Public Health England

Protecting and improving the nation's health

Newborn Pulse Oximetry Screening Pilot

Summary Report

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Public Health England leads the NHS Screening Programmes

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Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the 4 UK countries. The Screening Quality Assurance Service (SQAS) ensures programmes are safe and effective by checking that national standards are met.

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Executive summary

Background

Congenital heart defects (CHD) are the most common group of congenital malformations and one of the leading causes of infant death in the developed world. Early detection of critical CHD (CCHD) – that which causes death or requires invasive intervention before 28 days of age - may improve outcome. Current routine screening for CHD relies on a mid-trimester fetal anomaly ultrasound scan, involving imaging of the heart chambers, and a postnatal clinical examination involving assessment of the cardiovascular system. Both of these have a relatively low detection rate and a significant number of babies are discharged from hospital before CCHD is diagnosed. A proportion of these may die or present in such a poor clinical condition that the outcome, despite treatment, is compromised.

Pulse oximetry (PO), as an additional screening test to identify babies with CCHD prior to acute clinical deterioration has been widely reported and routine screening is being taken up or considered by many countries. In 2013, approximately 20% of maternity units in the UK were using some form of PO screening for CCHD; however the screening pathways varied significantly and little outcome data were available. Following the public consultation in 2013 and the publication of further UK evidence, the UK NSC proposed that the feasibility and impact of PO screening (in a wider clinical context) be examined in a pilot study involving maternity units across England. This report describes the results of the six month pilot.

Aims of the pilot study

- to evaluate the feasibility of implementing newborn PO screening on NHS services
- to establish the effect on clinical services when PO screening is undertaken as part of the newborn and infant physical examination NIPE Programme.

Participating Trusts

Fifteen Trusts were selected for the pilot - seven were already offering PO screening for newborn babies and eight had not previously introduced screening. The Trusts were chosen based partly on their willingness to participate, but mainly on the range of size of Trusts (number of deliveries per annum), the level of access to neonatal intensive care and paediatric cardiology and the geographical

location. The 15 participating Trusts ranged from high-volume, urban tertiary units to low-volume rural midwifery led units and were divided into two groups. Group A – seven Trusts who were already performing PO screening, but agreed to look to change where possible the existing newborn PO screening pathway (see Figure PO 1) for the duration of the pilot. Group B – eight Trusts who had not previously performed PO screening.

Newborn pulse oximetry screening pilot methodology

The pilot was conducted over two phases:
Phase one: Completion of baseline assessment questionnaire and retrospective data collection from a predefined dataset - commenced on 27th February 2015
Phase two: Pre phase 2 all pilot Trusts undertook a short 'baseline' prospective data collection phase prior to change or implementation of the pilot screening pathway. This was based on existing screening provision commenced June 2015 for one month:

Pilot PO screening undertaken 1st July – 31st December 2015:

Summary of key data findings

The following tables provide the key data findings from the pilot:

Table 1: PO screens performed as part of the pilot

Total number of PO screens performed	32,836 (complete screens)
Total number screen negative cases	**32,597**
Total number screen positive cases	**239**
Overall screen positive rate (SPR)	**0.73%**
Number of Critical Congenital Heart Disease (CCHD) cases identified	**8**
Total number of known false screen negative cases	**2**

Table 2: Critical congenital heart disease diagnoses identified by PO screening

CCHDs
Coarctation of the Aorta (CoA)
Critical pulmonary stenosis (PS), ventricular septal defect (VSD) and patent ductus arteriosus (PDA)
Critical PS x 2
Transposition of the great arteries (TGA) with VSD
TGA
Supracardiac total anomalous pulmonary venous drainage (TAPVD)
Hypoplastic aorta/CoA (hypoplastic left heart syndrome) and mixed TAPVD

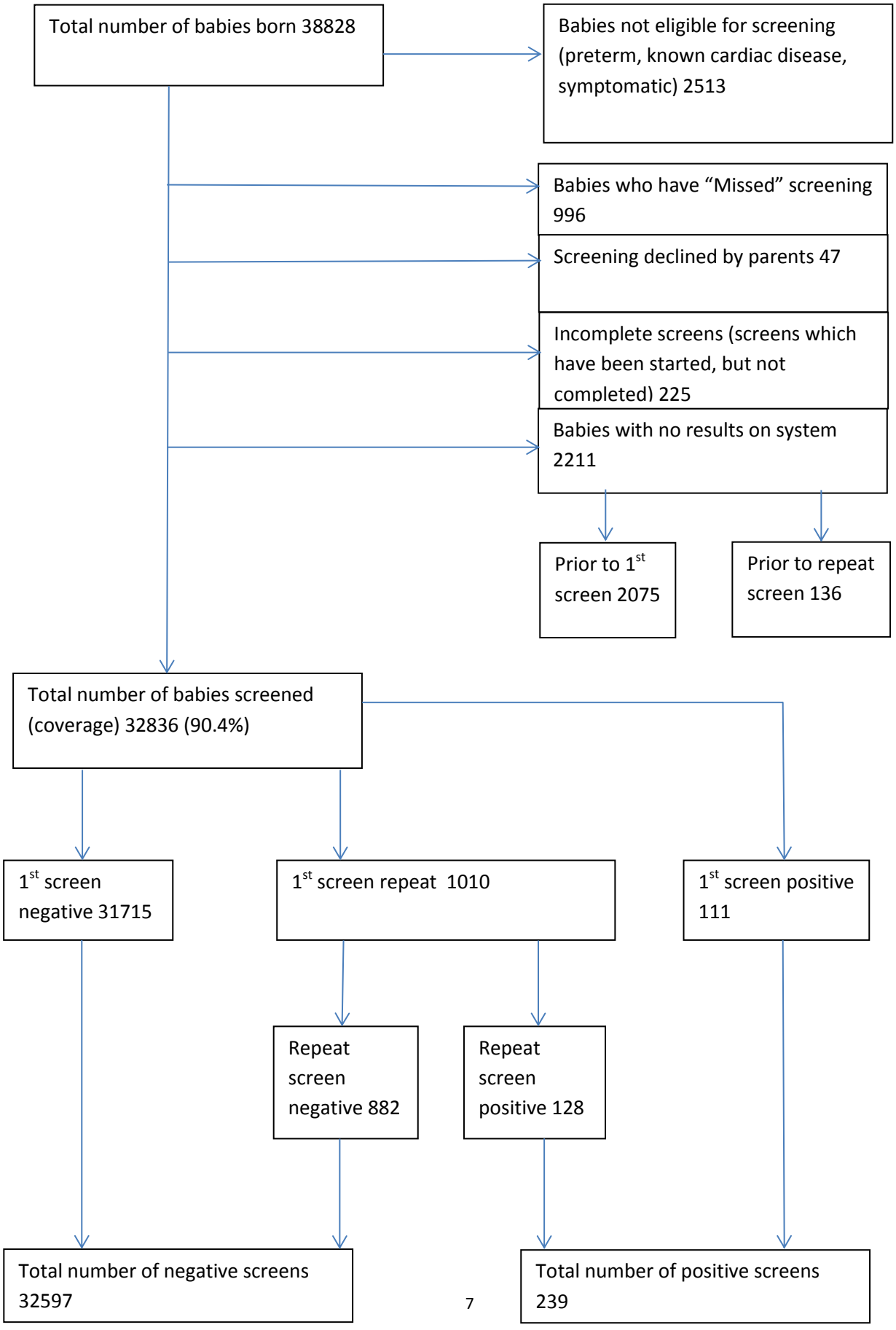
Table 3: False screen negative diagnoses missed by PO screening

False screen negative cases
CoA
Hypoplastic left heart syndrome

Newborn PO screening pilot data findings and related workforce issues

Table 1 provides the combined overall pilot data collated from the pilot Trusts using the NIPE SMART IT system and from the one Trust that collated data from the EPIC hospital information system.

Table 1: Combined data from NIPE SMART and non-NIPE SMART Trusts 1st July – 31st December 2015



Over the six month pilot period 38,828 babies were born in the participating pilot Trusts. Of these, 2,513 (6.2%) were ineligible for screening. A total of 32,836 babies (90.4%) who were eligible underwent PO screening as recorded on the NIPE SMART IT system (in 14 Trusts) or the EPIC HIS (in one Trust).

Of the 3,479 eligible babies who were not screened, 996 (2.6%) were recorded as being missed and in 47 (0.12%) cases parents declined screening. The remaining 2,436 (70% of unscreened eligible babies) had inadequate data recorded to assess the result of screening – in the majority of these (91%), no data was recorded on the NIPE SMART IT system. Discussion with the pilot Trusts indicated that a large number of these babies had been screened but the result not entered onto the system. However the precise numbers where this was the case is not available.

Only 52% of all babies received PO screening within the suggested target time of 4-8 hours, but 78% were screened within 12 hours and only 8.5% were screened after 24 hours. Reasons for these deviations from the agreed pathway were mainly relating to existing service model, time pressures and staffing issues.

Three trusts in Group A did not change from their established local pathway to the agreed pilot screening pathway. This resulted in very early screening (under 4 hours) for one Trust or late screening for two Trusts. PO screening in one Group B Trust was undertaken by the hearing screeners. It was not possible to determine the exact timing of lateness of the screening results.

Of the 32,836 babies who underwent PO screening 96.6% passed (in line with the PO pilot pathway) on the first screen, 3.1% had a result requiring a repeat screen. Of these 87% passed the repeat screen. Overall 239 babies (0.73%) had a screen positive result.

Of the 239 screen positive babies, 115 (48%) were admitted to the NNU for further assessment. Of the screen positive babies who were not admitted to NNU, 97% had transitional circulation, 2 babies had culture negative sepsis and in 2 babies the final diagnosis was not recorded.
The pilot screening pathway recommended that all screen positive cases were seen by a senior clinician. This occurred in 80% of cases. The number of screen positive cases within Trusts ranged from 0 to 52 (mean 16) which equates to an average of approximately one screen positive case every 11 days. (range 0-2 per week). Why the remaining 20% were not reported to have been seen by a senior clinician in line with the screening pathway is not clear, and is likely to be related to lack of availability or competing clinical demands.

Of the 114 babies admitted to NNU, eight babies (7%) had a CCHD and 86 (75%) had a significant illness which required medical intervention (43 cases of culture negative sepsis, 30 respiratory disorders, 6 PPHN, 3 culture positive sepsis and 5 non-critical CHDs). Only 22 babies (9% of all screen positives; 0.07% of all screened babies) were healthy babies who were admitted to NNU.

Most babies admitted to NNU (106; 93%) underwent investigations; the majority were blood tests and chest x-rays. Only 32 babies (28% of those admitted, 10% of all screen positives) underwent echocardiography.

66% of screen positive babies admitted to NNU stayed for longer than 24 hours and 47% required intensive or high dependency care. Fifty-eight babies required supplementary oxygen and eighteen required some form of positive pressure ventilatory support (six were ventilated and ten received CPAP/BiPAP)

Two babies with critical CHD and one baby with a serious CHD who were screen negative – i.e. passed PO screening and were false negatives. One of the CCHD babies died and the other presented in a collapsed state.

The screen positive rate was consistent with previous early PO screening studies as was the range and proportion of cardiac and non-cardiac diagnoses in screen positive cases.

Delayed Discharge

A total of 7 Trusts reported a delay in discharge due to repeat screen procedure. Out of a total of 897 repeat screens performed 12 (1.3%) resulted in a delay in discharge for screen positive babies. Of the 239 screen positive babies discharged was not delayed in 115 (48%). Discharge was reported as delayed in 68 (28%) but of these, over half (53%) had a significant clinical diagnosis which is highly likely to have delayed discharge anyway. Overall, discharge was reported as inappropriately delayed in 32 babies (13% of all screen positives). These babies all had transitional circulation.

Post-pilot questionnaire

The main findings were as follows:

- No Trust described that organisational changes were necessary for the successful implementation of the pilot.

- Some Trusts modified the agreed pilot screening pathway. Five Group A and one Group B Trust failed to adhere precisely to the pilot screening pathway;

specifically they did not perform PO screening at 4-8 hours after birth but varied the timing to suit staff availability, timing of discharge and integration with existing NIPE screening model. Two Group A Trusts who already had a PO screening test as part of the NIPE exam continued with this model and did not adopt the pilot screening pathway.

- 94% of Trusts stated that they did not identify an increase in the number of admissions to NNU following the introduction of PO screening. One Trust described an increase in admissions with one Consultant considering halting PO screening due to an over capacity of cots at that particular time. However the rest of the Consultant group decided that the benefits of PO screening outweighed the risks and continued with the pilot.

- Trust staff were not aware of any increase in the number of echocardiograms or cardiology consultations requested during the pilot.

- Some Trusts did experience staffing and time constraints in order to adhere to the pilot screening pathway:

- One Trust did not consider the extra workload involved in offering PO screening was justified by the number of cardiac cases identified

- No trusts employed additional staff to implement PO screening; however one Group B Trust would consider employing additional nursery nurses.

- No significant concerns were identified to suggest that PO screening would be unacceptable to parents. Three Group A Trusts did not alter the established local pathway for the pilot and was only willing to do so if a new pathway was based on a national recommendation to implement a standardised screening pathway

Newborn pulse oximetry screening pilot recommendations

Following on from the data analysis of the pilot and the feedback received from the pilot Trusts relating to the agreed pilot screening pathway, the pathway could be modified in the following ways:

  - timing of screening should continue to aim for first screen within 4-8 hours but a degree of flexibility earlier or later (up to 18-24 hours) is acceptable and could be considered .This may have the effect of the screening test being more easily embedded within routine clinical practice

    - a second retest (third screen) could be considered in babies who are screen positive but have a normal clinical assessment and no additional risk factors. This would potentially have the effect of reducing the number of screen positive cases

Additional recommendations from the pilot:

- health economic analysis is necessary to define further the true cost of introducing PO screening

- further analysis of the effect of PO screening on admissions to NNU (particularly the non-cardiac conditions) would be beneficial including using possible use of data generated by the UK Neonatal Data Analysis Unit (NDAU)

- the risks and benefits of linking PO screening to the NIPE examination could be explored further and recommendations made

- the entry of PO screening results and relevant risk factors to one IT system (or use of interoperability messaging technology) would be beneficial to increase the recording of screening results. Additional training and support following the introduction of the NIPE SMART for the entry of the PO screen results would be advantageous

The pilot has demonstrated that in general, it is feasible to introduce PO screening in an NHS environment, however there are important clinical considerations as highlighted above. The routine introduction of PO screening could be considered once these issues have been satisfactorily resolved.

Figure PO 1: Newborn PO Screening Pathway