Previsit Planning Improves Pneumococcal Vaccination Rates in Childhood-Onset SLE

Vidya Sivaraman, MD,* Kelly A. Wise, PharmD, BCACP, William Cotton, MD,* Fatima Barbar-Smiley, MD, MPH,* Ohood AlAhmed, MD,* Darby MacDonald, BS,* Stephanie Lemle, MBA,* Çağrı Yıldırım-Toruner, MD,* Stacy P. Ardoin, MD, MS,* Monica I. Ardura, DO, MSCSc

abstract

BACKGROUND: Childhood-onset systemic lupus erythematosus (c-SLE) is a complex autoimmune disease that requires systemic immunosuppressive therapy. Infections are the second leading cause of death in these patients, with invasive pneumococcal infections being a major preventable cause of morbidity and mortality. Pneumococcal vaccination is recommended in this population; however, vaccination rates remain low.

METHODS: The plan-do-study-act method of quality improvement was applied. We calculated baseline vaccination rates for pneumococcal conjugate and pneumococcal polysaccharide vaccines in patients with c-SLE in the rheumatology clinic from January 2015 to August 2016. We developed an age-based algorithm to simplify the vaccination guidelines. The clinical pharmacist and nurses performed weekly previsit planning to update vaccine records, make targeted recommendations, and ensure vaccine availability. The primary outcome measure was the percentage patients with of c-SLE seen per month who had received age-appropriate pneumococcal vaccination.

RESULTS: The percentage of children receiving at least 1 pneumococcal vaccine increased from 24.9% to 92.7% by 12 months. By 18 months, the compliance rate with both pneumococcal vaccines increased from 2.5% to 87.3%, with sustained results. No serious adverse events or disease flares were reported.

CONCLUSIONS: By identifying the major barriers to pneumococcal vaccination in our population with c-SLE, we significantly improved vaccination rates while decreasing time burden on providers. We attribute our success to a team-based quality improvement approach and plan to implement alerts in the electronic health record to streamline the process.

Childhood-onset systemic lupus erythematosus (c-SLE) is a multisystem autoimmune disease associated with high morbidity and risk of organ dysfunction. Children with c-SLE are more likely than adults to develop major organ involvement, warranting augmented immunosuppressive therapies to prevent irreversible damage. An unintended consequence of such treatments is an increased risk for infections. Additionally, c-SLE itself is associated with inherent immune abnormalities, such as hypocomplementemia and functional asplenia. As long-term outcomes in c-SLE have improved, infections have become the leading cause of hospitalizations and disease burden.1 Indeed, invasive pneumococcal diseases (IPDs) are 13 times more likely to occur in children and adults.
with systemic lupus erythematosus (SLE), with up to 5-times greater risk of hospitalization, resulting in increased morbidity and mortality. Although prevalence data in children with lupus are scarce, the morbidity associated with IPD in this population can be significant.

The 23-valent pneumococcal polysaccharide vaccine (PPSV23), composed of 23 pneumococcal serotypes, was licensed in the United States in 1983. The first pneumococcal conjugate vaccine, composed of purified capsular polysaccharide of 7 serotypes of Streptococcus pneumoniae, was licensed in 2000 and was replaced by a 13-valent pneumococcal conjugate vaccine (PCV13) in 2010. Patients born after 2010 would have received PCV13 as part of routine vaccination during the first 2 years of life. Clinicians should encourage a booster dose at 12 to 15 months.

In this quality improvement (QI) study, we evaluated our baseline compliance with pneumococcal vaccination recommendations in patients with c-SLE and identified barriers to vaccination and opportunities to increase pneumococcal vaccination in the rheumatology clinic through multiple plan-do-study-act cycles. Evaluation of our clinic population revealed a baseline pneumococcal vaccination rate of 2.5% during the 8 months before the study, with multiple opportunities for improvement. Our specific aim for this QI study was to increase completion of the pneumococcal vaccine series in patients with c-SLE to ≥50% within 1 year and to ≥80% in 2 years and to sustain that performance thereafter.

**METHODS**

**Context**

Nationwide Children’s Hospital (NCH) is a 476-bed pediatric quaternary care academic medical center in the midwestern United States. The interdisciplinary rheumatology team consists of 7 pediatric rheumatologists, 2 nurse practitioners, nurses, a social worker, a clinical pharmacist, and a QI data specialist. A multidisciplinary SLE and lupus clinic was started in September 2017; however, patients with c-SLE are seen in the lupus clinic and the general rheumatology clinic.

The QI team for this project included physicians from rheumatology, primary care, and infectious diseases; clinic registration staff; nurses; a clinical pharmacist; a QI data specialist; and parent representatives. We engaged the clinical pharmacist, who recently joined the rheumatology team, as a unique resource to improve vaccination rates.

**Inclusion and Exclusion Criteria**

Patients with a diagnosis of c-SLE (diagnosed before 18 years of age on the basis of International Classification of Diseases, 10th Revision codes listed in the problem list in the electronic health record [EHR]) receiving medical care in the pediatric rheumatology clinic at NCH from January 1, 2015, to August 31, 2016, were included in the baseline analysis. Patients with newly diagnosed c-SLE were included in the ongoing QI project. Children with neonatal lupus, isolated cutaneous lupus erythematosus, and overlap connective tissue diseases were excluded.

**Interventions**

The team met monthly and developed a key driver diagram to identify the major factors impeding the vaccination process in our clinic (Fig 1). On the basis of the initial assessment by the team, the key drivers for success included access to valid and reliable immunization records, identification of patients needing vaccination, clinician and staff engagement, and availability of pneumococcal vaccines (PCV13 and PPSV23) in the rheumatology clinic.

Our first intervention was focused on addressing the lack of vaccine records in the EHR and the availability of pneumococcal vaccines in the clinic. A letter was mailed to all patients with c-SLE or guardians and their primary care providers describing the importance of pneumococcal vaccination and requesting updated immunization records to be faxed to our office or brought to the next appointment. Vaccination history was then manually updated in the EHR.
after receipt of the vaccine records. Clinic nurses monitored the vaccine stock weekly and obtained hospital approval to stock both PCV13 and PPSV23 in all rheumatology clinic locations. We increased the stock of both vaccines from 2 to 10 doses each for ready administration during clinic visits.

The second intervention involved previsit planning as a result of the identification of ongoing barriers to vaccination. Pneumococcal vaccine recommendations are complex and can vary by patient’s age and vaccination history. Therefore, applying these recommendations created a significant time burden for providers during the clinic visits, in which disease management takes higher priority. Additionally, most of our rheumatology providers were not familiar with the pneumococcal vaccine guidelines in c-SLE. Furthermore, the clinical decision support function of the EHR system at our institution alerts providers of eligible routine vaccinations but not of the additional vaccines needed for high-risk disease states.

Weekly previsit planning (Fig 2) involved the following steps:

1. A weekly report of upcoming appointments for patients with c-SLE was generated by the QI informatics staff and distributed to the clinical pharmacist and physician QI team leader for review and determination of vaccine eligibility.

2. The clinical pharmacist entered all vaccination records into the EHR before the medical visit using available vaccine records and the statewide vaccine database (Ohio Impact Statewide Immunization Information System).

3. The clinical pharmacist identified candidates for pneumococcal vaccination on the basis of recent guidelines and provided patient-specific vaccination recommendations to the rheumatology team weekly.

4. The provider ordered the vaccine at the time of the clinic visit and notified the primary care provider that the vaccine had been administered via the after-visit summary.

The next intervention was the development of an age-based algorithm for PCV13 and PPSV23 vaccination based on current ACIP guidelines (Fig 3). The algorithm was a visual tool that consolidated the ACIP recommendations on the basis of age and previous vaccination status to expedite decision-making.

![Figure 1](image1.png)

**FIGURE 1** Key driver diagram of factors impacting rates of pneumococcal vaccination in patients with c-SLE.

![Figure 2](image2.png)

**FIGURE 2** Workflow for pneumococcal vaccination with PVP in an ambulatory subspecialty clinic. PVP, previsit planning.
during previsit planning and in the busy clinic setting. We educated the rheumatology providers and clinic staff on the guidelines and displayed the vaccine algorithm in the clinic workrooms. This simplified algorithm addressed gaps in provider knowledge and raised awareness of missed vaccine opportunities. We proposed that the vaccines (typically PCV13 followed by PPSV23) be given at consecutive visits ≥8 weeks apart, coinciding with routine clinical care and abiding with vaccine recommendations. On the basis of the monthly reports of vaccination with 1 or both pneumococcal vaccines, successive interventions were implemented to ensure sustained improvement (Fig 4).

**Study of the Intervention(s)**

Results of the interventions were reported monthly and shared with the providers by using control charts revealing the percentages of patients with c-SLE who had started the vaccine series and received both pneumococcal vaccines (Figs 4 and 5). In addition, we tracked the number of doses of PCV13 and PPSV23 given and the percentage of eligible patients vaccinated each month, and we performed chart review for root causes when the capture rate fell below 50% (data not shown).

**Measures**

The percentage of patients with updated vaccine records in the EHR was tracked as a process measure for the project. Patients were considered vaccine-compliant on the basis of age-appropriate pneumococcal vaccine recommendations if (1) they had completed the vaccine series or (2) they had received at least 1 of the pneumococcal vaccines and were not yet due for the next dose. Outcomes of interest included the percentage of patients who had received at least 1 dose of an age-appropriate pneumococcal vaccine and the percentage of patients who were fully

---

**Pneumococcal Vaccine Recommendations for High-Risk Patients**

<table>
<thead>
<tr>
<th>Age</th>
<th>Vaccine Series</th>
<th>PCV13</th>
<th>PPSV23</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–2 years</td>
<td>Give 1 PCV13 ≥8 weeks after most recent dose</td>
<td>Give second PCV13 ≥8 weeks after</td>
<td>Give second PPSV23 ≥5 years after first dose of PPSV23 (≥8 weeks after PCV13)</td>
</tr>
<tr>
<td>3–5 years</td>
<td>Give 1 PCV13 ≥8 weeks after most recent dose</td>
<td>Give PPSV23 ≥8 weeks after PCV13</td>
<td></td>
</tr>
<tr>
<td>≥6–18 years</td>
<td>No previous PCV13 or PPSV23</td>
<td>Give 1 PCV13</td>
<td>Give second PPSV23 ≥5 years after first dose of PPSV23 (≥8 weeks after PCV13)</td>
</tr>
<tr>
<td>≥19 years</td>
<td>No previous PCV13 or PPSV23</td>
<td>Give 1 PCV13</td>
<td>Give second PPSV23 ≥5 years after first dose of PPSV23 (≥8 weeks after PCV13)</td>
</tr>
</tbody>
</table>

**Notes:**
- PCV7, 7-valent pneumococcal conjugate vaccine.
- PCV23, 23-valent pneumococcal polysaccharide vaccine.
- PPSV23, 23-valent pneumococcal polysaccharide vaccine.

---

**FIGURE 3**

Pneumococcal vaccination algorithm for summarizing current guidelines for high-risk patients who are immunocompromised per ACIP recommendations. PCV7, 7-valent pneumococcal conjugate vaccine.
compliant with vaccine recommendations.

Analysis

We used statistical process control charts (p-charts) to examine our primary outcome measures. We followed the rules from the American Society for Quality to detect special cause variation\(^{24,26}\) as follows: (1) a single point outside the control limits, (2) 2 of 3 successive points on the same side of the centerline and >2 SDs from it, (3) 4 of 5 successive points on the same side of the centerline and farther than 1 SD from it, and (4) a run of 8 in a row on the same side of the centerline. In addition, \(P\) values were calculated to demonstrate statistical difference from the baseline vaccination rate over time.

Ethical Considerations

With this QI project, we aimed to improve processes for delivery of care on the basis of recommended standard of care for immunizations in children who are immunocompromised. Patients were not subject to randomization. Therefore, the institutional review board deemed the project exempt from review.

RESULTS

The NCH rheumatology clinic had 6906 outpatient visits per year in 2016–2017. During the study period, 87 discrete patients with c-SLE were seen in the rheumatology clinic, constituting 18 to 24 visits per month. Demographic data and clinical characteristics on these patients at the time of the most recent vaccination are shown in Table 1. Vaccine history in the EHR was up to date in 25.6% of patients at baseline and rose to 74% by 18 months after the first intervention.

The percentage of patients who had received at least 1 dose of an age-appropriate vaccine increased from 24.9% to 92.7% (\(P < .001\)), with rapid improvement as previsit planning was implemented and with sustained improvement over time (Fig 4).

The percentage of patients who completed the vaccine series with at least 1 dose of PCV13 and 1 dose of PPSV23 increased from 2.5% to 87.3%, with sustained improvement (Fig 5). For both measures, the goal rates were increased after the initial goals were met.

During the course of the study, we made additional observations on the basis of the wide age range and disease duration of the patient population with c-SLE. The majority of patients required a dose of PCV13, followed by PPSV23 at the next rheumatology visit, to complete the series. Some patients had been vaccinated with PPSV23 before the recommendation for the addition of PCV13 in patients who were immunocompromised was made in 2013.\(^{16,25}\) These patients required a dose of PCV13 to complete the series. Only the youngest patient (age 7) had received PCV13 as part of routine immunizations because PCV13 was introduced in the routine immunization schedule for children <6 years of age in 2010.

Vaccines were sometimes deferred at provider discretion in patients receiving high-dose steroids or recent anti-B-cell biological therapies that might impair immunologic response. We noted a drop in pneumococcal vaccine rates during influenza season (November 2017 to December 2017; Fig 4), when some providers ordered the influenza vaccine but missed opportunities for pneumococcal vaccination.

Adverse events from vaccination were minimal. One patient reported a local reaction at the vaccine site. No disease flares related to the timing of vaccination were observed. One patient refused vaccination with PPSV23 because of personal
preference. Clinic flow was not adversely affected by the additional time for vaccination because vaccine recommendations were known ahead of time with the help of previsit planning and the vaccine algorithm (plan-do-study-act step 3).

DISCUSSION

In our study, we describe successful implementation of QI methodology leading to significant and sustained improvement in pneumococcal vaccination in patients with c-SLE. Because infections are now the second leading cause of mortality in these patients after cardiovascular disease, preventive strategies must be a priority in long-term management.2,3 Indeed, pneumococcal vaccination in this high-risk population has been recently included as a quality indicator in the management of c-SLE.27–29 Although the Centers for Disease Control and Prevention and the European League Against Rheumatism recommend pneumococcal immunization, rates of pneumococcal vaccination in c-SLE and other rheumatic diseases remain low.17 Our baseline pneumococcal vaccination rate of children with c-SLE was 2.5%, in line with reported data from other pediatric centers,17 supporting the hypothesis that pneumococcal vaccines were not routinely addressed in the preventive care of older children and adolescents. This identified an opportunity to prioritize the process and improve quality patient care in an effort to improve patient outcomes.

One of our first goals was to identify factors impeding vaccination in our patients. Specific barriers to vaccination that have been cited in the literature include lack of provider recommendation, concerns about vaccine efficacy and safety, lack of vaccine availability in rheumatology clinics, incomplete immunization records, and insufficient time.30,31 The first substantial barrier to timely vaccinations in our cohort was availability of updated vaccine records in the EHR.30 To ensure reliable and up-to-date data, we obtained vaccination records from patients and primary care providers and the statewide vaccine database and entered all gleaned vaccine information into the EHR. Access to updated immunization records in the EHR before the rheumatology visit facilitated timely decision-making and allowed for targeted vaccine recommendations.

We then identified 2 significant provider-specific barriers to vaccine compliance: (1) lack of knowledge of the new pneumococcal vaccination guidelines and (2) difficulty in understanding the complexities of the vaccine recommendations (by age, previous pneumococcal vaccination, and time interval between doses). Similar results were found in a study of family medicine physicians, in which 40% patients with c-SLE seen in the rheumatology clinic who completed pneumococcal vaccination. A, Project awareness. B, Updating vaccine records and ensuring vaccine supply. C, Previsit planning. D, Vaccine algorithm.

TABLE 1 Demographic and Clinical Data of Patients With c-SLE at the Most Recent Vaccination Visit

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female sex, n (%)</td>
<td>75 (87)</td>
</tr>
<tr>
<td>Age, y, median (range)</td>
<td>18 (7–25)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>43 (50)</td>
</tr>
<tr>
<td>African American</td>
<td>30 (35)</td>
</tr>
<tr>
<td>Hispanic and other</td>
<td>13 (15)</td>
</tr>
<tr>
<td>Lupus nephritis (at any time), n (%)</td>
<td>27 (31)</td>
</tr>
<tr>
<td>Cyclophosphamide (at any time), n (%)</td>
<td>25 (29)</td>
</tr>
<tr>
<td>Anti-B-cell biologics in preceding year (rituximab and belimumab), n (%)</td>
<td>9 (10)</td>
</tr>
<tr>
<td>Steroids ≥20 mg/d, n (%)</td>
<td>9 (10)</td>
</tr>
<tr>
<td>Steroids &lt;20 mg/d, n (%)</td>
<td>35 (41)</td>
</tr>
</tbody>
</table>
of physicians were unable to determine the recommended pneumococcal vaccine and appropriate interval between vaccines in adults with high-risk medical conditions. Previsit planning addressed these barriers by identifying eligible patients for pneumococcal vaccines and communicating the need for vaccine with providers before the visit. Lastly, we developed an algorithm that served as a visual reminder of the recommendations for providers. The specialty pharmacist played a vital role in the success of this project. Pharmacists are a key resource in the management of young people with chronic diseases and in improving vaccination in the community. A clinical pharmacist joined our team in 2016 to expedite availability of specialty medications for our patients. In this QI project, the clinical pharmacist provided decision support for vaccination through previsit planning, thereby minimizing the time burden on busy providers and prompting the provider to order the correct vaccine. Provider cues and vaccine availability resulted in a significant improvement in pneumococcal vaccination rates (Figs 4 and 5). Authors of other QI studies have reported improvement in vaccination rates to 23.2% to 56.5%. We hypothesize that our greater success could be due to the addition of a clinical pharmacist in the specialty clinic setting.

Fluctuation in vaccination rates were observed when vaccines were held at provider discretion in patients receiving systemic corticosteroids or anti–B-cell biological therapies. A drop in pneumococcal vaccine rates was observed during influenza season (November 2017 to December 2017; Fig 4), when some providers ordered the influenza vaccine and missed opportunities for pneumococcal vaccination, likely because of the different ordering processes in the EHR. This issue is being addressed by the implementation of a streamlined order process and EHR alerts for both vaccines.

**Study Limitations**

One limitation of our study was the time needed for a manual chart review during previsit planning, which was estimated to be 30 to 45 minutes per week initially but decreased over time because more vaccine records were available in the EHR and most patients had completed the vaccine series. Cross-communication between statewide vaccine databases and the institutional EHRs will reduce this time burden in the future. However, primary care providers are not required to enter vaccine history into the statewide database, and it does not include vaccines that were administered in other states. Upgrades in the EHR that allow for real-time clinical decision support for vaccinations in high-risk individuals will also be critical in sustaining results in the long-term. We acknowledge that our success could be attributed to the availability of a clinical pharmacist in the specialty clinic setting. In institutions without a clinical pharmacist, a clinic nurse may be trained to perform previsit planning using these tools. Another limitation of our study was the lack of a defined process to capture reasons for missed vaccination opportunities to guide future improvements.

**Future Studies**

It is difficult to estimate the number of pneumococcal infections prevented by targeted vaccination in our population. Whereas no large studies exist to address this question, 1 study revealed that no cases of IPD occurred in patients with SLE after vaccination was implemented, compared with 5 cases in a 10-year period before vaccination. Long-term studies will be needed to reliably assess reduction in occurrence of IPD after vaccination in our patient population. The cost savings in preventing serious pneumococcal infections are also predicted to be considerable, but data are not available in children. We are also currently evaluating the immunogenicity of pneumococcal vaccination in the setting of immunosuppressive therapy.

Future efforts are being directed at implementing clinical decision support tools in the EHR and expanding the project to patients with other pediatric rheumatic diseases who are receiving immunosuppression as well as streamlining other appropriate vaccines on the basis of age or medical and/or risk indication in this population.

**CONCLUSIONS**

Our study highlights the benefits of previsit planning, including the role of a clinical pharmacist, in identifying patients and opportunities for optimizing vaccination in a high-risk population. These efforts led to improved and sustained pneumococcal vaccination rates in patients with c-SLE from 2.5% to 87.3% in a busy ambulatory subspecialty clinic. The success of our project and the lessons learned may be expanded to other high-risk patients receiving immunosuppressive therapies to reduce vaccine-preventable IPD and its associated morbidity and mortality.

**ACKNOWLEDGMENTS**

We thank the clinic nurses and staff, particularly Virginia Bennett, MA, and Jonnie Lee Hughes, RN, for their role in the successful implementation of this project.
REFERENCES


2. Luijten RK, Cuppen BV, Bijlsma JW, Derksen RH. Serious infections in systemic lupus erythematosus with a focus on pneumococcal infections. Lupus. 2014;23(14):1512–1516


ABBREVIATIONS

ACIP: Advisory Committee on Immunization Practices

c-SLE: childhood-onset systemic lupus erythematosus

EHR: electronic health record

IPD: invasive pneumococcal disease

NCH: Nationwide Children’s Hospital

PCV13: 13-valent pneumococcal conjugate vaccine

PPSV23: 23-valent pneumococcal polysaccharide vaccine

QI: quality improvement

SLE: systemic lupus erythematosus

13th ed.


Previsit Planning Improves Pneumococcal Vaccination Rates in Childhood-Onset SLE
Vidya Sivaraman, Kelly A. Wise, William Cotton, Fatima Barbar-Smiley, Ohoud AlAhmed, Darby MacDonald, Stephanie Lemle, Cagri Yildirim-Toruner, Stacy P. Ardoin and Monica I. Ardura

Pediatrics 2020;145;
DOI: 10.1542/peds.2018-3141 originally published online December 26, 2019;

Updated Information & Services
including high resolution figures, can be found at:
http://pediatrics.aappublications.org/content/145/1/e20183141

References
This article cites 28 articles, 5 of which you can access for free at:
http://pediatrics.aappublications.org/content/145/1/e20183141#BIBL

Subspecialty Collections
This article, along with others on similar topics, appears in the following collection(s):
Infectious Disease
http://www.aappublications.org/cgi/collection/infectious_diseases_sub
Vaccine/Immunization
http://www.aappublications.org/cgi/collection/vaccine:immunization_sub
Rheumatology/Musculoskeletal Disorders
http://www.aappublications.org/cgi/collection/rheumatology:musculoskeletal_disorders_sub

Permissions & Licensing
Information about reproducing this article in parts (figures, tables) or in its entirety can be found online at:
http://www.aappublications.org/site/misc/Permissions.xhtml

Reprints
Information about ordering reprints can be found online:
http://www.aappublications.org/site/misc/reprints.xhtml
Previsit Planning Improves Pneumococcal Vaccination Rates in Childhood-Onset SLE

Vidya Sivaraman, Kelly A. Wise, William Cotton, Fatima Barbar-Smiley, Ohoud AlAhmed, Darby MacDonald, Stephanie Lemle, Cagri Yildirim-Toruner, Stacy P. Ardoin and Monica I. Ardura

Pediatrics 2020:145;
DOI: 10.1542/peds.2018-3141 originally published online December 26, 2019;

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://pediatrics.aappublications.org/content/145/1/e20183141