intervention**


**Appendix**

A: Practice Readiness Assessment  
B: Pre-Implementation Office Systems Inventory  
C: Post-Implementation Office Systems Inventory  
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