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# **A Nationwide Assessment of Disparities in Primary Cleft Lip Repair**

A Thesis Submitted to the Yale University School of Medicine in Partial Fulfillment of the  
Requirements for the Degree of Doctor of Medicine

by

Connor J. Peck, MD Class of 2022

**Purpose:** This study examined the impact of patient race or ethnicity on the likelihood of experiencing delays to surgery, post-operative surgical complications, or prolonged hospital stays following primary cleft lip (CL) repair.

**Methods:** Patients who underwent CL repair were identified from two large national databases: the Kids Inpatient Database (KID) and the Pediatric National Surgical Quality Improvement Program (NSQIP) database. Primary outcomes were defined as treatment after 6 months of age, the presence of any surgical complication, and a hospital stay greater than 1 day. Chi-squared analyses were performed to compare outcomes across patients of different race/ethnicity, followed by multivariable logistic regression to adjust for various demographic and social factors. Secondary analyses assessed the impact of race/ethnicity on hospital charges, and compared results across the KID and NSQIP databases.

**Results:** There were 10,844 patients included in the study; 4917 patients from NSQIP, and 5927 from KID. Both databases showed significant differences ( $p < 0.001$ ) in the likelihood of experiencing delayed surgery, complications, and prolonged hospital stay among patients of different race/ethnicity. Delays in care were highest among Hispanic (OR 1.22 – 3.86) and Asian/Pacific Islander (OR 2.26 – 4.67) patients, complications highest among Black (OR 1.28 – 2.11) and Hispanic (OR 1.59 – 2.11) patients, and prolonged stays highest among Other (OR 2.27-3.67) patients. Multivariable regression showed a strong confounding influence of various patient factors ( $p < 0.001$ ), with a particularly strong relationship between baseline pre-operative health status and each of the primary study outcomes.

### **Conclusion**

There are significant differences in the likelihood of experiencing of delays, complications, and prolonged hospital stays among patients of different race or ethnicity. Advocacy efforts to ameliorate disparity in early infant health may subsequently improve health outcomes in CL repair.

## Acknowledgments

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## **Introduction**

Cleft lip and/or palate (CLP) is the one of most frequently occurring congenital differences in the United States, affecting approximately 1 in every 700 births.<sup>1</sup> CLP is caused by a disruption of normal embryologic development of the lip and palate, leading to non-fusion of maxillary and nasal prominences.<sup>2</sup> The severity of this deformity can vary widely, ranging from small unilateral clefts of the soft palate or lip to complete, bilateral malformation of the lip and palate with extension into the nasal airway. Although the specific etiology of CLP is still debated, increased risk has been linked to a variety of both genetic and environmental factors.<sup>3-6</sup>

In almost all forms of CLP, surgical intervention is required to restore normal function and appearance. The extent of surgical intervention required depends on the underlying deformity. For children with minor CLP, primary repair of the lip is usually performed prior to 6 months of age, with primary repair of the palate performed between the ages of 1 and 2. Adherence to these timing guidelines is important, as early intervention can disturb mid-facial development, and late intervention can predispose pathologic speech<sup>7-9</sup>. Improper closure of CLP can also predispose secondary malformations that may require multiple surgical interventions throughout a child's life. These include but are not limited to fistula repair, scar revision, alveolar bone grafting (ABG) to restore competence of the maxillary arch, and secondary rhinoplasty to correct CLP-associated nasal deformities.<sup>10,11</sup>

Uncorrected CLP and its associated secondary deformities can lead to various negative health sequelae, including difficulty with feeding and speech, dental abnormalities, and loss of hearing.<sup>12-14</sup> Patients can also experience significant

psychosocial challenges associated with a visible deformity. CLP patients have been reported to experience high rates of depression, anxiety, learning difficulties, and social challenges.<sup>15-20</sup> While surgical intervention alone does not ameliorate all of these challenges, appropriately timed and safely performed CLP surgery combined with longitudinal social support services (e.g. speech therapy) can substantially improve a patient's quality of life.

Despite the well-established indications and importance of timely surgery in CLP management, inequities in access to and quality of care may still exist. Previous studies have shown that socioeconomic and sociodemographic factors, such as insurance type, family income, and patient race/ethnicity, can influence longitudinal CLP care.<sup>21-26</sup> For example, one study showed that White/Caucasian children were more likely than their peers to receive timely primary cleft lip and palate repair, with African American and Hispanic children undergoing surgery almost 2 months later, on average, than Caucasian children.<sup>26</sup> In non-cleft settings, similar findings have been published—in studies of craniosynostosis, for example, race/ethnicity was identified as a cause of delayed age at time of care and higher overall hospital charges.<sup>27,28</sup> Various studies in surgical disciplines have demonstrated a destructive role of disparities, structural racism, and unconscious or conscious bias on the outcomes of surgical patients.<sup>29-31</sup>

Despite growing evidence that disparities exist in surgical care, only a minority of surgeons in the United States acknowledge their role in surgical care. A 2017 study showed that only 37% of surgeons agreed that there were disparities in any health care setting, and only 5% reported disparities within their personal practice.<sup>32</sup> These findings highlight the continued need to define and describe inequities in surgical practice. While



previous studies have begun to highlight the role of biopsychosocial factors in CLP care, there remains a paucity of evidence as to disparity CLP care, particularly in the case of CL repair. Previous studies have demonstrated delays to surgery, but have rarely examined the impact of such delays—nor the impact of social factors broadly—on the actual outcomes of CLP care in either the short-term or long-term post-operative period. One recent national study did identify higher short-term complication rates, longer hospital length of stay, and greater hospital costs associated with non-white patient race/ethnicity in cleft palate (CP) repair<sup>25</sup>; however, no such studies have been performed in the context of CL repair.

Given the importance of ensuring equitable outcomes and practices among all CLP patients, this study was designed to identify whether any disparities among patients of different race and/or ethnicity currently exist in the United States.

### **Purpose of Study**

The primary aims of this study are as follows:

1. Use two national databases to identify the impact of patient race/ethnicity on the likelihood of experiencing each of the primary study outcomes:
  - a. Delays to Surgery
  - b. Post-Operative Complications
  - c. Extended Hospital Stays
2. Identify confounders and/or predictors of each primary study outcome.

The secondary aims of this study are as follows:

1. Use data from the KID Inpatient database to assess the impact of patient race/ethnicity on total hospital costs.
2. Compare standard patient demographics and outcomes across the KID and NSQIP national databases.

We hypothesize that Underrepresented in Medicine (URIM) patients (Non-Hispanic Black and Hispanic) will experience delays in care, increased odds of complications, and extended hospital stays following primary CL repair in both national databases.

Secondarily, we hypothesize that non-Hispanic Black and Hispanic patients will incur greater hospital costs than patients of other race/ethnicity. We also hypothesize that there will be noticeable differences in parameters as reported by NSQIP and KID.

## **Methods**

### **Student Contributions**

The majority of this thesis work was performed solely by the senior author, Connor J. Peck. This includes the designing of study methods and approach, performing the data collection, performing statistical analyses, and drafting and writing every section of the current thesis. All other individuals contributing to this thesis did so through advising, supervising, editing, and revising of the manuscript materials.

### **Ethics Statement**

This study was deemed IRB-exempt by the Yale Institutional Review Board, as all patient data included was de-identified by national organizations prior to data analysis.

## **Human Subjects Research/Laboratory Animals**

Not applicable.

## **Methods Description**

### *Data Source and Data Extraction*

Two large national databases were used in this study. The data sources and methodology used to extract patient data from each are described below.

### Pediatric National Surgical Quality Improvement Program (NSQIP):

The National Surgical Quality Improvement Program (NSQIP) was started in the mid-1980s as a response to a US governmental mandate to improve surgical outcomes among the various Veterans Administration hospitals.<sup>33</sup> It was later adopted by the American College of Surgeons (ACS) in 2004 as a tool for measuring 30-day risk-adjusted outcomes across hospitals in the United States. The pediatric NSQIP was founded in 2012 as an expanded version of the original NSQIP database. In its current form, the pediatric NSQIP contains over 100 standardized variables collected from more than 700 contributing hospitals nationally.<sup>34</sup>

Data in the current study were collected from the Pediatric NSQIP databases from the years 2014-2018. Patients undergoing primary cleft lip repair were identified from NSQIP using the following primary current procedural terminology (CPT) codes:

- 40700: Plastic repair of cleft lip/nasal deformity; primary, partial or complete, unilateral

- 40701: Plastic repair of cleft lip/nasal deformity; primary bilateral, 1-stage procedure
- 40702: Plastic repair of cleft lip/nasal deformity; primary bilateral, 1 of 2 stages

Patients undergoing concurrent procedures of the maxilla or mandible were excluded from this study.

#### Kids Inpatient Database (KID):

The Healthcare Cost and Utilization Project (HCUP) was created in 1988 by the Agency for Healthcare Research and Quality (AHRQ) as a tool to provide healthcare-related administrative data to policymakers and researchers.<sup>35</sup> The Kids Inpatient Database (KID) is a large pediatric component of the HCUP designed to provide information regarding pediatric hospitalizations in the United States.<sup>36</sup> This database is created via comprehensive review of discharge materials among patients under the age of 21. The KID collects data from more than 4,000 hospitals in 48 states yearly, accounting for nearly 3 million pediatric hospital stays annually. The KID database is released for public use every 3 years.

For the current study, KID databases from the years 2006, 2009, and 2012 were included. Databases released prior to 2006 and since 2012 were excluded due to substantial heterogeneity in variables collected and inconsistency in diagnosis and complication coding variables.

All patients with a diagnosis of cleft lip or palate were identified from KID via the following International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes:

- 749.10-749.14: cleft lip only
- 749.20-749.25: cleft lip and palate

Following identification of child with a CLP diagnosis, children undergoing primary cleft lip repair using the following ICD-9-CM procedure code:

- 27.54: Repair of Cleft Lip

Patients undergoing concurrent procedures of the maxilla or mandible were excluded from this study.

Both of the databases in this study were selected due to specific benefits espoused by each. The pediatric NSQIP database is one of the most robust surgery-specific databases in the United States. As such, it provides great consistency in both procedural and complication coding. These factors make NSQIP ideal for assessing pediatric surgery specific outcomes.

In contrast, the KID is designed to capture all forms of pediatric hospitalization, including patients undergoing surgical procedures. As a function of its purpose to inform administrative and financial policies, the KID collects unique socioeconomic variables not available in NSQIP, such as zip-code based income quartiles, geographic location of the treating hospital, and insurance type.

### *Measures*

The primary independent variable of interest in this study was a patient's self-identified race or ethnicity. For both databases, patients were divided into the following categories: "White", "Black", "Hispanic", "Asian/Pacific Islander", or "Other". In the KID database, patients listed as having a Hispanic ethnicity were categorized only as Hispanic, regardless of race; thus, all other patients are assumed to be Non-Hispanic. Patients with missing race/ethnicity data were excluded from analysis. In the NSQIP database, "Hispanic Ethnicity" is coded separately from race; thus, this variable was recoded so that, similar to the KID database, patients with Hispanic ethnicity were listed as Hispanic, whereas patients of all other groups are non-Hispanic.

The primary study outcomes of interest were defined as follows:

- *The proportion of children receiving surgery later than 6 months of age.*  
Defined as a binary variable (Yes/No).
- *The proportion of children with a post-operative hospital stay greater than 1 day.* Defined as a binary variable (Yes/No).
- *The proportion of children experiencing one or more post-operative complications during their hospital stay.* Defined as a binary variable (Yes/No). The composite category of "any complication" was selected as an outcome of interest given the low overall frequency of any individual complication type, which precluded adequately powered statistical comparisons for complication subtypes. The specific complications included in this category varied for each database, and are described below:

- NSQIP: Complications collected included any occurrence of superficial incisional SSI, deep incisional SSI, organ/space SSI, deep wound disruption/dehiscence, pneumonia, nerve injury, sepsis, cardiac arrest unplanned intubation, unplanned readmission, or death.
- KID: Complications were identified via the following ICD-9 complication codes: 998.2 (accidental puncture); 998.6 (post-op fistula); 997.1 (cardiac complication); 998.3 (wound disruption); 998.12 (hematoma); 998.11 (hemorrhage); 997.39 (respiratory complication); 518.81, 96.7, 96.71, 96.72 (airway/respiratory failure); 997.32, 997.31 (pneumonia); 998.13 (seroma); 998.51 (infected seroma); 998.59, 998.3 (post-op infection); 998.83 (nonhealing wound); 998.8, 998.89, 998.9 (unspecified complication).

One secondary study outcome was defined as follows:

- *The cost of hospitalization.* Defined as a continuous variable (USD). Refers to the cost incurred to the hospital, not total charges to the patient or insurance company.

Several additional covariates were collected from each database for study analyses. The following covariates were directly taken from each study database:

- NSQIP: Sex (Male/Female), the presence of a bilateral cleft (Based on ICD diagnosis codes; Yes/No), the presence of a concurrent cleft palate (Based on ICD diagnosis codes; Yes/No), history of premature birth

(Yes/No), and American Society of Anesthesiologist Classification (ASA; Class I, II, III, or IV+).

- KID: Sex (Male/Female), The presence of a bilateral cleft (Based on ICD diagnosis codes; Yes/No), the presence of a concurrent cleft lip or cleft palate deformity (Based on ICD diagnosis codes; Yes/No), the primary expected payor (Medicare or Medicaid, Private, or Other), the income quartile of the patients residential ZIP code (1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup> quartile), the hospitals location/status (rural, urban non-teaching, urban teaching), region of the hospital in the US (Northeast, Midwest, South, West), and the disease severity class (1-4). The covariate “disease severity class” refers to a clinical staging variable within the KID database that predicts the likelihood of severe disease based on baseline disease characteristics (e.g. comorbidities). Thus, a higher disease severity class refers to greater overall patient comorbidity, not the extent of involvement of the cleft.
- The outcome variables of delay to treatment, prolonged LOS, complications, and costs were all included as co-variates in complementary multivariable analyses as described below.

### *Statistical Analysis*

Prior to outcome analysis, patient characteristics were compared across groups via chi-squared analyses, with descriptive interpretation. For primary outcome analyses, univariate chi-squared analyses were used to compare each study outcomes across race/ethnicity groups. In cases where differences were statistically significant, directed



post-hoc pairwise comparisons (e.g. repeated bivariable chi-squared analyses) were performed to compare each patient race/ethnicity group to White patients. In these cases, a Bonferroni correction was performed to adjust for multiple comparisons. Odds ratio's of each outcome were calculated for each race/ethnicity group in comparison to White patients.

Next, multivariable logistic regression was performed to control for each of the patient co-variables described above. In the multivariable regression for complications, the presence of a delay was included as a covariate; regression for prolonged length of stay included the presence of complication a delay or complication as separate covariates; regression for charges included the presence of a complication, delay, or prolonged LOS as three separate covariates.

There were several additional analyses performed in the KID database but not NSQIP. Within the KID database, which collects information related to total hospital charges, a log transformation was performed followed by an ANOVA to assess the impact of patient race/ethnicity on total hospital charges. This was followed by multivariable linear regression with the log-transformed cost as the dependent variable. Both statistical tests were followed by back-transformation to allow for interpretation. Charge estimates were reported as a "charge ratio" (CR), indicating the charge multiplier associated with the variable of interest. For example, a charge ratio of 1.5 among Black patients in comparison to White patients would indicate that charges among Black patients are, on average, 1.5 that of White patients, representing a 50% charge increase.

Last, chi-squared analyses were used to compare patient demographics and the proportion of patients experiencing each study outcome across the two study databases.

All statistical analyses were performed using R Open Access Statistical Software (Vienna, Austria).  $P < 0.05$  was set as significant throughout.

## **Results**

### **Demographics**

#### *Patient Demographics – Overall*

There were 10,844 patients who received cleft lip repair included in this study: 4917 cases from the NSQIP database, and 5927 from KID. Patient characteristics from each database are described separately below.

#### *Patient Demographics – NSQIP*

There were 4917 cases identified from the NSQIP database. The majority of patients were White (64.1%), followed by Hispanic (19.2%), Black (10.0%), Asian/PI (6.0%), or Other (0.6%) (**Table 1**). The majority of patients were male (63.3%). Concurrent cleft palate was seen in 56.0% of patients, and 24.5% of patients had a bilateral deformity.

There were several significant differences in patient characteristics based on patient race/ethnicity. Patient sex differed across groups ( $p < 0.001$ ), with White patients the most likely to be male. The presence of bilateral deformities ( $p < 0.001$ ) or a concurrent cleft palate ( $p < 0.001$ ) differed across groups, with the highest incidence of bilateral deformities among Hispanic (26.0%) patients and highest incidence of concurrent cleft palate among Asian/PI patients (65.9%). History of pre-term birth also differed ( $p < 0.001$ ), with higher rates of preterm birth among Black patients (13.6%).

Finally, the distribution of ASA class designations varied ( $p < 0.001$ ), with Black patients the most likely to have an ASA class of 3 or higher (15.6%).

**Table 1. Patient Demographics from the Pediatric NSQIP Database**

Parameter	Overall	White	Black	Hispanic	Asian/PI	Other	p-value
<b>N</b>	4917	3153	494	945	294	31	-
<b>Sex (% Male)</b>	63.3	65.6	57.3	62.5	51.7	51.6	<0.001
<b>Bilateral Cleft (%)</b>	24.5	25.5	19.4	26.0	22.2	0.0	<0.001
<b>Cleft Palate (%)</b>	56.0	53.6	59.1	60.0	65.9	0.0	<0.001
<b>History of Pre-Term Birth (%)</b>	10.1	9.8	13.6	10.8	6.8	6.5	<0.001
<b>ASA Class (%)</b>	-	-	-	-	-	-	<0.001
1 (least severe)	31.3	31.6	21.9	29.6	32.0	25.8	-
2	58.2	58.8	62.5	58.1	61.9	61.3	-
3	9.8	8.9	15.2	11.7	5.4	12.9	-
4+ (most severe)	0.7	0.7	0.4	0.5	0.7	0.0	-

#### *Patient Demographics – KID*

There were 5927 cases of cleft lip repair included in our analysis of the KID database. The majority of patients were White (62.8%), followed by Hispanic (22.2%), Other (5.6%), Black (4.7%), and Asian/PI (4.7%). The majority of patients were male (70.2%). Most patients paid via Medicare/Medicaid (56.7%) and lived in the 2<sup>nd</sup> (27.9%) or 3<sup>rd</sup> (27.1%) income quartiles. Surgery was most frequently performed at urban nonteaching hospitals (37.9%), and in the South (33.2%). Overall, 81.8% of patients were classified as having the lowest overall disease severity.

There were several significant differences in patient characteristics based on patient race/ethnicity (**Table 2**). Patient sex differed across groups ( $p < 0.001$ ), with White patients the most likely to be male (77.0%). White patients were also less likely to have a diagnosis of bilateral cleft lip (16.6%,  $p < 0.001$ ), but more frequently had a concurrent diagnosis of cleft palate (70.4%,  $p < 0.001$ ). Overall disease severity tended to be higher ( $p < 0.001$ ) among Black and Other patients than patients of other race/ethnicity. Payment differed across races ( $p < 0.001$ ), with the highest rates of private insurance use among Hispanic (60.1%) and Asian/PI (62.1%) patients, highest rates of public insurance among Black patients (69.4%), and highest rates of “other” (e.g. self-pay) insurance among Hispanic patients (13.5%). Patients also differed with respect to income quartile ( $p < 0.001$ ), with Black and Hispanic patients being the most likely to live in the bottom income quartile (45.9% and 42.5%, respectively), and Asian/PI patients the most likely to live in the highest (49.1%). There were significant differences in the type and location of treatment ( $p < 0.001$ ), with treatment at rural hospitals was more frequent among White (32.5%) and Black patients (31.5%), and treatment at urban teaching hospitals ( $p < 0.001$ ) higher among Asian/PI (37.2%) and Other (36.0%) patients. Geographic differences ( $p < 0.0001$ ) showed higher numbers of White patients in the South (36.5%), Black and Other patients in the Midwest (36.9% and 58.3%, respectively), and higher numbers of Hispanic and Asian/PI patients in the West (40.1% and 36.5%, respectively).

**Table 2. CL Repair Patient Demographics from the KID Database**

Parameter	Overall	White	Black	Hispanic	Asian/PI	Other	P-value
<b>N</b>	5927	3724	279	1316	277	331	-
<b>Sex (% Male)</b>	70.2	77.0	58.7	59.2	54.5	59.8	<0.001
<b>Bilateral Cleft (%)</b>	20.8	16.6	26.5	29.7	27.1	26.5	<0.001
<b>Concurrent Cleft Palate (%)*</b>	67.2	70.4	51.1	66.2	58.8	55.4	<0.001
<b>Primary Expected Payor (%)</b>	-	-	-	-	-	-	<0.001
Medicare/Medicaid	56.7	55.7	69.4	65.7	28.5	43.3	-
Private	36.1	39.4	26.3	20.8	62.1	46.4	-
Other	7.2	4.9	4.3	13.5	9.4	10.3	-
<b>Income Quartile of ZIP Code (%)</b>	-	-	-	-	-	-	<0.001
1 (lowest income quartile)	20.5	20.5	45.9	42.5	14.7	27.5	-
2	27.9	27.9	26.8	26.1	13.0	23.1	-
3	27.1	27.1	16.8	21.7	23.2	25.9	-
4 (highest income quartile)	24.5	24.5	10.5	9.7	49.1	23.5	-
<b>Hospital Location/Type (%)</b>	-	-	-	-	-	-	<0.001
Rural	31.0	32.5	31.5	27.5	27.4	30.8	-
Urban nonteaching	37.9	38.4	34.8	38.8	35.4	33.2	-
Urban teaching	31.1	29.1	33.7	33.7	37.2	36.0	-
<b>Region in US (%)</b>	-	-	-	-	-	-	<0.001
Northeast	12.9	15.4	8.6	7.2	8.3	8.5	-
Midwest	25.4	23.9	36.9	27.3	24.9	58.3	-
South	33.2	36.5	29.8	25.5	30.3	31.5	-
West	28.5	24.2	24.7	40.1	36.5	27.2	-
<b>Disease Severity Class (%)</b>	-	-	-	-	-	-	<0.001
1 (least severe)	81.8	81.4	78.4	82.9	85.9	79.6	-
2	13.1	13.9	12.2	12.4	11.5	12.7	-
3	4.3	4.2	8.1	3.7	2.2	5.5	-
4 (most severe)	0.8	0.5	1.4	1.0	0.4	2.2	-

## Primary Outcomes

### *Delay to Surgery – NSQIP*

The majority of children within the NSQIP database received primary CL repair within the first 6 months of life (69.1%). However, there were significant differences ( $p <$

0.001) in the likelihood of a child being delayed to surgery based on patient race/ethnicity (**Table 3**). In comparison to White patients (29.22%), delays were significantly increased among Asian/PI (48.30%, OR 2.26;  $p < 0.001$ ) and Hispanic (33.3%, OR 1.22;  $p = 0.011$ ) patients (**Table 4**).

After adjustment for covariates, delay to surgery was still associated with the Asian/PI group (OR = 1.38,  $p < 0.001$ ), but no longer significantly associated with any other group ( $p > 0.05$ ) (**Table 5**). Delays were also associated with a bilateral cleft diagnosis (OR = 1.13,  $p < 0.001$ ) and ASA classification of 2 (OR = 1.07,  $p = 0.022$ ), 3 (OR = 1.18,  $p = 0.002$ ), or 4 (OR = 1.83,  $p = 0.001$ ).

**Table 3. Percentage of Patients Experiencing Adverse Outcomes following CL Repair, by Race/Ethnicity.**

Parameter	Overall	White	Black	Hispanic	Asian/PI	Other	p-value
<b>Delayed Surgery (%)</b>							
NSQIP	30.93	29.22	30.16	33.55	48.30	32.26	<0.001
KID	13.38	8.09	22.79	25.35	29.14	24.42	<0.001
<b>Complication Rate (%)</b>							
NSQIP	2.58	2.16	4.45	3.39	1.36	0.00	0.007
KID	1.54	1.13	1.43	2.36	2.17	2.42	<0.001
<b>Prolonged LOS (%)</b>							
NSQIP	13.00	11.48	16.80	14.39	8.50	32.26	<0.001
KID	21.99	19.17	36.20	23.25	23.91	35.05	<0.001

### *Delay to Surgery – KID*

The majority of children (86.62%) received surgical CL repair prior to 6 months of age. However, there were significant differences ( $p < 0.001$ ) in the likelihood of a childhood being delayed to surgery ( $>6$  months) based on patient race/ethnicity. In comparison to White patients, delays were more frequent among Black (30.16%, OR = 3.35;  $p < 0.001$ ), Hispanic (33.55%, OR = 3.86;  $p < 0.001$ ), Other (35.05%, OR = 3.67;  $p < 0.001$ ), and Asian/PI (23.91%, OR = 4.67;  $p < 0.001$ ) patients.

After adjusting for co-variables, the odds of experiencing delays in care were no longer significantly higher than White patients among Black (OR = 1.29,  $p = 0.375$ ) or Other (OR = 1.66,  $p = 0.050$ ) patients, but were still higher for Hispanic (OR = 1.88,  $p < 0.001$ ) and Asian/PI (OR = 2.71,  $p < 0.001$ ) patients (**Table 6**). Increased odds of delayed surgery were also independently associated with “other” primary expected payor (OR = 1.64,  $p = 0.023$ ) and disease severity classes of 2 (OR = 1.89,  $p < 0.001$ ) or 3 (OR = 3.09,  $p < 0.001$ ). Decreased odds of delayed surgery were associated with living in higher income areas (3<sup>rd</sup> vs. 1<sup>st</sup> quartile OR = 0.68,  $p = 0.032$ ).

### *Risk of Complications – NSQIP*

The majority of patients (97.42%) experienced no complications following cleft lip repair. However, there were significant difference ( $p < 0.001$ ) in the proportion of patients experiencing a complication based on race/ethnicity. In comparison to White patients, the unadjusted odds of having a 30-day postoperative complication were significantly higher in Black (4.45%, OR = 2.11;  $p = 0.005$ ) patients and Hispanic

patients (3.39%, OR = 1.59;  $p = 0.038$ ), although the latter did not meet statistical significance within the Bonferroni correction.

After adjustment for covariates, increased odds of complications were still associated with Hispanic patients (OR = 1.03,  $p = 0.017$ ). Complications were also independently associated with an ASA classification of 4 (OR = 1.37,  $p < 0.001$ ).

#### *Risk of Complications – KID*

The majority of children in the study (98.46%) had no recorded post-operative complications; however, the percentage of children experiencing complications differed by race/ethnicity ( $p < 0.001$ ). In comparison to White patients, odds of experiencing at least one complication were elevated in Hispanic (2.36%, OR = 2.11;  $p = 0.001$ ) and Other (2.42%, OR = 2.17,  $p = 0.041$ ) patients, although the latter did not meet statistical significance after Bonferroni correction.

After controlling for co-variates, the odds of experiencing a post-operative complication were no longer increased ( $p > 0.05$ ) in any of the race/ethnicity cohorts. Instead, increased odds of complications were independently associated with patients with a disease severity score of 3 (OR = 1.09,  $p < 0.001$ ) or 4 (OR = 1.45,  $p < 0.001$ ).

#### *Prolonged Length of Stay – NSQIP*

The majority of children in the NSQIP database (87.00%) experienced a hospital stay of one day or less. However, there were significant differences ( $p < 0.001$ ) in the likelihood of experiencing a prolonged LOS among patients of different race/ethnicity. In



comparison to White patients, prolonged LOS was more common in Other (32.26%, OR = 3.67;  $p = 0.002$ ) and Black (16.80%, OR = 1.56;  $p = 0.001$ ) patients.

In multivariable regression adjusting for covariates, increased odds of prolonged LOS were still significantly associated with being Black (OR = 1.08,  $p = 0.040$ ) or Hispanic (OR = 1.09,  $p = 0.001$ ). Increased odds of prolonged LOS were also independently associated with a bilateral cleft (OR = 1.10,  $p < 0.001$ ), and an ASA classification of 3 (OR = 1.16,  $p < 0.001$ ). Decreased odds were associated with a delay to surgery (OR = 0.95,  $p = 0.031$ ).

#### *Prolonged Length of Stay – KID*

The majority of children in the KID database (78.01%) had a hospital LOS of one day or less. However, there were significant differences ( $p < 0.001$ ) in the proportion of children with a prolonged LOS associated with race/ethnicity. In comparison to White patients, the odds of experiencing a prolonged LOS was increased among Black (36.20%, OR = 2.39,  $p < 0.001$ ), Other (35.05%, OR = 2.17,  $p < 0.001$ ), and Hispanic (23.25%, OR = 1.28,  $p = 0.001$ ) patients.

After controlling for co-variates (including complications), the odds of experiencing a prolonged hospital stay were no longer increased in any race/ethnicity group, and were actually decreased in the Hispanic patients in comparison to White patients (OR = 0.85,  $p < 0.001$ ). Increased hospital stays were also independently associated with treatment in the Midwest (OR = 1.13,  $p < 0.011$ ) or South (OR = 1.12,  $p = 0.018$ ) in comparison to the Northeast, and were also associated with disease severity classes of 2 (OR = 1.13,  $p < 0.001$ ), 3 (OR = 1.09,  $p < 0.001$ ), or 4 (OR=1.82,  $p < 0.001$ ).

**Table 4. Odds Ratio's of Patients Experiencing Adverse Outcomes following CL Repair, by Race/Ethnicity.** Statistically significant values are bolded; the symbol \* indicates statistical significance after Bonferroni adjustment for post-hoc unadjusted analyses ( $p < 0.013$ )

Parameter	White	Black	Hispanic	Asian/PI	Other
<b>Delayed Surgery (&gt;6 months)</b>					
<b>NSQIP</b>					
Unadjusted OR	1.00	1.05	<b>1.22*</b>	<b>2.26*</b>	1.15
Adjusted OR	1.00	0.97	1.01	<b>1.38</b>	1.05
<b>KID</b>					
Unadjusted OR	1.00	<b>3.35*</b>	<b>3.86*</b>	<b>4.67*</b>	<b>3.67*</b>
Adjusted OR	1.00	1.29	<b>1.88</b>	<b>2.71</b>	1.66
<b>Complications</b>					
<b>NSQIP</b>					
Unadjusted OR	1.00	<b>2.11*</b>	<b>1.59</b>	0.63	-
Adjusted OR	1.00	1.02	<b>1.03</b>	1.03	-
<b>KID</b>					
Unadjusted OR	1.00	1.28	<b>2.11*</b>	1.28	<b>1.81</b>
Adjusted OR	1.00	0.99	1.00	1.00	0.99
<b>Prolonged Stay</b>					
<b>NSQIP</b>					
Unadjusted OR	1.00	<b>1.56*</b>	1.30	0.72	<b>3.67*</b>
Adjusted OR	1.00	<b>1.08</b>	<b>1.09</b>	1.01	<b>1.54</b>
<b>KID</b>					
Unadjusted OR	1.00	<b>2.39*</b>	<b>1.28*</b>	1.32	<b>2.27*</b>
Adjusted OR	1.00	0.99	<b>0.85</b>	0.95	1.09

**Table 5. Multivariable Logistic Regression for Primary Outcomes – NSQIP.**

Statistically significant values ( $p < 0.05$ ) are indicated in bold.

Variable	Delay (OR)	<i>P</i> value	Complications (OR)	<i>P</i> value	Prolonged LOS (OR)	<i>P</i> value
<b>Race</b>						
White	(reference)	-	-	-	-	-
Black	0.97	0.560	1.02	0.152	<b>1.08</b>	<b>0.040</b>
Hispanic	1.01	0.861	<b>1.03</b>	<b>0.017</b>	<b>1.09</b>	<b>0.001</b>
Asian/PI	<b>1.38</b>	<b>&lt;0.001</b>	1.03	0.177	1.01	0.731
Other	1.05	0.806	0.99	0.876	1.54	0.130
<b>Diagnosis</b>						
Bilateral Cleft (vs unilateral)	<b>1.13</b>	<b>&lt;0.001</b>	1.01	0.269	<b>1.10</b>	<b>&lt;0.001</b>
Concurrent Palate (vs lip only)	1.01	0.723	1.00	0.735	1.02	0.354
<b>Premature Birth</b>	1.09	0.052	1.02	0.186	1.06	0.105
<b>ASA Classification</b>						
1 (least severe)	(reference)		-	-	-	-
2	<b>1.07</b>	<b>0.022</b>	1.01	0.216	1.01	0.732
3	<b>1.18</b>	<b>0.002</b>	1.01	0.468	<b>1.16</b>	<b>&lt;0.001</b>
4 (most severe)	<b>1.83</b>	<b>0.001</b>	<b>1.37</b>	<b>&lt;0.001</b>	1.24	0.135
<b>Delay</b>	-	-	1.00	0.734	<b>0.95</b>	<b>0.031</b>
<b>Complication</b>	-	-	-	-	0.95	0.442
<b>Prolonged</b>	-	-	-	-	-	-

**Table 6. Multivariable Logistic Regression for Primary Outcomes – KID.**Statistically significant values ( $p < 0.05$ ) are indicated in bold.

Variable	Delay (OR)	P value	Complications (OR)	P value	Prolonged	P value
<b>Race</b>						
White	(reference)					
Black	1.29	0.375	0.99	0.296	0.99	0.844
Hispanic	<b>1.88</b>	<b>&lt;0.001</b>	1.00	0.815	<b>0.85</b>	<b>&lt;0.001</b>
Asian/PI	<b>2.71</b>	<b>&lt;0.001</b>	1.00	0.702	0.95	0.256
Other	1.66	0.050	0.99	0.801	1.09	0.057
<b>Diagnosis (%)</b>						
Bilateral Cleft (vs unilateral)	1.28	0.090	1.00	0.744	1.02	0.460
Concurrent Palate (vs lip only)	1.00	0.997	1.00	0.897	1.04	0.101
<b>Primary Payor (%)</b>						
Medicare/Medicaid	(reference)					
Private	1.26	0.126	0.99	0.946	1.04	0.107
Other	1.64	<b>0.023</b>	1.01	0.467	1.00	0.957
<b>Income Quartile</b>						
1 (lowest quartile)	(reference)					
2	0.83	0.279	1.00	0.756	0.96	0.213
3	<b>0.68</b>	<b>0.032</b>	1.00	0.846	0.96	0.174
4 (highest quartile)	0.81	0.279	1.00	0.967	1.00	0.988
<b>Hospital Type</b>						
Rural	(reference)					
Urban nonteaching	0.86	0.323	1.01	0.502	1.00	0.893
Urban teaching	0.94	0.739	1.00	0.714	1.03	0.364
<b>Region in US</b>						
Northeast	(reference)					
Midwest	0.76	0.311	1.01	0.440	<b>1.13</b>	<b>0.011</b>
South	0.90	0.685	1.01	0.355	<b>1.12</b>	<b>0.018</b>
West	0.80	0.420	1.01	0.553	1.09	0.087
<b>Disease Severity Class</b>						
1 (least severe)	(reference)					
2	<b>1.89</b>	<b>&lt;0.001</b>	<b>1.02</b>	<b>0.047</b>	<b>1.13</b>	<b>&lt;0.001</b>
3	<b>3.09</b>	<b>&lt;0.001</b>	<b>1.09</b>	<b>&lt;0.001</b>	<b>1.41</b>	<b>&lt;0.001</b>
4 (most severe)	3.98	0.058	<b>1.45</b>	<b>&lt;0.001</b>	<b>1.82</b>	<b>&lt;0.001</b>
Delay	-	-	1.00	0.951	0.99	0.605
Complication	-	-	-	-	<b>1.23</b>	<b>0.012</b>
Prolonged LOS	-	-	-	-	-	-

## Secondary Outcomes

### *Cost Analysis – KID*

The median total charge of the surgical admission was \$11,676. Without adjusting for any co-variates, charges differed widely across race/ethnicity cohorts ( $p < 0.001$ ), with the highest charges (in comparison to White patients) among Asian/PI (Cost Ratio = 1.83) and Hispanic (Cost Ratio = 1.81) patients (**Table 7**).

After controlling for all other co-variates, charges were still significantly increased among Hispanic (Cost Ratio = 1.23,  $p < 0.001$ ) and Asian/PI (Cost Ratio = 1.39,  $p < 0.001$ ) patients. Higher charges were also associated with living in highest income quartile areas (Cost Ratio = 1.11,  $p < 0.019$ ), disease severity classes of 3 (Cost Ratio = 1.47,  $p < 0.001$ ) or 4 (Cost Ratio = 5.45,  $p < 0.001$ ). and prolonged hospital stays (Cost Ratio = 1.542,  $p < 0.001$ ). Decreased charges were associated with private insurance type (Cost Ratio = 0.92,  $p = 0.020$ )

**Table 7. Unadjusted and Adjusted Charge Ratio for Surgical Admission (KID).** The symbol \* indicates statistical significance, which was derived from a single chi-squared analysis for unadjusted predictions and multivariable linear regression for the adjusted.

Charge					
	White	Black	Hispanic	Asian/PI	Other
Unadjusted CR*	1.00	1.60	1.81	1.83	1.67
Adjusted CR	1.00	0.90	1.23*	1.39*	1.02

### *Comparison of NSQIP and KID*

There were significant differences ( $p < 0.001$ ) across the NSQIP and KID databases for each of the outcome variables assessed (**Table 8**). The largest discrepancy was seen in the proportion of children reported as delayed to surgery (30.9% vs 13.4%).

**Table 8. Comparison of Basic Demographics and Primary Outcomes in NSQIP and KID Databases.** URIM = Under-represented in Medicine (Black/Hispanic/Other)

	NSQIP	KID	P Value
N	4917	5927	-
URIM Patients (%)	29.9	32.5	0.004
Sex (% Male)	63.3	70.2	<0.001
Bilateral Cleft (%)	24.5	20.8	<0.001
Concurrent Cleft Palate (%)	56.0	67.2	<0.001
Delayed to Surgery (%)	30.9	13.4	<0.001
Any Complications (%)	2.6	1.5	<0.001
Prolonged LOS (%)	13.0	21.2	<0.001

### **Discussion**

Inequity and disparity in cleft care in the United States has been previously demonstrated.<sup>21-23,25,26</sup> In cleft lip (CL) repair, however, an association between race or ethnicity and surgical outcomes has not been definitively established. In the current study, we aimed to identify the impact of patient race or ethnicity on the likelihood of experiencing negative events during the primary lip repair. We hypothesized that patients from underrepresented-in-medicine (URIM) groups—particularly Non-Hispanic Black or

Hispanic patients—would be more likely to experience short-term adverse events following CL repair.

Overall, our data demonstrated significant differences in the likelihood of experiencing delays, complications, and extended hospital stays among patients of different race or ethnicity. Both databases showed that the unadjusted odds of negative events occurring were almost ubiquitously lower among White patients, with few exceptions. This finding is similar to that of previously published study which demonstrated increases in complications, length of stay, and costs among patients receiving primary or revisionary cleft palate repair.<sup>25</sup> While the root causes of these findings are likely multifactorial, the use of two separate databases and various multivariable regressions may help highlight potential sources of disparity. The causes and implications of each finding in the current report warrant further discussion.

### **Delays to Surgery**

Timely repair of CLP is critical to achieve optimal outcomes and minimize long-term complications.<sup>37-39</sup> Our data supports previous studies which have demonstrated delays in CLP treatment among URIM populations, as both study databases showed increased likelihood of delays among Hispanic patients, and the KID database also showed delays among Black and Other patients.<sup>21,25,40</sup> Among other factors, these delays have been attributed to a lack of resources available (i.e. inadequate transportation, work obligations etc.), disparate geographic access to cleft centers, public insurance usage, language barriers, and medical mistrust.<sup>21-23,25,26,41-47</sup> Saha et al. also reported that in some cases, Black patients specifically delayed treatment to see practitioners of their own

race, of which there are few in surgical subspecialties.<sup>45</sup> Additional barriers that may affect certain URIM groups also include language and higher percentages of Medicaid insurance.<sup>48</sup>

While the NSQIP database does not contain data related to sociodemographic factors, analyses within the KID database may provide insight as to their role. Multivariable regression in KID showed that individuals living in higher income areas were less likely to experience delayed care, and uninsured patients more likely. Even though most cleft care centers provide cleft surgery for all children free of charge, there may still be financial and social challenges related to attending pre-operative visits, as well as fear of costs among the uninsured.<sup>49</sup>

Results from both databases also demonstrated a strong association between the severity of patient co-morbidities and timing of surgery, a finding likely explained by conscious decisions to delay surgery among children who may be at greater risk for surgical complication. While the “rule of 10s” used to screen patients prior to CL repair would be unlikely to affect children at the age of 6 months, surgeons may still be likely to delay cases until patients are optimized for surgery.<sup>50</sup>

Interestingly, the greatest delays to care were seen among Asian/PI patients. Additionally, even after adjusting for covariates, the odds of delayed surgery were still elevated among Hispanic, Asian/PI, and Other patients in the KID database, and Asian/PI patients in the NSQIP database. These findings point to alternative explanations for delays to care in these patient cohorts. Delays among Hispanic patients could be attributed to language barriers. Zaluzec et al. identified a 2-month delay in seeking cleft lip repair in non-English speaking families listing Spanish as the primary language.<sup>26</sup>



Among Asian patients, delays in age of presentation may stem from high adoption rates of children of Asian descent, which can be as high as 12% of cleft lip/palate patients at some centers.<sup>51,52</sup> While not well studied in cleft populations, insurance and/or immigration status may also prevent certain patients from accessing timely care.<sup>53</sup> Future studies might seek to better understand why delays are seen in these specific populations.

### **Risk of Complications**

In addition to delayed surgery, non-White patients were also more likely to experience complications following CL repair. Data from the KID database showed increased odds of complications among Black patients, while data from NSQIP showed increased odds of complications among Hispanic patients. These findings may be largely explained by differences in underlying comorbidity, as disease severity was the only independent predictor of increased complications in regression analyses within KID, and an ASA class of 4 an independent predictor of complications in NSQIP. While Hispanic patients were associated with increased odds of complications after adjusting for ASA class in NSQIP, the actual OR was very low (1.03), suggesting only a minimal difference in total complication risk. Thus, differences in overall risk of complication appear to be largely explained by differences in underlying child health.

Importantly, these findings do not suggest that disparities in surgical risk do not exist—the unadjusted odd's ratios point to a clear relationship between patient race/ethnicity and risk of surgical complications. Rather, they suggest that the disparities evident may be due to underlying health inequity rather than technical or care differences at the time of cleft surgery. Indeed, previous studies have demonstrated that minority

children—particularly those from low-income families—are disproportionately affected by a wide range of adverse outcomes early in life, including significantly increased rates of preterm delivery and low birthweight.<sup>54</sup> Socioeconomic disparities, which are often closely linked to racial disparity, may also predispose poor outcomes in pediatric health due to increased exposure to environmental stressors, lower birth weights, delayed access to care, and limited availability of health resources.<sup>55-57</sup> These early adverse events have been shown to predispose a wide range of poor health outcomes<sup>58</sup>, which could explain increased co-morbidity and risk for complication among minority CL patients.

Even with significant differences in the risk of complication, the actual complication rates following CL repair were low for all patients in both databases (1.54 – 2.58%). Delays in care also had no impact on the odds of short-term complication, a finding similar to data previously published showing no increased short-term risk of complication for delayed CP repair.<sup>40</sup> These findings highlight the immediate safety of CL repair, even among “high-risk” patients. While complications such as early wound dehiscence and infection have been reported to be common in developing settings, those due to lip repair in the United States are seldom reported in the literature, especially in the immediate post-operative period.<sup>59,60</sup> Thus, even in the setting of increased complication rates, safe surgery can still likely be offered to all patients, regardless of all race/ethnicity.

### **Prolonged Hospital Stays**

Preferences for hospital admission and treatment following cleft lip repair vary widely across centers in the United States.<sup>61</sup> While some providers may elect to keep

patients in the hospital for an afternoon or evening to monitor immediate post-operative results, others routinely perform CL repair in an outpatient setting. In either setting, however, a prolonged hospital stay—a stay requiring more than 1 night in the hospital—is relatively uncommon and generally contraindicated, as it can impose a significant financial burden and can put patients at risk for nosocomial infections and/or other hospital-related injuries.

The data in the current study suggest that the likelihood of experiencing a prolonged LOS is greater among URIM children, as both databases demonstrated greater odds of prolonged hospitalization among Black and Other children, with KID also demonstrating increased odds of prolonged hospitalization among Hispanic and Asian/PI patients. These prolonged hospital stays are likely partially attributable to increased baseline comorbidity and the increased complication risk, as greater baseline comorbidity was found to be a predictor of prolonged LOS in both the NSQIP and KID databases, with differences in LOS mitigated in the KID database after adjusting for disease severity and the presence of complications. Intuitively, it makes sense that patients with greater risk of complication and/or those who actually suffer complications are more likely to experience prolonged hospital stays.

The persistence of disparity among Black or Hispanic patient in the NSQIP database even after adjusting for ASA Class and the presence of complications, however, suggests that other factors—plausibly those contained in KID but not NSQIP—may play a role in determining LOS. While insurance, location, and socioeconomic status were not each independently associated with prolonged stays in the KID database, a combination of these factors could still plausibly have an effect. Although previous studies in non-cleft

pediatric populations are somewhat inconsistent as to whether disparities in LOS exist,<sup>62-</sup>  
<sup>66</sup> there is some evidence that a combination of parental, geographic, and social considerations may influence post-operative LOS.<sup>67</sup> For example, if a cleft provider is worried that follow-up may be difficult for a parent due to financial or geographic constraints, they may elect to keep the parent and patient in-house for an additional day to ensure there is adequate teaching (e.g. feeding) and short-term follow-up. The same may be true for parents with language barriers who do not speak English as a first language. Future single-institution studies may be helpful in elucidating specific causes for prolonged LOS among certain patients.

### **Increased Hospital Charge**

While the primary motivation of understanding care disparities is to ensure patient safety, it is important to also understand secondary consequences of disparity, such as financial burden. Studies in the early 2000's estimated that eliminating all health disparities would decrease direct medical expenditures by \$230 billion, with indirect expenditures totaling more than \$1 trillion for the years 2003-2006.<sup>68</sup> Although CL repair represents a minute portion of these calculations, the data in our study nonetheless support these previous data, showing a dramatic increase (60-83%) in hospital charges among non-White patients.

Interestingly, differences in charge persisted even after controlling for factors expected to contribute to costs, such as baseline comorbidity, complications, and length of stay. Multivariable analyses adjusting for these factors still showed significantly higher hospital charges among Hispanic and Asian/PI patients. The cause of these findings is

unclear, but may be secondary to variation among insurers, hospitals, and geographic locations that are not fully captured by the study co-variables. For example, two individuals living in the South with private insurance could still seek treatment at dramatically different facilities, with private insurance plans that are charged by hospitals at different rates. Thus, future research in more tightly controlled settings—for example, a comparison of charges across patients within a single health system—may be necessary for identifying specific causes of differences in charge.

### **Comparison of Pediatric NSQIP and KID**

The Pediatric NSQIP and KID are two of the largest and most well-validated national databases that collect data relating to pediatric surgical cases, including cleft lip. As such, these databases have served as a basis for a wide range of surgical outcomes research. Nonetheless, many studies have called these databases into question, citing discrepancies in provider coding and improper interpretation and analysis, among other issues.<sup>69,70</sup> Although not a primary aim of this study, our current project's utilization of two separate databases provided an opportunity to externally validate each database.

Direct comparison between NSQIP and KID showed significant differences in each of the parameters assessed, including differences in both the demographics described and the outcomes reported. Some of these differences may be easily explained. For example, since both databases sample patients from different hospitals in the country, a relative imbalance in demographics might be expected. Data related to complications are also expected to differ, as the specific complications collected in each differs slightly,

and NSQIP prospectively tracks 30-day complications as opposed to the complications in KID, which are based solely on discharge records.

Still, other differences in the two databases are harder to explain, and may be suggestive of discrepancies across the databases. For example, a 17% difference in the reported incidence of treatment after 6 months of age is difficult to justify, even in the context of the different time periods of each (NSQIP 2014-2019, KID 2006-2012). The relative underrepresentation of URIM patients in the newer NSQIP database may also raise questions as to the how and where data is collected, and its representative validity when used for outcome studies.

Importantly, even with discrepancies in the two study databases, both showed similar patterns with regards to race/ethnicity. In most cases, the analyses in each database supported the conclusions drawn from the other, suggesting that any discrepancies in the database were likely non-differential in the context of the study; that is, unlikely to bias results in regard to a certain race/ethnic group. Supportive findings in both study databases greatly improves the validity of the final study results.

### **Limitations**

There are several key limitations to this study. First, while the use of a heterogeneous national database increases statistical power (decreasing the possibility for type 2 error), this approach inherently limits study granularity. There may also be some errors in coding within each database (e.g. different utilization of ICD or CPT codes among providers). This may explain some of the significant variations between the KID and NSQIP database, which utilize different coding platforms and sample from different

hospitals. These discrepancies highlight concerns of internal accuracy within the databases themselves; however, these inaccuracies would be unlikely to differentially influence outcomes relating to patient race or ethnicity.

Second, although both databases capture hospital-based same day procedures, cleft care administered in other settings – such as an outpatient surgical center – may not be fully represented. This may lead to an over-representation of complex cases in the study database.

Third, there are limitations to certain statistical approaches in this study, specifically as they relate to race and ethnicity. While necessary for statistical comparison and a component of national databases, the assignment of specific race or ethnicity groups may arbitrarily combine very different groups and individuals. Multivariable regressions with race as a co-factor can also unconsciously reinforce assumptions of “race” as a factor independent from other socially-based covariates, which is not true.<sup>71</sup> The distinctions and data herein should not be interpreted or used to support outdated and incorrect practices regarding a biologic basis of race, which can be destructive and unconsciously (or consciously) promote racism within medical practice.<sup>72</sup>

Last, the data in the current study only reflect immediate or short-term complications and/or outcomes, which are often of less concern in cleft care than long-term sequelae. Even in cases where CL surgery is performed safely and without complication, long-term aesthetic or functional outcomes may still be poor. Future studies designed to investigate long-term outcomes would provide significant value in determining the efficacy of care and/or presence of disparity.

### **Summary/Future Steps**

Taken together, the data in this study demonstrate a significant but complicated relationship between patient race or ethnicity and basic short-term quality indicators in CL repair. Specifically, our data suggest a powerful role of pre-operative patient health in dictating short-term outcomes, reinforcing the importance of holistic clinical approach to CL care.

Within cleft centers and teams, research and policies should be pursued to understand and address population-specific challenges to care that may produce site-specific inequities. Rigid evaluation of practices and patient outcomes, including conversation and qualitative research with patients themselves, may inform areas for improvement. Education efforts and/or funding of health organizations that provide care to underinsured or uninsured individuals may help mitigate delays in care among socioeconomically disadvantaged minority patients. Free or reduced transportation services offered might help reduce geographic disparities to care and improve timely access.<sup>73</sup> In cases where English is not the primary language of cleft children and their families, increase access to interpreter services can be helpful. Increased diversity among medical providers may also play a role in ameliorating certain barriers to care.<sup>29</sup> Additional resources such as implementation of social workers or cleft care nurses to help coordinate the care patients require may prove beneficial.<sup>73</sup> Wagner et al. showed that the implementation of a Cleft Nurse Navigator (CNN) program helped ameliorate disparities in the care of their institution's patients with CLP,<sup>24</sup> as coordination of care via a cleft nurse navigator was shown to increase communication between family and cleft team members, and improve timing of care.



At a minimum, CLP providers should seek to become more familiar with the evidence for disparities and their potential implications in care. While the current study does not suggest discriminatory practices among cleft surgeons themselves—such an assumption is beyond the scope of the study—it does highlight the significant impact of social determinants with CL care. Specifically, our findings highlight the importance of underlying pediatric health in dictating outcomes in CL repair. As such, advocacy for policies and systems that combat disparities in all forms of pediatric health should be pursued. Efforts to uproot structural racism in all its forms are critical to ameliorating disparities in pediatric health which, in turn, may promote greater equity in cleft care.

### **Conclusion**

The results of this study are consistent with previously published data on racial disparities in cleft lip and palate care. Non-White children were significantly more likely to experience delays in care, complications, and prolonged hospital stays than White children. These differences appear to be mediated by a wide variety of factors, including baseline comorbidities and socioeconomic status. Advocacy for policies and structures designed to improve early infant health and streamline cleft care may help ameliorate disparities in care.

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