

## UK NATIONAL SCREENING COMMITTEE

### Screening for Congenital Heart Defects – Pulse Oximetry

12<sup>th</sup> March 2014

#### Purpose

1. This paper provides background on the review of screening for congenital heart defects and the addition of pulse oximetry to the pathway.

#### Background

2. This is the first time the UK NSC has formally assessed the evidence for antenatal and newborn screening for congenital heart defects.
3. Congenital heart disease screening is part of the physical examination of newborn babies and again at 6-8 weeks. On the advice of the UK NSC, the NHS Newborn and Infant Physical Examination (NIPE) Screening Programme was set up to oversee the implementation of a high quality and consistent newborn and infant physical examination. The NIPE Screening Programme offers parents the opportunity to have their child examined shortly after birth (within the first 72 hours). The examination includes a general physical check as well as examination of the baby's eyes, heart, hips and testes in boys. The examination is repeated at six to eight weeks of age.
4. A review of screening for congenital heart defects was carried out by Dr Rachel Knowles and Ms Rachael Hunter, University College London in July 2013. The review came to the conclusion that there is no reason to alter the current policy position that screening for congenital heart disease should be undertaken in the antenatal and newborn period
5. The committee is asked to consider the case for adding pulse oximetry to the testing regime for newborn screening for heart conditions.
6. The review was generally positive in terms of the value of using pulse oximetry as an adjunct to the infant physical examination and found it to be cost effective. However the review highlights the uncertainty on how many children with heart disease pulse oximetry would find that would otherwise have been missed by the physical examination. It also shows that an optimum screening protocol could not be identified from the literature.
7. It also points out that pulse oximetry is a test for levels of oxygen in the blood and as such is not specific for heart disease. The review was unable to come to a conclusion about how many babies with low oxygen levels but without heart disease would be found and what proportion of them would need subsequent tests and care. Estimates vary but they will overwhelm babies with heart disease by quite a significant amount.
8. More generally the review notes that screening in the antenatal and newborn periods are sometimes discrete activities which require integration. As such it recommends a pilot to explore a number of issues:
  - to determine antenatal screening coverage and its link with the newborn screening programme. For instance which infants should be excluded from

newborn screening by virtue of the fact that they had an antenatal diagnosis or referral for heart disease.

- to appraise the impact of antenatal diagnoses on pregnancy terminations and CHD prevalence at live birth (by specific defect where possible)
- to define optimal test procedures for oxygen saturation measurement and newborn clinical examination (including timing, pre- and post-ductal siting, number of repetitions and the temporal relationship between pulse oximetry and clinical examination)
- to clarify and test pathways for referral for further investigations after a screen positive result (including cardiac and non-cardiac causes)
- to develop information for parents and health professionals across the antenatal and newborn continuum
- to institute training for midwives and others involved in newborn screening using pulse oximetry
- to establish routine data systems (and/or routine data linkage, e.g. between screening programmes) for audit, quality assurance and monitoring of longer term outcomes.

## Consultation

9. A public consultation on the screening review took place between 19<sup>th</sup> September 2013 and 19<sup>th</sup> December 2014.
10. The consultation was structured around the outstanding issues highlighted by the review. The following national stakeholders were contacted directly: British Congenital Cardiac Association, British Heart Foundation, Children's Heart Federation, Royal College of General Practitioners, Royal College of Midwives, Royal College of Nursing, Royal College of Paediatrics and Child Health, Royal College of Surgeons, Tiny Tickers.
11. Responses were received from 9 national organisations and one US organisation: Royal College of Paediatrics and Child Health (RCPCH), this response was a combined response from RCPCH, British Association of Perinatal Medicine (BAPM) and Paediatricians with Expertise in Cardiology Special Interest Group (PECSIG). British Heart Foundation (BHF), Children's Heart Federation (CHFEd), Tiny Tickers, a separate response from PECSIG, Heatline Families, Down's Heart Group and Little Hearts Matter. In addition the US Children's National Heart Institute also submitted a statement.
12. Individual responses were received from 15 healthcare professionals and 5 members of the public. A further 235 responses were received from members of the public as part of the Children's Heart Federation's campaign for the introduction of pulse oximetry screening. The Children's Heart Federation also submitted a link to an e-petition for the introduction of pulse oximetry screening containing 4426 signatories.
13. A survey of paediatric units was also undertaken. This aimed to gather information on the extent of screening, to understand any variation in current pulse oximetry provision and practice, including their trust protocols (where they had them) and to find out if any units would be willing to take part in a pilot. A summary of this survey is attached in **Annexe A**.

## Responses

14. No respondents suggested that screening with pulse oximetry should not be introduced.
15. A summary of the responses from individuals, organisations, the Children's Heart Federation campaign has also been circulated. Full versions of the consultation responses, as well as the survey of paediatric unit current practice have been circulated as separate documents.
16. Despite the majority of respondents not using the UK NSC's response proforma the consultation questions provided a focus around which the responses might be loosely grouped (excluding the 235 patient experience submissions). A number of issues relating to each question are highlighted below (these are highlighted for discussion and may not be exhaustive):
  - **Question 1a: 'The review concludes that pulse oximetry is clinically useful and will increase the number of congenital heart defects detected in the newborn period. However, it also concludes that the optimal approach to screening (for example its timing, positioning of oximeter probes eg hand or foot or both, number of times the test should be repeated) cannot be clearly defined on the basis of the available studies. Do you agree with this conclusion?'**
  - Several respondents commented that two questions were being asked. Most respondents agreed that pulse oximetry is clinically useful, however a range of responses were received. These include:
    - one comment within the RCPCH response stated that this had not been proven beyond doubt especially for those who make use of pulse oximetry in symptomatic babies as opposed to a universal screening tool,
    - several respondents considered antenatal screening and clinical examination to be 'ineffective' and suggested that the addition of pulse oximetry would significantly improve the detection rate for congenital heart defects. However other respondents suggested that the additional detection rate of critical congenital heart defects would be more marginal, for example 1.5 cases / 2 years in a unit with 5000 deliveries each year,
    - several respondents considered that the detection of such a small number of cases of congenital heart disease was offset by the early detection of a range of other conditions associated with hypoxaemia, for example pneumonia, sepsis and PPHN,
    - other respondents considered pulse oximetry clinically useful but for reasons other than detection of congenital heart disease. These suggested that the underlying concept of screening with pulse oximetry should be broadened from detection of congenital heart defects to screening for hypoxaemia as a means of identifying a group of newborns 'at risk of deterioration and death' or to detect the 'early-unwell'.
  - Similarly a range of responses were received on the second part of the question, that an optimum approach to the use of pulse oximetry could not be identified from the literature. These ranged from:
    - there being no need to find an optimum approach as clinicians have experience of its use and can 'get on with it',

- there being no need to find an optimum approach as post implementation audit and evaluation being used to inform further refinements of screening practice,
  - that the conclusion was incorrect and what was known about timing, siting of probes and numbers of repeats provided sufficient information for implementation. Further trials to establish an optimum protocol would be of only marginal benefit and that national stakeholder consensus should be explored to establish a standardised protocol as the basis for national guidance and implementation.
- **Question 1b: Has the review satisfactorily summarised the literature relating to the practical application of the test? Please click either yes or no check boxes below.**
  - Most respondents had no comments to make on this question, however some detailed points about reporting of some studies were raised and some additional publications were submitted. These will be considered prior to submission to the UKNSC meeting on March 12<sup>th</sup>. Some general points which were raised included:
    - that the review's suggestion that there could be pressure to change the timing of the test was conjecture
    - that the review was conceptually flawed by use of the term 'false positive' to characterise non cardiac cases detected by pulse oximetry which were clinically useful.
  - **Question 2: 'Pathways for referral for further investigations after a screen positive result (including cardiac and non-cardiac causes). The review concluded that further information is needed on the management pathways for newborns with screen positive results and on the outcomes for newborns with non-cardiac conditions. This limits the evaluation of the overall benefit and acceptability of adding pulse oximetry to current practice. Do you agree with this conclusion?**
  - A number of themes were relevant to this question, these included:
    - the need for an integrated antenatal and newborn pathway. The need to develop IT systems was raised by some while others considered the NIPE smart system to be sufficient,
    - concern about increasing workload at key points in the pathway. For example PECSIG estimated that the current number of paediatricians with expertise in cardiology was insufficient to manage an increased volume of referrals. In addition a UK training package would be required for this group of paediatricians and this was not currently available,
    - concern about the complexity of pulse oximetry test results and the need for midwifery training in differential diagnosis,
    - concern about the logistic requirements arising from the use of pulse oximetry as a screening tool for example length of stay in screen positive / well babies, potential pressure on transport services, increasing pressure to deliver the test in units with relatively low staffing levels, increased call outs for incorrect readings,
    - however other responses, particularly from those with experience of screening with pulse oximetry, suggested that concerns about workload, complexity and logistics may be overstated. For example one response considered that concerns about pressure on clinical and diagnostic services may be grounded in an assumption that all screen positive

babies would be referred to a cardiologist. Others considered the level of training required to be minimal across the pathway,

- several responses were interested in finding out more about the number of cardiac and non-cardiac cases prior to implementation. While some responses suggested this might not be possible until screening had been implemented the units that currently screen may have data that could assist,
  - that NIPE's current post test pathway is not clearly defined and its patient information does not discuss a number of issues such as false negative results. Demanding these for pulse oximetry screening should therefore not be an obstacle to its approval.
- **Question 3: The review recommends the use of pilots to explore the issues relating to testing, referral and, in addition to explore information requirements, training needs, data and systems. Such pilots may also provide information on the resource implications arising from pulse oximetry screening. Does this recommendation accurately reflect the state of the current knowledge about pulse oximetry screening?**
  - The practical issues relating to the detail of this question are highlighted at several points above.
  - Of those answering this question directly, 3 answered yes, 5 answered no, 2 answered ambiguously. One respondent answered no but suggested that a nationally standardised protocol should be developed and that a staged introduction 'would give the opportunity to evaluate aspects of screening such as training, data collection and care pathways'. Where responses confirmed the need for preparatory work these three issues along with patient information were considered important areas to evaluate.

### FMCH Meeting

17. As the February 2014 FMCH meeting was cancelled a small subgroup of FMCH members and UK NSC officials met on 13<sup>th</sup> February 2014 to discuss the review, survey and the consultation responses and to agree a recommendation to the UK NSC.
18. The meeting took particular note of an unpublished report of screening in Birmingham which highlighted that, in terms of quantity, the main impact of early measurement of arterial oxygen saturation in addition to the current physical examination would be the detection of non-cardiac cases. The paper helped focus discussion at the meeting and underlined the importance of further evaluation prior to implementation.
19. The meeting considered and agreed that:
  - a pilot would enable further evaluation of pulse oximetry and that groups should be formed to agree a pilot protocol and the questions that should be answered by the evaluation work,
  - the Birmingham team should be approached regarding further audit work to understand more about the experience of screening, for example the number of hypoxaemic babies detected by the first pulse oximetry test, the diagnostic pathway and the number of non-cardiac cases not detected by the screening protocol,

- work should be undertaken to review the literature on neonatal hypoxaemia and its association with non-cardiac conditions (sepsis, pneumonia, persistent pulmonary hypertension),

### **Recommendation**

20. The UKNSC is asked to note the review, consider the above issues, and approve the recommendation to run a pilot for the use of postnatal pulse oximetry as an addition to the physical examination to detect congenital heart defects.
21. It is recommended that UK NSC require that a report on the lessons for the pilot be brought back to the UK NSC for formal consideration.

## **Annexe A**

### **CHD Screening Using Pulse Ox- Summary of Paediatric Unit Responses**

#### **In Brief**

A survey of paediatric units was undertaken. This aimed to gather information on the extent of screening, to understand any variation in current pulse oximetry provision and practice, including their trust protocols (where they had them) and to find out if any units would be willing to take part in a pilot.

The request for responses was initially emailed to each units' the Head of Midwifery on the 19<sup>th</sup> of September 2013 for discussion with the clinical lead for paediatrics or neonatology. Due to the limited number of responses a follow-up email was sent to non responders on 28<sup>th</sup> of November with a 1 month extension.

#### **Survey Responses**

- 181 units contacted
- 77 site responses in total
- Limited validity of findings around trust protocols (only 8 responders consistently answered these questions)

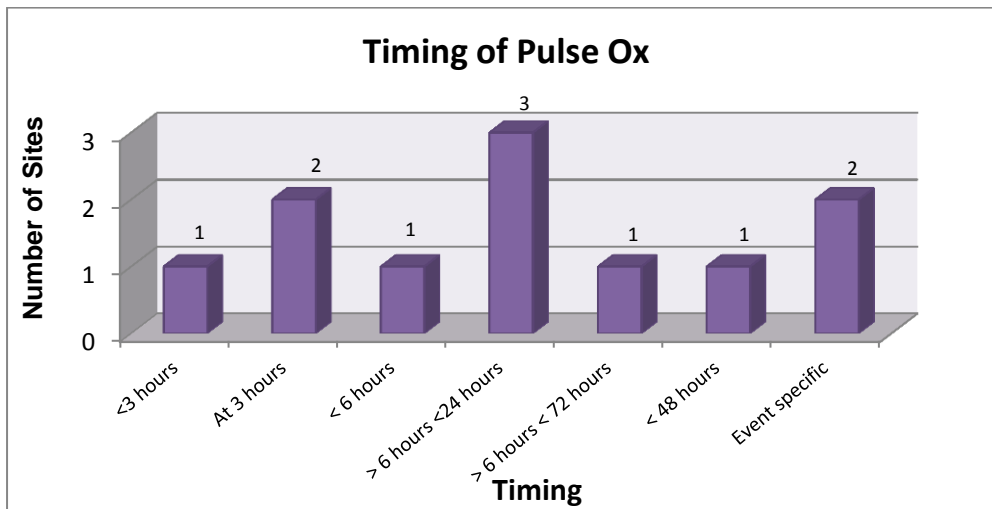
#### **Use or Plan to Use Pulse Ox**

- 27% (21) using pulse ox for screening of asymptomatic babies
- 21% (16) of those not currently using it have plans to introduce it
- 5% (4) no plans to introduce it
- 21% (16) Waiting for UK NSC decision
- 26% (20) No response

#### **Current pulse oximetry practice**

11 responses were received from units which currently screen using pulse oximetry.

## Variation in Protocol



- 60% using two limbs, 40% one limb (from the limited survey responses)
- Majority (but not all) used  $< 95\%$  cut offs
- Majority used  $\geq 3\%$  cut offs for pre and post-ductal measures
- However, one trust used a  $> 10\%$  cut off
- Variation in timing of repeat measures (between 30m and 2hrs)
- 5 of 8 sites who responded do not have a 2nd repeat

## Outcome Data and Pilot

- Seven trusts agreed to share their outcome data if needed (North Tees and Hatlepool, Calderdale and Huddersfield, Stockport, Ealing, Countess of Chester, Bradford and Sandwell & West Birmingham)
- 51 sites agreed to be part of any UK NSC pilot.