LETTER

# Potential benefits and harms of universal newborn pulse oximetry screening: response to the UK National Screening Committee public consultation

Pulse oximetry screening (POS) for critical congenital heart defects (CCHD) 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 POS for CCHD in all newborn babies.[1]

The main reasons given for the NSC's decision are outlined in the consultation cover note 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, 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 contains very little 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, eight 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 admitted to NNU (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 (ie, 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 POS for CCHD in light of our conclusions.

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