

The impact of routine predischarge pulse oximetry screening in a regional neonatal unit

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Received 15 November 2013

Accepted 22 February 2014

Published Online First

19 March 2014

ABSTRACT

Objectives (i) To evaluate the impact of routine early pulse oximetry screening on the rate of unexpected neonatal unit (NNU) admissions and the need for echocardiography. (ii) To review the outcomes of babies admitted as a result of a positive pulse oximetry screening test.

Design Retrospective review over a 40-month period.

Setting Level 3 NNU.

Patients All babies admitted as a result of positive pulse oximetry screening.

Main outcome measures Indication for admission, clinical diagnosis and management were collated.

Results 3552 babies were admitted during the study period. Of these, 1651 were unexpected admissions and 208/1651 (12.6%) were as a result of positive pulse oximetry screening. 165/208 babies (79%) had a significant clinical condition which required further intervention including 17 with congenital heart defect (CHD) (nine critical), 55 with pneumonia, 30 with sepsis and 12 with pulmonary hypertension. No baby died or collapsed on the postnatal ward during the study period. 61/208 babies (29%) had echocardiography and CHD was detected in 28%.

Conclusions Routine use of pulse oximetry screening identifies babies with CHD and other illnesses, which, if not identified early could potentially lead to postnatal collapse. It does not appear to overload clinical services, resulting in appropriate admission in the majority and a modest increase in the number of echocardiograms performed.

INTRODUCTION

Several recent, large multicentre studies have demonstrated the accuracy of pulse oximetry as a screening test for detecting critical congenital heart defects (CCHD).^{1–5} In 2012, a systematic review and meta-analysis of almost 230 000 screened babies reported a high specificity, moderate sensitivity and a low false positive rate, and concluded that pulse oximetry screening fulfils the criteria for universal screening.⁶ Pulse oximetry has also been shown to be acceptable to parents and clinical staff,^{7–8} and cost effective in the current UK setting.^{7–9} Routine screening for CCHD using pulse oximetry is being increasingly endorsed^{10–11} and was added to the recommended uniform screening panel in the USA in 2011.¹²

However, there are some concerns about this mode of screening for CCHD, particularly the number of false positive babies that may be identified and their clinical impact on neonatal unit admissions and echocardiographic services.¹³ There is a significant increase in the false positive rate if screening is performed before 24 h when compared with

What is already known on this topic

- ▶ Some critical cardiac defects are missed by antenatal ultrasound and routine clinical examination in the newborn period.
- ▶ Early detection of such anomalies can improve outcome.
- ▶ Pulse oximetry screening can improve detection.

What this study adds

- ▶ This addition of early pulse oximetry screening to existing screening improves detection of critical congenital heart defects to over 90%.
- ▶ Important non-cardiac conditions are also detected.
- ▶ The impact on echocardiographic services is modest.

after 24 h (0.5% vs 0.05%)⁶ and the PulseOx study in the UK which screened at a mean age of 12 h had a false positive rate of 0.8%.⁴ For these reasons, the US recommendation is for delayed screening after 24 h. In some countries, including the UK, the majority of term babies are discharged within 24 h, making delayed screening impracticable.

Most screening studies have reported that a significant proportion of the false positive babies (between 37% and 70%) had a serious non-cardiac condition (usually a respiratory problem or infection).^{1–5} The earlier babies are screened the more likely these conditions will be identified and be included as a false positive. However, the early identification of conditions such as pneumonia and other forms of early-onset sepsis, before the baby becomes unwell, may represent a 'secondary target' for pulse oximetry screening and be an important additional advantage of the test.

Following the end of recruitment to the PulseOx study,⁴ Birmingham Women's Hospital decided to continue early pulse oximetry screening as part of routine practice. No additional staff were employed to perform the test.

METHODS

Parents were informed of testing antenatally, and after obtaining postnatal verbal consent, all eligible babies underwent predischarge pulse oximetry screening. This was performed routinely on the postnatal ward, usually before 12 h of age



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To cite: Singh A, Rasiah SV, Ewer AK. *Arch Dis Child Fetal Neonatal Ed* 2014;**99**:F297–F302.

following admission from delivery suite. Functional oxygen saturations were measured in both right upper and either lower limb by a trained health professional (healthcare assistant or midwife) using a hand-held oximeter with a reusable probe. A saturation result of $<95\%$ in either limb or a difference of $>2\%$ between the readings (if both were $\geq 95\%$) was considered abnormal.⁴

Following an abnormal first test, an initial assessment was performed. If this was unremarkable, oximetry was repeated 1–2 h later. If the saturations remained abnormal on second testing, or if there were concerns following the initial assessment, babies were classified as test positive and were admitted to the neonatal unit for further assessment (figure 1).

Details of all unexpected admissions (including those as a result of positive pulse oximetry screening) were routinely collected. The clinical diagnosis, management, duration of hospital stay and outcome of babies who tested positive were reviewed retrospectively over the 40-month period between 1 April 2010 and 31 July 2013. Further clinical details were obtained from the admissions register, the patient's notes and the neonatal unit electronic database.

The Regional Cardiac Centre database at Birmingham Children's Hospital, the Regional Congenital Anomaly Register and local mortality database were interrogated to identify false negatives.

RESULTS

There were 25 859 live births during the study period. No parent declined pulse oximetry screening. Babies who were discharged from delivery suite were screened there; the majority were screened on the postnatal ward. Babies who were admitted directly to neonatal unit were not routinely screened.

A total of 58 babies were delivered following an antenatal diagnosis of CCHD and were not screened. Of these, 13 (22%) were diagnosed in locally-booked mothers and the rest were

mothers who booked elsewhere and transferred to our centre following antenatal diagnosis of CCHD (figure 2). Three other babies with CCHD were not screened (figure 2). One was symptomatic at birth with cyanosis, the other two had additional congenital abnormalities requiring neonatal unit admission and CCHD was detected following assessment.

During the study period, there were 3552 admissions to the neonatal unit and 1651 (46%) were unexpected. In all, 208 babies were admitted following positive pulse oximetry (0.8% of all live births; 5.8% of all admissions and 12.6% of all unexpected admissions). The median age at admission was 7.5 h (range 1–36 h).

All babies were initially evaluated by the most experienced clinician available (usually the attending middle grade clinician) to establish the most likely cause of the hypoxaemia (figure 3). Overall, 132/208 of the test positive babies (63%) received continuous oxygen therapy during their stay on the neonatal unit for a median duration of 2 days (range 1–15 days), 26 (12%) received continuous positive airway pressure (CPAP) or high flow oxygen therapy and 4 (2%) were ventilated.

A total of 103 babies (49.5%) had a significant respiratory illness (see table 1 for definitions) and 12 had persistent pulmonary hypertension (figure 3). Two babies were blood culture positive for Group B Streptococcus and 28 babies (13%) had blood culture negative sepsis associated with a significant rise in inflammatory markers (figure 3). Twenty of these babies had positive surface swabs for Group B streptococcus and eight had a lumbar puncture as a part of their sepsis workup (all CSF samples had negative microbiology). The other significant non-cardiac conditions in the test positive babies are listed in figure 3.

Only 43 test positive babies (21%) had transitional circulation (ie, no pathological diagnosis) (figure 3). These babies were either hypothermic ($n=18$) or had transient tachypnoea of newborn with no oxygen requirement ($n=17$). Babies with suspected sepsis who had no rise in inflammatory markers, negative

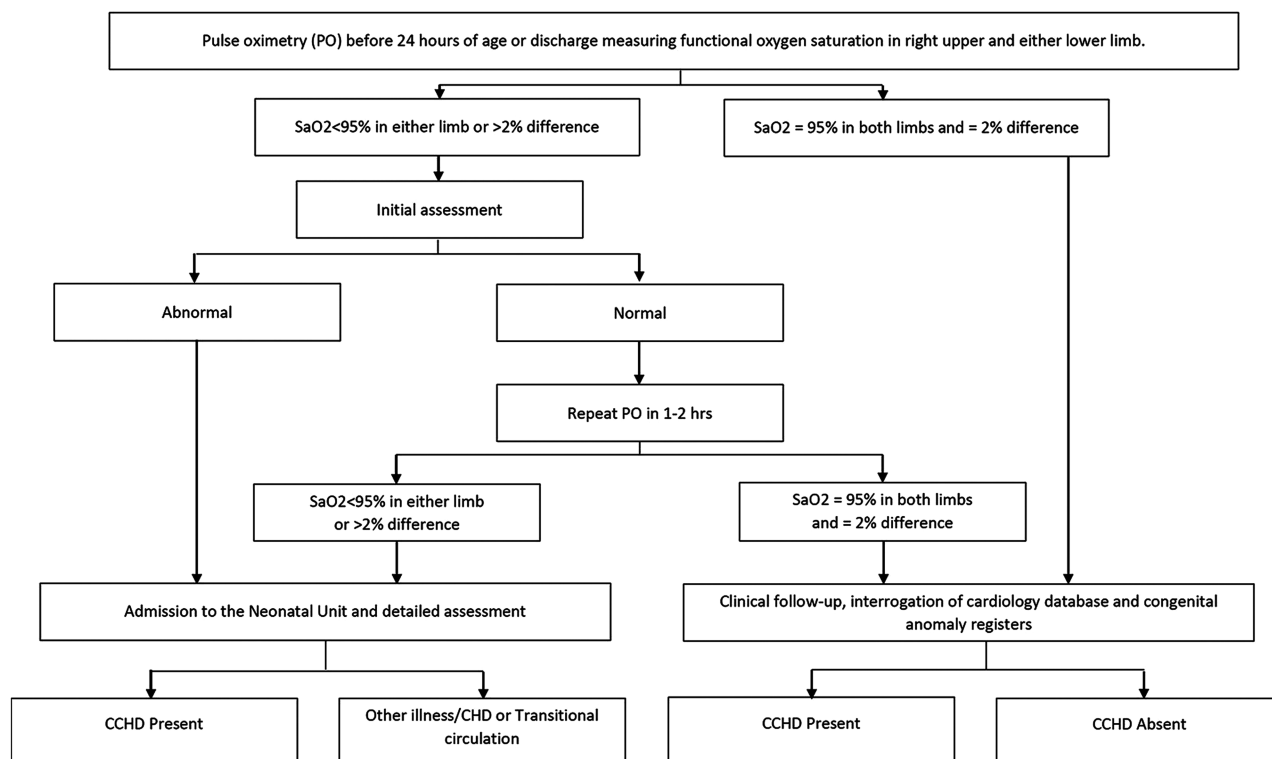


Figure 1 Pulse oximetry screening protocol.

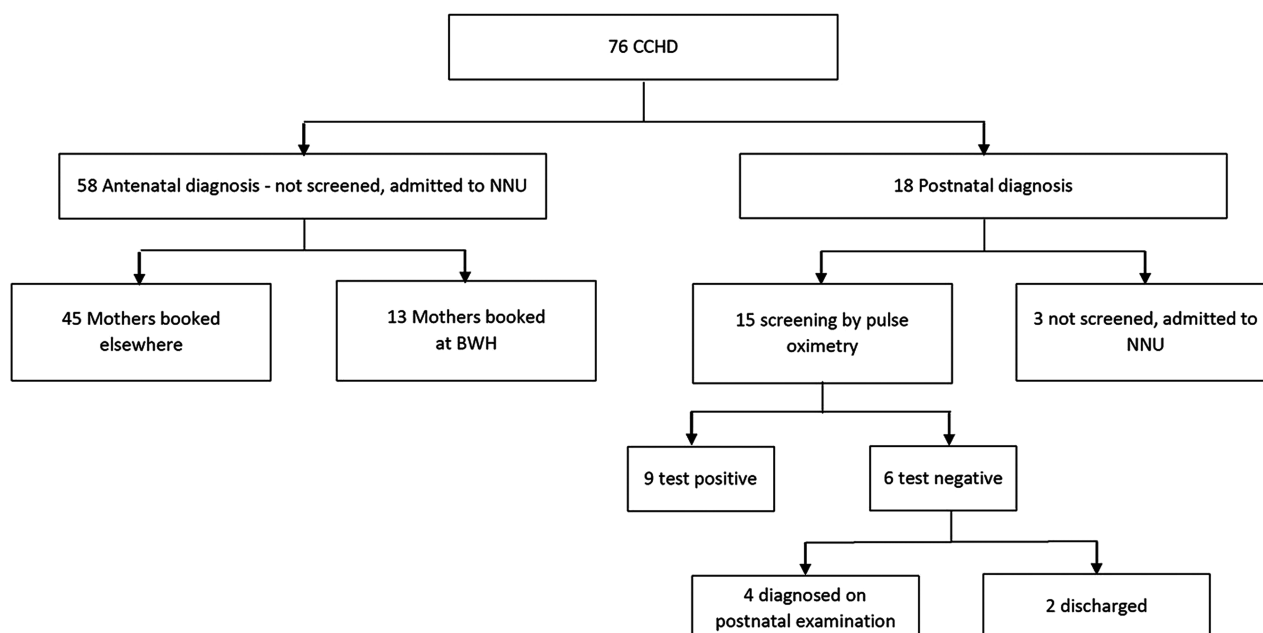


Figure 2 Outcomes of critical congenital heart defects.

blood cultures, normal chest X-ray or received antibiotics that were stopped following negative cultures at 36 h were also included in this group (n=8).

Echocardiography was done at the discretion of the attending consultant after clinical assessment. In all, 61 test positive babies (29%) underwent echocardiography during the admission and 17 (8%) had previously undetected congenital heart defect (CHD) (see table 2 for CHD definitions); 12 (6%) had major CHD (nine critical CHD and three serious CHD). The echocardiographic diagnoses in all 61 babies are outlined in table 3.

Four babies with CCHD passed pulse oximetry screening but were later noted to have a significant murmur on postnatal

examination which prompted a predischarge echocardiogram (figure 2). Three of these babies had aortic arch abnormalities and one had critical pulmonary stenosis. Interrogation of the regional databases identified two further babies with CCHD who were missed by pulse oximetry screening, antenatal ultrasound and postnatal examination. One baby had transposition of the great arteries; the other had coarctation of the aorta. Both passed pulse oximetry screening at 6 h and presented to accident and emergency with collapse and subsequently underwent surgery. During the 40-month period, no baby died with undiagnosed CCHD and none presented with acute circulatory collapse on the postnatal wards.

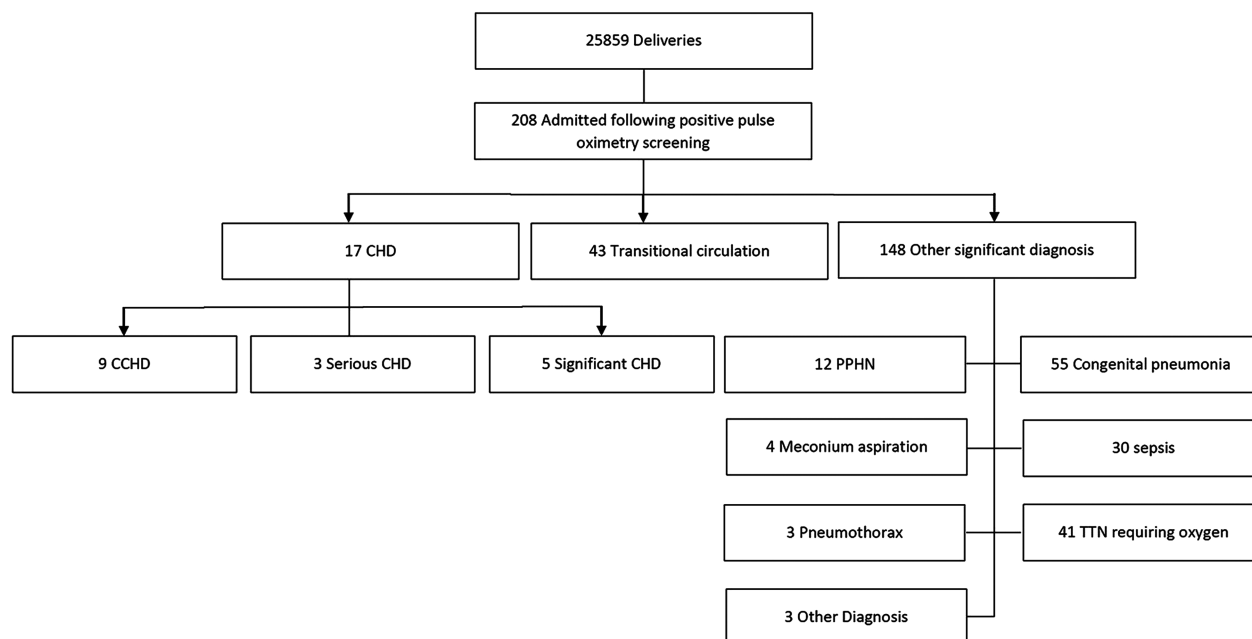


Figure 3 Outcomes of test positives following pulse oximetry screening.

Table 1 Definitions of diagnoses in babies with test positive pulse oximetry screening

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

Congenital pneumonia, meconium aspiration syndrome or TTN requiring oxygen were classified as significant respiratory illness.

CRP, C-reactive protein; TTN, transient tachypnoea of the newborn.

DISCUSSION

Our data confirm that routine pre-discharge pulse oximetry screening identifies previously undiagnosed CCHD. Overall, 94% of all babies with a CCHD born to local mothers were identified prior to discharge and 50% of those picked up post-natally were identified by pulse oximetry screening (60% of those who actually underwent screening). This is consistent with the reported test accuracy of the PulseOx study after those with an antenatal diagnosis were excluded.⁴ In addition, early screening (within 24 h) also identified many babies with potentially life-threatening respiratory and infective illnesses before clinical symptoms became apparent and, importantly, before the babies became significantly unwell.

Approximately 0.8% of all live births tested positive, which is also consistent with the results from the PulseOx study,⁴ and in a hospital with approximately 8000 deliveries per year, resulted in just over one neonatal unit admission per week.

Only nine out of 208 test positive babies had a previously undiagnosed CCHD; however, 13 babies from our local population had an antenatal diagnosis of CCHD and were not screened and three babies were not screened because they were admitted immediately to NNU (figure 2). Our local antenatal

Table 2 Definitions of congenital heart defect (CHD)

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 which requires regular monitoring beyond 6 months or requiring drug treatment but not categorised as serious or critical
Serious	Any defect not defined as critical which 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 intervention 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; total anomalous pulmonary venous connection

Non-significant and significant CHD are classified as minor CHD and serious and critical as major CHD.

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

Table 3 Significant echocardiographic findings in babies with test positive pulse oximetry screening

Transposition of great arteries	2
Severe pulmonary stenosis with Ebstein's anomaly	1
Pulmonary atresia	2
Coarctation of aorta/hypoplastic arch	3
TAPVD	1
Atrio-ventricular septal defect	1
Tetralogy of Fallot	1
Cardiomyopathy	1
Significant PDA	1
Significant VSD	3
Significant ASD	1
PPHN*	12

*PPHN defined clinically with preductal and postductal difference in saturations with echocardiogram findings of significant tricuspid regurgitation and evidence of right to left shunt across the PFO and/or PDA.

ASD; atrial septal defect; PDA; patent ductus arteriosus; PFO; patent foramen ovale; PPHN, persistent pulmonary hypertension of the newborn; TAPVD, total anomalous pulmonary venous drainage; VSD; ventricular septal defect.

detection rate for CCHD during the study period was 46%, which is comparable with the rate demonstrated in the PulseOx study⁴ and is slightly higher than the average detection rate across the UK.¹⁴ In regions with a lower antenatal detection rate, pulse oximetry screening is likely to identify more babies.⁴

Six babies with CCHD were missed by pulse oximetry screening, and two babies out of this group were missed by all screening tests. The majority of babies who were not identified by pulse oximetry screening in our cohort had aortic obstruction (4/6); these lesions may not necessarily be associated with hypoxaemia and this is consistent with other screening studies^{2-5 15} although, interestingly, we did identify three babies with such lesions by pulse oximetry screening (table 3).

The recent systematic review of pulse oximetry screening⁶ demonstrated the reduction of false positive rates when screening is performed after 24 h. In the UK, and other countries, there is an increasing tendency to early postnatal discharge within 24 h, making later screening impractical. However, it is important to remember that although later screening has a lower false positive rate,^{2 3 6} in studies employing this practice, up to half of babies with CCHD presented with symptoms before screening took place,^{2 3} including up to 9% of babies with CCHD presenting with acute collapse prior to discharge from hospital.²

An important additional benefit of pulse oximetry screening is the identification of non-critical CHD and serious non-cardiac illnesses. In our cohort these 'secondary screening targets' account for the majority of test positive babies. Overall, 79% of the false positives in our cohort had a significant illness requiring medical intervention. We have defined these conditions as rigorously as possible to ensure that only those babies with definite pathology were included. A baby with undetected congenital pneumonia or other forms of early-onset sepsis is equally at risk of acute postnatal collapse as a baby with CCHD. Most of these babies would present within 24 h and therefore would not be picked up by later screening. Some may have presented in a worse clinical state, potentially requiring intensive support and therefore their early diagnosis is beneficial, as treatment can be started before the disease progresses.

In the USA, routine pulse oximetry screening after 24 h of age is being performed in an increasing number of states. New Jersey was the first state to implement mandated pulse oximetry

screening in all birthing facilities and recently published the results of their state screening programme over a 9-month period.¹⁶ In their cohort a total of 72 694 babies were screened after 24 h and 30 babies had a diagnostic workup as a result of a positive test. Of the 30 positive tests, three babies had a previously undiagnosed CCHD and 17 had alternative diagnoses. The false positive rate was much lower in the New Jersey cohort than in ours (0.04% vs 0.8%); however, the number of screens required to detect a case of CCHD is much greater (24 231 screens vs 2873 screens to detect one CCHD). In addition, the detection of serious non-CCHD conditions is much lower; only 12 conditions meeting our criteria were detected in New Jersey compared with 156 babies in our cohort (6057 screens vs 165 screens to detect one non-cardiac condition). The differences may be explained by a higher antenatal detection rate for CCHD (the rate was not stated for New Jersey) and the likelihood that with later screening babies with CCHD and secondary conditions presented before screening could take place.

In 2013, Prudhoe and colleagues described a 10-year experience of postductal pulse oximetry screening in a UK centre¹⁵ with a broadly similar cohort to ours (29 925 vs 25 859 live births and 27 vs 24 CCHDs). In their study, only 29% of all postnatally diagnosed CCHDs were identified by pulse oximetry screening and 19% of all CCHDs were discharged home without diagnosis, compared with 50% of postnatally diagnosed CCHDs identified by pulse oximetry and only 6% of all CCHDs discharged home in our cohort. Possible explanations for this include: (i) the average age at screening is not described in the study by Prudhoe *et al*¹⁵ and may have been later than ours, allowing time for babies to present before screening took place and (ii) screening using only postductal saturations will miss babies with CCHD that would be identified using a preductal and postductal screening algorithm.¹⁷ In addition, the study by Prudhoe *et al*¹⁵ did not describe the false positive results and so the number of non-cardiac diagnoses identified by pulse oximetry screening is not known.

A common concern regarding routine pulse oximetry screening is the increased workload for echocardiography services.¹³ In the PulseOx study⁴ and the subsequent health economic analysis,^{7–9} all test positive babies underwent echocardiography. However, in our experience an echocardiogram is not always clinically indicated as some test positive babies rapidly return to normal saturations and others have a clear alternative diagnosis (usually a respiratory cause). In our cohort, only 29% of test positive babies had an echocardiogram, and 48% of those babies had a diagnosis which required an intervention or cardiology follow-up with 20% having a major CHD (table 3). This compares favourably with babies undergoing echocardiogram following detection of a heart murmur during the newborn examination. We recently reviewed our experience in this respect; over a 3-year period, 205 echocardiograms were performed as a diagnostic, pre-discharge assessment in babies with an asymptomatic murmur.¹⁸ In all, 60% of these babies had no significant abnormality and 34% had a septal defect only; only two babies (1%) had a CCHD. Over a slightly longer time period, we performed 61 echocardiograms following pulse oximetry screening and identified nine CCHDs. This equates to one CCHD identified per 100 echocardiograms for murmur and one CCHD per 6.8 echocardiograms for pulse oximetry screening.

One limitation of our data is that it is not possible to predict how many of the conditions (both cardiac and non-cardiac) identified by positive pulse oximetry screening would have been picked up prior to discharge had screening not occurred.

Because screening usually took place within the first 12 h, it occurred, in almost every case, before the routine clinical examination. We have tried to identify only those babies with a clinical condition which warranted medical intervention and it could be argued that these babies would have presented to clinical services anyway. So, earlier identification of these babies by pulse oximetry screening does not create additional admissions (with the exception of the minority of false positives who were healthy), but facilitates earlier admission and treatment. This potentially reduces the risk of disease progression, the length of admission and intensity of the treatment required. It is also conceivable that some of these babies could have been discharged home before obvious clinical symptoms developed and in these cases lack of access to medical intervention may have led to a worse outcome.

CONCLUSIONS

We have shown that pre-discharge pulse oximetry screening aids the early identification of babies with critical CHD and other serious illnesses which are known to cause sudden, unexpected postnatal collapse. Pulse oximetry screening results in appropriate admission in the majority, and a modest number of additional echocardiograms.

However, it is important to remember that pulse oximetry screening will not identify all babies with CCHD particularly those with aortic obstruction and therefore pulse oximetry should be used as an adjunct to existing screening methods rather than a replacement. In our experience, and the experience of others, this results in identification of over 90% of all CCHDs prior to discharge.

Acknowledgements We would like to thank Mr John Stickley from the Heart Unit at Birmingham Children's Hospital who interrogated the cardiac database and Ms Ann Tonks from the West Midlands Congenital Anomaly Register (Public Health England) who interrogated the congenital anomaly and mortality databases. We are indebted to the health care assistants and midwives at Birmingham Women's Hospital who provide the pulse oximetry screening service.

Contributors AS collated the data, performed the initial analysis, wrote the first version of the manuscript and edited subsequent versions. SVR coordinated the echocardiograms and edited the manuscript. AKE designed and initiated the study, edited and completed the final version of the manuscript.

Competing interests None.

Provenance and peer review Not commissioned; externally peer reviewed.

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Arch Dis Child Fetal Neonatal Ed 2014 99: F297-F302 originally published online March 19, 2014
doi: 10.1136/archdischild-2013-305657

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