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INVESTIGATING TREATMENT TIMING DISPARITIES WITHIN CLEFT CARE ALONG RACIAL AND SOCIOECONOMIC LINES: AN INSTITUTIONAL REVIEW

by

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Submitted in partial fulfillment of the requirements for the degree of

Master of

Science in Dentistry

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January 14th, 2022

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DEDICATION

I dedicate this thesis to my parents Delroy Miller and Eva Gordon, who made countless sacrifices for my education. I also dedicate this paper to every minority child that has a big dream.

“I trust that you will so live today as to realize that you are masters of your own destiny, masters of your fate; if there is anything you want in this world, it is for you to strike out with confidence and faith in self and reach for it.”

– Marcus Garvey

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ACKNOWLEDGEMENTS

As always, my thanks and praise firstly goes to God who without I am nothing. I'm eternally grateful for being blessed with the opportunity to pursue my life's ambitions. Secondly, I would like to thank my thesis advisor, Dr. Manish Valiathan who from the inception of this topic has been nothing short of supportive. Also, many thanks to Dr. Rany Bous for taking so much time to share in my passion for this topic. From start to finish, your guidance has helped to push this dissertation beyond what I thought it could be. To my thesis committee members Dr. Anand Kumar and Dr. Juan Martin Palomo, thank you both for the unlimited counsel and for sharing your wisdom. Special thanks to Sarah Pak who helped with collecting the vital data in this project. To my friends and family whose words of encouragement helped to push this project to completion, I thank you. Lastly, to my fellow classmates, I am grateful for this shared journey with you all.

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Abstract

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Introduction: The purpose of this study is to identify the impact of race and socioeconomic status on the age at which patients undergo (1) initial consultation with a cleft center (2) cleft lip repair, (3) cleft palate repair, (4) alveolar bone graft and (5) first orthodontic intervention in order to enable multidisciplinary cleft care teams to proactively support individuals at-risk of unfavorable delays.

Methods: This is a retrospective, institutional, non-interventional quality assessment and quality improvement study. Patient charts between January 1, 2009, and December 31, 2020 that included surgical intervention for cleft lip with/without palate were reviewed. Patients with syndromes were included to identify the potential impact of comorbidities on CLP care. Patients who have complicating medical conditions, diagnosed with isolated submucosal palate, adopted, underwent primary surgical intervention or speech and language evaluation were excluded. The final data set included ninety two

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patients. Demographic, socioeconomic, and care variables were collected from the electronic health records as necessary. Patient age at time of initial consult, cleft lip surgery, cleft palate surgery, alveolar bone grafting and orthodontic treatment were studied as the 5 primary outcomes.

Statistical Analysis: All tests were conducted in Statistical Package for the Social Sciences software. For the parametric variables, an independent T-test was used to compare the age in days for each intervention between White and Black patients, while the Mann-Whitney U-test was used to compare the non-parametric variables. In addition, ANOVA was used to compare the age at each intervention between different socioeconomic status levels.

Results: No significant differences were found along racial and socioeconomic lines for age at initial consult, lip repair, palate repair, alveolar bone grafting and orthodontics ($p < 0.01$). Additionally, a significant positive correlation was found between alveolar bone grafting ($p = 0.000$) with family size.

Conclusion: This study finds no treatment timing disparity based on race and socioeconomic status for the following treatment interventions: initial consultation, primary lip repair, primary palate repair, alveolar bone grafting and first orthodontic clinic visit.

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REVIEW OF THE LITERATURE

Health Care Disparity, Inequality and Inequity

Disparity is a concept that rightfully has garnered much attention due to the schism it inherently represents. It permeates through all arms of our society but health care is one aspect where it raises a high cause for concern. Historically, health care disparity has been difficult to qualify and quantify due to much debate over philosophical conflicts and the large gaps in scientific understanding of the determinants of health. In this paper, we aim to dive deeper into understanding what health care disparity is, its root causes and uncover methods of measuring in hopes of continuing the fight to alleviate its burden on our society.

Disparity, inequality and inequity are terms often used interchangeably to describe differences in public health; however they have very important nuances that lend them to represent different concepts. According to Carter-Pokras in her viewpoint article written in 2000, disagreements in the term choice center on whether a judgment of what is inevitable and unfair is included and how these judgments are made (1).

Health disparity is a term exclusively used in the United States while “health inequity” or “health inequality” are more commonly used internationally.

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Disparity and inequality are the most similar in concept generically meaning dissimilarities or variations in the health achievements of individuals and groups. Disparity, according to Carter-Pokras can be viewed as a difference in (1) environment, (2) access to, utilization of and quality of care (3) health status or (4) outcome of care (1). The National Prevention Council, formed under the Patient Protection and Affordable Care Act of 2010, identifies a health disparity as a difference in health outcomes across subgroups of the population that often is linked to social, economic, or environmental disadvantages. To illustrate this point with an example, a health disparity or inequality would be the greater prevalence of coronary heart disease in men of 70 years of age compared with men aged 20.

Conversely, health inequity refers to those inequalities in health that are deemed unfair or based on a societal injustice. The term “inequity” has a moral and ethical dimension. This concept is typically controversial due to additional considerations in its definition including behavior-related causes. The debate primarily revolves around the issues of free will and individual responsibility of self-care. A 1992 paper by Margaret Whitehead, who is a herald as a leader on this topic, looks at the concepts and principles of equity as understood in the context of the World Health Organization's Health for All policy (2). WHO defines equity as “the absence of avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically.” In other words, it implies that ideally,

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everyone should have a fair opportunity to attain his or her full health potential and, more pragmatically, that none should be disadvantaged from achieving this potential, if it can be avoided.

Social Determinants of Health Inequity

The condition of being healthy is dynamic and can be influenced by a number of environmental factors. The World Health Organization's Commission has defined the social determinants of health as "the conditions in which people are born, grow, live, work and age" and "the fundamental drivers of these conditions" (3).

According to Whitehead there are seven main determinants of health differentials:

1. Natural, biological variation.
2. Health-damaging behavior if freely chosen, such as participation in certain sports and pastimes.
3. The transient health advantage of one group over another when that group is first to adopt a health-promoting behavior.
4. Health-damaging behavior where the degree of choice of lifestyles is severely restricted
5. Exposure to unhealthy, stressful living and working conditions.

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6. Inadequate access to essential health and other public services.
7. Natural selection or health-related social mobility, involving the tendency for sick people to move down the social scale (2).

The consensus view from the literature suggests that health differences determined by factors falling into categories 1,2, and 3 above would not normally be classified as inequities in health and more so inequalities. Contrastly, those arising from categories 4, 5, and 6 would be considered by many to be avoidable and the resultant health differences to be unjust and thereby considered inequities. Whitehead writes that the seventh category is multi-layered as the original ill-health in question may have been unavoidable but the low income of sick people seems both preventable and unjust.

Regardless of the term choices, inequity cannot exist prior to or without inequality. For the purpose of this discussion, we will focus on the avoidable health differences termed as inequity.

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Why is Tackling Health Inequity Important?

Life expectancy, or the estimated average age of death, is among the most basic measures of a population's health. Research studies often use this metric to illustrate the significant gaps in mortality between different groups. There is consistent evidence that disadvantaged groups have poorer survival chances, dying at a younger age than more advantaged groups (4).

Margaret Whitehead highlights several examples in her article “The Concepts and Principles of Equity and Health”. In the United Kingdom, studies have shown that a child born to professional parents can expect to live over five years longer than a child born to an unskilled manual household does. In France, life expectancy of a 35-year-old university lecturer exceeds by nine years that of an unskilled laborer of the same age. In Spain, twice as many babies die among rural workers as among professionals. In addition, in 1987 the USSR saw higher infant mortality rates in urban areas (2). A study coming out of California in 2010 by Clarke et. al found a tremendous 19.6 (+/-0.6) year gap in life expectancy between groups of different socioeconomic status (SES) with the longest life expectancy being the highest SES quintile of Asian females (84.9 years) and the shortest being the lowest SES quintile of African-American males (65.3 years). African-American males living in the poorest 20% of California neighborhoods had life expectancy comparable to that reported for males living in developing countries (5).

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Globally, the scale of differences in mortality is still immense today. Bilal's 2019 comparative study coming out of Spain reported that low socioeconomic status was also strongly associated with mortality in both men and women of any age. Men and women of very low SES had 12.0 and 9.4 years lower life expectancy compared to men and women of high SES, respectively (6).

Health inequity also affects the experience of illness as Vlassof highlighted in his article. Disadvantaged groups not only suffer a heavier burden of illness than others suffer, but also experience the onset of chronic illness and disability at younger ages (7). In Finland for example, 42 percent of those on lower income suffer chronic illness as opposed to 18 percent of the high-income group (2). In a U.K. study of people who died prematurely in different neighborhoods, men and women in the poorer areas were likely to have been chronically ill or disabled for longer before death, and to have suffered a greater number of distinct health problems, than their counterparts in more affluent localities (8).

Other dimensions of health and well-being show a similar pattern of detrimental quality of life. In many countries for example, unemployed people have poorer mental health than those who are employed (9). Differences commonly show up for dental health too. In Norway, 44 percent of the lowest income group have their own teeth compared with 86 percent of the highest group (10).

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A Vicious Cycle

Many disadvantaged people appear to suffer a cycle of injustice. Through circumstances largely outside their control, they shoulder a heavy burden of ill health. Additionally, their impairment can reduce employment and earning opportunities. Consequently, by a lack of resources, poorer social groups may have little choice but to live in disadvantaged conditions that may endanger their health even further - a vicious cycle.

Likewise, personal health behavior options may be severely restricted by social and economic considerations. For example, a less nutritious diet may be chosen because of restrictions on income. Additionally, less physical activity may be undertaken because of lack of leisure facilities or of income or time to make use of them. Promotion of health-damaging products, for example alcohol and tobacco, may be targeted at certain groups in society, such as young working-class men making them more susceptible to the consumption of these products (2).

Nevertheless, with revelations such as these and more research into health inequities, there has been a concerted international urgency for government and other sectors to attend to these differences associated with social position. It is unrealistic to expect everyone in the population to have the same level of health, suffer the same type and degree of illness, and die after

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exactly the same lifespan. However, with effective and efficient health policies major health inequities can be significantly reduced.

History of Racial health care Inequity in America - Uncomfortable Truths

10 years ago, Braveman et al. concluded that health in the United States is patterned strongly not only along socioeconomic but also racial lines citing that worse health exists among minority ethnic groups (11). Williams in his 2016 article illustrated that even when SES is controlled, racial differences often persist. He writes that “higher disease rates for blacks (or African Americans) compared to whites are pervasive and persistent over time, with the racial gap in mortality widening in recent years for multiple causes of death. Residence in poor neighborhoods, racial bias in medical care, the stress of experiences of discrimination and the acceptance of the societal stigma of inferiority can have deleterious consequences for health” (12).

It would be remiss to discuss the racial inequities in health care without acknowledging the history of oppression of Americans of color. Dating back to the 1600s, African Americans have been subjected to systemic institutions that have been framed and created by Whites.This framework includes racial bias, racial ideologies, images, narratives, emotions, and inclinations to discriminate leading to an unequal and unjust society. This framework also underlines the fabric of the medical and public health institutions.

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Feagin (2014) highlights that over about 20 generations, whites have inherited socioeconomic resources from ancestors who benefitted unjustly from slavery, segregation, and other racial oppression. Simultaneously, people of color have been brought to impoverishment from this same unjust oppression. This wealth schism has restricted access of many Americans of color to better jobs, quality education, healthy neighborhoods, quality health care, and political power. Consequently, a person of color has to overcome many more barriers with fewer resources to be able to afford many of the necessities accessible to their white counterparts (13). In the upcoming sections, we will go into depth to show the longstanding history of this racial framework in health care and its continuing reality.

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Early History

Decades of research indicate that a serious U.S. public health problem involves systemic white racism and its negative effects on mostly Americans of color. To properly examine and deal with issues of racial inequities in health, a conceptual analysis of the framework and history from which it originates needs to be done. The U.S. is a country with a legacy of over three hundred years of slavery and legal segregation, which still permeates and shapes its institutions including public health.

Dating back to the mid- 1800s, blacks were often used as guinea pigs for medical experiments. A notable historical example includes James Marion Sims who is hailed as the “father of modern gynecology’’ who conducted surgical experiments on enslaved black women without anesthesia. Sims forced Anarcha, an enslaved girl suffering from fistulas, is a famed example of a patient Sims performed painful intravaginal procedures without anesthetic. Once his techniques were perfected, then he performed this surgery on whites with anesthesia (14). Lobbyist for Sims, who was himself a slave owner, claimed he was a man of his time. They also claim that the end justified the means being that the enslaved women would have wanted treatment regardless. However, it is notable that there is no record of their consent. Throughout the first half of the 20th century, black women were also recurring victims of involuntary sterilization and hysterectomies (15). Fannie Lou Hamer was a famous victim.

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Probably one of the most famous examples of unethical experimentation involving black subjects came in 1932 when the U.S. Public Health Service joined with Tuskegee Institute for a research study titled the “Study of Syphilis in the Untreated Male.” The team used six hundred Black subjects who participated without full consent or disclosure of the study. Even after good treatment for syphilis was discovered, white physicians withheld its cure to further examine how the disease ravaged these men. Many died or passed away (13). This led to pervasive mistrust of science in the black community, which still exists today and could explain why Covid-19 vaccination rates among African-Americans are low.

In 1945, white doctors working with the Atomic Energy Commission, injected plutonium into patients of color without consent to observe effects of radiation, without follow-up care (16). Probably one of the most infamous examples came in 1951 when Henrietta Lacks, a black woman, went to John Hopkins hospital for a lump in her abdomen. After being diagnosed with cancer and treated with radiation, blood samples were taken without her knowledge, which later were used to develop the polio vaccine and started a multi-billion dollar industry. For many years, Lacks and her family were never given financial compensation. Decades later in 2020 after much public backlash, a major biomedical-research organization has for the first time aimed to make financial reparation by gifting The Henrietta Lacks Foundation an undisclosed sum.

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These early examples of medical atrocities reflected a zeitgeist at the time that black lives were not of equal value. Fast-forwarding to more contemporary times, the inequities in care are less blatant and are masked more by socioeconomic issues that when uncovered, still reveal a racially charged problem stemming from injustice.

Contemporary History

Unfortunately, these health inequities are not just anecdotes of the past but are still deeply rooted and reflected in today's reality. In 2010, the Association of American Medical Colleges wrote that, African-American women are more likely to die of breast cancer than women of any other racial or ethnic group are. American Indians are nearly three times as likely to be diagnosed with diabetes as White Americans. Eighty-two percent of the pediatric AIDS cases consisted of African-American and Latino children (17). Such inequities cannot only be explained by an inherent biological variation in Americans of color, but are health consequences of a racial charged system.

Numerous studies demonstrate African Americans, Latinos, Native Americans, and Asian Americans receive a poorer quality of healthcare(18). One review noted that researchers have "repeatedly documented racial and ethnic differences in access to invasive diagnostic and therapeutic interventions for heart disease and stroke. Study findings have consistently

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indicated that African Americans are less likely to receive pharmacological therapy, diagnostic angiography and catheterization, and invasive surgical treatments for heart disease and stroke relative to white Americans with similar clinical disease characteristics" (19). Another study found black patients with lung cancer were less likely to receive the best surgical treatment than white patients (20, 21, 22). Researchers have also found barriers for blacks and the poor in getting kidney transplants, and that black patients are less likely to receive transplants than whites citing “subconscious bias” and “financial disincentives'' as reasons (23).

Literature has consistently reported higher incidence of morbidity for minorities. A 2007 study by Shiboski, highlighted that African-Americans had a significantly higher proportion of cancer, mainly in the tongue, that had spread to a regional node or to a distant site at diagnosis than Whites: 67% versus 49% of tongue cancers reported from 1973 to 1987 ($P < 0.001$), and 70% versus 53% of those reported from 1988 to 2002 ($P < 0.001$). They had a significantly higher proportion of tongue cancer that were >4 cm in diameter at time of diagnosis (59% versus 44%; $P < 0.001$), and black men in particular experienced lower 5-year relative survival rates than white men, in particular, for tongue cancer (25% versus 43% from 1973 to 1987, and 31% versus 53% from 1988 to 2002) (24). Racial and ethnic disparities in cardiovascular disease outcomes are also widely reported.

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The COVID-19 pandemic quickly showed a gravely significant and disproportionate death rate among Black Americans revealing persistent inequities and the need for solutions to address them. A systematic review and meta-analysis demonstrated that COVID-19 has disproportionately affected poor, highly segregated African American communities (25). It also found that a higher percentage of African Americans was associated with increased levels of social vulnerability and risk factors.

The experience and assessment of pain is another area racial differences are significantly evident. The Institute of Medicine has identified racial/ethnic minorities as being at risk for inadequately treated pain across many health care settings (26). Lange in 2017 reported that in the United States, over 60% of all deliveries use neuraxial labor analgesia; however, minority women are less likely to use neuraxial analgesia for labor than non-Hispanic white women even after controlling for patient age, metropolitan status (rural/urban), and the availability of anesthesiologists in the area (27). Additionally, maternal mortality is an important health status indicator, but remains unacceptably high in the US, and is even increasing especially for minority women. Women from racial and ethnic minority backgrounds face greater risks of maternal morbidity – unexpected outcomes of labor and delivery that negatively impact a woman's health – and mortality associated with childbirth. The CDC reports that Black and indigenous women are two to three times more likely to die from pregnancy-related causes compared with

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their white counterparts (28). A 2019 study by Vilda at al reports that across all states, increasing contemporaneous income inequality was associated with a 15% and 5-year lagged inequality with 14% increase in pregnancy-related mortality among black women after controlling for states' racial compositions and socioeconomic conditions (29).

In an effort to show that biological variation is not the overarching factor contributing to mortality differences or the incidence of disease among races, more researchers have been undertaking studies that use controls to eliminate confounders. For example, in a 2019 multiple-cohort study of 306, 100 patients with prostate cancer, Dess et al. found that societal factors and access to quality care, rather than genetics, contributes to a 2.5 times higher prostate cancer mortality rate for Black men, compared to non-Hispanic white men (30). Spratt provides reasons for this citing that “they generally get fewer PSA screenings, are more likely to be diagnosed with later stage cancer, are less likely to have health insurance, have less access to high-quality care and other disparities that can be linked to a lower overall socioeconomic status.”

A 2017 study by Saadi et al titled ‘Racial disparities in neurologic health care access and utilization in the United States’ found that among participants with known neurologic conditions, blacks were more likely to be cared for in the emergency department, to have more hospital stays, and to have higher per capita inpatient expenditures than their white counterparts (31). Zhang in 2016

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reported that Non-Hispanic blacks, Hispanics, and other minorities were less likely to report general dental visits both independently and adjusted for other demographic and socioeconomic factors, compared with non-Hispanic whites (32).

Disparity in Special Needs populations

Health care disparity permeates into even more vulnerable areas of care - pediatric care and children with special health care needs. These disparities are complex and multifactorial, and involve social determinants of health, as well as inequities in access to high-quality diagnostic procedures and treatments, supportive, psychosocial, and survivorship care (33). It is an agreeable fact that children, regardless of social group, should have the same chance of survival**.** A study showed that among 5,086 children with acute lymphoblastic leukemia enrolled in phase III Pediatric Oncology Group trials from 1981 to 1994, after adjusting for disease and treatment-era characteristics, Black race and Hispanic ethnicity remained independently associated with increased risk of mortality (33). A retrospective analysis of 8,447 children with acute lymphoblastic leukemia treated on Children's Cancer Group protocols demonstrated nearly identical survival disparities, recapitulating the independent association of Black race and Hispanic ethnicity

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with inferior overall survival and event-free survival in multivariable analyses (34).

Children with special care needs are especially known to require much higher levels of services and more costly care than the general pediatric population. Disparities within this group can have far-reaching adversities if not addressed. Part of the special care population includes children born with craniofacial anomalies. Craniofacial anomalies (CFA) are congenital deformities that affect a child's head and facial bones (35). They can range from mild to severe and include conditions such as cleft lip and palate, craniosynostosis, hemifacial microsomia, vascular malformation and hemangioma. Plastic and reconstructive surgery is often indicated for children suffering from such abnormalities.

Recent studies have revealed that there are inequities in care for children CFAs (36). Age at initial presentation and timeliness of care are particularly important for children with CFAs. In 2010, a multidisciplinary workshop organized by the Centers for Disease Control and Prevention and the National Foundation for Facial Reconstruction recommended that patients with suspected craniosynostosis be evaluated by craniofacial specialists in the prenatal period and no later than 3 months of age (37). Gandolfi in 2017 documents that there is a practice shift in the treatment of craniosynostosis that rely on an earlier age of initial presentation to take advantage of the pliability of the infant calvaria and the osteogenic capabilities of the dura to help shape the

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skull (38). Despite the importance of early evaluation, Gandolfi found that children with suspected craniosynostosis are frequently referred to see craniofacial surgeons beyond the opportunity window for time-sensitive techniques. Results of Mathijssen's 2015 study showed early referrals (<3 months) were more likely to be white (OR 4.52, 95% CI 1.82-11.19, P = .001), while children referred older than 12 months of age ('very late') for initial evaluation were more likely to be a nonwhite minority (OR 4.96, CI 1.91-12.9, P = .0001) (39). Lin et al in 2015 concluded that for pateints diagnosed with craniosynostosis, public insurance and nonwhite race/Hispanic ethnicity were statistically significant predictors for older age at surgery, when adjusted for other factors including sex, zip code median family income, year, and hospital factors such as size, type, region, and teaching status (40).

Furthering this narrative, Brown in his 2016 research identified another correlation between race and age at consultation in patients diagnosed with craniosynostosis (41). Of the 132 patients in their cohort, 88% were Caucasian and 12% were African American. African Americans had a significantly greater age at consultation compared with Caucasians (median 341 days [IQR 192–584 days] vs median 137 days [IQR 62–235 days], respectively; p = 0.0012). Even more recently, Sergesketter et. al 2018 concluded that craniosynostosis patients who are non-White (P < .0001), have a non-English primary language (P < .005), and have Medicaid insurance (P = .023) are at risk for delayed primary surgery, which may lead to increased 30-day readmission (36).

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Patients Born with Cleft Lip and/or Palate - Importance of Timely Treatment

The largest subgroup of patients with a CFA are patients born with cleft lip and/or palate (CLP). CLP represents a group of congenital deformities resulting in a fissure in the upper lip and/or palate due to faulty fusion post-conception (42). This condition represents the most common congenital birth defect, after heart defects, with an approximate prevalence of 1 in 700 live births (43). The condition predisposes children to a myriad of negative health outcomes including difficulty with feeding, hearing, speech (44 - 46). The management of CLP aims at timing the interventions to help the affected individual achieve specific developmental milestones. Children born with CLP usually require individualized, ongoing treatment from birth into adulthood (48). This care is costly as it involves an interdisciplinary team approach with over ten specialists. Total healthcare costs of children with CLP exceeds those without by about 8 times and the cost difference was largest in the first year of life by over $80,000 per child on average (49).

Access to specialized medical care is critical to decrease complications and minimize long-term morbidity. It has been reported that too early cleft repair can cause alterations in normal craniofacial growth, while late repairs can hinder speech and hearing development (50).

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Over the years, much has been documented about the communication problems associated with delayed cleft palate repair. Velopharyngeal insufficiency (VPI) occurs when the soft palate does not close tightly against the back of the throat, leading to air coming out the nose during speech. It is characterized by hypernasality and/or nasal air emission. VPI is commonly associated with patients with CLP. A study has reported that there is an increase by 6% for each month palate repair is delayed beyond 7 months (51). Chapman concluded that children with CLP who were less lexically advanced and younger at the time of palatal surgery exhibited better articulation and resonance outcomes at 3 years of age (52).

Delayed treatment in children with CLP have also been shown to be associated with increased surgical complications and alterations in normal craniofacial growth. Larger clefts are commonly associated with postoperative fistulas (53). Surgical results in these cases may also be less satisfactory especially as it relates to delays with lip repair and alveolar bone grafting. Later repairs pose a more technical challenge for surgeons as well. Finally, there are also psychosocial implications for patients including stigmatization, social exclusion, poor academic achievement and barriers to employment if treatment is undertaken later leading to unsatisfactory results (54).

While there are some studies that have investigated issues of access to care in children with special needs, empirical research on disparities in health services use among children with CLP is still in its very early stages.

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Significant Delays in Minority Populations

There are a few studies who have undertaken this initiative to uncover health care disparities for children born with CLP. One of the earliest happened in 2009 by Cassell at al (55). Their team examined the timeliness of primary cleft surgery, mean age at which surgery occurred, and factors associated with timely cleft surgery among children with CLP among children in North Carolina. They found that among children covered by Medicaid Black children were less likely to receive timely primary surgical cleft repair than their counterparts. They also found that factors such as prenatal care and geographic residence impacted the timeliness of care.

The disparity extends way beyond the state and institution level as found by national level studies. Abbot et al were the first in their 2011 study that examined an inpatient pediatric database to identify admissions for cleft palate repair between the years 2003 and 2008 (51). They found that palate repair was significantly delayed for patients with public insurance (1.2 weeks, P = .01), were nonwhite (1.5-3.5 weeks, P = .009), and had a diagnosis of cleft lip in addition to cleft palate (3.4 weeks, P = .006). As recently as 2021, Harb followed in Abbot's footsteps with a broader range that investigated disparity over a 12-year period using the Kids' Inpatient Database data (56). Over 7,218 children with cleft palate were included in the study and their findings revealed

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that Black, Hispanic, and Asian children with cleft palate were repaired later than their White counterparts. In addition, children of affluent families were repaired earliest, and economically disadvantaged children were repaired later than their peers. Wu et al in 2018 used the same database to conclude that race was a factor in treatment differences in cleft palate repair as white patients had fewer complications, shorter length of stay, and lower costs following repair (57). They also concluded that delayed age at treatment may predispose patients to adverse sequelae in minority populations, in terms of influencing length of stay and costs.

Other smaller studies came to similar conclusions. Silvestre and his team in 2017 examined a large, urban cleft referral center and found that African American and Hispanic cleft lip and palate patients received alveolar bone graft surgery, a vital treatment intervention in orofacial cleft care, approximately 1 year later compared with Caucasian patients (58). Another study coming out of Chicago urban craniofacial center by Zalzuzec in 2019 found that of the 89 children who underwent surgery, 87% were ethnic minorities (58% Hispanic, 25% African-American, 4% Asian/Other) and were delayed in comparison to their Caucasion counterpart (59). Caucasian children were the earliest to receive cleft lip repair at (3.5 months), African-Americans at 5-months ($P = 0.06$) and Hispanics at 4.8-months ($p = 0.07$).

Other researchers and pundits have attempted to look into the overall source of treatment variations based on racial and socioeconomic factors. Lynn

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in his 2018 single-center institutional study looking at the “Sociodemographic Predictors of Missed Appointments Among Patients With Cleft Lip and Palate” found that patients who were black (P = .04), not affiliated with a religion (P = .01), Medicaid users (P = .01), from an unstable social background (p = .01), or received need-based financial assistance (p = .00) were significantly more likely to miss appointments (60). Lynn followed up in 2020 by investigating the “Sociodemographic Predictors of Patient Age at Time of Cleft Lip and Palate Repair.” This study found Cleft lip repair was performed significantly later for patients identifying as Asian (18 weeks, P 1⁄4 .01) and patients with Child Protective Services contact (19 weeks, P 1⁄4 .01). Additionally, preliminary speech and language evaluation were performed significantly later for patients identifying as black (55 weeks, P 1⁄4 .03) (61).

Cost of care is a recurring theme when assessing barriers. As aforementioned, care for patients with special health care needs is costly. Specifically, CLP care requires a carefully coordinated, interdisciplinary approach, which involves multiple and ongoing treatment interventions from birth into adulthood. Treatment includes but is certainly not limited to multiple surgeries, orthodontics, prosthodontics, plus hearing, speech, learning and behavioral evaluations and therapies. According to Nidey in their systematic review, understanding differences in out-of-pocket spending is important to accurately assess financial burden on families and access to needed care (49).

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Health insurance type and coverage is yet another barrier to care. Mothers reported insurance payment caps, inadequate insurance coverage, especially for speech therapy, and high out-of-pocket costs, as main barriers to care (49). Abbot also reported that patients with public insurance received delayed palate repair compared to those with private insurance (51). As indicated by Pfeifauf in 2017, variation in state policy for coverage and access may also play a role in treatment timing variations (62).

Cleft care is best managed at an American Cleft Palate-Craniofacial Association approved team center (63). The ACPA have outlined standards of care for optimized treatment outcomes (64). Currently there are 175 ACPA-approved cleft teams in the US and Canada. In the absence of team care, families will seek community-based providers. The limitation of community-based care is that not all providers will have the high level of training as those that are a part of an approved team. Additionally, they may not have the resources to consult and coordinate with professionals on cleft teams about treatment milestones. One study that surveyed orthodontic residents and practicing orthodontists reported that nearly 64% and 83% of study participants, respectively, reported that they intended to treat individuals with craniofacial anomalies in the future (49). Further research is needed to investigate the amount and quality of training community-based providers receive in caring for children with CLP and how this affects treatment outcomes.

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There is still further research to be done to assess the extent of variations in access to care and to delve deeper into root sources of barriers, which inhibit access. Most of the studies involving patients with CLP investigates only one treatment intervention. There are multiple treatments involved in orofacial cleft care and it is worthwhile uncovering where treatment variations lie and are most significant. Subsequent studies can then dive deeper into the individual root causes.

To effectively achieve equitable survival in the United States and globally, collaborative research efforts are urgently needed to gain a better understanding of factors underlying disparate outcomes. The results of such studies can then be used to educate stakeholders including patients, providers, health systems, insurance companies, and government institutions for better resource allocation.

Explanation of the Systemic Framework: Patient, prover and systemic factors

Nevertheless, why do racial inequities persist today? Evidence-based research has shown that an amalgamation of patient factors, provider factors and systemic factors are at play (65).

Patient Factors

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Complex ties exist between race, socioeconomic status, and insurance coverage in the United States. Currently, uninsured/underinsured status, underlying comorbidities, and low-income status predict inadequate access to optimal and timely surgical care and poorer surgical outcomes, one study reports. All of these factors are typically found in a higher percentage of non-white persons, especially African-Americans, Hispanics and Native Americans. It is postulated that this hinders a growing population in the U.S. from receiving optimal care.

African Americans are statistically among the lowest earners and highest unemployed in today's U.S. society. According to the U.S. Census Bureau, African Americans median household income was $45, 870, while Whites and Asian households totaled $71, 231 and $94, 903 respectively between 2020 (66). According to data extracted in May 2020 from the U.S. Bureau of Labor Statistics, in the fourth quarter of 2019, African American workers had the highest unemployment rate nationally, at 5.9 percent, followed by Hispanic (4.2 percent), white (3.2 percent), and Asian workers (2.5 percent) (67). The widespread devastation in job losses in America due to the Covid-19 pandemic spiked the unemployment to 14.7%, the highest level since the Great Depression (68). Anne C.Wheeler in 2019 reported that children with family annual incomes less than $50,000 (Ref: >$100,000) were more likely to have caregivers that perceived availability and cost as barriers (69).

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Caregiver knowledge and awareness about their child's condition is also a factor that varies between groups and impacts care seeking behaviors. According to a 2018 study by Zuckerman et al, there are variances among parents in their knowledge and familiarity with common developmental disabilities (70). The study found that low-income Latino limited-English-proficient and other race parents have less familiarity or personal experience with developmental disabilities, and are less aware of their early signs compared to low-income white parents. Significantly more nonwhite participants reported that they had never heard of one or more of the common developmental disabilities compared with white participants (72% vs 52.3%; $P < .001$). Study findings suggest that interventions to reduce disparities in developmental disability diagnosis and treatment should include increasing information transfer to parents in racial/ethnic and language minority communities.

While this study assessed parents knowledge about more "invisible" anomalies (autism spectrum disorder (ASD), attention-deficit/hyperactivity disorder (ADHD), cerebral palsy, and Down syndrome), a similar situation might be at play for more "visible" craniofacial anomalies. It is also worthwhile to note that development delays accompany many craniofacial conditions. Conditions such as craniosynostosis where babies have an abnormal skull shape, are sometimes recognized by parents themselves before they are brought in for examination by a physician (39). If there is a delay in recognition,

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there will be a subsequent delay in diagnosis and treatment. It is worthwhile to examine if there is a disparity in recognition of physical abnormalities that would lead to treatment delays.

Another patient factor is the knowledge of available resources to help mitigate the care burden (49). The Family and Medical Leave Act (FMLA) of 1993 allows an employee to take an unpaid leave of absence to care for a sick family member or a newborn. Under this law, an employee is entitled to 12 workweeks of leave per 12 months. Generally, FMLA ensures that all workers are able to take extended leaves of absence from work to handle family issues or illness without fear of termination from their jobs by their employers or being forced into a lower job upon their return. According to a 2017 Issue Brief in IMPAQ International, while FMLA has increased leave-taking among eligible workers, overall effects have been modest partly because many who are eligible are unaware of the law's benefits and eligibility requirements (71).

Provider Factors

Mounting research has shown that racial framing in health care is due in part to "implicit" or "unconscious" bias of providers (72). Implicit attitudes are thoughts and feelings that often exist outside of conscious awareness, and thus are difficult to consciously acknowledge and control. Most health care providers appear to have some implicit bias (73). Several studies have used the implicit

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association test (IAT) to gauge racial bias of providers. Test results revealed that most whites associate images of black faces with negative words and traits (e.g., negative character traits). Most have more difficulty in linking photos of black faces to pleasant words and positive traits than they do for white faces (73). Analyses of thousands of face-reaction tests show the overwhelming majority of whites reveal an anti-black, pro-white bias (74).

William J. Hall in his 2015 systematic review says that most implicit biases may result in patients of color kept waiting longer for assessment or treatment than their White counterparts, or providers may spend more time with White patients than with patients of color (73). The National Academy of Medicine (NAM) stated that socioeconomic status alone couldn't account for all the healthcare disparities observed (75). They found that "racial and ethnic minorities receive lower-quality health care than white people—even when insurance status, income, age, and severity of conditions are comparable." NAM reported that minority persons are less likely than white persons to be given appropriate cardiac care, to receive kidney dialysis or transplants, and to receive the best treatments for stroke, cancer, or AIDS. It concluded by describing an "uncomfortable reality": "some people in the United States were more likely to die from cancer, heart disease, and diabetes simply because of their race or ethnicity, not just because they lack access to health care."

To effectively combat this issue, more education on individual biases can be initiated. Additionally, having more providers of color to reflect the

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minority distribution in the general population. According to an Association of American Medical Colleges report (2010), three quarters of those practicing medicine are white. Evidence suggests when physicians and patients share the same race or ethnicity, this improves time spent together, medication adherence, shared decision-making, wait times for treatment, cholesterol screening, patient understanding of cancer risk, and patient perceptions of treatment decisions (76,77).

Systemic Factors

The last factor in this discussion and arguably the most important are those that are “systemic” or “institutional” in nature. Institutional racism is a widely documented phenomenon outside of healthcare especially as it relates to law enforcement. Feagin writes, “Understanding systemic racism and how it shapes health and health care requires going beyond a conceptualization of individual racial biases disconnected from a broad white racial framing and associated structural power inequalities” (13).

Institutional racism involves practices, procedures, patterns, and policies that operate to privilege members of particular racial groups in every aspect of society (78). It is an exclusionary system where a group is denied access to rights and privileges conferred on some groups in the form of unearned advantage (79). The Macpherson Report defined institutional racism as “the collective failure of an organization to provide an appropriate and

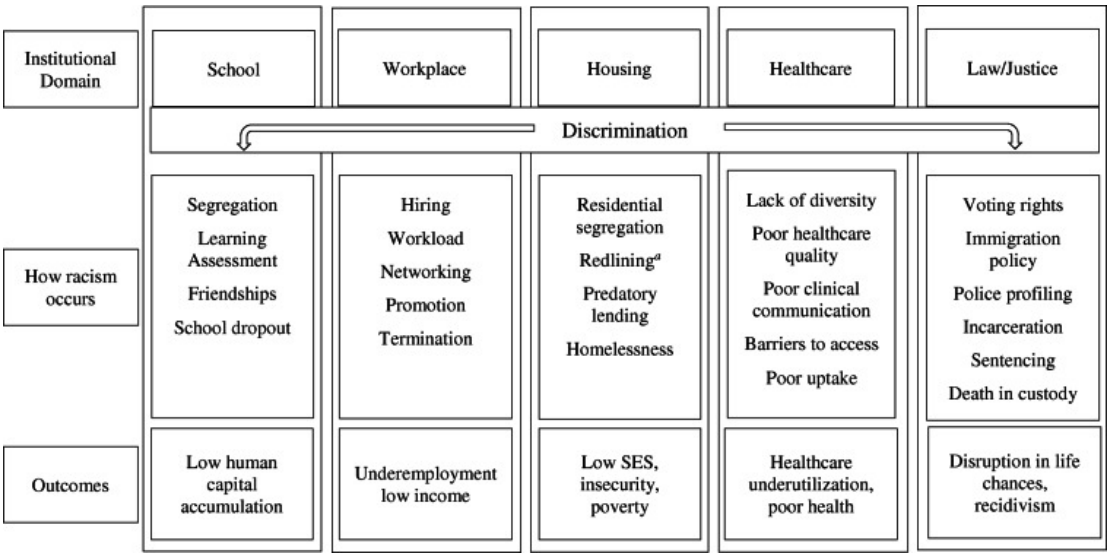
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professional service to people because of their color, culture or ethnic origin" (80). Carmichael and Hamilton (81) were the first to coin the phrase "institutional racism" in reference to the systemic nature of racism prevailing in the United States in the 1960s.

The institutional barriers produced from this system, precludes equitable access, health care services that adhere to a traditional individualistic ethos and ignore the cultural specificities of minority groups are likely to perpetuate existing disparities in health outcomes (82). In order to understand systemic racial inequities, we must first examine the institutions, which lead to them. The figure below taken from Elias et al 2021 publication outlines the different institutions and how racism within them has led to disparate outcomes (79).

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Figure 1



Elias, A., Paradies, Y. The Costs of Institutional Racism and its Ethical Implications for Healthcare. Bioethical Inquiry 18, 45–58 (2021).

The socioeconomic gradient of health is also well established in the United States and worldwide. Decades of research show a dose-response relationship between educational attainment and health in the United States (79). That is, the relationship between social advantage and health is incremental—with less advantaged groups experiencing a disproportionate burden of poor health and even relatively advantaged groups showing a deficit (83).

Another structural issue is the majority-white decision makers include public health researchers and policymakers, medical educators and officials, hospital administrators, and insurance and pharmaceutical executives, as well as important medical personnel.

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Another systemic dilemma known as the “Inverse Care Law” proposed by Julian Tudor Hart in 1971, describes when inequities in access arise from resources and facilities being unevenly distributed around the country (84). These resources are clustered in urban and more prosperous areas and scarce in deprived and rural neighborhoods. This leads to deprived communities who suffer the worst health having fewer medical resources.

According to Griffith 2017, the United States has the largest socioeconomic disparities in health care access of any wealthy country (85). The Affordable Care Act (ACA) was institutionalized to bridge income-related gaps in access to primary care providers and avoiding care due to cost. While the ACA has closed the absolute gap in insurance coverage between people in households with annual incomes below $25,000 and those in households with incomes above $75,000 (a relative reduction of 46 percent), it is not devoid of it’s issues especially as it relates to Craniofacial and orthodontic care.

Despite the importance of orthodontics for complete and adequate habilitation, third-party payers often deny coverage for orthodontic care of cleft palate and craniofacial patients on the basis that such procedures are cosmetic or medically unnecessary (86). There still exists no federal coverage mandate for orthodontic treatment of cleft palate and/or craniofacial anomalies, and the federal Patient Protection and Affordable Care Act (the “Affordable Care Act”) did not close this gap (87). Additionally only eighteen states statutorily mandate some type of coverage of cleft palate and/or craniofacial anomalies (62). Of the

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18, only 11 specify a legal standard for coverage (CT, HI, MA, VT, AR, FL, CA, CO, OR, SC, VA). Every state statute designating a legal standard adheres to either the “medically necessary” standard, or a closely related standard. These “medically necessary”-type qualifiers are problematic. The absence of additional language defining what constitutes medical necessity creates a burdensome landscape for parents and providers to navigate in determining the extent of coverage for patients with cleft palate and/or craniofacial anomalies. For example, the American Association of Orthodontics, in an effort to establish a universal definition of “medically necessary orthodontic care,” interviewed a cross-section of representatives from third-party insurance providers about their definitions of the term (88). Each insurance provider had a unique definition of what qualified for coverage. Currently, thirty-two states do not mandate coverage. This can mean treatment delays for minority patients who depend on insurance funding to foot these large medical expenses.

This lack of standardization in coverage determination across the insurance industry makes it difficult to predict insurance coverage, creating the need for patients and providers to await final determinations of coverage before proceeding with care. Patients and providers may also waste resources on time spent appealing insurance decisions. Disputes over medical necessity can therefore lead to orthodontic coverage denials and subsequent surgical intervention delays (89). In response to this problem, the American Association of Oral and Maxillofacial Surgeons issued a white paper in support of legislation

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requiring broad orthodontic care coverage for craniofacial patients until they reach the age of 26 (90).

The legislation reflects the AMA's definition of reconstructive surgery as that being performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. Cosmetic surgery, in contrast, is defined by the AMA as being performed to reshape normal structures of the body in order to improve the patient's appearance and self-esteem.

Institutional racism is not easy to detect, it is rarely visible to those that are privileged by it, and is sometimes undetectable to those impacted by it, thereby allowing it to persist. Patients are oftentimes oblivious because they have no comparison for how other patients of a different race are treated. Clinicians are often blind to their own implicit bias or justify and rationalize their explicit prejudices. Policymakers and administrators are often of the assumption that treatment is equitable despite the growing conflicting evidence because they are not surrounded by it. This research attempts to investigate further into the systemic factors that contribute to health care disparities.

Disparity Initiatives in the US

Equity in health care means equal access to available care for equal need, equal utilization and equal quality of care for all. In other words, the focus

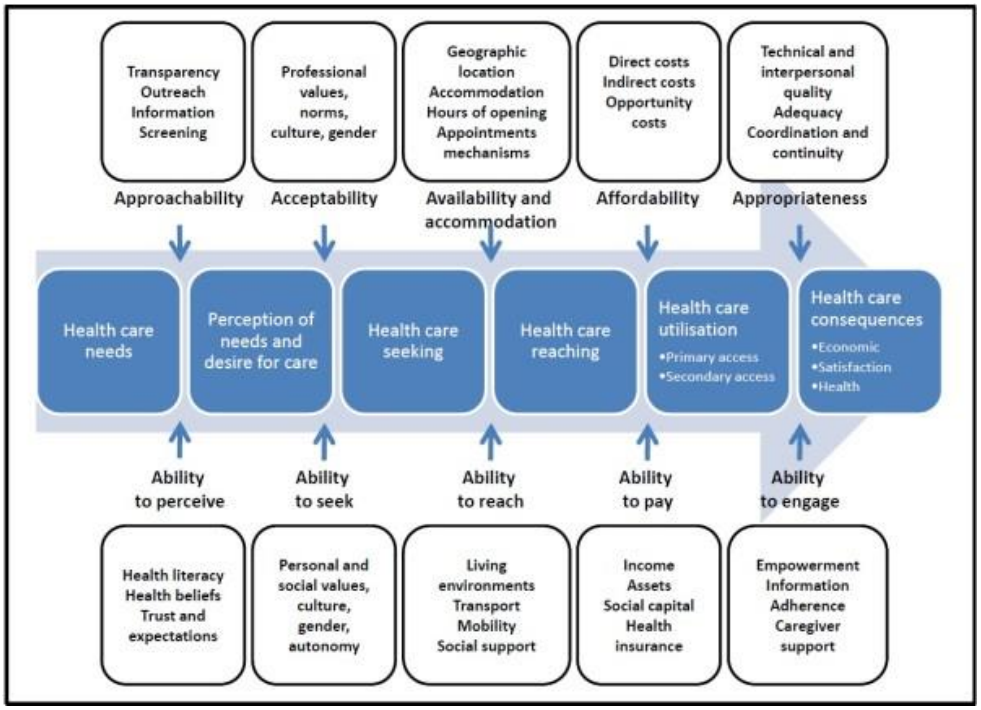
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is placed on accessibility, quality, and acceptability of the care offered to all sections of the population (91).

According to a 2013 systematic review by Levesque et al, access is defined as the opportunity to identify health care needs, to seek health care services, to reach, to obtain or use health care services, and to actually have a need for services fulfilled. They conceptualize five dimensions of accessibility: 1) Approachability; 2) Acceptability; 3) Availability and accommodation; 4) Affordability; 5) Appropriateness (85).

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Figure 2



Levesque, JF., Harris, M.F. & Russell, G. Patient-centred access to health care: conceptualising access at the interface of health systems and populations. Int J Equity Health 12, 18 (2013).

In this framework, five corresponding abilities of populations interact with the dimensions of accessibility to generate access. These abilities include: 1) Ability to perceive; 2) Ability to seek; 3) Ability to reach; 4) Ability to pay; and 5) Ability to engage.

The Department of Health and Human Services launched an initiative in 2010 called Healthy People 2020. The platform was built on four overarching goals- to increase quality and years of healthy life and to eliminate health disparities. While these goals are separate, they are not mutually exclusive. In

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order to increase life expectancy equally among social groups, the distance that separates them must be identified and eradicated (92).

The Action Plan advances five major goals: transforming health care; strengthening the infrastructure and workforce of the nation's health and human services; advancing Americans' health and well-being; promoting scientific knowledge and innovation; and upholding the accountability of HHS for making demonstrable progress. By mobilizing HHS around these goals, the Action Plan moves the country closer to realizing the vision of a nation free of disparities in health and health care.

Thornton et al in 2016 found sufficient evidence of successful outcomes to support disparity-reducing policy interventions targeted at education and early childhood; urban planning and community development; housing; income enhancements and supplements; and employment (93). Cost-effectiveness evaluations show that these interventions lead to long-term societal savings.

Eliminating health care inequity remains a public health priority and an ethical imperative worthy of a public policy intervention. A policy statement from the American College of Physicians writes that addressing some of the sources of institutional racism and harm through transparency and accountability measures is the first of many steps required to begin correcting historical racial injustices. Research consistently shows that where access to care is equal, outcomes disparities become indiscernible. Elucidating and ameliorating the

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structural mechanisms that limit access to care among minority populations will have a positive impact on reducing racial disparities.

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STATEMENT OF THESIS

Objective: The aim of this study is to compare the timing for five treatment interventions within cleft care along racial and socioeconomic lines. The age at which patients undergo treatment for (1) consult, (2) primary lip repair, (3) primary palate repair, (4) alveolar bone grafting and (5) first orthodontics clinic visit were investigated (1) between black and white patients and (2) among low, middle and high socioeconomic status.

Null Hypothesis 1: There is no difference in the timing of treatment interventions within cleft care between Black and White patients.

Null Hypothesis 2: There is no difference in the timing of treatment interventions within cleft care based on socioeconomic status.

Alternate Hypothesis 1: There is a significant difference in the timing of treatment interventions within cleft between Black and White patients.

Alternate Hypothesis 2: There is a significant difference in the timing of treatment interventions within cleft care based on socioeconomic status.

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MANUSCRIPT FOR PUBLICATION

Investigating Treatment Timing Disparities within Cleft Care along Racial and Socioeconomic Lines: An Institutional Review

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Introduction

Cleft lip with/without palate (CLP) represents a group of congenital deformities resulting in a fissure in the upper lip and/or palate due to faulty fusion post-conception (1). It is caused by both genetic and environmental factors. CLP is the most common congenital birth defect, after heart defects, with an approximate prevalence of 1 in 700 live births (2). Its prevalence varies based on demographic factors such as sex and race, for example males and persons of Asian descent are more likely to develop an orofacial cleft in comparison to their counterparts (3).

CLP predisposes children to a myriad of negative health outcomes. Consequently, delayed treatment has been linked to adverse outcomes such as increased surgical complications, alterations in normal craniofacial growth, speech and hearing difficulties (4-6). Additionally, CLP can cause children to experience psychosocial problems, including poor academic achievement and increased anxiety and depression (7). Given these deleterious effects, early and proper treatment of cleft palate is critical to the short and long-term well-being of these patients.

Over the past several decades, cleft lip and palate care protocols have changed considerably paralleling new developments in research. For example, palate repair has changed from approximately 24 months of age as it was in the late 1970s to 12 months today (8). Earlier surgical repair has proven to be safe for patients and has facilitated improved speech and language outcomes

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due to earlier intervention by speech and language pathologists (9). Conversely, new studies have shown that palate repair delay is associated with increased velopharyngeal insufficiency (10).

Children born with CLPs require more focused, team-coordinated and longitudinal care that is underscored by higher costs than the general pediatric population. Care is best managed at an American Cleft Palate-Craniofacial Association approved team center (11). Treating CLP can prove costly to both the affected families and health systems, and can be particularly challenging in low resource settings. Recent studies have shown that race, insurance type and socioeconomic status influence the treatment outcomes for orofacial clefts and minimize access to care (12 - 17). Moreover, sociodemographic and psychosocial factors have been identified as predictors of elevated missed appointment rates among patients with CLP and consequently lead to delayed treatment outcomes (18). Health care disparities within cleft care can have far-reaching adversities if not addressed.

10 years ago, Braveman et al. concluded that health in the United States is often, though not invariably, patterned strongly along both socioeconomic and racial lines citing that worse health exists among the most socially disadvantaged (19). While research into this is developing, there have been several cries for more targeted initiatives to examine and combat these health care disparities across more areas of care. There are multiple treatment interventions involved in orofacial care and it is worthwhile uncovering where

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treatment variations lie and are most significant. In order to progressively advance toward health equity in the care of patients with CLPs, associations between clinically accessible patient characteristics and measurable health outcomes should be identified.

The purpose of this study is to identify the impact of clinically accessible demographic, socioeconomic, and health care variables on the age at which patients undergo (1) initial consultation with a cleft center (2) primary lip repair, (3) primary palate repair, (4) alveolar bone graft and (5) first orthodontic visit in order to enable multidisciplinary cleft care teams to proactively support individuals at-risk of unfavorable delays. Research has demonstrated an average 3-week delay in surgery for minority patients nationally (16).

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Materials and Methods

This retrospective, non-interventional quality assessment and quality improvement study was reviewed and approved by the University Hospital institutional Review Board. The general study design utilized in this analysis has been previously described Lynn et al (18).

Patient charts between January 1, 2009, and December 31, 2020 that included surgical intervention for cleft lip with/without palate were reviewed. Only black and white patients were included. Patients who have complicating medical conditions, diagnosed with isolated submucosal palate or adopted were excluded. The final data set included ninety two patients. Demographic, socioeconomic, and care variables were collected from the electronic health records as necessary. Socioeconomic status was further assigned using a combination of insurance information and zip codes. To identify health disparities and progress toward health equity, patient age at time of initial consult, cleft lip surgery, cleft palate surgery, alveolar bone grafting and initial orthodontic screening were studied as the 5 primary outcomes.

A priori power analysis was done prior to data collection using an effect size of 0.90 calculated from a similar study. It was determined that a sample size of 27 per group would yield 95% confidence interval for a two-sided alpha of 0.05 with a beta of 0.10. The Bonferroni correction was done to counteract the problem of multiple comparisons. P values of ≤ 0.01 were considered statistically significant.

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Statistical Analysis

All tests were conducted in Statistical Package for the Social Sciences (SPSS 26.0) software. The Shapiro-Wilk test was used to determine normality of distribution of each of the five examined variables. For the normally distributed variables (parametric), an independent T-test was used to compare the age in days for each intervention between White patients and Black patients, while the Mann-Whitney U-test was used to compare the non-parametric variables. In addition, ANOVA was used to compare the age at each intervention between different socioeconomic status levels.

A secondary analysis was done to compare the impact of gender, insurance type and family size on treatment timing as past studies have shown these factors to have a significant effect. An independent T-test was used to compare the mean age difference between males and female patients for each treatment intervention. An independent t-test was also used to compare insurance time against treatment intervention. Finally, a Pearson's correlation coefficient was used to correlate the family size to the timing of each intervention.

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Results

Study Sample Characteristics

Ninety two patients were included in the study (Table 1). Less than half of the patients were female (44%), which is in accordance with the gender prevalence of CLP reported in the literature (Basseri et al., 2011). White individuals accounted for roughly three-quarters of the study sample (64 of 91 or 69.6%) while those identifying as black comprised 28 of 92 or 30.4%. The study sample consisted of patients diagnosed with and treated for cleft lip (9.8%), cleft palate (33.7%), and cleft lip and palate (56.5%). For the sociodemographic variables, 54.4% were Medicaid beneficiaries while 45.6% had private insurance. Most of the black patient sample had public insurance while the White cohort had a relatively even split between public and private insurances. There were 56, 2 and 33 patients of low, middle and high socioeconomic status respectively.

The mean patient age at the time of consult, cleft lip repair, cleft palate repair, alveolar bone grafting and initial orthodontics was 206 ± 444.8, 185.8 ± 149.7, 694.1 ± 695.6, 3513.1 ±5 91.54, 2981.2 ± 686.4 respectively. The standard deviation being greater than the mean at some of the time points suggest the presence of outliers in the study sample. Study results per treatment intervention are further shown in Table 2 and 3.

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Consult

68 patients were included in this sample set. A Shapiro-WIlk test revealed that the data within this treatment intervention was the only non-parametric variable ($p<0.01$). There were 47 white patients in this cohort versus 21 black patients. Black patients were found to have an overall initial consult time earlier than white patients. However, a Mann-Whitney test determined that overall no significant difference existed between the mean time to consultation of black and white racial cohorts ($p>0.01$).

There were 43 pat no significant difference was found between socioeconomic groups for time to get an initial consultation ($p>0.01$). Gender, insurance type and family size also showed no significant difference within this intervention.

Lip Repair

37 patients were included in this sample set. There were a total of 37 patients in this sample - 27 were White and 10 black. Black patients overall had earlier lip repair. Since the data was normally distributed, an independent t-test was performed, which revealed no significant differences between racial cohorts for time to complete primary lip repair ($p>0.01$). Additionally, no significant differences between socioeconomic groups for treatment timing

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within this intervention (p>0.01). Gender, insurance type and family size also showed no significant difference within this intervention.

Palate Repair

54 patients were included in this sample set. 36 were white and 18 were black. Black patients had an overall later palate repair. When looking at the range, there was a 1,185 day difference between the latest patients of both groups. In other words, the latest black patient was almost 3 years behind the latest White patient. However, results of the independent t-test revealed no significant difference between the mean age of racial cohorts for time to complete palate repair (p>0.01). Additionally, no significant difference was found between socioeconomic groups within this intervention (p>0.05). Gender, insurance type and family size also showed no significant difference within this intervention.

Alveolar Bone Grafting

26 patients were included in this sample set. The latest White patient received their ABG 1,226 days (3.4 years) later than their latest Black counterpart. However, the t-test was performed to determine no significant difference between racial cohorts (p>0.01). Additionally, no significant difference was found between socioeconomic groups within this intervention (p>0.01). However, a Pearson correlation coefficient test revealed a significant

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positive correlation between family size and alveolar bone grafting with larger family size showing an increased timing to complete ABG ($p = 0.000$). Gender, insurance type and family size also showed no significant difference within this intervention

Orthodontics

32 patients were included in this sample set. A t-test was performed to determine the difference between racial cohorts. No significant difference was found between black and white patients for time to get their first orthodontic visit ($p>0.01$). There was a 1,099 day difference between the latest patients of both groups, where the black patient was later.

Additionally, no significant difference was found between socioeconomic groups within this intervention ($p>0.05$). Gender, insurance type and family size also showed no significant difference within this intervention.

Discussion

Research suggests that the overall health of Americans has improved; however, disparities continue to persist among many populations within the United States. Racial and ethnic minority populations have poorer access to care and worse outcomes than their white counterparts. Approximately 20% of

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the nation living in rural areas are less likely than those living in urban areas to receive preventive care and more likely to experience language barriers.

There are several studies that have investigated and found health care disparity within cleft surgical cleft care. Most studies have looked at treatment delays per one intervention for example alveolar bone grafting or palate repair separately. However, these studies have found several variances along both racial and socioeconomic lines. Many have found that minorities, persons of low socioeconomic status, have public insurance, and large family sizes experience treatment delays (12 - 17).

Our study results finding no difference along any of those major variables does not negate the fact disparities exist. It does however show that in comparison to other health systems, the institution under study seems to be faring better. It then begs the question of why? What are the differences in the center of study that leads to a more egalitarian treatment outcomes. After carefully assessing the qualities of the care team there may be several contributing factors.

Work of social team

Social work is an integral part of any craniofacial care team. In fact, the American Cleft-Palate Craniofacial Association as a standard recommends approved teams to have available, either as part of the team or for referral, social workers and psychologists who are capable of addressing the

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psychological and social needs of the patient and family/caregiver (20). Under the umbrella of social services, the ACPA states that the team must have a means to initially and periodically assess and treat, as appropriate, the psychological and social needs of patients and families/caregivers and to refer for further treatment as necessary.

Despite this recommendation, every team functions differently. Some teams do not have a social worker as a team member and if they do, their job description and hours vary across teams. For example, the 2020 study by Lynn et al that found racial disparities in palate repair has a social worker that is only part-time within their care team (17). Similarly, the study coming out of North Carolina found that none of the ACPA approved teams in the state had a full-time social worker. In fact, there was one team that did not have one altogether. Additionally, not all social workers have the same level of training which directly impacts their function.

The social worker in this institute of study is a full-time dedicated employee who is responsible for understanding and linking a family's individual social determinants of health to treatment needs and proactively connects them to resources. The social worker meets with every family pre- and postnatally. The first visit is most important because it sets the tone to the families that they are well supported on their treatment journey and help with coping strategies. The social worker in conjunction with a nurse and plastic surgery team meets with the family for general counseling and to discuss surgical timelines. The

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social work team also gears the conversation towards how families are coping with the news of the diagnosis. Once the social worker gets a proper sense of the families individual needs and concerns, proper resource allocation can be done. The social team also maintains frequent visits throughout a family's treatment journey which helps to build trust and open communication. The social team at the UH center also offers a support group for families and patients to connect. Transport services to get to and from appointments are also offered to families.

Geographic Access

Access to high-quality care varies considerably by location, between rural and urban areas, as well as across smaller communities (21-22). When racial and ethnic groups are unevenly distributed across communities, geographic variation in health care has the potential to explain some health care differences. To produce overall differences in care, the choice of hospitals or clinics that different groups attend and variations in treatment within those institutions could reinforce each other, or cancel each other out, or one or another factor could be more important. For example, focusing on acute myocardial infarction, Skinner et al. (2003) found that, nationwide, black patients received care at lower-quality hospitals, where they tended to make up a larger proportion of the patients (23). Conversely, in a five-state study, Kahn et al. (1994) found that blacks received poorer care in acute care hospitals than whites in the same hospitals, but because more black patients

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in the study were seen at higher-quality urban teaching hospitals, their overall quality of care was no worse (24).

Chandra et. al writes in their study that a potentially large part of overall health disparities in the United States may be the consequence of regional differences in treatment and outcomes (25). Reducing geographic disparities in quality of care will benefit all Americans, but is likely to yield greater benefits to minority patients.

The disparities that occur when hospital or provider quality is worse in regions with a larger percentage of African Americans can be solved only by addressing the problem of geographic disparities in health care. Furthermore, reducing geographic disparities is likely to have a first-order impact on improving racial disparities in health care and health outcomes.

Cleveland, Ohio ranks high as a U.S. metropolitan area with one of the largest African-American populations with approximately 20% of its population being black. There are 3 ACPA-approved teams in Cleveland and 4 others in surrounding cities.

Local resources that are made available to underserved communities

The social team liaises families with resources like BCMH. BCMH or The Bureau for Children with Medical Handicaps is a local program operated by the Ohio Department of Health for children from Ohio, under the age of 21 with special medical needs or chronic medical conditions (26). BCMH can help

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cover unpaid medical bills or excessive medical costs due to services not covered by a primary health insurance plan. Providers must be approved to work with BCMH. The program covers diagnostic testing and treatment assistance which may include medical equipment/supplies, prescription medications, occupational therapy, physical therapy and more.

Another resource is Early Intervention (EI) which is a statewide system that provides coordinated early intervention services to parents of infants and toddlers with disabilities or developmental delays in Ohio (27). Every family served in EI will have a local EI team that consists of a service coordinator, service providers, and the family. Programs such BCMH and EI in addition to others help families of lower socioeconomic standing with support services to get their children on an equal playing field.

Conclusion

In comparison to national level data and other institutional studies, this study finds no disparity on the basis of race and socioeconomic status for the following treatment interventions: initial consultation, lip repair, palate repair, alveolar bone grafting and initial orthodontic clinic visit. Further studies are needed to confirm contributing factors that help to create a more egalitarian health system for children with cleft and factors that create further inequities.

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TABLE 1.-- Descriptive Statistics

Characteristics	Total N (%)	White N (%)	Black N (%)
	92	64 (69.6%)	28 (30.4%)
Assigned Sex			
Male	53 (56%)	36 (39.1%)	17 (18.5%)
Female	39 (44%)	28 (30.4%)	11 (12%)
Diagnosis			
Cleft lip	9 (9.8%)	8 (8.7%)	1 (1.1%)
Cleft lip + Palate	52 (56.5%)	35 (38%)	17 (18.5%)
Palate	31 (33.7%)	22 (23.9%)	9 (9.8%)
Insurance			
Private	41 (45.6%)	35 (38.9%)	6 (6.7%)
Public	49 (54.4%)	28 (31.1%)	21 (23.3%)
Socioeconomic Status			
Low	56 (61.5%)	33 (36.3%)	23 (25.3)
Middle	2 (2.2%)	1 (1.1%)	1 (1.1%)
High	33 (36.3%)	29 (31.9%)	4 (4.4%)

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TABLE 2.--Racial Effect on Timing of Consult, Lip repair, Palate Repair, Alveolar Bone Grafting and Orthodontics

	Racial Groups	N	(%)	Mean	Std. Deviation	Std. Error Mean	P-value
Consult	White	47	69.1%	205.8	436.8	63.7	0.658
	Black	21	30.9%	152.2	467.4	102.0	
Lip Repair	White	27	73.0%	185.1	129.5	24.9	0.077
	Black	10	27.0%	133.2	43.5	13.8	
Palate Repair	White	36	66.7%	634.6	498.4	83.1	0.338
	Black	18	33.3%	889.3	1044.7	246.2	
ABG	White	17	65.4%	3537.9	550.5	133.5	0.912
	Black	9	34.6%	3508.7	665.1	221.7	
Ortho	White	18	56.3%	2805.3	731.7	172.5	0.046
	Black	14	43.8%	3319.7	663.1	177.2	

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TABLE 3.--Socioeconomic Status Effect on Timing of Consult, Lip repair, Palate Repair, Alveolar Bone Grafting and Orthodontics

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Min	Max	P - value
						Lower Bound	Upper Bound			
Consult	low	27	492.4	919.8	177	128.5	856.3	6	3842	**0.32**
	high	16	843.1	1355	338.7	121.1	1565.1	12	5145	
	Total	43	622.9	1099	167.6	284.5	961.3	6	5145	
Lip Repair	low	15	149.4	61	15.7	115.5	183.2	8	242	**0.33**
	high	7	217.1	256.1	96.8	-19.8	454	37	766	
	Total	22	170.9	149.2	31.8	104.7	237.1	8	766	
Palate Repair	low	24	926	983.2	200.7	510.8	1341.2	310	3762	**0.95**
	high	13	906.1	679.5	188.4	495.4	1316.6	157	2577	
	Total	37	919	878.4	144.4	626.1	1211.9	157	3762	
ABG	low	12	3395	587.9	169.7	3020.9	3768	2218	4260	**0.33**
	high	10	3667	695.7	220	3169.3	4164.6	3013	5486	
	Total	22	3518	638.6	136.1	3235.2	3801.5	2218	5486	
Ortho	low	22	2910	795.3	169.5	2557.5	3262.7	16	3981	**0.27**
	high	12	3204	559.1	161.4	2848.5	3559	2678	4708	
	Total	34	3014	725.9	124.5	2760.4	3267.1	16	4708	

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TABLE 4.-- Correlation between Family Size and Consult, Lip Repair, Palate Repair, Alveolar Bone Grafting and Orthodontics

		Consult	Lip Repair	Palate Repair	ABG	Orthodontics
Family Size	Pearson Correlation	.339*	-.080	.284	.632**	.239
	Sig. (2-tailed)	.016	.699	.072	.000	.144
	N	50	26	41	30	39

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

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TABLE 5.-- Gender Effect on Timing of Consult, Lip repair, Palate Repair, Alveolar Bone Grafting and Orthodontics

	Gender	N	Mean	Std. Deviation	Std. Error Mean	p -value
Consult	Male	45	167.80	382.57	57.03	0.366
	Female	30	263.30	526.31	96.09	
Lip Repair	Male	28	179.25	127.43	24.08	0.686
	Female	13	199.92	194.41	53.92	
Palate Repair	Male	34	620.00	613.82	105.26	0.350
	Female	26	791.03	792.03	155.33	
ABG	Male	21	3535.23	569.90	124.36	0.795
	Female	15	3482.20	639.79	165.19	
Ortho	Male	21	3115.57	533.20	116.35	0.214
	Female	22	2852.90	797.71	170.07	

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TABLE 6. Insurance Effect on Timing of Consult, Lip repair, Palate Repair, Alveolar Bone Grafting and Orthodontics

	Insurance Type	N	Mean	Std. Deviation	Std. Error Mean	p-value
Consult	public	43	187.86	434.65	66.28	0.654
	private	31	235.61	470.54	84.51	
Lip Repair	public	20	139.40	42.77	9.56	0.057
	private	20	230.15	202.22	45.21	
Palate Repair	public	38	633.94	567.47	92.05	0.383
	private	22	798.04	879.86	187.58	
ABG	public	18	3401.00	456.75	107.65	0.261
	private	18	3625.27	696.70	164.21	
Ortho	public	22	2949.54	786.36	167.65	0.761
	private	21	3014.33	581.36	126.86	

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APPENDICES

Appendix A: IRB Approval

IRB Administration Offices
UH IRB Phone: 216.844.1529
CWRU IRB Phone: 216.368.6925

APPROVAL

Principal Investigator:	Manish Valiathan
Title:	Racial disparities in healthcare access among patients with orofacial clefts: examining treatment timing
IRB Number:	STUDY20201274
Submission Number:	MOD00016726
IRB Office:	UH IRB
Approval Date:	7/13/2021
Effective Date:	7/14/2021
Approval End Date:	N/A
Type of Submission:	Modification
Type of Review:	Expedited
Documents Reviewed:	None
Summary of Changes:	Adding Dr. Rany Bous and Sarah Pak to study team.

The IRB has reviewed this submission.

- Per Federal regulation, changes MAY NOT be made to any element of the current research without prior IRB approval, except to eliminate an immediate and apparent hazard to subjects enrolled in the study.
- Per Federal regulation, the research may not continue beyond the Approval End date. You must submit your continuing review 6-8 weeks before this Approval End date in order to maintain IRB approval. Failure to maintain IRB approval is human subjects non-compliance. Please note that if your study falls into a category that does not require an Approval End date, the institution may require a yearly "check-in" to confirm the status of the study.

***Approval by the IRB does NOT mean that you have permission to start your study. Prior to starting your study, you may be required to obtain (1) a coverage analysis for studies that involve patient care, regardless of source of funding, and/or (2) a contract with the Sponsor of your study or an agreement with any third-party collaborator that may receive UH or CWRU patient information in any format. Please ensure that all required approvals are obtained before initiation of research activity. ***

The UH IRB operates under HHS Federalwide Assurance (FWA) number 00003937 and IRB registration numbers 00000684, 00001691 and 00008600. The CWRU IRB operates under DHHS FWA00004428 and IRB registration number 00000683.

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Appendix B: Abbreviations

ABG - Alveolar bone graft

CLP - Cleft Lip and Palate

SES - Socioeconomic status