A. MAIN PROPOSAL

A.1. OVERALL GOAL AND OBJECTIVES

The overall goal of the UPMC Rheumatology Vaccination Improvement Project (***UR*VIP)** is to improve vaccination rates of herpes zoster (HZ), pneumococcal, hepatitis B, and influenza for all rheumatoid arthritis (RA) patients in University of Pittsburgh Medical Center (UPMC) Rheumatology outpatient clinics (ROC), with an emphasis on those receiving immunomodulatory medications.

***UR**VIP is expected to achieve an 80% or higher immunization rate for eligible RA patients (EP) over the two-year intervention period at each UPMC ROC and for each vaccine type.*

Key Objectives

1) To educate providers and EP on the current recommendations for vaccination established by the Advisory Committee on Immunization Practices [1-7] (ACIP) and the American College of Rheumatology [8] (ACR).
2) To create best-practice electronic medical record (EMR) alerts for electronically identified EPs based on predetermined criteria. EMR alerts will be linked to documentation and ordering of vaccine for the care providers.
3) To develop sustainable clinic work flow changes to implement ***U*RVIP** to ensure that EP are receiving the appropriate, recommended HZ vaccine (HZV), pneumococcal vaccine (PV), hepatitis B vaccine (HBV) and influenza vaccine administration; and EMR documentation.
4) To disseminate our system to other healthcare providers at UPMC and at other institutions.

A.2. TECHNICAL APPROACH

The ***U*RVIP** project will use the validated, continuous quality improvement method developed by the Institute for Healthcare Improvement for use in their "Methods and Tools for Breakthrough Improvement" course [9]. This method uses quarterly cycles to Plan-Do-Study-Act (PDSA) and the method has been used successfully by hundreds of health care organizations for similar quality improvement projects [9, 10]. This intervention incorporates provider education, a decision support system, integration of the intervention into the clinic workflow using ancillary staff, and ongoing feedback to and from the providers leading to the iterative PDSA cycles. The eligible RA patients are determined based on the ACR recommendations for vaccination based on age and immunosuppressed status [8].

A.2.a. Current Assessment of Need in Target Area

As outlined in the Pfizer Request for Proposals (RFP) [11], RA is the most common inflammatory arthritis in adults. Furthermore, RA patients are at an increased risk of infection due to comorbidities and immunosuppressive disease-modifying therapies. Many studies have shown that the risk of infection can be reduced using appropriate vaccination, and it is a safe, preventative strategy. As noted in RFP, despite ACIP and ACR recommendations on appropriate immunization in RA, the national and local rates of immunization remain below expectations [11-14].

Specifically, the relative risk of pneumococcal infections in unvaccinated RA patients on immunosuppression is 9.7 [15]. One-time immunization with PV in RA patients offers up to 10 years of protection against the development of pneumococcal pneumonia in RA patients on immunosuppression [15]. Regarding HZ, the risk of HZ is elevated by 1.5- to 2-times in patients with rheumatic and immune-mediated diseases [16, 17]. The HZ vaccine decreases the risk of shingles and post-herpetic neuralgia by 50-70% in healthy patients above 50 years-of-age [18, 19]. Moreover, the live, attenuated HZ vaccine was not associated with short-term risks for zoster, even in patients exposed to immunosuppression around the time they were vaccinated [20, 21]. Regarding HBV, potential of re-activation of HBV especially in rheumatic disease patients on immunosuppression and fatal consequences of fulminant liver failure is well documented [22, 23]. Despite effective HBV screening and vaccination availability and its recommendation in immunosuppressed RA patients, appropriate screening and vaccination rates remain low [23]. Immunosuppressed patients are at higher risk for severe complications from influenza or at higher risk for influenza-related outpatient, emergency or hospital visits [24]. Influenza vaccination is safe and efficacious in immunosuppressed rheumatic disease patients [25, 26].

For RA patients already taking or initiating therapy with long-term immunosuppressive agents, including all biologic and oral disease modifying anti-rheumatic drugs (DMARDs), the ACR Task Force Panel recommends pneumococcal vaccination (killed vaccine), influenza vaccination (killed vaccine), hepatitis B vaccination (if hepatitis risk factors are present, killed vaccine), human papillomavirus vaccination (HPV; through age 21 for males, 26 for females, recombinant vaccine), which follows the Center for Disease Control (CDC) recommendations [8, 27]. Additionally, HZV (live, attenuated vaccine) is recommended in RA patients above age 60 who are already on or who are initiating DMARD therapy as well as those who are initiating biologic therapies [8]. The CDC also recommends a one-time pneumococcal revaccination after 5 years for RA patients over age 65, if their primary vaccination was before age 65 and more than 5 years previous [8]. In addition to patients with traditional risk factors for HBV, it's screening have been recommended in all rheumatic patients on immunosuppressive regimens and unvaccinated patients should receive vaccination [22, 28]. Checking a hepatitis B surface and core antibody titer and hepatitis B surface antigen is a simple way of confirming immunization status. Eligible RA patients with negative hepatitis B surface and core antibody titers should be vaccinated if they are not currently infected (hepatitis B surface antigen negative).

Additionally ACR and ACIP recommend HPV vaccination to patients aged 11-12 years for prevention of cervical, vaginal, and vulvar cancer in females and genital warts, anal and penile cancer, and decreasing transmission to male partners. Vaccination is also recommended for males aged 13-21 years and females 13-26 years who have not been vaccinated previously or who have not completed the three-dose series. ***U*RVIP** will not pursue HPV vaccination as part of the proposed quality improvement in immunization because our patient population within UPMC ROCs is mostly above 18 years-of-age. Including HPV in ***U*RVIP** will benefit very few patients and is not cost, time, or effort-effective currently in our clinics. Moreover, it will lead to a duplication of efforts which are already in place by UPMC pediatricians. A recent patient census report for UPMC ROCs suggests that there are 1.45 % females aged 26 years or younger

and 0.3 % males aged 21 years or younger. Most of these patients are already immunized due to a very proactive HPV vaccination program for adolescent patients in UPMC Pediatrics.

Despite the risk of infections from vaccine preventable diseases in RA and available evidence and guidelines for protective effect of vaccine in RA, especially immunocompromised patients, there is currently no system-wide process or tools to identify high-risk RA patients and pursue appropriate ACR-recommended vaccinations in our UPMC ROCs.

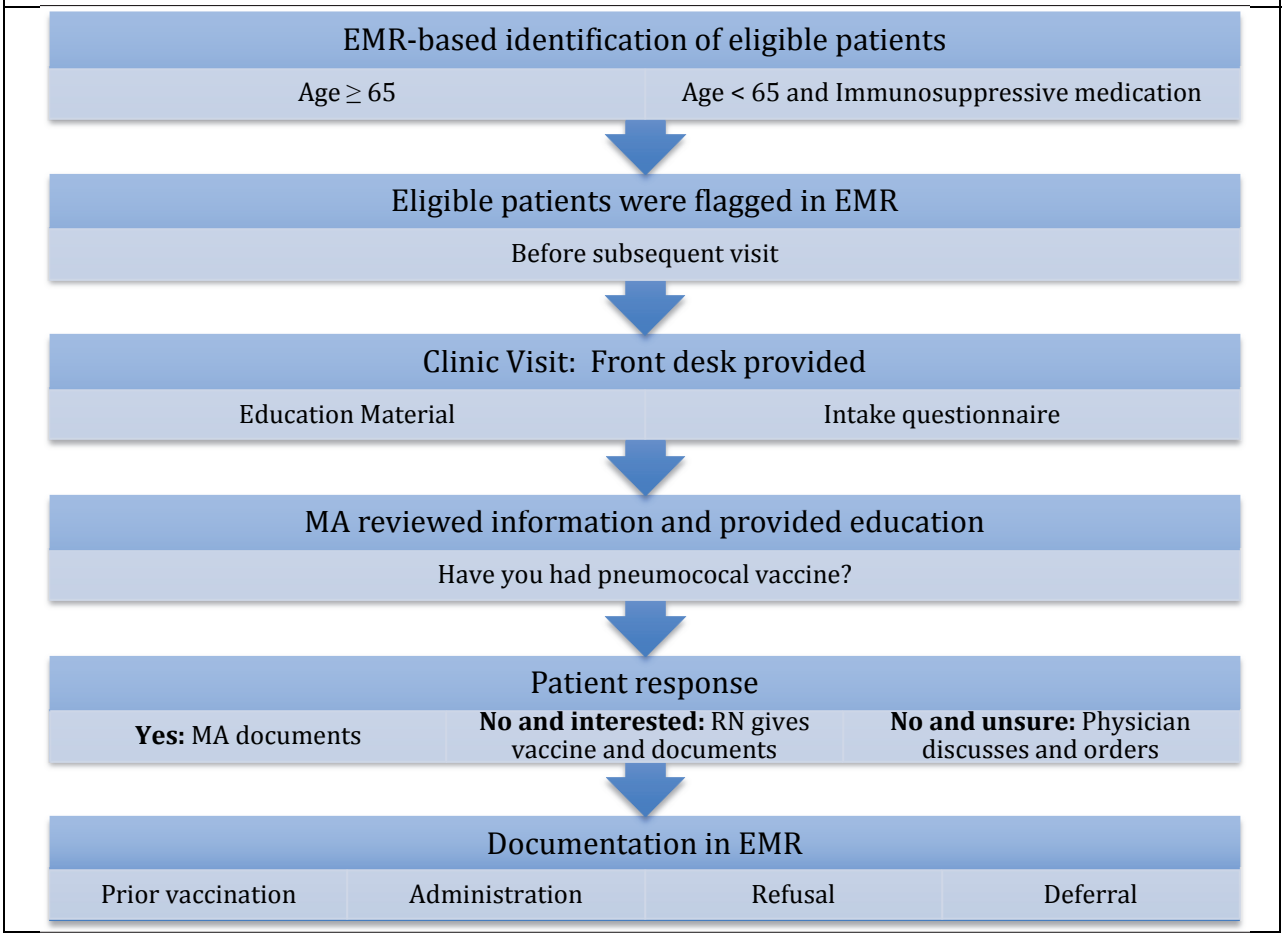
A.2.b. Quantitative Baseline Data Summary

UPMC is one of the largest health care networks in the U.S., with more than 3.6 million outpatient visits annually. As part of a UPMC quality improvement initiative, Dr. Larry Moreland, Chief of Rheumatology and Clinical Immunology, convened a series of meetings of UPMC rheumatologists in 2011-2012. One of the key messages from these meetings was a need for education regarding current vaccination recommendations. Barriers identified were the result of a lack of provider and patient awareness, a lack of knowledge about current ACIP and ACR recommendations, assumptions on which of a patient's physicians would order vaccinations, busy outpatient specialty practices, lack of a system-wide approach towards immunization of EP, and barriers to accurately document immunization status. HZV rates may also be low in part due to previous perceptions about safety issues without substantial randomized trial data.

As a result of these meetings, we set out to study and improve the rate of PV and EMR documentation at one UPMC ROC. This demonstrates our proactive approach towards quality improvement efforts in our Division based on current literature. According to EMR-based reports generated by our EpicCare and UPMC information technology teams, the PV rate among EPs in one UPMC ROC was 15%, and the HZV rate was even lower at 13.5%. The aim of our pilot study was to improve the rate of both administration of PV and EMR documentation in immunosuppressed patients taking DMARDs and biologic agents at a university-based rheumatology clinic. The intervention was directed on any immunocompromised, adult patients regularly seen in our primary university-based rheumatology clinic. Eligible patients were identified through the EMR, and patients without documentation of prior PV were flagged before their clinic visit (**Figure 1**). Flagged patients received written educational materials, counseling as needed, and questionnaires to confirm PV eligibility when they arrived at their next clinic visit. The medical assistant (MA) confirmed the EMR information regarding PV status and documented in the EMR if PV had already been administered. A registered nurse (RN) administered and documented PV, if the patient met immunization criteria. This intervention also included a provider education component. Physician approval or involvement with the patient was required in only a few cases. The pre- and post-intervention data for this pilot study were collected with help of UPMC information technology, using EMR-based report generation from the patient's main EMR summary sheet and vaccination page. Our EMR, EpicCare, has a dedicated system for immunization documentation, which is integrated into the patient clinic visit page and can be easily accessed by physicians as well as ancillary staff members.

After the 9-month intervention, we performed a pre- and post-intervention comparison (see **Figure 2**). Using PV and HZV rates as surrogate markers for the baseline immunization rates for patients in UPMC ROCs, we determined that the rates in our network were sub-optimal [14], which mirrored the national average [5]. Pre-intervention, only 193 of 969 (19.7%) patients had received PV, compared to post-intervention rates of 561 of 1,254 (44.7%) EPs. Additionally, we documented 145 (11.6%) patients who either refused, who had previously received PV, or whose physician deferred for various reasons. A total of 56.3% either received PV or EMR documentation of PV or declined PV, which was significantly better than the pre-intervention rate of 20% ($p<0.0001$). This pilot data demonstrates that the scope of the local problem is large, similar to what has been documented nationally.

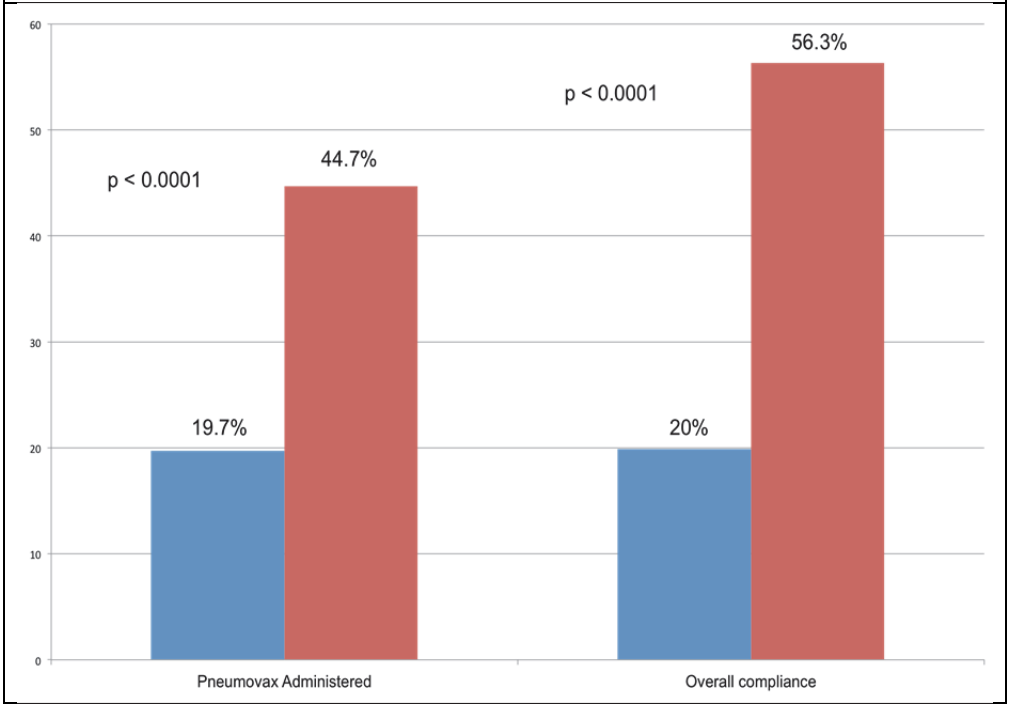
Figure 1. Flow chart for EMR-based identification, administration, and documentation of vaccinations.



Our pilot study demonstrated that implementation of an EMR- and ancillary staff-based intervention significantly improved both vaccination and documentation rates, with minimal input from the rheumatologists. This study also demonstrates that a lack of documentation of previous vaccination, patient refusal, and physician deferral only explained sub-optimal vaccination in a small number of patients (11.6%). Since the intervention was integrated within the regular clinic workflow, provider workloads were not noticeably increased. Our results

demonstrated that focusing on the identification of eligible patients, who are starting treatments with or who are already being treated with immunosuppressant medications, and providing feedback to physicians about eligible patients, and designing workflow to integrate vaccination into routine clinical practice is warranted in order to provide appropriate vaccination in an effective and efficient manner. Although this project was highly successful and informative, it was a small pilot project, limited to only one of the UPMC ROCs. There is a need for implementing this model to all UPMC ROCs, with increased automation using the EMR. This proposal will result in incorporation of improved interventions, with more automation, for PV and other ACR-recommended vaccinations for RA patients into the entire UPMC infrastructure at all of the UPMC ROCs. The workflow designed and automation programmed into EpicCare will be easily incorporated into other healthcare systems using this highly popular EMR.

Figure 2. Pneumococcal vaccine administration and overall compliance (administration and documentation of deferral or refusal) rates pre- and post-intervention. Blue bars are pre-intervention and red bars are post-intervention.



In addition to our PV initiative, there are initiatives to improve influenza vaccination rates for all patients at UPMC. A proactive, extensive influenza vaccination program is done annually by all UPMC clinics, not just UPMC ROCs. UPMC Health Plan further incentivizes members to receive the influenza vaccine, and this program is administered at multiple sites to both patients and health care workers. However, a targeted approach towards RA patients, as outlined in our current plan, will further improve the immunization rates for influenza.

A.2.c. Primary Target Audience

***U*RVIP** will target eligible adult (over 18 years of age) RA patients in 17 UPMC ROCs. UPMC ROCs cater to more than 45,000 rheumatology outpatient visits with a large active RA population of more than 4,000 patients. Thus, ***U*RVIP** will positively impact and benefit RA patients by improving immunization rates. ***U*RVIP** also target rheumatologist and clinical staff with a) educational on importance of immunization in RA patients, b) by providing feedback and peer immunization rates, c) making individual rheumatologist and clinic staff an integral part of the project. ***U*RVIP** target patient's perception with education.

A.2.d. Intervention Design and Methods

Intervention Design and Overview: The ***U*RVIP** will use multiple components to generate system-wide changes that will ensure that EPs are receiving the appropriate, recommended vaccines: a) education of EP and providers; b) system-wide clinic workflow changes; and c) EMR based identification and best-practice prompts and documentation of immunization, d) rapid cycling of data to provide feedback to physicians and continuously improve the system until the best outcome is achieved (Plan-Do-Study-Act, PDSA [9, 10]). At the end, we will perform a pre- and post-intervention comparison. This project has received Quality Improvement (QI) approval from the UPMC Quality Council (see **Section E**), which is an endorsement of the quality, importance, and potential impact of the current proposal. It also demonstrates UPMC QI team's interest in the current proposal.

Intervention Period Summary:

1) Pre-Intervention Phase: 7/1/2013 to 9/30/2013
   a) Retrospective data collection on baseline immunization rates of PV, HZV, influenza and HBV in previous year.
   b) Examine baseline deficiencies and associated factors.
2) Intervention Phase: 10/1/2013 to 9/30/2015.
   a) Develop and implement EMR best-practice alerts.
   b) Create and revise clinic workflow.
   c) Educate patients, physicians, and staff regarding vaccinations.
   d) Feedback of results (1/1/2014 to 9/30/2015), with individual- and peer-performance comparisons to physicians on a quarterly basis.
   e) Web-based survey of physicians and staff and quarterly clinic meetings to understand the barriers and solutions.
   f) Biannual EP survey to identify patient perceptions, knowledge, and barriers.
3) Post-intervention phase: 10/1/2015 to 12/31/2015
   a) Continue to track compliance and vaccination rates for further improvement and sustainability.
   b) Disseminate ***U*RVIP** model to other specialty areas of UPMC, particularly primary care clinics.
   c) Present and publish ***U*RVIP** results to national meetings and peer-reviewed journals to help other medical centers implement our model.

Eligible patient criteria for various vaccinations:

1) **All adult patients** >=18 years with diagnoses of RA who are seen at the UPMC ROC between October 1st 2013 to March 31, 2015
2) **Medication criteria:** if patient is on or is prescribed any of the following medications:
   i) DMARD medications: hydroxychloroquine (HCQ), methotrexate (MTX), leflunomide, sulfasalazine, minocycline, tofacitinib.

   ii) Biological medications: anakinra, abatacept, etanercept, infliximab, adalimumab, certolizumab, golimumab, rituximab, and tocilizumab.

   iii) Steroids: corticosteroids (> 10 mg equivalent of prednisone > 3 months).
3) **Vaccination Specific criteria:**
   i) For pneumococcal vaccination (PV):
      (1) Any RA patients age ≥ 65 years regardless of immunotherapy status.
      (2) For RA patients < 65 years: only if currently on or going to start DMARD or biological or steroids.
      (3) Re-vaccination with pneumococcal vaccine:
         (a) One-time pneumococcal revaccination after 5 years interval for RA patients with above criteria (# i2).
         (b) For RA patients with age > 65 years one time revaccination if primary vaccination was before 65 years of age and > 5 years ago.
   ii) For zoster vaccination (HZV):
      (1) All RA patients ≥ 60 years meeting criteria # ii2 OR ii3 below.
      (2) Patients who either currently on or going to start DMARDs or steroid immunosuppressive medications.
      (3) RA patient who are going to start one of the biologics.
   iii) For seasonal influenza vaccination:
      (1) All adult RA patients seen during annual Flu season only (October – March) should receive this vaccination regardless of immunosuppressive status. In case of vaccine shortage priority is given to patients who are currently on or going to start DMARDs, biologics or steroids as well as other high risk population like health care workers and patients with comorbidities.
   iv) Hepatitis B vaccination (HBV):
      (1) All adult RA patients with risk factors for Hepatitis B (IV drug abuse, multiple sexual partners and health care workers) AND
      (2) Any adult RA patient who is currently on or going to start DMARDs or biologics or steroids should be checked for hepatitis B status (Hepatitis B surface antigen [HbSAg], surface antibody [HbSAb] and core antibody [HbcAb]).
      (3) All RA patients meeting above criteria iv1 or iv2 - should be vaccinated if HbSAb titer is negative or < 10 IU/ml (i.e not previously immune) and patient is not currently infected (negative HbSAg) and not immune due to previous infection (HbcAb).

4) Exclusion Criteria:

i) Any patient who had rituximab in last 6 months or cyclophosphamide in last 3 months should not get HZ vaccine due to uncertain safety data. For other vaccinations (PV, influenza and HBV) physicians may decide to give vaccinations several months after rituximab or cyclophosphamide. However, it is most desirable to give vaccinations before start of these agents.

ii) Any patient who have a) ever received HZ or b) pneumococcal vaccination in last 5 years or had one-time re-vaccination, c) either immune/infected with hepatitis B, or d) have received influenza vaccine in the season.

iii) Patients with contra-indication or allergic to vaccine: usually allergy to any component of vaccine or severely compromised cardiovascular and/or pulmonary function in whom a systemic reaction would pose a significant risk.

iv) HZV is contra-indicated in any known immunodeficiency states like primary or acquired immunodeficiency states, leukemia, lymphoma or other malignant neoplasms affecting the bone marrow or lymphatic system and AIDS/HIV.

v) Pregnant and lactating females.

vi) Acute illness including fever.

Details of the planned interventions:

Pre-intervention phase 7/1/2013-9/30/2013:

We will determine baseline rate of each vaccination for EPs according to eligibility criteria for the pre-intervention period (7/1/2012 – 6/30/2013). Vaccination compliance rate will be determined when these conditions exist: 1) patient received vaccination, 2) EMR documented refusal, 3) physician deferred because of contraindication. Baseline rate of patients who received vaccination before start of DMARDs/biological drug regimen will be recorded. We will also obtain demographic and other clinical information (age, gender, race and other rheumatic disease diagnosis, medications) from EMR. Vaccination and compliance rates will also be computed by rheumatologist, and rheumatology clinic. Patient's primary care physician information will also be reported. This data will be analyzed to understand the deficiencies by various factors like rheumatologist, clinics and clinical features or drugs and will be used to device intervention strategies in the target areas. The information gained in this phase is critical for appropriate development of efficient best-practice alerts and clinic workflow in intervention phase.

Intervention phase: 10/1/2013 to 9/30/2015:

Develop and implement EMR alerts and ancillary staff based vaccination process:

We will develop an EMR based best practice alert (BPA) which will have integrated vaccine eligibility verification for individual patient, documentation and vaccine order capability (**Figure 3).** Using our pilot project results and experience as well as baseline information from pre-intervention phase analysis, we will develop the EMR and ancillary staff based workflow integrated with BPAs prompt/alerts for maximum efficiency and automation. Each vaccine will have unique prompts and alerts due to differing recommendation criteria and depending on the EP's current and future medications.

Current procedures in the UPMC ROCs require that medical assistants (MA)/licensed practical nurse (LPN) to perform medicine reconciliation of all medicines at each visit. The vaccine BPA prompts and alerts will appear during this reconciliation procedure, prompting the MA to perform a workflow similar to that described below in **Figure 4.** If patient meets criteria for more than one vaccine then both BPA will appear which will need to be addressed. MA will query the EP to determine vaccination status and document any prior vaccinations. EP with no prior vaccination will be queried to confirm eligibility for vaccines and educated on the importance of vaccination in RA patients especially while on immunosuppressive medications. MA will inform the patient that based on the criteria set forth by your physician and ACR you should receive appropriate vaccination. Agreeable EPs will receive PV, HZV, HBV and influenza vaccine from the clinic nurse who will also document vaccination in EMR. If a patient's insurance status is unclear or if it doesn't allow vaccination outside of primary care or pharmacy, then a prescription will be given to the patient. In this case if EP received vaccination elsewhere MA will document on subsequent visit.

Figure 3. Example of a typical best practice alert.

Eligibility: This patient has RA and aged ≥ 60 years of age and on DMARD but not currently on biological drugs.
Given above criteria this patient has high risk for Herpes Zoster infection and is eligible for Herpes Zoster vaccination.

Please select one of the following:

1: Yes, to be given→ link to order vaccine and documentation.

2: Not to be given → (please select one of the reasons)

a) Patient refused
    1) Resolve for this visit only. 2) Resolve for 1 year.

b) MD deferred due to other medical reasons. Note reasons.
    1) Resolve for this visit only. 2) Resolve for 1 year.

c) Not indicated. Note reasons.
    1) Resolve for this visit only. 2) Resolve for 1 year.

3: Already given→ Link to EMR Immunization tab to document immunization.

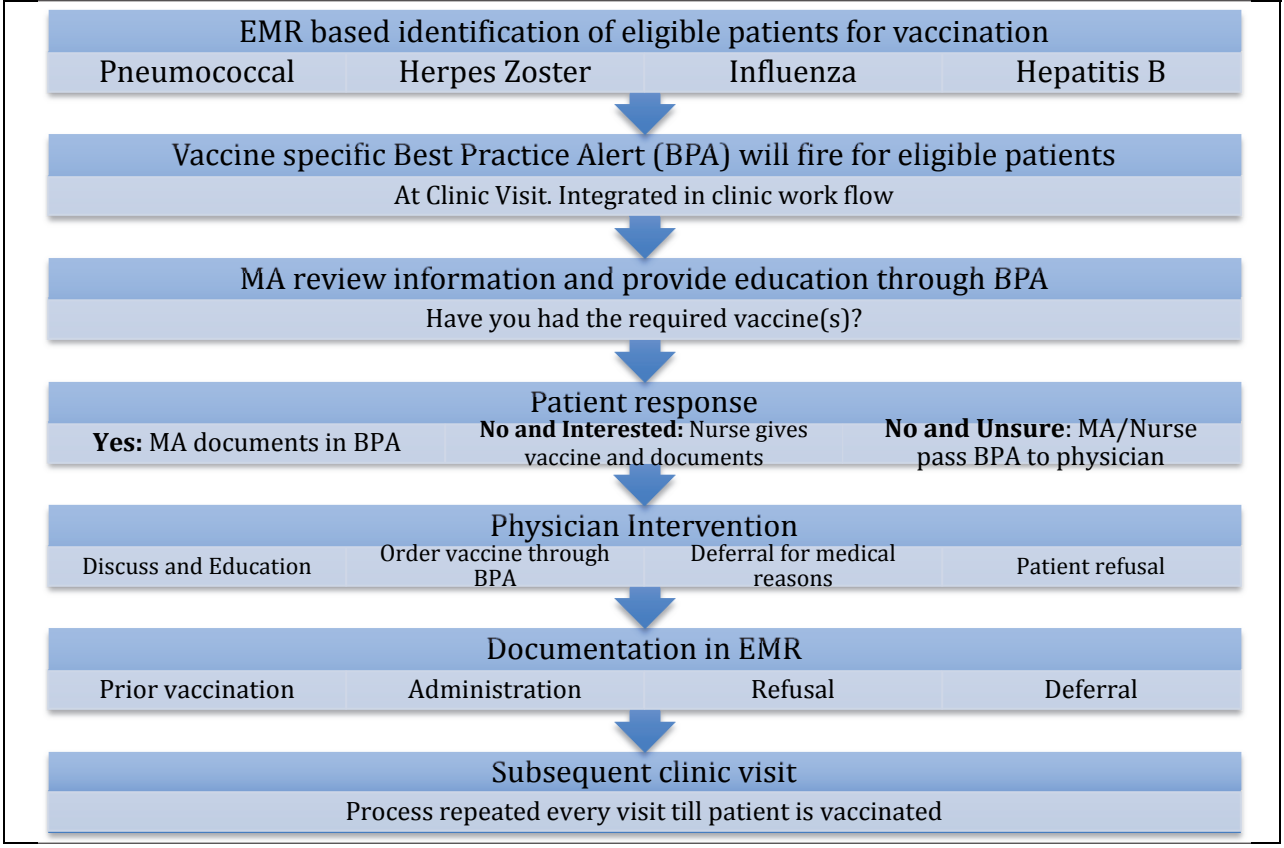
When a patient has additional questions or declines, then the alert will be passed to the rheumatologist for resolution at that clinic visit. The rheumatologist will discuss the vaccine requirement with patients and either order the vaccine(s) if patient agrees or document the refusal or deferral reasons. If patient has received prior vaccination then MA/LPN will document it so that next time the alert will not come up.

Subsequent visit: BPA will not fire on subsequent visit if patient was vaccinated and was documented in EMR. If refusal or deferral were documented then BPA will fire again if patient

continues to be eligible as per the criteria. If patient received vaccination outside our clinic based on our recommendation it may not have been documented in EMR, in such situation BPA will appear again prompting MA to document the vaccination status. This way the process is automated until patient receives appropriate vaccination.

First time immunosuppressive drug (DMARDs or biological or steroids): A BPA will also appear if physician orders any biological or DMARDs medication on RA patient for the first time for patient meeting the eligibility criteria (inclusion/exclusion). This scenario usually occurs during new diagnosis of RA. This will prompt physician to order appropriate vaccination on the visit such that patient will get vaccinated before immunosuppressive medication which is ideal. This is very important for HZ vaccination where patients should be vaccinated prior to starting biological agent. BPAs will have vaccine order capabilities so to decrease workload of the physician. To resolve the BPA physician will either document prior vaccination status or will order vaccine so that patient can get vaccine before the start of immunosuppressive medication. If patient refuse or immunization is deferred for medical reason then it is documented appropriately through BPA.

Figure 4. Flow sheet for EMR based identification, administration and documentation of pneumococcal vaccination.



Nurse intervention: For patients requiring pre-authorization of DMARDs (some cases) and Biological drug (almost all cases) for new medication for RA, nurse will verify vaccination status

similar what is currently done for PPD documentation (tuberculosis test) prior to first biologics. The nurse workflow will be similar to MA workflow using BPA described above. Eligibility will be determined using EMR based system and BPA will appear for all eligible patients. This will ensure that more and more patients receive vaccination prior to immunosuppressive medication especially biologics are initiated. This is very important for herpes zoster vaccine where it should be given before starting biologics.

Specific plan for each vaccination: The general intervention plan will remain the same for all vaccinations as outlined in flowchart form in **Figure 4**, but there will be slight modifications for each specific vaccine based on the specific requirements and recommendations [2-6, 8, 24, 27].

Vaccine co-administration: If patient fulfills the criteria for more than one vaccination like pneumococcal and HZ vaccination, co-administration of both the vaccine can be considered. However, if possible the administration of the two vaccines 4 weeks apart for full antibody response is preferable. Co-administration with influenza vaccine is allowed. Hepatitis B vaccination follows 3-dose schedule and thus can be co-administered if required with other vaccination.

Patient, physician and staff education regarding vaccination:
Education regarding the importance and safety of vaccination and evidence-based recommendations will be a crucial component of ***U*RVIP.**

Rheumatologists at UPMC will be provided bi-annual education in the form of formal presentations with pertinent disease- and vaccine-related information. They will earn education credit unit for this activity accounted for annual QI and safety credit requirement for licensure. Rheumatologist and staff education will also be provided in small group meetings will be performed quarterly for each clinic to provide interactive sessions with opportunities to address concerns, misconceptions and clarify and update recommendations.

All clinic staff will be educated regarding the ***U*RVIP**, the importance of immunization in EP, especially in EPs who are going to start immunosuppression therapies, and the current ACIP and ACR recommendations. An assessment module, specific to these learning objectives, will be developed in the University of Pittsburgh Health Sciences eLearning Environment for Internet-Based Studies in Education and Research, and all clinic staff and providers will be expected to complete this module. This module will be updated and mandated annually (and for all new hires), as vaccination recommendations and clinic staff change. Finally, posters step-by-step flow charts with vaccine information will be designed and displayed in all clinical areas and exam rooms.

EP education will be done at each clinic visit by ancillary staff and reinforced by physicians as needed. Patient-education pamphlets will be designed and will be placed in the waiting areas. Pneumococcal, HZ, Hepatitis B and Influenza infection and vaccination educational material will print out for every EP, through the existing check-out system, whether the patient received the vaccination(s) or not.

Web based survey of physicians, staff and patients, and quarterly clinic meetings to understand the barriers and solutions:
Small group meetings will be performed quarterly for each clinic to reinforce the information as well as for troubleshooting the project and improving vaccination rates at each site. Each clinic may have unique workflow requirements and/or barriers in integrating the vaccination quality improvement project. A web-based survey will be conducted for all physicians and staff on a quarterly basis and for patients on a biannual basis to ask about their experiences, barriers, and recommendations on the process. Providers will also have an opportunity to provide positive and negative feedback during the quarterly clinic meetings, in addition to the web-based survey. Many of our RA patients already use email for communication and will be able to complete electronic surveys via email or on the web.

A.2.e. Evaluation Design
A.2.e.i. Intervention Assessment: 1/1/2014 – 6/31/2015:
We will commence collection of the pre-intervention data at the start of this award, and will include data from the previous 12 months. We will determine the baseline vaccination rates at all UPMC ROCs by evaluating the proportion of EP who were eligible, but unvaccinated with PV,HZV, HBV and influenza vaccine and those who were vaccinated or documented refusal or deferral in our EMR. We will also determine the proportion of eligible EP who received vaccination prior to the start of immunosuppressive therapies. In either group, the reason for being unvaccinated will be recorded when it is available. Each EP's rheumatologist; rheumatology clinic staff; rheumatology clinic; primary care physician (PCP) and clinic; demographic characteristics; concurrent meds; and clinical data will be derived from the EMR system (EpicCare). The same data elements will be reported quarterly throughout the intervention study period. We plan to collect his baseline information with the help of our quality improvement team and information technology team at UPMC using our EpicCare EMR-based report generation system. Our pneumococcal vaccine project has demonstrated our collaborative effort with our QI and IT teams.

We will perform a pre- and post-intervention comparison quarterly and at the end of the study period to determine if vaccination rates are improving as a result of the intervention. A pre- and post-intervention comparison will be stratified by clinic, rheumatologist, therapies, PCP, demographic factors, co-morbid conditions, and disease activity and type, especially to track compliance and improvement. Quarterly comparisons will be used to demonstrate trends and will identify barriers, and help adjust the intervention to drive continuous improvement. Data from web-based surveys and quarterly clinic meeting will also be analyzed to understand the road blocks in the process. Quarterly adjustments to the workflow and intervention will be focused on making the process more practical, easy, efficient, and sustainable. We will determine what factors (e.g., patient age or race or certain physicians, clinics, etc) lead to lower vaccination rates and will intensify our efforts in those areas. Quarterly vaccination rate data will be provided to clinics/physicians as feedback on how well they are performing as compared to other clinics/doctors (anonymously) which itself will be an incentive for clinics/physicians to perform similar to their peers. We will provide more support and education to units/physicians

not performing well. Patients and providers will be identified by code and not by names in these reports.

This feedback and modifications in the workflow or interventions will allow continuous improvement every quarter and will drive better immunization practice and rates.

Improvement Results:

1. % change in vaccination rates over time for each vaccination and for each ROC
2. % change in physician performance for vaccination rates with peer comparison in respective clinic and over all ROCs.

We expect to achieve > 80% immunization rates in all UPMC ROCs over 2 years as well as to educate patients and the rheumatology community.

Statistical analyses: A pre- and post-intervention comparison will be performed using incident rate ratio for vaccination rates. Demographic and clinical characteristics will be compared for pre- and post-intervention RA patient groups using *chi* square, t-test, or non-parametric test, depending upon the variable distribution. Patient factors associated with noncompliance will be evaluated using logistic regression. Control run charts will assess trends and improvement over time for the vaccination rates.

Continuous improvement: Any recommendations for improvement of the EMR and ancillary staff based flow for vaccinations will be discussed with all clinics and implemented on a quarterly basis after discussed with the health care teams. Quarterly adjustments will be focused on making the process more practical, easy, efficient, and sustainable.

Long-term sustainability: Success of the ***U*RVIP** will be presented to the clinic providers and over the course of the study to engage and motivate providers. Continuous adjustment and improvement at each step will lead to a process that is efficient, sustainable, and user-friendly. We expect it to become a routine standard practice in our UPMC rheumatology clinics after the 2 years of this project.

Innovation: EMR and ancillary staff based intervention using BPA is unique as it integrates the quality into the clinic workflow without increasing physician burden. At the same time it allows physician supervision as well as intervention if a physician disagrees with vaccination for medical reasons or a patient wants to discuss vaccination with his/her physician as the actual administration of vaccine(s) is done after physician-patient encounter. EMR-based measures can be uniformly applied to all clinics without need for developing multiple, different clinic-specific programs. Moreover, since EpicCare is one of the most widely-used EMRs in similar institutions in the US, the funded work here can easily be adopted at other institutions. The goal is to develop an intervention that is efficient and can be sustained long-term without much external support. The intervention will be automated, and we will provide constant feedback to the physicians and clinics on their performance compared to their peers, which motivates better results. We have successfully developed a pilot program of pneumococcal vaccination in

one of our academic clinic and shown positive results, which now need to be expanded further and instituted across all of our clinics.

A.2.e.ii. Intervention Outcome

We expect to achieve > 80% immunization rates in all UPMC ROCs as well as to educate patients and the rheumatology community. Although our pilot intervention resulted in a statistically significant increase in PV rate compared to the pre-intervention rate at one UPMC ROC, we believe that this proposal will allow us to reach a rate of 80% over 2 years in all vaccination programs outlined. Further, we expect that the rate of infections related to pneumococcal, HZ, hepatitis B, and influenza infections will decrease over the intervention period, leading to decreases in overall inpatient visits for infections.

A.2.e.iii. Audience Engagement

During the intervention period, the target population will be surveyed anonymously, on a bi-annually basis, via an internet-based instrument to understand their level of engagement. For EP without access to internet, we will provide an alternative. If necessary, we will incentivize patients who complete the survey in a timely manner. The UPMC ROCs are equipped with internet access, and we have experience with internet-based instruments (see **Section C**). UPMC rheumatologists and clinic staff will also have opportunity to provide feedback for the processes through quarterly surveys or clinic meetings and will inform us of their level of engagement as well. Patients, physicians and staff are an integral part of ***U*RVIP** and will be engaged at every step of the process and their feedback and suggestions are required for the continuous improvement cycles.

A.2.e.iv. Dissemination

Dissemination will occur as follows: 1) quarterly reports to clinic providers to drive increases in vaccination rates; 2) presentation of aggregate, preliminary results at national and international conferences; 3) publication of results in peer-reviewed journals; and 4) moving this system from UPMC ROCs to UPMC primary care clinics, which utilize the same EMR. Using these results, Drs. Aggarwal and Moreland will have the necessary data to lobby UPMC to create a system-wide change for improving vaccination rates. This proposal will fund the necessary creation and iterative improvements of EMR best-practice alerts and education resources. Once developed, Drs. Aggarwal and Moreland will involve the *Donald D. Wolff Jr. Center for Quality Improvement and Innovation* at UPMC and Dr. Steve Shapiro, who will disseminate the final model throughout UPMC. UPMC is moving their physician incentive plans from volume- to quality-based. If successful, then this project can serve as one of the quality-based incentive programs for rheumatologists at UPMC. Moreover, since UPMC utilizes EpicCare for ambulatory EMR, the workflow developed can be easily ported to other healthcare systems across the nation.

A.3. Detailed Workplan and Deliverables Schedule

The project will commence by July 1, 2013, as described above and in this section.

Table 1. Goals and Deliverables for the *U*RVIP Project	
Goals and Deliverables	**Expected completion (Month/Year)**
To educate providers and EP on the current recommendations for vaccination established by the ACIP and the ACR.	
1. Develop a physician education workshop for biannual physician continuing education.	7/2013-9/2013
2. Develop assessment module in the University of Pittsburgh Health Sciences eLearning Environment for Internet-Based Studies in Education and Research.	8/2013-10/2013
3. All physicians and ancillary staff complete the assessment module with a minimum score of 80% correct.	12/2013
4. Develop and hold quarterly meetings for each clinic for education and assessment.	10/2013-9/2015
5. Develop patient education materials for clinic visits.	7/2013-12/2013
6. Use patient education materials at clinic visits.	12/2013 onward
7. Refine patient education materials as warranted.	1/2014 onward
8. Design, print, and post step-by-step flow charts in clinical areas and exam rooms.	7/2013-12/2013
To create best-practice EMR alerts for electronically identified EPs based on predetermined criteria. EMR alerts will be linked to documentation and ordering of vaccine for the care providers.	
9. Develop best-practice alerts for all vaccinations.	9/2013-12/2013
10. Refine best-practice alerts and the EMR programming.	12/2013-9/2015
11. Regular meetings with the UPMC IT teams, QI teams, and EpicCare teams.	10/2013-9/2015
To develop sustainable clinic work flow changes to implement *U*RVIP to ensure that EP are receiving the appropriate, recommended HZ vaccine (HZV), pneumococcal vaccine (PV), hepatitis B vaccine (HBV) and influenza vaccine administration; and EMR documentation.	
12. Develop survey material for physicians, staff, and patients	7/2013-12/2013
13. Develop a clinic workflow for all vaccinations.	10/2013-9/2015
14. Quarterly meetings to inform clinic staff of workflow changes and to solicit feedback for subsequent improvements in workflow and refinements in educational materials	10/2013-9/2015
15. Survey physicians, staff, and patients anonymously to assess barriers and progress	1/2014-9/2015
16. Reports generated quarterly from EpicCare and the QI teams. Analysis of the quarterly and cumulative reports. Dissemination of the results for feedback at the quarterly clinic meetings to inform health care providers of progress.	1/2014-9/2015

17. Implement changes in the best-practice alerts and clinic workflow to ensure continuous improvement based on patient, physician, and staff feedback and the reports generated.	1/2014-9/2015
To disseminate our system to other healthcare providers at UPMC and at other institutions.	
18. Meet regularly with Dr. Shapiro to disseminate the deliverables system-wide	7/2015-12/2015
19. Engage Donald D. Wolff Jr. Center for Quality Improvement and Innovation to assist in disseminating the deliverables	7/2015-12/2015
20. Perform final statistical analysis	7/2015-12/2015
21. Interim abstract presentation at national conference	6/2014
22. Final abstract presentation at national conference	11/2015
23. Publication in peer-reviewed journal	12/2015

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