

UPMC RHEUMATOLOGY VACCINATION IMPROVEMENT PROJECT (URVIP)

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Abstract:

The overall **URVIP** goal was to improve herpes zoster (HZ), pneumococcal, Hepatitis B and Influenza vaccination rates for eligible rheumatoid arthritis (RA) patients (EP) who were starting treatment or already being treated with immunosuppressive medications in University of Pittsburgh Medical Center (UPMC) Rheumatology Outpatient Clinics (ROC).

Scope: UPMC ROC vaccination compliance rate was suboptimal at 10-20%. Thirteen ROCs care for 4000+ RA patients annually. This project targeted high-risk RA patients (immunosuppressed) to improve vaccination rates. The project focus on education, electronic medical record based best practice alert, efficient clinic work flow was geared towards long term self- sustainability to continue benefitting RA patients for years to come. It's interventions are easily generalizable to the UPMC health system and other institutions.

Methods: The **URVIP** was implemented using multiple components to ensure that EPs were receiving the appropriate, recommended vaccines: a) education of EP and providers for vaccine recommendations; b) system-wide clinic workflow changes; and c) Developing and implementing best-practice alert prompts. The project evaluation was designed as pre- post comparison. Rates were compared using Chi Square test among the clinics and providers. Quarterly feedback of results to the clinics and providers with ongoing counseling and education as needed were key components of the project.

Results: All UPMC ROCs improved their vaccination rates in all four vaccines. Pneumovax rates improved to 77.3% from 27% at baseline, Herpes zoster from 10.1% to 62.4%, Hepatitis B vaccination improved from 41% to 80% from first 6 months to 12 months of intervention and influenza from 37.5 to 59.6%. Documentation rates ranged from 60 to 94% for different

vaccines and were significant improvement. BPAs were liked by the providers and did not substantially increase their work load.

Conclusions: Electronic identification of vaccine eligibility and BPA significantly improved vaccination rates for Herpes zoster, Pneumovax, Influenza and Hepatitis B.

Key Words: Best Practice Alert, Electronic Medical Record, Rheumatoid Arthritis, vaccination, quality improvement, immune-suppressant therapy

UPMC Rheumatology Vaccination Improvement Project

URVIP goal was to improve vaccination rates for high risk RA patients on immunosuppressive therapy. The four common and effective vaccines targeted were Herpes Zoster (HZ), Pneumococcal (PV), Hepatitis B (HepB), and Influenza (Flu).

Objectives:

- 1) To educate providers and eligible patients (EP) on the Advisory Committee on Immunization Practices' (ACIP) and American College of Rheumatology's (ACR) recommendations on vaccination;
- 2) To create clinic and network changes and electronic medical record (EMR) best-practice alerts designed to identify EP and their vaccination status;
- 3) To create system-wide changes to ensure that EP are receiving the appropriate, recommended vaccine administration; and
- 4) To disseminate our system to other healthcare providers at UPMC and at other institutions.

Scope:

Background: 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. 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. **URVIP** 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 **URVIP** 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

Assessment of need for the Intervention:

Baseline Summary and Preliminary Studies. As part of an UPMC quality improvement initiative, Dr. Larry Moreland, Chief of Rheumatology, convened a series of meetings of UPMC rheumatologists, led by, Dr. Rohit Aggarwal, Assistant Professor and Medical Director of the UPMC Falk Rheumatology Clinic. Vaccination rates in EP were identified as a key quality area. Using PV rates to assess the baseline, we learned that immunization rates in UPMC ROCs were suboptimal, which mirrored the national data. PV rate in one UPMC ROC was 15%, and the

HZV rate was even lower. Within the entire UPMC ROC network, low PV and HZV rates 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, and barriers to accurate documentation of PV status. HZV rates may also be low in part due to previous perceptions about safety issues without substantial randomized trial data.

Based on the ACR's 2012 recommendations, we conducted a study to improve the rate of PV at one UPMC ROC (1). EPs were identified through the EMR, and EPs without documentation of prior PV were flagged manually. Flagged EP received written educational materials, counseling, and questionnaires to confirm eligibility when they arrived for their clinic visit. The medical assistant (MA) confirmed the EMR information regarding PV status and documented in the EMR if PV had already been administered. An RN administered and documented PV, if the patient met immunization criteria. After the 9-month intervention, 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% ($p < 0.0001$). Our pilot study demonstrated that implementation of an EMR and staff-based intervention significantly improved both vaccination and documentation rates with minimal input from the rheumatologists. Although this project was highly successful and informative, this was a small pilot project, limited to only one of the UPMC ROC, and there was a need for more efficient model to all UPMC ROCs and the entire UPMC infrastructure, with increased automation using the EMR.

Settings: URVIP targeted eligible RA patients who are starting treatment with or who are already on immunosuppressant medications in UPMC 13 ROCs, 2 academic and 11 community based clinics. All clinics were using same EMR system (EpicCare) and providers at each clinic

were capable of receiving BPA and prescribe vaccination.

Participants: UPMC ROCs catered to 4000+ RA patients annually. Their eligibility criteria differed for specific vaccines. BPAs were designed to identify eligible patients for specific vaccines and provider received respective BPA at the time the office visit. Vaccine specific criteria are detailed in methods.

Baseline vaccination rates for vaccines were suboptimal at all clinics. Baseline vaccination rates were 10.1% for herpes zoster, 24% for pneumococcal vaccination, 41% for hepatitis B and 37.5% for influenza.

Methods:

Our *URVIP* was a continuous quality improvement project which followed the “Plan, do, Study, Act” (PDSA) methods. It was a pre-post-intervention design to evaluate the intervention impact on the vaccination rates. The project targeted all eligible adult (over 18 years of age) RA patients seen in thirteen (two academic and eleven community) UPMC Rheumatology outpatient clinics (ROC). These UPMC clinics cater to more than 45,000 rheumatology outpatient visits and have a large active population of more than 4,000 RA patients. The study period was July 2012 to June 2013 for baseline data and February 2014 to January 2015 for intervention phase. The *URVIP* project had received approval from the institutional quality council as a quality improvement project.

Eligibility for specific vaccination in RA patients:

All RA patients seen at one of the clinics with following criteria during the study period were

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) Herpes Zoster vaccination (HZV):

(1) All RA patients \geq 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) 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.

Interventions: URVIP focused on developing decision support system consisting of Best Practice Alerts (BPAs) in outpatient electronic medical record (EMR) in EPICCare system, modify clinic workflow as required to facilitate incorporation of BPA process efficiently, educating providers, staff, and eligible patients on the current vaccination recommendations for

immunosuppressed patients.

EMR based best practice alert system: We developed EMR based BPA for each vaccination which had integrated vaccine eligibility verification for individual patient, vaccine documentation and ordering capability (Figure 1). We made 2 independent BPA for medical assistants (MA) or licensed practical nurse (LPN) and other for physicians. The patient was identified electronically from EMR according to above predetermined eligibility criteria. The BPA appeared in real time at the time of the patient visit. Current procedures in the UPMC ROCs require that MA or LPN perform medicine reconciliation of all medicines at each visit during rooming of the patient. The BPA was designed to appear during this reconciliation procedure on eligible patients. If BPA appeared, then MA/LPN queried the patient to determine vaccination status and verify eligibility for the specific vaccine for which BPA fired, or document prior vaccination through BPA itself. The MA educated RA patient on the importance of vaccination especially while on immunosuppressive medications. Agreeable patient either received the vaccine from the clinic nurse who also documented vaccination in EMR or received a prescription for the vaccination and instructed to go to nearby pharmacy for vaccination. If patient received prescription then the documentation of actual vaccination is done at subsequent visit in the EMR. Only when an eligible patient had additional questions or declined vaccine to MA/LPN, then the alert was passed to the rheumatologist for resolution at the clinic visit. The rheumatologist discussed the vaccine requirement, risk vs. benefits with patients and either order the vaccine if patient agreed or documented the refusal or deferral reasons.

Documentation of prior vaccination and completed vaccination at the visit turned off the

BPA for appearing again at the subsequent visits. If patient refused or had acute illness the BPA fired again after 6 months interval, if patient reported allergy it was turned off for a year and if no action or deferred to PCP BPA fired again at the subsequent visit provided patient continued to be eligible as per the criteria. If patient received vaccination elsewhere BPA continued to fire until appropriate documentation occurred in the EMR. This way the process was automated until patient received appropriate vaccination and/or documentation.

First time immunosuppressive drug (DMARDs or biological or steroids) prescribed: A

BPA was also designed to appear if physician ordered any biological or DMARDs medication for the first time for RA patient meeting the eligibility criteria. 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 is started. This is very important for HZ vaccination where patients should be vaccinated prior to starting biological agent.

Patient, physician and staff education: Education regarding the importance and safety of vaccination and evidence-based recommendations was a crucial component of *URVIP*.

Rheumatologists at UPMC were provided education in the form of formal presentations at rheumatology grand rounds with pertaining disease- and vaccine-related information.

Rheumatologist and staff education was also provided in small group meetings performed regularly for each clinic to provide interactive sessions with opportunities to address concerns, misconceptions, and clarify and update recommendations.

An online assessment module, specific to these learning objectives and clinic work flow and BPA was developed and all clinic staff were asked to complete this module. Web-based surveys were

conducted for all physicians and staff on a biannual basis to enquire about their experiences, barriers, and recommendations on the process. Feedback from these meetings, presentations and assessment modules were compiled and guided the need for further education and follow up for an individual or clinic. Finally posters of step- by-step flow charts for the vaccination workflow were designed and displayed in all clinical areas and exam rooms (Figure 2). Communication between the physicians, clinic managers, and study staff was ongoing. Each clinic environment was unique, and minor adjustments were made to facilitate workflow depending on the needs of each clinical group. Patient education was provided at each clinic visit by ancillary staff and reinforced by physicians as needed. Patient-education material was printed from BPA for every eligible patient regardless of whether the patient received the vaccination or not to allay any misconception about vaccination.

Barriers encountered in URVIP Journey:

Developing and implementing BPAs were challenging. Since each BPA had several inclusion/exclusion criteria for patient eligibility it was difficult and time consuming process for EpicCare team. We piloted each BPA at one clinic first where the PI, Dr. Aggarwal worked. Thus it was easier to get the feedback from the staff and faculty to sort out issues, clinic flows and test BPA that it fired for EP and did not omit any EP. This helped the project when it was implemented in all other clinics. Individual eligibility situations have arisen (*e.g.*, a patient who should be eligible does not have the BPA appear), and those have been resolved via working with the EMR team in specific incidents. This has improved the overall eligibility screening of the project.

There was initial reluctance from a few physicians to respond to the BPAs and take appropriate actions. Providing peer performance data i.e. comparing each physician rates with their peer and

showing them quarterly improvement and comparisons really helped in improving the compliance as due to peer pressure no physician wanted to look bad on the graphs. Moreover, some physicians who didn't understand the process requested one to one session to understand the project and how to navigate the BPA and do proper vaccination.

Because of the more complex criteria for laboratory results and a series of Hepatitis vaccination to be tracked it was more challenging to develop Hepatitis B vaccine BPA, implementing and educating providers for this vaccination process. Hepatitis B education for provider understanding of the processing of the BPAs issue was been resolved via additional educational sessions and revised materials.

Outcome analysis: The vaccination and documentation rates for each vaccine type were compared during the pre-and post-intervention phases for overall rates, and by all clinics and providers. The pre-intervention data was collected from EMR report queried using same eligibility criteria for patients seen at ROCs during 7/1/2012 to 6/30/2013. Demographic characteristics and vaccination information were collected. The post-intervention data for 18 months post implementation after the go live date for BPA were collected for same variables with additional BPA information regarding frequency of BPA appearance, acknowledgement of BPA and actions taken by MA/LPN or physician on BPA. Vaccination compliance was recorded as administered, prescribed and reasons for deferral or patients declined. Vaccination rates were calculated as actual number of vaccination and prescription given divided by total number of eligible RA patients, multiplied by 100. Documentation rates were calculated as actual number of vaccination given or vaccination ordered or documented reasons for not giving vaccination including patient refusals divided by total number of eligible RA patients, multiplied by 100.

Statistical analyses: A pre- and post-intervention comparison was performed using chi square

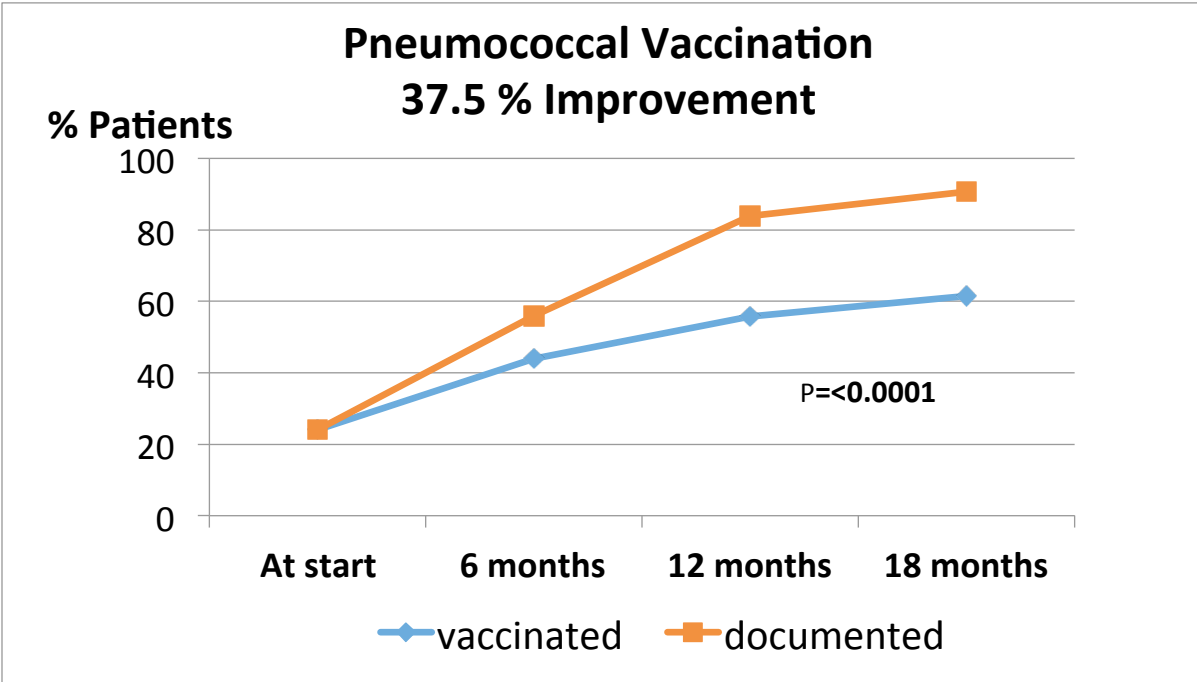
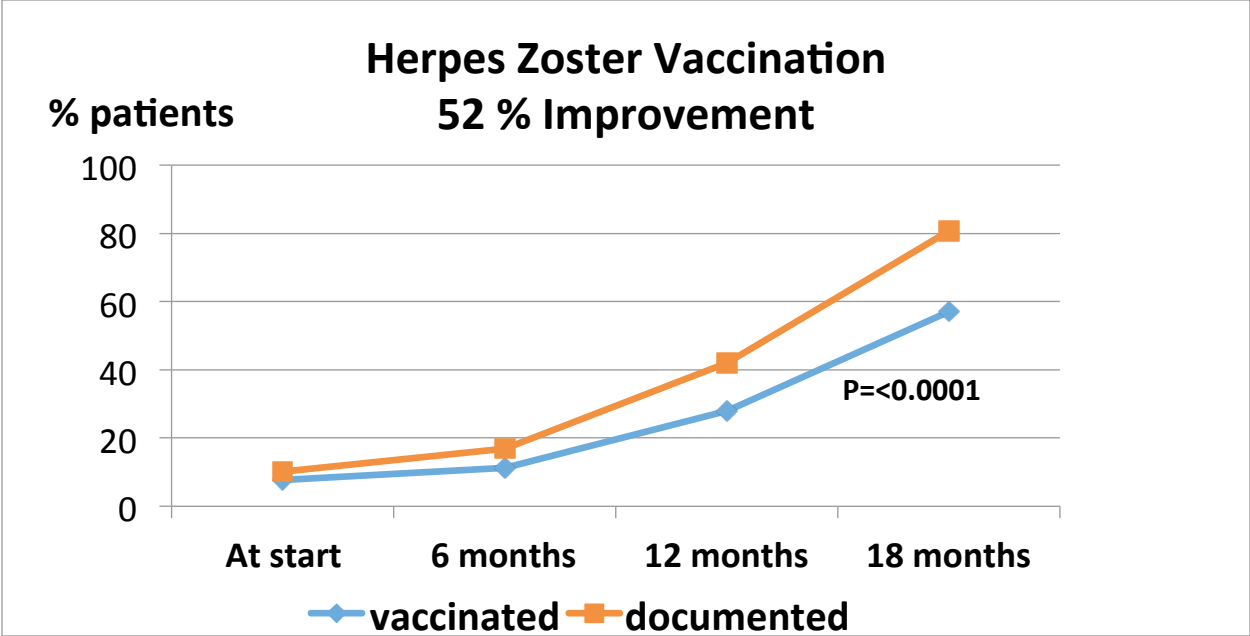
test for vaccination rates. Demographic characteristics were compared for pre- and post-intervention RA patient groups using *chi* square and t-test depending upon the variable distribution.

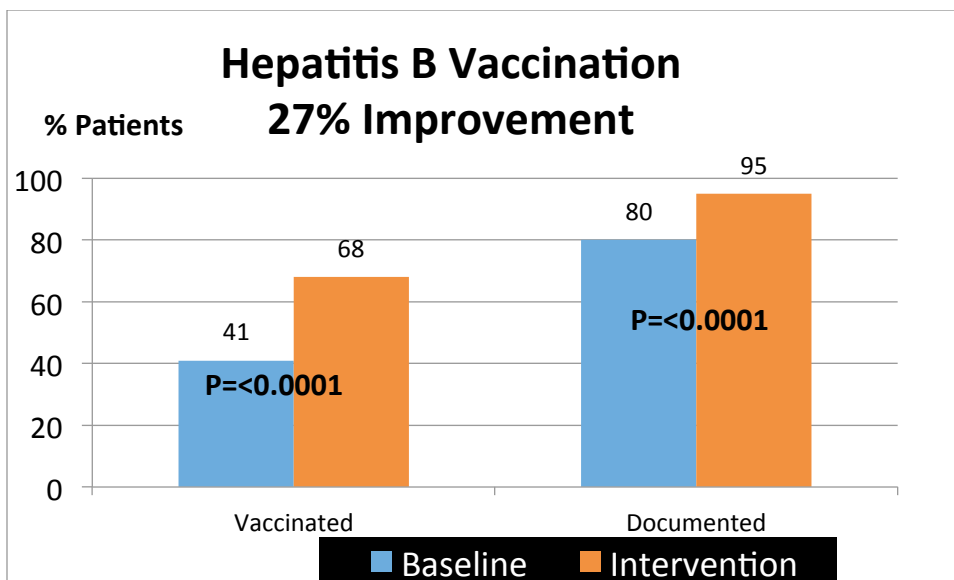
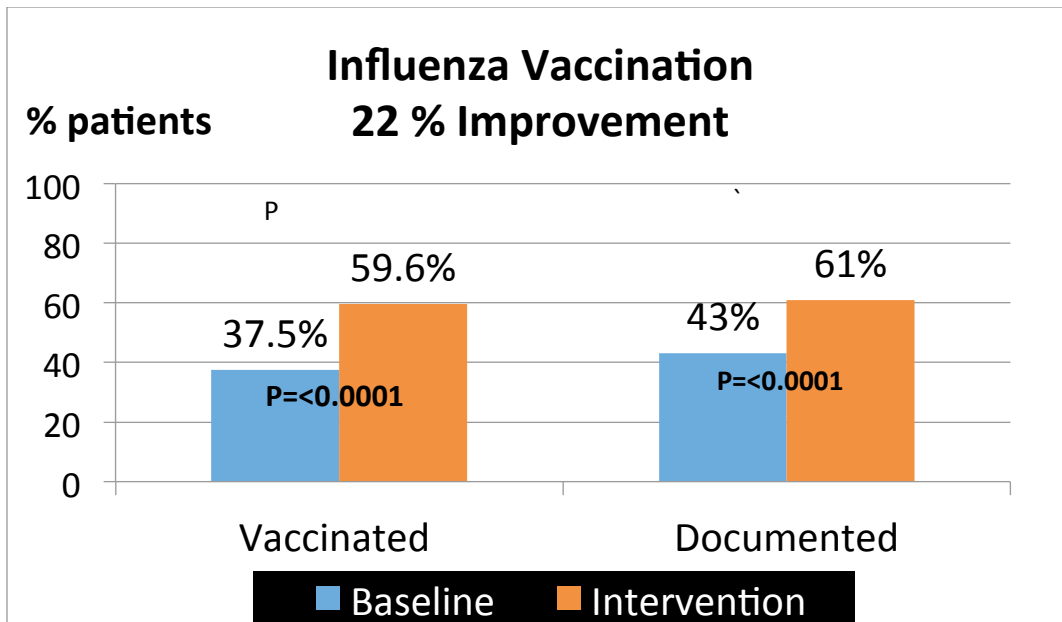
Results: A total of 3657 RA patients were screened for eligibility for four Vaccinations. Their demographic characteristics were: 76% females, mean age 62.3 years range 18 to 100 years, race 14.4% minorities. During the intervention phase 33 faculty physicians and 7 fellows were educated and counseled for the vaccination guidelines and BPA process and clinic flows. At each clinic MAs and LPNs, a total of 36 staff and 7 clinic managers were also educated.

Thirty-three physicians were surveyed to assess the usability and efficiency of BPA. The response rate was 45%. Majority (74%) of physicians who responded liked the BPA process and commented that vaccine was easy to order from the BPA. Eighty percent of the responding physicians believed BPA positively impacted patient care. It did not increase their burden or work time considerably.

In addition an educational module and self- assessment questionnaire was administered to clinic staff at all clinics with purpose of educating them and getting feedback for the URVIP project.

There was a significant improvement observed in each of the four vaccination administration as well as documentation as shown in the graphic representation below. Herpes Zoster vaccination rate improved from 10% to 62% (52% improvement, $p > 0.0001$); Pneumococcal vaccination rate improved from 24% to 61.5% (37.5% improvement, $p > 0.0001$); Influenza vaccination rate improved from 37.5 % to 59.6% (22% improvement, $p > 0.0001$); Hepatitis B vaccination rate improved from 41% to 68% (27% improvement, $p > 0.0001$).





List of Publications and Presentations:

1. Heena Sheth, Siamak Moghadam-Kia, Hilary Peterson, Larry Moreland, Rohit Aggarwal. Electronic Medical Record based Best Practice Alert using Ancillary Staff Improved Pneumococcal Vaccination and Documentation among Immunosuppressed Rheumatoid Arthritis Patients. *Arthritis and Rheum* 2014;66(11 Suppl):S591.
2. Heena Sheth, Siamak Moghadam-Kia, Rayford June, Hilary Peterson, Davi Sa Leitao, Larry Moreland, Rohit Aggarwal. Improving Herpes Zoster Vaccination and Documentation for Rheumatoid Arthritis Patients in Rheumatology Clinics. *Arthritis and Rheum* 2014;66(11 Suppl):S592.
3. A manuscript titled "Herpes Zoster vaccination in high risk Rheumatoid Arthritis patients: a quality

improvement project” has been submitted to the Journal of Rheumatology. Attached

4. Pneumococcal vaccination manuscript in progress. Draft attached

Figure 1: Example of best Practice Alert

The screenshot shows a clinical alert window titled "PREVENTIVE HEALTH (1 Advisory)". The alert message, displayed in an orange box, reads: "(2550) This patient is at high risk for Herpes Zoster infection, he/she may be eligible for HZ vaccine. Open smartset to order vaccine, document reason not given or document historical vaccine given. Then click Accept." Below the message is an "Acknowledge reason:" field with a search icon and a copy icon. Three buttons are visible: "Pt declined", "Pt on prednisone >= 20 mg/day", and "Pt on Biologics or cytoxan in last 6 mth...". A fourth button, "Other medical reason", is partially visible. Below these buttons, there are two checked options: "Open SmartSet: ZOSTER VACCINE preview" and "Click here to document historical Zoster shot". At the bottom of the window are three buttons: "Accept & Stay", "Accept", and "Cancel".

Figure 2: Clinic Process Flow Chart

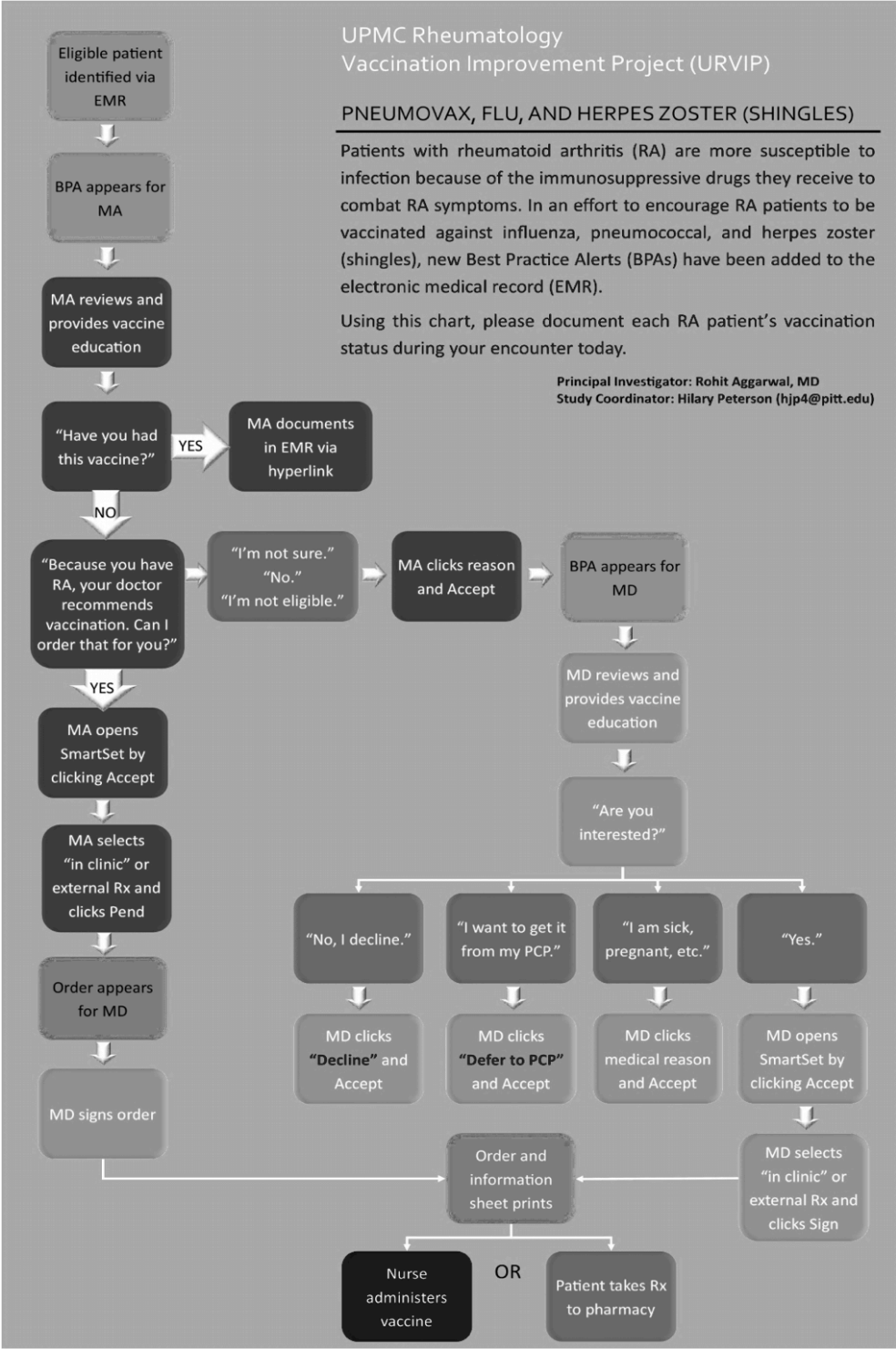


Figure 3: BPA actions and outcomes for Herpes Zoster at one year:

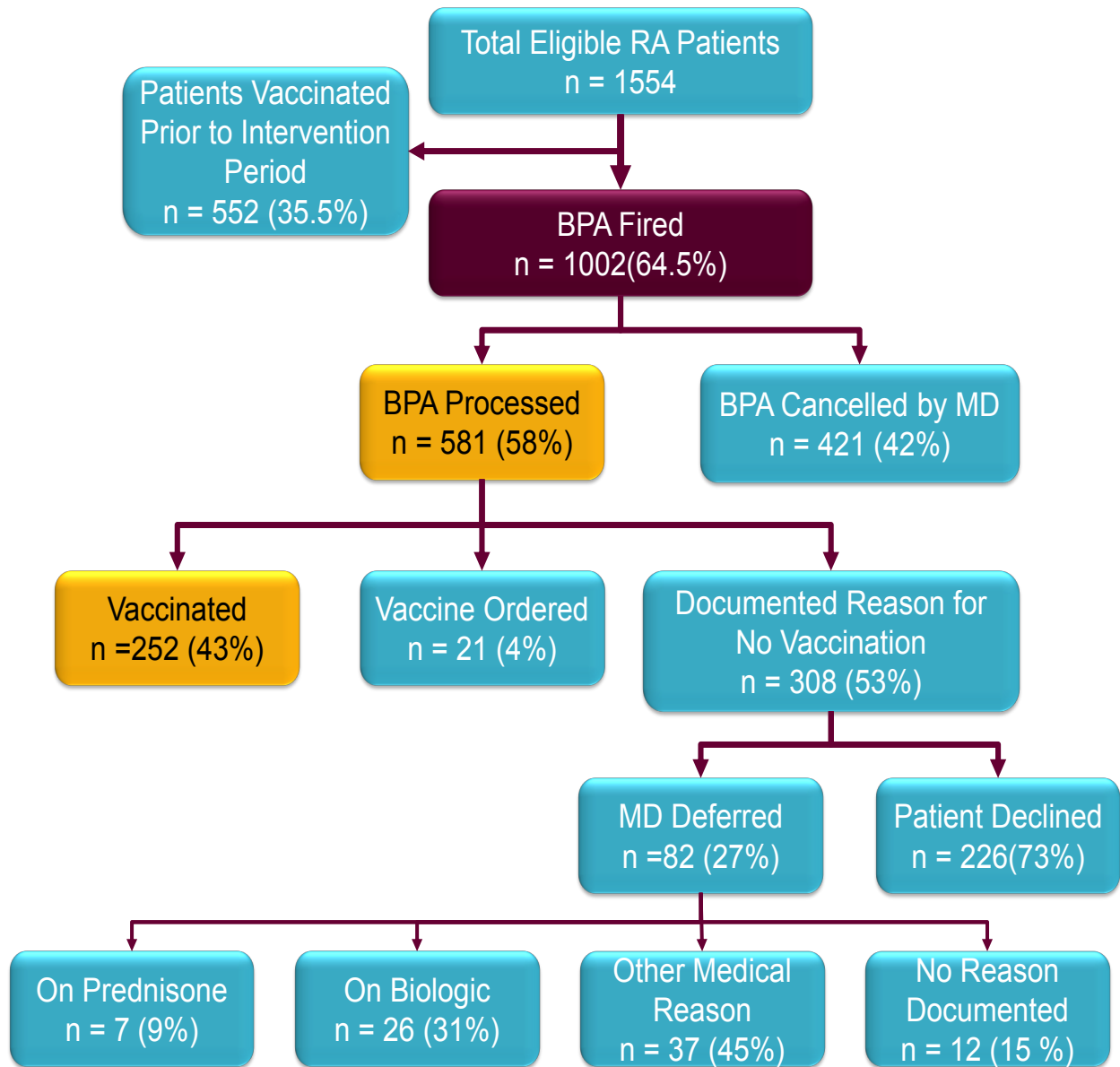
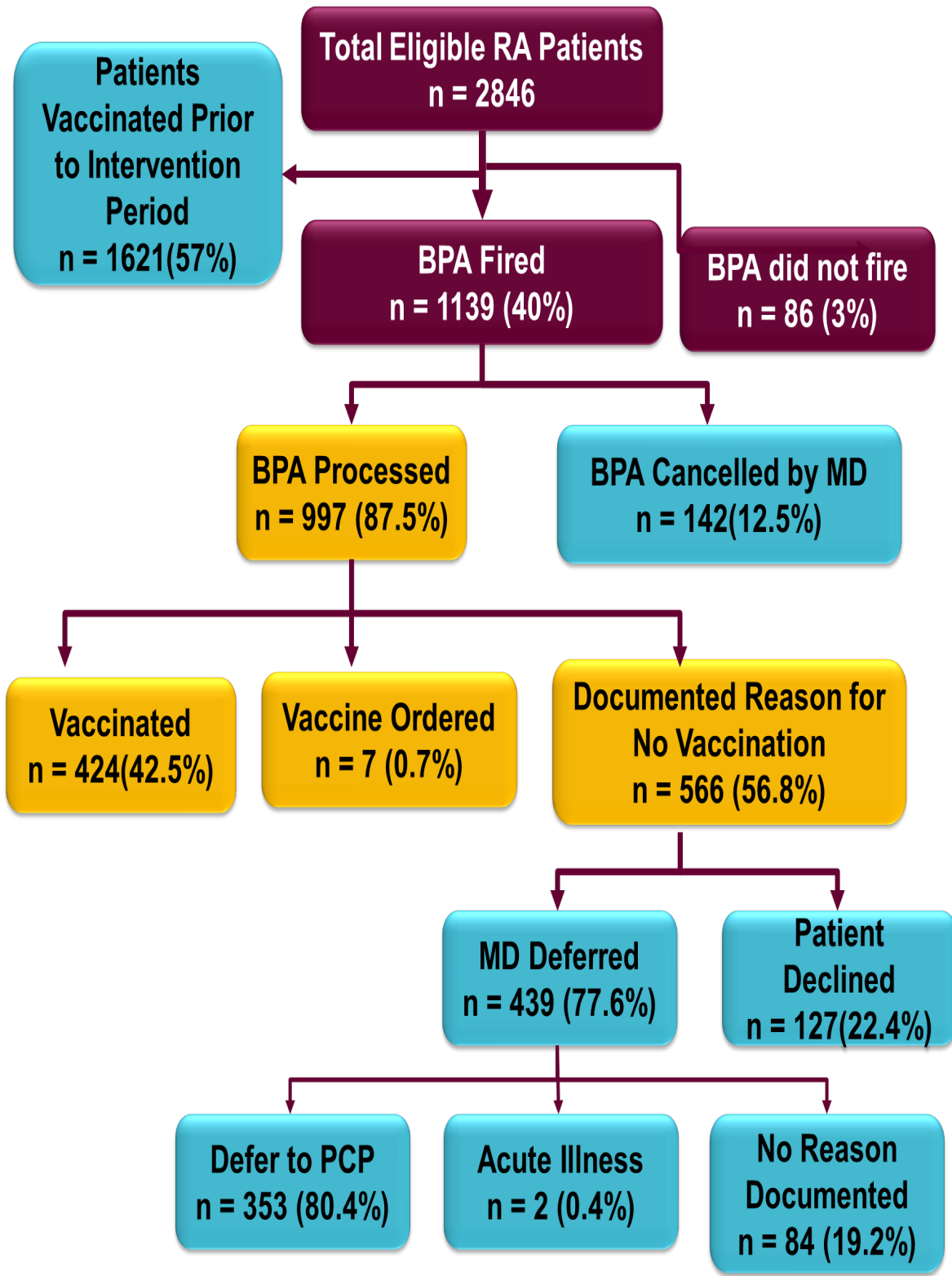


Figure 3b: BPA actions and outcomes for Pneumovax at one year:



Patient Education Materials: Example

SmartTex PNEUMOVAX INSTRUCTIONS

t rich text

You have just received your Pneumovax Vaccination. Some persons receiving the pneumovax vaccine may experience one or more of the following symptoms:

<u>SYMPTOM</u>	<u>RESPONSE</u>
1. Redness, tenderness, or a hardened area at site of injection which may last 24-48 hours.	Use cold compresses on day of injection and warm compresses on the following days.
2. Fever, discomfort or muscle pain beginning 6-12 hours after receiving vaccine and lasting 1-2 days	Take aspirin, Tylenol or whatever you ordinarily take every 4 hours. If fever persists beyond 48 hours, call the doctor. (PERSONS UNDER AGE 18 RECEIVING INFLUENZA VACCINE SHOULD NOT BE GIVEN ASPIRIN!)
3. Allergic responses such as flushing, and round raised itchy areas or various respiratory tract symptoms of hypersensitivity occur very rarely.	REQUIRES MEDICAL ATTENTION Call the Clinic Number.

Date Vaccinated: @TD@

PLEASE REMAIN IN THE CLINIC FOR 15 MINUTES AFTER RECEIVING THE VACCINE.

about the Pneumovax Vaccine:

- The Pneumovax vaccine does NOT give you the pneumonia. It is a dead vaccine.
 - If you have received a vaccine in the past and got sick shortly afterwards, it was NOT from the vaccine. It takes 2 weeks for the vaccine to take effect.
 - Pneumococcal disease can lead to severe health problems, including pneumonia, blood infections, and meningitis.
 - Pneumococcal infections can be hard to treat because some strains are resistant to antibiotics. This makes prevention through vaccination even more important.
 - Common reactions to the vaccine are mild and usually involve muscle soreness in the effected arm.
 - It takes less than 10 seconds to get a pneumococcal vaccine. The slight pinch when the vaccine is given is very mild compared to the severe body aches that the disease causes.
 - Everyone on an immunosuppressing drug should get a flu vaccine as they are higher risk for catching the virus.
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