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Authors

Manja, V
Mathew, B
Carrion, V
[et al.](#)

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Critical Congenital Heart Disease Screening by Pulse Oximetry in a Neonatal Intensive Care Unit

Veena Manja, MBBS^{1,2}, Bobby Mathew, MRCP³, Vivien Carrion, MD³, and Satyan Lakshminrusimha, MD³

¹Division of Cardiology, State University of New York at Buffalo, Buffalo, New York

²Clinical Epidemiology and Biostatistics (Health-Research Methodology), McMasters University, Hamilton, Ontario, Canada

³Division of Neonatal-Perinatal Medicine, State University of New York at Buffalo, Buffalo, New York

Abstract

Critical congenital heart disease (CCHD) screening is effective in asymptomatic late preterm and term newborn infants with a low false positive rate (0.035%).

Objective—(1) To compare 2817 NICU discharges before and after implementation of CCHD screening; and (2) to evaluate CCHD screening at < 35 weeks gestation.

Methods—collection of results of CCHD screening including preductal and postductal SpO₂ values.

Results—During the pre-CCHD screen period, 1247 infants were discharged from the NICU and one case of CCHD was missed. After 3/1/12, 1508 CCHD screens were performed among 1570 discharges and no CCHDs were missed. The preductal and postductal SpO₂ values were 98.8±1.4% and 99±1.3% respectively in preterm and 98.9±1.3% and 98.9±1.4% in term infants. Ten infants had false positive screens (10/1508=0.66%).

Conclusions—Performing universal screening in the NICU is feasible but is associated with a higher false positive rate compared to asymptomatic newborn infants.

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Address correspondence to: Satyan Lakshminrusimha, Division of Neonatal-Perinatal Medicine, Women and Children's Hospital of Buffalo, 219 Bryant St, Buffalo NY 14222, Phone: 716878767, Fax: 7168787945, slakshmi@buffalo.edu.

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1. Veena Manja drafted the initial manuscript, conducted analysis and approved the final manuscript as submitted.
2. Bobby Mathew collected data, revised the manuscript and approved the final manuscript as submitted.
3. Vivien Carrion implemented the protocol, collected data, revised the manuscript and approved the final manuscript as submitted.
4. Satyan Lakshminrusimha conceptualized and designed the study, implemented the protocol, collected data, critically reviewed the manuscript, and approved the final manuscript as submitted.

Keywords

quality improvement; congenital heart disease

Introduction

Critical congenital heart disease (CCHD) is generally defined as congenital heart defect that requires surgery or catheter intervention within the first year of life or may cause significant morbidity and mortality in the first weeks of life¹. Universal newborn pulse oximetry screening to detect CCHD was added to the recommended uniform screening panel (RUSP) by the Health and Human Services Secretary in 2011. CCHD screening through pulse oximetry (SpO₂) is being implemented by many states and is shown to be cost-effective for asymptomatic newborn infants². The false positive rate among asymptomatic newborn infants is low (0.035%)^{3, 4}.

Approximately 10–12 % of all newborn infants are admitted to neonatal intensive care units (NICU). Many NICUs including ours routinely monitor SpO₂ for all admissions. Limited data are available regarding CCHD screening in the NICU. Iyengar et al reported 250 patients discharged from the NICU with CCHD screening at Northwestern University but did not report any positive screens⁵. A recent commentary suggested three options for screening in the NICU: (i) consider that all NICU patients, by default, already undergo screening and not perform additional screening by pre-post ductal oxygen saturation difference; (ii) perform screening similar to that in normal newborn nursery in infants 35 weeks and higher gestation or (iii) screen all infants admitted to the NICU⁶. Many state governments recommend universal screening and do not differentiate between infants cared in the NICU vs. those admitted to newborn nursery.

Prior to initiation of CCHD screening, infants in our NICU did not undergo simultaneous preductal and postductal SpO₂ monitoring unless there was suspicion of persistent pulmonary hypertension of the newborn (PPHN) or congenital heart disease (CHD). Our objective is to describe our experience with CCHD implementation in the NICU and to evaluate and report compliance with this procedure/process. We aim to report the frequency of CCHD diagnoses among NICU discharges. We evaluated readmissions with a primary diagnosis of CCHD to the Emergency Department or Pediatric Intensive Care following discharge from the NICU before and after implementation of CCHD screening. We also evaluated the results of CCHD screening and false positive rate among NICU discharges born at < 35 weeks and ≥ 35 weeks postmenstrual age (PMA).

Methods

The NICU at Women and Children's Hospital of Buffalo serves as the regional perinatal center for Western New York. There were 61,869 births in Western New York per year between 1/1/2010 and 12/31/2013 (average 15,467 per year). Of these 6,944 infants were admitted over the four year period to any level 2/3 neonatal intensive care (11.2%) and had SpO₂ monitoring during their stay in the NICU (average 1,736 per year). Of these, 3,152 patients (average 788 patients per year) were admitted to the NICU at the Women and

Children's Hospital of Buffalo. Only discharges from this NICU were evaluated in this study. The unit policy during this period was to maintain SpO₂ between 91 and 95% in both preterm and term infants requiring supplemental oxygen.

Routine CCHD screening was implemented for all NICU discharges in early 2012. We conducted screening using Masimo Rad 7 pulse oximeters (Masimo Corporation, Irvine CA) and disposable probes. All patients in our NICU are continuously monitored with a pulse oximeter throughout their stay. The same probe was used to sequentially determine the right upper limb and a lower limb SpO₂. Each screening attempt was conducted over a three minute period with the infant in the supine position. The pulse oximetry measure was considered complete once the wave form on the plethysmograph was stable⁷. Infants discharged in 2010 and 2011 (pre-CCHD screen) were compared to NICU discharges from March 2012 to March 2014 (post-CCHD screen). All discharges were screened according to AAP guidelines with the following exceptions⁷. The screen was performed 24–48 hours prior to discharge from the NICU and at least 24 hours after weaning to room air (if the infant required supplemental oxygen). An echocardiogram was performed if the infant met the following criteria: (i) failed CCHD screen on room air (and if a prior echocardiogram was not performed during the NICU stay for other indications). Failed CCHD screen was defined as an SpO₂ <90% in any extremity, a persistent SpO₂ of 90–94% in both preductal and postductal sites on three attempts or a persistent preductal to postductal SpO₂ difference > 3%^{7, 8}, (ii) unexplained need for oxygen (unable to maintain SpO₂ 90% in room air), or (iii) inability to wean oxygen prior to discharge. A revised algorithm currently in use in our NICU was recently published⁹. In order to detect false negatives, encounters and referrals to pediatric cardiology office, Emergency Department (ED), Pediatric Intensive Care Unit (PICU) and coroner's office were evaluated.

Statistical analysis

The demographic features, incidence of echocardiographic evaluation in the pre- and post-CCHD screening epochs and among preterm and term infants were analyzed by unpaired 't' test or Chi-square test as appropriate. Significance was accepted at $p < 0.05$.

Results

Comparison between pre-screen and post-CCHD screen periods

During the pre-CCHD screen period, 1533 infants were admitted to the NICU at Women and Children's Hospital of Buffalo and 1247 of them were directly discharged home (table 1). Excluding prenatally suspected CCHD, twelve infants were diagnosed with CCHD based on clinical presentation during this period. 465 infants (37.3% of discharges) underwent echocardiography for clinical indications during this period. Sixty eight infants (5.5% of discharges) were sent home with oxygen supplementation. Five of these infants had moderate bronchopulmonary dysplasia (BPD) and did not have an echocardiogram prior to discharge. One infant with interrupted aortic arch and anomalous left subclavian artery was not diagnosed and discharged from the NICU in spite of continuous SpO₂ and blood pressure monitoring¹⁰. The precise site of pulse oximetry probe placement (pre- or postductal) could not be ascertained from our medical records. This infant was noted to have

absent femoral pulses at one week of age at the pediatrician's office, was referred to cardiology for an echocardiogram which led to the diagnosis. The echocardiogram demonstrated complete interruption of the arch beyond the right subclavian artery. The left subclavian artery and descending aorta were supplied exclusively by the ductus arteriosus.

In early 2012, CCHD screening was reviewed with community pediatricians, hospital faculty, residents/ fellows, nurse practitioners/ physician assistants and nurses. A PowerPoint presentation with a flow chart and a color coded saturation chart ¹⁰ were utilized in the NICU.

Between March 2012 and March 2014, 1508 CCHD screens were performed among 1570 discharges (figure 1). During the first month of implementation, nursing compliance with CCHD screen was 68%, improved to 92% by the 6th month and was 100% in 2013–14. Excluding prenatally diagnosed CCHD, 16 infants were diagnosed with CCHD based on abnormal physical examination and transferred to cardiac surgical service. 505 (32.2% of discharges) underwent echocardiogram for medical indications prior to discharge. Sixty four infants were discharged home with supplemental oxygen. Five of these infants did not have an echocardiogram for medical indications. These infants underwent echocardiogram to determine the etiology of oxygen need as per the modified CCHD algorithm. Four of these infants had a normal echocardiogram (1 – patent ductus arteriosus, PDA/ patent foramen ovale, PFO; 3 – PFO). One infant had supracardiac total anomalous pulmonary venous return (TAPVR). The preductal and postductal SpO₂ were 88 and 91% respectively prior to oxygen supplementation in this infant.

Results of pulse oximetry screen

The median preductal and postductal SpO₂ values were 99% (range – 90 to 100%) and 100% (range 92 to 100%) respectively. No infant had a SpO₂ value < 90% (by unit policy, these 64 infants were on supplemental oxygen). Eighteen infants in room air did not meet pass-criteria (18/1508= 1.2%) on first attempt of pulse oximetry screening (figure 1). One infant had both preductal and postductal SpO₂ between 90 and < 95% and did not change with repeated screening attempts. Four infants had preductal SpO₂ > postductal value by > 3%. Postductal SpO₂ exceeded preductal SpO₂ by > 3% in 13 infants. After repeat preductal and postductal SpO₂ measurements, 10 infants (0.66%, figure 1) failed the screen (1-<95%, 3-preductal > postductal SpO₂ by >3% and 6- postductal > preductal SpO₂ by > 3%). Echocardiogram showed mild pulmonic stenosis, AV malformation and patent foramen ovale or patent ductus arteriosus (PFO/PDA) or PPHN in these infants. Postductal SpO₂ exceeded preductal SpO₂ by > 3% in 6 infants. Three infants had normal anatomy (PFO ± PDA), and one had tricuspid regurgitation. Two infants whose postductal saturations were 100% and preductal were 96% on final repeat screen were labeled as passed and discharged home without an echocardiogram. None of the infants discharged from the NICU were diagnosed to have CCHD on follow-up visits to their pediatrician/ family practitioner, ED/ PICU or readmission during the period of CCHD screen. Of note, one infant discharged from a level 1 nursery after a normal CCHD screen was readmitted and transferred to us with CCHD during the same period (ventricular septal defect with transverse arch hypoplasia and coarctation of the aorta). Two infants with failed CCHD screens in level 1

nursery were transferred to the NICU during this period (one with tetralogy of Fallot and another with TAPVR).

Differences between preductal and postductal SpO₂

Fifty two percent of infants had the same preductal and postductal SpO₂. Preductal saturations were higher than postductal in 18% of infants and less than postductal in 30% of infants. The frequency distribution of the difference between preductal and postductal oxygen saturations is shown in figure 2.

Differences between preterm and term neonates in the NICU

There was no significant difference in SpO₂ values in preterm (<35 weeks PMA) and term (≥ 35 weeks PMA) infants. The cut-off of 35 weeks was chosen as all infants < 35 weeks PMA are initially admitted to the NICU in our institution. More preterm infants had at least one prior echocardiogram for clinical indications (43 vs. 27%, $p < 0.01$ by Chi² test). The false positive rate was not significantly different between preterm and term infants (table 2).

Discussion

Many states including the state of New York have mandated universal pulse oximetry screening of all newborn infants. March of Dimes estimates that about 10–15% of U.S. babies spend time in a NICU each year. These infants undergo multiple physical examinations and are continuously monitored by pulse oximetry. There is limited literature on the use of pulse oximetry screening in the NICU^{5, 6, 10}. To our knowledge this study represents the largest series of universal CCHD screening among the NICU population.

Universal screening for CCHD was implemented initially in our NICU as a quality improvement measure following the discharge of a term infant with interrupted aortic arch¹⁰. It is not clear if we would have detected this patient by CCHD screening. Detection rates for coarctation of aorta are < 60% by CCHD screening³. Although precise detection rates for interrupted aortic arch by pulse oximeter screening are not known and this diagnosis has been missed by CCHD screen⁸, we speculate that the saturations in the left upper limb and lower limbs (ductal-dependent systemic circulation) in this infant would be < 90%. Simultaneous preductal and postductal SpO₂ measurement at CCHD screen may be beneficial in the NICU. Moreover, infants already have a disposable pulse oximeter probe reducing the cost of CCHD screen in the NICU.

Approximately a third of the discharges from our NICU had a prior echocardiogram for medical indications. In the current study, these infants were also screened; we have recently revised our protocol and infants who have had prior echocardiograms in the NICU are not screened. Instead the date of the echocardiogram and the main findings are recorded in the CCHD screen folder of the electronic medical record significantly reducing the number of screens required in the NICU.

During the two-year period of screening, only one patient with CCHD (TAPVR) was diagnosed using the screen algorithm. This term infant was symptomatic with an unexplained oxygen need and this echocardiogram would have been performed as part of his

medical evaluation irrespective of the CCHD screening protocol. Since TAPVR would have likely been diagnosed even without CCHD screening in place, the probability of a new CCHD diagnosis from a screening program in the NICU is not known with certainty. Pooled data from many NICUs are needed to evaluate the precise true positive rate of CCHD screening in the NICU and the costs involved per additional CCHD diagnosed. There were no cases of CCHD detected among NICU discharges in the Pediatrician/ family practitioner's office, cardiology or Emergency Department/ PICU. The Women and Children's Hospital of Buffalo is the only Pediatric Emergency Department / PICU and neonatal/ pediatric transport team in Western New York.

One notable difference when compared to non-NICU neonates in the current study is the high rate of false positive screens in the NICU population. Meta-analyses of large population-based studies of newborn pulse oximetry screening conducted after the first 24h after delivery among asymptomatic newborn infants, demonstrate a low false-positive rate of 0.035⁴ to 0.05%¹¹. The false-positive rate in our study was significantly higher at 0.66% in a high-morbidity NICU population. As almost a third of patients undergo echocardiography in our NICU, this false positive rate results in a small additional need for echocardiograms. Similar high false positive rates are documented for high-risk population with endocrine/metabolic newborn screen (1.05% in term infants vs. 6.9% in preterm infants, 6% for low birth weight and 4.9% for infants with chronic illness)¹².

Two-thirds of these false-positive screens were secondary to a postductal SpO₂ in the 99–100% range and a preductal SpO₂ of 95–96% (n=13 on first attempt and 6 after subsequent attempts). In infants with both pre- and postductal SpO₂ 95%, if preductal to postductal difference of >3% was not a criterion for screen failure, the false positive rate in our NICU would be reduced to 0.07%, similar to the rate in asymptomatic newborn infants. It is interesting to note that among studies conducted > 24h of life, Riede et al evaluated foot oximetry only in 41,445 births and demonstrated a sensitivity of 77.8% and a false-positive rate of 0.1%¹³. In contrast, de-Wahl Granelli et al conducted simultaneous preductal and postductal oximetry in 39,821 births with a sensitivity of 62% and a false-positive rate of 0.17%⁸.

Ten neonates had postductal SpO₂ exceed preductal SpO₂ by >3% on the first attempt suggestive reverse differential "cyanosis". Two CCHD lesions are associated with reverse differential cyanosis. The first is transposition of great arteries (TGA) associated with PPHN¹⁴ or TGA with coarctation/interrupted aortic arch^{15, 16}. The SpO₂ in these patients is often < 80%. The second condition reported in one case with reverse differential cyanosis is supradiaphragmatic TAPVR¹⁷. The preductal SpO₂ was 80% and postductal SpO₂ was 93% on 60% inspired oxygen in this patient. Patients with both preductal and postductal SpO₂ 95% in room air are highly unlikely to suffer from TGA or TAPVR. Should infants with postductal SpO₂ exceeding preductal SpO₂ by >3% and with baseline preductal *and* postductal SpO₂ of greater than 95% on room air be considered to have passed the screen (with no possibility of CCHD)?

Approximately half of the NICU patients had no difference between preductal and postductal SpO₂ (figure 2), but postductal SpO₂ was significantly higher than preductal

values in the NICU population ($99 \pm 1.3\%$ vs. $98.8 \pm 1.4\%$, $p < 0.0001$). Interestingly, a similar trend was observed in normal newborn infants 24h after birth¹⁸.

In spite of presentations and color charts readily available in the NICU with the correct algorithm for the screen, two infants with failed screens (with postductal SpO₂ of 100% and preductal SpO₂ of 96%) were erroneously labeled as passed and were discharged without an echocardiogram. Intensive and repeated educational efforts and close collaboration between neonatal and cardiology services can mitigate such errors. There are several limitations to this study. We did not evaluate the optimal timing for CCHD screen in the NICU. We performed the screen 24–48h prior to discharge along with other screening tests such as car-seat challenge and hearing screen. It is possible that screening may be conducted earlier (at 24–48 h of age for neonates in room air and 24 h after weaning to room air in infants requiring supplemental oxygen / respiratory support). Secondly, not all NICUs monitor patients SpO₂ continuously throughout the length of stay. Finally, the incidence of CCHD is low and the current single-center study is underpowered to make any definitive conclusions in this population.

We conclude that performing universal screening in the NICU is feasible but may not be effective as a stand-alone tool. A thorough history and physical examination will provide clues to the diagnosis of CCHD in many infants. Pulse oximetry screening may enhance the effectiveness of CCHD diagnosis by clinical examination. CCHD can potentially be missed by not performing a pre- and postductal SpO₂ screen prior to discharge in the NICU. The false-positive rate for CCHD screen is higher in the NICU compared to asymptomatic newborns in a level 1 nursery and is mainly due to >3% difference in pre- and postductal SpO₂. Data analyses from multiple units are needed to determine the precise false-positive and true-positive rate and effectiveness among neonates admitted to the NICU.

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Abbreviations

CCHD	critical congenital heart disease
NICU	neonatal intensive care unit
PDA	patent ductus arteriosus
PFO	patent foramen ovale
PMA	postmenstrual age
SpO₂	pulse oximetry oxygen saturation
TAPVR	total anomalous pulmonary venous return

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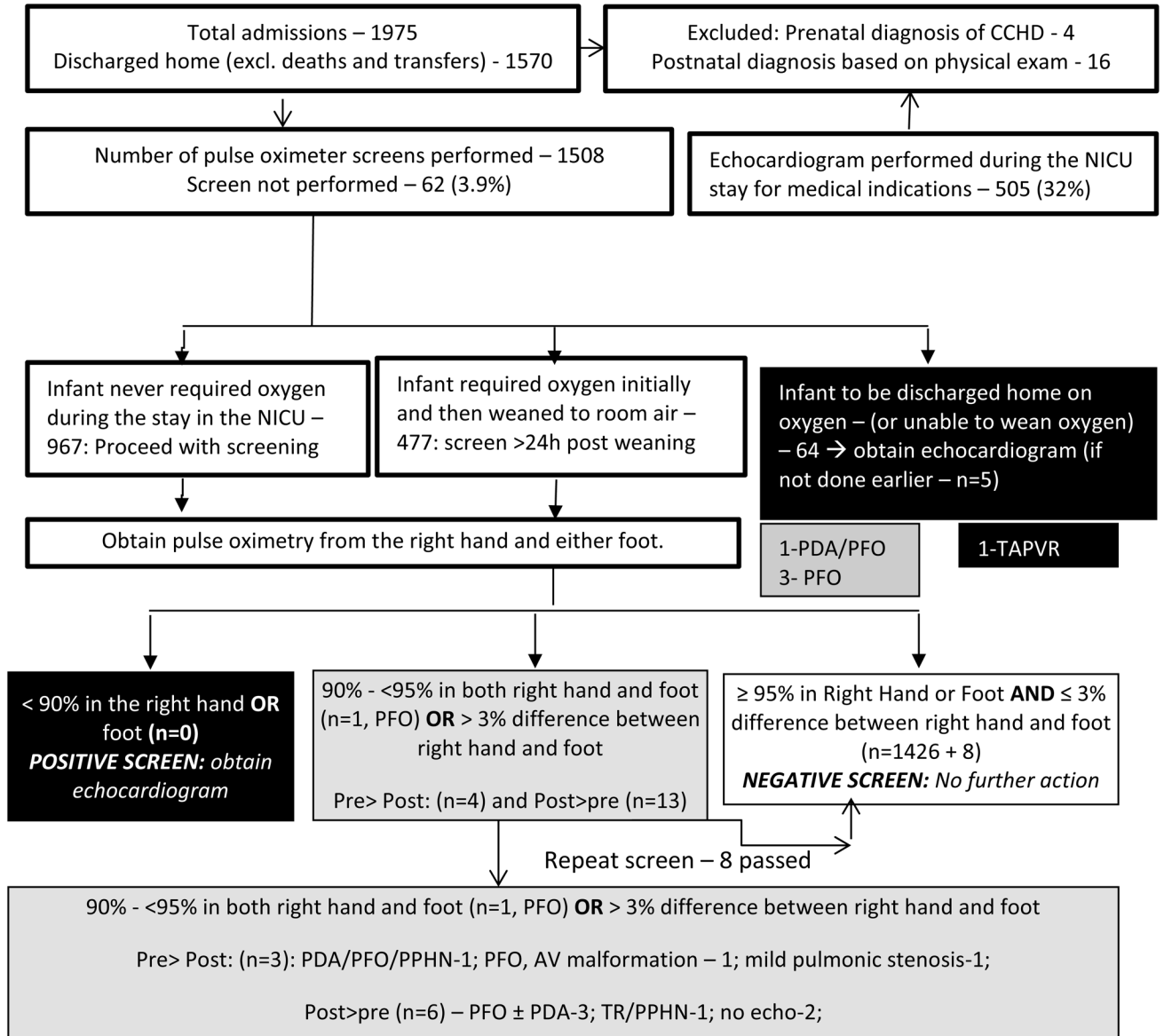


Figure 1.

Flowchart showing distribution of patients based on universal screen conducted in the NICU from March 2012 to March 2014. Abbreviations: CCHD – critical congenital heart disease, NICU – neonatal intensive care unit; PDA – patent ductus arteriosus; PFO – patent foramen ovale; PPHN – persistent pulmonary hypertension of the newborn; TAPVR – total anomalous pulmonary venous return.

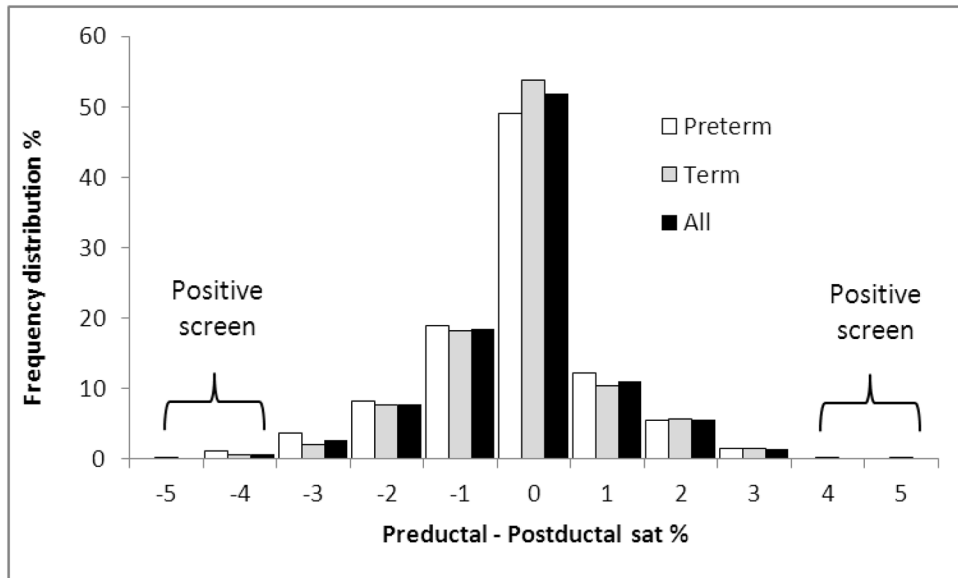


Figure 2. The frequency distribution (%) of the difference between preductal and postductal saturations in preterm (less than or equal to 34 weeks 6/7 days PMA) and term neonates (greater than or equal to 35 weeks 0/7 days PMA) and all infants.

Table 1

Patient characteristics pertaining to CCHD at Women and Children's Hospital of Buffalo NICU during period 1 (Jan 2010 to Dec 2011 – no CCHD screening) and period 2 (March 2012 to March 2014 – CCHD screening)

	No CCHD screening (Jan 2010 – Dec 2011)	CCHD screening (Mar 2012 to Mar 2014)
Total number of admissions	1533	1975
Number of direct discharges home (excluding transfers, transfer of service and deaths)	1247	1570
Number of CCHD diagnosed during the NICU course (excluding antenatal diagnosis)	12	16
Number of CCHD screens performed	n/a	1508 (96.1% of discharges)
Infants with echocardiograms performed for clinical indications	465 (37.3% of discharges)	505 (31.8% of discharges)
Infants discharged home on oxygen (or unable to wean off oxygen prior to CCHD screen)	68	64
Infants unable to be weaned to room air prior to screen who have not had an echo for clinical indication	5	5
True positives	N/A	1 – TAPVR (unexplained oxygen requirement)
Missed patients – readmissions and underwent intervention	1 – interrupted aortic arch	0

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Table 2

CCHD screen characteristics at < 35 weeks gestation and ≥ 35 weeks gestation at birth [data are shown as mean (SD)]

	“Preterm” < 35 weeks	“Term” ≥ 35 weeks
N	619	889
Gestational age weeks	31.1 (2.8) Range – 22 to 34	38 (1.7) Range – 35 to 41
Birth weight grams	1700 (598) Range – 438 to 5081	3146 (679) Range – 1318 to 6010
Race:		
Caucasian	385	554
Black	168	205
Hispanic	39	44
Asian/other	27	86
Postmenstrual age at CCHD screening (weeks)	36.9 (2.5) Median – 36.4 Range – 33.3 to 46.7	39.4 (2.2) Median – 39.3 Range – 35.6 to 50
Preductal SpO ₂	98.8 (1.4)% Median – 99% Range – 92 to 100%	98.9 (1.3)% Median – 99% Range – 93 to 100%
Post ductal SpO ₂	99.1 (1.3)% Median – 100% Range – 94 to 100%	98.9 (1.4)% Median – 99% Range – 92 to 100%
Pre-post difference	– 0.23 (1.2)%	– 0.14 (1.3)%
Echocardiogram for clinical indications	264 (43%)	241 (27%)*
Echocardiogram as baby was being discharged on oxygen (and had not had an echocardiogram before for clinical indication)	2/57 patients not weaned off oxygen by discharge	3/7 patients not weaned off oxygen by discharge
False positive screen	3 (0.48%)	7 (0.78%)
True positive screen	0	1

* p < 0.01 by Chi² test