The potential benefits and harms of universal newborn pulse oximetry screening. Response to the UK National Screening Committee public consultation

Ewer, Andrew; Deshpande, Sanjeev A; Gale, Christopher; Stenson, Benjamin J; Upton, Michele ; Evans, Claire; Oddie, Sam

DOI:
10.1136/archdischild-2019-317859

Archives of
Disease in Childhood

The potential benefits and harms of universal newborn pulse oximetry screening. Response to the UK National Screening Committee public consultation.

Journal:	*Archives of Disease in Childhood*
Manuscript ID	Draft
Article Type:	Letter (correspondence)
Edition:	not in use
Date Submitted by the Author:	n/a
Complete List of Authors:	Ewer, Andrew; Birmingham Womens Hospital, Neonatal Unit Deshpande, Sanjeev; Shrewsbury and Telford Hospital NHS Trust, Neonatal Unit; Princess Royal Hospital, Neonatal Unit Gale, Chris; Imperial College London, Academic Neonatal Medicine Stenson, Ben; Neonatal Unit, Simpson Centre for Reproductive Health, Royal Infirmary of Edinburgh, Edinburgh, Neonatology Upton, Michele; NHS Improvement, Patient Safety Lead; NHS England , Patient Safety Evans, Claire; Warrington and Halton Hospitals NHS Foundation Trust Oddie, Sam; Bradford Royal Infirmary, Bradford Neonatology
Keywords:	Newborn, Pulse oximetry, Screening, congenital heart defect

Dear Editor

Pulse oximetry screening for critical congenital heart defects has consistent test accuracy[1], meets the criteria for a universal screening test[1] and reduces mortality.[2]

In May 2019 the National Screening Committee (NSC) announced a public consultation on its decision not to introduce routine pulse oximetry screening (POS) for critical congenital heart defects (CCHD) in all newborn babies.[1]

The main reasons given for the NSC's decision are outlined in the consultation covernote as follows:

i) *'A positive result from pulse oximetry will generate some harms, including: parental anxiety, a longer stay in hospital, possible transfer to the neonatal unit [NNU], further tests to assess for non-symptomatic conditions.*

ii) *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.*

iii) *For babies with CHD [congenital heart defects] 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.'*

Following the NSC UK PulseOx pilot study[3] and in the absence of comparator data, the NSC convened an expert Workgroup to provide a pragmatic consensus view on the questions relating to outcomes, harms and benefits. As clinical members of a Workgroup invited by the NSC to offer expert advice on these issues at a meeting in June 2018, [4] we are disappointed that the NSC decision not to recommend screening for these same issues does not reflect the conclusions that we reached.

The purpose of the workshop was …*'to look at [the] conditions [identified by POS] 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.'*

Although the NSC decision document does not contain any data on the numbers of babies that would be affected by POS, our discussions - which were based on data from the NSC PulseOx pilot study (2015)[3] - considered these in detail.

We identified that out of 32 597 babies screened, 114 babies (0.35%) who tested positive were admitted to NNU, of which 8 had a CCHD (5 babies had non-critical CHD but were not admitted). A further 82 of the babies admitted to NNU (72% of the total admitted) had a significant non-cardiac illness. Although this group are technically false positives for the purposes of screening for CCHD, 8 distinct conditions were identified (congenital pneumonia, persistent pulmonary hypertension of the

newborn, culture positive and culture negative sepsis, meconium aspiration, pneumothorax, transient tachypnoea of the newborn and respiratory distress syndrome) which required treatment; only 22 babies (0.07% of all babies screened) were healthy (transitional circulation [TC]).[4]

We considered the relative benefits and harms in babies who were diagnosed with the eight non-cardiac conditions as a result of POS. We concluded that in six of the eight conditions there was clear benefit to early identification (i.e. highly likely to result in improved outcome). In one condition (culture-negative sepsis) there was the potential for overtreatment but clear benefit to the genuine cases and we concluded '*it is better to treat suspected cases as the outcome of non-treatment of sepsis is serious'.* For babies with TC and minor pneumothoraces (Ptx) we concluded that there was no benefit and these babies were subjected to the harms of delayed discharge (12 hours maximum) and unnecessary investigation (blood tests and x-rays) but this accounted for only 23 babies (22 TC and 1 Ptx) - 0.07% of all babies screened.[4]

In our opinion, these figures demonstrate that there are clear benefits in the majority of those false positives detected by POS who are admitted to NNU, (early detection and timely intervention) and there are modest harms (delayed discharge, overtreatment) in a minority.

These views are not reflected in the NSC's statement and we urge them to review their decision not to introduce routine newborn pulse oximetry screening for critical congenital heart defects in light of our conclusions.

Word count 665

References

1. Plana MN, Zamora J, Suresh G, Fernandez-Pineda L, Thangaratinam S, Ewer AK. Pulse oximetry screening for critical congenital heart defects. Cochrane Database of Systematic Reviews 2018, Issue 2. Art. No.: CD011912. DOI: 10.1002/14651858.CD011912.pub2.
2. Abouk R, Grosse SD, Ailes EC, Oster ME. Association of US State Implementation of Newborn Screening Policies for Critical Congenital Heart Disease With Early Infant Cardiac Deaths. *JAMA.* 2017;318(21):2111–2118. doi:10.1001/jama.2017.17627
3. https://legacyscreening.phe.org.uk/pulse-oximetry
4. https://legacyscreening.phe.org.uk/documents/pulse-oximetry/NPOSP%20End%20Project%20Report.pdf
5. https://legacyscreening.phe.org.uk/documents/pulse-oximetry/Notes%20of%20workshop%20June%202018.pdf

Authors

Andrew Ewer, Professor of Neonatal Medicine, Institute of Metabolism and Systems Research, University of Birmingham and Honorary Consultant Neonatologist, Birmingham Women's and Children's Hospital, Birmingham, UK

Sanjeev Deshpande, Consultant Neonatologist, Princess Royal Hospital, Telford, UK

Christopher Gale, Senior Clinical Lecturer in Neonatal Medicine, Imperial College London and Honorary Consultant Neonatologist, Chelsea and Westminster NHS Trust London, UK

Benjamin Stenson, Professor of Neonatal Medicine University of Edinburgh and Consultant Neonatologist Royal Infirmary of Edinburgh, Edinburgh, UK

Claire Evans, ANNB Screening Midwife, Warrington and Halton Hospitals NHS Foundation Trust, Warrington, UK.

Michele Upton, NHS Improvement Head of Maternity and Neonatal Transformation Programmes

Sam Oddie, Professor of Neonatal Medicine, Centre for Reviews and Dissemination, University of York and Consultant Neonatologist, Bradford Royal Infirmary, Bradford, UK.

The authors declare no conflict of interest

AKE was a clinical adviser to the NSC regarding POS and the clinical lead on the PHE pulse oximetry pilot. SD is Hon. Treasurer, British Association of Perinatal Medicine (BAPM). CE was project lead for the PHE pulse oximetry pilot. SO is the Clinical Lead for the National Neonatal Audit Project (NNAP)