RESEARCH ARTICLE


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ABSTRACT

OBJECTIVES: Infantile hypertrophic pyloric stenosis (IHPS) is the most common reason for abdominal surgery in infants; however, national-level data on incidence rate and resource use are lacking. We aimed to examine the national trends in hospitalizations for IHPS and resource use in its management in the United States from 2012 to 2016.

METHODS: We performed a retrospective serial cross-sectional study using data from the National Inpatient Sample, the largest health care database in the United States. We included infants aged ≤1 year assigned an International Classification of Diseases, Ninth Revision, o r International Classification of Diseases, 10th Revision, code for IHPS who underwent pyloromyotomy or pyloroplasty. We examined the temporal trends in the incidence rate (cases per 1000 live births) according to sex, insurance status, geographic region, and race. We examined resource use using length of stay (LOS) and hospital costs. Linear regression was used for trend analysis.

RESULTS: Between 2012 and 2016, there were 32 450 cases of IHPS and 20 808 149 live births (incidence rate of 1.56 per 1000). Characteristics of the study population were 82.7% male, 53% white, and 63.3% on Medicaid, and a majority were born in large (64%), urban teaching hospitals (90%). The incidence of IHPS varied with race, sex, socioeconomic status, and geographic region. In multivariable regression analysis, the incidence rate of IHPS decreased from 1.76 to 1.57 per 1000 (adjusted odds ratio 0.93; 95% confidence interval 0.92–0.93). The median cost of care was $6078.30, whereas the median LOS was 2 days, and these remained stable during the period.

CONCLUSIONS: The incidence rate of IHPS decreased significantly between 2012 and 2016, whereas LOS and hospital costs remained stable. The reasons for the decline in the IHPS incidence rate may be multifactorial.

www.hospitalpediatrics.org
DOI:https://doi.org/10.1542/hpeds.2019-0112
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HOSPITAL PEDIATRICS (ISSN Numbers: Print, 2154-1663; Online, 2154-1671).
FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.
FUNDING: No external funding.
POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.
COMPANION PAPER: A companion to this article can be found online at www.pediatrics.org/cgi/doi/10.1542/peds.2019-0254.

Drs Donda and Dapaah-Siakwan conceptualized and designed the study; drafted the initial manuscript; designed the data collection instruments; coordinated the supervised data collection, and critically reviewed the manuscript; Drs Bhatt and Asare-Afriyie conceptualized and designed the study and drafted the initial manuscript; Drs Ayensu, Sharma, Amponsah, and Hesse carried out the initial analyses and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted.
Infantile hypertrophic pyloric stenosis (IHPS) is the most common reason for abdominal surgery in the first 6 months of life. Most infants with IHPS present with signs and symptoms within the first 2 to 12 weeks of life. The exact etiology of IHPS is unknown, but environmental factors such as maternal smoking and alcohol use during pregnancy, exposure of infants to macrolides, prematurity, bottle-feeding, and genetic factors have been implicated in the occurrence of the condition. The incidence rate varies over time and geographic region. In the United States, the rate varies from 1.33 to 3 per 1000 live births depending on the state where the study was conducted and the type of data used. The nationwide incidence rate of IHPS in the United States is unknown. Recent studies from other countries have revealed that the incidence rate of IHPS is declining or increasing. Authors of a few studies conducted in the United States have examined the trends in the incidence rate of IHPS. Most of them were completed before 2003 in specific geographic regions in the United States. One recent study in which authors used data from a birth defect surveillance registry from 11 states in the United States revealed a downward trend in the incidence rate of IHPS from 2007 to 2010 despite an overall stable trend between 1999 and 2010. Authors from another study examined data from the US Military Health System and found no significant change in the incidence rate of IHPS between 2001 and 2012. Although these studies provide useful information on the incidence rate of IHPS, they are limited to a few states, are not nationally representative, and thus may lack external validity. Furthermore, national-level estimates of resource use (length of stay [LOS] and hospital cost) in the management of IHPS are lacking. In the current study, we sought to determine the temporal trends in the incidence rate of IHPS hospitalizations and the associated resource use in its management from 2012 through 2016 using data from the National Inpatient Sample (NIS).

METHODS

Study Design and Data Source

We performed a retrospective serial cross-sectional analysis of data from the NIS from 2012 through 2016. The raw data were obtained from the Agency for Healthcare Research and Quality (https://www.hcup-us.ahrq.gov). The NIS, a part of the Healthcare Cost and Utilization Project (HCUP), sponsored by the Agency for Healthcare Research and Quality, is the largest publicly available all-payer inpatient health care database in the United States. The NIS represents a random 20% stratified sample of all discharges in the United States. The sampling frame included 44 states from 2012 through 2014, 46 states in 2015, and 47 states, including the District of Columbia, in 2016. Supplemental Fig 3 reveals the HCUP partner states in each of the census regions as of 2014. Unweighted, the 20% stratified sample contains 7 million hospital stays each year. When weighted, the NIS estimates >35 million hospitalizations nationally each year. This sampling frame represents >97% of the US population. Each individual hospitalization in this database is deidentified and maintained as a unique entry with 1 primary discharge diagnosis, <30 secondary diagnoses along, and <15 procedure codes during that hospitalization. Researchers and policy makers use the NIS to make national estimates of health care use, access, charges, quality, and outcomes. The NIS was redesigned starting in 2012. The sample design was revised to create a sample of discharge records from all HCUP-participating hospitals, rather than all discharge records from a sample of hospitals. The discharge universe (the >4500 acute care hospitals included in HCUP) was revised to exclude long-term acute care hospitals. The new sampling strategy produces more precise estimates than the previous NIS design by reducing sampling error. Therefore, we chose to analyze the 2012–2016 NIS data to ensure consistency and uniformity of the data during the study period. The NIS data are made available yearly, which allows for analysis of trends over time. The NIS has been used to estimate population-level trends in numerous conditions. The study involved publicly available deidentified data and was thus exempt from review by the institutional review board.

Study Population

Pyloric stenosis cases were defined as infants hospitalized for IHPS (International Classification of Diseases, Ninth Revision [ICD-9], and International Classification of Diseases, Tenth Revision [ICD-10], diagnostic codes 750.5 and Q40.0, respectively), who underwent pyloromyotomy or pyloroplasty before their first birthday (ICD-9 procedure codes 44.3 or 44.2 or ICD-10 procedure codes 0DB7, 0DT7, or 0D77). Pyloromyotomy has been the standard of care for IHPS in the United States for decades, but we included hospitalizations with codes for pyloroplasty to ensure complete identification of all hospitalizations with IHPS. Sample weights provided by the NIS for each year were applied to generate national-level estimates of the number of hospitalizations with IHPS. Although medical treatment of IHPS with atropine is practiced in some countries, it is not the recommended standard of care for the management of IHPS in the United States. Thus, any cases of IHPS medically managed were excluded from the study. Because each record in the NIS database corresponds to a discharge, infants whose final disposition was coded as transferred out to other short-term facilities, skilled nursing care, or intermediate care facilities were identified by using the “DISPUNIFORM” variable and were excluded to avoid duplication of the data at the receiving facility. This exclusion criterion has been used in other studies on neonatal conditions that used the NIS. Details of the population derivation are shown in Fig 1.

Definition of Variables

Patient-level characteristics such as sex, race, median household income as per zip code (<$36,000, $36,000–$44,999, >$45,000), primary payer (Medicare or Medicaid, private insurance, self-pay, other), and hospital-level characteristics such as hospital location (rural or urban) and teaching status (rural, urban nonteaching, and urban teaching), hospital bed size (small, medium, and large), and hospital...
Infant (<1 year of age) population from years 2012–2016
N (weighted) = 21 234 819

Excluded: 421 065 hospitalizations transferred to short-term or other type of facility

Infants with hypertrophic pyloric stenosis identified by using the ICD-9-CM code 750.5 or ICD-10-CM code Q40.0 and had pyloromyotomy or pyloroplasty
n (weighted) = 32 450

Neonates (≤28 days old) identified with ‘Neomat’ variable
n (weighted) = 11 260

Infants (aged ≥29 days to ≤1 year)
n (weighted) = 21 190

FIGURE 1 Study population derivation and eligibility flowchart.

The adjusted cost for each year was calculated in terms of the 2016 cost after adjusting for inflation according to the latest consumer price index data released by the US government. This enabled us to standardize the costs over the study period.

Outcomes
We analyzed national trends in IHPS hospitalizations, costs, and LOS over time during the study period. The incidence rate of IHPS was calculated by dividing the weighted number of IHPS hospitalizations by the number of live births, and this was reported as the number of IHPS hospitalizations per 1000 live births. The number of live births for each year and for each geographic region and sex was obtained from the live births data provided by the HCUP in the NIS. Incidence rates for IHPS and their trends over the study period were also determined according to race, sex, the expected payer (Medicaid, private insurance, etc), and socioeconomic status (SES). Race was categorized as white, non-Hispanic black, Hispanic, Pacific Islander, and others. As defined previously, SES was determined on the basis of the source of payment for the admission. “High SES” included individuals with private insurance or private health maintenance organization coverage, whereas “low SES” consisted of those who were self-pay, had Medicaid, or had no insurance. Resource use was assessed by using the LOS and the inflation-adjusted total hospital cost for each IHPS hospitalization. Median and interquartile ranges (IQRs) were used to summarize the data for LOS and inflation-adjusted hospital cost because the data were not normally distributed.

Statistical Analysis
Continuous variables were reported as medians and IQRs, and categorical variables were reported as proportions with 95% confidence intervals (CIs). χ² test, t test, or analysis of variance with post hoc Tukey honestly significant difference test for multiple comparisons were used for unadjusted analysis depending on the data. Linear regression was used to determine trends over time. To assess the variables that were associated with IHPS and to determine the effect of calendar year on the

region (northeast, Midwest, south, and west; see Supplemental Fig 3) were abstracted. Hospitalizations with IHPS were divided into 2 age groups: neonates (0–28 days old) by using the “AGE_NEONATE” variable and infants (29–364 days old). Neonates were identified by using the “Neomat” variable, which identifies discharges with neonatal and/or maternal diagnoses and procedures. To calculate the estimated cost of hospitalization, the NIS data were merged with cost-to-charge ratios available from the HCUP. We estimated the cost of each inpatient stay by multiplying the total hospital charge with the cost-to-charge ratio provided by HCUP.30

FIGURE 2 Temporal trends in the incidence rate of pyloric stenosis in the United States from 2012 to 2016.
incidence rate of IHPS, multivariable logistic regression analysis was performed with sex, age group, race, primary payer, household income, hospital bed size, and hospital location and teaching status as covariates. The results of this adjusted analysis are presented as odds ratios (ORs) with 95% CIs. Statistical analyses were performed by using SPSS 23.0 (SPSS Statistics, IBM Corporation). A 2-sided \( P < .05 \) was considered significant for all analyses.

RESULTS

There were 20,808,149 live births over the period of 2012–2016, of which 32,450 were assigned an ICD-9 or ICD-10 diagnosis of pyloric stenosis. The overall cumulative incidence rate of IHPS for the study period was 1.56 per 1000 live births. The demographic and hospital characteristics of the infants hospitalized with IHPS during the study period are described in Table 1. In summary, 82.7% were boys, 53% were of white race, and 94.4% had private (31.1%) or public (63.3%) health insurance (Medicare or Medicaid). A majority of the hospitalizations were admitted in large (63.8%) urban teaching hospitals (90.3%). Household income was distributed across income quartiles.

Table 2 reveals the trends in the incidence rate of IHPS hospitalizations in terms of age group, sex, race, census region and mode of payment as well as resource use (LOS and hospital cost) across the years of the study period. The incidence rate (expressed as per 1000 live births) of IHPS varied significantly by age group (infants > neonates; \( P = .001 \), sex (2.65 in boys vs 0.58 in girls; \( P = .001 \)), race (African American patients < Hispanic and white patients), SES (1.46 in low SES vs 1.07 in high SES; \( P = .004 \)), and census region. These differences were confirmed on multivariable logistic regression analysis (Table 3).

The overall cumulative incidence rate of IHPS decreased from 1.76 in 2012 to 1.57 per 1000 live births in 2016 (Fig 2), and this was statistically significant in adjusted analysis (adjusted OR 0.93, 95% CI 0.92–0.95; see Table 3). In subgroup analysis, there was a significant downward trend in the incidence rate among neonates (0.64–0.48 per 1000 live births; \( P = .01 \)) and Pacific Islanders (0.42–0.32 per 1000 livebirths; \( P = .02 \)). There were no other trends in the remaining subgroups during the study period as shown in Table 2. The median LOS was 2 days (IQR, 2–3 days) and the median cost of hospitalization was $6078 (IQR, $4695–$8262). There was no significant change in the LOS and hospital cost during the study period.

DISCUSSION

Using the NIS, a nationally representative database, we have reported contemporary incidence rates and trends in IHPS from 2012 to 2016 and examined the resource use for the management of IHPS among infants in the United States. We have demonstrated that the cumulative annual incidence rate of IHPS was 1.56 per 1000 live births and there was a decrease in the cumulative annual average incidence rate (1.76–1.55) during the study period. In addition, we have shown that the LOS and hospital cost for IHPS remained stable during the study period. The current study is 1 of the largest analyses on the IHPS hospitalizations in the United States, extending our knowledge by examining the temporal trends in the incidence rate and health care resources used for its management.

The overall cumulative incidence rate of 1.56 per 1000 live births is lower than the rate of 2.0 per 1000 live births reported by Kapoor et al\(^{8} \) using data from population-based birth defects surveillance registries from 11 states in the United States between 1999 and 2010. These registries cover 35% of newborn deliveries in the United States, whereas the NIS covers 97% of the US population. The differences between these 2 rates may be because of the different databases used for these studies and the different time periods during which these studies were conducted. Kapoor et al\(^{8} \) also noted that the incidence rate of IHPS declined from 2.5 to 1.7 per 1000 live births from 2006 to 2010. This is consistent with our finding of a declining trend in the incidence of IHPS from 1.76 in 2012 to 1.57 per 1000 live births in 2016 for the entire United States. The declining rate of IHPS has also been reported in other Western countries.\(^{11,12,25,36} \) Factors such as young maternal age, preterm birth, maternal smoking, bottle-feeding with formula, and macrolide antibiotic exposure in first 2 weeks of life have been strongly associated with IHPS.\(^{5} \) Maternal age <20 years is associated with a higher risk of IHPS in some studies, and data from the Centers for Disease Control and Prevention have revealed a consistent increase in both the mean maternal age (27.7–28.7 years) and maternal age at first pregnancy (25.4–26.6 years) between 2010 and 2016.\(^{37} \) Concurrent with this decrease, pregnancies in women <20 years of age has significantly decreased since 2007.\(^{37} \) Likewise, smoking prevalence among pregnant women and among women of reproductive age, in general, has fallen in the United States.\(^{38,39} \) Formula feeding is another risk factor for IHPS.\(^{1,40} \) Again, data from the Centers for Disease Control and Prevention reveals that exclusive breastfeeding rates through the first 3 months of age in the United States has been increasing since 2010.\(^{41} \) Exposure to macrolides within the first 3 months of life is associated with an increased risk of pyloric stenosis.\(^{52} \) Macrolides are indicated for the treatment of pertussis and perinatal chlamydial infections in newborns and infants. These diseases are on a downward trend in the United States, and presumably, prescriptions for and subsequent exposure of newborns to these have also decreased over time.\(^{1,5,43} \) In addition, the Affordable Care Act was signed into law in May 2010, greatly expanding medical coverage in the United States.\(^{46} \) This massive expansion really began to go into effect in 2014 with Medicaid expansion. However, it is certainly possible that increased health care coverage could have led to better pregnancy planning and increased early and adequate prenatal care.\(^{47} \) This could have contributed to the decline of IHPS rates in the United States. Therefore, the reasons for the declining incidence rate of IHPS may be multifactorial.

In terms of age, we observed a decline in the incidence rate in neonates <28 days old but not in infants. The reasons for this observed trend are not clear from the published literature, but this observation...
Baseline demographic and hospital characteristics of hospitalizations with IHPS in the United States from 2012 to 2016.
could mean that the age at presentation of IHPS is increasing. We found no significant trends with respect to race and ethnicity (white, African America, and Hispanic patients), sex, insurance status or SES, and census region. However, our finding that the incidence rate is higher in boys and those of white race is consistent with observations made in previous studies. Authors of few

### TABLE 2 Trends in the Incidence and Resource Use for Pyloric Stenosis in the United States (2012–2016)

<table>
<thead>
<tr>
<th>Year</th>
<th>Overall 2012–2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>4 195,055</td>
</tr>
<tr>
<td>2013</td>
<td>4 143,563</td>
</tr>
<tr>
<td>2014</td>
<td>4 162,885</td>
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<tr>
<td>2015</td>
<td>4 177,375</td>
</tr>
<tr>
<td>2016</td>
<td>4 129,261</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>20,808,149</td>
</tr>
</tbody>
</table>

*P* values for student's *t* test or analysis of variance as appropriate.

**Incidence rate expressed as number of cases per 1000 live births.**

1. White versus Hispanic patients, *P* = .05; White > African American patients, *P* = .001; Hispanic > African American patients, *P* = .001.
3. Midwest > West, *P* = .001; South > Midwest, *P* = .006; other pairwise comparisons not significant.

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**Resource use**

<table>
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</tr>
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3. Midwest > West, *P* = .001; South > Midwest, *P* = .006; other pairwise comparisons not significant.
Higher odds of IHPS. The con... higher social class (de... the results thus... studies have evaluated the association... Low... SES is an... educational status was associated with a higher incidence of IHPS. SES is an important determinant of pregnancy outcomes. Lower SES is associated with lower mean maternal age at first pregnancy and a higher incidence of smoking during pregnancy. Both factors are associated with a higher risk of pyloric stenosis as explained previously. However, Dodge reported in a study from Ireland that that higher social class (defined on the basis of parental occupation) was associated with higher odds of IHPS. The conflicting result from this may arise from differences in patient populations and the definition of SES used.

In our study, we provide unique insights into the resource use required for the management of IHPS at the national level. The median LOS from the current study was 2 days, and this is consistent with the LOS of 2 to 3 days previously reported. The median estimated cost of care of $6078.30 is comparable to the cost of $5351 reported in another population-based study in the United States. Authors of other studies have reported hospital charges of $7938 to $11,312. It is instructive to point out the differences between hospital charges and hospital costs. The charges are the expenses incurred by the hospital in taking care of their patients, and these vary widely across hospitals and geographic regions in the United States. Hospital costs for IHPS across years, and there was no significant change over time. Likewise, there was no significant change in LOS over the study period. These are reassuring in the present era when much emphasis is being placed on containing health care costs in the United States.

The limitations of this study, like all others conducted by using administrative databases, are well described. Large databases such as the NIS are susceptible to coding errors, omissions, and duplications. However, the HCUP has instituted mechanisms to ensure the validity of the data in NIS. Additionally, IHPS is a major discharge diagnosis and more likely to be coded correctly because such coding is related to billing for inpatient hospital care. Because surgery is the standard of care for IHPS in the United States, valid ICD-9 and ICD-10 procedure codes for pyloromyotomy and pyloroplasty were used to identify hospitalizations with IHPS. Codes for both pyloromyotomy and pyloroplasty were used to identify patients with IHPS to ensure complete identification of all hospitalizations with IHPS. However, the overwhelming standard of treatment of IHPS in the United States is pyloromyotomy; therefore, many of those who were coded as having a pyloroplasty may in fact have been designated so incorrectly. In addition, the data used were for discharges rather than for individual patients, so data may have been represented more than once for any given year. Most likely, surgeries were not repeated; however, readmission for, say, infection and other medical problems may have been the culprit. The NIS database does not include clinical information such as the type of feeding (breast milk or formula feeding) and birth order and medications such as macrolide exposure before the diagnosis of IHPS. Therefore, we could not directly evaluate whether changes in these were associated with the decline in the incidence rate of IHPS in this study.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Adjusted OR (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year</td>
<td>0.92 (0.91–0.93)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>1.00 (Reference)</td>
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</tr>
<tr>
<td>High</td>
<td>0.47 (0.46–0.48)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1.00 (Reference)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>0.22 (0.21–0.23)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>1.00 (Reference)</td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>0.29 (0.28–0.31)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Hispanic</td>
<td>0.85 (0.83–0.88)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Pacific Islander</td>
<td>0.20 (0.18–0.22)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Hospital region</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Northeast</td>
<td>1.00 (Reference)</td>
<td></td>
</tr>
<tr>
<td>Midwest</td>
<td>1.33 (1.28–1.38)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>South</td>
<td>1.26 (1.22–1.30)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>West</td>
<td>0.98 (0.94–1.02)</td>
<td>.32</td>
</tr>
<tr>
<td>Hospital bed size</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>1.00 (Reference)</td>
<td></td>
</tr>
<tr>
<td>Medium</td>
<td>0.99 (0.96–1.03)</td>
<td>.65</td>
</tr>
<tr>
<td>Large</td>
<td>1.57 (1.52–1.63)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Teaching status of hospital</td>
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<td></td>
</tr>
<tr>
<td>Rural</td>
<td>1.00 (Reference)</td>
<td></td>
</tr>
<tr>
<td>Urban nonteaching</td>
<td>2.36 (2.13–2.61)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Urban teaching</td>
<td>13.77 (12.50–15.12)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>
There appears to be a trend toward laparoscopic pyloromyotomy, but because there is no ICD-9 or ICD-10 code for this, we could not examine the trends in the type of IHPS repair and neither were we able to examine the effect of open versus laparoscopic repair on LOS and hospital cost.\(^6\) However, a multivariable logistic regression analysis was performed by using all the relevant data available in the NIS to assess the factors associated with the incidence of IHPS. As with any retrospective administrative data analysis, there is a potential for bias from missing data. However, it is unlikely that the missing data would have a significant impact on the results because of the large sample size of the current study. Although we classified SES according to the expected payer on the basis of previous studies, this should be interpreted with caution because the children of wealthy parents may be self-paying and thus not of low SES. Finally, we studied the trends in the incidence rate of IHPS and its associated resource use over a 5-year period. It is possible that if we had included the years before 2012, the results obtained could have been different.

There are several strengths to our present study. The NIS is the largest all-payer inpatient health care database in the United States, and it is uniquely equipped to capture all IHPS hospitalizations across the United States irrespective of payer or insurance status. Previous studies on IHPS in the United States had hitherto used databases limited to single states or a few states, which may not be nationally representative.\(^5,8,16–18\) Furthermore, the NIS is released each year, and this allows for the longitudinal analysis such as the trends in the incidence rate of IHPS and its associated resource use over time. To our knowledge, the current study is the first to provide national-level data on hospital cost for the management of IHPS in the United States.

**CONCLUSIONS**

The cumulative incidence rate of IHPS in the United States declined from 1.76 to 1.57 per 1000 live births between 2012 and 2016. The incidence rate of IHPS varied by race, SES, sex, and geographic region. The LOS for IHPS remained low at 2 days without any significant change during the study period. Similarly, the cost of hospitalization remained stable.

**Acknowledgments**

We acknowledge HCUP, sponsored by the Agency for Healthcare Research and Quality, Rockville, Maryland, and its partner organizations that provide data to the HCUP. A list of all HCUP data partners is available at https://www.hcup-us.ahrq.gov/db/hcupdatapartners.jsp.

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