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Determining Adherence to Quality Indicators in Sickle Cell Anemia Using Multiple Data Sources

Cindy E. Neunert, MD, MSCS,1 Robert W. Gibson, PhD, MSOTR/L,2 Peter A. Lane, MD,3,4 Pragya Verma-Bhatnagar, MD, MPH,5 Vaughn Barry, PhD, MPH,3,4 Mei Zhou, MS, MA,6 Angela Snyder, PhD, MPH6,7

**Introduction:** Advances in primary prophylaxis have resulted in improved outcomes for patients with sickle cell anemia (SCA; i.e., hemoglobin SS- and Sβthalassemia). Standard prophylactic measures include a first pneumococcal polysaccharide vaccine (PPV) and transcranial Doppler ultrasound (TCD) at age 2 years. Though efficacious, evidence suggests that delivery of these interventions is suboptimal. This study reports adherence to these measures and examines concordance across various data sources, using Registry and Surveillance for Hemoglobinopathies project data.

**Methods:** Retrospective database and SCA center chart review identified children with SCA aged 24–36 months between January 1, 2004, and December 31, 2008. PPV and TCD administration were determined through Medicaid and Children’s Health Insurance Program administrative claims data, medical record review, and Georgia Registry of Immunization Transaction and Services. Analysis was conducted in 2015.

**Results:** A total of 125 children met inclusion criteria. Forty-five (36.0%) children had documentation of both interventions, whereas 19 (15.2%) had no documentation of either intervention. Sixty-one (48.8%) children obtained only one intervention. Of these, more were likely to have had PPV than TCD (77.0% vs 23.0%, respectively, p<0.001). Agreement between claims data and medical record review was moderate for PPV (κ=0.55) and substantial for TCD (κ=0.74).

**Conclusions:** No single, reliable data source for tracking standard of care for children with SCA statewide was found. According to study data, prophylaxis measures were not universally implemented during the surveillance period. Further research is needed to adequately track changes over time, determine risk groups, and develop methods of evaluating important metrics.

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**Introduction**

Sickle cell disease (SCD) is the most common genetic disorder identified by newborn screening (NBS) in the U.S. Major causes of morbidity and mortality in children with SCD include invasive pneumococcal infection1,2 and stroke.3,4 Advances in comprehensive care have resulted in improved outcomes.5 Primary prevention against pneumococcal disease includes prophylactic antibiotic therapy starting in infancy and immunization with the pneumococcal 13-valent conjugate vaccine (PCV) and the pneumococcal polysaccharide vaccine (PPV).1,6,7 In 1998, the large
randomized Stroke Prevention Trial in Sickle Cell Anemia (SCA) demonstrated that chronic transfusions prevent stroke in high-risk children with hemoglobin SS- and Sβ0-thalassemia, that is, SCA, which is identified by transcranial Doppler ultrasonography (TCD) screening. 8 Thus, the standard of care for children with SCA includes PPV and TCD, both initiated at age 2 years.210 Although these interventions show efficacy in reducing major complications,11–17 evidence suggests that significant barriers limit their implementation,18–22 including access to subspecialty care, family and provider education, and sociodemographic factors.7,9

In 2011, the U.S. DHHS launched an initiative to improve care for people with SCD, which included the development of population-based surveillance strategies to identify individuals living with SCD and other hemoglobinopathies.23 In addition, Healthy People 2020 objectives include preventive health metrics for people living with hemoglobinopathies. Seven states, including Georgia, were funded by the Centers for Disease Control and Prevention (CDC) and the National Heart, Lung, and Blood Institute to develop and pilot statewide surveillance systems through the Registry and Surveillance for Hemoglobinopathies (RuSH) project.22

Using Georgia RuSH data, two metrics related to Healthy People 2020 Blood Disorders and Blood Safety objectives are examined:

1. Objective 1: Increase the proportion of people with hemoglobinopathies who receive recommended vaccines, using the receipt of the first dose of PPV as a metric.
2. Objective 4: Increase the proportion of people with hemoglobinopathies who receive early and continuous screening for complications, using the initiation of TCD screening as a metric.

This study explores the utility of using administrative claims and statewide immunization databases to assess adherence with preventive guidelines and contributes to the development of quality of care metrics specific to individuals with SCA.

Methods

A subset of data from the Georgia RuSH Project that included clinical records from Georgia’s NBS program; the comprehensive sickle cell centers at Georgia Regents University (GRU); Grady Health System; and Children’s Healthcare of Atlanta (CHOA); and administrative claims data from Georgia’s Medicaid and Children’s Health Insurance Program, State Health Benefit Plan, and the Georgia Hospital Association was used to perform a retrospective cohort study. All confirmed case patients had confirmatory hemoglobin electrophoresis testing and a documented clinical diagnosis in the medical record. Insurance claims data from Medicaid and the Children’s Health Insurance Program were available for 70% of the confirmed case patients (2,986/4,288).3

Administrative claims data were used to identify receipt of PPV and TCD, using specific procedural codes. In addition to the RuSH data, the Georgia Registry of Immunization Transactions and Services (GRITS) and medical record review from CHOA and GRU, the same programs that provided laboratory confirmation of SCD diagnosis to the RuSH data, were used to identify receipt of PPV and TCD. All study procedures received approval or exemption from the relevant IRBs. The Georgia Departments of Community Health and Public Health reviewed and approved the data requests, ensuring data privacy safeguards were in place.

Included here were children from the RuSH data set with hemoglobin SS- or Sβ0-thalassemia, who were aged 24–36 months between January 1, 2004, and December 31, 2008, and had public insurance coverage for at least 9 of 12 months. This criterion ensured adequate claims data and eliminated children who moved out of the state or changed health coverage. Children with a history of stroke before age 2 years and who did not receive care at CHOA or GRU were excluded. TCD examinations were conducted at the site of sickle cell care, whereas PPV may have been given at the comprehensive sickle cell center, local health department, or the primary care provider. All data were analyzed in 2015.

The primary outcome variables were adherence to PPV immunization and TCD screening, defined as the proportion of children with SCA who received their first PPV and TCD between ages 24 and 36 months. These outcomes were selected as they both occur between the second and third birthday, are unique to patients with SCA, and relate directly to a Healthy People 2020 objective. TCD screening was identified in the RuSH administrative claims data by using Current Procedural Terminology (CPT) codes 938XX, which represent both complete and limited TCDs. Immunization with PPV was identified using CPT code 90732 for Pneumovax 23 administration. A child was considered to have had PPV immunization if this CPT code was present in the claims data during the period from 2 weeks before age 2 years through age 3 years, and considered to have had TCD screening if the corresponding CPT codes were present between the second and third birthdays. Administration of the first dose of PPV was documented from GRITS. Medical record reviewers recorded clinic visit dates during the child’s third year of life, whether or not a PPV or TCD was documented, and the date of administration.

Descriptive statistics and outcome measures were reported. Kappa statistics compared measures of agreement between data sources. Three data sources were compared for PPV: administrative claims data, medical record review, and GRITS. Only the first two data sources were relevant to compare TCD adherence. A κ-statistic of 0.2–0.4 was considered “fair agreement,” 0.4–0.6 was considered “moderate agreement,” and 0.6–0.8 was considered “substantial agreement.”23 Dependent-sample t-tests were conducted to compare differences in proportions, and Mantel–Haenszel trend tests were used to assess PPV and TCD adherence across calendar years. A p-value of <0.05 was considered statistically significant. All analyses were done using SAS, version 9.3.

Results

A total of 4,288 children and adults were identified by Georgia RuSH between 2004 and 200824 with a
confirmed diagnosis of SCD; of these, 2,837 had SS- or Sβ0-thalassemia. A total of 285 were aged 2–3 years, and 143 (50%) were enrolled in public insurance coverage for at least 9 of 12 months. Eighteen children were excluded: one had a stroke prior to age 2 years and 17 had no GRU or CHOA medical record available. The remaining 125 children were included in this analysis. Of the 125 included children, the majority were African American (85.6%) and classified as non-Hispanic (89.6%). The study population was balanced with regard to gender (47.2% male).

Prevalence rates of PPV and TCD for all three data sources are outlined in Table 1. Children were more likely to have PPV documented than TCD in all three data sources (92/125=73.6% vs 59/125=47.2%, p<0.001). Approximately one third of children had evidence of receiving PPV and TCD, whereas 15.2% (n=19) had no documentation of either intervention. Children who had only obtained one intervention (n=61) were more likely to have had PPV (47/61=77.0%) than TCD (14/61=23.0%) (p<0.001). Trends in prevalence are outlined in Table 2. There was no trend by birth cohort for TCD screening. For PPV, there was no change in overall adherence based on birth cohort using at least one data source. There was, however, an increasing trend in the claims data as well as documentation in GRITS.

For patients without either intervention (n=19), nine had inadequate follow-up, four received the interventions outside the study window, four had inadequate documentation of the intervention timing, and one had inadequate data to determine the reason. One child had no reason listed for not receiving PPV and did not receive TCD because of chronic transfusions. Of patients missing only PPV (n=14), the most common documented reason was insufficient or no documentation (n=12); loss to follow-up (n=1); and not available at the clinic (n=1). Similarly, for the 47 children missing only TCD, the most common reason was insufficient documentation (n=31);

Table 1. Prevalence of SCD Specific Interventions Documented by at Least One Data Source

<table>
<thead>
<tr>
<th>Intervention documented at least once between ages 2 and 3 years</th>
<th>n (%) (N=125)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPV and TCD</td>
<td>45 (36.0)</td>
</tr>
<tr>
<td>PPV only</td>
<td>47 (37.6)</td>
</tr>
<tr>
<td>TCD only</td>
<td>14 (11.2)</td>
</tr>
<tr>
<td>Neither PPV nor TCD documented</td>
<td>19 (15.2)</td>
</tr>
<tr>
<td>Total receiving PPV</td>
<td>92 (73.6)</td>
</tr>
<tr>
<td>Total receiving TCD</td>
<td>59 (47.2)</td>
</tr>
</tbody>
</table>

PPV, pneumococcal polysaccharide vaccine; SCD, sickle cell disease; TCD, transcranial Doppler ultrasonography.

Table 2. Prevalence of SCD-Specific Interventions by Source and Birth Year, 2003–2005

<table>
<thead>
<tr>
<th>Birth year</th>
<th>At least one source (n=92)</th>
<th>Medicaid or CHIP (n=55)</th>
<th>Clinical chart (n=63)</th>
<th>GRITS (n=69)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>p-value testing across birth year</td>
<td>&lt;0.01</td>
<td>0.06</td>
<td>0.01</td>
</tr>
<tr>
<td>2003 (n=36)</td>
<td>22 (61.1)</td>
<td>7 (19.4)</td>
<td>12 (33.3)</td>
<td>14 (38.9)</td>
</tr>
<tr>
<td>2004 (n=51)</td>
<td>40 (78.4)</td>
<td>27 (52.9)</td>
<td>30 (58.8)</td>
<td>29 (56.9)</td>
</tr>
<tr>
<td>2005 (n=38)</td>
<td>30 (78.9)</td>
<td>21 (55.3)</td>
<td>21 (55.3)</td>
<td>26 (68.4)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Birth year</th>
<th>At least one source (n=59)</th>
<th>Medicaid or CHIP (n=49)</th>
<th>Clinical chart (n=53)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>p-value testing across birth year</td>
<td>0.63</td>
<td>0.32</td>
</tr>
<tr>
<td>2003 (n=36)</td>
<td>15 (41.7)</td>
<td>11 (30.6)</td>
<td>12 (33.3)</td>
</tr>
<tr>
<td>2004 (n=51)</td>
<td>26 (51.0)</td>
<td>22 (43.1)</td>
<td>23 (45.1)</td>
</tr>
<tr>
<td>2005 (n=38)</td>
<td>18 (47.4)</td>
<td>16 (42.1)</td>
<td>18 (47.4)</td>
</tr>
</tbody>
</table>

Note: Boldface indicates statistical significance (p<0.05); Values are n (%) unless otherwise indicated.

CHIP, Children’s Health Insurance Program; GRITS, Georgia Registry of Immunization Transactions and Services; SCD, sickle cell disease; TCD, transcranial Doppler ultrasonography.
intervention obtained outside the study window (n=13); loss to follow-up (n=2); and poor adherence with clinic visits (n=1).

Among children who had PPV documented by any of the three data sources (n=92), GRITS was identified as the most inclusive data source (69/92=75.0%) compared with medical record review (63/92=68.5%) and administrative claims (55/92=59.8%). Among children who had TCD documented by either of the two data sources (n=59), medical record review (53/59=89.8%) and administrative claims (49/59=83.1%) were similarly useful.

Table 3 shows the percentage of children who had an intervention documented by data source. The level of agreement (Table 4) between administrative claims data and medical record review was moderate for PPV (κ=0.55) and substantial for TCD (κ=0.74). Furthermore, agreement with GRITS was moderate for administrative claims (κ=0.46) and fair for medical record review (κ=0.26). Twenty-three children were identified for whom no administration of PPV was recorded in GRITS; however, a claim was processed or documentation was found in the medical record.

### Discussion

During the 5-year study period, findings suggest that the standard of care was suboptimal, particularly for TCD screening, and that discordance existed between data sources. Only 36.0% of children had documentation of both PPV and TCD, and 15.2% of children received neither intervention. These findings support previous studies demonstrating suboptimal adherence with primary SCD prevention in children.

The PPV and pneumococcal prevention strategies have decreased bacterial infections. Despite this decline, few studies have monitored adherence to vaccination rates. This study found 73.6% of children received their first PPV at age 2 years. A case-control study of pneumococcal vaccine adherence (PCV7 and PPV) in Michigan using Medicaid claims data between

### Table 3. Comparison of PPV and TCD Documentation Status by Data Source (N=125)

<table>
<thead>
<tr>
<th>Documentation</th>
<th>PPV Documented in Medicaid or CHIP, n (%)</th>
<th>Not documented in Medicaid or CHIP, n (%)</th>
<th>TCD Documented in Medicaid or CHIP, n (%)</th>
<th>Not documented in Medicaid or CHIP, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documented in clinical chart</td>
<td>45 (36.0)</td>
<td>18 (14.4)</td>
<td>43 (34.4)</td>
<td>10 (8.0)</td>
</tr>
<tr>
<td>Not documented in clinical chart</td>
<td>10 (8.0)</td>
<td>52 (41.6)</td>
<td>6 (4.8)</td>
<td>66 (52.8)</td>
</tr>
<tr>
<td>Documented in GRITS, n (%)</td>
<td>45 (36.0)</td>
<td>10 (8.0)</td>
<td>24 (19.2)</td>
<td>46 (36.8)</td>
</tr>
<tr>
<td>Not documented in GRITS, n (%)</td>
<td>26 (20.8)</td>
<td>36 (28.8)</td>
<td>43 (34.4)</td>
<td>20 (16.0)</td>
</tr>
</tbody>
</table>

CHIP, Children’s Health Insurance Program; GRITS, Georgia Registry of Immunization Transactions and Services; PPV, pneumococcal polysaccharide vaccine; TCD, transcranial Doppler ultrasonography.

### Table 4. Measures of Agreement Between Data Sources for Documentation of PPV and TCD

<table>
<thead>
<tr>
<th>Prophylactic measure</th>
<th>Data source comparisons</th>
<th>Overall agreement, %</th>
<th>Kappa</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPV</td>
<td>Medicaid and CHIP compared to clinical chart</td>
<td>77.6</td>
<td>0.552</td>
</tr>
<tr>
<td></td>
<td>Medicaid and CHIP compared to GRITS</td>
<td>72.8</td>
<td>0.463</td>
</tr>
<tr>
<td>TCD</td>
<td>Medicaid and CHIP compared to clinical chart</td>
<td>87.2</td>
<td>0.735</td>
</tr>
</tbody>
</table>

CHIP, Children’s Health Insurance Program; GRITS, Georgia Registry of Immunization Transactions and Services; PPV, pneumococcal polysaccharide vaccine; TCD, transcranial Doppler ultrasonography.
2001 and 2008 revealed 72% of children with SCD received at least one pneumococcal vaccine by age 3 months and 73% had three documented by age 24 months. These rates are similar to the 73.6% observed in this study. Lower rates of PPV adherence were seen in a retrospective cohort of Wisconsin Medicaid claims conducted between 2003 and 2007, with only 49.8% of children aged 2–18 years adherent with PPV vaccination.22 Taken together, studies using claims data find approximately 25%–50% of children with SCD have not received timely vaccination against invasive pneumococcal disease. The proportion of children receiving PCV-23 by age 3 years was higher among children in a single-center cohort (82.4% in 1994 and 100% in 2006), likely representing the difference between single-center experiences and universal surveillance data. In this study, PPV rates did increase over time based on claims data and GRITS, likely reflecting the increased efforts of CDC during this time to create immunization information systems as well as improved coding.

In this study, adherence with TCD (47.2%) was lower than for PPV, possibly reflecting poor initial adoption of the relatively newer TCD screening guidelines.8,9 Others have shown improvement in TCD implementation over time since the Stroke Prevention Trial in SCA in 1998.18,19 In a study18 of the Kaiser Permanente Medical Care Program, screening rates were 1.8 per 100 person-years prior to 1998, increasing to 5.0 per 100 person-years in 1998–1999 and even further to 11.4 per 100 person-years following 1999. Similarly, Tennessee Medicaid claims data showed the incidence of TCD screening to be 2.5% in 1997 and as high as 68.3% in 2008.19

Another rationale for increased screening rates is the availability of oral iron chelators, which provide an alternative to deferoxamine and shift the risk–benefit of chronic transfusions. The Georgia population may be unique in that it has a relatively large number of rural patients who receive care at public health clinics where screening was not available onsite until after 2009. This likely accounts for the low TCD screening rates; adherence might be better in a more modern cohort.25 This highlights the complexity in delivering technology-based interventions such as TCD in rural settings. Efforts directed at understanding and addressing barriers to receiving the standard of care that incorporate all stakeholders are needed.

Because some of the guidelines for preventive care of patients with SCD are genotype specific, the use of a statewide data system for the surveillance of SCD has an advantage over general health service data sources for measuring quality of care. The RuSH surveillance system in Georgia contains laboratory-confirmed SCD genotypes for 4,288 individuals that are matched to the administrative data sources. Identification of SCD based on ICD-9-CM coding contained in administrative data sets alone does not accurately differentiate SCD genotypes and would not identify individuals who should be receiving particular preventive screenings. Even with ICD-10 coding, it will not be possible to distinguish between all SCD genotypes. State public health departments are strategically positioned to create longitudinal surveillance systems for children with SCD and other genetic disorders, because they typically administer and have access to birth records, NBS data, and immunization registries. Most state public health departments can also link these data to Medicaid and hospital administrative data under their public health authority. Several states, including North Carolina, California, and Michigan, have developed NBS follow-up systems.26

Some discordance between the data sources used to measure receipt of the preventive interventions was found. Concordance between administrative claims data and medical record review was substantial for TCD (κ=0.74) and moderate for PPV (κ=0.55). Validation data from the Tennessee study found procedure claims for TCD (using similar codes in addition to CPT codes 76506 for ultrasound head and 76536 for ultrasound soft tissues of head and neck) to be 90.5% sensitive with a positive predictive value of 100% compared to medical records.19 Although the κ-statistics are adequate, in neither case was there 100% concordance. It was hypothesized that the majority of discordance would come from a positive claim that was not documented in the medical record; nevertheless, this was not found. Both the medical records and administrative claims had an equal number of missing data; however, GRITS provided an additional source of comprehensive information to document PPV.

The higher concordance rate for TCD compared with PPV is likely because TCD screening was easier to identify in medical records as it is usually conducted in the same location as specialty patient care. By contrast, immunizations for children followed in the specialty clinics were often administered at a different site, such as the primary care physician’s office, and therefore the status in the medical record often lacked detail. Additionally, if the vaccination was provided at a health department clinic, a Medicaid/Children’s Health Insurance Program claim was unlikely to be generated as vaccines are provided free of charge to publicly insured children. For this reason, many providers rely on the statewide GRITS data system for immunization tracking. Although these barriers to tracking interventions might be unique to the state of Georgia, they further highlight the need for general, centralized tracking mechanisms.
Findings suggest that no single inclusive data set exists for measuring adherence with PPV and TCD in SCD; use of all three data sets provided the most robust data. State-based immunization registries may offer the best documentation of immunization adherence, even for special populations. Similarly, administrative health insurance data such as Medicaid claims can be used to appropriately identify receipt of a TCD screen. Moreover, in order to precisely measure both interventions, these data sources require linkage, at the individual level, to a surveillance system or patient registry containing SCD genotypes.

These population-based prevention metrics for SCD are also applicable to health systems, clinics, and individual practices as the U.S. healthcare system moves to population-based financing models like accountable care organizations, global payment structures, and additional value-based purchasing models. Many providers are developing patient registries, modifying electronic health records to include relevant indicators of risk, and utilizing patient navigators to reach out to patients to reduce access barriers and improve the quality of care.\(^\text{27}\)

Developing and testing care metrics is the first step in improving quality of care for individuals with chronic diseases like SCD.

**Limitations**

This study is limited in its retrospective nature and the assumption that charges and other documentation of an intervention were accurate. The data are also limited in that only medical records at specialty providers were included in the review; adherence may be different for patients followed elsewhere or if primary care medical records were also available for review. The use of health information exchanges may provide more transparent sharing of patient data between primary care and specialty providers. Children who did not have public insurance for 9 of 12 months were excluded to create a continuously insured cohort; inclusion of children who lack continuous coverage would likely reduce screening rates. Study data may not be representative of all SCD populations such as more-urban populations, those privately insured, or in publicly insured cohorts with annual eligibility periods rather than 6-month periods as was the case in Georgia. PPV or TCD adherence rates beyond age 3 years were not measured. Lastly, patient and provider factors that might influence adherence were not assessed.

**Conclusions**

Using the Georgia RuSH population-based surveillance database, including administrative claims data, GRITS, and medical record review, adherence with PPV immunization and TCD screening among children aged 2 years with SCD were assessed between 2004 and 2008. Findings suggest adherence was not universal and a significant portion of patients did not receive these important interventions during that period. Although no single, comprehensive data source for documenting population-based care metrics was found, state-based surveillance systems that link at-risk children through NBS programs with administrative records or immunization registries to document clinical events can be used to monitor preventive care for young children with SCD. Immunization registries are the best source for documenting pneumococcal vaccination, and administrative claims data are similar to chart review in monitoring TCD use over time. Both of these metrics may also be of use to providers developing their own quality-monitoring systems within their practices.

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