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Pulse Oximetry Screening: Association of State Mandates with Emergency Hospitalizations

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Abstract

We evaluated the association between implementation of state mandated pulse oximetry screening (POS) and rates of emergency hospitalizations among infants with Critical Congenital Heart Disease (CCHD) and assessed differences in that association across race/ethnicity. We hypothesized that emergency hospitalizations among infants with CCHD decreased after implementation of mandated POS, and that the reduction was larger among racial and ethnic minorities compared to non-Hispanic Whites.

We utilized statewide inpatient databases from Arizona, California, Kentucky, New Jersey, New York, and Washington State (2010–2014). A difference-in-differences model with negative binomial regression was used.

We identified patients with CCHD whose hospitalizations between three days and three months of life were coded as “emergency” or “urgent,” or occurred through the emergency department. Numbers of emergency hospitalizations aggregated by month and state were used as outcomes. The intervention variable was an implementation of state mandated POS. Difference in association across race/ethnicity was evaluated with interaction terms between the binary variable indicating the mandatory policy period and each race/ethnicity group. The model was adjusted for state-specific variables such as percent of female infants and percent of private insurance.

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Competing Interests

Dr. Chang is the founder, CEO, and majority shareholder of QT Medical. QT Medical manufactures ECG devices. Dr. Chang is also the founder and CEO of NeoVative, a Research & Development company for wearable medical devices. The authors declare that there is no conflict of interest regarding the study.

Ethics Approval

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the 1964 Declaration of Helsinki and its later amendment. The study was approved by Lundquist Institute for Biomedical Innovation IRB (18CR-32121–01).

We identified 9,147 CCHD emergency hospitalizations. Among non-Hispanic Whites, there was a 22% (Confidence Interval [CI] 6%–36%) decline in *CCHD emergency hospitalizations* after implementation of mandated POS, on average. This decline was 65% less among non-Hispanic Blacks compared to non-Hispanic Whites.

Our study detected an attenuated association with decreased number of emergency hospitalizations among Black compared to White infants. Further research is needed to clarify this disparity.

Keywords

critical congenital heart disease; congenital heart disease; CCHD; pulse oximetry screening; birth defects; racial/ethnic disparity

INTRODUCTION

Congenital heart disease (CHD) occurs in approximately 1% of U.S. live births [1,2]. Critical congenital heart disease (CCHD) is a CHD that requires medical intervention within one year of life and occurs in 25% of CHD cases [1]. A study found that only 75.2% of infants diagnosed with CCHD survived to one year, compared with 97.1% of infants with non-critical CHD [3]. For women who have healthcare access, prenatal detection rates for CHD vary by hospital. Detection can be as low as 60% when limited to four-chamber views, and as high as 90% with added outflow and trachea views, with detection more likely in better-equipped hospitals such as teaching institutions [4–7].

In an effort to detect CCHD in a timely manner and reduce deaths attributable to late-detected CCHD, pulse oximetry screening (POS) was added to the newborn Recommended Uniform Screening Panel in 2011 [8]. POS is a non-invasive, quick, and cost-effective process conducted between 24 hours of life and discharge [8]. By 2018, all U.S. states and Washington D.C. had passed policy mandates to conduct POS among seemingly healthy newborns [9], with most states allowing families to decline screening for personal or religious reasons [10].

Implementation of POS provides an opportunity to improve morbidity and mortality due to CCHD through early detection and intervention. As expected, an association between the implementation of statewide screening mandates and decreased mortality among infants with CCHD has been reported [11]. In addition to death rates, it is important to study hospitalization rates, as they are often used as global indicators of overall health and well-being for patients. In this study, we evaluated the association between implementation of POS and hospitalizations, specifically limiting our sample to “urgent,” “emergency,” or emergency department (ED) admissions. We defined these three admission types as *CCHD emergency hospitalizations*, which exclude scheduled hospitalizations for interventions and diagnostic procedures. We hypothesized that *CCHD emergency hospitalizations* decreased after implementation of POS, and that the reduction was larger among racial and ethnic minorities compared to non-Hispanic White infants. We have two rationales for this hypothesis. First, cyanosis may be less apparent during physical examination of babies with darker skin color, such that missed diagnoses among non-White patients could be reduced

with addition of POS to the physical examination. Second, due to disparities in wealth and healthcare access, a higher proportion of non-White and Hispanic infants may have been born in hospitals with lower prenatal detection rates. For example, it has been reported that Black patients are more likely to undergo surgery at lower-resourced hospitals, less likely to receive care from board-certified physicians and high-volume surgeons, and less likely to have access to newer medical technology [12–15]. POS is a simple and affordable procedure. Therefore, we hypothesized that the implementation of POS was more beneficial among under-resourced and marginalized populations.

MATERIAL AND METHODS

Data Sources

We utilized 2010–2014 statewide inpatient discharge data from1] Arizona (AZ), 2] California (CA), 3] Kentucky (KY), 4] New Jersey (NJ), 5] New York (NY), and 6] Washington (WA), representing 27% of U.S. live births throughout the study period. [16] Datasets for AZ, KY, NJ, NY, and WA were obtained from State Inpatient Databases (SID), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality, [17] while inpatient datasets for CA were obtained through the Office of Statewide Health Planning and Development (OSHPD) [18]. The number of live births per month and year in each state was obtained using the Centers for Disease Control and Prevention's Wide-ranging Online Data for Epidemiologic Research (WONDER) [16].

Identification of Patients

This study centered on patients with the following seven CCHD conditions, as identified by *International Classification of Diseases, Ninth Edition, Clinical Modification* (ICD-9-CM) codes: 1] hypoplastic left heart syndrome, 2] pulmonary atresia (with intact septum), 3] dextro-transposition of the great arteries, 4] truncus arteriosus, 5] tricuspid atresia, 6] tetralogy of Fallot, and 7] total anomalous pulmonary venous connection. These conditions are typically classified as primary screening targets because they present with hypoxemia [8,19,20]. Associated ICD-9-CM codes and descriptions are provided in Supplemental Table 1. Critical coarctation and interrupted aortic arch also require intervention within one year of life. However, the sensitivity to identify them with POS is reported to be less than 50% [21–23]. These conditions are not considered primary targets for CCHD screening [24–26], and were not included in the original list of seven lesions identified by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) in their recommendation to add newborn screening for CCHD to the Recommended Uniform Screening Panel [8]. Therefore, we did not include these two conditions in our analyses.

We identified infants admitted to the hospital between three days and three months of life. This time-frame was selected because the recommended window for POS is between 24 hours of life and newborn discharge [8,27], with newborn discharge typically occurring around 48 hours of life, and our preliminary study revealed that 75% of hospitalizations for patients with CCHD occurred within three months of life. To avoid counting transfers from a state without mandatory POS, only patients with a zip code of residence matching the state in which the newborn discharge record was created were included in the dataset.

Measurements

The exposure variable was *implementation of state mandatory screening policy*. We examined the number of patients whose hospitalizations between three days and three months of life were coded as *CCHD emergency hospitalizations* for each state, based on birth year and month of each patient. *CCHD emergency hospitalization* rate was calculated per 10,000 live births for corresponding years, months, and states, and used as the primary outcome of interest. Birth year and month were provided in datasets for CA, KY, NJ, and NY, but not AZ or WA. Instead, AZ and WA provided month and year of hospital admission and age of patient (in days) at the time of admission. We assumed that the admission month and birth month were the same when age at admission was ≤30 days, that birth month was one month before admission month when age at admission was between 31 and 60 days, that birth month was two months before admission month when age at admission was between 61 and 91 days, etc.

Statistical Analyses

A difference-in-differences model using month and year as the study unit was used to detect the changes in number of *CCHD emergency hospitalizations* after the implementation of POS. Dates *before* a news release to the state's medical community recommended POS or the legislative passage of the screening mandate was announced were defined as the *no-policy* period, and dates *after* the effective date of mandatory implementation constituted the *mandatory-policy* period. We defined a third timeframe as the *non-mandatory policy* period. This period begins when a news release to a state's medical community recommends POS or announces the legislative passage of the mandate, and ends at the effective date of the statewide mandatory policy. This is a transitional timeframe during which screening practices are generally unknown, as discussed in a previous study [11]. For example, some hospitals may have started screening as a result of the recommendation, while others may have waited until screening was mandatory. We included a dichotomous variable, which indicated *non-mandatory policy* status as one of the adjustment variables. Detailed information on the policy publication date and implementation date for each state is provided in Supplemental Table 2.

Negative binomial regressions using number of live births as an offset and state random effects were applied. Because the data were repeatedly measured within states, residual correlations were possible. These correlations would affect the standard errors of the estimates and in turn, affect p-values. State random effects accounted for this correlation. In order to capture time-invariant factors in each state, state fixed effects were also included. Additionally, year-month fixed effects were included to absorb time-specific factors common across all states. The following state characteristics were calculated from the inpatient datasets and included as adjustment variables: 1] percent of infants residing in zip codes corresponding to the lowest income quartile, 2] percent of female infants, and 3] percent of patients with private insurance. In addition, statewide unemployment rate for each year and month was estimated from census data and included as an adjustment variable [28]. Percent of infants residing in zip codes corresponding to the lowest income quartile and percent of patients with private insurance were included as adjustment variables because higher mortality among infants of a low socioeconomic status [32], and disparity in health

outcomes among patients with congenital heart disease across insurance type [33–35] has been reported. Percent of female infants was included because of the known differences in health across sex [36]. Unemployment rate was included as an indicator of socioeconomic status at the state level. Race/ethnicity was categorized as follows: 1] non-Hispanic White, 2] non-Hispanic Black, 3] Hispanic, and 4] other. The models included the interaction terms between the binary variable indicating the mandatory policy period and each race/ethnicity group to evaluate the difference in association of implementation of mandatory screening policy and decreased emergency hospitalization across race/ethnicity.

Birth date was limited to birth month and year, due to human subject research protections. Therefore, we included infants born during the month the policy was mandated only if the effective date was the first day of the month. For example, we excluded infants born in January 2014 in NY from the analyses because it is impossible to identify whether they were born before or after the implementation date for the statewide policy mandate (January 27, 2014).

Sensitivity analyses

First, we excluded the *non-mandatory policy* period from the analysis. Second, number of *CCHD emergency hospitalizations* were aggregated by quarter, instead of month, and we used quarter and year as a study unit. Third, we included *CCHD emergency hospitalizations* between three days and six months, instead of three months, to check whether our choice of three months was sensitive to the analyses. Fourth, we used quarter and year as a study unit and restricted *CCHD emergency hospitalizations* to between three days and three months.

All analyses were completed using Stata Version 14.2 (StataCorp LLC, College Station, TX). The Institutional Review Board at The Lundquist Institute for Biomedical Innovation approved this study under the “exempt” category. Informed consent was not required.

RESULTS

We identified 9,147 records (*mandatory policy*: 1,929; *non-mandatory policy*: 855; *no-policy*: 6,363) of patients admitted as *CCHD emergency hospitalizations* (Tables 1).

We detected a significant association between implementation of state POS mandates and lower number of *CCHD emergency hospitalizations* among non-Hispanic White infants (Incidence Rate Ratio [IRR]: 0.78, 95% Confidence Interval [CI] 0.64–0.94, p=.01). On average, there was a 22% (95%CI 6%–36%) decline in *CCHD emergency hospitalizations* among non-Hispanic White infants after implementation of state POS mandates. The association between implementation of state POS mandates and decline in *CCHD emergency hospitalizations* was significantly attenuated among non-Hispanic Black infants compared to non-Hispanic White infants (IRR: 1.65, 95%CI 1.17–2.33, p = .01). On average, hospitalizations declined 65% less among non-Hispanic Black infants compared to non-Hispanic White infants. We did not detect any association among patients identified as Hispanic or other race compared to non-Hispanic White patients (Table 2).

All three sensitivity analyses mirrored the results of the main analyses, although the reduction in emergency hospitalizations among non-Hispanic White infants after POS implementation was not statistically significant, likely due to the smaller sample size (Supplemental Table 3).

DISCUSSION

Using six 2010–2014 statewide inpatient databases, we found an association between implementation of state POS mandates and lower number of *CCHD emergency hospitalizations* among non-Hispanic White infants.

Our study supported the results of Abouk et al. [11], which found an association between implementation of state POS mandates and reduced mortality rates among patients with CCHD. Several other studies reported a limited or negligible beneficial effect for universal POS, but these studies were conducted within a single hospital, healthcare system, or region with high prenatal CCHD detection rates, i.e., 60–80% [37–40]. Substantial disparities in prenatal CCHD detection rates have been reported, with rates in teaching hospitals as high as 71–100% and rates in non-teaching hospitals as low as 0–39% [41].

Our study and that of Abouk et al. [11] differed from the others in that: 1] both used an administrative population-based database which included hospitals with a wide range of prenatal detection rates, and 2] both conducted analyses at the aggregate level, which could introduce ecological fallacy. Therefore, individual-level analyses including hospitals with low rates of prenatal detection are needed.

The significantly greater association of POS implementation and lower number of *CCHD emergency hospitalizations* for non-Hispanic White infants compared with non-Hispanic Black infants was a novel finding of this study. This result was opposite our initial hypothesis that the association would be greater among racial and ethnic minorities compared to non-Hispanic White infants. One possible explanation is that POS was not fully implemented among Black infants so that some received improper screening or no screening at all. Another possible explanation involves the accuracy of pulse oximetry readings across a range of skin tones. Although darker skin does not usually affect pulse oximetry readings in the 90%+ SPO_2 ranges determinant for infant screenings, there is evidence that pulse oximetry can underestimate the severity of very low oxygen concentrations for infants with darkly pigmented skin [42–44]. The cut-off values for positive POS results among infants with dark skin have never been validated. It is possible that the effect of POS differs based on skin color. Further research is needed to understand the differences in POS policy effects so that disparities can be reduced.

There are several limitations to this study. First, because of the limited availability of personal identifiers, the same individuals could have been included in the analyses multiple times. Second, the hospitalization records utilized were not linked with birth records, so we were not able to confirm the place of birth. Third, information surrounding POS practices is lacking. It is possible that hospitals in states with mandatory policies did not perform POS, and that hospitals in states without mandatory policies began implementing the POS

process before it was required. It is also possible that the screenings were not performed correctly, and thus not all cases of hypoxemia were identified. As was argued in a previous study [11], our current study evaluated the association of implementation of state mandatory POS policies and lower number of *CCHD emergency hospitalizations*, rather than the effect of POS itself. Further investigation, paired with insight into individual hospital screening practices, will overcome this limitation. Fourth, the lack of detailed clinical information and possible miscoding in administrative datasets may cause misclassifications, although we limited hospitalizations to those flagged as "emergency," "urgent admission," or admission through the emergency department in order to reflect the urgency for inpatient care. For example, it is possible that infants with CCHD had emergency hospitalizations for Respiratory Syncytial Virus (RSV) infection. However, this occurrence is random, regardless of POS implementation, so our results should not be affected. Fifth, the number of live births for each year and month by race/ethnicity was only available based on the mother's race/ethnicity, rather than that of the infant. Therefore, misclassification was possible. Sixth, prenatal detection may have improved during this period, as medical technology improves in general in time. Black patients are less likely to have access to newer medical technology [15]. Therefore, the differences in changes in trend after the implementation of the screening between non-Hispanic White and Black patients could represent the difference in access to prenatal care. Our DID model minimizes the bias from the general trend in improvement of CCHD prenatal detection, unless the timing of the improvement of CCHD prenatal detection and the implementation of POS coincide. Last, the most recent data analyzed in this study was from 2014, in order to avoid the mandatory transition from ICD9CM to ICD10CM, which occurred in October 2015. Using the data from earlier years of implementation of the screening enabled us to investigate the initial response to implementation. On the other hand, the implementation level of an intervention usually improves through natural diffusion over time [45]. Periodic assessments over longer observation periods using more recent data are needed.

CONCLUSIONS

We detected an association between implementation of state mandated POS and a reduced number of *CCHD emergency hospitalizations* among non-Hispanic White infants. This association was attenuated among non-Hispanic Black infants. POS is a simple and affordable procedure compared to the echocardiograms needed to accurately detect CCHD prenatally. Thus, further research to clarify the attenuated beneficial effect among Black infants is important so that POS may be used in the future to close the gap in timely CCHD detection rate across race/ethnicity.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1.

Descriptive statistics among individuals with CCHD emergency hospitalizations, 2010–2014

	Total (n=9,147)		No policy (n=6,363)		Non-mandatory policy (n=855)		Mandatory policy (n=1,929)		*p-value*
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	
Age in months, mean (SD)	1.71	0.77	1.72	0.77	1.68	0.77	1.69	0.78	.11
Sex									
Male	5,006	54.73	3475	54.61	473	55.32	1058	54.85	
Female	4,141	45.27	2888	45.39	382	44.68	871	45.15	.92
Race/Ethnicity *									
Non-Hispanic White	3,674	40.17	2609	41.00	352	41.17	713	36.96	.01
Non-Hispanic Black	1,039	11.36	664	10.44	104	12.16	271	14.05	<.01
Hispanic	2,852	31.18	1949	30.63	276	32.28	627	32.50	.34
Other race	1,582	17.30	1141	17.93	123	14.39	318	16.49	.02
Insurance type									
Public	5,782	63.21	4039	63.49	560	65.50	1183	61.39	.08
Private	2,834	30.98	1997	31.39	242	28.30	595	30.88	.19
Self-pay	176	1.92	96	1.51	16	1.87	64	3.32	<.01
Other insurance	352	3.85	230	3.62	37	4.33	85	4.41	.21
Income Quartile									
1 (lowest)	2,245	24.54	1666	26.18	225	26.32	354	18.35	<.01
2	1,866	20.40	1318	20.71	161	18.83	387	20.06	.40
3	1,716	18.76	1258	19.77	146	17.08	312	16.17	<.01
4 (highest)	3,320	36.30	2121	33.33	323	37.78	876	45.41	<.01
State									
Arizona	1,400	15.31	1217	19.13	183	21.40	0	0.00	<.01
California	2,376	25.98	1386	21.78	282	32.98	708	36.70	<.01
Kentucky	907	9.92	563	8.85	145	16.96	199	10.32	<.01
New Jersey	774	8.46	283	4.45	52	6.08	439	22.76	<.01
New York	3,100	33.89	2324	36.52	193	22.57	583	30.22	<.01
Washington	590	6.45	590	9.27	0	0.00	0	0.00	<.01

*Some percentage columns may not add up to 100% due to missing patient demographic information

Table 2.

Results from regression models[a] to evaluate the association between implementation of statewide mandatory screening policies and emergency hospitalizations[b]

	Adjusted IRR[c]	[95% CI[d]]		P value
Policy Periods				
Mandatory policy	0.78	0.64	0.94	.01
Non-Mandatory	0.92	0.79	1.06	.24
No policy	Reference			
Interaction term				
Interaction term between Mandatory policy and Non-Hispanic Black	1.65	1.17	2.33	<.01
Interaction term between Mandatory policy and Hispanic	1.24	0.66	2.35	.50
Interaction term between Mandatory policy and Other	1.31	0.69	2.50	.42
Race/ethnicity				
Non-Hispanic White	Reference			
Non-Hispanic Black	0.33	0.24	0.45	<.01
Hispanic	1.03	0.53	2.01	.92
Other	0.58	0.33	1.01	.06

[a] Adjusted by *non-mandatory* pulse oximetry screening policy status, percent of female infants, percent of infants who resided in the lowest income quartile, percent of patients with private insurance, and state unemployment rate

[b] Emergency hospitalizations included infants whose records indicated an “emergency” or “urgent” hospitalization or occurred through the emergency department

[c] Incidence Rate Ratio

[d] Confidence Interval