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Implementing a Nurse-Driven Protocol for Pneumococcal Vaccination in an Academic Rheumatology Clinic

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ABSTRACT. ***Objective.*** Rheumatology patients are at high risk for complications from pneumococcal infections. The goal of this study was to assess the feasibility of implementing a nurse-driven pneumococcal vaccination protocol based on the 2012 Advisory Committee on Immunization Practices (ACIP) guidelines within an academic rheumatology clinic. Our aims were to increase (1) pneumococcal conjugate vaccine (PCV13) and pneumococcal polysaccharide vaccine (PPSV23) monthly vaccination rates in immunosuppressed patients aged 19 to 64 years, and (2) the overall proportion of immunosuppressed patients aged 19 to 64 years who have received both PCV13 and PPSV23 vaccinations by ≥ 10% over a 2-year period.

Methods. We identified eligible adults in the electronic medical record using a search protocol based on preset medication group. We obtained baseline pneumococcal vaccination rates in 2019, calculating the proportion of patients who were unvaccinated, partially vaccinated (received either PCV13 or PPSV23), or fully vaccinated. We created a pneumococcal vaccination protocol based on 2012 ACIP guidelines and converted it into a standing medical order to be implemented by the nursing staff. Postintervention vaccination rates were calculated monthly and at the end of the study period. Multiple comparison testing was performed to assess for significant postintervention changes.

Results. The average rate of monthly vaccination with either PCV13 or PPSV23 increased from 4.3% in 2019 to 12.6% in 2021. The proportion of patients who were fully vaccinated increased from 14.6% in 2019 to 26.2% in 2021. Both changes were statistically significant.

Conclusion. It is feasible to employ a nurse-driven protocol for improving pneumococcal vaccination rates in immunosuppressed patients, despite difficulties posed by coronavirus disease 2019 (COVID-19) pandemic disruptions.

Key Indexing Terms: pneumococcal vaccines, quality improvement

Streptococcus pneumoniae (*S. pneumoniae*) is a gram-positive diplococcus responsible for multiple invasive infections including bacteremia, meningitis, and pneumonia. Immunocompromised adults are at a 20-fold increased risk for invasive pneumococcal infections.[1] Autoimmune rheumatic disease is an independent risk factor for invasive pneumococcal infections.[2,3] Disease-modifying antirheumatic drug (DMARD) therapy potentiates the risk. DMARDs encompass multiple classes of drugs, including conventional synthetic (eg, methotrexate, leflunomide), biologic (eg, adalimumab, abatacept), and targeted synthetic (eg, tofacitinib, apremilast). Pneumococcal vaccination protects against infection[4] and is safe in patients with rheumatic diseases.[5]

The 2012 statement from the Advisory Committee on Immunization Practices (ACIP) recommends that adults aged ≥ 19 years with immunocompromising conditions including rheumatic disorders, or those individuals receiving immunosuppressive agents, should receive a dose of pneumococcal conjugate vaccine (PCV13), followed by a dose of pneumococcal polysaccharide vaccine (PPSV23) at least 8 weeks later, followed by a repeat PPSV23 dose at least 5 years after the initial PPSV23 dose, unless the initial PPSV23 was given at age 65 years or older.[6] The European Alliance of Associations for Rheumatology provides a strong recommendation to consider pneumococcal vaccination in most patients with rheumatic diseases.[4]

Despite these recommendations, vaccination against *S. pneumoniae* in rheumatology patients remains low.[7,8] Potential barriers have been identified, including low patient awareness, competing priorities in patient care, uncertainty about patients' vaccination status, and concern for lack of vaccination safety and efficacy.[4,9,10] Studies have shown that using nurse-driven models, as well as patient and physician reminders, can improve

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pneumococcal vaccination rates.[11,12] Further, Lu and Nuorti found that pneumococcal vaccination varies substantially by age, with coverage being lower among eligible adults aged 18 years to 49 years than those aged ≥ 50 years.[13]

We studied the effects of a quality improvement (QI) project using a nurse-driven protocol on pneumococcal vaccination rates among adult patients aged 19 to 64 years with rheumatic diseases in an academic rheumatology practice. Our aims were to increase (1) PCV13 and PPSV23 monthly vaccination rates in immunosuppressed patients aged 19 to 64 years, and (2) the overall proportion of immunosuppressed patients aged 19 to 64 years who have received both PCV13 and PPSV23 vaccinations by ≥ 10% over a 2-year period.

METHODS

Target patient identification. Subjects were identified in the electronic medical record (EMR) using an automated search protocol based on age (19-64 yrs) and preset DMARD medications (Supplementary Table S1, available from the authors upon request). If the patient was identified to be on active DMARD treatment, this served as a prompt for the clinic staff to then review the patient's chart to evaluate whether the patient had received PCV13 and/or PPSV23 in the past; missing vaccinations were confirmed with the patient.

Full immunization was defined as having received at least 1 dose of both PCV13 and PPSV23 vaccinations with appropriate intervals based on the US Centers for Disease Control and Prevention (CDC) guidelines.[6] Partial vaccination was defined as having received either PCV13 or PPSV23 vaccinations, but not both. If the patient has received PPSV23 ≥ 5 years ago, he or she was considered vaccinated with PPSV23 for the purposes of data collection. Nursing staff were encouraged to administer the repeat dose of PPSV23 to those patients who received PPSV23 ≥ 5 years ago, if appropriate (ie, if the patient was not due for PCV13 vaccine at that visit). Unvaccinated patients were those who had received neither PCV13 nor PPSV23 vaccinations.

Statement of ethics and consent. The University of Texas (UT) Southwestern institutional review board (IRB) determined this QI project to be exempt and therefore did not require IRB approval. No patient consent was obtained for this project, which used only deidentified patient data.

Tool and workflow development. We created a pneumococcal vaccination protocol based on 2012 ACIP recommendations[6] (Figure 1) and converted it into an institution-approved standing medical order (SMO) to be used by the clinic staff. The intervention was implemented at the primary UT Southwestern main campus clinic practice, which employs 3 clinic nurses and 3 medical assistant staff for multiple providers that are equivalent to approximately 4 full-time equivalent providers. A nurse-driven workflow was developed for vaccination implementation in the clinic (Figure 2) starting January 2020. Notably, because of the existence of the protocol and SMO, the nursing staff were not required to discuss the vaccination administration with the physician provider prior to administering the vaccination. We monitored the administration of vaccinations monthly to ensure that vaccinations were administered according to protocol. We relied on monthly clinic staff feedback to implement Plan-Do-Study-Act (PDSA) cycles[14] to improve the workflow and monthly vaccination rates. In June 2020, we developed a SmartPhrase (documentation tool) in our EMR (Epic) for documentation of vaccine administration or refusal within the visit notes to allow for tracking. Nursing or medical assistant staff inserted the SmartPhrase in the vaccination encounter note after the administration of the vaccine, with options for "refused," "agreed," or "will provide [external records of prior vaccination]." If the patient refused, the clinic

For all adult patients
1) On immunomodulating therapy or with intent to start immunomodulating therapy, or
2) Significant immunocompromising conditions: CSF leaks, cochlear implants, congenital or acquired asplenia, sickle cell disease, chronic renal failure, congenital or acquired immunodeficiency, generalized malignancy, HIV infection, Hodgkin's disease, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, solid organ transplant.

-Absolute contraindication: allergy to PCV13/PPSV23 or Tdap vaccination.
-Consider deferring pneumococcal vaccination for patients on Rituximab or receipt of Rituximab in the last 6 months (see below for further guidance*).

Prior pneumococcal vaccination status:	Recommendation:
No pneumococcal vaccinations or unknown vaccination history	- Give PCV13 then PPSV23 at least 8 weeks later - 5 years later, repeat PPSV23 unless previous PPSV23 given at age ≥ 65
1 dose PPSV23	- Give PCV13 at least 1 year after PPSV23 - Repeat PPSV23** at least 5 years after previous PPSV23 and at least 8 weeks after PCV13 if the previous PPSV23 was administered at age <65
2 doses PPSV23	- Give PCV13 at least 1 year after last PPSV23
PCV13 only	- Give PPSV23 at least 8 weeks after PCV13 - Repeat PPSV23 at least 5 years later
PCV13 and 1 dose PPSV23	- Repeat PPSV23 at least 5 years after previous PPSV 23** and at least 8 weeks after PCV13 if the previous PPSV23 was at age <65 - Nothing to do if the previous PPSV23 was at age ≥ 65
PCV13 and 2 doses PPSV23	- Nothing to do if patient is under 65 years old at time of completion of vaccination. If over age 65, see recommendations below ***

*For patients undergoing consideration for Rituximab therapy, it is optimal to give pneumococcal vaccines at least two weeks prior to therapy. For patients currently receiving Rituximab therapy, wait at least 6 months after the last dose of Rituximab before administering pneumococcal vaccination.

**Revaccination with PPSV23 before the age of 65 is not required in patients with CSF leaks or cochlear implants and in immunocompetent patients (includes those with alcoholism, chronic heart, liver, lung disease, cigarette smoking and diabetes mellitus).

***If patient completes both PPSV23 doses prior to age 65, he or she is eligible to receive another dose of PPSV23 after age 65, at least 5 years after the prior PPSV23 and at least 8 weeks after PCV13.

Figure 1. Pneumococcal vaccination protocol for significantly immunocompromised patients aged ≥ 19 years. Adapted from 2012 ACIP pneumococcal vaccination guidelines.[6] ACIP: Advisory Committee on Immunization Practices; CSF: cerebrospinal fluid; PCV13: pneumococcal conjugate vaccine; PPSV23: pneumococcal polysaccharide vaccine; Tdap: tetanus, diphtheria, and pertussis.

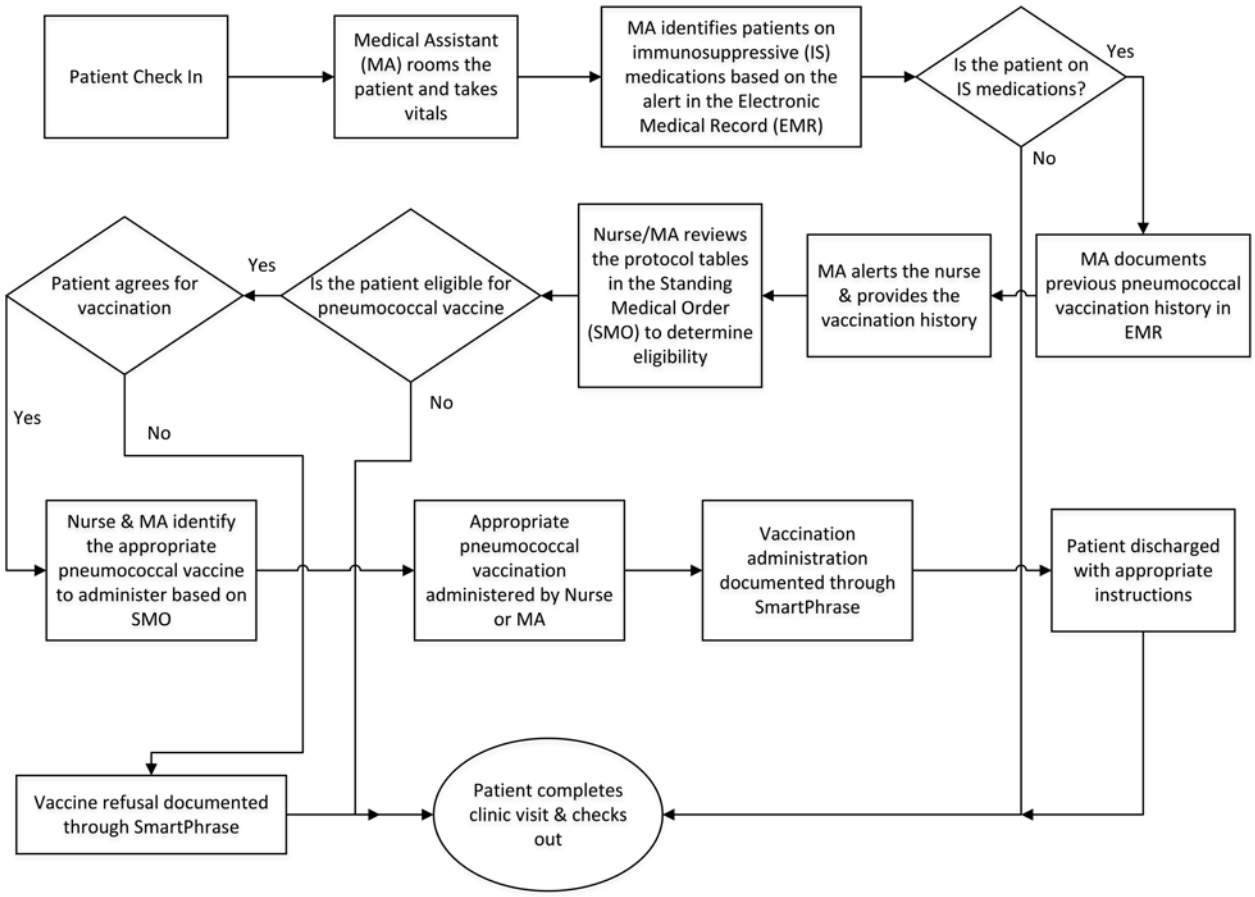

Figure 2. Nurse-driven clinical workflow for pneumococcal vaccination. EMR: electronic medical record; IS: immunosuppressive; MA: medical assistant; SMO: standing medical order.

staff had an option of documenting the reason for refusal. Based on staff feedback, we simplified the documentation tool to increase staff adherence in October 2020. We collected data on the number of refusals each month as part of the total data collection on vaccine administration and gathered reasons for vaccine refusal, if provided. The staff were instructed to withhold the vaccine if contraindications were present (Figure 1) or if the patient refused. Additionally, in accordance with CDC recommendations and because of the theoretical risk of diminished immunogenicity and increased potential for side effects,[15] we asked the staff to withhold the vaccination if the patient was within 2 weeks of receiving the coronavirus disease 2019 (COVID-19) vaccine. This recommendation was in place until May 2021.

PDSA cycles. Each month was considered a unique PDSA cycle. We assessed monthly rates of vaccination with either PCV13 or PPSV23 of the following: (1) previously unvaccinated patients (series initiation), (2) partially vaccinated patients (series completion), and (3) patients eligible for vaccination (unvaccinated and partially vaccinated; series administration). We also assessed monthly rates of documented vaccine refusals. We then had monthly staff meetings to discuss barriers and obstacles encountered in using the protocol each month, and we implemented changes to the process as needed. Some cycles included retraining and education on the protocol, whereas others required changes in the workflow, such as implementing SmartPhrase for documentation of vaccine administration and refusals.

Education. We educated the clinic physician and advance practice providers on the ACIP guidelines for pneumococcal vaccination.[1] Multiple educational sessions were held for the staff to review the protocol and workflow; retraining was performed as needed.

We placed CDC educational brochures and posters in waiting and exam rooms in our clinic to increase patient awareness and acceptance of the pneumococcal vaccination.

Outcome. We calculated the baseline vaccination rate of PPSV23, PCV13, or both vaccines from January 1 to December 31, 2019, by obtaining average monthly rates of pneumococcal vaccinations defined by eligible patients receiving either the first dose of the pneumococcal series (series initiation), second dose of pneumococcal series (series completion), or either first or second dose of pneumococcal series (series administration). We also calculated proportions of patients seen in 2019 who were unvaccinated, partially vaccinated, or fully vaccinated at the time of their first clinic visit, and the proportions of patients who received appropriate (ie, according to CDC guidelines) pneumococcal immunizations in 2019.

The start date for the intervention phase of the project was January 1, 2020. Postintervention pneumococcal vaccination rates were calculated monthly. Documentation of vaccination refusal by patients was monitored monthly. We assessed the percentage of unvaccinated, partially vaccinated, and fully vaccinated patients in our clinic and compared this with baseline rates.

After the project end date on December 31, 2021, we assessed yearly proportions of patients who received appropriate vaccinations from 2020-2021. The 2019 numbers were considered our baseline.

A data analyst (CW) assisted with data extraction from the EMR. Importantly, only appropriately given vaccinations (as per the 2012 CDC guidelines[6]) were assessed.

Statistical analysis. Data were expressed as percentages representing monthly vaccination rates and proportions of patients with pneumococcal

immunization as described above. A multiple comparison test of proportions using the Levy method[15] was performed to compare the 3 years for each set of proportions.

RESULTS

The UT Southwestern main campus rheumatology clinic provided care to approximately 180 patients in the target age group per week prior to the COVID-19 pandemic. During the pandemic, the number of patients seen in the target age group decreased to approximately 120 patients per week, with an additional 60 to 70 patient visits conducted by telehealth weekly.

At baseline, the average monthly series initiation rate was 3.9% and series completion rate was 6.2%. Overall, we were vaccinating 4.3% of eligible patients per month (series administration; Table 1). We improved average monthly rates of pneumococcal vaccination from 3.9% to 8.8% for unvaccinated patients and from 6.2% to 21.1% for partially vaccinated patients between 2019 and 2021. Overall, average series administration monthly rates improved from 4.3% in 2019 to 12.6 % in 2021. Improvement in all average monthly rates over a 2-year period was statistically significant based on multiple comparison testing.

Figure 3 demonstrates monthly vaccination rates from 2020 to 2021, with the decrease in monthly rates reflecting clinic closures and partial reopenings as a result of the COVID-19 pandemic. We were able to achieve our goal of ≥ 10% improvement in monthly vaccine administration during some of the months during the study period, with significant variations month to month.

Table 2 describes proportions of patients who were unvaccinated or fully vaccinated at baseline and at the end of each year for 2019, 2020, and 2021. In 2019, we had a high proportion of unvaccinated patients (68.2%) and a low proportion of fully vaccinated patients (8.2%) at baseline, which improved by 9.8% and 6.4%, respectively, by the end of the year. By 2021, the proportion of unvaccinated patients decreased to 57.3% and the proportion of those who remained unvaccinated by the end of 2021 was 40.5%, signifying that 16.8% of patients received PCV13, PPSV23, or both during the year. Similarly, in 2021, the proportion of fully vaccinated patients increased by 9.7%. We decreased the proportion of patients who remained unvaccinated by the end of the year between 2019 and 2021 from 58.4% to 40.5% by increasing the proportion of patients who had received PCV13, PPSV23, or both vaccines over 2 years. We also increased the proportion of fully vaccinated patients seen in our clinic over the 2-year intervention period. These changes were statistically significant. Further, we met our goal of ≥ 10% improvement in the overall proportion of immunosuppressed patients aged 19 years to 64 years who have received both PCV13 and PPSV23 vaccinations over a 2-year period.

In addition, we improved the percentage of eligible patients who were receiving appropriate vaccinations as per CDC guidelines (Figure 4). The change in the percentage of partially vaccinated patients who completed the series reached statistical significance, whereas the increase in percentage of unvaccinated patients who became partially vaccinated failed to reach statistical significance.

Table 1. Average monthly vaccination rates by year.

Vaccination Series Status	2019	2020	2021	*P* (2019 vs 2020)	*P* (2020 vs 2021)	*P* (2019 vs 2021)
		%				
Series initiation	3.9	5	8.8	NS	**< 0.05**	**< 0.05**
Series completion	6.2	10.3	21.1	NS	**< 0.05**	**< 0.05**
Series administration	4.3	6.2	12.6	NS	**< 0.05**	**< 0.05**

Values in bold are statistically significant. NS: not significant at $P > 0.05$.

DISCUSSION

Our single-center intervention consisted of a nurse-driven protocol, patient educational resources, and monthly feedback meetings with the staff. We were able to increase the proportion of patients who have received at least 1 dose of either PCV13 or PPSV23 by the end of the intervention period by a statistically significant margin. Thus, we demonstrated that our QI initiative is a practical strategy to improve pneumococcal vaccination

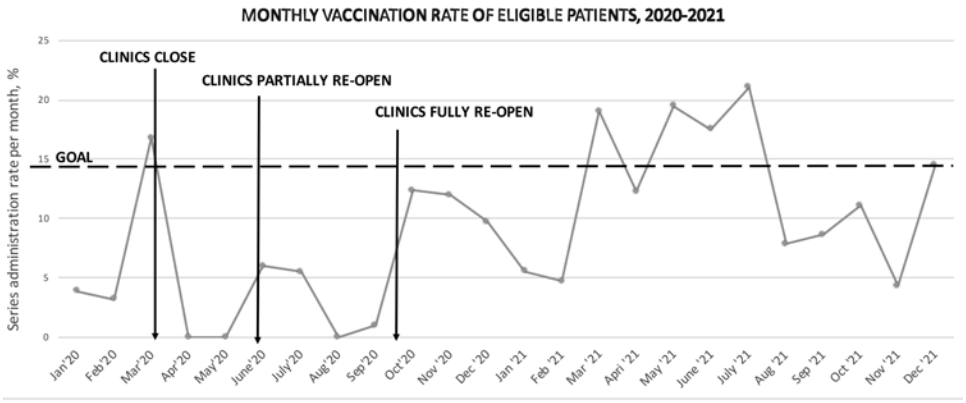

Figure 3. Monthly vaccination rates during intervention period. Series administration—monthly rate of PCV13 and/or PPSV23 vaccine administration to either unvaccinated or partially vaccinated patients. PCV13: pneumococcal conjugate vaccine; PPSV23: pneumococcal polysaccharide vaccine.

Table 2. Change in vaccination status among clinic patient population following intervention.

Vaccination Status	2019, n = 1797[a]	2020, n = 1209[a]	2021, n = 1369[a] %	*P* (2019 vs 2020)	*P* (2020 vs 2021)	*P* (2019 vs 2021)
Unvaccinated at baseline	68.2	60.9	57.3	< 0.05	NS	< 0.05
Unvaccinated by the end of the year	58.4	49.2	40.5	< 0.05	< 0.05	< 0.05
Fully vaccinated at baseline	8.2	13.4	16.5	< 0.05	NS	< 0.05
Fully vaccinated by the end of the year	14.6	19.1	26.2	< 0.05	< 0.05	< 0.05

[a] No. of patients with at least 1 clinic visit during the year, who were aged 19 to 64 years at the time of any visit during the year and who were on one of the prespecified disease-modifying antirheumatic drugs during ≥ 1 visit during the year. NS: not significant.

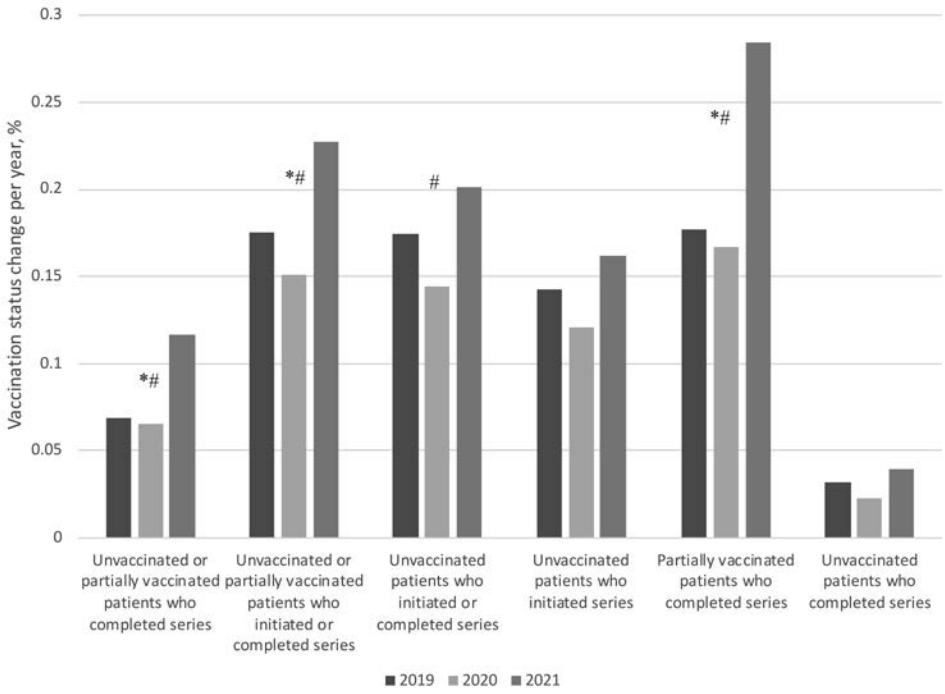

Figure 4. Change in vaccination uptake in eligible patients per year. * *P* significant at < 0.05 for difference between 2019 and 2021. # *P* significant at < 0.05 for difference between 2020 and 2021.

among rheumatology patients, which could be replicated at other clinics. We had continued improvement over the 2-year intervention period, even despite COVID-19 pandemic-associated clinic closures and reduction in in-person clinic visits, emphasizing the sustainability of our method.

Previous studies have found multiple barriers to vaccination in rheumatology patients,[7,10] leading to low vaccine uptake in this population.[16,17] Approaches to rectify this have included multifaceted QI initiatives using reminders and regular feedback, which are useful for improvement in pneumococcal vaccination uptake.[18] Additionally, simple point-of-care paper reminders to rheumatologists have been demonstrated to significantly increase vaccine uptake among patients with rheumatic diseases, owing to increased recommendation by providers.[17] A prior study demonstrated a significant and large increase in vaccine uptake with the use of electronic methods to identify patients eligible for vaccination as well as implementation of best practice advisory (BPA) reminders, with the capability to order, administer, and document vaccination.[12] Although we did not employ electronic BPAs, our study used electronic identification of eligible patients and SMOs, enabling nursing staff to order and administer appropriate vaccination without need for physician involvement. Another important component of our intervention was a regular audit of vaccination rates each month and monthly feedback sessions with the clinic staff, a strategy that has been shown to be highly effective among

healthcare providers to achieve sustained improvements in care.[19]

Our study had several strengths. We were able to monitor vaccination rates monthly with real-time feedback to the clinic staff, allowing quick changes to the PDSA cycle. We worked closely with a data analyst who had a standardized process for extracting and reporting data, improving reliability of the reported data. The protocol that we developed was easy to understand based on staff and physician feedback. This protocol also did not pose a significant burden to providers, nurses, or patients and its implementation should be easily generalizable to the other satellite rheumatology clinics and specialty clinics within and outside UT Southwestern medical center. Although our nurse-driven protocol had several steps, our clinic staff were eager to learn about the protocol and enthusiastic in its implementation, suggesting that this protocol could be applied to a variety of clinical environments. We were able to achieve a statistically significant improvement in the proportion of patients who received PCV13 and/or PPSV23 or both by the end of the study period, likely owing to our ability to perform immediate vaccinations in our clinic, a barrier previously cited.[20] However, the proportion of fully vaccinated patients at our center was relatively low at baseline as compared to other centers[20,21]; thus, our clinic had substantial opportunity for improvement.

Our study had several limitations. First, the COVID-19 pandemic significantly affected our ability to implement the protocol consistently, limiting an objective assessment of its efficacy. The pandemic led to a significant decrease in in-person patient visits within the target age group, leading to a reduction in the uptake of the protocol. The pandemic also created competing priorities that often superseded pneumococcal vaccinations. We encountered another hurdle because of limited supply of pneumococcal vaccines at the start of the intervention period. Additionally, our data review was limited to the UT Southwestern EMR, raising the possibility that prior vaccinations done outside of our healthcare system may have been missed, which would falsely lower baseline vaccination rates. Although Texas has ImmTrac2, a system for patients to have their vaccinations registered in the state registry, at this point it is not widely used by patients, as participation requires authorization and enrollment. Therefore, we were unable to rely on state records to obtain vaccination status. Finally, the SmartPhrase to document vaccine refusals had variable adherence, limiting our knowledge of how much patient refusals limited vaccination rates.

In conclusion, our QI project demonstrated that a nurse-driven protocol is an effective and attainable way to increase pneumococcal vaccinations. After the study completion date, the CDC released new pneumococcal vaccination guidelines that updated the 2012 protocol and provided an option of 20-valent pneumococcal conjugate vaccination to be administered to achieve full vaccination status, among other changes.[22] The new recommendations will work to our advantage in improving vaccination rates while using the existing process map. Reducing the number of vaccines that need to be given in a year will ultimately improve vaccination outcomes. The existing protocol for vaccination catch-up of previously partially vaccinated patients will continue to be used in our clinic while a new protocol using the new CDC guidelines for unvaccinated patients is under development.

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