



UK National
Screening Committee

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Consultation on the use of pulse oximetry as an additional test in the Newborn and Infant Physical Exam

Aim

1 To publicly consult on whether the evidence presented supports the decision to approve the recommendation against using pulse oximetry as an additional test in the newborn and infant physical exam (NIPE).

Current position

2 Public Health England (PHE) undertook a review of the extent to which pulse oximetry met the UK National Screening Committee (UK NSC) criteria for screening, particularly focussing on the harms and benefits of potential for over-diagnosis, over-treatment, false positives, false reassurance, uncertain findings, and complications.

3 The review informed a recommendation to the UK NSC against using pulse oximetry as an additional test in the newborn and infant physical exam (NIPE).

4 This is because there is currently insufficient evidence to suggest that there is a greater benefit to babies with the inclusion of pulse oximetry than that afforded by the current screening programme alone. It is also noted that there are harms associated with screening and the further investigations following a positive screening result.

5 The review is attached* which identified some key points from the research† which led to the final recommendation to the UK NSC, in particular that:

- A positive result from pulse oximetry will generate some harms, including: parental anxiety, a longer stay in hospital, possible transfer to the neonatal unit, further tests to assess for non-symptomatic conditions.
- For many of these babies the further investigations will be unnecessary and the baby will be identified as healthy. This is a false positive result.
- For babies with CHD or other non-cardiac condition it is not clear that investigations and identification of these conditions will lead to any better outcome than a diagnosis at the time the baby becomes symptomatic.

* Review and recommendation received by UK NSC February 2019

† Specifically 4 papers attached that were commissioned to provide data to inform the questions relating to conditions identified in addition to cCHD, outcome comparisons between PO and routine screening, and cost effectiveness analysis.

- Despite repeated efforts to identify, assume, or model data it was not possible to provide a comparator dataset. This means that the review could not say whether using pulse oximetry led to better outcomes for babies than routine screening alone.
- A lack of comparator data also meant that it was not possible to model cost effectiveness of pulse oximetry for cCHD and the other conditions identified.
- A lack of comparator data means that the review could not say with any certainty that the use of pulse oximetry would do more good than harm to *all* those offered screening.

6 Because the review was unable to assess the benefits and harms of pulse oximetry compared to routine screening alone, the recommendation was against the introduction of pulse oximetry as an additional test in the routine screening programme.

Background

7 Pulse oximetry is used to measure the concentration of oxygen in the blood.

8 Low levels of oxygen in the blood is called hypoxaemia.

9 Hypoxaemia in newborn babies is an initial and normal part of acclimatisation following birth, but hypoxaemia can also indicate a problem that might benefit from further investigation.

10 In most cases babies who are hypoxic will also show symptoms in which case they will be managed according to clinical need and pulse oximetry could be used to monitor their treatment

11 There is currently no recommendation for using pulse oximetry as a systematic population screening tool

12 The UK NSC was asked to consider the use of pulse oximetry as part of the NIPE (one element of the antenatal and newborn screening programme) to identify hypoxaemia in non-symptomatic babies.

13 To consider the use of pulse oximetry in population screening, the UK NSC has to understand the extent and balance of the benefits and harms to patients receiving the screen.

14 A positive result in non-symptomatic babies would generate further investigation to help identify a condition that might benefit from earlier intervention.

15 Previous research has shown that the use of pulse oximetry in newborns, as an additional test in the routine NIPE screen, will generate positive results that determine additional investigations which lead to the identification of critical congenital heart defects (cCHD)

16 A recent pilot study[‡] agreed with previous research for pulse oximetry screening for cCHD, but also identified that a number of babies were identified as hypoxic which were subsequently identified as healthy babies or babies with other non-cardiac conditions.

[‡] Evans et al 'Newborn Pulse Oximetry Screening Pilot' (May 2016) PHE Crown publications

17 This means that the UK NSC has to include consideration of these other outcomes in the overall assessment of harms and benefits of pulse oximetry screening.

18 The pilot study showed that of 32,836 babies who had a pulse oximetry screen, there were 239 babies who tested positive for hypoxaemia. Of these there were 14 babies who went on to receive a diagnosis of CHD (including critical CHD).

19 Of the other babies testing positive for hypoxaemia, 82 had other, non-cardiac, conditions some of which may have benefitted from identification at the non-symptomatic stage (4 of these had more than one diagnosis).

20 There were 8 babies who had no diagnosis and the remaining 135 babies that were identified as hypoxic were healthy on investigation.

21 Public Health England undertook a review of the extent to which pulse oximetry met the UK NSC criteria for screening, particularly focussing on the harms and benefits of potential for over-diagnosis, over-treatment, false positives, false reassurance, uncertain findings, and complications.

Conclusions

22 Because the review was unable to assess the benefits and harms of pulse oximetry compared to routine screening alone, the review recommended against the introduction of pulse oximetry as an additional test in routine screening.

23 As advocates of pulse oximetry continue to assert that screening is worthwhile and the use of pulse oximetry machines continues to rise, and because the current evidence is insufficient to make a judgement, it is suggested that alongside the recommendation to the UK NSC, a proposal is submitted to the National Institute for Health Research (NIHR) for further research.

24 Should the NIHR agree to undertake further research then this should focus on gathering comparator data and could feed into a future review of the evidence for consideration by UK NSC.

Consultation

25 A three month consultation will be opened to consider views on:

- The UK NSC National Screening Committee (UK NSC) approval of the recommendation against using pulse oximetry as an additional element to the newborn and infant physical exam (NIPE).

26 Views from consultees and stakeholders are sought on the following question:

- Was the evidence presented sufficient to support the decision to approve the recommendation against using pulse oximetry as an additional element to the newborn and infant physical exam (NIPE).