Improvement in Herpes Zoster Vaccination in Patients with Rheumatoid Arthritis: A Quality Improvement Project

Heena Sheth, Larry Moreland, Hilary Peterson, and Rohit Aggarwal

ABSTRACT. ***Objective.*** To improve herpes zoster (HZ) vaccination rates in high-risk patients with rheumatoid arthritis (RA) being treated with immunosuppressive therapy.

Methods. This quality improvement project was based on the pre- and post-intervention design. The project targeted all patients with RA over the age of 60 years while being treated with immunosuppressive therapy (not with biologics) seen in 13 rheumatology outpatient clinics. The study period was from July 2012 to June 2013 for the pre-intervention and February 2014 to January 2015 for the post-intervention phase. The electronic best practice alert (BPA) for HZ vaccination was developed; it appeared on electronic medical records during registration and medication reconciliation of the eligible patient by the medical assistant. The BPA was designed to electronically identify patient eligibility and to enable the physician to order the vaccine or to document refusal or deferral reason. Education regarding vaccine guidelines, BPA, vaccination process, and feedback were crucial components of the project interventions. The vaccination rates were compared using the chi-square test.

Results. We evaluated 1823 and 1554 eligible patients with RA during the pre-intervention and post-intervention phases, respectively. The HZ vaccination rates, reported as patients vaccinated among all eligible patients, improved significantly from the pre-intervention period of 10.1% (184/1823) to 51.7% (804/1554) during the intervention phase ($p < 0.0001$). The documentation rates (vaccine received, vaccine ordered, patient refusal, and deferral reasons) increased from 28% (510/1823) to 72.9% (1133/1554; $p < 0.0001$). The HZ infection rates decreased significantly from 2% to 0.3% ($p = 0.002$).

Conclusion. Electronic identification of vaccine eligibility and BPA significantly improved HZ vaccination rates. The process required minimal modification of clinic work flow and did not burden the physician's time, and has the potential for self-sustainability and generalizability. (First Release November 15 2016; J Rheumatol 2017; 44:11–17; doi:10.3899/jrheum.160179)

Key Indexing Terms:

HERPES ZOSTER | VACCINATION | QUALITY IMPROVEMENT
RHEUMATOID ARTHRITIS | BEST PRACTICE ALERT | ELECTRONIC MEDICAL RECORD

Rheumatoid arthritis (RA), the most common inflammatory arthritis in adults, affects 0.5%–1% of the general population[1]. Patients with RA are at an increased risk of herpes zoster (HZ) infection because of autoimmune disease activity, immunosuppressive disease-modifying therapies, and other comorbidities. RA disease severity, particularly erosive disease and previous joint surgery, use of immunosuppressive therapy, and corticosteroids are significantly associated with HZ infection in patients with RA[2]. The risk of HZ is 1.5× to 2× in patients with rheumatic and immune-mediated diseases[3,4]. HZ is caused by the reactivation of latent varicella zoster virus and manifests as an acute, painful vesicular rash and is often complicated by chronic pain or post-herpetic neuralgia. Patients with RA are also vulnerable to more severe infection and complications compared with patients without RA[5,6].

Many studies have shown that the risk of infection can be reduced with appropriate vaccination, and it is a safe preventive strategy. The HZ vaccine decreases the risk of shingles and post-herpetic neuralgia by 50%–70% in healthy patients above 50 years of age[7,8]. The observational study[9] on Medicare enrollees, age more than 60 years with autoimmune diseases and including patients with RA (about 60% of study patients), spondyloarthropathies, psoriasis, and inflammatory bowel disease, showed that < 5% patients had received the HZ vaccine, and among those who had received

From the Department of Medicine, University of Pittsburgh School of Medicine, and Rheumatology Division, Department of Medicine, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, USA.

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H. Sheth, MD, MPH, Department of Medicine, University of Pittsburgh School of Medicine; L. Moreland, MD, Rheumatology Division, Department of Medicine, University of Pittsburgh Medical Center; H. Peterson, BA, Rheumatology Division, Department of Medicine, University of Pittsburgh Medical Center; R. Aggarwal, MD, MS, Rheumatology Division, Department of Medicine, University of Pittsburgh Medical Center.

Address correspondence to Dr. R. Aggarwal, Associate Professor of Medicine, Division of Rheumatology and Clinical Immunology, Department of Medicine, University of Pittsburgh, 3601 5th Ave., Suite 2B, Pittsburgh, Pennsylvania 15261, USA. E-mail: aggarwalr@upmc.edu

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vaccination, there was an absolute rate reduction of 7/1000 cases, and it was effective (number needed to treat of 142). Moreover, the live, attenuated HZ vaccine was not associated with short-term risks for HZ infection, even in patients exposed to immunosuppression around the time that they were vaccinated[10]. Published guidelines from the American College of Rheumatology (ACR)[11] and the Advisory Committee on Immunization Practices (ACIP)[12,13,14,15,16] recommend the HZ vaccine for patients with RA of 60 years and older receiving non-biologic disease-modifying antirheumatic drug (DMARD) therapies or before biologic treatments. The Center for Disease Control (CDC) has recommended that individuals receiving lower dose prednisone (< 20 mg/day) or methotrexate (MTX) and azathioprine at doses used for rheumatic diseases may safely receive the HZ vaccine[17]. Despite the CDC and ACR/ACIP recommendations on appropriate immunization in RA, the rates of immunization remain low[11,12,13,14,15].

Preventive care for patients with RA remains suboptimal because the rheumatologist focuses on the disease activity and medication monitoring, and may expect the primary care physician to address the preventive care. Primary care physicians may be unaware of guidelines related to RA diseases or may hesitate to prescribe a live vaccine in an immunosuppressed patient. Therefore, strong links for communication and education for patients and physicians are essential to improve the vaccination rates. There are several barriers to proper vaccination of patients in rheumatology clinics: lack of provider and patient awareness, lack of physician knowledge about current ACIP and ACR recommendations, inappropriate assumptions that physicians make in ordering or not ordering vaccinations, busy outpatient specialty practices, lack of a system-wide approach toward immunization, and lack of ways to accurately document immunization status. HZ vaccination rates may also be low in part because of previous perceptions about safety issues.

Our initiative to improve HZ vaccination rates at rheumatology outpatient clinics was based on developing a real-time electronic medical record (EMR)-based alert system coupled with patient/staff education to facilitate clinic workflow for vaccination with ongoing continuous improvement using the feedback and interval assessments. This initiative was a part of the University of Pittsburgh Medical Center (UPMC) Rheumatology Vaccination Improvement Project (URVIP).

MATERIALS AND METHODS

The HZ vaccination improvement project was a continuous quality improvement project that followed the "Plan, Do, Study, Act" methods[18]. It had a pre- and post-intervention design to evaluate the effect on the HZ vaccination rates. The project targeted all eligible patients with RA as per criteria described below who were seen in any of the 13 (2 academic and 11 community) UPMC rheumatology outpatient clinics. These clinics cater to more than 45,000 rheumatology outpatient visits annually and have a large active population of about 4000 patients with RA. The study period was July 2012 to June 2013 for the pre-intervention phase and February 2014 to January 2015 for the post-intervention phase. The URVIP project was reviewed by our institution as a quality improvement project and therefore it did not require approval from the institutional review board.

Eligibility for HZ vaccination in RA. All patients with RA (age ≥ 60 yrs) seen at one of the rheumatology clinics during the study period were included if they were receiving or prescribed any oral DMARD or corticosteroids (10 mg equivalent of prednisone > 3 mos) or if they were going to be treated with one of the biological/small molecule drugs. DMARD were one of the following medications: hydroxychloroquine, MTX, leflunomide, sulfasalazine, or minocycline. Biological/small molecule drugs were one of the following: anakinra, abatacept, etanercept, infliximab, adalimumab, certolizumab, golimumab, rituximab (RTX), tocilizumab, or tofacitinib. The exclusion criteria for receiving the HZ vaccination were (1) having received RTX in the last 6 months or cyclophosphamide in the last 3 months, (2) allergy to HZ vaccine or its components, (3) severely compromised cardiovascular or pulmonary function, (4) immunodeficiency, (5) pregnancy and lactation, and (6) acute illness or fever. Patients may develop severe systemic reaction if they have severe debilitating illnesses such as cardiopulmonary-compromising diseases and primary or acquired immunodeficiency states, leukemia, lymphoma or other malignant neoplasms affecting the bone marrow or lymphatic system, or human immunodeficiency virus.

Interventions. The HZ vaccination improvement project focused on developing a decision-support system consisting of best practice alerts (BPA) in outpatient EMR called the EpicCare system; modifying clinic workflow as required to process BPA efficiently; educating providers, staff, and patients on the current vaccination recommendations for immunosuppressed patients; as well as physician feedback and interval assessment to drive improvement in the process.

EMR-based BPA system. We developed an EMR-based HZ BPA which integrated vaccine eligibility verification, documentation, and ordering capability (Figure 1). We made 2 independent BPA: 1 for medical assistants (MA) and licensed practice nurses (LPN) and the other for physicians. The patient was identified electronically from the EMR according to the predetermined eligibility criteria. The BPA appeared in real time at the time of the patient visit. At the UPMC rheumatology clinics, MA or LPN performed medicine reconciliation at each visit during patient registration. The BPA was designed to appear during this reconciliation procedure on eligible patients. If the BPA appeared, then MA/LPN verified the eligibility for the HZ vaccine or documented prior vaccination through the BPA itself. Patients with RA were educated on the importance of vaccination while receiving immunosuppressive medications. Agreeable patients either received the HZ vaccine from the clinic nurse or a prescription and information on nearby pharmacies that provide the vaccination. Some of the community clinics did not have the facility for vaccine storage and patients seen at these clinics were given a prescription to get a vaccination at the pharmacy. For patients receiving the HZ vaccine in clinic, documentation was completed in the EMR that would prevent the appearance of the BPA during the next visit, whereas if the HZ vaccine were given elsewhere, the documentation was completed at the subsequent visit. The EpicCare patient chart also has the immunization records from the Pennsylvania Statewide Immunization Information System and all the UPMC hospital clinics. This information is visible when a physician or MA opens the immunization history field in the chart. It is the provider's responsibility to verify and update the chart, which was deemed necessary to prevent duplication of records.

The BPA for physician appeared on the system only when an eligible patient had additional questions or declined vaccine from an MA/LPN during medicine reconciliation prior to seeing the physician. The rheumatologist further discussed the HZ risk and vaccine benefits with patients and ordered the vaccine or documented the refusal or deferral reasons (Figure 1).

Documentation of prior vaccination and completed vaccination at the visit turned off the BPA from appearing again at the subsequent visits. If refusal or deferral were documented, then the BPA appeared again during the next visit if the patient continued to be eligible, as per the criteria. If the patient received vaccination elsewhere, the BPA continued to appear until appropriate documentation occurred in the EMR. Under this method, the

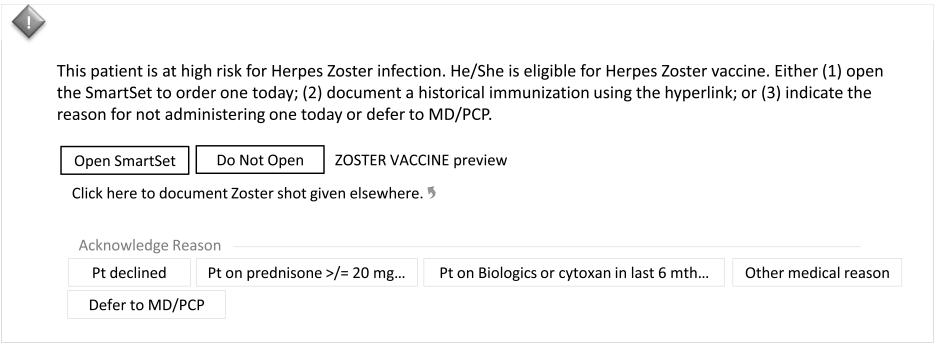

Figure 1. Herpes zoster vaccine best practice alert. PCP: primary care physician; pt: patient.

process was automated until the patient received appropriate vaccination and/or documentation. All visits per patient during the study period were evaluated. For patients with multiple visits and the BPA appearing more than once, last visit documentation was considered in the study results.

BPA for first-time prescription of immunosuppressive therapy. A BPA was also designed to appear if the physician ordered any biological or DMARD medication for the first time for the patient with RA meeting the eligibility criteria. This usually occurred for newly diagnosed patients with RA. This ensured that the patient would get vaccinated for HZ before biologic medication was started, as per recommendations.

Patient, physician, and staff education. Education regarding the importance and safety of vaccination and evidence-based recommendations was a crucial component of URVIP and the HZ vaccine improvement project. Rheumatologists were provided education in the form of formal presentations at rheumatology grand rounds with HZ disease- and vaccine-related information. Rheumatologist and staff education was also provided in small group meetings performed biannually for each clinic to provide interactive sessions with opportunities to address concerns, clarify misconceptions, and update recommendations. Clinic managers and MA were specifically asked to report any issues with vaccination process, such as insurance issues and adverse events.

All clinic staff members were asked to complete an online assessment module, incorporating learning objectives, clinic work flow, and BPA information. Web-based surveys were conducted for physicians and staff to evaluate their experiences, barriers, and recommendations regarding the process. Feedback from the meetings, presentations, and assessment modules guided further education and process change. Finally, posters displaying step-by-step flowcharts for the vaccination workflow were posted in all clinical areas and examination rooms (Figure 2). Communication among the physicians, clinic managers, and study staff was ongoing. Quarterly reports of vaccination and documentation rates for clinic and individual providers were regularly provided with peer comparison.

Each clinic environment was unique, and minor adjustments were made to facilitate workflow as required. Patient education material was printed from the BPA for every eligible patient, outlining vaccine instructions and common misconceptions about vaccination.

Outcome analysis. All eligible patients with a visit during the pre- or post-intervention period were included for analysis. The HZ vaccination and documentation rates were compared during the pre- and post-intervention phases for overall rates, and by clinics and providers. The pre-intervention data were collected from the EMR query using the same eligibility criteria for patients seen at rheumatology clinics from July 1, 2012, to June 30, 2013. Demographic characteristics and vaccination information were collected. The post-intervention data for 12 months (February 2014 to January 2015) after the go-live date for the BPA were collected for the same variables with additional BPA information regarding frequency of the BPA appearance and actions taken by MA/LPN or physician. Vaccination compliance was recorded as administered, prescribed, and reasons for deferral or patients declined. Vaccination rates were calculated as percentage of the actual number of vaccination and prescription given per total number of eligible patients with RA. Documentation rates were calculated as percentage of the actual number of vaccinations given or ordered or documented reasons for not prescribing vaccine per total number of eligible patients with RA.

Statistical analyses. Demographic characteristics were compared for the pre- and post-intervention RA groups using the chi-square test or the Student t test, depending upon the variable distribution. A pre- and post-intervention vaccination rates comparison was performed using the chi-square test.

RESULTS

We evaluated 1823 eligible patients with RA during the pre-intervention phase and 1554 patients in the post-intervention phase. The demographic characteristics for the 2 groups are shown in Table 1. The HZ vaccination rates (vaccinated and vaccine ordered) and documentation rates (vaccinated, vaccine ordered, and declined or deferred) in the pre-intervention period was 10.1% (184/1823 patients) and 28% (510/1823 patients), respectively. The HZ vaccination rates improved significantly from the pre-intervention period of 10.1% to 51.7% (804/1554) during the intervention phase ($p < 0.0001$). The documentation rates increased from 28% to 72.9% (1133/1154, $p < 0.0001$; Figure 3). During the post-intervention phase, 552 patients (35%) were documented in the EMR documentation, and the BPA did not appear for them during the visit. For the remaining 1002 patients, the BPA appeared because they were eligible patients without prior vaccination or documentation (Figure 4). The BPA appeared 1299 times for these patients, thus the BPA appeared for 297 patients at 2 visits during the intervention period. Among the eligible intervention group, 174 patients (11.2%) were receiving steroids and 1380 (88.8%) were receiving DMARD.

Among 1002 patients for whom the BPA appeared, 581 (58%) resulted in either a vaccination [252 (43%) vaccinated, 21 (4%) vaccine prescribed] or documentation of reasons the vaccine was not prescribed [308 (53%); Figure 4]. The majority of patients who did not get vaccinated had refused vaccination (226/308 patients, 73%) or were deferred for medical reasons (82/308 patients, 27%). Patients were deferred for receiving high-dose prednisone (7 patients, 9%) or biologic therapy (26 patients, 31%), or for another medical

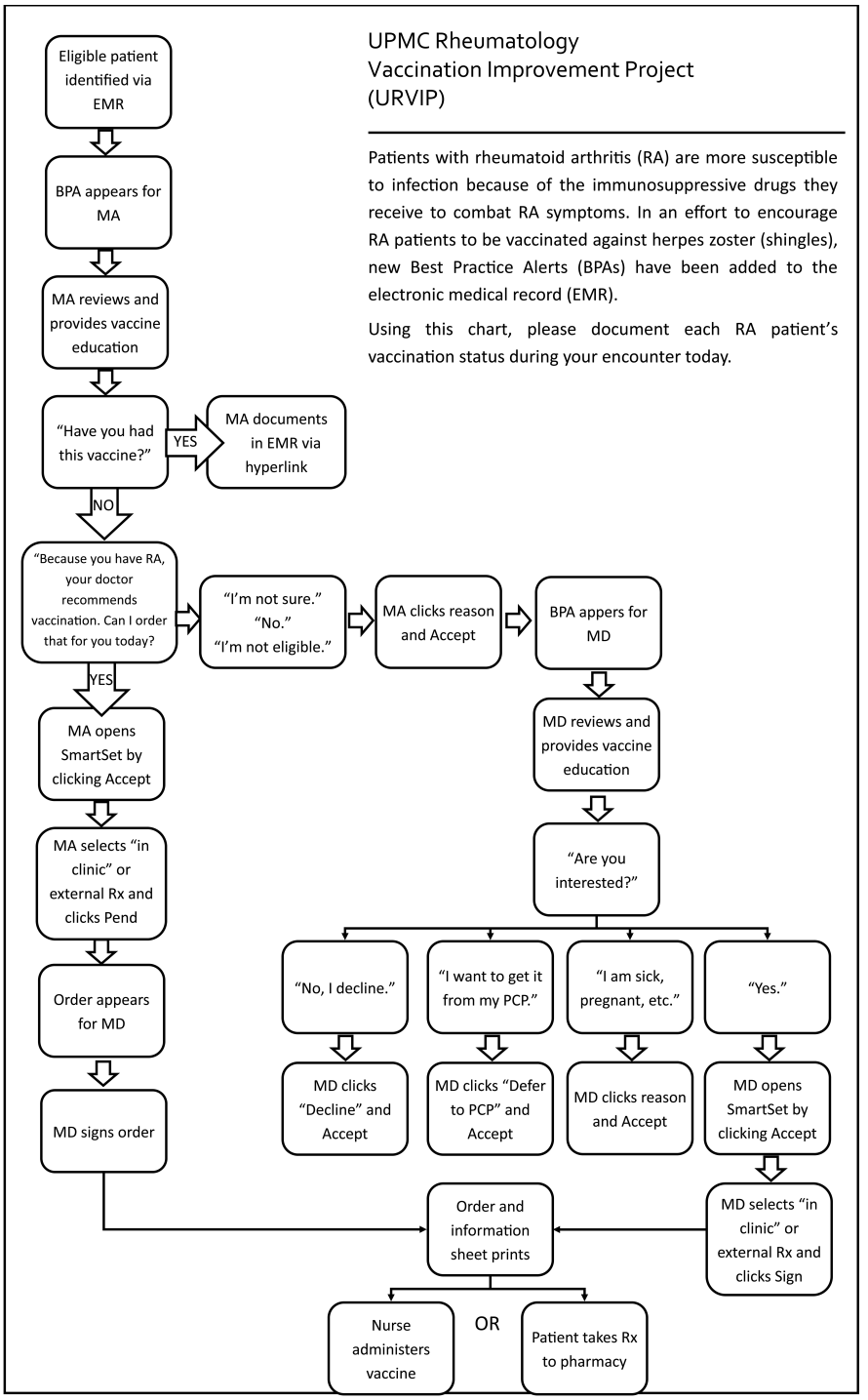

Figure 2. Clinic process flow chart. UPMC: University of Pittsburgh Medical Center; RA: rheumatoid arthritis; BPA: best practice alerts; EMR: electronic medical record; MA: medical assistants; PCP: primary care physician.

reason (37 patients, 45%). For 12 patients (15%), no reason was documented.

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

All physicians and clinics improved their individual HZ

Table 1. Demographic characteristics of patients with rheumatoid arthritis. Values are n (%) unless otherwise specified.

Characteristics	Baseline Cohort	Post-intervetion Cohort	p
Vaccine-eligible patients, n	1823	1554	—
Age, yrs, median (range)	69 (60–101)	70 (60–95)	0.9
Patients < 65 yrs	426 (23.4)	376 (24.2)	0.57
Female	1336 (73.2)	1123 (72.3)	0.52
White	1580 (86.7)	1372 (88.2)	0.61

vaccination and documentation rates during the intervention period. Thirty-six patients (2%) developed HZ infections during the pre-intervention phase, compared with only 5 patients (0.32%) in the post-intervention group (p = 0.002). Among the 5 patients, 1 patient had received the HZ vaccine, 1 was deferred because of biologic therapy, 1 declined, and 2 patients had an HZ infection prior to office visits. There were no adverse effects of vaccines reported. There were no other concerns or insurance issues reported from any of the clinics.

DISCUSSION

Patients with RA, particularly those receiving immunosuppressive therapy, are at high risk for more severe HZ infection and post-herpetic neuralgia. Despite national recommendations, HZ vaccination rates remain poor. Rheumatologists commonly focus on rheumatic disease management, leaving preventive care to the primary care providers. However, HZ vaccination rates in some primary care practices may also be suboptimal (some were observed at 10%), even in patients with chronic conditions[18]. The 2013 US adult HZ vaccination rates varied from 9.5% to 27.4% in different ethnic groups[19]. Many of the patients with RA may not visit their primary care doctors regularly, and primary care providers may not be aware of specific guidelines for immunizations pertaining to patients with RA. In addition, physicians may be hesitant to give a live vaccine to a patient being treated with immunosuppressive therapy. These reasons make it imperative to vaccinate patients with RA in rheumatology outpatient clinics.

Our URVIP was successful, with significant improvement in vaccination and documentation rates for HZ. The project appears to be very effective, with significant reduction noted in HZ disease in the intervention group. It addressed the barriers commonly encountered in specialty and primary care clinics: lack of time and lack of awareness of current guidelines[19]. Our project used a decision-support system in the form of BPA, ancillary staff, education, counseling, and feedback of results to the providers, with continuous improvement in processes. Our project was innovative in developing BPA for eligible patients based on diagnosis, age-specific criteria, and their immunosuppressive therapy. To our knowledge, there has been no such study reported in the RA population. A similar decision-support system has been successful in improving vaccination rates in a primary care practice[20]. In a primary care practice, a Web-based, decision-support system had improved HZ vaccination rates, and physicians reported saving 5 min of their time for preventive services[21]. Our project also did not increase physician time and was not reported to be cumbersome in most of the survey responses. Besides BPA, which identified eligible patients, our project used ancillary staff for verification, ordering vaccines, and documenting in the EMR. BPA were passed to physicians only to verify and sign the orders or to address patient concerns. Use of ancillary staff and provider recommendations are known to improve immunizations[22].

Education was a key component of the project. Interactive sessions were helpful in addressing misconceptions and clarifying the guidelines. Similarly, provider feedback and education had improved antibiotic management[23]. Our study physicians and clinic managers appreciated that their patient data were compared with their peers' data, and perceived that comparison as an opportunity to provide better care, a step that is likely to result in improved immunization rates in the future. BPA were designed to continue appearing on the

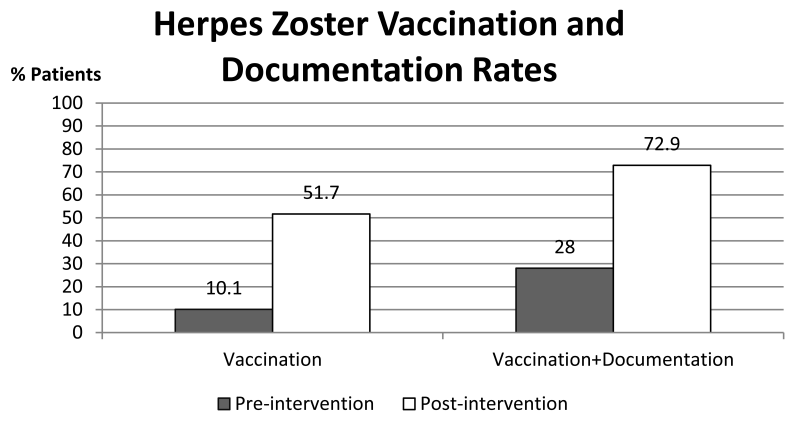

Figure 3. Improvement in herpes zoster vaccination rates.

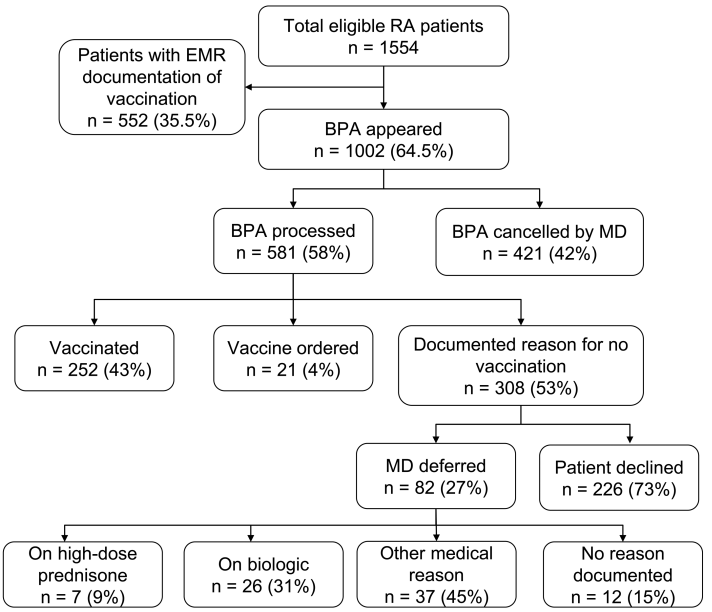

Figure 4. BPA actions and outcomes for intervention group. BPA: best practice alerts; RA: rheumatoid arthritis; EMR: electronic medical record.

system at subsequent visits, which will identify patients refusing vaccination and readdress their misconception and concerns for safety.

Our project had the support of a research coordinator, who served as the contact person for concerns and queries; that might have driven some increase in compliance. This resource may not be available in the future, which is a limitation of our current study. However, the process is automated and sustainable without a coordinator, except for requiring periodic education, particularly of newly hired staff and physicians. We also did not collect insurance information for the patients. Insurance concerns may have influenced vaccination compliance. However, all our rheumatology clinics could bill for Medicare, and insurance was not reported as a barrier for administering the vaccine from any of the clinics.

We used BPA in the EpicCare system, which is the EMR used in many institutes across the nation. This process can be easily adapted at other institutes and across the UPMC health system hospitals for all vaccinations. We did not find any adverse events from the vaccine. If such an event was not brought to the rheumatologist's attention and was addressed by the primary care physician, then it may have been missed. However, major events would have been communicated to the rheumatologist. We also noted very rare HZ disease occurrence in the intervention group, which demonstrates the efficacy and safety of the vaccination.

Electronic BPA and an ancillary staff–based protocol in rheumatology improved HZ vaccination rates. The process is innovative, generalizable, and sustainable.

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