# Neonatal Cleft Lip Repair in the United States: Trends and Safety Using NSQIP

*2024 Orthodontic Faculty Development Fellowships (OFDFA)*

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# FollowUp Form

## *Award Information*

*In an attempt to make things a little easier for the reviewer who will read this report, please consider these two questions before this is sent for review:*

- *Is this an example of your very best work, in that it provides sufficient explanation and justification, and is something otherwise worthy of publication? (We do publish the Final Report on our website, so this does need to be complete and polished.)*
- *Does this Final Report provide the level of detail, etc. that you would expect, if you were the reviewer?*

### Title of Project*

Neonatal Cleft Lip Repair in the United States: Trends and Safety Using NSQIP

### Award Type

Orthodontic Faculty Development Fellowship Award (OFDFA)

### Period of AAOF Support

July 1, 2024 through June 30, 2025

### Institution

The Board of Trustees of the University of Illinois

### Names of principal advisor(s) / mentor(s), co-investigator(s) and consultant(s)

Veerasathpurush Allareddy, Maysaa Oubaidin, Flavio Sanchez, Mohammed Elnagar, Soumya Padala

### Amount of Funding

$30,000.00

### Summary/Abstract*

(Referring to your original abstract, summarize the findings of your project)

Cleft lip repair is a crucial procedure that restores both form and function, esthetics and feeding, in babies born with cleft lip with or without cleft palate. Due to the risks of general anesthesia, surgeons defer the procedure until patients are 3 to 5 months old. As neonatology and pediatric anesthesia advanced, earlier surgery in neonates has become possible. Earlier surgery may help caregivers bond with their newborns,

normalize growth and development for patients, and result in less scarring and thus better surgical outcomes. This proposal aims to identify recent trends in neonatal cleft lip repair and to examine complication rates and hospital outcomes using the American College of Surgeons National Surgical Quality Improvement Program Pediatric (ACS NSQIP Pediatric). The 2012-2021 pediatric patient user files, which include de-identified data on patients undergoing surgeries across participating hospitals in the United States, will be used to identify all patients under 12 months of age who underwent primary repair of cleft lip. This study aims to (1) identify trends in neonatal cleft lip repair in the United States over the 10-year period and to (2) examine if age of patient and a mix of patient related factors are associated with 30-day post-surgical outcomes such as length of hospital stay, operation time, and occurrence of complications. Artificial intelligence techniques or machine learning models that effectively process the big datasets will be developed to better adjust for patient level factors to identify risk factors for complications and related outcomes following neonatal cleft lip repair.

Comment: *Include the abstract of the OFDFA proposal in the allotted space.*

# *Respond to the following questions:*

## Detailed results and inferences:*

If the work has been published, please attach a pdf of manuscript below by clicking "Upload a file".
<u>OR</u>
Use the text box below to describe in detail the results of your study. The intent is to share the knowledge you have generated with the AAOF and orthodontic community specifically and other who may benefit from your study. Table, Figures, Statistical Analysis, and interpretation of results should also be attached by clicking "Upload a file".

kanwal-et-al-2025-association-between-cleft-lip-and-or-palate-and-hospitalization-outcomes-among-newborns-in-the-united.pdf
Research: The study has been completed and published in the Cleft Palate and Craniofacial Journal (please see the attached manuscript). We found that there were over 15,000 hospitalizations involving newborns with the diagnosis of cleft lip and/or palate (CLP) in 2020 to 2022 across the United States. Length of stay, hospital charges, and mortality were significantly higher among the newborns with CLP compared to those without CLP, even after controlling for confounders. Our findings prompt cleft providers to weigh the risks of surgical cleft lip repair in the first four weeks of life against potential benefits.

Teaching: At the institutional level, I served as the sole course director for Craniofacial Anomalies for orthodontic and pediatric dentistry residents. I expanded the ABO clinical exam prep course for orthodontic residents and met with each resident throughout the year to simulate the clinical exam, systematically preparing the graduating class for their board exam toward full certification. I continued to serve on the planning committee for the Annual International Graber Symposium and developed programs for the 4th, 5th, and now the 6th symposium in 2026. For any classes or lectures that I delivered, I sought and received peer evaluations from other faculty members. In addition, I met with my mentor bi-weekly to seek advice on my performance and to discuss areas for improvement and career trajectory.

Education: As a healthcare outcomes researcher, I have been using big data analytic techniques to examine large, publicly available databases. To further develop my research skills in big data analysis, I enrolled in the MIT Sloan School of Management's online short course titled Artificial Intelligence (AI) in Health Care. This course widened my knowledge on the AI techniques, such as machine learning, that have been developed in cutting-edge translational research and how AI can be applied in all areas of health care delivery. The certificate program, "AI in Health Care: From Strategies to Implementation" from the Harvard Medical School Executive Education helped me examine the existing AI systems in health care and how AI can be applied in the future to improve patient outcomes while maintaining security and ethical guidelines. In addition to classroom learning, I attended regional and international meetings such as the Midwestern Society of Orthodontists Annual Session and the AAO Annual Session to enhance clinical judgment and skills.

Clinic: I have continued to supervise craniofacial and other complex cases at the postgraduate orthodontic clinic at University of Illinois Chicago. In addition, I am part of the combined OMFS-Orthodontic case discussion meetings held once a month on average for multidisciplinary treatment planning of surgical cases. Through the AAO Annual Session and the International Graber Symposiums, I expanded my knowledge in the clinical orthodontics.

The research, teaching, educational, and clinical skills obtained through the OFDFA were invaluable in achieving an important career milestone: successfully obtaining tenure as of July 2026.

Comment: *OFDFA has several objectives at the research, teaching, educational, and clinical levels. The attached article only reports the research achievements. Please describe the accomplishments in the other areas that were made possible due to the fellowship.*

*Please list the accomplishments in all areas that were made possible due to the fellowship. Do not restrict the final report to research accomplishments only.*

## Were the original, specific aims of the proposal realized?*

We realized the original specific aims of the proposal with some modifications. We had intended to use the American College of Surgeons National Surgical Quality Improvement Program Pediatric (ACS NSQIP Pediatric). We were not able to obtain the data. We obtained the National Inpatient Sample, which is the largest inpatient database available in the United States. We used the latest three years of datasets (2020-2022) largely due to the major change in the practice of medicine nationally, i.e. the launch of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) in coding and classifying medical diagnoses and procedures. Using the NIS, we were able to identify short-term trends in neonatal cleft lip repair in the United States and examine association between the age of patient and a mix of patient related factors with outcomes such as length of hospital stay, charges and in-hospital mortality.

## Were the results published?*

Yes

## Have the results of this proposal been presented?*

Yes

## To what extent have you used, or how do you intend to use, AAOF funding to further your career?*

The support from AAOF has helped me become productive in all areas of my career, including research, teaching, clinic, and service. In the realm of research, the funding has led to the publication of an article in the Cleft Palate and Craniofacial Journal, presentation at the 2026 Annual AAO Meeting. The funding from the AAOF has supported research personnel who, in turn, will start their dental school education and residency program, thanks to their productive involvement in the research project.

### Accounting: Were there any leftover funds?

$18.31

## *Published*

### Citations*

You indicated results have been published. Please list the cited reference/s for publication/s including titles, dates, author or co-authors, journal, issue and page numbers

Kanwal B, Allareddy V, Han MD, Elnagar MH, Ahn G, Vogel S, Venugopalan SR, Oubaidin M, Lee MK. Association Between Cleft Lip and or Palate and Hospitalization Outcomes Among Newborns in the United States. Cleft Palate Craniofac J. 2025 Oct 27:10556656251388715. doi: 10.1177/10556656251388715. Epub ahead of print. PMID: 41143988.Y

### Was AAOF support acknowledged?

If so, please describe:

Yes. The AAOF grant was listed as a funding source on the manuscript under "Funding."

## *Presented*

### Please list titles, author or co-authors of these presentation/s, year and locations:*

Title:  Hospitalization Outcomes Following Cleft Lip Repair Among Neonates in the United States
Authors: Bushra Kanwal, Veerasathpurush Allareddy , Maysaa Oubadin, Michael Han, Vaibhav Gandhi, Sofie Vogel, Gloria Ahn , Min Kyeong Lee
2026 AAO Annual Meeting, Orlando, FL (e-poster presentation)

Title: Systemic Health Complications and Adverse Events in those Hospitalized with CLP.
Authors: Maysaa Oubaidin, Sofie Vogel, Gloria Ahn, Michael Han, Min Kyeong Lee MK, Veerasathpurush Allareddy.
2026 AAO Annual Meeting, Orlando, FL (e-poster presentation)

### Was AAOF support acknowledged?

If so, please describe:

Yes, the support from AAOF was mentioned in our manuscript and poster presentations.

# *Internal Review*

## Reviewer comments

Please list the accomplishments in all areas that were made possible due to the fellowship. Do not restrict the final report to research accomplishments only.

## Reviewer Status*

Incomplete (needs more information)

# File Attachment Summary

## *Applicant File Uploads*

- kanwal-et-al-2025-association-between-cleft-lip-and-or-palate-and-hospitalization-outcomes-among-newborns-in-the-united.pdf

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# Association Between Cleft Lip and or Palate and Hospitalization Outcomes Among Newborns in the United States

**Bushra Kanwal, BDS, MDS, MOrth, RCSEd, FOrth, RCSEd[1], Veerasathpurush Allareddy, BDS, MBA, MHA, PhD, MMSc[1], Michael D. Han, DDS, MD[2], Mohammed H. Elnagar, DDS, MS, PhD[1], Gloria Ahn, DDS[1], Sofie Vogel, BS[1], Shankar R. Venugopalan, DDS, DMSc, PhD[3], Maysaa Oubaidin, DDS, MS[1], and Min Kyeong Lee, DMD, DMSc[1]**

**Abstract**

**Objective:** To examine the association between the occurrence of cleft lip and/or palate (CLP) in newborns (compared to newborns without CLP) and in-hospital outcomes such as mortality, length of stay (LOS), and hospital charges.
**Design:** Retrospective study.
**Setting:** National.
**Patients:** The National Inpatient Sample database for the years 2020-2022 was used in the present study. All newborns were included in the study. They were grouped into newborns born with CLP and newborns without CLP.
**Interventions:** None.
**Main outcome variable:** In-hospital mortality, LOS, and hospital charges. Multivariable regression models were used to examine outcomes.
**Results:** Of 10,422,242 newborn hospitalizations in 2020 through 2022, 15,300 were diagnosed with cleft lip and/or palate (CLP). During this period, the in-hospital mortality rate was significantly higher among newborns with CLP (3.9%) compared to those without CLP (0.03%). Hospitalization charges for newborns with CLP were substantially higher than those without CLP (mean charges of $106,617 versus $22,671). The average LOS in those with CLP was 10.5 days compared to 3.4 days in those without CLP. In-hospital mortality, LOS, and hospital charges were significantly higher in newborns with CLP compared to those without CLP after controlling for potential confounders ($P < .001$).
**Conclusions:** The overall incidence rate of CLP among hospitalized newborns was 1.468 per 1000 newborns during the study period. Following controlling for a variety of patient and hospital-related variables, in-hospital mortality rate, LOS, and hospital charges were significantly higher among newborns with CLP compared to those without CLP.

**Keywords**
cleft lip and/palate, incidence, mortality

## Introduction

Cleft lip and/or palate (CLP) is among the most common congenital anomalies worldwide, with significant variation in prevalence across geographic regions.[1,2] These orofacial clefts are associated with numerous health challenges, including difficulties with feeding, growth, speech, cognitive development, and behavior. Management typically requires coordinated, long-term care involving surgical, medical, nutritional, dental, and psychosocial interventions, beginning in infancy and often extending into adulthood.[3]

Newborns with CLP who also present with additional congenital anomalies exhibit significantly higher mortality rates than those without associated conditions.[4,5] Even in the absence of other anomalies, infants with CLP face a higher risk of neonatal and infant mortality compared to those without

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CLP.[4,6] This elevated risk is compounded by increased hospital admission rates, longer hospital length of stay (LOS) than older groups like infants, and significantly higher hospitalization costs.[7,8] The financial burden on families and the healthcare system is substantial, due not only to direct medical expenses but also to indirect costs such as lost parental productivity and long-term care requirements.

Previous research[7,8] has examined racial, ethnic, and regional variations in the prevalence of CLP; however, no study to date has investigated how these demographic factors relate to in-hospital mortality, hospital charges, and LOS among newborns with and without CLP. Additionally, while several studies[8–11] have assessed the long-term treatment costs associated with treatment of CLP, there is a lack of focused research on hospitalization costs incurred during the newborn period, which is a critical time for medical intervention.

Understanding the early healthcare utilization patterns and associated costs for newborns with CLP is essential for shaping policies and clinical practices aimed at ensuring timely, equitable, and effective care. This information is crucial for developing targeted public health strategies and resource allocation plans that address the lifelong healthcare needs of individuals born with CLP. The aim of this study is to examine the association between the presence of CLP and hospitalization outcomes such as in-hospital mortality, length of stay in hospital, and hospitalization charges.

## Materials and Methods

**Description of Database**: The National Inpatient Sample (NIS) for the years 2020 to 2022 was used for the current study. The NIS is one of the component databases of the Healthcare Cost and Utilization Project (HCUP) of Agency for Healthcare Research and Quality (AHRQ). It was developed to conduct health outcomes, costs, and access to care analyses to help with health policy decision making. The NIS provides information on close to 30 million hospitalizations each year across the entire United States and has information on over 200 patient and hospital-related variables. All patient encounters during a hospitalization are captured in the database.[12] These datasets provide valuable sources for capturing rare conditions or diseases and adverse events that would not be possible with smaller datasets. The NIS provides information on several patient-level variables, including age, sex, race, insurance status, primary reason for hospitalizations, co-morbid burden, procedures performed during hospitalization, type of admission, disposition status, hospitalization charges, and LOS. The NIS has been specifically designed to facilitate health outcomes and economic research. Each discharge or hospitalization in the NIS has a discharge weight that can be used to project all estimates to national levels.

**Selection of Cases**: The ICD-10-CM Birth Indicator variable was used to select all hospitalizations that indicated birth of a newborn during the years 2020 to 2022. Both planned (elective) and unplanned (emergency or urgent) admissions were included in the study. In this cohort, those with CLP were identified using ICD-10-CM codes in the 40 diagnosis fields of the NIS dataset.[13] The ICD-10-CM codes used to identify those with CLP are listed in Table 1. The follow-up period for each of the hospitalization was their duration of stay in the hospital. Data was obtained from AHRQ-HCUP following completion of data user agreement. The study was granted IRB exempt status.

**Study Outcomes**: The primary outcomes of interest in the present study included: disposition status of newborn (died in hospital versus other disposition status), LOS, and hospital charges. Hospital charges were adjusted to the 2022 $ value using the Bureau of Labor Statistics Inflation Calculator for Medical Care.[14] In the analytical models, in-hospital mortality was coded as a binomial variable while LOS and hospital charges were log-transformed due to their highly skewed distribution.

**Independent Variables**: The primary independent variable of interest was: born with a CLP and the comparison group was those newborns without a CLP. Other independent variables (co-variates) whose effects were adjusted in the regression models included: birth indicator (diagnosis reported as born in a hospital versus others), year of birth, sex, race, type of admission (elective versus emergency/urgent), geographic region of hospital, and hospital location/teaching status. Based on the description provided by HUCP-AHRQ, a hospital is considered a teaching hospital if it has one or more Accreditation Council for Graduate Medical Education-approved residency programs, is a member of the Council of Teaching Hospitals, or has a ratio of full-time equivalent interns and residents to beds of .25 or higher.[12] All the independent variables were included based on prior literature that has examined the impact of various patient- and hospital-level factors on outcomes such as in-hospital mortality, length of stay in hospital, and hospitalization charges.[5,7–9]

**Analytical Approach**: Simple descriptive statistics were computed to summarize the data. The NIS stratum variable was used as the "stratum," the unique code assigned to a hospital was used as the "cluster," and the discharge weight for each hospitalization was used as the "weight" variable to project to national levels. To quantify the impact of a newborn having a CLP on outcomes, three different multivariable regression models were used. For in-hospital mortality, a multivariable logistic regression model was used. The simultaneous effects of all independent variables on in-hospital mortality were examined. Odds ratios and 95% confidence intervals (95% CI) were computed for each level of independent variable. Clustering of outcomes is a common issue while using large datasets. Clustering is typically present at the hospital level, i.e., a group of patients having treatment at a hospital have similar outcomes, probably due to commonalities in processes of care at that particular hospital. Clustering of outcome effects needs to be adjusted in the regression models so that variances, which are used to compute the 95% confidence intervals are accurate. If clustering is not adjusted, the error terms are not accurate. The effects of clustering of outcomes were adjusted in all three multivariable regression models. Variances were computed using a Taylor linearization method

**Table 1.** Types of Clefts Among the CLP Cohort.

| Type of cleft (ICD-10-CM code) | | Total $N = 15{,}300$ |
|---|---|---|
| Cleft palate (Q35) $N = 5{,}815$ | Cleft hard palate (Q35.1) | 455 (3%) |
| | Cleft soft palate (Q35.3) | 1,665 (10.9%) |
| | Cleft hard palate with soft palate (Q35.5) | 460 (3%) |
| | Cleft uvula (Q35.7) | 430 (2.8%) |
| | Cleft palate, unspecified (Q35.9) | 2,895 (18.9%) |
| Cleft lip (Q36) $N = 3{,}025$ | Cleft lip, bilateral (Q36.0) | 205 (1.3%) |
| | Cleft lip, median (Q36.1) | 35 (0.2%) |
| | Cleft lip, unilateral (Q36.9) | 2,785 (18.2%) |
| Cleft palate with cleft lip (Q37) $N = 6{,}525$ | Cleft hard palate with bilateral cleft lip (Q37.0) | 90 (0.6%) |
| | Cleft hard palate with unilateral cleft lip (Q37.1) | 260 (1.7%) |
| | Cleft soft palate with bilateral cleft lip (Q37.2) | 50 (0.3%) |
| | Cleft soft palate with unilateral cleft lip (Q37.3) | 195 (1.3%) |
| | Cleft hard and soft palate with bilateral cleft lip (Q37.4) | 410 (2.7%) |
| | Cleft hard and soft palate with unilateral cleft lip (Q37.5) | 700 (4.6%) |
| | Unspecified cleft palate with bilateral cleft lip (Q37.8) | 1,430 (9.3%) |
| | Unspecified cleft palate with unilateral cleft lip (Q37.9) | 3,450 (22.5%) |

*Note.* The sum of individual cell counts may not add up to the global total of 15,300, since in some hospitalizations, more than one code might have been recorded. The sum of cleft palate ($N = 5{,}815$), Cleft lip ($N = 3{,}025$), and cleft palate with cleft lip ($N = 6{,}525$) is 15,365. These cases were recorded in 15,300 births. Consequently, in 65 births, more than 1 type of cleft was recorded.

assuming a with replacement design. For hospital charges and LOS, the log-transformed values were modeled as the dependent variables in the multivariable linear regression models. Taylor series with replacement method was used for estimating the variances and Robust Binder method was used for estimating the standard errors in the two linear regression models. For all three models, the stratification variable was the NIS stratum and the primary sampling unit was each individual hospitalization. In all three models, the potential confounding effects of place of birth, year of birth, sex, type of admission, race, geographic region of hospital, and location/teaching status of hospital were adjusted. All statistical tests were two-sided, and a $P$-value of <.05 was deemed to be statistically significant. Statistical analyses were conducted using SAS Version 9.4 (Cary, NC) and SAS Callable SUDAAN Version 11.0.3 (Research Triangle Institute, NC).

## Results

During the years 2020 to 2022, a total of 10,422,242 newborns were accounted in the NIS database (Table 2). Of these, 15,300 had a diagnosis of CLP. The characteristics of newborns with and without CLP are presented in Table 2. The vast majority (over 99%) of newborns were reported as "born in a hospital." Over 55% of newborns with CLP were male (compared to 51.1% of newborns without a CLP). 56.2% of newborns with a CLP were White (compared to 50.7% of newborns without a CLP). Nearly all (99.8%) newborns both with and without CLP were admitted on an emergency/urgent basis. Close to 40% of all newborn admissions were in the Southern United States. 79.8% of newborn hospitalizations with a CLP occurred in urban teaching hospitals (compared to 75.5% without CLP).

The different types of clefts are presented in Table 1. Cleft palate with cleft lip occurred in 6,525 newborns while cleft lip only occurred in 3,025 newborns and cleft palate only occurred in 5,815 newborns. Sixty-five newborns had recorded more than one type of cleft. Overall, 48.3% of the total clefts were unilateral.

Disposition status information, hospitalization charges, and LOS are presented in Table 3. Approximately 78% of newborns with a CLP were discharged routinely (compared to 96.8% of all newborns without a CLP). Six hundred newborns with CLP expired in the hospital. The mortality rate in newborns with a CLP was 3.9% compared to 0.3% in newborns without a CLP. Close to 13% of newborns with CLP were transferred to another short-term hospital for in-patient care versus 1.7% of newborns without a CLP.

The mean hospitalization charges (inflation adjusted to 2022 United States $ value) for newborns with CLP ranged from $93,161 (in 2020) to $114,049 (in 2022) (Table 3). The mean hospitalization charges for newborns without a CLP ranged from $21,777 (in 2020) to $23,132 (in 2022). The mean LOS for newborns with a CLP ranged from 9.9 days (in 2020) to 10.9 days (in 2022). The mean LOS for newborns without a CLP was 3.4 days across all years. Among the CLP cohort, across all years, those with a cleft palate only had the highest mean hospitalization charges and LOS followed by those with cleft palate with cleft lip, and those with cleft lip only (Table 3).

The summary of estimates from the multivariable logistic regression model examining the simultaneous effects of all independent variables on in-hospital mortality are presented in Table 4. The primary independent variable was born with or without CLP. Newborns with CLP were associated with a significantly higher odds of in-hospital mortality compared to newborns without a CLP (odds ratio [OR] = 15.59, 95% CI = 12.94-18.79, $P < .001$) after adjusting for all confounding factors. Newborns reported as "born in a hospital" were associated

**Table 2.** Descriptive Characteristics.

| Characteristic | | All newborns excluding those with CLP $N =$ 10,406,942 | Newborns with CLP: Any of cleft lip, cleft palate or cleft palate with cleft lip (CLP) $N = 15{,}300$[a] | Cleft lip $N = 3{,}025$ [a] | Cleft palate $N = 5{,}815$ [a] | Cleft palate with cleft lip $N = 6{,}525$ [a] |
|---|---|---|---|---|---|---|
| Birth indicator | Birth diagnosis reported on record, born in a hospital | 10,373,503 (99.6%) | 15,195 (99.3%) | 3,005 (99.3%) | 5,775 (99.3%) | 6,480 (99.3%) |
| | Birth diagnosis reported on record, born outside hospital | 32,775 (0.3%) | 105 (0.7%) | 20 (0.7%) | 40 (0.7%) | 45 (0.7%) |
| | Birth diagnosis reported on record, unspecified as to place of birth | 665 (<0.001%) | 0 | 0 | 0 | 0 |
| Year of birth | 2020 | 3,442,246 (33.1%) | 5,065 (33.1%) | 990 (32.7%) | 1,910 (32.8%) | 2,205 (33.8%) |
| | 2021 | 3,479,877 (33.4%) | 5,185 (33.9%) | 1,120 (37%) | 1,950 (33.5%) | 2,130 (32.6%) |
| | 2022 | 3,484,820 (33.5%) | 5,050 (33%) | 915 (30.2%) | 1,955 (33.6%) | 2,190 (33.6%) |
| Sex | Data available for $N =$ | 10,400,588 | 15,290 | 3,025 | 5,815 | 6,515 |
| | Male | 5,316,339 (51.1%) | 8,485 (55.5%) | 1,920 (63.5%) | 2,600 (44.7%) | 3,990 (61.2%) |
| | Female | 5,084,249 (48.9%) | 6,805 (44.5%) | 1,105 (36.5%) | 3,215 (55.3%) | 2,525 (38.8%) |
| Race | Data available for $N =$ | 9,344,418 | 13,925 | 2,690 | 5,305 | 5,990 |
| | White | 4,736,005 (50.7%) | 7,825 (56.2%) | 1,645 (61.1%) | 3,035 (57.2%) | 3,185 (53.2%) |
| | Black | 1,377,804 (14.7%) | 1,550 (11.1%) | 260 (9.7%) | 615 (11.6%) | 675 (11.3%) |
| | Hispanic | 1,972,259 (21.1%) | 2,725 (19.6%) | 414 (15.4%) | 940 (17.7%) | 1,380 (23%) |
| | Asian or Pacific Islander | 511,315 (5.5%) | 595 (4.3%) | 115 (4.3%) | 275 (5.2%) | 215 (3.6%) |
| | Native American | 66,475 (0.7%) | 180 (1.3%) | 35 (1.3%) | 45 (0.8%) | 100 (1.7%) |
| | Other races | 680,560 (7.3%) | 1,050 (7.5%) | 220 (8.2%) | 395 (7.4%) | 435 (7.3%) |
| Type of admission | Data available for $N =$ | 12,403,147 | 15,270 | 3,025 | 5,795 | 6,515 |
| | Emergency/Urgent | 10,387,387 (99.8%) | 15,245 (99.8%) | Discharge information cannot be presented since "elective" status individual cell counts are <=10 | | |
| | Elective | 15,760 (0.2%) | 25 (0.2%) | | | |
| Geographic region | Northeast | 1,683,458 (16.2%) | 2,130 (13.9%) | 440 (14.5%) | 920 (15.8%) | 775 (11.9%) |
| | Midwest | 2,165,036 (20.8%) | 3,345 (21.9%) | 750 (24.7%) | 1,195 (20.5%) | 1,410 (21.6%) |
| | South | 4,154,539 (39.9%) | 6,365 (41.6%) | 1,105 (36.5%) | 2,465 (42.4%) | 2,835 (43.4%) |
| | West | 2,403,909 (23.1%) | 3,460 (22.6%) | 730 (24.1%) | 1,235 (21.2%) | 1,505 (23.1%) |
| Hospital location and teaching status | Rural | 891,906 (8.6%) | 1,070 (7%) | 270 (8.9%) | 405 (7%) | 400 (6.1%) |
| | Urban non-teaching | 1,659,594 (15.9%) | 2,015 (13.2%) | 450 (14.9%) | 815 (14%) | 755 (11.6%) |
| | Urban teaching | 7,855,443 (75.5%) | 12,215 (79.8%) | 2,305 (76.2%) | 4,595 (79%) | 5,370 (82.3%) |

[a]The sum of individual cell counts may not add up to the global total of 15,300, since in some hospitalizations, more than one code might have been recorded. The sum of cleft palate ($N = 5{,}815$), cleft lip ($N = 3{,}025$), and cleft palate with cleft lip ($N = 6{,}525$) is 15,365. These cases were recorded in 15,300 births. Consequently, in 65 births, more than 1 type of cleft was recorded.

with lower odds for in-hospital mortality compared to those "born outside hospital or unspecified as to place of birth" (OR = 0.20, 95% CI = 0.16-0.24, $P < .001$). Female newborns were associated with lower odds for in-hospital mortality compared to males (OR = 0.88, 95% CI = 0.84-0.93, $P < .001$). Newborns admitted on an elective basis had higher odds for in-hospital mortality (odds ratio = 1.91, 95% CI = 1.17-3.10, $P = .01$). Blacks (OR = 2.17, 95% CI = 2.00-2.36, $P < .001$), Hispanics (OR = 1.15, 95% CI = 1.05-1.26, $P < .001$), Native Americans (OR = 1.48, 95% CI = 1.03-2.12, $P = .03$), and other races (OR = 1.63, 95% CI = 1.45-1.84, $P < .001$) had higher odds for in-hospital mortality compared to whites. Newborns in the Northeast had a lower odds for mortality (OR = 0.79, 95% CI = 0.69-0.90, $P < .001$) while newborns in the Southern region had a higher odds for mortality (OR = 1.30, 95% CI = 1.18-1.44, $P < .001$) compared to newborns in Western region of the country. Newborns in rural (OR = 0.40, 95% CI = 0.34-0.47, $P < .001$) and urban non-teaching hospitals (OR = 0.44, 95% CI = 0.39-0.49, $P < .001$) had lower odds of mortality compared to urban teaching hospitals.

The summary of estimates from the multivariable linear regression model examining factors associated with LOS are presented in Table 5. The outcome variable (LOS) was log-transformed due to the skewed distribution and the log-transformed LOS was used as the dependent variable in the model. The primary independent variable was born with or without CLP. Positive estimates indicate a longer LOS, while negative estimates indicate a shorter LOS compared to the reference group. After adjusting for all variables, newborns with a CLP had significantly longer LOS compared to newborns without a CLP (Estimate = 0.6498, 95% CI =

**Table 3.** Outcomes (Disposition Status, Hospitalization Charges, and Length of Stay in Hospital).

| Outcomes | | All newborns excluding those with CLP data available for $N = 10,406,233$ | Newborns with CLP $N = 15,295$ | Cleft lip $N = 3,025$ | Cleft palate $N = 5,815$ | Cleft palate with cleft lip $N = 6,525$ |
|---|---|---|---|---|---|---|
| Disposition status following hospitalization | | | | | | |
| Routine discharge | | 10,074,368 (96.8%) | 11,960 (78.2%) | 2,805 (92.7%) | 4,185 (72%) | 5,025 (77%) |
| Transferred to a short-term hospital for inpatient care | | 177,765 (1.7%) | 1,975 (12.9%) | 90 (3%) | 1,115 (19.2%) | 770 (11.8%) |
| Other transfers: includes skilled nursing facility (SNF), intermediate care facility (ICF), another type of facility | | 12,825 (0.1%) | 185 (1.2%) | DS | 85 (1.5%) | 95 (1.5%) |
| home health care | | 110,265 (1.1%) | 575 (3.8%) | 75 (2.5%) | 270 (4.6%) | 235 (3.6%) |
| Discharged against medical advice | | 4,360 (0.04%) | 0 | DS | 0 | 0 |
| Died in hospital | | 26,650 (0.3%) | 600 (3.9%) | 40 (1.5%) | 160 (2.7%) | 400 (6.1%) |
| Hospitalization charges and length of stay in hospital | | | | | | |
| Mean hospital Charges, adjusted | 2020 | $21,777 (685) | $93,161 (10,374) | $36,363 (7759) | $139,909 (19,370) | $77,560 (14,994) |
| to year 2022 $ Value (standard error of mean) | 2021 | $23,093 (705) | $112,394 (12,250) | $36,049 (8135) | $149,069 (17,831) | $120,132 (21,413) |
| | 2022 | $23,132 (757) | $114,049 (15,138) | $69,947 (26,093) | $154,527 (22,160) | $96,266 (16,908) |
| Length of stay in hospital (standard error of mean) | 2020 | 3.4 days (0.04) | 9.9 days (0.74) | 5.1 days (0.74) | 13.4 days (1.25) | 8.9 days (1.12) |
| | 2021 | 3.4 days (0.04) | 10.6 days (0.78) | 5 days (0.93) | 14.5 days (1.42) | 10.2 days (1.19) |
| | 2022 | 3.4 days (0.04) | 10.9 days (0.91) | 6 days (1.10) | 15.6 days (1.59) | 8.8 days (1.01) |

DS = discharge information cannot be presented since some individual cell counts are <=10 (per data user agreement with HCUP-AHRQ)

**Table 4.** Predictors of In-hospital Mortality (Multivariable Logistic Regression Analysis).

| Characteristic | | Odds ratio (95% CI) | *P*-value |
|---|---|---|---|
| Born with a cleft lip and/or palate | Yes | 15.59 (12.94-18.79) | <.001 |
| | No | Reference | |
| Birth indicator | Birth diagnosis reported on record, born in a hospital | 0.20 (0.16-0.24) | <.001 |
| | Birth diagnosis reported on record, born outside hospital or unspecified as to place of birth | Reference | |
| Year of birth | 2020 | 1.01 (0.92-1.12) | .80 |
| | 2021 | 0.96 (0.87-1.06) | .41 |
| | 2022 | Reference | |
| Sex | Female | 0.88 (0.84-0.93) | <.001 |
| | Male | Reference | |
| Type of admission | Elective | 1.91 (1.17-3.10) | .01 |
| | Emergency/Urgent | Reference | |
| Race | Black | 2.17 (2.00-2.36) | <.001 |
| | Hispanic | 1.15 (1.05-1.26) | <.001 |
| | Asian/Pacific Islander | 0.93 (0.79-1.10) | .40 |
| | Native American | 1.48 (1.03-2.12) | .03 |
| | Other races | 1.63 (1.45-1.84) | <.001 |
| | Missing race information | 1.93 (1.74-2.15) | <.001 |
| | White | Reference | |
| Geographic region | Northeast | 0.79 (0.69-0.90) | <.001 |
| | Midwest | 1.05 (0.93-1.18) | .42 |
| | South | 1.30 (1.18-1.44) | <.001 |
| | West | Reference | |
| Hospital location and teaching status | Rural | 0.40 (0.34-0.47) | <.001 |
| | Urban non-teaching | 0.44 (0.39-0.49) | <.001 |
| | Urban teaching | Reference | |

**Table 5.** Predictors of Length of Stay in Hospital (Multivariable Linear Regression Analysis).

| Characteristic | | Mean length of stay in hospital (in days) | Parameter estimate (95% CI) | *P*-value |
|---|---|---|---|---|
| Born with a cleft lip and/ or palate | Yes | 10.5 | 0.6498 (0.5996 to 0.7001) | <.001 |
| | No | 3.4 | Reference | |
| Birth indicator | Birth diagnosis reported on record, born in a hospital | 3.4 | −0.2500 (−0.2778 to −0.2223) | <.001 |
| | Birth diagnosis reported on record, born outside hospital or unspecified as to place of birth | 5.7 | Reference | |
| Year of birth | 2020 | 3.4 | 0.0062 (−0.0065 to 0.0189) | .34 |
| | 2021 | 3.4 | 0.0040 (−0.0089 to 0.0168) | .55 |
| | 2022 | 3.4 | Reference | |
| Sex | Female | 3.3 | −0.0431 (−0.0451 to −0.0411) | <.001 |
| | Male | 3.5 | Reference | |
| Type of admission | Elective | 5.4 | 0.1515 (0.0923 to 0.2108) | <.001 |
| | Emergency/urgent | 3.4 | Reference | |
| Race | Black | 4.5 | 0.1431 (0.1361 to 0.1500) | <.001 |
| | Hispanic | 3.2 | −0.0056 (−0.0141 to 0.0029) | .19 |
| | Asian/Pacific Islander | 3.1 | 0.0385 (0.0291 to 0.0479) | <.001 |
| | Native American | 3.7 | 0.1112 (0.0864 to 0.1361) | <.001 |
| | Other races | 3.6 | 0.0474 (0.0380 to 0.0567) | <.001 |
| | Missing race information | 3.2 | 0.0096 (−0.0014 to 0.0206) | .09 |
| | White | 3.2 | Reference | |
| Geographic region | Northeast | 3.5 | 0.1449 (0.1308 to 0.1590) | <.001 |
| | Midwest | 3.2 | 0.0720 (0.0570 to 0.0870) | <.001 |
| | South | 3.7 | 0.1275 (0.1144 to 0.1406) | <.001 |
| | West | 3.1 | Reference | |
| Hospital location and teaching status | Rural | 2 | −0.2067 (−0.2177 to −0.1957) | <.001 |
| | Urban non-teaching | 2.6 | −0.1056 (−0.1162 to −0.0949) | <.001 |
| | Urban teaching | 3.7 | Reference | |

0.5996-0.7001, $P < .001$). On average, those born with CLP had 10.5 days length of stay (compared to 3.4 days for those without CLP). Other significant independent variables associated with LOS included: birth indicator (place of birth), sex, type of admission, race, geographic region of hospital, and hospital location/ teaching status of hospital.

The summary of estimates from the multivariable linear regression model examining factors associated with hospital charges are presented in Table 6. Like LOS, hospital charges showed a skewed distribution, and the log-transformed hospital charges was used, with positive estimates indicating higher hospital charges while negative indicating lower charges compared to the reference group. After adjusting for all variables, newborns with CLP had significantly higher hospital charges compared to newborns born without CLP (Estimate = 0.9429 CI = 0.8759-1.0099, $P < .001$). The overall mean hospitalization charges for those with CLP were $106,617 (compared to $22,671 for those without a CLP). Other variables significantly associated with hospital charges included: place of birth, sex, type of admission, race, geographic region, and hospital location/teaching status.

## Discussion

This study provides nationally representative estimates of hospitalizations among newborns with and without CLP using the latest available datasets, with a focus on mortality and healthcare resource-related factors. Several notable findings were observed. Epidemiologically, our data showed some differences compared to other studies, most notably, a lower incidence of CLP of 1.468 per 1,000 newborns. In a study analyzing 14 population-based birth defect registries, CLP was identified as the second most common congenital anomaly after Down syndrome, and the adjusted prevalence of CLP was approximately 10.63 per 10,000 live births (about 1 in 940) between 2004 and 2006.[15] A study analyzing 13 US-based population birth registries from 2016 to 2020, cleft lip and palate was the fourth most common birth defect with a prevalence of 9.69 per 10,000 live births, after clubfoot, trisomy 21 (Down syndrome) and pulmonary valve atresia stenosis.[16] Another study of a sample from up to 41 registries in the United States showed CLP prevalence ranging from 7.2 to 7.9 per 10,000 live births from 2006 to 2018.[17] On the other hand, epidemiologic data from the 2008 NIS database showed national estimates of 5.87 per 10,000 live births. This highlights the variability based on different databases and time periods. Moreover, Egbe's study[18] using the same NIS database did not include subjects whose racial category was "Other," or missing, which accounted for 1,365 subjects with CLP in this study. This suggests variations attributable to methodological and time variations across studies, and also highlights the

**Table 6.** Predictors of Hospital Charges, Adjusted to Year 2022 Levels (Multivariable Linear Regression Analysis).

| Characteristic | | Mean hospital charges | Parameter estimate (95% CI) | *P*-value |
|---|---|---|---|---|
| Born with a cleft lip and/or palate | Yes | $106,617 | 0.9429 (0.8759 to 1.0099) | <.001 |
| | No | $22,671 | Reference | |
| Birth indicator | Birth diagnosis reported on record, born in a hospital | $22,723 | −0.4201 (−0.4577 to −0.3826) | <.001 |
| | Birth diagnosis reported on record, born outside hospital or unspecified as to place of birth | $44,750 | Reference | |
| Year of birth | 2020 | $21,881 | −0.0738 (−0.1141 to −0.0335) | <.001 |
| | 2021 | $23,225 | −0.0139 (−0.0548 to 0.0270) | .51 |
| | 2022 | $23,264 | Reference | |
| Sex | Female | $21,180 | −0.1708 (−0.1757 to −0.1659) | <.001 |
| | Male | $24,339 | Reference | |
| Type of admission | Elective | $74,218 | 0.3867 (0.0932 to 0.6802) | .01 |
| | Emergency/urgent | $22,612 | Reference | |
| Race | Black | $30,619 | 0.1837 (0.1662 to 0.2013) | <.001 |
| | Hispanic | $23,782 | 0.0225 (0.0033 to 0.0417) | .02 |
| | Asian/Pacific Islander | $24,568 | 0.0959 (0.0703 to 0.1215) | <.001 |
| | Native American | $23,094 | 0.1439 (0.0899 to 0.1979) | <.001 |
| | Other races | $30,647 | 0.1157 (0.0821 to 0.1492) | <.001 |
| | Missing race information | $17,668 | −0.0520 (−0.0789 to −0.0251) | <.001 |
| | White | $19,907 | Reference | |
| Geographic region | Northeast | $28,470 | 0.2987 (0.2420 to 0.3554) | <.001 |
| | Midwest | $17,473 | −0.0740 (−0.1107 to −0.0373) | <.001 |
| | South | $22,038 | −0.1419 (−0.1791 to −0.1047) | <.001 |
| | West | $24,900 | Reference | |
| Hospital location and teaching status | Rural | $6083 | −0.5032 (−0.5314 to −0.4750) | <.001 |
| | Urban non-teaching | $14,133 | −0.1466 (−0.1788 to −0.1145) | <.001 |
| | Urban teaching | $26,553 | Reference | |

comprehensive methodology of this study. CLP consistently ranks among the most prevalent craniofacial anomalies documented in the literature,[2,19] despite this diversity. These findings need to be carefully interpreted by researchers and policymakers to inform funding decisions, healthcare planning, and resource allocation for CLP care.

Among the newborns diagnosed with CLP, our study findings align with previous literature, which consistently report the highest prevalence among males,[10,20,21] White infants,[7,17,22,23] those born in the Southern region of the United States,[8] and who seek care in urban teaching hospital settings.[7,8,22] These demographic patterns underscore the importance of targeted public health strategies and resource allocation to address regional and population-specific needs in the diagnosis, treatment, and long-term care of affected individuals.

Our study found that 0.03% of newborns without CLP died in the hospital, compared to a significantly higher in-hospital mortality rate of 3.9% among those with CLP (odds ratio = 15.59, 95% CI = 12.94-18.79, $P < .001$). A meta-analysis from 2013 reported that infants with CLP anomalies exhibit a higher infant mortality rate than those born without CLP.[5] Multiple medical complications, such as feeding problems, surgery-related events, airway management and infections, congenital defects and chromosomal anomalies, and preterm birth often contribute to these deaths.[5,24–26] Although the exact causes of in-hospital deaths cannot be determined from the nature of the study, we identified that having a diagnosis of CLP, born outside hospital, being male, elective admission, certain race or ethnic groups (Black, Hispanic, Native American), located in the Southern region and urban teaching hospitals are independently associated with higher odds of mortality. Although the causation of increased mortality cannot be determined based on this study, awareness of these risk factors can allow implementation of measures to lessen mortality risk among neonates with CLP. These include reinforcement of screening and counseling of expectant families to identify potential complications associated with the birth and providing holistic prenatal care, as well as further analysis into healthcare resource utilization among different regions and hospital settings.

Although White newborns accounted for the highest proportion of births both with CLP (56.2%) and without CLP (50.7%), they experienced lower mortality rates compared to Black, Hispanic, and other racial/ethnic groups, consistent with the results published by Huang.[27] While the White population has been shown to have higher prevalence of overall birth defects compared to other races[18] this inverse relationship between CLP prevalence and mortality could suggest that factors beyond incidence, such as access to care, quality of treatment, and socio-demographic factors significantly influence health outcomes.[21]

Compared to the Western region, the Southern United States exhibited higher odds of infant mortality and a greater incidence of CLP, whereas the Northeast showed both lower mortality and lower CLP incidence. This could be partially attributed to the higher number of births overall, and of newborns with CLP in the South compared to the other regions. Additionally, hospital charges in the South and Midwest tended to be lower than those in the West, whereas the Northeast had the highest charges. Contributing factors may include differences in healthcare infrastructure, insurance coverage, hospital pricing practices, and socio-demographic conditions.[21,28] Future large-scale studies are needed to explore regional disparities influencing the hospitalizations patterns and the mortality rates in newborns.

Hospitalization outcomes for newborns with CLP underscore a substantial burden on the healthcare system compared to those without CLP.[29] These infants experience significantly longer LOS and higher hospitalization charges, particularly when presented with complications, associated congenital anomalies, and neonatal repair.[7,24,26] In our study, the financial burden was consistently elevated across all three years. In 2020, hospitalization charges for newborns with CLP averaged \$93,161, 4.2 times higher than the \$21,777 for those without CLP. This disparity increased in 2021, with charges reaching \$112,394 for CLP cases compared to \$23,093 (4.8 times higher), and continued in 2022 at \$114,049 versus \$23,132 (4.9 times higher). While the LOS remained relatively constant for newborns without CLP (approximately 3.3 days), it increased annually for those with CLP, from 9.9 days in 2020 to 10.6 days in 2021 and 10.9 days in 2022. Among the CLP cohort, those with a cleft palate only had higher mean hospitalization charges and LOS compared to those with cleft palate with cleft lip, and those with cleft lip only. While it is difficult to discern the exact reasons for differences in hospitalization charges and LOS among these groups, we could speculate that the severity of comorbid burden and hospital resource utilization might have been different. Beyond the clinical and direct financial burdens, these challenges also impose substantial indirect costs, including parental loss of work productivity, emotional strain, and potential educational disruptions for siblings. These findings highlight the broader societal impact of CLP beyond immediate medical care.

Teaching hospitals are associated with improved outcomes for patients who need complex elective care.[22] According to prior published studies,[30–32] teaching hospitals offer better quality of care in terms of reduced mortality rates, lower hospital readmission rates, better management of complications, better economics in terms of lower hospitalization charges or costs, and shorter durations of stay in the hospital. However, in our study, although highest number of hospitalizations occurred in urban teaching hospitals in cohorts (those with CLP and those without CLP), urban non-teaching and rural hospital locations had lesser in hospital mortality risk compared to urban teaching location. They also had reduced LOS and lesser hospital charges compared to teaching hospitals. This apparent contradiction may be explained by the fact that urban teaching hospitals are more likely to manage complex or high-risk cases, which could naturally result in higher observed mortality, longer hospitalizations, and greater costs.

This study has several notable strengths that meaningfully contribute to addressing the current knowledge gap. The present study examined the association between CLP and hospitalization outcomes. Several limitations require interpretation of the results with caution. While national databases like NIS allow access to extensive data allowing computation of more accurate estimates, they do not contain granular details as would be the case with studies with smaller samples. For example, because in-hospital mortality was all-cause, we were not able to determine whether the causes of mortality were plausibly related to CLP. The database is subject to administrative coding errors, although this is not unique to national or similar large-scale databases. Regarding costs, this study's data was limited to hospitalization charges only, and could not include elements such as professional fees, reimbursements, and indirect costs. It is also important to note that the database was limited to inpatient data. Considering the extensive continued care involved with CLP and associated conditions, it is likely that the cost involved with the care of CLP is only partially represented in this study. Finally, use of in-patient databases underestimates the incidence of birth defects. However, there is a lack of a nationalized population-based birth defects registry in the United States. Our study reports on hospitalization outcomes and this adds new findings to the existing literature on this topic.

## Conclusions

Based on a nationally representative inpatient sample from 2020 through 2022 in the United States, in-hospital mortality rate was significantly higher among newborns with CLP compared to those without CLP. LOS and hospitalization charges were substantially higher in newborns with CLP compared to those without CLP. Among those with CLP, those with a cleft palate only had higher hospitalization charges and LOS than those with cleft palate with cleft lip, and those with cleft lip only. The findings from this study could be used to shape policy and clinical practice changes to improve outcomes and resource allocation and utilization.

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### Ethical Approval

This study was approved as exempt from full review by the Office of Human Subjects Protection, Protocol_STUDY2024-1486 on 5/14/2025.

### Consent to Participate

Informed consent was not required for this study as it involved retrospective data analysis without any direct patient interaction or intervention.

### Informed Consent

There are no human participants in this article, and informed consent is not required.

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