Temporal trends in routine predischarge pulse oximetry screening: 6 years' experience in a UK regional neonatal unit

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ABSTRACT

Objectives To evaluate the continued impact of pulse oximetry screening (POS) in a regional neonatal unit (NNU) and identify trends in screening outcomes in comparison with our previous experience.

Design Retrospective review of admissions between April 2013 and March 2019 (the current study) and comparison with previously published data (the 2014 study).

Patients All infants >34 weeks completed gestation admitted to NNU as a result of positive POS.

Outcome measures Indication for admission, diagnosis, investigations and management.

Results There were 49 375 livebirths and 253 NNU admissions as a result of positive POS (0.5% of livebirths; compared with 0.8% in 2014). 247/253 (97.6%) of those admitted had a significant diagnosis requiring medical intervention (compared with 79% in 2014) and the proportion of healthy babies (with transitional circulation) admitted decreased from 21% to 2.4%. 22 (9%) babies admitted as a result of a positive POS were found to have a previously undiagnosed congenital heart defect (CHD) of which eight were critical CHDs (CCHDs). This accounted for 73% of all undiagnosed CCHD undergoing POS. The antenatal detection rate of CCHD was 75% compared with 46% in 2014. No baby died or collapsed on the postnatal ward during the study period. The proportion of babies with CCHD identified before discharge improved from 94% to 99%.

Conclusions Routine POS, in addition to antenatal screening and postnatal examination, continues to contribute to the improvement of our overall CCHD detection rates. We have demonstrated an overall reduction in the admission of healthy babies and therefore workload following a positive test.

What is already known on this topic?

- Early detection of critical congenital heart defect (CCHD) can improve outcome and prevent postnatal collapse.
- Some CCHD is missed by routine antenatal ultrasounds and postnatal examination.
- Pulse oximetry screening (POS) identifies CCHD not detected by routine antenatal ultrasound and postnatal physical examination.

What this study adds?

- Over time, experience with POS leads to fewer admissions particularly in babies who are healthy.
- Pulse oximetry still detects babies with CCHD that are missed by antenatal ultrasound, but the numbers decrease as antenatal detection rates improve.
- Babies with important non-cardiac conditions remain the majority of babies detected by POS.

INTRODUCTION

Routine newborn predischarge pulse oximetry screening (POS) is a simple, non-invasive tool for identifying critical congenital heart defects (CCHDs), which would otherwise be missed by antenatal ultrasound and postnatal physical examination.[1] POS is acceptable to parents and clinical staff,[2] has been shown to be cost effective in various healthcare settings[3 4] and meets the criteria for routine newborn screening.[5 6]

Meta-analysis of 437 000 screened babies has shown consistent test accuracy with moderate sensitivity and high specificity for the detection of CCHD.[6] Non-critical CHD[7] and non-cardiac conditions such as respiratory disorders and sepsis are also detected.[8]

In 2011, POS was added to the USA recommended screening panel,[9] and by 2018, all US states had adopted screening.[10] Analysis of over 27 million US births showed that introduction of POS reduced neonatal mortality from CCHD by 33% and from other cardiac causes by 21%.[11] Many other countries have also adopted or recommended POS including Austria, Canada, Germany, Poland, Nordic countries, Spain, Latin American countries, China, Israel, New Zealand, Saudi Arabia, Abu Dhabi, Kuwait, Qatar and Sri Lanka.[10 12]

Currently in the UK, although over 50% of all neonatal units (NNUs) perform POS,[13] the National Screening Committee (NSC) has not yet recommended its routine use; citing concerns regarding cost, insufficient evidence of improved outcomes and potential harms such as unnecessary investigations and admissions, longer hospital stay and parental anxiety.[14 15]

POS was initially set up at Birmingham Women's Hospital (BWH) as part of the PulseOx study,[7] following the end of the study screening continued as routine postnatal care.

We previously reported our initial experience of POS admissions between April 2010 and July 2013

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(the 2014 study), demonstrating that in addition to identifying babies with CCHD, POS also picked up babies with important non-cardiac conditions, many of which were potentially life-threatening diagnoses.[8]

In this study, we evaluated the continued impact of POS over a longer period in order to compare with our previous experience[8] and to further address the concerns raised by the NSC.

METHODS

Routine POS was performed on all eligible babies >34 completed weeks' gestation (including homebirths)[16] as previously described[8] using the pulseOx algorithm.[7] Briefly, functional oxygen saturations were measured in the right hand and either foot using a hand-held pulse oximeter and reusable probe, usually around 4–8 hours of age but as early as 2 hours in homebirths and early discharges. An abnormal result is defined by a saturation of <95% in either limb (or a difference of >2% between the two readings) on two occasions or any saturation <90%. Babies who were admitted to NNU before screening took place (eg, antenatal diagnosis or early onset of symptoms) were excluded.

All test positive babies were reviewed by the neonatal team and, if further investigation or treatment was required, admitted to NNU. All those admitted as a result of POS between 1 April 2013 and 31 March 2019 were identified through the Badgernet neonatal database. Data on clinical diagnosis, investigations, management, length of stay and other outcomes were collected.

The patient database from the tertiary paediatric cardiac centre at Birmingham Children's Hospital and the local mortality database were also interrogated to identify false negatives for CCHD.

This study was registered with the Birmingham Women's and Children's Hospital Research and Development Department and in accordance with the UK National Research Ethics Service guidance, neither individual informed consent nor formal research ethics committee review was required as the study was undertaken by the direct clinical care team using information previously collected in the course of routine care.

RESULTS

There were 49 375 livebirths during the study period, and no parents declined POS. Babies born in hospital were screened on delivery suite or postnatal ward, most commonly the latter.

Two hundred and twenty-four babies were born following an antenatal diagnosis of CCHD. Of these, 57 (25%) were diagnosed in locally booked women and the rest booked elsewhere and were transferred to our Fetal Medicine Centre for ongoing care. All babies with an antenatally diagnosed CCHD were admitted to NNU shortly after birth and a further eight babies with CCHD were admitted because of early onset symptoms (figure 1). None of these babies underwent POS. For locally booked women, CCHD antenatal detection rate was 75% (57/76; figure 1). In the 2014 study, the antenatal detection rate was 46% (table 1).

A total of 5262 babies >34 completed weeks' gestation were admitted, and 253 (5%) were as a result of a positive POS (figure 2), that is, 0.5% of all livebirths (compared with 0.8% in 2014). This equates to around 3.5 admissions per month (compared with 5.2 in 2014) table 1.

Median age at admission was 6.1 hours with 90% admitted within 12 hours and 95% within 24 hours. All babies were immediately assessed by a senior clinician in order to establish the cause of the low saturations.

Two hundred and forty-seven out of 253 (97.6%) of admitted babies had a significant condition, which required treatment (table 2). One hundred and forty-eight (58%) babies had a respiratory illness and 19 had persistent pulmonary hypertension. Fifty-three (21%) were diagnosed with sepsis including three with (blood) culture positive for group B Streptococcus (GBS). All cases of culture negative sepsis had a significant rise in inflammatory markers (table 2). Nineteen of these babies had positive skin swabs for GBS and six for *Escherichia coli* and 42 had a lumbar puncture (all cerebrospinal fluid samples were sterile). The other significant non-cardiac conditions are listed in figure 2.

Two hundred and thirty-nine out of 253 babies (94%) received supplemental oxygen during the admission: 122 low-flow oxygen, 90 high-flow oxygen, 10 received CPAP and 17 (7%) received invasive ventilation. Median duration of admission was just under 5 days (4 days 23 hours).

Only six (2.4%) of the admitted babies had no pathological diagnosis, that is, transitional circulation.

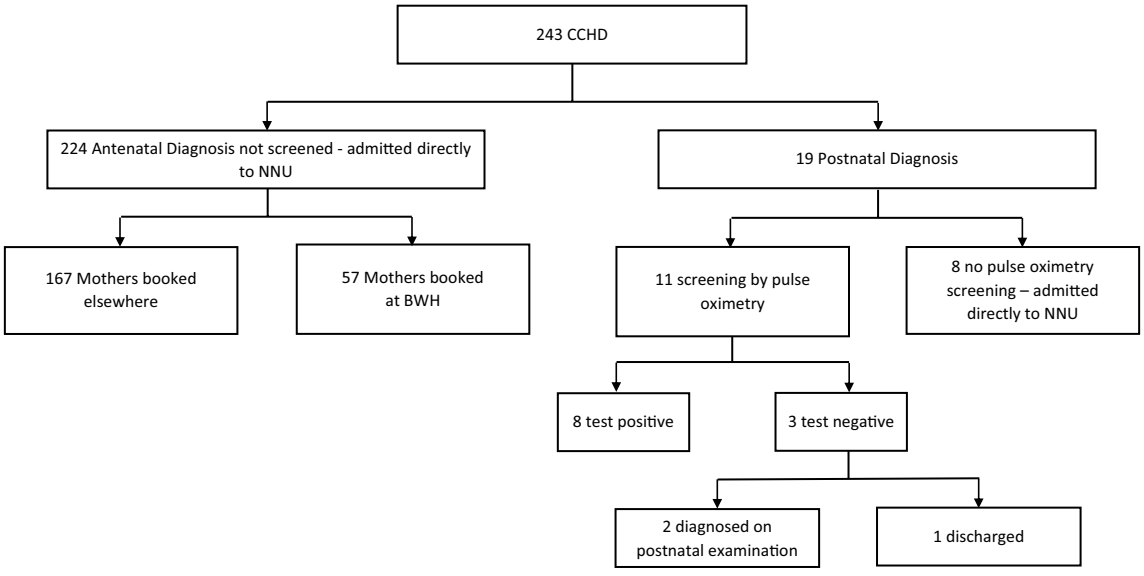

Figure 1 Outcomes of CCHD. CCHD, critical congenital heart defect; NNU, neonatal unit.

Table 1 Cohort comparisons

	2010–2013 (40 months)	2013–2019 (72 months)
Live births	25 859	49 375
Admission positive POS	208 (0.8%)	253 (0.5%)
Admission/month positive POS	5.2	3.4
AN diagnosis CCHD	46%	75%
CCHD identified by POS	9	8
Major CHD identified by POS	12	17
Screens per CCHD	2873	6171
Screens per major CHD	2155	2904
Screens per non-cardiac Δ	175	219
CCHD identified predischarge	94%	98.7%
+ve POS undergoing echo	29%	26%
Abnormal echos (for positive POS)	48%	54%
'Healthy' positive POS admissions	43 (21%)	6 (2.4%)

CCHD, critical congenital heart defect; POS, pulse oximetry screening.

Echocardiography was performed according to clinical indication. In total, 67 babies (26%) had an echocardiogram and a previously unsuspected cardiac condition was identified in 22 (eight critical, nine serious and five significant defects; tables 3 and 4) or 9% of all test positive babies admitted. Sensitivity of POS for the detection of CCHD was 73% (compared with 60% in 2014). Three babies with an unidentified CCHD had a negative POS result (figure 1). Two were identified on postnatal examination and one baby had a negative result for all screening tests (antenatal ultrasound, postnatal examination and POS) and was discharged home. In the latter baby, CCHD was diagnosed while still asymptomatic, following readmission for another reason. This was the only baby with a CCHD to be discharged undiagnosed during the study (98.7% overall detection rate). There were no neonatal deaths from CCHD during the study and none presented with acute circulatory collapse on the postnatal ward.

Table 2 Definitions of non-cardiac diagnoses in babies with test positive pulse oximetry

Congenital pneumonia	Raised inflammatory markers (CRP >10 mg/L)±positive culture, radiological changes on chest X-ray, oxygen requirement (for longer than 2 hours), antibiotics for ≥5 days
Meconium aspiration syndrome	History of meconium staining of liquor, respiratory distress, oxygen requirement (for longer than 2 hours), radiological changes on chest X-ray
Sepsis	Raised inflammatory markers (CRP >10 mg/L)±positive culture, antibiotics for ≥5 days
TTN requiring oxygen	Tachypnoea with radiological changes of fluid retention, oxygen requirement (for more than 2 hours), no rise in inflammatory markers or positive culture

Congenital pneumonia, meconium aspiration syndrome or TTN requiring oxygen were classified as significant respiratory Illness. TTN - Transient tachypnoea of the newborn

DISCUSSION

We report our 6-year experience of POS in order to make direct comparison with our previous findings in 2014 and identify trends in admission diagnoses, particularly in the light of improving antenatal detection of CCHD.

Overall, the proportion of babies with CCHD identified before discharge improved from 94% (in 2014) to 98.7%. Over the two periods, there was an increase in antenatal detection of CCHD– 46% in 2014 to 75% in this study, and the proportion of babies with CCHD identified by POS has therefore decreased. However, 19 babies with CCHD were still missed by antenatal screening of which POS identified eight. POS also detected nine babies with serious CHD who were missed by antenatal ultrasound (figure 1). This equates to over one CCHD identified by POS per year and almost three major (critical plus serious) CHDs per year. Our antenatal detection rate of 75% is higher than the UK national average (around 50% for cardiac defects requiring intervention within 1 year, regional range 34.3%–65.9%.).[17] Although the absolute number of babies with CCHD identified by POS per year has decreased, the overall test sensitivity

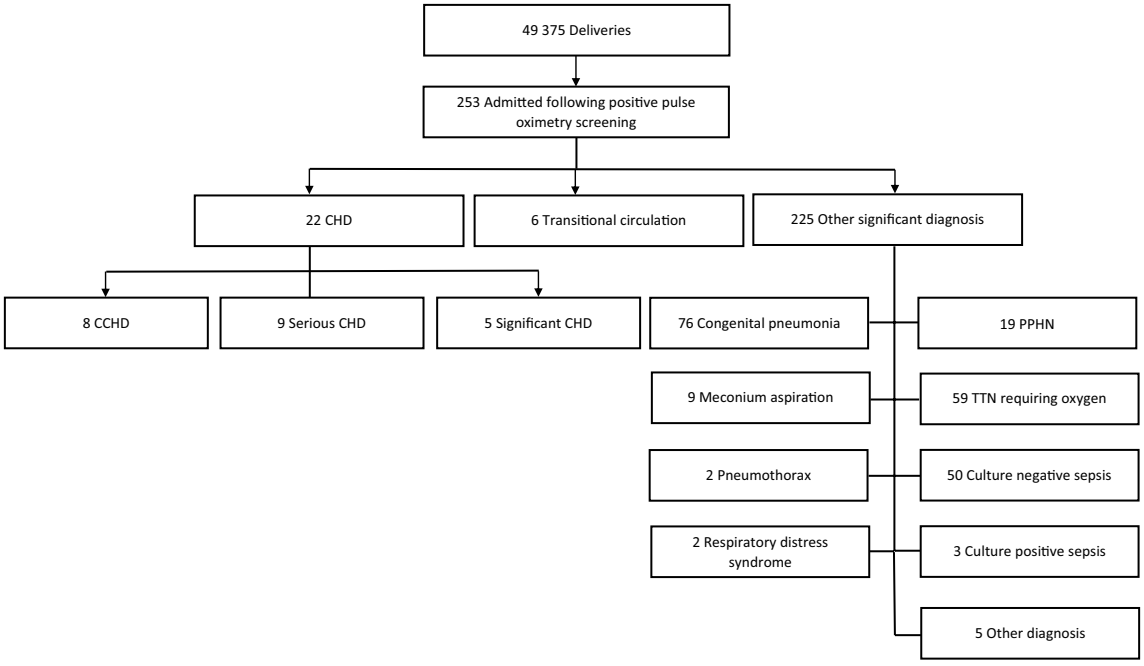

Figure 2 Outcomes of POS test positives. CHD, congenital heart defect; POS, pulse oximetry screening; PPHN, persistent pulmonary hypertension of the newborn.

Table 3 Definitions of congenital heart defects (CHDs) from Ewer *et al*[7]

Non-significant	Presence of any one of the following at birth no longer detected at 6 months: small PDA; small PFO/ASD; muscular VSD; mildly abnormal turbulence at branch pulmonary artery.
Significant	Above defects persisting for longer than 6 months of age. Also any cardiac lesion that requires regular monitoring beyond 6 months or requiring drug treatment but not categorised as serious or critical.
Serious	Any defect not defined as critical that requires intervention or results in death between 1 month and 1 year of age.
Critical	All infants with hypoplastic left heart, pulmonary atresia with intact ventricular septum, simple transposition of the great arteries or interruption of the aortic arch. All infants dying or requiring surgery within the first 28 days of life with the following conditions: coarctation of the aorta; aortic valve stenosis; pulmonary valve stenosis; tetralogy of Fallot; pulmonary atresia with ventricular septal defect; and total anomalous pulmonary venous connection.
Non-significant and significant CHD are classified as minor and serious and critical as major CHD	

ASD, atrial septal defect; PDA, patent ductus arteriosus; PFO, patent foramen ovale; VSD, ventricular septal defect.

was 73% (compared with 60% in 2014). In hospitals with a lower antenatal detection rate, POS is likely to identify a higher proportion of CCHD babies.

We previously reported that 29% of test positive babies underwent echocardiography and 48% of these had a diagnosis requiring treatment or cardiac follow-up.[8] In the present study, 26% of POS test positive babies had an echocardiogram and 54% had a significant diagnosis (CHD or persistent pulmonary hypertension of the newborn; table 4). Our consistent practice has been only to perform echocardiograms in test positive babies in whom an alternative diagnosis for hypoxaemia has not been established. As we previously reported,[8] this compares favourably with the number of babies undergoing echocardiography for murmur.[18]

The proportion of babies with CCHD that were false negative (ie, missed by POS) decreased from 40% (6/15) in 2014 to 27% (3/11) in this study. Two of the three false negative babies had aortic obstruction—the defects most commonly missed by POS.[19] However, the proportion of aortic obstruction identified by POS in our centre increased from 43% in 2014 to 60%, although overall numbers are small.

In 2014, we calculated identification of one CCHD for every 2873 screens performed.[8] This number had decreased to one CCHD every 6171 screens for the reasons stated previously but still compares favourably with other reported screened cohorts (eg, one CCHD every 24 231 screens in New Jersey).[20]

Table 4 Significant echocardiographic findings in babies with test positive pulse oximetry screening

Transposition of great arteries	2
Critical pulmonary stenosis	1
Pulmonary atresia	2
Pulmonary stenosis	1
Coarctation of aorta	3
Truncus arteriosus	1
Atrioventricular septal defect	2
Tetralogy of Fallot	2
Aortic stenosis	1
Tricuspid valve abnormality	1
Patent ductus arteriosus	2
Ventricular septal defect	3
Atrial septal defect	1
Persistent pulmonary hypertension of the newborn (PPHN)*	14

Five babies with PPHN were diagnosed clinically and did not have echocardiography.
*PPHN defined clinically with preductal and postductal difference in saturations with echocardiogram findings of significant tricuspid regurgitation and evidence or right to left shunt across the patent foramen ovale and/or patent ductus arteriosus.

Importantly, the overall proportion of babies admitted to NNU following a positive POS has fallen from 0.8% of livebirths in 2014 to 0.5%—a fall in admissions with positive POS from 5.2 to 3.5 babies per month (table 1). This reduction, particularly the reduction of admissions of healthy babies, may have occurred as a result of greater experience with POS. In 2014, 42% of babies admitted and diagnosed with transitional circulation were hypothermic; it is possible that active thermal care on the postnatal wards prior to a repeat screen reduced admission rates. In addition, staff are more familiar with POS and perhaps have greater confidence observing babies with borderline saturations and a normal examination on the postnatal ward to allow the saturations to normalise without needing NNU admission.

In 2014, the majority of test positive babies had non-cardiac conditions requiring intervention (71%); in this study, this increased to 89%. This was mainly due to a reduction in the admission of healthy babies with transitional circulation as the frequency of admission for non-cardiac causes did not increase. In both cohorts, the main non-cardiac conditions were respiratory and infective. The number of screens performed to identify one non-cardiac condition has remained similar, that is, one non-cardiac condition per 219 screens compared with every 175 screens in 2014. Our data show that overall admission rate and therefore NNU workload as a result of POS has reduced compared with 2014.

As in our previous cohort, no baby on the postnatal ward presented with collapse as a result of cardiorespiratory or early-onset infective conditions. In addition, there were no unexpected neonatal deaths from these conditions in either study period. We have previously described the benefit of earlier screening in order to prevent collapse in the first day of life.[19] Studies where screening takes place later describe more babies with CCHD presenting with symptoms or collapse before screening takes place and identify fewer babies with non-cardiac conditions (which tend to present within 24 hours after birth).[19] These factors also contribute to the higher false positive rate seen in earlier screening,[5 6] but it should be remembered that a false positive (any test positive baby who does not have CCHD) is still hypoxaemic, often with a potentially serious condition.

Our data compare favourably with the largest reported UK cohort undergoing POS that was published in 2020 and analysed data from over 138 000 babies (76 232 screened using POS) over an 11-year period (2001–2011).[21] Only data on CCHD detection were reported and a comparison between two screening, and one non-screening, hospitals was made. The rate of postdischarge diagnosis in the screened population was 7/100 000 and 13/100 000 in the unscreened population. The rate in the unscreened population was almost twice as high as the screened, and both were higher than our postdischarge diagnosis rate of

2/100 000. In the 2020 study, screened babies underwent post-ductal saturation testing only, which is likely to miss more babies with CCHD.[10 19] The proportion of non-cardiac conditions identified was not reported and so no comparison can be made.

As we have previously stated, it is clear from our study that as antenatal screening improves, this reduces the number of babies with CCHD who require postnatal diagnosis, therefore decreasing the number potentially detected by POS. Our antenatal detection rate (75%) is much higher than the national average but one in four CCHD cases are still missed. Assuming a CCHD rate of 1–1.8/1000 livebirths,[22] this equates to 175–350 UK babies missed per year with an antenatal detection rate of 75%, or 350–630 babies with the current detection rate of 50%.[17]

Although not target conditions for POS, detecting serious CHDs and significant respiratory and infective diagnoses are important additional benefits, as recognised by clinicians.[14 15] POS unequivocally improves outcomes for CCHD,[11] but there are no published data on the test accuracy of POS for detecting non-cardiac conditions, or evidence to indicate improved outcome for these disorders. However, clinical common sense would suggest that earlier detection of potentially life-threatening conditions while the baby is still asymptomatic and the initiation of prompt treatment would halt disease progression and likely reduce morbidity and mortality. Additionally, babies with suspected sepsis identified by POS comprise a small proportion of all newborns requiring investigation and treatment for suspected sepsis. Estimates suggest that up to 20%[23] may receive antibiotics as a result of adherence to the current NICE guidance for early onset sepsis[24]—a significantly greater proportion than the 0.3% of screened babies diagnosed with sepsis as a result of POS.

Some babies may potentially be harmed following POS as it may lead to overdiagnosis, delayed discharge and parental anxiety. Over the two study periods, we report a significant reduction in the number of healthy babies admitted to NNU as a result of a positive screen, to only 2.4%, which equates to only 0.02% (1 in 5 000) of the screened population.

POS was universally accepted by parents, and we are not aware of concerns from parents regarding testing. In the PulseOx study, a full psychological analysis of mothers' responses to POS was obtained, which found no evidence of increased anxiety, even in mothers of babies with a false positive result.[2]

There are limitations to our study. Babies were identified by interrogation of a neonatal database that relies on accurate data input. It is possible that some babies were incorrectly coded. To reduce the risk of misclassifying data entry, multiple data sources were investigated and cross-referenced, and the clinical notes of all babies included were carefully analysed. We accept that some babies with a CCHD may have presented or died out of region, and therefore, we may not have captured them in our analysis, but it is likely that there would be notification of this event.

CONCLUSIONS

The repeat evaluation of the POS programme in our hospital has highlighted a number of important findings. As our experience with POS has developed, this has resulted in fewer test positives requiring admission and fewer healthy babies admitted. As the proportion of babies with antenatally detected CCHD increases, the number of babies with these conditions picked up by POS decreases; however, POS still regularly picks up babies with CHD who are at risk of discharge without diagnosis (approximately 10% of test positives). The majority of babies identified by early POS have respiratory or infective diagnoses, most of which are likely to benefit from earlier treatment.

Our data strongly suggest that the harms are negligible and are significantly outweighed by the benefits of POS.

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