Public Health England

Newborn and Infant Physical Examination (NIPE) Screening Programme
Newborn Pulse Oximetry Screening

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) –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 and a postnatal clinical newborn examination

Pulse oximetry (PO), as an additional screening test to identify babies with CCHD prior to acute clinical deterioration has been widely reported and is being taken up as an adjunct to existing screening or considered by many countries. In 2017, approximately 40% 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.

Aims and objectives of the pilot study

The aims of the pilot were to:

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

The objectives of the pilot were to:

- identify existing PO screening pathways already in use within the participating Trusts
- describe the variation between the maternity services within a defined number of Trusts in respect to clinical workload, protocols and

resources associated with existing routine PO screening carried out on newborns.

- describe the variation between those Trusts in respect to clinical workload, and resources associated with implementing routine PO screening as a new screening test carried out on newborns
- audit screening outcomes in all eligible babies: all cardiac diagnoses, non-cardiac diagnoses in screen positive babies, referrals after a positive cardiovascular screen following NIPE or PO, deaths within 1 month of birth, through the collection of data and analysis
- develop information for parents and resource media for health professionals to be used in the pilot
- support delivery of training for health care professionals involved in newborn screening using PO in the pilot.

Participating Trusts

15 Trusts were selected to participate in the pilot. 7 Trusts were already offering PO screening for newborn babies and 8 had not previously introduced screening. Trusts were chosen based on their willingness to participate, and the need to recruit a 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 Trusts ranged from high-volume, urban tertiary units to low-volume rural midwifery led units and were divided into two groups. Group A where 7 Trusts who were already performing PO screening, but agreed to look to change where possible the existing newborn PO screening pathway (see Figure 1) for the duration of the pilot. Group B were 8 Trusts who had not previously performed PO screening.

Newborn pulse oximetry screening pilot methodology

The pilot was conducted over 2 phases.

Phase 1

Phase 1 involved the completion of baseline assessment questionnaire and retrospective data collection from a predefined dataset. This phase commenced 27 February 2015.

Phase 2

In 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 that commenced in June 2015 for one month.

Phase 2 of the pilot involved PO screening to be undertaken as outlined below by all Trusts from 1 July to 31 December 2015:

- alignment to the pilot screening pathway in those Trusts already undertaking newborn PO and collect data to record impact of any change (group A)
- the introduction of PO screening as a new element of the NIPE programme in selected pilot Trusts and collection of data to record impact of any change (group B)

Agreed screening pathway

The pilot Project Board agreed a pilot screening pathway which was disseminated to all participating pilot Trusts. All pilot trusts agreed to attempt to adhere to the pilot screening pathway as much as possible but some were mindful of the potential impact on the local clinical service and existing service models.

Summary of main data findings from UK pilot

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

Of the 239 babies with a screen positive test result, data was received back on 231.
There were 14 diagnoses of CHD - including 8 CCHDs and 1 serious CHD and 4 significant CHDs. Of the remaining 225 screen positive babies 86 (36%

of total screen positives) had a significant non-cardiac condition –mainly respiratory or infective conditions which required treatment.

Critical congenital heart defects diagnoses identified by PO screening during the active screening phase of the pilot as below:

- 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

False screen negative diagnoses (not detected by PO screening):

- CoA
- Hypoplastic left heart syndrome

Adherence to recommended screening pathway

52% of all babies received PO screening within the suggested target time of 4- 8 hours. 13% were screened between 0 and 3 hours and 13% between 8 and 11 hours. 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. The timing of the second screening PO also varied with 23.8% being carried out within 2 hours and 70.6% within 3 hours.

3 trusts, who were already screening, 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 2 Trusts. PO screening in one Trust was undertaken by the hearing screening team and screening was undertaken later than the recommended screening pathway timing. In the Trusts who started screening as part of the pilot, one performed screening early and one late.

Timing of first screen all sites. (includes incomplete screens)

Proportion screened 4 to 12 hours = 65%
before 18 hours = 85%
before 24 hours = 91%,

Timing of 1st screen:	
0-3 hours	4335 (13%)
4-7 hours	17039 (52%)
8-11 hours	4136 (13%)
12-17 hours	2462 (7%)
18-23 hours	2004 (6%)
24+ hours	2764 (8%)
Not documented	313 (1%)

Post pilot actions
An end report was produced in 2016 and the UK NSC decided at their meeting in June 2016 that post pilot, it was important to carefully consider the balance of risks and benefits for the screen positive babies who did not have Critical Congenital Heart Disease and the UKNSC's opinion was that they could only consider introducing routine newborn pulse oximetry screening after investigating these important issues.

Evaluation work (undertaken by the Health Economics Unit, University of Birmingham) to understand whether these 'extra screen positive' babies get more benefit than harm from screening and to assess the additional impact on NHS services of caring for these babies has been undertaken.

NSC pulse oximetry screening workshop

A workshop of clinical and academic experts was held on 22nd June 2018 and discussions took place regarding the harm v clinical benefit of newborn pulse oximetry screening for the 'additional conditions 'identified by use of newborn pulse oximetry screening (including congenital pneumonia, sepsis, transient tachypnoea of the newborn, transitional circulation).
A summary of the discussions at this meeting can be found below

Attendees 22nd June 2018

Name	Organisation	Role
Graham Shortland	UKNSC	Group Chair
Sanjeev Deshpande	British Association of Perinatal Medicine	Hon. Treasurer Consultant Neonatologist
David Elliman	PHE	NIPE Clinical Lead
Claire Evans	Warrington Hospitals NHS Trust	ANNB Screening Midwife (Former PHE Pulse Oximetry Pilot Project Lead)
Andy Ewer	Birmingham Women's Hospital	Professor of Neonatal Medicine and honorary Consultant
Chris Gale	Imperial College London / Chelsea and Westminster NHS Trust	Senior Lecturer in Neonatal Medicine and Honorary Consultant Neonatologist
Karen Hooper	NHS Improvement	Patient Safety Lead – Maternity and Neonates
Anne Mackie (pm only)	PHE	Director of Screening
Sam Oddie	Bradford Teaching Hospitals	Consultant Neonatologist Lead for NNAP
Michele Upton	NHS Improvement	Head of Maternity and Neonatal Transformation Programmes
Andrew Rostron	PHE	National ANNB Programmes Lead
Ben Stenson	NHS Scotland	Consultant Neonatologist Royal Infirmary of Edinburgh
Jill Walker	PHE	National Programme Manager NIPE
Written apologies		
Dr Wilf Kelsall,	Cambridge University NHS Trust	Consultant Neonatologist
Cathryn Seagrave	Wye Valley NHS Trust	Consultant in Paediatrics
Nim Subhedar	Liverpool Women's Hospital	Consultant Neonatologist

Aim of the workshop.

Pulse oximetry will pick up any baby that is hypoxaemic, whatever the cause or condition. The purpose of the workshop was to look at these conditions and discuss, with an expert group, what would have been the natural history of unscreened babies and whether all would have needed treatment and whether there may have been unnecessary harm. There is little information in the scientific literature on this area.

Summary of discussion

David Elliman offered the background regarding the role of the UKNSC and how PO would sit within the context of the existing NIPE screening programme if implemented. There was discussion regarding how addition of PO newborn screening would be classed - as a new programme or a modification of the existing NIPE programme

Andy Ewer then presented data relating to the identification of non-cardiac conditions both from the UK pilot and from Birmingham Women's Hospital.
The conundrum relating to the presence of hypoxaemia in important non-cardiac conditions and also in slowly adapting healthy newborns was highlighted along with the concerns of potential overdiagnosis of conditions associated with hypoxaemia.

Evidence relating to the frequency of non-cardiac conditions reported in the major PO screening publications were discussed highlighting that they were often inadequately reported and there were no uniform definitions for these conditions.

Data from Birmingham Women's and the UK pilot showed a degree of consistency in the identification of these non-cardiac illnesses when standard definitions of the major conditions were applied and most conditions detected were predictable – e.g. transient tachypnoea of the newborn (TTN), congenital pneumonia, persistent pulmonary hypertension of the newborn (PPHN), early onset sepsis etc.

It was therefore acknowledged that PO is an effective addition to the current screening procedures for Critical Congenital Heart Defects (CCHD). However, as it tests for hypoxaemia, and thus identifies additional conditions other than the target of the programme, hence the discussion today.

Conclusions from the initial discussion

- PO screening can be implemented across various maternity provider settings (large, small , tertiary, district general level , community setting)
- Standard protocols are essential and would need to be reviewed if PO screening was rolled out. Concordance is important and pilot recommended timescales of 4-8 hours of age may need to be reviewed (?4-12 hours)
- Clinical care for screen positive babies should be standardised wherever possible, but allowing for some minor regional variation
- Equipment used should be defined by specification, but particular brands of equipment should not be recommended. A robust procurement process was used in pilot to defined equipment specification
- Referrals – discussion regarding grade of clinician reviewing after initial screen positive – should be the most senior person available (could be doctor or senior midwife/ ANNP)
- Timing – not all Trusts were able to meet recommended timescales, some deliberately screening earlier and others later, due to the models employed in Trusts.
- Tertiary centres had higher screen positive rate in pilot? why – could this be that they have a higher risk population.
- Of the screen positive babies in the UK pilot, 50% were admitted to NNU.
- 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). 22 babies (9% of all screen positives; 0.07% of all screened babies) who were admitted to NNU, had no clinical disorder.
- 5 babies who had screening undertaken in the community setting (after home birth) were screen positive (two with Transitional circulation , one Cold baby with poorly perfused feet, one with TTN requiring 0_2, and one diagnosis recorded as ‘treat as normal’)

Conclusions on benefits and harms

The group then considered each ‘additional non-cardiac condition’ detected by the use of PO screening in the pilot to agree the clinical benefit or harm in detecting these conditions

Pneumothorax

There was one case in the pilot cohort. The definition as to what constitutes a significant pneumothorax is complicated. Most spontaneous pneumothoraces resolve with no treatment. There is therefore no benefit in identifying babies with asymptomatic pneumothoraces,

Decision - no additional clinical benefit. Harm from unnecessary investigations (blood tests and x-ray) and delayed discharge

Transient Tachypnea of the Newborn (TTN)

There were 11 cases in the pilot cohort. TTN is often a retrospective diagnosis once other causes have been ruled out. Any tachypnoeic baby will be observed on NNU. Overall use of PO screening will lead to diagnosis that will be of benefit to most in this cohort. Early identification and intervention leads to a benefit as it prevents a spiral into a serious condition, thus optimising treatment and reducing morbidity. Early identification is a more positive experience for parents.

Decision - of clinical benefit

Meconium aspiration

Two cases in the pilot cohort. Most should be on a Newborn Early Warning Score chart, but some may not be recognised at birth. There is a higher risk of deterioration than with TTN.

Decision – of clinical benefit

Congenital Pneumonia

11 cases in the pilot cohort. Without treatment most babies would die. The risk is higher with every hour of delay.

Decision - of clinical benefit

Persistent pulmonary hypertension of the newborn (PPHN)

Six cases in the pilot cohort. This is defined as evidence of PPHN on echo that doesn’t fit any other category. All babies in the pilot cohort had echocardiograms. Early detection may prevent or reduce the risk of clinical deterioration.

Decision – of clinical benefit

Respiratory Distress Syndrome (RDS)

Four cases in the pilot cohort. It is much more common in preterm infants but can occur in term or near term infants. Babies with the condition deteriorate with time. 100% of babies benefit if the condition is detected early.

Decision - of clinical benefit

Sepsis – culture positive

Three cases of culture positive sepsis occurred in the pilot group. All cases benefit from treatment.

Decision - of clinical benefit

Sepsis – culture negative

43 cases in the pilot cohort. Those cases that are genuine sepsis would all benefit from treatment. Probably over treated. Those who do not have sepsis will be 'over treated', however it is better to treat suspected cases as the outcome of non-treatment of sepsis is serious.

Decision - of clinical benefit to a proportion. Harm from unnecessary investigations (blood tests and x-ray) and delayed discharge to the remainder.

Transitional circulation

135 in the pilot cohort. Of the total of 239 babies who tested positive, 56% (135) had a final diagnosis of transitional circulation (i.e. healthy babies with delayed adaptation and no pathological condition). The vast majority (113 babies; 84%) of these were not admitted to NNU and, following assessment, remained on the postnatal ward with the mother. 22 with transitional circulation were admitted to NNU, most of these (73%) underwent some form of investigation but all were discharged within 12 hours.

Decision – no clinical benefit. Harm from unnecessary investigations (blood tests and x-ray) and delayed discharge in a minority.

Delay in discharge for screen positive babies

Of the 239 screen positive babies discharged was reported as 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, 12 babies had discharge delayed due to needing a repeat screen performed which turned out to be negative (1.3% of all repeat screens).

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