

## UK National Screening Committee

### **Newborn screening for critical congenital heart disease and significant non-cardiac conditions related to hypoxaemia using pulse oximetry screening**

**08 November 2019**

#### **Aim**

1. To ask the UK National Screening Committee (UK NSC) to make a recommendation on the need for further research on the use of pulse oximetry (PO) in the newborn period before introducing the test as part of a nationally managed screening programme for conditions related to neonatal hypoxaemia.

#### **Current recommendation**

2. Screening for critical congenital heart disease (cCHD) is currently offered as part of the FASP 18+0 to 20+6 week scan and in the newborn period and at 6 to 8 weeks as a component of the Newborn and Infant Physical Examination (NIPE). cCHD can also be detected in the first trimester using ultrasound but this is not offered as part of an approved, nationally managed, screening programme.
3. There is no current recommendation for using pulse oximetry as a systematic population screening tool.

#### **Background**

4. The use of PO has been a feature of the newborn testing pathway for many years. It has been formally on the UK NSC's agenda since 2012. In 2012 the focus of discussion was the use of the test to detect cCHD as an adjunct to NIPE in babies who are clinically well. Research has shown that using PO in such babies in the early hours of life will identify newborns with mild hypoxaemia leading primarily to the identification of non cardiac conditions which are associated with low oxygen levels (eg sepsis and respiratory infections). 97% of babies who receive an abnormal result from a PO test have something other than a hear problems. This would be a significant change to the NIPE screening programme and neonatal care.

5. Following the conclusion of a formal evidence review in [2014](#), the focus shifted to understanding the impact of PO as it would be applied in the whole clinically well newborn population. This mainly took the form of two projects funded by Public Health England (PHE):
  - a pilot which aimed to compare units using PO with those not using PO in terms of conditions detected, logistics, resource use and costs
  - a cost effectiveness evaluation which used data from the pilot to estimate the health benefit and cost per case of cCHD and other significant conditions detected. This was important as previous estimates had focused solely on cCHD as the outcome of interest
6. These two projects failed to address these questions. Inadequate data collection in the non PO units during the pilot caused major uncertainty in the modelling and, as such, no reliable estimate of cost effectiveness could be generated. The cost effectiveness report concluded that primary research would be required to address this issue.
7. Papers reporting this and other work this work were considered with a summary document at the UK NSC's February 2019 meeting. At this meeting it was agreed, that there was insufficient evidence on the evidence of benefits to outweigh the harms associated with screening, and insufficient evidence to demonstrate cost-effectiveness.
8. It was also agreed to open the work undertaken since 2012 to a public consultation. The consultation sought views on the whether the evidence presented was sufficient to support the UK NSC's agreed position.

### **Consultation**

9. A report of the consultation and the consultation papers themselves have been circulated with the meeting papers.
10. The responses register a high level of interest in PO as a means of detecting cCHD in the newborn. This aspect of screening using PO dominated the responses. About 40% of units have implemented the test and the responses suggest that this is valued by health professionals, third sector organisations and individual members of the public. However there is variation in practice and some debate about how many

extra babies with cCHD are found and whether they were healthier than would be case if they had not had a PO test.

11. The responses also acknowledge that PO in the early hours of life will identify non cardiac conditions. While this is generally considered positive, there is recognition that this is an under researched area and that little is known about it.
12. A significant minority of responses register an interest in finding out more about the optimal use of PO in, what is already, a very active pathway with multiple cCHD detection points in both the antenatal and newborn periods. 60% of units do not use PO which creates an opportunity to respond positively to this theme in the consultation.

### **Recommendation**

13. To ensure that a significant change to the aims and objectives of the NIPE Programme and neonatal care is made on the basis of sound evidence, it is recommended that:
  - opportunities should be sought for further research to explore the value of screening with PO to reduce the morbidity and mortality through detection and management of conditions related to neonatal hypoxaemia. This is particularly important given the failure of the pilot to collect relevant data relating to these outcomes in units which did not screen using PO.
  - in units where PO is already established as a practice, these units are asked to remain open to participation in research until the UK NSC has sufficient evidence to make a recommendation on the use of PO in a nationally managed screening programme.

## **1. Dr Katherine Wood - UK Neonatal Grid Trainee Group Representative**

For the attention of the members of the National Screening Committee:

### **Re: Pulse Oximetry Screening in Newborn and Infant Physical Examination**

I am writing to you on behalf of the UK National neonatal grid trainees in response to your recent decision not to approve pulse oximetry screening to be a part of the newborn and infant physical examination (NIPE).

We, as neonatal grid trainees, are a group of senior registrars from across the United Kingdom who have been selected to complete our paediatric training within neonatology in order to specialise within in the field. We are therefore the future consultants of UK neonatology and as a result feel our opinion is an important one to consider.

After canvassing views on pulse oximetry screening (POS), the unanimous opinion from the trainees was in support of POS to be included in the newborn and infant physical examination (NIPE).

The reasons for this decision are summarised below;

- Newborn babies have gone through the most complex physiological transition of their lives and are a vulnerable group of patients. As clinicians looking after these babies on a day to day basis we know it can be hard to spot the babies who are unwell early by examination alone. Early detection of serious conditions, before a baby collapses, results in a more systematic and less time critical approach to the patient, allowing for implementation of treatment before the situation becomes potentially life threatening. Therefore, a tool as simple and as non-invasive as pulse oximetry measurement will improve our ability to look after our patients in a safer and more effective way.
- False positive results have been raised in the National Screening Committee (NSC) report as one of the reasons for deciding against POS. False positive results are commonly due to non-cardiac conditions, but the majority of these conditions also benefit from early detection and treatment. We feel that the benefit in implementing treatment in these patients as early as possible outweighs the potential harm to the patients who turn out to be healthy with transitional circulation (which from the NSC screening pilot study was only 0.4% of the patients screened, a figure similar to that seen in meta-analysis). If we don't screen for hypoxaemia we may not know it is present and as the clinicians looking after newborn babies every day we strongly believe that no baby should be sent home with hypoxaemia.
- We feel that the concern that the NSC has about increasing parental anxiety is unfounded. As a group, we work in neonatal units around the country, many where POS has already been introduced, so we have first-hand experience of this level of parental anxiety. A parent will undoubtedly be anxious if their baby has to be admitted due to a low oxygen saturation, but we see that for the majority of parents their priority is to ensure their baby is safe and understand the need for further investigations in order to achieve this. The benefit in detecting and treating unwell babies outweighs unnecessary anxiety.
- In response to the concern raised about length of stay in hospital and over-treatment of non-significant diagnoses; the pilot study carried out by the NSC showed only 13% of babies with transitional circulation had further investigations (0.05% of all babies screened) and of those

who had transitional circulation only 16% were admitted (0.06% of all babies screened). All the babies admitted with transitional circulation were discharged within 12 hours. These figures show to us that a very small proportion of all babies screened will have some extra investigations and a marginal delay in discharge. Again, it seems the benefit of picking up and treating the cardiac and non-cardiac conditions outweighs these concerns.

We are in unanimous support for POS as an additional test in the NIPE, and as the voice for the future of neonatal medicine I sincerely hope you take our view into consideration when you review your decision.

Yours sincerely,

Dr Katherine Wood

UK Neonatal Grid Trainee Group Representative

**On behalf of the following signatories giving support to the pulse oximetry screening in newborn examination:**

Dr Katherine Wood (Thames Valley (Oxford) Deanery)

Dr Natalie Batey (East Midlands Deanery)

Dr Rebecca Lancaster (Yorkshire and Humber Deanery)

Dr Katy Barnes (Kent, Surrey, Sussex Deanery)

Dr Susanna Sakonidou

Dr Lucy Green (West Midlands Deanery)

Dr Sarah Walton (East of England Deanery)

Dr Ourania Kaltsogianni (London Deanery)

Dr Amelia Shaw (Yorkshire and Humber Deanery)

Dr David Gallacher (Wales Deanery)

Dr Alex Cleator

Dr Vix Monnelly (Scotland Deanery)

Dr Kate Hooper (Thames Valley (Oxford) Deanery)

Dr Helen Moore (West Midlands Deanery)

Dr Clodhna Godden (Scotland Deanery)



Dr Yousef Gargani

Dr Oliver Walker (Wales Deanery)

Dr Andrew Brunton (Scotland Deanery)

Dr Andrea Warnock (East Midlands Deanery)

Dr Catriona Macdougall (East of England Deanery)

Dr Emily Hoyle (North Western Deanery)

Dr Zoe Porteous (Scotland Deanery)

Dr Mark Attard

Dr Katherine Millard (East Midlands Deanery)

Dr Jean Yong (Thames Valley (Oxford) Deanery)

Dr Katherine Broad

Dr Cat Armstrong (North Western Deanery)

Dr Hannah Wood (West Midlands Deanery)

Dr Jenna Deeming (North Western Deanery)

Dr Lucy Fullerton (London Deanery)

Dr Anne Bean (North Western Deanery)

Dr Sadaf Bhayat (London Deanery)

Dr Hannah Spierson (North Western Deanery)

Dr Paul Cawley (Wales Deanery)

Dr Hushi Hu

Dr Isabel Mawson (London Deanery)

Dr Olayinka Kowobari (West Midlands Deanery)

Dr Alix Fonfe

Dr Hannah Brophy (North Western Deanery)

Dr Helen McDermott (West Midlands Deanery)

Dr Chris Course (Wales Deanery)

Dr Daniela Vietan (West Midlands Deanery)

2. Dr James Webbe

<b>Name:</b>	Dr James Webbe	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	Imperial College London		
<b>Role:</b>	Paediatrician, parent of child admitted to intensive care unit		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>Yes</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Consultation document Page 1, Point 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.	The research shows clear clinical benefit through early detection of important, potentially fatal illnesses. Most of the 'harms' described are utterly unimportant and should not have any relevance on the whether pulse oximetry is implemented (see below).	
Consultation document Page 1, Point 5	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	None of these harms are significant. I note that there is no patient/parent representation on this committee. Including these as 'important' outcomes suggests that the committee have no idea what actually matters to new parents (and their babies). Parental anxiety, length of stay and further testing are all of minimal importance to any patient, parent or clinician (especially when weighed against outcomes including death or disability from unrecognised serious illness like sepsis). At present your document does not present ANY 'harm' from this intervention.	

<p>Consultation document Page 1, Point 5</p>	<p>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</p>	<p>There does not appear to be any representation of patients/parents on the screening committee – this may be why you have reached such a nonsensical conclusion. This process is utterly invalid if you do not allow the people who are actually affected (patients and parents) to tell you what matters. The ‘experts’ who have taken part clearly have no connection to the real world if they consider these harms to be significant. Ask any patient/parent whether about the importance they attach to survival versus some extra tests: the majority will overwhelmingly prioritise survival.</p>
<p>Consultation document Page 1, Point 5</p>	<p>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</p>	<p>In particular no evidence is presented anywhere that pulse oximetry increases parental anxiety. Parents could be reassured that their baby is being fully investigated / treated / observed. As a parent I would be worried that my baby had not been fully tested to ensure they were healthy. As there is no evidence to support this alleged anxiety you must remove all references to anxiety until you have evidence to support that this hypothetical ‘harm’ even exists. Again, you have failed utterly to engage with patients/parents and seem to just be guessing what they think and want. Engage parents/patients in this process.</p>
<p>Consultation document Page 1, Point 5</p>	<p>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.</p>	<p>In the workshop document you state there is evidence of clinical benefit for TTN, meconium aspiration, congenital pneumonia, PPHN, RDS and culture positive sepsis. This statement is inconsistent with your own discussions (in addition to being factually incorrect).</p>
<p>Consultation document Page 2, Point 10</p>	<p>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</p>	<p>“In most cases” is different from all. All screening is needed to detect disease in asymptomatic (or unrecognised) illness, which clearly is possible in this population. This should be changed to “some babies who are hypoxic will not show symptoms and pulse oximetry may be needed to allow them to be investigated and treated appropriately”</p>





Consultation  
document  
Page 3, Point 20

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

You should highlight that most of these babies remained with their mothers, and most did not have delayed discharge. For most false positive babies absolutely no 'harm' of any kind was entailed.

3. Dr xxxx xxxx

<b>Name:</b>	xxxx xxxx xxxx xxxx	<b>Email address:</b>	xxxx xxxx
<b>Organisation (if appropriate):</b>	xxxx xxxx		
<b>Role:</b>	xxxx xxxx		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">No</p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<p><i>Please use a new row for each comment and add extra rows as required.</i></p> <p>My comments do not relate to a specific part of text, however I wish to make overall comments in my role as a fetal and paediatric cardiologist. Whilst I wholly understand the need and desire to improve identification of major forms of congenital heart disease (by this I refer to those that require surgical / catheter-based intervention in the first year after birth) before discharge home, there is already a government screening programme that has been implemented to improve prenatal screening of these lesions (Fetal Anomaly Screening Programme, April 2015 update).</p> <p>In order to improve National detection of major congenital heart disease there was an additional ultrasound view that was added to the 18-20 week routine screening ultrasound, the so-called 'three vessel and tracheal view'. When performed correctly by trained individuals the ultrasound screening views of the heart should detect the majority of forms of major congenital heart disease. A limitation of ultrasound is where there is maternal obesity/fibroids, but in such cases with</p>	

		<p>optimisation of the ultrasound settings, the heart can usually be visualised sufficiently to identify an abnormal structure.</p> <p>Although many areas in the UK have low rates of prenatal detection, some areas in the UK have had excellent prenatal screening such that the vast majority of cases of major congenital heart disease are diagnosed before birth.</p> <p>The 2015 Fetal Anomaly Screening Programme (FASP) is still being implemented across the UK. This requires training and resources, particularly in the areas where the prenatal diagnosis remains low. Given that FASP 2015 has not been fully cascaded, would it be better if resources are allocated to this existing screening programme so that it can become more effective? The impact/complications to expectant mothers and the baby of a falsely abnormal ultrasound screen which is then reported as normal by a fetal cardiologist is less than the false positive rate of neonatal pulse oximetry screening.</p> <p>It is also important to note that if the arterial duct is patent when the PO is undertaken, the result may be normal. This is evidenced by one of false negative cases in the data presented with hypoplastic left heart syndrome. Classical hypoplastic left heart syndrome should be identified on prenatal ultrasound screening as all cardiac views would be abnormal.</p> <p>In order to help decide on the whether a new screening programme is required, it would be good practise to review the impact of the existing screening programme (prenatal ultrasound) to identify:</p> <ul style="list-style-type: none"><li>- How many pregnancies were screened at 18-20 weeks</li><li>- How many cases of major CHD were identified</li><li>- How many case of major CHD were missed from screening (ie how many attended the ultrasound examination)</li><li>- Post mortem results from neonatal deaths to identify cases of major CHD which die before a diagnosis is made</li></ul>
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		<ul style="list-style-type: none"> <li>- How many pregnancies did not have the 18-20week prenatal ultrasound screening.</li> </ul> <p>Cardiac surgical data is collated annually by each Trust undertaking surgery for congenital heart disease and submitted to NICOR, this includes whether there was an antenatal diagnosis. There is also a national congenital heart disease database to record all prenatal cases of congenital heart disease which should be going live soon. All UK specialist centres for fetal cardiology would be expected to enter all prenatally diagnosed cases.</p> <p>The report written by Knowles et al was written in 2014 and refers to historic data from a different era of prenatal screening and quotes low rate of prenatal cardiac diagnosis from the paper by Bull in 1999. Routine prenatal screening for major CHD has greatly improved over the last 10-20 years; in terms of views used in screening but also ultrasound technology. Given this, but particularly the changes in requirements for prenatal ultrasound screening over the last 4 years, it would be informative if an update were to be provided regarding its efficacy in the diagnosis of major CHD rather than the reliance on historic data.</p> <p>It is unclear from the documentation I had access to whether the British Congenital Cardiovascular Associations members were made aware of this consultation process. (I am a member and have not heard about this consultation process through the BCCA). It would be important to have the views of the BCCA members which includes fetal cardiologists, paediatric cardiologists and also paediatricians with a special interest in cardiology are taken in consideration in this process, particularly with regards to provisions for urgent echocardiography for pulse Ox positive scans.</p>
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4. Vicky Gooden

<b>Name:</b>	Vicky Gooden	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	N/A		
<b>Role:</b>	Mother to a CHD toddler		
<b>Do you consent to your name being published on the UK NSC website alongside your response?</b>			
Yes			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Consultation covernote 2019 page 2	The overwhelming statistics showing between 4-10 per 1000 live births present with CHD and that they amount to 40% deaths in congenital anomalies	This is alarming enough and should be a basis in which to agree a standardised approach to ensure every possible route of detection of a CHD is applied at birth.	
Consultation covernote 2019 page 5	Most infants born with CHDs in the UK are diagnosed before one year of age (mine wasn't) but 25% of infants born with CHDs are NOT diagnosed before discharge and up to 15% are still not diagnosed by the time they die.	This is staggering. And I believe I am right in saying that of every 6000 babies born, 1000 are sent home with a serious heart condition, undetected. My babies issue (large ASD) was not diagnosed antenatally or in any postnatal checkups.	
Consultation covernote 2019 page	The whole Pulse Oximetry rundown	The simplicity of this test is fantastic. The cost of the machine required I believe is circa £700 which is absolutely nothing in the grand scheme of things. Via my own social media where I have shared the story of my	



16		<p>little toddlers recent corrective CHD surgery, I have been approached by a number of midwives around the country who use PO currently and are aghast at that fact that its not mandatory nationwide. They tell me the test takes minutes and a number of them have successfully detected anomalies that would've otherwise been missed. For such a simple, cheap test that even a junior clinician could undertake there is no excuse for any infant with an underlying CHD to be sent home after birth for what could lead to tragic consequences. I believe all parents would be in support of this additional, pain free test on their new born.</p>
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5. Dr Vicki Smith

<b>Name:</b>	Dr Vicki Smith	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	NA		
<b>Role:</b>	Parent		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>Yes</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Consultation covernote Section 5	Generation of harms from a positive result	<p>Last year (2018) I gave birth to my 2<sup>nd</sup> child at home. This was a planned homebirth although I maintained some concerns right up until the late stages of labour that I was a distance from hospital and there would therefore be a delay if certain medical assistance was required. Anything that could be done or said to reassure me regarding the health of my baby before, during and after the birth was invaluable. This includes the pulse oximetry test. As a colleague of Prof Ewer I was already aware of the benefits of this test. However, it became vital to me when the midwives left just 2-3 hours after the birth. As part of the initial post-natal checks, this was an enormous reassurance of good health that meant we could enjoy our first night with our new baby. I would also like to comment that, should the test have given a positive result, I would absolutely rather have known that the oxygen levels were low and have been transferred to the hospital for further tests, even if this was a false positive result. Overall I believe that, if the outcomes of this test are clearly explained to parents, the benefits will clearly outweigh these perceived harms. Furthermore I would urge the Committee to consider the test in the context of homebirth where it will be 1) a source of reassurance to parents once the midwife team have left and 2) a critical indicator of CHD in newborn babies who are not in close proximity to the necessary neonatal care during the first 24-48 hours of their lives.</p>	

6. Vimal Vasu

<b>Name:</b>	Vimal Vasu	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	East Kent Hospitals University NHS Foundation Trust		
<b>Role:</b>	Consultant Neonatologist/Clinical lead		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><u>Yes</u>      No</p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	

Dear UK NSC

I have read the consultation documents (available at <https://legacyscreening.phe.org.uk/pulse-oximetry>) and below I provide a case to explain why I fundamentally disagree with the UK NSCs:

- (i) recommendation against using pulse oximetry as an additional test in the newborn and infant physical examination (NIPE)
- (ii) (View that UPO would cause unwarranted harm to an un-screened comparator group.

I would also support both professional and parental advocates of the view that the detection of mild hypoxia is indeed worthwhile and would comment that UPO is now the standard of care (screening) in many countries based on the robust evidence to date (arguably more so than some of the existing UK screening tests).

Rather than respond point by point in the table above, please find the rationale for my professional views below. These represent the collective view of the 6 neonatal consultants<sup>1</sup> in my department. 4 of our neonatal consultant team have an interest in neonatal cardiology and perform echocardiography. We have seen first hand the benefits in the use of UPO as a screening test for CHD and in the diagnosis of conditions leading to hypoxia in the newborn period:

Yours Sincerely, Dr Vimal Vasu

<sup>1</sup> Dr Vimal Vasu, Dr Amit Gupta, Dr Kwoksean Mun, Dr Shelley Chalmers, Dr Shaveta Mulla, Dr Vinit Shah



## **Case to support the use of UPO as a screening tool**

1. Congenital heart disease (CHD), the condition which universal pulse oximetry (UPO- the test) aims to detect is an important public health problem both in terms of frequency and severity.
2. The incidence, prevalence and natural history of the different types of CHD are understood along with the serious consequences of missed diagnoses, late diagnoses and no treatment.
3. There is now overwhelming evidence from a number of different countries and from different resource settings and healthcare systems that UPO is an effective screening tool for congenital heart disease.
4. Without UPO, the diagnosis of CHD is based upon a combination of antenatal screening and postnatal clinical examination. Both of these 'tests' have inherent problems that preclude improving the detection of CHD
5. Unfortunately, the UK detection rate for CHD through antenatal sonography is variable by both Trust & CCG footprint and nationally no better than 50%.
6. The newborn infant physical examination is not a reliable tool for the detection of CHD. This is compounded by the fact that there is trend toward earlier discharge of mums and babies from hospital at a time where the baby's circulation is still transitioning from fetal life.
7. This effectively means that the combination of antenatal sonography and postnatal examination is far from optimal in diagnosing CHD. Addition of pulse oximetry screening to the above 2 tests moves the detection of CHD from sub optimal toward optimal.
8. UPO is simple, safe, precise and validated. My own clinical experience with the use of UPO in our large DGH in Kent is that the test is very well accepted by parents and even if the test needs repeating to establish/confirm a normal or abnormal value, the parents are accepting of this. If they do express anxiety, it is 'appropriate' anxiety.
9. We have had approximately 3 experiences where but for the use of UPO, babies with serious critical congenital heart disease (critical pulmonary stenosis, total anomalous pulmonary venous drainage, transposition of the great arteries with VSD) would have been discharged home. All these babies were deemed to have had normal antenatal sonography and normal postnatal

clinical examinations. But for the use of UPO, all would have likely presented extremely unwell to our emergency department.

10. We have also had a number of other cases where we have detected hypoxia (a lower than normal oxygen saturation level) where the cause was not congenital heart disease. It appears that the UK NSC feels this is harm (parental anxiety, a longer stay in hospital, neonatal unit admission, and additional tests).
11. I would respectfully disagree with this view and would argue that the identification of any baby with hypoxia is an important and potentially serious finding in a newborn baby. We have identified babies who have had bloodstream infection, meconium aspiration syndrome and congenital pneumonia, who but for UPO, would have gone undetected with serious health consequences. In such cases, the harms as cited by UK NSC are not in fact harms but merely represent an appropriate escalation in the care of a newborn infant with hypoxia (an abnormal finding).
12. This often results in an increase length of hospital stay, admission to a neonatal unit and additional tests, all of which are entirely appropriate. Likewise, the parental anxiety that is cited as a harm by the NSC is in fact, entirely appropriate where a baby has been identified as hypoxic through UPO. The identification of non-cardiac causes of hypoxia is not a harm.
13. It is, in fact, in the eyes of the neonatal clinical community, a benefit. I accept that UPO is not designed to screen for these other conditions (bloodstream infection, meconium aspiration and congenital pneumonia) but in helping clinicians identify these very serious health problems, UPO has additional clinical value above and beyond its utility as a screening tool for CHD.
14. Our experience is that UPO has been relatively straightforward to implement and it is performed as part of the midwifery role. Where we have had cases of mild neonatal hypoxia, midwives have commented on how they might have discharged a baby but for the UPO.
15. It must be noted that if the UK NSC recommendation is upheld, then many Trusts who perform UPO (and will likely do so irrespective of the UK NSC decision) may require additional resources in order to perform UPO.
16. The intervention following the detection of hypoxia is indeed effective and self-evident. Babies with CHD are stabilised if born at a local hospital and referred

(usually as an emergency) to a specialist centre for treatment. In many cases, this treatment will require corrective heart surgery. Earlier identification of CHD through UPO means that the baby is in a more stable clinical condition (often pre-symptomatic), meaning the baby is more stable for emergency transfer and surgical treatment. This is very likely to translate into better long term outcomes for the baby.

17. The intervention where a baby is detected as hypoxic but not because of CHD is also self-evident. It will often require careful explanation of possible diagnoses to the parents, a period of monitoring (either on the postnatal ward or on the neonatal unit) and other treatments (e.g. IV antibiotics) and investigations (blood tests/ chest X rays). Neonatal clinicians will individualise these interventions depending on the clinical circumstances of each case.
18. In my experience to date, these interventions are accepted by families without 'undue or inappropriate' anxiety and are deemed a reasonable approach to a baby with hypoxia. It is disappointing that the clinical views of neonatal doctors regarding parental acceptance of UPO has not been evaluated systematically and that the UK NSC consultation of UPO has not actively sought out the view of parents or of parent advocate organisations such as BLISS. Without these additional views, the recommendation of the UK NSC is severely flawed.

7. XXXX XXXX

<b>Name:</b>	XXXX XXXX	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	John Radcliffe Hospital, Newborn Care Unit, Oxford		
<b>Role:</b>			
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">Yes      <u>No</u></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<p><i>Please use a new row for each comment and add extra rows as required.</i></p> <p>I'm quite disappointed about the outcome of the NSC's decision regarding the universal screen with POS. The evidence is obvious and clear and has been for a while now. I actually wondered why this has not been introduced earlier.</p> <p>I do not see that this test would increase parental anxiety any more than detecting a heart murmur on a physical examination. If something than anxiety should be less as with a positive POS result a fairly urgent echocardiography would be performed while with a heart murmur parents often have to wait weeks long for further clarification. I also find it important that most false positive tests do detect other important neonatal abnormalities (eg. sepsis), hence true false positive results are very low.</p>	

8. Dr xxxx xxxx

I am a xxxx xxxx (retired now) and parent of a xxxx xxxx born at 23w in xxxx xxxx and cared for at xxxx xxxx NNU.

I would like you to reconsider your decision re pulse oxymetry screening in neonates.

As a xxxx xxxx, and later a xxxx xxxx I delivered the current screening of clinical examination, and am well aware of its flaws as a stand alone screen. First you need experience to reduce false negatives ie, missing a problem, and certainly there are plenty of false positives where babies with innocent murmurs are referred to cardiology. Parents were always grateful to have their child checked and told they were well. Adding pulse oxymetry would reduce false positives.

The equipment is universal, relatively cheap, already in all units, and easy to use.

I hope you will reconsider.

Dr xxxx xxxx

Birmingham

## 9. Michele Upton (NMC 92101060) | Head of Maternity and Neonatal Transformation Programmes, NHS Improvement

XXXX XXXX XXXX XXXX XXXX

National Screening Committee

Evidence Team

By email

Maternity Transformation  
Programme/Nursing

Area 6C  
Skipton House  
London Road  
SE1 6LH

XXXX XXXX XXXX XXXX XXXX

16<sup>th</sup> August 2019

Dear Colleague

### NHS England and NHS Improvement response to the Consultation on Pulse Oximetry Screening in newborns

NHS England and NHS Improvement have carefully considered the National Screening Committee's documents supporting the consultation on the use of pulse oximetry as an additional test in the Newborn & Infant Physical Exam.

We believe that further evidence is required to support the decision to approve the NSC recommendation against using pulse oximetry as an additional element to the newborn and infant physical exam (NIPE). Given the inconclusive findings of the research and economic analysis to date, we support the proposal of a further HTA funded research trial in centres that are not currently screening. This would then inform a review of the evidence for consideration by the NSC in the future.

We are aware that many tertiary units currently undertake either full or targeted screening and have immediate pathways and resource to diagnose and follow up babies with positive results. We also recognise the value of POS in detecting serious conditions other than cCHD, including sepsis, PPHN and pneumonia and which lead to earlier intervention.

However, screening in some non-tertiary centres presents a range of challenges including access to the right pathway when pulse oximetry identifies a potential problem. Smaller units may find it difficult to provide the necessary echocardiogram reliably and promptly in house. A network approach to the provision of prompt high quality echocardiography would need to be in place to mitigate the impact of the false positive rate and likely involve a number of transfers over significant distances.

XXXX XXXX XXXX XXXX XXXX

with its attendant disruption to families and early mother infant attachment. The false positive rate is therefore more of an issue in these units, many of who are currently not screening.

It is our view that the evidence presented to support the decision to approve the recommendation against using pulse oximetry as an additional element to the newborn and infant physical exam (NIPE) was insufficient. We support the proposal for a well-funded trial in units which are not screening.

We hope that the points raised in this letter are helpful in decision-making in an area where there are many perspectives to balance, but where there may also be unintended outcomes to policy intentions. NHS England and NHS Improvement clinical advisers would be happy to provide more detailed advice on specific issues if it would be of further help.

Yours sincerely

XXXX XXXX

**Professor Neil Marlow**  
Chair, Neonatal Critical  
Care Transformation review  
Chair Neonatal Clinical  
Reference Group  
  
NHS England Specialised  
Commissioning

XXXX XXXX

**Mr Matthew Jolly**  
National Maternity Safety  
Champion  
National Clinical Director,  
Maternity & Women's Health  
  
NHS England and NHS  
Improvement

XXXX XXXX XXXX

**Dr Jacqueline Cornish**  
National Clinical Director,  
Children and Young  
People and Transition to  
Adulthood  
NHS England and NHS  
Improvement



10.

XXXX XXXX XXXX XXXX

<b>Name:</b>	XXXX XXXX	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	XXXX XXXX		
<b>Role:</b>	XXXX XXXX		

Do you consent to your name being published on the UK NSC website alongside your response?

Yes No

Section and / or page number	Text or issue to which comments relate	<b>Comment</b> <i>Please use a new row for each comment and add extra rows as required.</i>
	Concerns regarding false negative cases	<p>Assessment of the newborn after birth using visual inspection alone is not able to reliably detect cyanosis. We accept that our eyes can not assess yellow jaundice after birth and have introduced a NICE guideline that requires all babies with possible yellow jaundice to have their bilirubin measured. The consequences of missing a jaundiced baby with levels high enough to cause injury to the brain are well-accepted.</p> <p>Why then would professionals be expected to make a visual assessment of cyanosis and risk missing serious congenital heart, respiratory conditions and early sepsis, all of which can also have tragic outcomes including death and long-term disability, when there is a simple non-invasive test available to us and present in all perinatal centres in the UK?</p> <p>Implementing saturation monitoring for pulse oximetry is not difficult and many units have staff trained already and equipment available. The technique is less invasive than a blood test, or heel prick test, and much easier and more</p>





		<p>reliable than the hip and heart auscultation test which are dependent much more on the examiner's experience and distractions and noise around.</p> <p>As a neonatologist I want to know if there are babies that require additional treatment for sepsis and respiratory conditions causing cyanosis, early on, because then I can implement treatment that has a much greater chance of saving the baby's life and reducing morbidity including cerebral palsy.</p> <p>As a group of professionals we no longer rely on visual assessment of colour of a newborn baby at birth and have implemented saturation monitoring for resuscitation and stabilisation. We should also not rely on visual inspection of colour hours to days later when we perform the NIPE for the same reason, as this is unreliable and we may well miss reversible clinical conditions by not doing so.</p> <p>There is one condition that may be a real true false positive: this is where there is delayed reduction in pulmonary resistance and a clinically non-significant persistent pulmonary hypertension of the newborn. Mild transient versions of this condition may not warrant invasive intensive care but will be detected by pulse oximetry screening. Such babies should be assessed by the neonatal team and a decision made at senior level regarding their need for on-going monitoring or intervention. These babies are less common than those babies with congenital heart disease, respiratory conditions and sepsis, so on balance do not warrant not implementing pulse-oximetry screening in my opinion.</p>
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To whom it may concern,

I am writing with regards the debate about pulse oximetry tests for newborns. My XXXX XXXX was born in XXXX XXXX and at the time of his birth we had no idea that there was anything wrong with XXXX XXXX. I now know that XXXX XXXX was taking part in a trial of the newborn pulse oximetry test and it is this that saved XXXX XXXX life. XXXX XXXX passed all other elements of the newborn test and the doctor was remarking on how well XXXX XXXX was doing, when she started getting readings of around 60% when doing pulse oximetry on XXXX XXXX lower limbs. In hindsight XXXX XXXX was quite sleepy and XXXX XXXX breathing was uneven but these symptoms are not unusual in newborns, and several midwives who saw XXXX XXXX had no concerns about XXXX XXXX. The low oximetry readings caused the doctor to seek advice from senior colleagues and within a couple of hours our XXXX XXXX was diagnosed with a heart defect and he was on life support in neonatal intensive care. XXXX XXXX had surgery at XXXX XXXX for a coarctation of the aorta, and also he has aortic and mitral valve stenosis which is closely monitored. To date XXXX XXXX has had two balloon valvuloplasties of XXXX XXXX aortic valve and we are expecting this to be replaced at some point in the next few years. We were told many times how lucky we were that XXXX XXXX condition was picked up when it was, rather than later when the outcome could have been very different.

Without the pulse oximetry test that was done, we would have been sent home and I am told that XXXX XXXX would likely have deteriorated and eventually collapsed. As first time parents, having been reassured by several midwives and a doctor who felt that XXXX XXXX presentation had been normal, I do not know at what point we would have been concerned enough to seek medical attention. If XXXX XXXX had stopped breathing while XXXX XXXX was sleeping, we may not have noticed for a long time. The thought that had he been born in a hospital only a few miles away that was not part of this trial, is just horrifying.

I understand there are drawbacks to testing all newborns as it may pick up more benign conditions and cause unnecessary treatment. When our XXXX XXXX was born XXXX XXXX, XXXX XXXX was also tested with pulse oximetry due to our previous experience

with our son. Initially **xxxx xxxx** scores were worryingly low in her lower limbs, but on testing again a few minutes later they improved. We were then kept in a few hours longer for observations, but it was quickly clear that **xxxx xxxx** was fine, readings were good and we were discharged. This may have caused extra cost to the NHS, but this is minimal when compared to what would have happened had we taken our **xxxx xxxx** home, and **xxxx xxxx** collapsed at home causing either death, or a hypoxic brain injury.

I have worked in the **xxxx xxxx** and understand that all decisions such as this have to be considered very carefully, and a cost benefit analysis must be made, but this is a simple and cheap test, and I would be doing my son a disservice if I did not argue for the very thing that saved his life. I'm horrified to think what all of our lives could have been without this simple test.

Thank you for your time reading this.

Kind regards

**xxxx xxxx**

**12.** Andrew Tometzki

<b>Name:</b>	Dr Andrew Tometzki	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	South Wales and South West Congenital Heart Disease Network		
<b>Role:</b>	<b>Clinical Director SWSW CHD Network &amp; Consultant Paediatric Cardiologist</b>		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>Yes</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
	General comment	<p><i>Please use a new row for each comment and add extra rows as required.</i></p> <p>I am responding following a request by the British Congenital Cardiac Association (BCCA) for Network Leads in Congenital Heart Disease to comment on this consultation. I do so as the Clinical Director for a large Congenital Heart Network across the South West of England and South Wales.</p> <p>I would like to report that within our Network there are some neonatal/maternity units that have adopted PO screening as routine in full, assessing pre and post ductal saturations. Others have done so partially by using post ductal saturation measurements alongside clinical examination. However, other clinical groups have not adopted PO screening for the reasons outlined in the consultation documents.</p> <p>I therefore believe it right to indicate, given the variable uptake of units within our network, that there appears to be a need for a more robust evidence base.</p> <p>The SWSW CHD Network is keen to consider active engagement in any further studies on the use of PO screening.</p>	

13. Tom Skeath

<b>Name:</b>	Thomas Skeath	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	James cook university Hospital		
<b>Role:</b>	Neonatal Doctor		
<p>Do you consent to your name being published on the UK NSC website alongside your response?</p> <p style="text-align: center;">Yes</p>			
Section and / or page number	Text or issue to which comments relate	Comment	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
1 and 5	Interpretation of screening,	I agree that for 13(14) cardiac cases the pick up is low from 32000 infant but similar numbers can be picked up for the rarer metabolic diseases were a painful procedure is required often needing a retest. The procedures required for this screening are pain free.	
		The next aspect if that a total of 96 true positives were found in regard for neonatal disease that would have otherwise not been identified. 96 from 32000 is 0.3% detection, for a process that takes 1 minute this means that an unwell infant is identified for every 6 hours of work. If the early identification reduces hospital or medical input by a day (arbitrary figure with no basis) this would be a net saving of	
		18 hours of cost. The addition time including false positives is small given that the pick of any disease from that group is 96/239 which is a very high detection rate of disease. If we examined antibiotic use for true sepsis our numbers would be far far worse.	

XXXX XXXX XXXX XXXX XXXX

**Birmingham Women's  
and Children's**  
NHS Foundation Trust

National Screening Committee

Wellington House  
133-155 Waterloo Road  
London  
SE1 8UG

7 August 2019

XXXX XXXX

Re: National Screening Committee public consultation on pulse oximetry screening

Following the decision of the UK National Screening Committee not to recommend pulse oximetry screening as an addition to the newborn and infant physical exam (NIPE), we, the body of consultant neonatologists at the Birmingham Women's and Children's Hospital (where pulse oximetry screening was pioneered in the UK), would like to join the public consultation and present our views on this decision.

The Committee's report states that "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 further states that "there are harms associated with [pulse oximetry] screening and the further investigations following a positive screening result."

We have been screening with pulse oximetry (POS) since 2009 and our local experience (which was published in Archives of Disease in Childhood in 2014) is in line with the findings of the NSC PulseOx pilot study of 2015 (Public Health England. Newborn Pulse Oximetry Screening Pilot End Project Report. 2016.) which identified that only 0.07% of all babies screened were subjected to the relatively mild harms of delayed discharge (12 hours maximum) and unnecessary investigations (blood tests and X-rays) with no benefit. As the report states, 72% of the babies admitted to the neonatal unit following a positive POS had a significant non-cardiac illness. In our firmly held clinical opinion, this false positive group for CCHD clearly benefitted from early identification and treatment of significant respiratory pathologies and sepsis.

Although true false positives, where no further treatment is necessary are identified, based on our experience and feedback from parents and families, this does not increase parental anxiety and families welcome the additional testing offered. This is also in line with previously published studies (Ewer AK et al. Pulse oximetry as a screening test for congenital heart defects in newborn infants: a test accuracy study with evaluation of acceptability and cost-effectiveness. *Health Technol Assess* 2012; 16: 1–184. and Narayan IC et al. Maternal acceptability of pulse oximetry screening at home after home birth or very early discharge. *Eur J Pediatr* 2017; 176: 669–72.).

It is our strong view that pulse oximetry is beneficial to the majority of test positive babies and we do not recognise or accept the concerns raised which relate to excessive harms outweighing the clear benefits. Consequently, we kindly ask the Committee to reconsider their decision and to recommend pulse oximetry screening to be introduced as a supplement to the newborn and infant physical exam (NIPE), as based on our long-standing local experience, we passionately believe this will benefit all babies across the UK.

Kind regards,

Dr Manobi Borooah

Dr Matt Cawsey

Dr Amrit Dhillon

Professor Andrew Ewer

Dr Gemma Holder

Dr Matt Nash

Dr Vishna Rasiah

Dr Anju Singh



**By your side**

**15. Dr. Kristin Tanney**

<b>Name:</b>	Dr Kristin Tanney	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	Manchester University NHS Foundation Trust		
<b>Role:</b>	Consultant Neonatologist and Clinical Lead for Newborn Intensive Care Unit, St. Mary's Hospital, Manchester		
<b>Do you consent to your name being published on the UK NSC website alongside your response? Yes</b>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b> <i>Please use a new row for each comment and add extra rows as required.</i>	
Consultation covernote page 1, point 4	"It is also noted that there are harms associated with screening and the further investigations following a positive screening result."	At MFT, we would argue that none of the harms mentioned (parental anxiety, longer hospital stay, possible transfer to NICU or further testing) outweigh the potential benefits of earlier detection of pathology. We have been performing POS for several years, and have not found a significant increase in admissions, workload or investigations required due to "false positives" although we have not formally collected this information to-date.	
Consultation covernote page 1, point 5	"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."	Discovering pathology before hospital discharge is surely preferable for several reasons. However, we recognise that we are a big centre with resources to investigate for cardiac conditions, and that not every birthing unit has these facilities. To clarify the benefit of POS in large numbers of babies, we would support pursuing more robust evidence in favour of (or against) the practice.	
Consultation covernote page 3, point 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-	Neonatology and Cardiology teams in MFT believe that, although the "numbers needed to treat" may be low, such a simple and inexpensive screening tool is beneficial if it identifies even 14 cardiac babies (and 82 non-cardiac but	



	symptomatic stage (4 of these had more than one diagnosis)."	hypoxic babies), some of whom may have become more unwell without early intervention.
Consultation covernote page 3, point 24	"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."	We would be very much in support of gathering further evidence (which is more robust and complete) to assess effectiveness of POS, and would be keen to take part in this study if feasible. Having carried out POS for several years, clinical teams in our hospitals would find it difficult not to carry out this simple test which forms a routine part of our NIPE examination. We await further updates from UK NSC but for now have no plans to change our current practice.



UK National  
Screening Committee

16. Suzie Hutchinson



**Little Hearts Matter**

UK National Screening Committee  
PHE Screening  
Floor 5  
Wellington House  
133-155 Waterloo Road  
London SE1 8UG

6<sup>th</sup> August 2019

Dear UKNSC

**Re: Pulse-oximetry Screening for Critical Congenital Heart Defects NSC Consultation**

As the representative of over 5800 members, all affected by single ventricle heart disease, I am writing to contribute the Little Hearts Matter response to the request for more information to support the introduction of Oxygen Saturation Screening in the neonatal period. I am submitting my response by letter as the provided consultation pro-forma does not allow for comment or expansion of any of the issues that need exploring as part of the consultation.

#### **New Born Screening**

**"Your newborn baby will be offered some screening tests in their first 6 to 8 weeks..**

**Most babies are healthy and won't have any of the conditions the screening tests are looking for.**

**But for those babies who do have a health problem, the benefits of screening can be enormous.**

**Early treatment can improve their health and prevent severe disability or even death.**

**The screening tests are quick and simple, and won't harm your baby in any way.**

**It is recommended that your baby has the tests, but you can decline them if you wish."**

continued/...

I will use your reasons for not introducing O<sub>2</sub> Saturation Screening to highlight Little Hearts Matters comments.

*"For babies with CHD or other non-cardiac conditions 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."*

Undiagnosed complex heart conditions can result in the death or serious brain damage of a child with a single ventricle heart condition after birth. Little Hearts Matter has a number of members that have experienced the loss of their child before a diagnosis was made. They were discharged home, collapsed and died before a diagnosis was made.

Currently only 53% of CCHD is diagnosed before birth and even though single ventricle heart conditions make up a large proportion of conditions diagnosed it does not, and will not, provide a 100% detection rate in the near future.

6 hourly discharge has led to newly delivered babies being discharged into the community before any symptoms of CHD can be seen, non-detection from standard tests has led to collapsed children at home, emergency admission and poor short and long term outcomes in this complex patient group.

*"A positive result from pulse oximetry will generate some harm including: parental anxiety, a longer stay in hospital, possible transfer to the neonatal unit, further tests to assess for non-symptomatic conditions."*

Having set out **your** NHS statement above re the need for neonatal screening this O<sub>2</sub> Saturation test decision statement is extraordinary. All neonatal tests could create the need for a longer stay in hospital, a higher degree of investigation and careful consideration of the results. Your conclusion that it would cause a greater concern for this group of parents rather than any other is inaccurate and discriminatory. One could suggest that no neonatal screening should be offered if this was the reason given to exclude testing.

As an organisation that works with families at all stages of diagnosis and with parents who seek further investigations for subsequent pregnancies, after a CCHD diagnosis in a previous child, we know that if tests are explained correctly and the results are described correctly parents are grateful that all possible outcomes have been explored, even if the test has shown a false negative.

As O<sub>2</sub> Saturation testing is non invasive, unlike the spot test that detects complex but much rarer conditions, 1 in 10,000 children have PKU, 1 in 4,000 children have Cystic Fibrosis, and it is a test that has been supported by midwifery teams and is now part of routine testing across the US, it is extraordinary that it has caused such a debate in the UK. Are the 1 in 136 (145 from BHF) children with a congenital heart condition, or the 25% of those who have a complex cyanotic condition that would need prompt, if not urgent, treatment after birth not as important?

continued/...



O<sub>2</sub> Saturation testing kits are not expensive. They provide a non-invasive and mainly accurate test when seeking out cyanotic heart conditions and, as a sub-set, other respiratory conditions. Our parents test their diagnosed children at home with SATS monitors so it is clear that testing does not require high levels of medical training. Inclusion of this test in the Neonatal Screening portfolio across the UK would be beneficial for any child with CCHD and other children with previously undetected respiratory conditions.

Little Hearts Matter welcomes a further opportunity to contribute to this most recent consultation and urges you to reconsider your proposal not to include this simple and easily administered test.

On a personal note I look to you to create every opportunity for a diagnosis of CCHD to be made, before and after birth. Screening allows for informed decision making and better outcomes, not just survival, for the children. I don't like my first contact with a family to follow the death of their child because they have collapsed at home and not been in time for any treatment. Sadly often the diagnosis of a single ventricle heart condition then comes as the result of their baby's post-mortem.

Yours sincerely

XXXX XXXX XXXX XXXX XXXX

**Suzie Hutchinson RGN; RSCN  
Chief Executive**

17. XXXX XXXX

Dear Sirs /Madam,

I wish to add my support to the movement to provide pulse oximetry tests in the neonate to help diagnose CHD.

This appears to be relatively cheap test that has the potential to save lives and I feel strongly that this should be available in all maternity units.

I feel that the cost of introducing the test would be negligible in comparison to the cost benefits of early diagnosis of heart disease in the newborn.

Kind regards,

XXXX XXXX

18. XXXX XXXX

<b>Name:</b>	XXXX XXXX	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	XXXX XXXX		
<b>Role:</b>	Lead NNU consultant		
<p>Do you consent to your name being published on the UK NSC website alongside your response?</p> <p style="text-align: center;">No</p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Not sure	cost	<p>Please can the guidance ensure that the cost of pulse oximetry probes, and pulse oximeters are not too high, ie can we ensure that non disposable probes are used, and that work is carried out with manufacturers to ensure this is purchased by the NHS at sensible prices, ie sensible procurement.</p> <p>The same applies regarding pulse oximeters – we will need to have many around in the community and wards , and the cost can be high.</p>	

19. Benjamin Stenson

<b>Name:</b>	Benjamin Stenson	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	Neonatal Unit, Royal Infirmary of Edinburgh		
<b>Role:</b>			
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>Yes</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Whole document	Decision against screening on the basis that potential harms may outweigh benefits	I was a member of the consultation group who attended the pulse oximetry workshop in 2018 at which the committee sought advice on assessing the risks and benefits of screening. I consider that there was no measured potential harm from screening that was sufficient to offset the benefit in reduced mortality and morbidity to infants with serious congenital heart disease and that in addition there were infants with other conditions who would also benefit from earlier recognition and treatment. I was disappointed by the decision of the screening committee not to recommend screening and hope that this decision is changed after the consultation.	

20. Jon Staines

<b>Name:</b>	Jonathan Staines	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>			
<b>Role:</b>	Consultant Paediatrician		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>Yes</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
From the summary	<p><b>18</b> <i>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).</i></p> <p><b>19</b> <i>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).</i></p>	<p>These figures suggest that 40% of infants who were hypoxic had either CHD (some critical) or other, non-cardiac condition (some of which may have benefitted from being identified). How is that not useful?</p>	
		<p>In Ayrshire we have been performing pulse oximetry as a routine part of the neonatal screening examination for more than a decade. We have <u>no</u> false positives. If oxygen saturations levels are lower than normal then the infant needs careful assessment. We certainly find babies who are desaturated but with normal hearts but there is always a</p>	





		<p>cause for this. We have had babies with significant sepsis , with delayed transition and other conditions as well as those with congenital heart disease.</p> <p>The test is quick and non invasive. It can be performed whilst the parents are being questioned before the baby is examined so adds no time to the newborn screening examination.</p> <p>Not to recommend this as a routine part of the newborn examination makes no sense.</p>
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**21.**Dr Yogen Singh

Dear NSC officer,

Please find a statement from PECSIG (Paediatricians with Expertise in Cardiology Special Interest Group) in response to National Screening Committee's public consultation on its decision not to offer pulse oximetry screening to all newborn babies in the UK. PECSIG is one of the major stake holder in initial diagnosis and management of infants with congenital heart defects in the UK.

As a group, we strongly support pulse oximetry screening for detection of congenital heart defects in all the newborns.

Kind regards and best wishes,

Yogen

Dr Yogen Singh | Consultant Neonatologist and Expertise in Paediatric Cardiology

## **Pulse Oximetry Screening for Detection of Congenital Heart Defects**

### **Statement of Paediatricians with Expertise in Cardiology Special Interest Group (PECSIG) in response to National Screening Committee's public consultation on its decision *not to offer pulse oximetry screening to all newborn babies in the UK***

Yogen Singh<sup>1</sup>, P Venugopalan<sup>2</sup> on behalf of Paediatrician with Expertise in Cardiology Special Interest Group (PECSIG)\*

<sup>1</sup> *Consultant Neonatologist and Paediatrician with Expertise in Cardiology, Cambridge University Hospitals NHS Foundation Trust*

<sup>1</sup> *Associate Lecturer University of Cambridge School of Clinical Medicine, UK*

<sup>2</sup> *Consultant Paediatrician with Expertise in Cardiology at Brighton & Sussex University Hospitals NHS Trust*

*Dr Yogen Singh is Academic and Educational Lead, and Dr P Venugopalan is the Chair Person for the PECSIG.*

Paediatrician with Expertise in Cardiology Special Interest Group (PECSIG) is a professional body providing care to newborns and children with suspected or confirmed congenital heart defects across over 180 hospitals in the UK. PECSIG members are the frontline healthcare professionals in the NHS who are often involved in diagnosis of congenital heart defects in the newborn infants, especially when no antenatal diagnosis of CHD has been made or suspected. Being a major stake holder in providing care to infants with CHDs we are writing this statement in response to National Screening Committee's public consultation on its ***decision not to offer*** pulse oximetry screening to all newborn babies in the UK.

Congenital heart defects (CHD) is a leading cause of infant death accounting for up to 40% of all deaths from congenital defects and 3-7.5% of infant deaths in the developed world (Lloyd 2003). Overall incidence of CHD is around 7-8/1000 while the incidence of critical CHD varies between 2-2.5 per 1000 live birth (Lowell 2012).

### **What is the current screening programme for heart defects in newborn babies?**

All babies are currently screened for heart defect while still in the womb (antenatal ultrasound) and following birth (postnatal clinical examination).

□ **Fetal anomaly screening (FAS) by antenatal ultrasound** – According to NICOR 2018 report *less than half (42%)* of babies with congenital heart defects that require intervention were identified between 2014 and 2017. Between different health regions in the UK There remains significant variability in the rate of identification of CHDs on FAS across the UK – ranging from 33-62%.

**Newborn Physical Examination (NIPE Postnatal examination)** – Despite best efforts examination routine newborn physical examination (*NIPE*) *fails to identify about 45% of babies* with critical CHDs and more worryingly up to *one-third infants with critical CHDs can be sent home with undiagnosed heart condition*. These infants carry the risk of collapsing at home, poor outcome from late diagnosis and sadly some of these infants may die from undetected critical CHDs.

### **Research has consistently shown that adding pulse oximetry screening as an adjunct to the existing screening programme can identify 75-92% of critical CHDs.**

Following a public consultation the UK National Screening Committee (NSC) summarised its decision as: ‘...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.’

**PECSIG being a major stake holder we have serious concerns regarding the decision to not to offer pulse oximetry screening to all newborns – which means up to one-third babies with undiagnosed critical CHDs will continue to go home undiagnosed from hospital putting them at significant risk.**

For some babies, the consequence of going home with an undiagnosed CHD will be fatal. Others will be admitted to hospital as an emergency following an acute collapse, their outcome having been significantly compromised by late diagnosis both in terms of success of cardiac surgery and long term morbidity related to the consequences of brain injury from ischemia.

As a group we do not agree there is not sufficient evidence to implement routine pulse oximetry screening in the UK.

Research in over half a million babies has consistently shown that when pulse oximetry screening is safe, simple, easy to perform, cost-effective and acceptable to parents. It has moderate sensitivity and high specificity in detecting critical CHDs and as front line clinicians we see added value by recognising other potentially unwell babies with non-cardiac conditions such as sepsis, pneumonia, PPHN and pneumothorax.

High quality studies have been published in well renowned journals such as the Lancet and include randomised controlled trials, systemic reviews and meta-analysis. All the studies have consistently showed it to be a simple, highly specific, cost-effective and acceptable method to detect critical CHD in asymptomatic infants

There has been significant progress towards implementation of pulse oximetry screening in developed countries. In 2005, the Swiss Society of Neonatology and the Swiss Society of Paediatric Cardiology recommended that all neonates in Switzerland should undergo first day pulse oximetry screening and in 2010, this was also recommended by the Polish Ministry for Health. Now it has been implemented in United States of America (USA) – all states have implemented pulse oximetry screening for routine screening of CHDs since July 2018.

We, PECSIG group of professionals at front line in managing these babies, believe triple screening (antenatal ultrasound screening, routine examination of newborn and pulse oximetry screening) to detect critical CHD will detect up to 75-92% cases.

We strongly feel that pulse oximetry screening should be offered to all the newborns in the UK. We appreciate it has limitations in not being able to detect ALL cases with CHDs but detection of up to 92% infants with critical CHDs can save lives in some babies while improving long term outcome in many others. This will also offer added value by identifying a significant number of cases with infection (sepsis), respiratory infections and other serious conditions in asymptomatic babies and it will in minimise the risk of collapse in at risk infants in the hospital and at home

22.John Simpson

<b>Name:</b>	XXXX XXXX	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	XXXX XXXX		
<b>Role:</b>	XXXX XXXX XXXX XXXX		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">Yes      No</p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
N/A	Composition of advisory group	No paediatric cardiologist i.e. holder of CCT in Paediatric Cardiology was included. Nor any individual with expertise on prenatal diagnosis e.g. fetal cardiologist. Inclusion of such would have answered some of the points below	
Covernote	Decision not to implement: “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”	<p>The paper in JAMA (Abouk 2017) examined the impact of introduction of pulse oximetry. There was a 33% reduction in early deaths due to critical congenital heart disease and further reduction due to other cardiac causes.</p> <p>Comment: There is sufficient current evidence to recommend pulse oximetry screening as has happened in the USA and many other European countries.</p> <p>Further comment:</p>	

		<p>The suggestion of submission to NIHR for further research needs to be examined critically.</p> <p>Given that around 50% of UK units have already initiated in a patchwork “postcode lottery fashion” such a study would only be able to recruit from non-implementing areas.</p> <p>If a randomised trial was proposed, I strongly suspect that many parents would not consent to being randomised either to get pulse oximetry or not. Most would opt to have the test.</p> <p>It is difficult to conceive of an effective design. Otherwise, we are left comparing regions which has been the basis for existing research.</p>
Knowles and Hunter review p7	<p>“Mortality has declined in recent decades due largely to advances in intensive medical care and surgical technologies, nevertheless prevention of clinical deterioration prior to intervention is likely to be the key to future improvements in survival, neurocognitive outcomes and quality of life in childhood and adulthood.”</p>	<p>The conclusion of the NSC recommendation states : “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”</p> <p>The NSC covernote conclusion is not true. There is evidence of benefit of diagnosis of many cardiac lesions, typically duct dependent, in terms of mortality, morbidity and quality of survival, particularly neurological.</p> <p>Reference to the AHA statement on neurodevelopmental outcome of CHD would have informed opinion</p> <p>The statement of Knowles and Hunter is accurate and underscores the need for pulse oximetry screening</p>
N/A	Discrimination by race /colour	<p>The perception of cyanosis during newborn examination is impacted by many factors. Amongst these, it is well recognised that perception of cyanosis is better in white / Caucasian infants than those who are Asian or Black.</p>

		From my personal experience of working in Sri Lanka over decades, the use of pulse oximetry is critically important over the clinical perception of cyanosis. Thus, infants of non-white race are likely to be disproportionately disadvantaged by failure to implement pulse oximetry.
Covernote	“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.”	The Cochrane review 2018 (Plana et al) included almost 500 000 screened patients with a sensitivity of 78.5%, specificity 99.8% and false positive rate 0.23%. Implementation at a regional unit in the UK (Singh 2014) led to a positive puls ox result in 0.8% of livebirths, amounting to 1 admission per week. Furthermore, the evidence demonstrates that 30-70% of infants with an apparent “false positive” diagnosis have another significant medical condition meriting treatment.
Covernote 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 overdiagnosis, over-treatment, false positives, false reassurance, uncertain findings, and complications.	The current system of neonatal assessment (without pulse oximetry) generates substantial false positive referrals. Thus, non-introduction does not make this better but worse. Similar for false reassurance. Our group published data in 2019 (Mawson et al) examining the proportion of infants with known CHD (prenatally diagnosed) that met each pulse oximetry threshold. Thus, the potential lesions which will not be reliably detected by pulse oximetry can be focused on by other means including clinical examination.
PO Research review	“Unfortunately after much work and discussion, the results of the analyses are considered unsound. This is because there is no nationally accepted prevalence for the target condition of CCHD and other significant diagnosis with which to calibrate the many assumptions.”	Would not the inclusion of specialist paediatric cardiologist input have assisted in the this matter ?

23. xxxx xxxx

I think this screening should be offered to all babies. My xxxx xxxx has recently been diagnosed with a heart condition. xxxx xxxx is a new born and is now being treated however early detection of these types of conditions is vital especially for the young.





24.xxxx xxxx

Dear whom it may concern.

I am writing my views on the decision that this test should not be added to the routine testing of newborns. I totally disagree and believe that this test SHOULD be added to the mandatory routine checks. As a heart mum this is something that saddens me to see. These tests could save lives.

Thank you,

xxxx xxxx

25. xxxx xxxx

Dear Sir/Madam,

It is with concern that I write this email having recently been made aware that the NHS are not to routinely test for pulse oximetry. I hope that by including a synopsis of my personal experience, it may prompt you to reconsider and realise what a few minutes testing can do.

I am the mother of a xxxx xxxx. xxxx xxxx was not picked up during any pregnancy scans. My xxxx xxxx was born at 9.50 am fortunately ( as it turns out) I haemorrhaged and was therefore kept in overnight. At around 1am, I was approached by a midwife who had concerns about my xxxx xxxx slight blue tinge and were taking xxxx xxxx to have some basic tests. A few hours later xxxx xxxx was in xxxx xxxx xxxx xxxx hospital where xxxx xxxx had open heart surgery at 5 days old. Had I not haemorrhaged, I would have been home. I have wondered how long it would have taken me to notice xxxx xxxx was a blue baby? I doubt that as a first time tired mother I would have noticed in a dimly lit room. How long would it have taken me to realise something was very wrong and know that emergency treatment was needed rather than a doctors appointment? Would I have been too late?

I implore you to reconsider this decision - a few minutes testing may not in itself save a life, but it could certainly lead to quicker diagnosis and treatment.

I thank you for reading this.

Yours sincerely

xxxx xxxx

26.Dr Anna Nancy SEALE

<b>Name:</b>	Anna Nancy Seale	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	Birmingham Women's and Children's Hospital NHS Trust		
<b>Role:</b>	Consultant Fetal and Paediatric Cardiologist		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>Yes</b></p>			
<b>Comment</b>			
<i>Please use a new row for each comment and add extra rows as required.</i>			
<p>I am writing to give my full support to the introduction of pulse oximetry as an additional test in the Newborn and Infant Physical exam. Myself, as well as my colleagues working with-in Paediatric Cardiology at Birmingham Children's Hospital, believe this addition to screening will improve detection of children with major congenital heart disease.</p> <p>Cardiac defects are the most common congenital defect. Historically the newborn screen in the United Kingdom has depended upon detection of heart murmurs and palpation of femoral pulses – these methods can be quite subjective and difficult assessments. In addition, some of the most common serious forms of congenital cardiac anomalies are frequently not associated with a murmur (e.g. Transposition of the Great Arteries, Coarctation of the aorta, Hypoplastic left heart syndrome). Failure to detect these defects in a timely manner leads to death or frequently <b>serious morbidity</b> before surgical/ catheter intervention e.g. <b>Brain injury</b>.</p> <p>Although prenatal diagnosis of congenital heart disease has improved, some serious forms of congenital heart disease remain difficult to detect prenatally (e.g. coarctation of the aorta, total anomalous pulmonary venous connection) or ultrasound features only become obvious after the second trimester screening scan (e.g. severe pulmonary valve and aortic valve stenosis). Pulse oximetry screening will help detect these lesions all of which have successful treatments.</p>			

The work from Professor Ewer and colleagues has shown that not only does pulse oximetry help detection of cardiac defects; it also has an important role in detection of other serious non-cardiac problems which can also allow treatment before babies have **serious (and expensive) morbidity**.

The argument that this test causes too much anxiety to parents simply does not make sense. If correctly communicated, I am sure parents would prefer to know that their child is well prior to discharge home and would find the extra tests reassuring.

In conclusion, I fully support the introduction of pulse oximetry to the newborn and infant physical exam. I work in a major congenital heart centre with many local neonatal units undertaking pulse oximetry screening; I have clearly seen many patients benefit from early detection of congenital heart disease with excellent results following intervention.

To whom this may concern

The pulse oximetry test is a valuable tool in screening for underlying heart abnormalities and can save baby's lives, this tool has certainly achieved this in Leicestershire and Rutland. Surely this screening is a positive tool in potentially preventing neonatal mortality and therefore the impact this has on families if their baby dies once taken home. It would be of great benefit to the families of the UK if this screening were a national compulsory test. As a NIPE practitioner, I feel that the pulse oximetry screening is a crucial piece of equipment that will aid the detection of potential heart anomalies and other potential structural anomalies.

Yours hopefully

xxxx xxxx xxxx xxxx

28. Mrs XXXX XXXX

Good afternoon

I wish to share my views on pulse oximetry testing to be carried out on all newborn babies. I feel I am in a very strong position when I say this simple test is of the utmost importance following my own experience regarding this subject.

On the XXXX XXXX our beautiful baby XXXX XXXX XXXX XXXX XXXX was born via a planned C-Section. Very quickly we had concerns about XXXX XXXX as he had very little interest in feeding and remained sleepy. He maintained a slight blue tinge and at times felt cold and clammy to touch. We were reassured all was ok and perfectly normal.

At 36 hours old XXXX XXXX collapsed and was rushed to intensive care. An Echo scan resulted in a diagnosis of Hypoplastic Left Heart Syndrome - a very rare and serious heart condition.

We were transferred to Great Ormond Street Hospital where doctors and nurses worked night and day but despite their very best efforts XXXX XXXX was too unwell due to the damage caused to XXXX XXXX organs when he sustained the collapse to undergo the first stage of a 3 stage surgical procedure. We were moved to our local hospice where on the XXXX XXXX XXXX XXXX passed away in our arms at 5 weeks and 1 day old.

Without doubt we feel that if a Pulse Oximetry test had been carried out at XXXX XXXX birth it would have shown dangerously low oxygen levels, action would have been taken and XXXX XXXX would not have collapsed meaning not only would he have avoided the pain, distress and horror of the collapse but there is also a very high chance he would have been strong enough to undergo surgery and still be here today.

Whilst I appreciate the concerns regarding false results and the added anxiety to the new parents I feel this is a very small price for potentially saving a baby's life. Points have been raised that it should be left to the midwives and doctors to pick up on signs of any problems however as our situation proves this cannot be relied upon. Such a simple non-invasive low cost check will make a huge difference and will save lives. The devastation my family and I are going through cannot be allowed to happen.

If you need any further details from me please do get in touch as this is an area I feel incredibly strongly about.

XXXX XXXX XXXX XXXX

XXXX XXXX

XXXX XXXX

29. XXXX XXXX

Good morning,

I kindly but sternly ask you to reverse the decision not to add pulse oximetry tests to the mandatory and routine checks on newborns. Why on earth would this not be added? It would be one of the most important tests a newborn baby and its family could have. Our baby XXXX XXXX has Hypoplastic Left Heart Syndrome, and has so far had 2 open heart surgeries and one heart catheter. XXXX XXXX is XXXX XXXX this month. Luckily, XXXX XXXX was diagnosed at the anomaly scan and a treatment pathway was set for XXXX XXXX. However, there are so many families out there that are undiagnosed. So many families that take their newborn home, happy as can be, until a few days later they wake to find their baby has died. No warning. No explanation. Utter devastation and heartbreak. Their lives will never be the same. They will never recover.

In truth, our lives will never be the same either, due to the fact that we couldn't take our baby home until XXXX XXXX was 2 months old, that we'd seen her hooked up to every machine going, her chest had been torn open, she had lines everywhere, pumping her little body with drugs that were keeping her alive. But at least she is still with us, thanks to that vital diagnosis at 20 weeks.

If you introduced mandatory pulse oximetry tests for all newborns, other families could have the opportunity to still have their child with them. They could have that vital diagnosis made, and their baby would receive the care it needs.

You have the chance to save so many little lives. And all it takes is one little test. Please reconsider your decision and give families either A) Peace of mind B) A chance to save their child's life.

XXXX XXXX

XXXX XXXX

A response to the Consultation on the use of pulse oximetry as an additional test in the Newborn and Infant Physical Exam on behalf of the Children's Heartbeat Trust.

Children's Heartbeat Trust is Northern Ireland's leading children's heart charity, providing practical and emotional support to children, young people and families affected by congenital heart disease (CHD). CHD is the most common birth defect in Northern Ireland with over 200 babies born each year with a heart condition. Through the delivery of a wide range of support services including financial support, counselling, research, respite caravans and medical equipment, Children's Heartbeat Trust works with these heart families to support them and their child to live long, healthy and happy lives, and acts as an advocate for their needs - both clinically and holistically.

Children's Heartbeat Trust welcome the opportunity to respond to the UK National Screening Committee's (NSC) consultation on the use of pulse oximetry screening and we have set out our comments as below.

1. Children's Heartbeat Trust respectfully disagree with the NSC's conclusion that pulse oximetry screening provides no better outcomes than routine screening.

Unfortunately the current routine screening practice consisting of antenatal ultrasound screening and postnatal examination does not provide a consistent level of critical congenital heart disease (CCHD) identification across the United Kingdom.

The 2018 NICOR report (table 12a) notes that current practice of antenatal ultrasound screening in the UK detects less than half of babies with heart defects that require interventions, and that this varies greatly between hospitals with only a 33% rate of successful identification in the lowest performing regions compared to 62% in the highest.

Additionally, postnatal examination fails to identify roughly 45% of babies before collapse with CCHD and up to 30% are sent home without a diagnosis. In these instances a baby with CCHD can be discharged only to be rushed to hospital a few days or weeks later with heart failure. At which point the baby requires unplanned urgent treatment. Delaying the treatment until an infant becomes critically ill can lead to higher risks of mortality, longer stays in ICU and a higher incidence of serious complications, as well as significantly increasing the emotional trauma for the infant, their parents and family.

Research consistently shows that when pulse oximetry is added to the existing programme of screening the identification rate for CCHD increases to between 90 and 95%. Thus the pulse



oximetry test has been proven successful at diagnosing serious heart conditions that might otherwise have gone undetected.

Children's Heartbeat Trust believe that the introduction of this test, enabling the earliest treatment of infants with CCHD before they become acutely ill, will allow clinicians to provide the most appropriate interventions and reduce emergency incidents. This can only improve outcomes for these vulnerable infants.

2. Children's Heartbeat Trust respectfully contests the NSC's conclusion that the harms associated with screening and further investigations following a positive screening result outweigh the benefits.

Analysis from the NSC's pulse oximetry pilot (pg110-111) illustrates that about 8 out of 10 babies who are admitted to the Neonatal Unit after a positive test will have a condition that is considered to require treatment which will have been detected early due to the pulse oximetry test. The analysis shows that as well as identifying CCHD, the screening can also detect other conditions such as infection and breathing problems.

Children's Heartbeat Trust do not consider the detection of these other pathologies as a harm, but rather a benefit in favour of introducing pulse oximetry screening. Our position echoes that set out by expert clinicians at the Pulse oximetry screening workshop of 22 June 2018 who outlined the clear clinical benefit that early diagnosis for this range of conditions will bring.

As a family support charity, Children's Heartbeat Trust are acutely aware of the concerns that additional testing and unnecessary longer stays in hospital may impact negatively on parental anxiety levels. However, given the small amount of time undertaken to clarify a positive test (most babies who do not pass the test and are healthy are identified within an extra hour or two and discharged as normal) it is our opinion that any associated parental anxiety will not lead to significant anxiety problems especially when contrasted with the potential anxiety levels of parents whose baby's CCHD has gone undiagnosed and requires unplanned treatment.

3. Equality of Access

A national survey undertaken in 2016 (Mikrou P, Singh A, Ewer AK. Arch Dis Child Fetal Neonatal Ed 2017; 102: F558-F559) indicates that 40% of maternity units in the UK are routinely performing pulse oximetry screening. This rate of occurrence varies dramatically across the regions with uptake in Wales at 75% compared with 14% uptake in Northern Ireland.

This raises serious questions around the equity of care provided throughout the UK with babies being born in regions with a low screening rate at a clear disadvantage to those that are born in regions with a higher screening rate. A national recommendation from the NSC for all UK maternity units to adopt pulse oximetry screening would greatly reduce this concerning disparity in practice.

4. Other Comments

Children's Heartbeat Trust would urge the NSC to reconsider their decision not to introduce pulse oximetry as an additional test in the Newborn and Infant Physical Exam.

Pulse oximetry screening can only enhance the current screening and detection of CCHD in babies and infants and Children's Heartbeat Trust believe that this early identification can be life-saving.

Furthermore, the ability to detect CCHD as early as possible is of increased significance in Northern Ireland given that the region no longer has paediatric cardiac surgical services, meaning any child



requiring intervention or surgery for a heart defect must travel outside of the country to access treatment. In these circumstances a baby's chances of survival and long term quality of life are much improved by enhancing and improving all areas of screening and early detection, including the introduction of pulse oximetry screening.

I consent to my name being published on the UK NSC website alongside this response.

If any further comment or clarification is required please contact;

Sarah Quinlan MBE

Chief Executive

Children's Heartbeat Trust

XXXX XXXX XXXX XXXX

31. XXXX XXXX

I am writing to ask you to please reconsider NOT recommending pulse oximetry at the newborn check. I cannot understand why it isn't recommended. My XXXX XXXX died of undiagnosed HLHS aged 4 days. Pulse oximetry would have alerted medical staff and his parents to his condition. Even if it hadn't changed the outcome, they could have spent his few precious hours together instead of the traumatic experience they had.

Pulse oximetry is non-evasive, cheap and quick.

Please reconsider. Parents and babies do not deserve to go through what my sister and brother in law did.

XXXX XXXX

### 32. XXXX XXXX and XXXX XXXX

Our youngest XXXX XXXX, XXXX XXXX, was born in XXXX XXXX and we brought XXXX XXXX home on the same day - seemingly healthy - we - including her older XXXX XXXX and XXXX XXXX - were instantly besotted with XXXX XXXX and XXXX XXXX completed our family.

When XXXX XXXX was XXXX XXXX - despite being a good colour, feeding well, and putting on weight we were concerned that XXXX XXXX was breathing quickly so we raised our concerns with our community midwife on the day XXXX XXXX was meant to be discharged - she listened to our concerns and arranged for her to be seen in A&E. This is when our world began to fall apart. XXXX XXXX deteriorated very quickly and it became clear that XXXX XXXX was very sick. One of the first things they did in A&E was check XXXX XXXX oxygen levels - they were dangerously low. They struggled to get blood from XXXX XXXX. XXXX XXXX had a chest x-ray and a heart scan. This is when XXXX XXXX was referred to the nearest specialist hospital (70 miles away) who gave advice over the phone and specialist transport was arranged. In a whirlwind we arrived at the specialist hospital where XXXX XXXX was diagnosed at 11 days old with a very rare critical Congenital Heart Defect - Hypoplastic Left Heart Syndrome (HLHS) in essence XXXX XXXX was born with only half a working heart. This is a rare condition that occurs in 1 in 5,000 babies and is normally diagnosed antenately at 20 weeks so it was a horrific shock.

The first few hours were critical and XXXX XXXX urgently needed open heart surgery to save XXXX XXXX life. We learnt that this was to be the first of a three stage surgical plan that she must follow for XXXX XXXX to have any chance of survival. Although we were given the choice we were both in no doubt that we wanted to follow this path to fight for our precious baby girls life. XXXX XXXX underwent life saving treatment including 6 major surgeries due to complications - spending a total of 6 weeks in intensive care. XXXX XXXX condition is both palliative and life limiting. XXXX XXXX will require treatment for the remainder of her life.

The second stage was done when XXXX XXXX was 7 months old and the third stage of the surgical plan is around school age - so when XXXX XXXX is around 4. All of these surgeries have risks but the alternative would give XXXX XXXX no chance of survival. After these surgeries it is unclear at this stage how long XXXX XXXX can live with the circulation that the 3rd surgery can provide - it is likely that XXXX XXXX will require a transplant in her adult life.

The shock and delay in treatment continues to be a great cause of stress and anxiety due to how traumatic the experience was. We couldn't prepare our two older children so it was obviously very traumatic for them too.

Had **XXXX XXXX** been given the non-invasive pulse oximetry test sooner **XXXX XXXX** condition could've been picked up sooner- which would've meant **XXXX XXXX** didn't need to be admitted with cardiogenic shock. **XXXX XXXX** very nearly died. Had it not been for our parental concern for her high respiratory rate she would have died.

Due to the fact **XXXX XXXX** was so critical **XXXX XXXX** length of stay on paediatric intensive care was longer and with extra complications and more surgeries than **XXXX XXXX** most likely wouldn't have required had **XXXX XXXX** condition been diagnosed sooner.

Not only should pulse oximetry testing be part of the newborn examination but also by community midwives as it is known that the ductus arteriosus normally closes within the first week after birth.

With Hypoplastic left heart syndrome "Whilst the ductus arteriosus is still open (patent), the blood will pass from the lung artery into the body artery and then around the body. When the duct closes, the baby will no longer have oxygen flowing to their body. Gradually, without medical intervention, the baby would become sicker and die." (Extracted from Little hearts matter website 2019).

The description of harm in the consultation documents- harm from unnecessary tests (blood and x-ray) seems like a small risk in comparison to a potential death. If the 'harm' from a blood test or an x-ray potentially saves the babies life surely that harm is better than the alternative. I cannot comprehend another parent would think otherwise. Parent anxiety at having a false positive screen is surely far outweighed by the consequence of a missed diagnosis of a critical CHD?

**XXXX XXXX** and **XXXX XXXX**

33.XXXX XXXX

Dear NHS,

My XXXX XXXX was rushed to hospital at 10 days old and diagnosed with Congenital Heart Defects. Thankfully following surgery XXXX XXXX is now fine. Around 5 hrs after birth my son had pulse oximetry testing his sats were 100%. When I look back at a video of XXXX XXXX at XXXX XXXX I can see his breathing is too fast. The midwife visited at 5 days. If the midwife had done a pulse oximetry test as part of the 5 days check it would have flagged something was wrong with my baby and he would have been able to be treated sooner.

5hrs after birth was too soon for the test for my XXXX XXXX. I'd love to see pulse oximetry testing made mandatory after birth and at the 5 day midwife check. It's such a simple test and would allow midwives to be more thorough in their checks. Thankfully my local hospital is carrying on the pulse oximetry testing of newborns as they have seen the benefits in not only detected CHD but also picking up cases of sepsis.

Please make pulse oximetry testing mandatory before discharge from hospital and at the 5 day check for newborn babies.

With thanks,

XXXX XXXX

34. XXXX XXXX

We are close to a baby named XXXX XXXX who has CDH. Please make pulse oximeter testing mandatory and routine as it gives babies like XXXX XXXX and their parents the best chance at a normal life.

Sincerely,

XXXX XXXX

35. XXXX XXXX

<b>Name:</b>	XXXX XXXX	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	XXXX XXXX		
<b>Role:</b>	XXXX XXXX		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">Yes      No</p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
	I agree that screening with saturations is likely to cause more harm (anxiety and unnecessary investigations). We have anecdotal evidence that pulse oximetry could also be falsely reassuring as babies with left heart lesions don't have low sats in the first day or 2 when the screening NIPE is done. We have today transferred out a 4 day baby with an interrupted aortic arch who did not have low saturations.		



## 36. Professor Sir Nilesh Samani



### Statement on pulse oximetry as an additional test in the Newborn and Infant Physical Exam

9<sup>th</sup> August 2019

#### Professor Sir Nilesh Samani, Medical Director at the British Heart Foundation

"We want every child born with congenital heart disease to have the chance to live a long and healthy life, and an early diagnosis can be critical.

"Pulse oximetry measures the amount of oxygen present in the blood by using a special sensor placed on the fingertip, ear or toe. Reduced oxygen in the blood can be an early sign of congenital heart disease, and pulse oximetry provides a quick and painless way to detect this in neonates. Neonatal pulse oximetry screening has now been adopted across the USA and many other countries. A recent Cochrane review including data from nearly half a million babies also supported the wider introduction of pulse oximetry screening in asymptomatic new-borns."

The UK national screening committee recently reviewed whether pulse oximetry should be added to routine neonatal and infant screening, and recommended against this addition. The British Congenital Cardiac Association, the specialist professional body has raised concerns about the decision<sup>2</sup>. The BHF supports these concerns and recommends that they are fully considered before a final decision is made."

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<sup>1</sup> Plana MN, Zamora J, Suresh G, Fernandez-Pineda L, Thangaratnam S, Ewer AK. Pulse oximetry screening for critical congenital heart defects. Cochrane Database of Systematic Reviews 2018, Issue 3. Art. No.: CD011912.

<sup>2</sup> British Congenital Cardiac Association (2019) - Pulse-oximetry screening for critical congenital heart defects NSC Consultation -

37. XXXX XXXX

I absolutely cannot believe that 11 years after XXXX XXXX life was saved by pulse oximeter testing at birth we are still talking about this!

It is absolutely imperative that this is brought in. We do the least screening of newborns in the developed world.

XXXX XXXX was born in XXXX XXXX UHND hospital who, at the time were trialing the test in conjunction with XXXX XXXX..

XXXX XXXX sats were 72% and falling fast. XXXX XXXX would have died at home. Surely the fact XXXX XXXX is 11 and now due to start secondary school is the only evidence you need. It costs nothing.

A few false positives people wont mind to have the security that their baby is ok?

Here is one of the news article we did at the time. XXXX XXXX XXXX XXXX XXXX XXXX

Kind regards

XXXX XXXX

XXXX XXXX

**38.** Sam Wallis

<b>Name:</b> Sam Wallis		<b>Email address:</b> xxxx xxxx	
<b>Organisation (if appropriate):</b> Bradford Teaching Hospitals			
<b>Role:</b> Consultant Neonatologist with interest in Cardiology Bradford – Neonatal Intensive Care Unit. No on-site Paediatric Cardiology.			
<b>Do you consent to your name being published on the UK NSC website alongside your response?</b> Yes			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b> <i>Please use a new row for each comment and add extra rows as required.</i>	
Consultation cover note (p1) and report content	<ul style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>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.</li> </ul>	<p>I strongly disagree with the findings of the UK NSC on this issue. I believe there is a fundamental misapprehension of the risks and benefits as described.</p> <p>Although I appreciate that it is difficult to determine the extent of all the positive outcomes from the data provided, there is evidence that earlier diagnosis of critical congenital heart disease is beneficial, and in non-cardiac conditions such as sepsis / pneumonia the overwhelming weight of clinical opinion is that early identification and treatment is in the patient's interest.</p> <p>We have been routinely performing oxygen saturation screening in all newborns for several years. We do not recognise the assertion that there are harms associated with Pulse Oximetry and we have seen considerable benefits from early diagnosis of both cardiac and non-cardiac conditions.</p>	

		<p>We believe with appropriate training of staff, information/explanation for parents and clear local guidance then many of the putative (and unsubstantiated) disadvantages described in your report are invalid.</p> <ul style="list-style-type: none"> <li>- In our experience saturation screening does not lead to increased parental anxiety. Parents are in general reassured by the additional clinical information this provides. They are aware routine pulse oximetry is standard practice in many parts of the UK and the wider world and are more anxious if it isn't performed.</li> <li>- We have not seen any evidence of longer hospital stay or inappropriate admissions of well babies to the neonatal unit. The overwhelming majority of positive screens admitted to the neonatal unit have an underlying illness – the first indication of which is often an abnormal saturation check.</li> <li>- As described elsewhere, one of the main benefits of saturation screening has been the early identification of non-cardiac illness which has then allowed prompt intervention. It is very likely that in these cases, earlier treatment has reduced the length of stay, number of investigations and parental anxiety, as babies were managed before they became seriously unwell.</li> <li>- We have not seen any notable increase in demand for early Echocardiography. Bradford is a non-cardiac centre but is able to provide an Echo service. Inappropriate transfer of babies for tertiary cardiac opinion has not occurred.</li> <li>- If a baby has a positive screen but is well, with a normal examination, then they are routinely rechecked an hour later which, with appropriate reassurance for families, reduces the risk of inappropriate admission and unnecessary anxiety.</li> <li>- Our midwifery colleagues, who routinely perform saturation measurements, have told us that pulse</li> </ul>
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		<p>oximetry adds to their assessment and enables them to escalate concerns to the medical team much more clearly and specifically.</p> <ul style="list-style-type: none"><li>- The use of the term “false positive” is misleading in this context. Abnormal saturations suggest hypoxia. Whilst this may resolve without intervention, this is a significant finding and as a clinician, I do not want hypoxic babies on the postnatal ward or discharged home, unless they have been carefully reviewed and I am confident that this is a transitory phenomenon.</li></ul> <p>Given that much of the current NIPE content has no/ minimal evidence of any real benefit, it does not make sense to exclude pulse oximetry on the basis of some speculative “harms” and in the face of high quality research supporting it’s use.</p>

**39.**Sam Oddie

<b>Name:</b>	Sam Oddie	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>			
<b>Role:</b>	Professor Sam Oddie  Consultant Neonatologist Bradford Neonatology  Honorary Professor Hull York Medical School  Clinical Lead, National Neonatal Audit Programme  Member of NSC Pulse Oximetry Expert Advisory Group		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>Yes</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Whole document	Whole document (see text)	<p><b>Response to NSC consultation on Pulse Oximetry Screening (POS)</b></p> <p>THE NSC have sought consultation on the question:</p>	

		<p><i>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).</i></p> <p>The answer to this question is that, if a detailed read is made of the available evidence in the NSC consultation documents, sufficient evidence is presented to make clear that the NSC should have made a different recommendation. Had the NSC presented further information, from external literature, which they unaccountably chose to ignore, the case in favour of implementation of POS would have been still clearer. There are serious concerns about the presentation of information as part of this consultation, which is inaccurate, incomplete, over long, and set out with grossly insufficient clarity. The information presented is unsuitable for a public consultation, and therefore fails in its aim of accountable decision making. Among the problems with the consultation are the following:</p> <p><b>1) Insufficient emphasis given to benefits of POS</b></p> <p>In the covernote document, the NSC say:<sup>1</sup>  <i>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.</i></p> <p>This language is very revealing. It says, in words, that the review concentrated on the harms and benefits of negative outcomes (“<i>over-diagnosis, over-treatment, false positives, false reassurance, uncertain findings, and complications</i>”). Review of the covernote and associated documents makes clear that little emphasis is given to the benefits that may be accrued by implementation of POS. In particular the reduction in mortality from CCHD seen in very large studies appears to be</p>
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unmentioned by the NSC.<sup>2</sup> Unaccountably, the NSCs review is dominated by parochial UK based data, and ignores the benefits demonstrated in very large diagnostic studies, and effectively summarised in the relevant Cochrane review.<sup>3</sup>

Further, there is an element of bias demonstrated by the NSCs handling of this subject. While the NSCs documents are usually of high quality, and high academic rigour, this is sadly not the case in the handling of POS. The errors apparent in the NSCs evidence review all appear to lean in the direction of resisting implementation of POS, despite multinational (and within UK) implementation. Examples of these errors are noted below. That clinicians have had to wait for the NSC to catch up shows the NSC in a poor light, at best. At worst, from the perspective of one who has seen significant clinical benefit from POS, the NSCs position will be seen as a reason for hospitals to abandon their existing evidence based adoption of this excellent practice. International evidence suggests this will increase UK infant mortality still further.<sup>4</sup>

## 2) Suggestion that current screening for CCHD does not need to be enhanced

The NSC position appears to be that:

*...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.*<sup>1</sup>

Aside from the fact that the covernote effectively ignores the benefits of POS in detecting CCHD, this assertion demonstrates that the NSC has both ignored the advice of its own reviews as to benefits, and as to whether there might be important harms associated with cases the NSC chooses to regard as “false positive”. (I dispute the utility of the expression “false positive” to describe screen positive cases who do not turn out to have





		<p>congenital heart disease – from any rational parent perspective a false positive case can only be one where there is no significant pathology demonstrated).</p> <p>The NSCs duty is to balance benefits from proposed screening against associated harms. It has failed in this duty. The benefits of POS are clearly laid out in the accompanying documents, but are buried and invisible to all but the most dogged of readers. As an example, the research review states:<sup>5</sup></p> <p><i>The 2016 pilot study findings supported those of the 2014 review which presented evidence to demonstrate that pulse oximetry, as an extra stage in the clinical examination, increases the detection rate of critical or life-threatening CHDs at the newborn screening opportunity.</i></p> <p>Further evidence of benefit can be seen in the Knowles review posted on the NSC site, which states:<sup>6</sup></p> <p><i>There is now considerable research evidence to demonstrate that pulse oximetry, as an adjunct to clinical examination, increases the detection rate of critical or life-threatening CHDs at the newborn screening opportunity.</i></p> <p>Further the Knowles review makes clear that the so called criteria for a screening test are essentially already met by the time of its publication in 2014.</p> <p>(It is timely to consider the questions raised by Knowles in 2014 for the NSC pilot, and to ask which of the questions remain unanswered:</p> <ul style="list-style-type: none"><li>• <i>determining screening coverage</i></li><li>• <i>appraising the impact of antenatal diagnoses on pregnancy terminations and CHD prevalence at live birth</i></li><li>• <i>defining optimal test procedures for oxygen saturation measurement and newborn clinical</i></li><li>• <i>clarifying and testing pathways for referral for further investigations after a screen positive result</i></li><li>• <i>the development of information for parents and health professionals across the antenatal and newborn continuum</i></li><li>• <i>instituting a training curriculum for midwives and others involved in newborn screening using pulse oximetry</i></li></ul>
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- *establishing routine data systems*

I would strongly argue that these questions have received satisfactory answers already)

The NSC expert panel that met in June 2018 were noted by the NSC as believing:<sup>7</sup>

*It was therefore acknowledged that PO is an effective addition to the current screening procedures for Critical Congenital Heart Defects (CCHD)*

Therefore the evidence of benefit is clear, even within the NSCs own publications.

However, no such summary statement of benefits appears in the covernote.<sup>1</sup>

In having a position against POS along these lines, there is a clear assumption to be made that current clinical screening is adequate. However, the data summarised by Knowles et al (and shown on the NSC site) make clear that for CCHD cases, around half remain undetected by clinical examination under existing screening procedures (see p 15 of “Screening for Congenital Heart Defects” Knowles et al 2014).<sup>6</sup> The NSCs unwillingness to countenance implementation of POS will do harm by failing to enhance the existing screening programme.

### **3) Suggestion of Important net Harm**

The evidence that there is harm as a result of POS is, the NSC argues, real. The NSC convened an expert panel to review data generated by the pilot. The perspective of this group of clinical experts is at the very least under represented in the NSC documents, and in particular in the covernote which will be the limit of reading of many non expert consultees. Put more bluntly, the NSC seems to be showing clear signs of choosing to disagree with its own experts, for reasons that are unclear.

Specifically, the NSC say:<sup>1</sup>



		<p><i>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).</i></p> <p><i>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).</i></p> <p><i>20 There were 8 babies who had no diagnosis and the remaining 135 babies that were identified as hypoxic were healthy on investigation</i></p> <p>Any reader of these points would most reasonably infer that a large number of babies were admitted to neonatal units and/ or were investigated. This is false, as the NSC POS pilot makes clear, only 114 were admitted to a neonatal unit.<sup>8</sup> Of these, only 110 had investigations – which underlines a further false impression conveyed by point 20 above. The 135 referred to in point 20 were deemed healthy by a repeat screening, and not further investigation. This is important because in the view of the expert group, as well as in the view of jobbing clinicians, a threshold for even minor or moderate harm is not met until there is either separation of a baby from their mother, or investigations such as placement of an intravenous cannula.</p> <p>Point 19 above is the clearest statement made by the NSC that they disagree with their own expert panel. The NSC statement says babies diagnosed with other serious medical problems “<i>may</i>” have benefitted from early identification. However, the perspective of the expert panel was far less equivocal. The notes of the panel make clear that in many cases, the natural history of the conditions without treatment was in fact death. This respondent was a member of the</p>
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expert panel. It is specious to suggest that earlier diagnosis would not be advantageous in such cases.

The impression is not given that in fact of babies who were screen positive only a very small proportion (0.08%, 25 babies) were admitted, investigated and ultimately found not to have benefitted from identification.<sup>1</sup> This is despite the fact that this was the view of the expert group.<sup>7</sup> It would be entirely legitimate for the NSC to disagree with its own expert group, but to do so without making clear that it was doing so, or providing any evidence to support its perspective appears illogical and incoherent at best.

#### **4) Examples of inaccurate statements in consultation documents**

Covernote – statement 20:

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

This is false. The only investigation most of these patients received was a second application of a screening procedure. I imagine the NSC will be very uncomfortable about such an important, and yet basic, error in a public facing document.

The further document: Research Review<sup>5</sup> states:

*The pilot data identified that of 239 babies testing positive with PO screening, 82 (or 86) patients did not have CHD but did have a significant other non-cardiac condition and 135 babies were in fact healthy. All of these screen positive babies had further investigations.*



		<p>This is untrue, for the reason outlined above. Reapplication of a pulse oximeter can not be seen as an investigation, and the expert group did not classify this as a harm.</p> <p>In my view the NSC should review the entire set of documents for errors such as these, and republish them. The duration of the consultation should be extended, and the reason for this extension (namely false statements in the consultation documents) be made clear. I believe the NSC should review how such errors came to be made, and publish the results of this review.</p> <p><b>Clinicians' Perspective</b></p> <p>We have been conducting POS in my hospital since 2010. At the time of introduction, I was the only clinician on site with echocardiography experience. I had concerns that the additional echo load might be a problem for my basic skills. This proved unfounded, as the subsequently published evidence base has shown. In practice, our screening has been delivered by midwifery and midwifery support staff. Screen positives are managed in accordance with the Pulseox and NSC pilot protocols. Very early discharges are managed with an approach including POS. We have occasional admissions to the neonatal unit, and many infants develop clinical signs such as tachypnoea after admission. In line with published literature, we have seen patients admitted with a wide variety of serious pathologies, such as early onset infection/ septicaemia, meconium aspiration syndrome, as well as congenital heart disease of a variety of forms. Local clinicians are strongly supportive of implementation. During the same period I can vividly recall being asked to attend a patient in the emergency department who had been born in another hospital and who presented in collapse from an undiagnosed CCHD. In retrospect, there was good evidence this devastating case might have been detected had effective POS been in place in the neighbouring</p>
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hospital. This is but one dramatic example of why I will never willingly abandon POS.

This consultation is seriously problematic, in part because the number of cases of the target condition will remain small even in the hands of paediatric emergency care practitioners in the largest tertiary centres. CCHD is rare. The NSC has understated the potential for benefit, and is not communicating with groups best placed to note the scale of patient benefit to CCHD cases.

The NSC should play its part in supporting earlier diagnosis, because there is only a small amount of harm to a small number of screen positive well patients, but a large amount of gain to be accrued by a similar number of those who have the target CCHD conditions. The evidence of clinical gain, including mortality reduction, is likely to apply to UK populations. This is important because UK infant mortality is rising.<sup>9</sup> It is very likely that those screen positive cases with non CCHD pathologies are major beneficiaries.

Professor Sam Oddie

Consultant Neonatologist Bradford Neonatology

Honorary Professor Hull York Medical School

Clinical Lead, National Neonatal Audit Programme

Member of NSC Pulse Oximetry Expert Advisory Group

References:



		<ol style="list-style-type: none"><li>1) <a href="https://legacyscreening.phe.org.uk/documents/pulse-oximetry/Consultation%20covernote%202019.pdf">https://legacyscreening.phe.org.uk/documents/pulse-oximetry/Consultation%20covernote%202019.pdf</a></li><li>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. <i>JAMA</i> 2017; 318: 2111–18.</li><li>3) Plana MN, Zamora J, Suresh G, Fernandez-Pineda L, Thangaratinam S, Ewer AK. Pulse oximetry screening for critical congenital heart defects. <i>Cochrane Database Syst Rev</i> 2018; 3: CD011912.</li><li>4) Oddie SJ, Stenson B, Wyllie JP, Ewer AK. UK consultation on pulse oximetry screening for critical congenital heart defects in newborns. <i>The Lancet</i>. Online July 1st 2019. <a href="http://dx.doi.org/10.1016/S0140-6736(19)31515-6">http://dx.doi.org/10.1016/S0140-6736(19)31515-6</a></li><li>5) <a href="https://legacyscreening.phe.org.uk/documents/pulse-oximetry/PO%20Research%20Review.pdf">https://legacyscreening.phe.org.uk/documents/pulse-oximetry/PO%20Research%20Review.pdf</a></li><li>6) <a href="https://legacyscreening.phe.org.uk/documents/pulse-oximetry/CHD%20and%20PO%20First%20Review%20Doc.pdf">https://legacyscreening.phe.org.uk/documents/pulse-oximetry/CHD%20and%20PO%20First%20Review%20Doc.pdf</a></li><li>7) <a href="https://legacyscreening.phe.org.uk/documents/pulse-oximetry/Notes%20of%20workshop%20June%202018.pdf">https://legacyscreening.phe.org.uk/documents/pulse-oximetry/Notes%20of%20workshop%20June%202018.pdf</a></li><li>8) <a href="https://legacyscreening.phe.org.uk/documents/pulse-oximetry/NPOSP%20End%20Project%20Report.pdf">https://legacyscreening.phe.org.uk/documents/pulse-oximetry/NPOSP%20End%20Project%20Report.pdf</a></li><li>9) Office for National Statistics. UK drops in European child mortality rankings. 2017. <a href="https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/childhealth/articles/ukdropsineuropeanchildmortalityrankings/2017-10-13">https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/childhealth/articles/ukdropsineuropeanchildmortalityrankings/2017-10-13</a> (accessed June 11, 2019).</li></ol>
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40. XXXX XXXX

To whom it may concern,

I am writing to express my concern at the decision to not introduce pulse oximetry as a screening test after birth across the UK. I personally think this is an error and should be reconsidered.

My XXXX XXXX was born in XXXX XXXX and had displayed some issues in regards to XXXX XXXX weight gain not following the growth chart as expected. This was put down to issues in regards to low milk supply and breastfeeding but also lead to to hospital stays to review volumes for combination feeding. During my sons third hospital stay at doctor listened to his heart and heard an 'innocent murmur' but referred us to cardiology to rule out anything.

When my XXXX XXXX was XXXX XXXX old we arrived at the cardiology appointment and that day were admitted to hospital as my son had was diagnosed with a cardiac abnormality that had been previously undetected during scans in pregnancy and the three prior hospital stays. Our consultant says that either his abnormality is quite rare or it is usually something that goes undetected so we were very lucky that it had been picked up. XXXX XXXX diagnosis was that XXXX XXXX had a hypoplastic cervical aortic arch with some subclavian arteries also being misplaced anatomically. This had been causing his heart to have to work much harder than normal to compensate for the pressure changes within his own system and so he required open heart surgery when he was five months old.

The only reason this had been picked up was due to my own little milk supply and breastfeeding. If pulse oximetry had been performed post birth it would have been picked up much sooner and could have been addressed sooner also.

I fear that there will be children that my son will call his friends who will go on diagnosed for years until it is potentially too late to resolve an issue. Pulse oximetry screening post birth will result in saving many lives for being such a minor procedure.

Please reconsider and make this a standard across the health care services in the UK

Your sincerely

XXXX XXXX  
XXXX XXXX



41. XXXX XXXX

To whom it may concern,

I disagree with your findings and believe that the pulse oximeter test should be performed as part of the babies first checks.

My XXXX XXXX was born with a severe congenital heart defect, which wasnt picked up on any scans and he wasnt born a blue baby. Instead it was picked up on the off chance at 24 hours old when XXXX XXXX lips went dusky. We were still in hospital as XXXX XXXX was born via cesarean section. If, however, I had given birth naturally I would have already been at home with no idea that he had a heart condition. I would have had to watch my son turn bluer and bluer and then hope that an ambulance got to him in time and realised that his baby duct was closing.

Why would you put numerous lives at risk when the test takes a few seconds and could save thousands upon thousands of lives? Are their lives not worth the money or the few seconds of time it takes because they are newborns?

Kindest regards

XXXX XXXX (XXXX XXXX XXXX XXXX)



42. xxxx xxxx xxxx xxxx

Dear NHS

Please could you revise your decision to not recommend the use of a pulse oximeter with all new born babies.

My xxxx xxxx was discharged from hospital deemed well. At three months old xxxx xxxx had a spell and stopped breathing. xxxx xxxx had undiagnosed Tetralogy of Fallots. Luckily I was able to bring xxxx xxxx back, many parents would not.

If he had of had this simple test it would never of come to that. Please advise all maternity staff to complete this 2 minutes test.

Kind regards xxxx xxxx RNMH and my xxxx xxxx

xxxx xxxx < xxxx xxxx >

[Sent from Yahoo Mail on Android](#)

43.XXXX XXXX

<b>Name:</b>	XXXX XXXX XXXX XXXX	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	XXXX XXXX		
<b>Role:</b>	Consultant Neonatologist with Expertise in Cardiology, lead for cardiology		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>No</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
	False positives	In our experience this has not been as issue. Pulse oximetry screening is well embedded in our Trust, performed at the time of NIPE by midwife or junior paediatric trainee. It is accepted well by parents.	
Sensitivity analysis by Hunter and Knowles 2012, Pg 71	Cost effectiveness	The analysis by published in 2014 comments on PO being 92% likely to be cost effective even if antenatal diagnosis rate is 90% at willingness to pay £100,000/timely diagnosis when target condition is cCHD. This conclusion should still apply to the data from 2015 Pilot for timely diagnosis of cCHD if willingness to pay is £20,000 - £30,000/QALY as there would have been 24 cases of timely diagnosis/100,000 babies screened. (24x5x20,000)	
	Local experience	1. Trust is currently dealing with a complaint where a baby with coarctation presented acutely unwell with acidosis on day 6 of life, having stayed in hospital for 4 days due to feeding issues and there were no cardiovascular abnormalities on examination during this time. This was before PO was being	



		<p>used routinely in our Trust. The baby underwent surgery and survived (long term outcome yet unknown). In this scenario one would be unable to reassure parents that everything possible to make an earlier diagnosis was done.</p> <p>2. We have recently diagnosed a baby with hypoplastic arch on day 1 of life due to failed PO. Underwent surgery with good outcome.</p>
	Staff experience	<p>We are a level III neonatal unit and have been using PO for last 3 years. We have found it to be a simple and acceptable test and have not identified any significant concerns expressed by the frontline staff who use it.</p> <p>I am the lead for cardiology in our trust and represent the views of neonatal and midwifery staff who feel inclined to continue PO screen.</p>

44. XXXX XXXX

Dear sir/madam

I would like to express my support for this screening for all infants. I would like you to consider this email as such. I believe the pulse oximetry screening should become an additional test at birth.

Yours faithfully

XXXX XXXX

Get Outlook for Android

45.XXXX XXXX

To the Committee

I am a health professional with a teaching commitment. I have little experience of research and none of the subject of ethics or of policy-making. I make my decisions in practice based on evidence and an experience. So I'm looking at this from a naive point of view, but that makes it easier to see clearly what is wrong with the decision made

I know it is possible to look at recent figures from the neonatal units that do POS and from those who don't, and compare figures from each. You can also compare figures in the unit with POS to a year before PulseOx started. And you could ask parents whose babies were subjected to further testing whether they were still displeased about that testing once the baby was home and well.

And then, in this ideal and theoretical world, would you be able to look at the figures showing that POS had picked up babies with CHD that otherwise would have been missed, and feel comfortable? People like me struggle to understand that it's acceptable to let babies die to avoid a few tests that, to everyone's relief, turn out to be to have been a necessary.

And if cost is the deciding factor, how can it be argued that the costs of the tests performed on the well babies plus the cost of early treatment of CHDs is more than the long-term treatment of babies made chronically unwell by late diagnosis of CHD's?

Finally, using the word 'disadvantages' would be more fair, reasonable and sensible than the word 'harms'.

I urge you to reconsider.

Sincerely

XXXX XXXX



46. xxxx xxxx

To committee members

I would impress on the committee to re-look at the evidence they have based their decision not to make pulse oximetry part of newborn routine testing. My xxxx xxxx was in heart failure by the time xxxx xxxx was diagnosed 72 hours after birth and we very nearly lost him... this simple test at birth would have avoided the trauma involved for him and for us..

Please please rethink

xxxx xxxx

Sent from my iPhone

**47.Dr David Quine**

<b>Name:</b>	David Quine	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	NHS Lothian		
<b>Role:</b>	Neonatal Consultant		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>Yes</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
General comment	Thanks for a really good and useful review of the evidence regards pulse oximetry screening for CHD. From seeing all the critical comments on Twitter etc regards your review I felt I needed to read and make comment regards your review. I think that you have done an appropriate review and critical review of the evidence for and against oxygen screening and should stand by your outcomes against the onslaught of people with invested interests. Just because we can do screening tests does not mean we should. Screening tests need unbiased, critical review and outcomes of these reviews should be respected. If the evidence for screening is not there then further research is needed not a rush to implement at all costs.		



48.XXXX XXXX

<b>Name:</b>	XXXX XXXX	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>			
<b>Role:</b>	XXXX XXXX	XXXX XXXX	
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>No</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<p><i>Please use a new row for each comment and add extra rows as required.</i></p> <p>I support the conclusion of the national screening committee that using pulse oximetry should not be recommended. Further research is required to ascertain the effect in terms of over investigation, anxiety and cost of the large numbers of false positive babies which will be identified if this screening is introduced. In addition, in my experience significant life threatening left heart defects can give reassuring normal saturations and therefore there is a false negative problem with this screening as well.</p>	

49.xxxx xxxx

Dear Sirs ,

This is such a easy test to perform .

In the pilot study significant diseases were detected ,congenital heart disease ,sepsis and respiratory illness earlier than otherwise .

If a baby developed symptoms poor feeding ,unusual colour ,fast breathing the first test that is performed is pulse oximetry .

Early diagnosis means a better outcome and has been the rationale for antenatal screening for congenital heart disease with echocardiography for many years .Late diagnosis of sepsis has worst results nothin mortality and long term morbidity.

Pulse oximetry is routinely used to check for (screen for ) problems during general anaesthesia even in low risk routine cases .

No serious harm was generated . Much is made of a lack of comparative model .Not an unusual occurrence in medicine .

I would strongly support the neonatal pulse oximetry screening program .

Thank you for the opportunity to comment .

xxxx xxxx

xxxx xxxx Sent from my iPad



Do you consent to your name being published on the UK NSC website alongside your response?

Yes

No

Section and / or page number	Text or issue to which comments relate	Comment <i>Please use a new row for each comment and add extra rows as required.</i>
	Roll out of service	It is vital this service is provided across the UK. This should be available to all areas and not just be based on a

postcode lottery.

51.xxxx xxxx

I am writing this email for you to reconsider pulse oximetry screening on all newborn baby's my grandson xxxx xxxx was born xxxx xxxx 2012 a healthy baby xxxx xxxx as we thought. at 6 weeks old xxxx xxxx became seriously ill very quickly where an emergency ambulance had to take xxxx xxxx to hospital. on route xxxx xxxx suffered resperatry failure on arrival at xxxx xxxx xxxx xxxx had cardiac arrest. That afternoon he arrested a further 3 times, whitnessed by myselfe my husband, son and daughter in law, this will live with us forever.

xxxx xxxx was then transferred to xxxx xxxx childrens hospital and diagnosed with a rare tumour in the heart. xxxx xxxx had open heart surgery to remove the mass which also resulted in a mitral valve transplant . xxxx xxxx has had another 2 open heart operations since with more to come and countless hospital visits with a 60 mile round trip each time, and will spend his whole life on wharfryn.

We feel had pulse oximetry been carried out xxxx xxxx condition may have been diagnosed sooner, and the tumour removed without causing as much damage to xxxx xxxx heart and maybe not needing a life changing valve transplant and saving the familly the trauma of seeing there very precious xxxx xxxx & xxxx xxxx being ressusitated which will live with us forever.

yours sincerely

xxxx xxxx

52.xxxx xxxx

I wish to express my surprise that you are not proposing that pulse oximetry screen would occur on all new born babies.

I am aware that a pilot study showed that of 32,836 babies who had a pulse oximetry screen, there were 239 babies who tested positive for hypoxaemia.

- 14 benefited from early diagnosis and subsequent treatment
- 82 other conditions were identified
- 8 with no diagnosis
- 135 babies identified as hypoxic on further investigation

As a parent myself I would much prefer that low oxygen levels in my child were picked up as early as possible. I appreciate that there is a risk of unnecessary concern for some parents but provided parental anxiety is managed well by empowering them with information, surely the benefit of the early diagnosis for those who have conditions outweighs potential anxiety?

I understand that Most babies are picked up by the test and are healthy are correctly identified within an hour or two and are not admitted to the neonatal unit so there is not significant unnecessary pressure on the Neonatal unit. Indeed the pilot indicates that less than one in a thousand of those screen with an incorrect positive are actually admitted to the unit and are usually discharged within 12 hours

I therefore would ask that Pulse Oximetry Screening should occur for new born babies.

Regards

xxxx xxxx

Member of the NI Assembly

xxxx xxxx)



53.xxxx xxxx ( xxxx xxxx)

To Whom It May Concern,

It has come to my attention that it is the intention of the NHS not to include pulse oximetry as a mandatory test for newborn babies. I would like to explain how this test saved my son's life and urge you to reconsider.

My xxxx xxxx, xxxx xxxx, was born on the xxxx xxxx at full term following an uneventful pregnancy and normal foetal anomaly scan. Luckily xxxx xxxx was born in a large hospital where all newborns are examined by a paediatrician prior to discharge, I hate to think of the outcome had he been born in a midwife led unit or at home. The paediatrician detected a heart murmur but was not overly concerned, he planned to check xxxx xxxx again the next day before we left for home. At this check he brought a pulse oximetry machine. Upon using this machine xxxx xxxx's saturation levels were so low that he was immediately transferred to intensive care. The low saturation levels were unrelated to the murmur and caused by an additional heart condition called transposition of the great arteries. The murmur was related to a hole in his heart which would have been unlikely to cause him problems. I am thankful every day that the murmur was detected prompting the pulse oximetry test; had it not been performed we would have been sent home for outpatient follow up and Tom would have gone into heart failure in the following days. Luckily, Tom's condition was detected in time and he had open heart surgery the following week. xxxx xxxx is now a healthy three year old who has a completely normal life.

I urge you to reconsider this decision. Pulse oximetry is cheap, non invasive and causes no distress to the infant. Considering cost, it is significantly cheaper to treat an infant who is stable than one who is admitted in heart failure. What can be more important than saving babies lives?

I look forward to your response.

Kind Regards

xxxx xxxx

Sent from my iPhone

54. XXXX XXXX

Hi

I'm writing to express my concern about the decision not to include pulse oximetry in the standard tests for newborns. This seems like a very odd decision, based on the claim that it might be stressful for parents. It's far more stressful for parents to deal with congenital defects detected later in life, and lack of diagnosis can be very serious.

I was born with heart defects. They were detected by accident when I was admitted to hospital as a child, after an accident. I was lucky, and I had surgery to fix the issues when I was 7. Many children go undiagnosed, and this results in hundreds of deaths every year.

The fact that this could be avoided by a quick, cheap and non-invasive test is great. I really can't understand why it isn't being included in standard tests. It could save lives, and the reasons given for not using it are very wooly.

I hope the consultation and experiences from actually CHD patients will encourage you to reconsider that decision.

Regards,

XXXX XXXX

<b>Name:</b>	xxxx xxxx	<b>Email address:</b>	xxxx xxxx
<b>Organisation (if appropriate):</b>	xxxx xxxx		
<b>Role:</b>	Vice President for Science and Research		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><u>Yes</u>    <b>No</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
	See full comments below	<p><i>Please use a new row for each comment and add extra rows as required.</i></p> <p>The UK National Screening Committee is consulting on whether the evidence presented to it supports the Committee's decision to approve the recommendation against using pulse oximetry as an additional test in the newborn and infant physical exam (NIPE). Oddie and colleagues argue in a recent letter to the Lancet<sup>1</sup> that the Committee's decision is flawed. They cite evidence that contradicts the Committee's view in one specific respect, and argue for an alternative interpretation of the data from the NSC-commissioned pilot study of pulse oximetry.</p> <p>In response to the assertion that "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", Oddie et al cite North American data that "in a birth cohort of over 26 million infants, overall mortality from critical congenital heart disease was reduced by 33% after introduction of POS in individual states".</p>	





		<p>The NSC cover note for the consultation states that “A recent pilot study<sup>2</sup> 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.”</p> <p>Both the NSC and Oddie et al cite the results from the pilot study, but choose to emphasise different aspects of those results. For the NSC, the emphasis is on the high false positive rate – 143 of 239 – with the attendant potential for harm in respect of further unnecessary investigation, stress to families and possible transfer of infants. For Oddie et al, the primary emphasis was on the 96 of the 239 that had either critical cardiac disease, or another diagnosis (such as sepsis) that merited acute intervention, although additional work was cited suggesting that the perceived “harms” were generally limited in scope and severity. Oddie and colleagues are clear that oximetry does not replace clinical assessment, and variability in the establishment of the postnatal circulation may affect the reliability of testing before 24 hours of age.</p> <p>The NSC is recommending further research; Oddie and colleagues point out that other countries have already started using pulse oximetry as a screening test, that 40% of UK hospitals already use it in that role, and are pressing for immediate nationwide introduction.</p> <p>The Royal College of Paediatrics and Child Health promotes the well-being of children and their families. Infant and neonatal mortality is increasing in this country according to the Office for National Statistics,<sup>3</sup> and we are falling in the league table of developed nations on this metric. Mortality is highest in the groups with most deprivation, amongst whom Black Asian and Minority Ethnic groups are over-represented – coincidentally those in whom it may be more difficult to visually assess</p>
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		<p>perfusion and oxygenation. More needs to be done to improve outcome in these vulnerable infants.</p> <p>Whilst pulse oximetry may fail the NSC criteria, it seems that paediatricians weigh the balance of benefit and harm differently. It appears likely that if the NSC do not change their view and mandate the introduction of oximetry, paediatricians will take a pragmatic view on introducing pulse oximetry in the context of local need. The College will support them in that view, whilst encouraging further research to identify the factors which in combination will provide the optimal benefit (e.g. timing and repetition of testing) and possible harmful impacts from such testing.</p>
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1. Lancet. 2019 Jul 13;394(10193):103-104. doi: 10.1016/S0140-6736(19)31515-6
2. Newborn Pulse Oximetry Screening Pilot End Project Report. Public.screeninghelpdesk@nhs.net; 2016.
3. <https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsregistrationssummarytables/2017>

56. XXXX XXXX

<b>Name:</b>	XXXX XXXX XXXX XXXX	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>			
<b>Role:</b>	Neonatal Consultant		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><del>Yes</del>      <b>No</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Page 1, Consultation covernote	<p>“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).</p> <p>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.”</p>	<p>This is a general comment about the conclusions drawn by the review.</p> <p>I was a junior doctor when the PulseOx study was carried out, have worked as a neonatal consultant in hospitals using the oxygen saturations in the PulseOx method and am a parent.</p> <p>I am staggered to see the words “harms associated with screening”. Surely it is better to know that a baby has a low level of oxygen than not?</p> <p>The further investigations following a positive result may include a heart scan or blood tests or a chest x-ray. These should be done only after clinically reviewing a patient and making an informed clinical decision. I regularly see newborn babies who have been found to be unwell/have an infection etc at an earlier stage by using the PulseOx test. I have never heard a parent or family member express displeasure that a review and tests were done after a PulseOx test.</p> <p>I have also found that less babies are found at a moribund, sick state after earlier pickup.</p>	

57. **XXXX XXXX**

To whom it may concern:

It has been brought to my attention that in there is life-saving test to identify newborn babies with critical congenital heart defects.

Researching into this further I have also learnt that the NHS is advising against all newborn babies having this test taken after birth despite it saving lives according to the extensive research and study undertaken by University of Birmingham.

I think this is a fatal under sight by the NHS to not screen every newborn and I would like my views included into the consultation.

Regards

**XXXX XXXX**

58. XXXX XXXX

My view is this test should be rolled out nationally. I am fortunate enough to live in XXXX XXXX and have had both of my children delivered at XXXX XXXX. My first child was born before the pulse oximetry trial and my second child was born in XXXX XXXX during the trial.

I outline below my post-natal experiences with both of my children.

XXXX XXXX, who is now 11 was born at XXXX XXXX on a Sunday afternoon in September XXXX XXXX. All of my scans and treatment during my pregnancy with him were carried out there too. XXXX XXXX was 9 days overdue and was delivered by emergency Caesarean section. At the time of XXXX XXXX birth he had an undiagnosed heart condition. On the morning following XXXX XXXX birth he had all the medical tests that new born babies have and the young doctor who examined him discovered a heart murmur-this resulted in him being transferred to the neonatal unit at BWH. He was kept there overnight and on Tuesday morning I was told he'd got a chest infection and was being treated with antibiotics. I was not allowed to take XXXX XXXX back to the ward with me because XXXX XXXX had 'been a naughty boy' and had vomited after feeding. He was still being treated for a chest infection on the Wednesday and luckily I was still an inpatient too. On the fourth day after his birth I was called down to the neonatal unit at around 6.00am and was told XXXX XXXX has a serious cardiac condition. A scan was carried out by XXXX XXXX from XXXX XXXX Children's Hospital and we were told XXXX XXXX had Unbalanced AVSD with small left ventricle. XXXX XXXX is treated as a child with Hypoplastic Left Heart Syndrome. Following diagnosis and an emergency baptism, Freddie was blue lighted to XXXX XXXX Children's Hospital where 1 week later he received life saving surgery. He has gone on to have all 3 stages of surgery and is thriving.

XXXX XXXX was born in XXXX XXXX. I had many scans during my pregnancy with her because of the complications I had had with XXXX XXXX. XXXX XXXX was 17 days early and was also delivered by emergency Caesarean section. When I was transferred to the ward a couple of hours after delivery, Lily was quite blue so the nursing assistant carried out a pulse oximetry test which showed her SATS were perfectly normal. This immediately put me at ease.

I will never know if a pulse oximetry test at birth would have sped up the process of diagnosis for XXXX XXXX, but it may have done. XXXX XXXX little body went into organ failure and nobody expected him to survive. If one little test can prevent babies from suffering the way Freddie did then it has to be worth it.

The test is quick and painless. It would ultimately save the NHS money by detecting medical issues in their infancy. The peace of mind it offers to families is priceless.

Thanks for reading my views on the issue.

Regards

XXXX XXXX

59. xxxx xxxx

Dear National Screening Committee,

I am a neonatal grid trainee in Birmingham and have completed my entire paediatric training within the region and so pulse-oximetry has been my "norm". The one hospital that did not use it made me feel a little uneasy. I fully support the use of pulse-oximetry and I hope I can shed a little light as to why.

My experience at pulse-oximetry is very positive. I have reviewed many babies with a positive pulse-oximetry result of "failed pulse-ox" and find that whilst most do not have a (critical) congenital cardiac defect, many have illnesses that require respiratory support and admission to the neonatal unit; including ventilation. Regardless of the illness, it cannot be argued that it is better for these babies to collapse either on the postnatal ward or at home before they receive the treatment they need. There is evidence that babies with critical congenital cardiac defects do worse if they present in shock - I would argue that this is something to avoid given the low pick up with antenatal screening; as low as 20% in some centres. You have suggested waiting until babies are symptomatic before checking saturations, I would argue this is far far too late and find the suggestion to wait abhorrent.

I find pulse-oximetry very useful in reducing unnecessary term admissions. I have reviewed many term babies shortly after birth with some respiratory distress and by using pulse-oximetry, I am able to keep most of them with their mother and thus prevent unnecessary admissions. Parents actually find this reassuring.

When babies require admission to the neonatal unit all parents are scared; regardless of the cause. Indeed, when their child is unwell, most parents are afraid; I cannot imagine the fear of your baby being blue. I have found all parents to be incredibly grateful that such a simple test has detected a problem. If it is determined that the baby does not have a serious diagnosis such as a cardiac defect or pneumonia, parents are relieved but do not complain about the cannula and x-rays - they say thank you for checking my child.

The Birmingham pilot study demonstrated that parental anxiety is not increased following a positive screening and that 80% of the babies admitted to the neonatal unit following a positive screen had a potentially serious condition. Length of stay is not markedly increased as babies who are unwell require treatment and hospitalisation and babies who are well are discharged with an extended stay of an hour or two.

In summary, I believe pulse-oximetry is an essential part of neonatal screening and I will stand alongside Professor Ewer and the University of Birmingham in pushing for this to be carried out nationally.

Yours Sincerely

xxxx xxxx ST7 Neonatal Grid Trainee

60. XXXX XXXX

Dear Pulse oximetry screening committee,

I would like to endorse the pulse oximetry screening as an addition to NIPE as a national screening tool for the following reasons.

1. Currently only 50% of CCHD (at best) are detected by antenatal scan and NIPE. This increases significantly with pulse oximetry. Therefore significantly reducing the potential of a post natal collapse due to a duct dependant heart lesion and therefore survival chances.
2. It is a cost effective and simple test that is both acceptable to parents and staff once implemented.
3. It is a vital tool in clinical decision making for a baby
4. I understand one of the the screening committee's concerns is the rate of false negatives the test can bring up. In response to this I would have two comments:
  - I. I do not have statistics for this but I have noted a reduction in false negatives as staff have become accustomed to the equipment over time.
  - II. False negatives for CCHD are still hypoxic babies on the post natal ward. This has been a vital tool in detecting babies with sepsis before they are showing any outward clinical signs of sepsis The screening committee should consider if they are happy for hypoxic septic babies to be discharged home as a result of false negatives'

Please consider carefully all the above points in your assessment of whether to recommend pulse oximetry as a national screening tool for CCHD.

Kind regards.

XXXX XXXX

ANNP

Birmingham Women's and Children's NHS Trust.

**61.Lawrence Miall**

<b>Name:</b>	Dr Lawrence Miall	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	Leeds Teaching Hospitals NHS TRust		
<b>Role:</b>	Consultant Neonatologist with expertise in Cardiology		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>Yes</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
6	False positive rate and actions	<p>We have been doing saturation screening in Leeds since 2009. We use a single post ductal measure <math>\geq 95\%</math> as cut off. We do the test at the time of the NIPE exam which is usually within the first 12-36 hours of life.</p> <p>We find the test to be very well accepted (if anything appreciated) by the parents and of very little discomfort to the baby. Once the monitor has been purchased the cost is minimal, other than a few minutes of time. We have encountered far fewer false positives than we expected and the majority of these have had significant other pathology such as pneumothorax, PPHN, sepsis. The number of babies without CHD requiring further assessment by cardiologists has been minimal, as paediatric/neonatal assessment was able to diagnose and treat the majority where an alternative cause was found. I feel the assessment of the implication of false positives in this study does not represent the reality that all parents are inherently looking for reassurance that their newborn baby is health and well and an objective measure with SAO2 is able to do this more effectively than clinical examination alone, which is highly variable in expertise. Clinical cyanosis is notoriously difficult to detect visually in newborn babies.</p> <p>Regardless of the national decision we would plan to continue saturation screening in our local institution, we are that convinced of its benefits and lack of significant harms.</p>	



62. xxxx xxxx

<b>Name:</b>	xxxx xxxx	<b>Email address:</b>	xxxx xxxx
<b>Organisation (if appropriate):</b>			
<b>Role:</b>	Parent		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">Yes      No**</p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<p><i>Please use a new row for each comment and add extra rows as required.</i></p> <p>Our baby xxxx xxxx, xxxx xxxx was born with an undiagnosed heart condition (Hypoplastic Left Heart Syndrome) in August 2008. Sadly this had not been picked up during our 20 week scan or at birth. We went home 36 hours after xxxx xxxx was born and he became unwell 24-36 hours later. By the time we had returned to hospital and our son was examined at A&amp;E it was too late. We were sent up to xxxx xxxx Hospital in London by emergency ambulance and despite numerous attempts by both hospitals to stabilise our son, within 2 hours, our baby died. As you can imagine, this was a huge shock to our family. We had no idea there was anything wrong with our xxxx xxxx. Our eldest xxxx xxxx was left without his brother and we lost all the hopes and dreams we had had for our little boy. His death has left a gaping hole in our family. Had his condition been picked up sooner – either at his 20 week scan, or even at birth – we would have undoubtedly had choices and more importantly, preparation. As it was, we had neither of these. We believe the pulse oximetry test would save many families from the heartache we suffered and we support the campaign to have pulse oximetry tests made compulsory for all newborns. It is such a simple test and while it may not help everybody, why would you not allow such a non-invasive test to be available for parental peace of mind? We hope that you will seriously consider the statements sent to you from families and campaigners and think of all those families that could benefit from the pulse oximetry test. It is 2019, we do not believe that so many babies should be still be dying from undiagnosed heart conditions. Thank you for reading this statement.</p>	

63. XXXX XXXX

Yes yes yes ABSOLUTELY they should be done! They save lives!

How many babies might go home with an undiagnosed heart condition and die or become seriously ill without this piece of kit?



64. XXXX XXXX

I would like to submit my views regarding the pulse oximetry screening being available to all babies. I believe that this is critical screening for all newborns at time of birth, and will save lives.

Kind regards,

XXXX XXXX

This test saved a friend of mine's baby's life the day they were due to leave the hospital I dread to think what would have happened had it not been picked up, this little girl is now a happy toddler after heart surgery at only a couple of days old, this test should be without a doubt mandatory !

66.Liz McKechnie

<b>Name:</b>	Liz McKechnie	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	Leeds Teaching Hospitals Trust		
<b>Role:</b>	Neonatologist		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">Yes</p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
General comment on whole decision	<p>The recommendations of the pilot are to implement. The economic assessment was unable to come to a conclusion. We have used pulse oximetry as part of our Newborn Exam for nearly 10 years and it has saved many babies from being discharged home with an undiagnosed cardiac condition. It is a short time parents are left anxiously wondering if their baby has CCHD or not and they would happily accept that – if communication is good, support appropriate and their baby is diagnosed as having a normal or abnormal heart.</p> <p>The test is cheap and fulfils every screening test criteria thrown at it. Most hospitals will have a paediatrician able to echo the baby and discuss via telemedicine any concerns.</p> <p>It is scandalous that this test is potentially being withheld from patients.</p>		

67. XXXX XXXX

The removal of this would be such a negative move for a number of reasons

1. It's a quick non invasive test
2. It does pick up some of the more subtle abnormalities that may need follow up and also means that parents can be informed early
3. Parents often worry about the heart and whilst fetal scans are getting better, some cardiac conditions are missed.
4. The idea that this increases parental anxiety is based on what? Yes parents are initially anxious but once the diagnosis is clarified one way or another they are reassured that at least it was picked up, yes we are lucky to have on site Echo expertise, which reduces the anxiety, but parents that are having to be transferred are generally happier that a definitive diagnosis is being made.
5. The potential back lash from parents groups when a heart defect is missed and the baby is an SID or in extremis, when a potential early warning screening test has been withdrawn.

It would be very interesting to hear from BLISS and cardiac charities on this move, especially as it cannot be done for financial reasons as the kit has all been bought!

Bw

XXXX XXXX

XXXX XXXX

XXXX XXXX

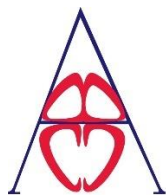
XXXX XXXX



68.xxxx xxxx xxxx xxxx

Yes please, this MUST be a necessity.

69.Dr Alan Magee



BRITISH CONGENITAL CARDIAC ASSOCIATION

UK National Screening Committee  
PHE Screening  
Floor 5  
Wellington House  
133-155 Waterloo Road  
London  
SE1 8UG

17<sup>th</sup> July 2019

Dear UKNSC,

Re: Pulse-oximetry screening for critical congenital heart defects NSC Consultation

On behalf of the council of the British Congenital Cardiac Association, I would like to respond to the UK National Screening Committee Consultation on the use of pulse oximetry as an additional test in the Newborn & Infant Physical Exam. The BCCA is the only body that represents the interests of everyone looking after children and adults with congenital heart disease including physicians, surgeons, nurses and cardiac physiologists. As such we are determined to improve outcomes for congenital heart disease and one of the major ways to achieve this is by early detection.

We understand that earlier this year the NSC reviewed pulse oximetry and decided not to introduce routine pulse oximetry for the detection of critical congenital heart disease (CCHD) in the newborn the reasons for which are given in the Consultation cover note. I would like to respond to each reason you gave in turn:

- 1) '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'

Data from the NSC UK pilot in reporting from 2015 showed that the positive test rate was between 0.7 and 0.8%. Of those who turn out not to have a cardiac condition up to 80% have a significant illness requiring treatment such as sepsis or pneumonia. Therefore for the vast majority of babies testing positive will require admission to the neonatal unit and further investigations purely on clinical grounds. In addition, the measured anxiety scores in mothers were not significantly higher in mothers of neonates with false positive results compared with mothers of those with true negative results.



- 2) 'For many of these babies, further investigations will not be necessary and the baby will be identified as healthy. This is a false positive result.'

This statement is not supported by the evidence. In the pilot study, only a minority 23 out of the 32597 screened had minor respiratory conditions which delayed discharge to a maximum of 12 hours and had unnecessary investigations in the form of blood tests and X-rays. In addition positive testing has not led to an increase in the demand for echocardiography.

- 3) '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.'

This is clearly not true. Neonates are still presenting acutely unwell due to CCHD which has not been detected on antenatal scans. Although ante-natal detection is improving, it still only detects around 53.5% of CCHD in the UK with wide regional variation (National CHD Audit 2017-18, NICOR). An argument which has been advanced is that with improved prenatal detection, pulse oximetry screening is unnecessary but recent Dutch data with a 73% prenatal detection data refutes this both on accuracy (1) and cost effectiveness, particularly when both cardiac and non-cardiac morbidity is considered. A large study in the US clearly (2) demonstrated that those states who implemented routine newborn screening using pulse oximetry was associated with a significant decrease in infant cardiac deaths of 33% between 2007 and 2013 when compared to states without these policies. Pulse oximetry screening is now mandatory practice for all babies born in the US.

Therefore we would strongly urge the NSC to review their decision not to recommend routine screening for Critical Congenital heart Disease.

Yours sincerely

XXXX XXXX

Dr Alan Magee  
President, British Congenital Cardiac Association  
Consultant Paediatric Cardiologist

#### References:

1. Narayan IC *et al.* Accuracy of Pulse Oximetry Screening for Critical Congenital Heart Defects after Home Birth and Early Postnatal Discharge. *J Pediatr.* 2018;197:29-35.
2. Abouk R, Grosse SD, Ailes EC, Oster ME. Association of US State Implementation of Newborn Screening Policies for Critical Congenital Heart Disease. *JAMA* 2017;381:2111-2118

70.Dr Una Mac Fadyen

<b>Name:</b>	Una Mac Fadyen	<b>Email address:</b>	xxxx xxxx
<b>Organisation (if appropriate):</b>			
<b>Role:</b>	Consultant Paediatrician		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">Yesx      No</p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Covernote section5	Clinical examination in the first 72 hours	Babies are increasingly discharged home within 24 hours increasing the risk of duct dependent lesions presenting after discharge	
Antenatal screening	Nuchal translucency	Nuchal lucency relates to risk of Down syndrome and not CHD which is a secondary finding and not the likely rationale for termination of pregnancy	
Covernote	Potential harms due to false positive results or unnecessary investigations etc	It is not solely an abnormal oximetry that causes parental anxiety which is equally or more related to abnormal clinical findings. Femoral pulse assessment requires skill and the newborn examiners vary in their experience and so competence both in their skills and ability to explain their clinical findings.	
Workshop July 2018	NNU admissions	Admission to NNU may not incorporate those infants who transfer direct to cardiology, surgery or PICU	
Covernote	False negative missed cCHD	Rhere can be few more distressing experiences for parents than seeing their presumed healthy baby collapse and even die in their home within hours or days of discharge home after birth. This was the scenario in the past when we had no effective treatment tp offer for HLHS but now surgery is a realistic option	



		<p>but with the chance of successful outcome greatly influenced by pre-operative status and risk greatly increased if the infant has been profoundly acidotic with poor systemic perfusion. Pre-clinical detection of the critical output compromise and maintained patency of the ductus arteriosus</p> <p>In addition the impact of suspected missed diagnosis on the newborn examiner can be seriously adverse</p>
Literature review	Addition to newborn physical examination	<p>Our local audit of introducing oximetry to our newborn examination procedure was readily incorporated, aided examiner confidence, did not add to time of examination or unacceptable added investigations, parents reported feeling reassured by the explanation leaflet</p>



71.xxxx xxxx

Dear National Screening Committee,

I have read that you have recommended that the pulse oximetry is not added to the mandatory new born screenings. I please urge that you re consider this.

My xxxx xxxx was taken to hospital when he was 3 days old with suspected dehydration- within 2 hours of being in hospital he was in complete heart failure and peri arrest. He was resuscitated and nearly died. Because of his late diagnosis he now has lots of scar tissue on his heart - something that bugs us all to this day as it could have been prevented. Our whole family have to live with this and so does my xxxx xxxx. Please, help other babies. This could change the lives of so many family's.

I really hope you reconsider.

Kindest regards,

xxxx xxxx  
xxxx xxxx

xxxx xxxx xxxx xxxx

Please find our story on why pulse oximetry is so important and needs to be made compulsory.

Our story -

I have xxxx xxxx children. I had finished at 4 but fell pregnant with twins on the coil. My twins were born at 35+6 a planned c section after amazingly getting as far as we did considering it was a very tough pregnancy with scans every week from 12 weeks until the last one at 35 weeks. xxxx xxxx and xxxx xxxx were born weighing 5lb 1 and 4lb 1. xxxx xxxx being the smaller twin who we were advised to terminate in the womb due to a growth issue. Something I would never entertain. xxxx xxxx and xxxx xxxx had TAPS twin to twin transfusion, xxxx xxxx not enough blood and xxxx xxxx too much. xxxx xxxx spent a week in scbu and needed his blood thinned twice during xxxx xxxx stay. xxxx xxxx came home after exactly a week when I finally felt rested and eventually thought we were back to some sort of normality.

How very wrong as our lives were to be changed forever. At 7 weeks old xxxx xxxx suffered a cardiac arrest during a feed and required 14 mins of CPR. Luckily his daddy knew how to do this and immediately started as I frantically dialed 999 left the phone on speakerphone and left the house. I couldn't watch my baby laying there blue and lifeless. I called xxxx xxxx xxxx xxxx who works for the ambulance service who helped his grandson too. They had an air ambulance on standby. I remember trying to get hold of my sister ringing and ringing pleading for her to answer the phone. She did and came instantly. I didn't know that my eldest xxxx xxxx who was 7 at the time had stood and watched those working on xxxx xxxx. I only found this out when his behaviour changed a few months later.

xxxx xxxx was taken to our local hospital and he was discharged 3 days later with a diagnosis of whooping cough! He had no cough! A few days later xxxx xxxx did the same again this time for 4 mins and again he was taken to our local hospital and was discharged a day later with reflux! When it happened again we refused to take xxxx xxxx home. I begged them to check his heart. I'd been googling and this was the only thing I could find and in my mind that could be why. They wouldn't entertain me and told me he had been checked thoroughly. Not only did we have the 5 children at home 1 of them was a newborn twin and I felt so tied. Their dad was staying overnight with xxxx xxxx and I would go the whole day. I wanted to be there for doctors rounds because I knew we would have to take xxxx xxxx home and I really didn't want to. Exactly 2 weeks after xxxx xxxx 1st arrest was the day they finally found xxxx xxxx murmur. It was found through xxxx xxxx back during the doctor x s rounds that morning whilst I was there. I had told them we were not taking him home. A child doesn't just stop breathing for no reason!! It was a junior doctor who could see my fears. The room had never been so busy in the whole time xxxx xxxx had been in. I didn't take in how serious it was and remember just thinking it's Ok he will be Ok now we know. He had an echo straight away which was when I was told he had a VSD and a COA. That meant nothing to me!! I called his dad and I was asked if I wanted xxxx xxxx to go

to Bristol or to Southampton. I told them I couldn't make that decision in case the outcome wasn't what we wanted and I didn't want to be saying we should have picked the other hospital. XXXX XXXX was retrieved that same day by XXXX XXXX picu team, they ventilated him for the journey. We arrived early evening and we were taken in to picu and I was given a room in the XXXX XXXX rooms. The room was lovely and a place I could get my head down although I didn't sleep at all. My mind still in a blur I called XXXX XXXX ' XXXX XXXX to say I couldn't be here alone and she made the 90 min journey to come and be with me. Their dad and I decided although we knew he should have been there too our other children and newborn needed us! XXXX XXXX coarctation was severe and his surgery was set for first on the list in the morning. We got no sleep and was in and out of picu through the night. XXXX XXXX went down first as planned and what felt like a lifetime was 7 hours and he was alive. XXXX XXXX was miraculously home 4 days after surgery but for those nights I stayed in the Ronald room and will forever be grateful.

XXXX XXXX has had 4 operations in his 6 years of life and has had more admissions than I would be able to remember but he is a very happy and cheeky little boy.

Our children have been affected hugely and my XXXX XXXX XXXX XXXX has suffered the most. It was only 2 years ago that I realised all this time he had been having nightmares and flash backs of the night he witnessed the CPR and he still thought we were going to lose XXXX XXXX any day. XXXX XXXX has been under XXXX XXXX now for just under a year. I will get my little XXXX XXXX back how he was before all this if it's the last thing I do! Thank you to all involved in our son's care. I'll never be able to repay you but what I can do is volunteer within the NHS at our local hospital and that is what I am now doing!

XXXX XXXX

XXXX XXXX

XXXX XXXX

XXXX XXXX XXXX XXXX [Sent from Yahoo Mail on Android](#)

73. XXXX XXXX

To whom it may concern,

I am writing to tell you of my families experience of having a baby born with Congenital Heart Disease and to plead with you that you would not withhold this safe, painless and vital test from all newborns in the UK.

In the summer of 2008 my husband XXXX XXXX and I were delighted to find out we would be having a second XXXX XXXX, a sibling for our almost 2 year old XXXX XXXX XXXX XXXX. My pregnancy was fairly straight forward, just as my first. I had a slightly longer spell of morning sickness but nothing that would tell me there could be anything to worry about.

I attended XXXX XXXX hospital for my antenatal appointments and also due to that clinic being very busy had scans at XXXX XXXX hospital in XXXX XXXX My 20 week ultrasound did detect our XXXX XXXX heart condition.

Our XXXX XXXX XXXX XXXX was born 30th XXXX XXXX XXXX XXXX, one week early. I had a normal delivery and a seemingly healthy baby. That first night in hospital XXXX XXXX was quite unsettled and didn't feed very well but the following day she was checked over, given the all clear and we were sent home. One week later XXXX XXXX collapsed at home in my arms. We rushed to XXXX XXXX A&E where the doctors and nurses desperately tried to make her stable. XXXX XXXX was so badly collapsed that they could not insert IV lines anywhere but had to do Intraosseous Cannulation - we watched them drill 4 times into each of our tiny 6lb 7oz XXXX XXXX s shins. XXXX XXXX was then quickly transferred to the PICU at the XXXX XXXX XXXX XXXX for Sick Children where more doctors and nurses tirelessly tried to resuscitate her for a further 45 minutes. My husband and I were brought into a side room and told that there was no hope for our baby - that a scan would be carried out on her heart to save us the trauma of a post mortem.

Family who had gathered at the hospital with us were given the devastating news that our precious baby was going to die.

Amazingly hope did come when we met the man who would become XXXX XXXX cardiologist for the next 10 years, XXXX XXXX. He explained XXXX XXXX heart condition - Coarctation of the Aorta, 2 VSD's, Bicuspid Aortic Valve, mitral valve regurgitation. XXXX XXXX would have to have an emergency operation to repair the Coarctation but as XXXX XXXX was so unwell they would place a PA band and deal with the VSD's at a later date. The operation was a success. XXXX XXXX was moved some days later to the heart ward Clark Clinic.

This was quite a shock to the system for us, going from the constant one on one care of the PICU nurses to being encouraged to be hands on with XXXX XXXX care.

One thing we frequently witnessed the wonderful nurses do was check XXXX XXXX saturation levels by Pulse Oximetry. Never once were we anxious this was causing her harm or distress and we were relieved to see XXXX XXXX levels rise and remain consistent. One of XXXX XXXX amazing nurses commented to us as we were being discharged, that we were taking home a healthier baby than we had unknowingly after her birth. So very true. XXXX XXXX is now

10. As I write this I am overcome by so many of the raw emotions these memories stir up. It's hard to imagine all **XXXX XXXX** went through at times and I have struggled with anxiety and the stress of the trauma.

I think about what I have read with regards to the consultation and that pulse Oximetry Screening has not been recommended and I just can't get my head around it.

To think of other parents going through what we have been through or worse makes my heart ache. Surely any parent would do whatever necessary to ensure they were taking home a healthy baby or a baby who may have a heart (or other condition) but who is being given the proper diagnosis and care. And when it is known to work why hold it back?

I would have gladly welcomed a safe painless and simple test in place of what happened to my **XXXX XXXX**.

Please, please reconsider.

**XXXX XXXX**



My xxxx xxxx was born at the xxxx xxxx Women's Hospital on xxxx xxxx.

Whilst xxxx xxxx was born seemingly healthy xxxx xxxx struggled to maintain his temperature and after 4 hours was taken to the neonatal unit for antibiotics. However, xxxx xxxx soon presented with breathing difficulties and turned blue. We almost lost him. Thankfully a consultant heard my partners panic and came in to see what was happening. He soon diagnosed TGA and our son was intubated.

I strongly feel that a pulse oximetry test would have identified this condition earlier and there was a real fear that had I had a straight forward birth we could easily have been on our way home.

Despite all the scans, of which I had many due to a previous pre term birth, xxxx xxxx contrition was not picked up in the womb and there are still a large number of post natal diagnosis of CHD.

I strongly believe that this simple test could save and improve the lives of many babies born with heart defects and should be as routine as a temperature check.

Any anxiety caused by having this test pails in comparison to fear of loosing your baby once a CHD presents itself.

xxxx xxxx



75.xxxx xxxx

Dear sir/Madame

I am sending this email in support for the need of pulse oximetry screening, and it to be made mandatory as part of new born screening. As a mother of a child who had HLHS we where lucky to find out at our 20 week scan, but I have meet other heart parents who have been less fortunate.

Early detection is so important for these babies, and especially the babies in Northern Ireland as we do not have children's heart surgery services. Leaving family's from Northern Ireland having to travel for surgery.

Your faithfully

xxxx xxxx



76.Massimo

August 9, 2019



Re: UK National Screening Committee recommendation against using pulse oximetry as an additional element to the newborn and infant physical exam

Dear Sir or Madam:

Masimo has remained steadfast in its commitment to improving patient outcomes and reducing the cost of care for more than thirty years. For this reason, we at Masimo feel compelled to address our concerns regarding the recent UK National Screening Committee (NSC) decision to not mandate critical congenital heart disease (CCHD) screening with pulse oximetry for newborns within the UK.

Citing concerns about over-diagnosis, false positives, excessive treatment, and unnecessary worry, Public Health England has concluded to not implement CCHD screening with pulse oximetry, despite the scientific evidence that concludes otherwise.<sup>1-3</sup> While we understand the concerns outlined by the committee, we strongly disagree with the concluding recommendations. Millions of British citizens rely on Public Health England to make health decisions that reflect their best interest, which we believe should include a mandate to screen newborns with both physical exam and measure-through motion and low perfusion pulse oximetry to ensure not one case of CCHD is missed.

Masimo invented Signal Extraction Technology® (SET®) pulse oximetry, which accurately and reliably measures arterial blood oxygen saturation and pulse rate through motion and low perfusion. Clinicians, like Dr. Sola and Dr. Granelli, discovered unique uses for pulse oximetry that led to reduced retinopathy of prematurity (ROP) in neonates and increased CCHD detection in newborns, respectively. Before the advent of SET® pulse oximetry, CCHD screening caused too many false positives and false negatives, as you have noticed. However, when reviewing the CCHD studies that solely use SET®, all show high sensitivity and specificity, and have not only proven to save lives, but also to be cost effective.<sup>1</sup> Unfortunately, some governments or clinical bodies that recommended CCHD screening, do not cite SET®, and some do not even specify measure-through motion and low perfusion pulse oximetry, which could lead to too many false positives and false negatives.

Over the course of the last three decades, we have proven to the medical community that pulse oximetry powered by SET® has immense value. Used to monitor more than 100 million patients around the world annually, SET® is the primary pulse oximetry technology at 9 of the top 10 hospitals listed in the 2018-19 *U.S. News and World Report* Best Hospitals Honor Roll. Clinical studies show CCHD to be one of the most common birth defects, affecting up to eight in every 1,000 babies born in the UK. While CCHD may be detected through physical exam alone, failing to diagnose it in the early days of a child's life carries significant risks. If

not addressed immediately, these risks can result in death. By mandating SET® pulse oximetry with physical exam during screening, these risks could be mitigated.



The benefits of SET® pulse oximetry alongside physical exam can be found in the clinical literature. In a European prospective study of 39,821 infants, researchers observed an increase in CCHD detection from 63% with physical exam alone to 83% with physical exam in conjunction with the use of Masimo SET® pulse oximetry.<sup>1</sup> That is a very significant increase (20%) in detection sensitivity simply through the use of a quick, noninvasive test – suggesting that true risk lies not in over-diagnosis but rather in under-diagnosis. This study also showed that the specificity for CCHD detection increased from 98% to 99% with the addition of pulse oximetry. A higher specificity indicates a lower rate of false alarms, which addresses one of the concerns of the NSC.

Furthermore, in the largest CCHD screening study to date (over 122,738 subjects), researchers demonstrated that the combined use of pulse oximetry and clinical assessment led to an increase in sensitivity to detect CCHD from 77.4% to 93.2%.<sup>2</sup> Cumulatively, six studies, representing over 284,800 infants and including Dr. Ewer’s study conducted in Britain, SET® pulse oximetry, in conjunction with clinical assessment, improved screening sensitivity compared to routine physical exam alone.<sup>1-6</sup> In fact these studies have shown such significant improvements in screening efficacy that the worldwide clinical community now recommends screening for CCHD with pulse oximetry.<sup>7</sup>

SET® pulse oximetry is not only available on Masimo monitors, but has been integrated in over 50 manufacturers’ products, including, small and large companies, such as Bitmos, GE, GeTeMed, Mindray, and Philips. If this decision is reversed, and to honor our commitment to improving patient outcomes and reducing the cost of care, we aim to make our technology accessible to every single maternity ward within the UK. We pledge to work with Public Health England and the NHS to develop economical solutions that ensure every hospital in the country, and every baby born in your care, has access to SET® pulse oximetry to screen for this silent and deadly affliction.

We would welcome the opportunity to further discuss this matter with you.

Sincerely,

XXXX XXXX  
Eric Jackson MD  
Chief Medical Officer, Masimo

XXXX XXXX  
Augusto Sola MD  
VP of Medical Affairs, Neonatology, Masimo

XXXX XXXX  
Steven J Barker, PhD, MD  
Chief Science Officer, Massimo

XXXX XXXX  
Stacey Orsat  
President EMEA, Masimo

References

1. de-Wahl Granelli A et al. Impact of Pulse Oximetry Screening on the Detection of Duct Dependent Congenital Heart Disease; A Swedish Prospective Screening Study in 39,821 Newborns. *BMJ* 2009;338:a3037.
2. Zhao QM et al. Pulse oximetry with clinical assessment to screen for congenital heart disease in neonates in China: a prospective study. *Lancet*. 2014 Aug 30;384(9945):747-54.
3. Ewer AK et al. Pulse Oximetry Screening for Congenital Heart Defects in Newborn Infants (Pulseox): A Test Accuracy Study. Ewer AK et al. *Lancet*. 2011 Aug 27;378(9793):785-94.
4. Granelli et al. Noninvasive Peripheral Perfusion Index as a Possible Tool for Screening for Critical Left Heart Obstruction. *Acta Paediatr* 2007; 96(10): 1455-9.
5. Meberg et al. First Day of Life Pulse Oximetry Screening to Detect Congenital Heart Defects. *J Pediatr* 2008; 152:761-5.
6. Schena F et al. Perfusion Index and Pulse Oximetry Screening for Congenital Heart Defects. *J Pediatr*. 2017 Apr;183:74-79.
7. Kemper et al. Strategies for implementing screening for critical congenital heart disease. *Pediatrics*. 2011 Nov;128(5):e1259-67. doi: 10.1542/peds.2011-131

Dear Members of the National Screening Committee,

**Re: Request for Pulse Oximetry to become standard of care for all newborns**

I am writing to express my concerns about the recent decision of the committee to reject pulse oximetry screening for all babies born in the UK.

In my opinion, the concerns raised by the committee are exaggerated and by no means compare with the benefits that the test provides for the babies, their families and the NHS.

Below I aim to provide a rebuttal to the concerns raised.

Parental anxiety

As a mother of two healthy girls who had the pulse oximetry test, I simply don't understand how the decision has been partly based on this assumption.

If given the option, no parent would reject a quick, painless and effective test to detect potentially serious defects in their newborn baby.

We were lucky enough to have the test done at the Birmingham Women's Hospital, and this test did not create any anxiety at all.

On the contrary, I would have become really anxious if my daughters had not been screened due to lack of suitable equipment in our hospital but I had found out that such a simple test was available elsewhere. The anxiety of the unknown is always worse than that resulting from facts.

The committee is also underestimating the capacity of NHS staff to effectively communicate with parents. One minute would suffice to explain why the test is so beneficial and avoid any signs of anxiety.

False positives and negatives

No test is perfect. I understand that the rate of false positives with pulse oximetry is between 0.7% and 0.8%, meaning 70-80 in 10000 babies. In my opinion this rate is very low and any potential increase in the workload for UK neonatal units related to an extended hospital stay, cannot compare with the quality-adjusted life years that can be gained by the early diagnosis and treatment of screened babies.

The rate of false negatives is even lower, but these should not be taken into account considering that the alternative is no testing at all.

Insufficient evidence

This test has been already approved in many countries following the publication of overwhelming scientific evidence and the recommendation made by representatives from major scientific paediatric societies across Europe.

It is therefore quite difficult to understand why the committee considers there is no sufficient evidence to support this test.



This decision can also discourage UK clinical researchers to think out of the box and drive innovation and change in the future.

In summary, I strongly encourage the committee to reconsider their decision and support the implementation of pulse oximetry for all newborns across the UK.

I suggest the committee considers giving green light to the new test and examining the outcomes of the new screening program after 2-3 years.

Many thanks in advance for considering my views.

Kind regards,

XXXX XXXX

XXXX XXXX

Institute of Cancer and Genomic Sciences

University of Birmingham

Edgbaston, Birmingham B15 2TT

XXXX XXXX

78. XXXX XXXX

Dear Sirs,

I am writing in view of the impending deadline for the public consultation with regards to whether pulse oximetry screening should be recommended to be undertaken on a national level.

I have concerns that your guidance is to not adopt this, despite a positive result from the study, and the example set by other countries worldwide who have chosen to implement this life saving non-invasive screening process. We always hear about how the NHS is the pinnacle of health care, yet here we seem to be outdone by our peers.

As a researcher, it concerns me that positive results can be disregarded, seemingly as a cost saving exercise through avoiding potentially unnecessary extended hospital stays whilst further investigations are undertaken in those false positive situations.

As a mother, I would far rather be forced to remain in hospital longer in a false positive situation than to be discharged with a newborn with a potentially fatal condition, in the false knowledge that my baby has been given a clean bill of health.

It is shameful that infant and neonatal mortality rates in the UK are comparatively high to other countries, and that despite our high standards of research, progress in reducing these rates has stagnated.

I urge you to reconsider this decision.

Best wishes,

XXXX XXXX

XXXX XXXX



79. xxxx xxxx

Dear whoever it may concern

I'm a 32 year old who is currently 26 weeks pregnant with my second child.

Our first child, xxxx xxxx sadly passed away aged 9 days old. xxxx xxxx had hypoplastic left heart syndrome. xxxx xxxx was diagnosed with xxxx xxxx heart condition at 20 weeks antenatally. MWe had time to prepare ourselves and xxxx xxxx for surgery and equip ourselves with all the information we needed.

I can not imagine not knowing about xxxx xxxx heart condition and not knowing would of been so much harder. This non invasive test is a no brainer for me. I'm lucky enough to be having xxxx xxxx brother at Birmingham women's hospital and so he'll be routinely screened. Early diagnosis is key and if one family and their baby can be saved then I don't see why this isn't a standardised test.

I implore you to consider this screening test.

Yours sincerely

xxxx xxxx

Sent from my iPhone

80. XXXX XXXX

Hi as a mum to heart warriors my views on this are very strong being in some of the horrific positions since XXXX XXXX was born. From being resuscitated In front of me twice. Emergency pace maker and. Pace makers failing. My little XXXX XXXX is XXXX XXXX he has no underlying heart beat . My little XXXX XXXX condition was picked up before birth so i am one of they lucky ones. But this test should be compulsory after every baby is born as being part of a heart group used to many horror story's of going home thinking you have a healthy. Baby in realty it's not even had its heart checked. And is a walking time bomb closed to death because. No-one seems to think it's important to check a baby's heart Let's not forgot the trauma and horrific experience that the parents need to go through to give there baby a fighting chance. Needs to be compulsory no doubt.

Get [Outlook for iOS](#)

Having incorporated routine pulse oximetry as part of the standard examination of the newborn in Ayrshire for over 9 years I am appalled by the claim that “... 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.”

We introduced the test because of the harm done to a particular infant whose complex congenital heart disease (CCHD) would have been detected much earlier (before collapse) had his haemoglobin oxygen saturation been checked. I recognise that national policy cannot be based on anecdotal evidence but there is ample scientific evidence, summarised in the 2018 Cochrane Review by Plana et al., that this is “a highly specific and moderately sensitive test for detection of CCHD with very low false-positive rates.”

The Cochrane Review findings are borne out by our local experience since 2010, which has more than convinced us that this is a simple, cheap and effective test with no time or resource implications (our newborn maternity assistants check post-ductal saturation while the midwife or doctor who will perform routine examination of the newborn takes the feeding history; if post-ductal saturation is below 98%, pre-ductal is also checked). If saturation

We have detected several cases of cyanotic congenital heart disease where the cyanosis was not yet clinically apparent; in addition we have detected at least two cases of coarctation of the aorta. Of the “false positive” infants (i.e. those without CCHD), several have had significant problems other than CCHD including (a) some simple “delayed adaptations” - detection and appropriate treatment have probably averted the development of more severe persistent pulmonary hypertension that could have resulted in serious illness and invasive and expensive treatment - and (b) some pre-symptomatic infants who were in the early stages of sepsis.

Numbers of infants detected are small but lives have undoubtedly been saved by this simple and cheap intervention. I strongly advocate including it in routine neonatal screening.

XXXX XXXX

Consultant Paediatrician and Neonatologist

NHS Ayrshire & Arran

To whom it may concern ,

I follow a charity tiny tickers and have today seen the nhs have decided that the pulse oximetry test is not mandatory as a newborn check.

I think this is very shocking as such a simple test could save potentially so many life's. My baby was pre diagnosis antenatally with a heart condition however was perfectly healthy at birth it was only 24 hours later when using the pulse oximetry test that xxxx xxxx SATS were discovered to be dangerously low at 75, meaning xxxx xxxx needed putting in NICU as an emergency and depended on oxygen for quite some time. If it wasn't for this test then even having a diagnosis we could have been sent home to only imagine what would happen and thinking of the potential of him not being here now is very scary!

I'm forever thankful and grateful for that test and giving my child a chance to live .

I feel like for something that is such a quick test should be routinely offered to help those before its to late.

I will continue to support and challenge all decisions made regards these tests as I'm proof of how important they can be .

I could only imagine what it must be like not knowing pre birth about a heart condition and how much more important these tests are

I hope that this will be passed on to the national screening committee and hope the decision throughout till August will be reconsidered.

Sent from my iPhone

We use 12 point Arial in all our correspondence to make it easier for people to read. All our publications are available in alternative formats.

83. XXXX XXXX

Hi

I understand that the NHS has decided not to make pulse oximetry testing in newborns mandatory and I implore you to look again at this decision.

Our soon to be 15yr old XXXX XXXX was born with non dx heart defects. XXXX XXXX was born dusky and put on oxygen - XXXX XXXX pinked up and we were eventually transferred to the ward. Not long after arriving on the ward XXXX XXXX went into arrest and was rushed away - we were briefly able to see XXXX XXXX after XXXX XXXX had been resuscitated and before XXXX XXXX was moved to nicu. We didnt see XXXX XXXX again for 7hrs - yes 7hrs!! All we were told in this time was that they were running tests and XXXX XXXX was very poorly. At 11pm that night we were informed that XXXX XXXX had CHD and would be transferred an hr away to specialist hospital. We then didnt see him till 12 noon next day. My XXXX XXXX spent 3mths in hospital and at 1 point we were told to say goodbye to XXXX XXXX . After several more arrests, 23hrs a day pump feeding and out of this world care from XXXX XXXX team he eventually became strong enough to have ohs. XXXX XXXX now has learning difficulties and autism.

During all this time our then 2.5yr old was pushed from pillar to post.

Had our XXXX XXXX been tested straight after XXXX XXXX birth I believe XXXX XXXX condition would have been picked up many hours earlier and XXXX XXXX wouldnt have suffered the original arrest or become so poorly.

It's a simple check which will make such a difference to sooo many babies and families lives. Please please please re consider your decision.

Kind regards

XXXX XXXX

84.XXXX XXXX

Please I urge you to test each single baby when they are born We also nearly lost our baby to a undiagnosed TGA when XXXX XXXX was a month old.

We was constantly being told XXXX XXXX was ok when XXXX XXXX was clearly not and XXXX XXXX eventually went into a cardiac arrest while at home which was the most terrifying thing to experience.

Thank fully after a 4 month stay at the Royal Brompton in London and Addenbrooke's in Cambridge we finally brought our XXXX XXXX home.

If XXXX XXXX condition had been identified then it would of not been so traumatic for us all to cope with and we still struggle with what happened daily.

Please PLEASE don't let any other families go through what we went through

Thank you

XXXX XXXX

Sent from my iPhone

Sent from my Samsung Galaxy smartphone.

To whom it may concern, I am extremely worried that Pulse Oximetry Screening has been made not compulsory for newborns.

My XXXX XXXX was born with the serious defect, Double Inlet Left Ventricle. This was missed when XXXX XXXX was born, and missed repeatedly by midwives and GPs when he was discharged. It was literally my mother's instinct that saved XXXX XXXX life. I was told a few more days and XXXX XXXX may not have made it.

XXXX XXXX was admitted to hospital with o2 saturation's of 90%. With the pulse oximetry test this would have been picked up on in seconds after XXXX XXXX was born and XXXX XXXX would not have had to struggle for 10 days alone.

Please, reconsider this decision. I am amongst thousands of worried parents, I would not wish what we went through on my worst enemy.

Kind regards

XXXX XXXX

Dear to whom this may concern.

I've seen an article through Facebook regarding checking newborn babies saturation levels to detect early heart defects. My first born xxxx xxxx was born 40+1 which was a 'normal textbook pregnancy' I was told. The labour was ok but needed help in theatre at the very last part. xxxx xxxx needed help breathing when xxxx xxxx first came out but thankfully came round. If only xxxx xxxx was checked out properly even after 24hrs xxxx xxxx heart defect would have probably been picked up. BUT at 6 weeks old my new born baby xxxx xxxx stopped breathing in my arms! My whole entire world stopped...

After a 40 minute wait for an ambulance then a journey to our local hospital with the critical care team coming over from xxxx xxxx Hospital it took them 8 hours to stabilise xxxx xxxx so xxxx xxxx was 'stable' enough for them to transport xxxx xxxx to BCH.

xxxx xxxx was found to have a benign mass on xxxx xxxx mitral heart valve. xxxx xxxx first emergency open heart surgery they removed the mass and repaired the valve but 10 days later was again rushed back into theatre having a mechanical mitral heart valve fitted as xxxx xxxx was too badly damaged to repair itself.

How can my 'healthy' 6 week old baby xxxx xxxx be put through all this when having a simple saturation test might have possibly prevented all this from happening and could have been picked up so much sooner when xxxx xxxx was born?

After a 7 week stay in BCH our baby xxxx xxxx was safe enough to come home. xxxx xxxx was now on numerous medications daily and on twice daily injections which I was trained to give him. BUT at 6 months old our nightmares were to return when xxxx xxxx was once again rushed back in to theatre needing xxxx xxxx mechanical mitral heart valve replacing for the second time. It was devastating, why can't our xxxx xxxx have a rest?! Why did it have to be our xxxx xxxx?! But against all the odds xxxx xxxx pulled through and is now a 6 year old xxxx xxxx who loves football. Looking at xxxx xxxx you wouldn't have a clue of anything xxxx xxxx been through in his young life so far and needing further surgery for when xxxx xxxx body needs it, we still have that agonising wait. We have 6 monthly reviews at BCH and yearly reviews with our local paediatrician at our local hospital. xxxx xxxx now takes daily medication and will need to for the rest of xxxx xxxx life AND all this could have and might have been prevented if xxxx xxxx

had the early oxygen saturation testing?! Why is this even been considered- it should be done and it will be if we continue fighting for it.





We shouldn't have been put through this as a family and no other families should need to go through this at all. We are in the year 2019 this will and NEEDS to be done for EVERY newborn baby.

With regards

XXXX XXXX

87. xxxx xxxx

I fully believe that this should be a mandatory test carried out on every single new born. Although it may only save one or two lives in each hospital, those one or two lives are massive to the families they belong to! It will undoubtedly save a life.

My xxxx xxxx was one of those lives and thankfully xxxx xxxx was in a hospital that had and used a pulse oximetry on the maternity ward. This should be used!

88.xxxx xxxx

I would just like to share my views that this test should be available to all new born babies.

Our son, xxxx xxxx, was born xxxx xxxx2017 at the xxxx xxxx, Northern Ireland. This was by way of planned Caesarean section after a normal pregnancy.

No concerns were picked up at the 20 week scan.

Just prior to our discharge from hospital one of the nurses noticed that xxxx xxxx was a little "blue."

Tests confirmed the devastating news that xxxx xxxx had HRHS along with other heart defects.

We were transferred to xxxx xxxx Childrens' hospital but unfortunately we lost our xxxx xxxx on xxxx xxxx 2017.

I feel very strongly that this test should be available to all new born babies as I always think that our xxxx xxxx suffered for the first 2 days of xxxx xxxx life when a simple test could have meant that xxxx xxxx could have had immediate medical treatment.

Thanks

xxxx xxxx

Sent from my iPhone

To whom it may concern

My view on this subject is strongly in favour of this very simple test being rolled out nationally.

I myself was born with a congenital heart condition called Fallot's Tetralogy. I had 2 major cardiac operations at 7 and 8 at the XXXX XXXX Hospital back in the mid seventies. Since then I have suffered with Atrial Fibrillation and am on anticoagulants and antihypertensives for life. I also had insertion of a permanent pacemaker in 2001.

Luckily I have managed to lead a fairly normal life and went on to become a registered nurse and have 2 healthy children.

However, there have been certain limitations on the way I live my life and if this could be avoided for future generations by a totally non-invasive test like pulse oximetry then I think it would be morally reprehensible not to introduce this nationally at the earliest opportunity.

Kind regards

XXXX XXXX

90.XXXX XXXX

NHS

I strongly believe that pulse oximetry testing should become a mandatory part of testing newborn babies. A member of my family was born with a serious heart condition and many children's lives are put at risk because they are not being tested by the quick, easy and painless method. It is a 'no-brainer' really- why are we not testing babies?

XXXX XXXX

91. XXXX XXXX

Hello

I hope I'm doing this correctly, I would like to say why I feel it is very important that all newborns are given the pulse oximeter test.

Our fourth child XXXX XXXX was born XXXX XXXX 2001, apart from bad sickness I had had a relatively easy pregnancy and my XXXX XXXX was a healthy 8:1 when born, XXXX XXXX was given the normal new born tests and we were sent home.

When our XXXX XXXX was four days old we noticed XXXX XXXX had slowed down with XXXX XXXX feeding, at five days old the midwife came out and originally thought we should try different teats on XXXX XXXX bottles. Thankfully she returned a few hours later and immediately looked at our XXXX XXXX, said she didn't like XXXX XXXX colour and called for an ambulance.

We arrived at our local hospital where XXXX XXXX was stabilised and we were told he was being sent to XXXX XXXX, we were also told XXXX XXXX may not make the journey.

Our XXXX XXXX was diagnosed with hypo plastic left heart this basically meant the left hand side XXXX XXXX heart was under developed. There are three stages of surgery and then the only option is a transplant.

XXXX XXXX spent a very long time in the children's hospital XXXX XXXX was very ill. XXXX XXXX had stages 1 & 2 but due to having a severe leak on XXXX XXXX tricuspid valve stage 3 was not an option and so XXXX XXXX was placed onto the transplant list . December 2003 our XXXX XXXX caught a simple cold, too many this would not have been a major issue but because XXXX XXXX heart issues this made XXXX XXXX really poorly and XXXX XXXX was admitted once again to hospital, February 2004 XXXX XXXX collapsed in hospital and ended up on intensive care at XXXX XXXX . XXXX XXXX condition deteriorated very quickly and on XXXX XXXX 2004 we were told that no more could be done and we had to make the horrendous decision to turn off our XXXX XXXX life support. XXXX XXXX was 2 years and 8 months.

Next month ( August 5th) XXXX XXXX would have celebrated XXXX XXXX 18th birthday.

We truly believe that had our XXXX XXXX been given the pulse oximetry test at one day old they would have noticed something was wrong. Yes XXXX XXXX

still would have had the condition hypo plastic left heart but [REDACTED] would have been able to have been transferred to [REDACTED] earlier to begin treatment . We are not saying [REDACTED] story would have had a different ending but we will never know, what we do know is from the day [REDACTED] was born and began to breath independently a small valve in [REDACTED] heart was slowly shutting . In a child with a normal heart this is fine but as [REDACTED] left side was not working properly this valve shutting meant [REDACTED] body was slowly going into shut down. [REDACTED] collapsed at five days old , had [REDACTED] had the test at one day old it most definitely would have meant [REDACTED] have been admitted earlier and not sent home. Also had our midwife not have come back that particular day with different bottle teats we would have just put our [REDACTED] down for a sleep and that would have been it we would have lost [REDACTED] at five days old. We are grateful that we had [REDACTED] for 2 years and 8 months and we use the word grateful very loosely as it's still not long enough but many little ones don't get to their first birthday with this condition.

I doubt there will be a parent anywhere who will refuse this test if it meant finding out if anything is wrong with their newborn. Yes while waiting for the results they will be worried and most of the time all will be fine, but there's always going to be the few that are not like our [REDACTED]. This test could have given our [REDACTED] a better chance, it most certainly would have enabled the hospital to pick up that something was wrong and [REDACTED] have been admitted to [REDACTED] earlier and before the valve had closed.

Our local hospital the [REDACTED] did do it for a short time , I know this as my [REDACTED]who is now 11 was one of the first newborns in [REDACTED] to have it, I don't think they do it now but unsure. But all hospitals should do it regardless of where they are situated, it is a simple non invasive test so why are hospitals not doing it.

[REDACTED]

Sent from my iPhone

92. XXXX XXXX

Dear Sir/Madam,

I am writing to you to hopefully get the message across that the pulse oximetry test IS added to the newborn check!

We suffered 3 months of not knowing our XXXX XXXX had CHD!

We struggled trying to get XXXX XXXX to put weight on etc!

People kept thinking it was our fault, which it wasn't!

We tried our best!

Very stressful time which could have been avoided!

At didn't help that XXXX XXXX was also tongue tied and that took 2 weeks to be diagnosed and treated!!

At 3 months old our XXXX XXXX collapsed at home and rushed blue lighted to local hospital then transferred to children's ward once stable!

It took 3 days for them to find and tell us our XXXX XXXX had a heart murmur and upon investigation a large concerning VSD and an ASD!

This could have been avoided had the pulse oximetry test been available!

We had 3 months of stress etc and we also have a young XXXX XXXX as well!!

Please put this very important test on the newborn checklist!!! It will help lots of people!

Regards

XXXX XXXX



93. XXXX XXXX

When my two children were born, the only tests I'm aware they went through were the APGAR scales, heel prick and hip dysphasia screening. I'm so grateful that they didn't have heart problems. If I was a new mum now, I would want to come home from hospital with my baby, reassured that, having undergone pulse oximetry, I would have less to worry about. If there was a false positive finding, at least my baby would be fully screened which would reassure me. I understand that PO has low false negative findings, but if that were the case I would still obviously have to deal with it and surely the information given to new parents should include signs to look out for that should be dealt with immediately. In the case illustrated, when mum was concerned about her baby's projectile vomiting, she waited til the next day to get a gp appointment when she should have taken the child to ED. So alongside tests like PO should come sound education to help parents make important decisions if they are concerned about their child's health. The Department of Health's reluctance to roll out PO and make testing mandatory throughout the UK suggests budget controls that don't look closely at the bigger picture and the consequences of delayed diagnosis and added costs therein. It doesn't make sense to ignore this issue.

XXXX XXXX

Sent from my iPhone



Dear UK NSC,

Please find below Tiny Tickers' formal response to the UK NSC consultation on pulse oximetry screening. We have elected to write a letter rather than use the online response form so we are able to better expand on relevant points, and have referred to pulse oximetry screening as POS throughout, for brevity.

### **Tiny Tickers and pulse oximetry testing**

Tiny Tickers is a national charity that aims to improve the detection, diagnosis and treatment of babies with congenital heart disease (CHD). We were established 20 years ago by Dr Helena Gardiner, a world-renowned fetal cardiologist.

Many of our supporters and beneficiaries are families of babies who have congenital heart disease, including a significant proportion whose babies, tragically, have passed away. This number includes those whose babies died with their heart condition undiagnosed. Our mission is to prevent this happening, through improved antenatal and postnatal detection.

We are a voice for families – representing thousands of supporters and beneficiaries who link with us through our social media channels, our private forum, our website and other methods. Our CEO, Jon Arnold, has been a Public and Patient Voice representative on the NHS England Clinical Reference Group for CHD for the last five years.

One of our charitable projects is to fund and place POS machines. Since 2018, we have placed nearly 100 machines in NHS Trusts across the UK. The pace of demand for these machines is increasing, and has continued to do so since the UK NSC's recommendation was published.

We are seeing a sustained trend for NHS Trusts to adopt POS for newborns. The last national survey of hospitals offering the test (which was carried out before our project began) showed around 40% offered it – and our belief is that this proportion has now grown because of our project and NHS Trusts' continued desire to adopt the test.

We believe there would be significant benefits to patients if POS was available to all newborns, and if there was national oversight of the continued rollout of the test (for example, a standardised testing protocol, collation of results etc).

### **Evidence of benefit**

We'd like to respond to the following comment in the Consultation Covernote:

“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.”

The benefits of timely detection of CHD are well-documented and evidenced:

- In some cases, detection prior to the baby falling into the early stages of heart failure saves lives;
- In others, it will prevent the neurological damage and developmental delays that can be caused by heart failure;
- It can prevent emergency transfers and the associated stress for families and costs to the NHS;
- It can prevent potential emergency surgeries and the costs and stress associated with consequential cancelled planned operations;
- Antenatal detection enables parents to consider choices and for a care plan to be formulated before the baby is born – including alternatives for the site of birth if necessary;
- Antenatal detection enables parents-to-be to begin to deal with the difficulties and distress a diagnosis of CHD brings, prior to their baby being born.

When Tiny Tickers began training sonographers in the techniques and skills needed to recognise an abnormal heart at the 20 week anomaly screening, the UK’s average antenatal detection rate was just 23%. That figure has now more than doubled to around 50%, but that still means that half of babies with CHD are not detected prior to birth. For critical CHD, antenatal detection rates vary from 33-62% - still a very wide variation.

We note the research that shows antenatal screening combined with POS can mean 90% of critical CHDs can be spotted before babies are discharged from hospital. We note, too, research from the US showing a 33.4% reduction in deaths from CHD after states implemented mandatory POS compared with prior periods and states without screening policies (JAMA, 2017). We regularly hear anecdotal evidence from hospitals where we have placed POS machines, and from parents, of the benefits of screening – instances where babies have been picked up by POS; or cases where a lack of POS may have contributed to newborns being discharged with their CHD undetected.

Tiny Tickers believes this combination of effective antenatal screening plus the safety net of POS in the newborn period would mean more babies are detected sooner – saving lives; improving long-term outcomes; and providing a better pathway for these babies and their parents.

Taking all of this into account, we believe there is compelling evidence of the benefit of POS, and that the next steps in the development of POS must be the introduction of the test across the UK, with national overview of performance, standards, results and pathways.

### **Harms associated with false positives**

We’d like to respond to the following comment in the Consultation Covernote:

“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.”

Research shows that of 10,000 babies screened with pulse oximetry, 73 will test positive and 35 will be admitted to a neonatal unit. Of those, 28 will have a condition that requires treatment, while just seven will ultimately be ‘harmed’. In this instance, ‘harm’ being that they are found to have no conditions that require treatment but undergo unnecessary testing, and have their discharge delayed. This represents 0.07% of all babies screened, and means that four babies benefit for every one baby who undergoes unnecessary tests.

We believe this is a low risk of harm, and an acceptable level considering the very tangible and potentially life-saving benefits to those babies who do have conditions detected following a POS.

We would also make the point that the majority of the consultation identifies as ‘false positive’ results are actually conditions that it is clinically important to have diagnosed – eg sepsis – and we fail to understand why detection of these conditions is considered a false positive rather than a clear additional benefit of pulse oximetry screening. This is a very difficult sentiment to explain to parents, because it appears to make very little logical sense.

Further, our understanding is that this level of false positive rate is significantly better than those for some other screening programmes, including newborn hearing screening (one baby benefits for every 30 babies harmed); and mammography for breast cancer screening (300 of every 400 women testing positive will not have cancer and will have had unnecessary invasive biopsy testing).

Newborn hearing and breast cancer screening programmes are clearly very important. We draw comparison merely to highlight our concern that the apparent harms of a positive pulse oximetry screening result are being given too much weight in the NSC report and are being considered disproportionately to other harms of other screening tests.

The harms to patients, their families and the NHS of undetected CHD (death, neurological issues, developmental delays, psychological trauma, anxiety and stress, emergency transfers, cancelled operations etc) far, far outweigh the harms of a false positive POS result (delayed discharge, additional testing). We do not feel this has been taken into full consideration or given proper weighting and we urge that this point be reconsidered.

### **Parent and public view**

We feel that more can be done to assess parent and public attitudes to POS, particularly regarding acceptability of the harms associated with false positive results. We feel that research should be commissioned by the UK NSC into this topic prior to any final decision being taken. What we have heard from our supporters and beneficiaries is an overwhelming desire from parents and the public to see POS being offered to all newborns. As a result of the significant levels of feedback we were receiving, we conducted a short survey into attitudes about POS. Full results are provided as an appendix to this document; an overview is presented here:

- 2,123 people completed the survey. Of these, 61.1% had no direct experience of CHD.
- When asked if they would want their newborn to have POS, 99.2% (2,106 respondents) answered yes.
- When asked how they would feel if, following a positive POS result, their baby then had further examinations before it was confirmed he/she was
- perfectly well (so a true ‘false positive’), 98.3% (2,086 respondents) selected the answer “that would be acceptable to me, I would rather know that any concerns had been

followed up even if there were found to be no problems”. In contract, just 0.6% (12 respondents) selected the answer “that would be unacceptable to me, the thought of undergoing additional unnecessary tests would put me off wanting my baby to have a pulse oximetry test”.

- When asked, if they were to have a baby, how important they felt it was that he/she had a pulse oximetry test, 79.8% (1,694 respondents) said “vital”, 19.7% (418 respondents) said “important”, and 0.5% (11 respondents) said “not important”.

Based on these results, there is a clear desire among members of the public that POS is offered to all babies. Additionally, members of the public feel that the harms identified in the Consultation Covernote are not significant enough to outweigh the benefits of babies being tested.

We decided to do this survey to give some indication of public attitudes, because we felt that not enough research had previously been done into this very important part of considering the impact of any screening test. We acknowledge this is not a formal piece of research, but believe it gives a strong indication of attitudes and would urge the UK NSC to commission research into public attitudes if any doubts about public confidence in POS remain, and prior to any final decision.

In addition, we recognise that contributing an official response to a public consultation can be a barrier to many, so we offered the opportunity for parents with lived experience of CHD to make comments on our social media platforms that we would pass onto the consultation – they are attached as an appendix to this document.

We believe it is important that these lived experiences of parents of babies with CHD are taken into account. We would highlight the following:

XXXX XXXX, **mum to** XXXX XXXX

:

“I lost my son XXXX XXXX to undiagnosed transposition of the great arteries. After meeting with one of the region’s heart surgeons, we learnt of the pulse oximetry test and he explained to us that it wasn’t currently part of the mandatory newborn tests. “We have managed to bring in the test at our local hospital, which was fantastic, but felt like a small step on a very big journey. I struggle speaking about my XXXX XXXX and I feel my grief is private and not something to shared. But I challenge myself, because I don’t want another family to go through this trauma. After we lost XXXX XXXX I thought the pulse oximetry machines wouldn't make it any further than my local hospital. This consultation is a chance for all us parents to tell the NHS how strongly we believe all newborns should have the test, and I’m happy to add my voice to Tiny Tickers’ calls for the test to be offered to every baby.”

XXXX XXXX , **parent of a heart patient:**

“Our baby XXXX XXXX was born in July 2018, all seemed well and we were discharged from hospital. But, when XXXX XXXX had XXXX XXXX two week midwife check, XXXX XXXX hadn’t really put on much weight – XXXX XXXX was only just back at XXXX XXXX birth weight. The midwife brushed it off – but, as it turns out, XXXX XXXX wasn’t feeding well at all and was asleep due to exhaustion. At four weeks old XXXX XXXX developed horrendous diarrhoea – XXXX XXXX was admitted to hospital and it was there that they found the heart murmur. XXXX XXXX had scans and was rushed to the specialist heart unit in XXXX XXXX. XXXX XXXX had a small ASD, a large VSD and coarctation of the aorta. It was

decided xxxx xxxx needed to put weight on before surgery, and xxxx xxxx eventually had surgery at 13 weeks old. “If xxxx xxxx had had the pulse oximetry test at birth xxxx xxxx heart defects would have been detected and xxxx xxxx would have received her life-saving surgery sooner.

xxxx xxxx has suffered significant developmental delays as a result of being poorly for such a long time during a crucial development stage. It is absolutely terrifying to think what could have happened to xxxx xxxx if xxxx xxxx hadn't got diarrhoea and xxxx xxxx heart issues hadn't been found accidentally. The pulse oximetry test is absolutely necessary and should be part of the standard newborn checks. It will absolutely save lives. We must do all we can to make sure babies are not sent home severely ill, like my xxxx xxxx was xxxx xxxx, mum to xxxx xxxx : “I absolutely cannot believe that 11 years after my xxxx xxxx, xxxx xxxx, life was saved by pulse oximetry testing at birth we are still talking about this! It is absolutely imperative that this is brought in. xxxx xxxx was born at the University Hospital of xxxx xxxx who, at the time, were trialling the test in conjunction with Birmingham. xxxx xxxx SATs were 72% and falling fast. xxxx xxxx would have died at home. Surely the fact xxxx xxxx is 11 and now due to start secondary school is the only evidence you need.”

We have received a large number of similar stories and sentiments, and hope that the public consultation is an opportunity for the views of people with lived experience of CHD to be taken into account and given the appropriate weighting.

### **Our conclusion**

We'd like to respond to the following comments in the Consultation Covernote:

“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.”

“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)?”

With an increasing number of NHS Trusts now adopting POS as standard, there is a growing inequality across the UK – currently there is a postcode lottery where around half of newborns will be tested, and half won't. This is unacceptable.

The rollout of POS is happening, with the percentage of NHS Trusts offering the test continuing to grow – this cannot be ignored. We believe this is a very positive development, but we feel it is necessary for the NHS nationally to ensure uniformity of delivery and standardisation of the test – and that the best method for that to be achieved is for it to be brought into the national screening programme.

The question is no longer whether the test should, or will, be offered – it is now about how the on-going rollout and oversight of the test is managed to ensure it is of maximum benefit to patients.

Tiny Tickers has been listening to cardiologists, neonatologists, midwives, researchers, experts overseas, other patient representative groups, and to parents. There is overwhelming and near unanimous support for POS.

We believe that the consultation process has not presented sufficient evidence to support the decision to approve the recommendation against using POS as an additional element to the newborn and infant physical exam. Quite the opposite we feel there is plenty of evidence that this



test helps save babies' lives, and should be recommended. At the very least, further research should be undertaken by the NIHR prior to any final decision, as mentioned as a possibility in the Consultation Covernote.

Too many of our supporters are parents who have lost their babies to undetected CHD. Timely detection of CHD saves lives. Pulse oximetry testing is a simple, evidenced and effective tool in the armoury of those working to detect CHD. It is wrong that only half of newborns currently have access to this test, and we urge reconsideration of the recommendation not to offer POS as part of the NIPE programme.

Thank you for listening to our comments.

Jon Arnold

Tiny Tickers Chief Executive



## Appendix One – Tiny Tickers’ survey

For a period of ten days during the consultation period, we ran a public survey. This short survey was designed to gather public views on pulse oximetry testing and attitudes towards the associated harms as suggested in the consultation materials.

We recognise that responding to a public consultation is a barrier for many, and felt that this survey was an effective method of gathering opinions. The survey was run on the Google survey platform, and contained links to the UK NSC consultation website for further reading. The results showed an overwhelming public support for newborns being offered the test. Here are the results:

The survey was completed by 2,123 people. Of those, 61.1% had no direct experience of CHD. We felt this was important, as there may be an assumption that respondents with direct experience of CHD could be more favourable to testing.

Question: Would you want your newborn baby to have a pulse oximetry test? 99.2% (2,106 respondents) answered: “Yes, I would want my baby to have a pulse oximetry test.” 0.2% (5 respondents) answered: “No, I would not allow my baby to have a pulse oximetry test.” 0.6% (12 respondents) answered: “I’m not sure.”

Question: How would you feel if, following a positive pulse oximetry test, your baby then had further examinations before it was confirmed he/she was perfectly well? 98.3% (2,086 respondents) answered: “That would be acceptable to me. I would rather know that any concerns had been followed up, even if there were found to be no problems.” 0.6% (12 respondents) answered: “That would be unacceptable to me. The thought of undergoing additional unnecessary tests would put me off wanting my baby to have a pulse oximetry test.” 1.2% (25 respondents) answered: “I’m not sure.”

Question: If you were to have a baby, how important would you feel it was that they had a pulse oximetry test: 79.8% (1,694 respondents) answered: Vital 19.7% (418 respondents) answered: Important 0.5% (11 respondents) answered: Not important

## Appendix Two – Views of parents with lived experience of CHD

Due to the high volume of feedback we were receiving during the consultation period, we posted on social media channels asking for the views of parents with lived experience of CHD. We recognise that many find formally responding to an NHS consultation a challenging process, so wanted to reflect their views in our response.

Here is a selection of the most relevant responses:

**Kaileigh:** “My daughter was diagnosed with TOF, right aortic arch & MAPCAs at 18 months old, she was surviving on SATs of around 50%, she had open heart surgery 3 weeks after diagnosis. A simple pulse ox test could possibly have diagnosed her at birth.”

**Steph Bruce:** “When my first daughter was born 8 years ago she wasn’t offered the test and was sent home with an undetected heart defect called coarctation of the aorta which wasn’t detected until she was 3 years old when she took poorly and was admitted into hospital and they discovered the heart defect. In August 2018 I gave birth to a little boy he was having all his routine tests before we left the hospital which included the pulse oximetry test and that’s when they discovered his low oxygen levels he was taken to SCBU and was later

placed on a ventilator and transferred to an intensive care unit where we was told he had sepsis and persistent pulmonary hypertension. It was a very scary time but thankfully he made a full recovery and had he been sent home without the test then his story could of been a lot different. I cannot understand why a simple and potentially life saving test is not mandatory.”

**Anh Nowottny-Nguyen:** “I did not think about CHDs at all, and wasn’t made aware of them at all, until my latest pregnancy where it’s been detected in a scan. This simple testing can save lives, so I don’t understand why it’s not mandatory for all newborns, because parents need all the information they can get at a time when life can throw up so many changes and surprises, to make sure their babies are safe. Please make this testing mandatory for all newborns.”

**Samantha Lloyd:** “I absolutely cannot believe that 11 years after my son, Ethan’s, life was saved by pulse oximetry testing at birth we are still talking about this! It is absolutely imperative that this is brought in. Ethan was born at the University Hospital of North Durham who, at the time, were trialling the test in conjunction with Birmingham. His SATs were 72% and falling fast. He would have died at home. Surely the fact he is 11 and now due to start secondary school is the only evidence you need. “A few false positives? People won’t mind to have the security that their baby is okay.”

**Katy Widdowson:** “Our baby girl was born in July 2018, all seemed well and we were discharged from hospital. But, when she had her two week midwife check, she hadn’t really put on much weight – she was only just back at her birth weight. The midwife brushed it off – but, as it turns out, she wasn’t feeding well at all and was asleep due to exhaustion. At four weeks old she developed horrendous diarrhoea – she was admitted to hospital and it was there that they found the heart murmur. She had scans and was rushed to the specialist heart unit in Leicester. She had a small ASD, a large VSD and coarctation of the aorta. It was decided she needed to put weight on before surgery, and she eventually had surgery at 13 weeks old. If she had had the pulse oximetry test at birth her heart defects would have been detected and she would have received her life-saving surgery sooner. She has suffered significant developmental delays as a result of being poorly for such a long time during a crucial development stage. It is absolutely terrifying to think what could have happened to her if she hadn’t got diarrhoea and her heart issues hadn’t been found accidentally. The pulse oximetry test is absolutely necessary and should be part of the standard newborn checks. It will absolutely save lives. We must do all we can to make sure babies are not sent home severely ill, like my daughter was.”

**Sam Bradburn:** “I had only wished this was available when my daughter now 6 was born. She was sent home 3 days after my c section with the all clear over the next few weeks she had trouble feeding wasn’t putting weight on we tried everything health visitor made me feel like I was doing something wrong. At 6 weeks old she was admitted to hospital to see why she wasn’t feeding after 3 days in hospital a doctor listened to her chest decided to do a mini heart scan then told us they think something could be wrong with her heart but only speculating and they were going look at sending us to a specialist hospital the next day and then he came back and said we were going to Freeman hospital tonight she was hooked up to monitors put in an ambulance after she was settled in a freeman and a doctor came to see us to tell us she had AVSD.”

**Saff Eaglestone:** “We found out our daughter had TOF at my fetal cardiac scan so we were prepared for what was to come but we know some aren’t so lucky and at times the outcome can be fatal. Why this test isn’t mandatory I do not know.”

**Laura Pryde:** “We didn’t have any tests and our baby’s heart condition was not picked up at any of my scans (I had a lot due to a testing pregnancy). Our heart warrior was in heart failure by the time he had his open heart surgery at 6 weeks old. Luckily I took him to A&E the day after he was born or we could have been in a very different situation now.”

**Louise:** “My baby was discharged with an undetected CHD and ended up in Glasgow having heart surgery at ten days old. He’s lucky to be here now - nearly nine years later.”

**Marie:** “My daughter was born with a complex CHD which was not picked up on any prenatal scans and only picked up after she was born. I had 2 further children after her which were both given additional scans and pulse ox carried out due to this. All non invasive and very quick.”

**Kelly:** “We were lucky to have this carried out which meant further testing and scans diagnosed CHD which wasn’t picked up on ultrasound. I wasn’t aware that it depends on postcode!”

**Jackie:** “My little girl has a complex CHD, thankfully we knew prenatally, however, we were told that she could have presented fine and being a third baby could have gone home fairly early - before all the ducts etc had finished closing - and if this was the case it would have been fatal! It’s a non-expensive lifesaver. We offer anomaly scanning, we use a stethoscope on the paediatric check before a baby goes home etc etc, all of which could also cause parent anxieties!!!!”

**Gillian:** “My eldest niece went into heart failure at 8 days old – completely missed and undetected. This test may have detected the various heart defects she had. Thankfully now a healthy and happy 7 year old.”

**Eleanor:** “We almost lost our girl to heart failure. It wasn’t picked up at birth. We were very lucky she survived.”

**Natasha Pye:** “I lost my son Tommy to undiagnosed transposition of the great arteries. After meeting with one of the region’s heart surgeons, we learnt of the pulse oximetry test and he explained to us that it wasn’t currently part of the mandatory newborn tests. We have managed to bring in the test at our local hospital, which was fantastic, but felt like a small step on a very big journey. I struggle speaking about my son and I feel my grief is private and not something to shared. But I challenge myself, because I don’t want another family to go through this trauma. After we lost Tommy I thought the pulse oximetry machines wouldn’t make it any further than my local hospital. This consultation is a chance for all us parents to tell the NHS how strongly we believe all newborns should have the test, and I’m happy to add my voice to Tiny Tickers’ calls for the test to be offered to every baby.”

95. xxxx xxxx

Dear Sir/Madam,

I have just been reading the article about Pulse Oximetry testing on the Tiny Tickers website.

As parents of a sixteen month old xxxx xxxx that was born with CHD and undiagnosed until six and a half weeks old, this test is critical for helping to save childrens lives.

Our little xxxx xxxx was two weeks away from death when xxxx xxxx CHD was discovered.

An emergency operation at the xxxx xxxx saved xxxx xxxx life on bank holiday Monday last year.

xxxx xxxx has just undergone open heart surgery to repair a large VSD.

This surgery then led to a leaky heart valve being discovered which had been repaired too.

Thank God that the NHS and all their many wonderful experts were able to save xxxx xxxx little life.

We are forever grateful to them.

Many times we have watched this test performed on our xxxx xxxx accurately showing xxxx xxxx oxygen levels.

This must now be made standard to help save as many childrens lives as possible.

Please could you consider my views for the upcoming consultation on Pulse Oximetry testing ad standard NHS procedure.

Thank you

Yours Sincerely

xxxx xxxx



*UK National  
Screening Committee*

96. Royal College of Paediatrics and Child Health

<b>Name:</b>	John Furness		<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate): Are you responding on behalf of a specialty group, special interest group or CSAC? If so, please note.</b>	<b>Consultant Paediatrician</b>  <b>Not replying as part of a group</b>			
<b>Role:</b>	Consultant Paediatrician			
<b>Do you consent to your name being published on the UK NSC website alongside your response?</b>				
Yesx				
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>		
		<i>Please use a new row for each comment and add extra rows as required.</i>		
All especially p3	<b>All</b> however for ease of understanding I have linked my comments to Screening for Congenital Heart Defects External review against programme appraisal criteria  for the UK NSC  Version 4.0, April 2014	Reviewing the usefulness of using pulse oximetry against screening criteria is helpful but needs to be interpreted in context. They have been used strictly and therefore made conclusions invalid.  Pulse oximetry does not just screen for congenital heart disease (CHD) or other serious neonatal conditions. It is an objective improvement to the newborn examination. Newborn examination is performed in most hospitals by inexperienced junior doctors. Feedback from these doctors, my peers and my own experience is that newborn femoral pulses are not easy to examine. The use of		

		oximetry on the lower limbs adds objectivity to the examination and can actually save time. Thus assessment of these tools using the correct diagnosis of CHD is inappropriate and invalid.
Section 3	As above	This states; “ All the cost effective prevention measures should have been implemented as far as possible: Not Applicable” I disagree. Pulse oximetry is a cost effective measure and has not been implemented as far as possible.
Section 7 page 20	As above	Acceptable to the population. As a consultant paediatrician I was contacted through my department director because a local newspaper wanted to know if we were using pulse oximetry (PO). Their article was asking why some hospitals had introduced this and others not. They saw this as an article which people would buy their paper for, out of outrage that PO was not used universally in the NHS. The press is a useful barometer of public opinion and would not campaign for things that the majority of their readers disagree with.
Section 13 page 24		Randomised Controlled Trials are not applicable to an intervention that improves and complements examination technique. Were there RCTs of stethoscopes, US, CT, x rays and MRI?
Section 14 page 24		Please see my comment on section 7 above. The public want it and think it is unacceptable not to do it. In my experience where we used it in County Durham and Darlington staff doing examinations want it because it aids the accuracy of their examination. Cardiologists and neonatologists want it because contrary to expectations they have not been swamped with unnecessary cases.
Section 15 page 25		The benefit is early diagnosis of critically ill children. In my experience no parent or staff involved have objected or felt the degree of anxiety generated was inappropriate or delay in discharge unwarranted.
Section 16 p 16		Training costs are minimal. Staff already use pulse oximetry routinely. The machines are the main cost. This is capital and a few hundred pounds each.
Section 21 page 28		Public demand for doing this on everyone will increase but once implemented this tool cannot be increased: NIPE is universal.

97. **XXXX XXXX**

I am absolutely heartbroken and appalled to learn today that the NHS don't think pulse ox screening at birth should be mandatory.

Pulse ox screening is a non expensive non invasive test and it saves lives.

1 in 100 babies are born with some form of CHD and CHD kills more children than all cancers combined.

I was lucky that my **XXXX XXXX** defects were picked up during pregnancy but for many families that isn't the case. I know of far too many families who were sent home with their babies only for them to later discover their babies had CHD. It should never ever happen.

Yours sincerely

**XXXX XXXX**



**98.**Joanna Heath

<b>Name:</b>	Joanna Heath	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	Children's Heart Federation		
<b>Role:</b>	Project Manager		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>Yes</b></p>			
<p>CHF's comments on the consultation regarding the importance of using pulse oximetry as an additional test for NIPE are based on:</p> <ul style="list-style-type: none"> <li>• Views of parents</li> <li>• Views of some clinicians</li> <li>• Views of informed patient representatives</li> <li>• Participation in discussions with the NIPE Advisory Group</li> </ul> <p>Most parents would welcome an additional test to see whether their child has a cardiac or respiratory problem before it becomes symptomatic, because they believe outcomes would be better if treatment is started before the newborn shows signs of clinical distress.</p> <p>They understand the issues of false negatives and positives and generally would prefer for their baby to undergo tests which would later prove unnecessary in order to ensure that their baby is well.</p> <p>Parents feel that pulse oximetry testing would fit in well with the existing NIPE test because it is non-invasive and in fact most new mothers are familiar with the test having probably also recently been tested.</p> <p>CHF understands there may be administrative issues/data recording issues regarding the test because it can show both respiratory or cardiac problems but we feel this should not be a barrier to the test. However we would point out that the heel prick test covers nine different conditions and therefore we do not understand the problem.</p>			



CHF does not believe the test should or would replace clinical observation it is simply a means of identifying conditions where symptoms cannot yet be seen. We have also had reports that indicate clinical observation cannot necessarily be relied upon.

#### Case 1

*"We were concerned because she was a blue shade in colour but the midwives assured us that this was because she was born outside and was probably cold. A junior doctor examined her and said she was fine. After 36 hours of myself and my partner expressing our concerns about her colour and saying we thought there was a problem a senior doctor took us seriously. The pulse oximetry test showed that her oxygen levels were only 38 percent and that her heart was racing. A second test with a different machine showed the same result. We were asked to leave while the SCBU doctors examined her further, at this point P stopped breathing and had to be resuscitated." KA March 2019*

#### Case 2

*"E had very little interest in his bottle and appeared particularly sleepy and floppy, his skin had a slightly blue tinge and at times felt cold and clammy to touch. Despite querying these concerns with midwives we were told that this was quite normal and nothing to worry about. During the course of that second night E collapsed and was rushed to intensive care. We spent the next five weeks at Great Ormond Street Hospital but despite their best efforts, he was unable to recover well enough to go through the first stage of surgery."*

*"We firmly believe that this level of distress could have been prevented in the hours after birth when a pulse oximetry test would have shown that his oxygen levels were dangerously low". MF May 2019*

#### Case 3

*"It took two cardiac arrests at seven and nine weeks of age for them to eventually discover my sons heart condition." LTT May 2019*

#### Case 4

*"Four months and a half we went back and forth, and his paediatrician didn't realize he had a complete heart block. He received his first pacemaker when he was five months." LB May 2019*

#### Case 5

*"Without question, I took nine hours of telling Doctors that something was wrong with my son, refusing to leave the hospital until he was seen to. It could help detect and maybe prevent further heart and organ damage." TH July 2019*

We would argue that a common-sense approach is taken to the health economics analysis e.g. when considering the cost of training and equipment take into account the fact that the nurses administering the test will already have been trained in pulse oximetry and that the foot-device for the baby can be used on the pulse oximeter in the same way as the finger-device is used on the mother.

**We asked parents their thoughts on the potential anxiety caused by “false positives”.**

*“Having had my week-old daughter collapse at home in my arms due to a serious undetected heart condition, I can say without question, some anxiety, over what should be a routine test would be much preferred.”* LB July 2019

*“After a few years it could become the norm, and no one will think anything of it so anxiety will drop. It could also be mentioned when you have your regular antenatal appointments, also cutting down on anxiety.”* CW July 2019

*“I have a twelve-year-old with a CHD. Trust me it's worth the brief anxiety.”* RW July 2019

*“Just like every other newborn screening test, there may be a small percentage of false positive tests, which will require a retest before they leave hospital or after a couple of days at home. It is completely worth it.”* TR July 2019

*“Thinking of the children that were missed and how easily avoided it is definitely worth the anxiety given the alternative which could prove fatal for some.”* MH July 2019

CHF is aware that many maternity units already offer pulse oximetry testing as standard because they recognise the benefits of this simple test. CHF strongly recommends that the pulse oximetry test be extended to **all** maternity units.

99.XXXX XXXX

<b>Name:</b>	XXXX XXXX	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>			
<b>Role:</b>	Mother to a CHD baby		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>No</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Covernote point 20	There were 8 babies who had no diagnosis and the remaining 135 babies that were identified as hypoxic were healthy on investigation.	This is an incredibly small % of the total included in the study. $(8+135)/32836= 0.00435\%$	
Covernote point 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 overdiagnosis, over-treatment, false positives, false reassurance, uncertain findings, and complications.	Yes overdiagnosis is not good, but I'm sure it would have been more costly for treatment in the long run had my XXXX XXXX condition not have been picked up before permanent damage was done, not to mention the heartache of losing a child because of it.	
Covernote point 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.	This is such a simple test, we should be world leaders in advancing it. This should be up to doctors as to whether they would want it included. Tiny Tickers would not be giving out pulse oximetry machines were it not wanted. It is the only	

		objective test available for CHD not reliant on levels of training and experience.
Covernote point 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.	This could be done by introducing the test to the newborn screening. There is sufficient potential benefit to introduce it. The benefits outweigh the harms.
Covernote point 26	<p>Views from consultees and stakeholders are sought on the following question:</p> <ul style="list-style-type: none"> <li>• 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).</li> </ul>	<p>Yes. From your own report:</p> <p>“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).</p> <p>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).</p> <p>20 There were 8 babies who had no diagnosis and the remaining 135 babies that were identified as hypoxic were healthy on investigation.”</p> <p>So of those who tested positive, over half needed treatment in some way, and the only objective way of confirming this.</p> <p>The “Healthy when investigated” makes up 0.0043% of the total number tested which is very small. The approach needed to conduct these test could easily mitigate stress for parents by making it standard and explaining its only one part of a newborn test.</p>
Specific points addressed below	Case study of my daughter	My xxxx xxxx was born in November 2017 with a very Large VSD with a misaligned heart wall next to the hole. We were incredibly lucky to have had it picked up on our 20 week scan. This meant



care plans could be put in place immediately after birth. Although not immediately life threatening, **xxxx xxxx** was medicated for heart failure from 3 weeks old. Surgery was planned for before **xxxx xxxx** was 3 months old, and we faced the challenge of getting **xxxx xxxx** to the minimum weight for the operation. **xxxx xxxx** had a cancelled surgery at 10 weeks, and **xxxx xxxx** final surgery at 11 weeks of age.

We were incredibly lucky to have a well-trained scanner at our 20-week scan, and scans are very much an art form, and looking at the detection rates, won't every tick up all heart issues. If it hadn't had been detected then, the only other current way of detecting it is listening to the heart, and again this is dependent on people having sufficient training to hear a heart murmur. It's not a clear science to non-heart specialists, and it's very subjective way of checking. My **xxxx xxxx** looked fine. It could easily have been missed.

The only way of checking for CHDs more objectively is through a pulse oximetry test. Yes it may pick up other issues as well, although these are things I would have wanted to know about anyway, eg infections. It is such a simple test, even having to complete it several times would cause little distress, especially if it was treated as standard procedure.

If my **xxxx xxxx** condition hadn't been picked up on **xxxx xxxx** scan (and the probability is against detection), and the heart murmur undetected, which again is very possible, we'd have been sent home. **xxxx xxxx** condition would have led to heart failure setting in from about 4 weeks old, and may not have been picked up until **xxxx xxxx** collapsed. By this point **xxxx xxxx** would likely have sufficient fluid build up in **xxxx xxxx** lungs to



		<p>cause permanent lung damage, an enlarged heart and other permanent damage to xxxx xxxx heart. Had xxxx xxxx have survived, xxxx xxxx condition could have been much more complex, and possibly unfixable, leaving xxxx xxxx disabled.</p> <p>As it is, we could have experienced specialists monitor xxxx xxxx , treat xxxx xxxx, and plan for xxxx xxxx heart repair. xxxx xxxx heart operation at 11 weeks has been deemed a success and we are hopeful xxxx xxxx may not need more treatment in the future. Unless you saw xxxx xxxx scar, you would not have known xxxx xxxxhad been that ill.</p> <p>Please allow all CHD babies the chance my xxxx xxxxhad by including the objective pulse oximetry test in the newborn test.</p>
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100. XXXX XXXX

Dear Sir/Madam,

A friend of mine sadly lost XXXX XXXX baby XXXX XXXX a few days after XXXX XXXX was born due to a heart condition that wasn't detected before mother & baby left hospital after birth. I understand from a Facebook post by Tiny Tickers (the tiny hearts charity) that the NHS has recommended that the pulse oximetry test is NOT added to the mandatory & routine testing of newborns. If this is true then I'm sorry to say that I find that extremely disappointing & very sad! To see other parents go through the pain & heartache of watching their child die the way XXXX XXXX & XXXX XXXX lost their XXXX XXXX is completely distressing & deeply heartbreaking! If it was my child I would want the test before taking my baby home to make sure he/she was completely healthy or treated before leaving hospital (or at least started treatment). Please think again & let the babies have the tests that could help save their lives. We all know the earlier these conditions are detected the better the chances of survival!

Many thanks & best wishes

XXXX XXXX



102. XXXX XXXX

To whom it may concern,

Please reconsider your decision not to offer pulse oximetry as a standard screening of newborn babies in the UK.

If this screening had been available in the UK when my three year old XXXX XXXX was born his chronic heart condition would have been picked up at birth and we as parents would not have been completely blindsided when XXXX XXXX condition was eventually picked up.

I am haunted by the 'what ifs' involved with XXXX XXXX being so young and vulnerable for the first three months of XXXX XXXX life. If we had known about XXXX XXXX condition then we could have been more cautious in XXXX XXXX early days.

I think it would be neglectful to not offer this simple, pain free screening test.

Please reconsider

XXXX XXXX

**103.** XXXX XXXX

As the XXXX XXXX of a child who received a very late diagnosis of Tetralogy of Fallot when XXXX XXXX was four and a half years old, I write to urge you to reconsider your recommendation not to roll out Pulse Oximetry testing of new born babies.

You cite 'parental anxiety' 'false positives' and 'false negatives' as potential harms arising from the testing .I can assure you that the 'harms' suffered by parents as they receive the diagnosis following an echo cardiogram, MRI or cardiac catheterization procedure far exceeds any 'harm' resulting from a diagnosis obtained by wrapping a small probe around a baby's hand and foot to measure its oxygen levels.

My XXXX XXXX suffered considerably in the four years before XXXX XXXX diagnosis and had to undergo an echo cardiogram and catheterization procedure to obtain this. This was then followed by 2 open heart surgeries and, more recently, keyhole surgery.

If I had been offered the chance of Pulse Oximetry testing when XXXX XXXX was born, I would most definitely have accepted it and avoided the trauma we have suffered.

Congenital heart defects need to be identified as early as possible to enable treatment to begin to enable the child to experience an improved quality of life. If Pulse Oximetry testing can facilitate this then it is imperative that it is offered to all parents, regardless of where they live, as part of the Newborn and Infant Physical Exam.

**104.** XXXX XXXX

Dear sir/madam,

I am writing to ask that the decision not to recommend pulse oximetry screening for all babies be reviewed by the committee. It is a simple, non-invasive test and it saves lives.

Yours faithfully,

XXXX XXXX

105. XXXX XXXX

<b>Name:</b>	XXXX XXXX	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	XXXX XXXX		
<b>Role:</b>	XXXX XXXX		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">Yes      No</p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
9-10, notes from workshop	"Harm from unnecessary investigations (blood tests and x-ray) and delayed discharge"	<p>This is a misuse of the word "harm". "Inconvenience" might be more apt. Balancing the inconvenience experienced by the false positives against major morbidity and mortality experienced by the true positives, if not detected early, it would be more reasonable to conclude that PO should be implemented as part of the NIPE, not just for detection of CHD but for other conditions too. Potential morbidity and mortality in true positives, for both CHD and other conditions, if not detected early, is not considered in this document.</p> <p>PO should be implemented as part of the NIPE.</p>	

106. [REDACTED]

To whom it may concern

I am emailing to request a change in the NHS position regarding pulse oximetry testing Which is presently not part of the mandatory and routine testing of newborns. I believe this is an appalling decision and write to plea for this policy to be changed.

It shock and horrifies me that in this day and age, with the equipment and technology available, that this isn't part of the standard checking when babies are born.

I was scanned every week from 24 weeks during pregnancy and kept In hospital for 4 months being observed due to high risk conditions, yet not once was my [REDACTED] heart condition detected. After the birth, [REDACTED] was observed and monitored in the TCU for a week and again no one detected [REDACTED] [REDACTED] condition because whilst [REDACTED] appeared fine, inside was a different story. By 12 weeks [REDACTED] defect was so obvious that [REDACTED] heart murmur was listened to by most hospital staff and students because everyone was so surprised it hasn't been picked up on before.

A simple pulse oximetry test could have been the key to [REDACTED] diagnosis. Instead we were sent home with a baby who deteriorated rapidly over the first 12 weeks of [REDACTED] life and was clearly in distress unbeknown to [REDACTED] new parents who were told it must be colic/ reflux/ allergy to milk etc.

We could have lost our [REDACTED] and know many heart parents who have. This shouldn't be happening. We are failing these babies because a simple test is not being undertaking.

Myself and my family have raised £14,000 ourselves to fund pulse oximetry machines to be placed in local maternity wards. Costing only around £700 each and only needing one per ward- the expensive is minimal! And I refuse to believe that the reason it's not been implemented as a routine procedure is due to cost because tht would be absurd? So I really don't understand the NHSs reason for not including this vital test for newborns as standard?

My [REDACTED] had [REDACTED] first open heart surgery at 8 months and will continue to have open heart Surgeries for life. I feel very passionately that this test must be mandatory.



I am confident that all parents would rather receive this test and have their baby's heart checked immediately after birth. It is painless and takes no time at all so I really do not understand the NHS's latest decision. If they have a critical heart defect, this can help save their life.

Too many babies are being born and dieing because their defect goes undetected and this should not be happening. Not when there is a chance to stop it. And so simply and quickly done.

I am writing to urge plead and employee the NHS to reconsider their position on this testing.

Thank you

XXXX XXXX

**107.** Dr Elizabeth Herrieven

<b>Name:</b>	Dr Elizabeth Herrieven	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	Hull University Teaching Hospitals NHS Trust		
<b>Role:</b>	Consultant in Paediatric Emergency Medicine		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>Yes</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Cover note page 3	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).	No, I do not believe there has been sufficient evidence presented to support the decision to withhold a potentially life-saving, simple screening tool from babies in the UK.	

108.

XXXX XXXX

<b>Name:</b>	XXXX XXXX	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>			
<b>Role:</b>	Parent of child with congenital heart disease		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">Yes      <u>No</u></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Covernote Point 5	The review could not say that pulse oximetry screening led to better outcomes for babies than routine screening alone	The review of POS against NSC criteria published in 2014 noted that 'early detection in the fetal or newborn period is essential to provide anticipatory care at delivery or soon after birth and to prevent death before definitive management can be initiated or the morbidity consequent on cardiovascular collapse. Children with CHDs classified as 'duct dependent' are particularly likely to experience cardiovascular collapse during the first few days of life as the fetal circulation is replaced by the neonatal circulation and the arterial duct closes. Cardiovascular collapse, characterised by severe hypoxaemia, shock and acidosis, can have significant long-term effects as a consequence of significant multi-organ insults including hypoxic-ischaemic brain injury. Poor clinical status at the time of intervention increases interventional mortality and has an adverse effect on outcome.'	



		<p>In the UK, antenatal screening detects only 43% of CCHD, with wide regional variation. Routine newborn clinical examination fails to identify up to 45% of CCHD before acute collapse and up to a third of cases present after hospital discharge. (Oddie et al, Lancet).</p> <p>In the USA where POS is routine, death from critical heart defects was reduced by one third in babies offered pulse oximetry screening compared with those who were not offered it.</p> <p>The evidence presented overwhelmingly does <u>not</u> support the decision of the NSC not to recommend POS as an additional element to the NIPE. The decision should be reversed.</p>
Covernote Point 5	A positive result from pulse oximetry could generate some harms including parental anxiety	<p>A positive result may generate anxiety among parents and where the result is a false positive this could be considered a harm however psychometric analysis has shown no significant increase in anxiety among mothers of babies with false-positive results compared with mothers of babies with true-negative results. (Oddie et al, Lancet)</p> <p>Where the result is a true positive it would be reasonable to assume that parental harm resulting from the screen is likely to be the same as or less than the harm that would have resulted from a baby presenting with symptoms at a later date (a false negative).</p> <p>I cannot find evidence in the supporting documentation provided of appropriate consideration having been given by NSC to the harms in terms of parental anxiety that result from discharging a baby following routine screening which is false negative. Routine screening failed to identify that our son (born April 2008) had cCHD (Transposition of the great arteries). We learned subsequently that TGA was clearly visible on his fetal anomaly scan, but missed. Despite being discharged from hospital 3 days after birth, the NIPE did not identify any problems. At home a visit from the community</p>

		<p>midwife at which we asked about his colour resulted in reassurance there was nothing wrong. At 7 days old our xxxx xxxx deteriorated incredibly rapidly being unable to feed, unable to open xxxx xxxx eyes, unresponsive, cold and turning blue. We rushed xxxx xxxx to paediatric A&amp;E where xxxx xxxx SATS were found to be 40%. TGA was diagnosed in A&amp;E following an echo by a doctor who came over to the hospital from the xxxx xxxx, it was fortunate that there was a leading national centre so close by. It took 5 hours to move our xxxx xxxx 5 minutes down the road to the xxxx xxxx as xxxx xxxx condition was so unstable by that point. During this time xxxx xxxx was first cared for by a huge number of people in A&amp;E and then by staff from the xxxx xxxx. A diagnosis of cCHD brings enormous but inevitable anxiety to any parents but receiving the diagnosis late in an emergency situation was absolutely terrifying and hugely distressing. For years afterwards I experienced flashbacks on a regular basis and found myself increasingly unable to stop thinking of the 'what ifs' i.e. what if we hadn't taken xxxx xxxx to A&amp;E because xxxx xxxx would have died in the night. My own personal recovery from the experience has taken several years.</p> <p>Through my involvement with charities working in this area I have since heard numerous stories of the distress and anxiety experienced by parents of children with both cCHD and CHD who received a late diagnosis. I do not think this has been sufficiently considered by the NSC when weighing up the balance of harms and making the decision not to recommend introduction of POS as an additional element in the NIPE.</p>
<p>Covernote Point 21</p>	<p>...particularly focusing on the harms and benefits of over-diagnosis, over-treatment, false positives, false reassurance, uncertain findings and complications</p>	<p>It is not clear why the review particularly focused on these aspects and not the potential benefits. What about accurate and timely diagnosis, appropriate treatment, true positives and false reassurance from routine screening as well as false reassurance from POS?</p>

<p>Covernote Point 22</p>	<p>The review was unable to assess the benefits and harms of pulse oximetry compared with routine screening alone</p>	<p>There is a wealth of evidence that POS is beneficial for babies with cCHD demonstrated by research involving almost half a million babies.(University of Birmingham). The low prevalence of CCHD means large implementation studies are needed to show statistically significant improvements in newborn outcomes. POS is mandatory for all babies in the USA and in a birth cohort of over 26 million infants, overall mortality from CCHD was reduced by 33% after introduction of POS in individual states. (Oddie et al, Lancet).</p> <p>In UK studies, including the 2015 NSC pilot study, the positive test rate was consistently between 0.7% and 0.8%. Up to 80% of babies who are admitted to a neonatal unit after a positive test have a non-cardiac condition, such as pneumonia or sepsis, that required treatment and some of these conditions are potentially life-threatening if treatment is delayed. The workshop convened to consider the harm versus clinical benefit of newborn pulse oximetry screening for these additional conditions found that there was clinical benefit in detecting them. There was some harm in a minority of cases of transitional circulation, a proportion of the culture negative sepsis cases and in the one case of pneumothorax identified. In all other cases there were no harms and detection was beneficial. Of all the babies who screened positive, 87% either didn't need delayed discharge or had appropriately delayed discharge.</p> <p>On the basis of these findings it is extremely difficult to understand how the NSC has come to the view that POS should not be recommended. Inappropriate weight has been given to the potential harms of false positives which are not serious or common.</p>
<p>Consultation cover note, point 23</p>	<p>The use of pulse oximetry machines continues to rise</p>	<p>During the very lengthy period in which the NSC has been considering the addition of POS to the newborn and infant physical exam, the use of POS has grown internationally and in hospitals across the UK, to the extent that over 40% of UK hospitals now use it. In a recent survey of hospitals that were not performing POS,</p>



		<p>almost two-thirds were considering it (University of Birmingham). POS has also been introduced as mandatory for all babies in the United States of America and introduced in other European countries. (Oddie et al, Lancet 2019). A European consensus statement strongly advocated routine POS across Europe.</p> <p>In the UK the charity Tiny Tickers has been running a campaign to raise funds to place machines in hospitals to enable more babies to be screened by this method and they have provided machines to 35 hospitals to date. My family has raised funds for Tiny Tickers to purchase two machines.</p> <p>It seems inevitable given (1) POS is now considered best practice and leading to positive outcomes in other countries and (2) there is significant clinical and public support for it in the UK, that its use will continue to rise irrespective of what the NSC recommends. Unfortunately in the absence of a recommendation in favour of screening from NSC, use of POS will continue to be an unacceptable post-code lottery and the opportunity to develop a nationally standardised approach to the screening test and subsequent pathway will be missed. This may lead to different approaches being taken in different localities which may affect outcomes and also the ability to conduct further research in this area.</p> <p>The NSC should recognise that its recommendation is evidently out of step with the views of a large number of clinicians and hospitals in the UK, who have introduced POS based on their own reviews of the evidence.</p>
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109. XXXX XXXX

Our XXXX XXXX had an undiagnosed heart condition- Transposition of the Great Arteries.

XXXX XXXX condition had not been picked up in any scans or after birth. XXXX XXXX appeared to be very healthy. It was only the valve between the two sides of the heart started to close in the hours following XXXX XXXX birth that XXXX XXXX condition deteriorated. A midwife at the XXXX XXXX noted XXXX XXXX appeared blue in some lights and asked to do a pulse oximetry test. It was then that they realised XXXX XXXX had seriously low oxygen levels and we were able to be transferred to the XXXX XXXX for surgery. For us- we had no idea there was anything wrong with our XXXX XXXX and we would have just taken XXXX XXXX home not knowing. The quick thinking of the XXXX XXXX meant that they were able to pick up that something was not right. Scans had failed to pick the condition up. Although the test didn't tell us what was wrong with XXXX XXXX heart, it did mean that doctors knew there was something wrong and could investigate further and send us to the best people to look after XXXX XXXX.

Our experience with the NHS was a very positive one and we are eternally grateful for our XXXX XXXX life. We campaigned after XXXX XXXX surgery for the pulse oximetry pilot. We were sent to the XXXX XXXX for the best possible care for XXXX XXXX and cannot praise the NHS enough for what they have done. The equipment is already in the hospital for us it's a no brainer. Why wouldn't you check babies? I understand it could cause some temporary stress or worry but it can pick up the conditions that have been missed and allow for further investigation either determine there is a problem, or there isn't. For us it is so important that this be implemented as for us the pulse oximetry test literally saved our XXXX XXXX life.

110.

To whom it may concern,

I'm writing with regards to the consultation on pulse oximetry screening for congenital heart defects. I urge you to recommend that this simple test is implemented as part of normal newborn checks. Our second **XXXX XXXX**, **XXXX XXXX**, was born on the 24th June in **XXXX XXXX**, via elective c-section. All was fine with **XXXX XXXX** initial checks, apart from a heart murmur, for which we were given a follow-up appointment in September. I'd found it a little difficult to feed **XXXX XXXX**, but this was attributed to **XXXX XXXX** being born via c-section, me struggling to breastfeed my other **XXXX XXXX**, and my milk not having "come in". However, at eight days old, **XXXX XXXX** was sleeping a lot. When it took over an hour to get **XXXX XXXX** to consume 20ml expressed milk, we sought advice. Our community midwife referred us to the GP, who examined **XXXX XXXX** and sent us to A&E. Once we were there, it very quickly became apparent that there was something seriously wrong.

After five hours there, where there was a real possibility of losing **XXXX XXXX**, **XXXX XXXX** condition was stabilised and we were transferred to **XXXX XXXX**. There, **XXXX XXXX** and **XXXX XXXX** team quickly identified a coarctation of the aorta. The prostin given to **XXXX XXXX** to reopen the duct wasn't working sufficiently, and **XXXX XXXX** had open heart surgery later that day. I'm delighted to report that **XXXX XXXX** made a full recovery and is developing very well, but that could very easily not have been the case. I've read widely about pulse oximetry since all this happened and I understand that whilst it wouldn't necessarily have picked up **XXXX XXXX** condition, it can work to detect other congenital heart defects. With it being simple and non-invasive, it's cost-effective. I imagine that **XXXX XXXX** treatment must have cost tens of thousands of pounds, if not more. The surgeon commented that **XXXX XXXX** arch repair operation was the seventh that **XXXX XXXX** team had done in a fortnight. Even if pulse oximetry only works in half of cases, it must offer a significant financial saving versus emergency hospital admissions.

I've discussed our experience with friends both with children and who are expecting their first baby. The feeling from them is unanimous: that they would want to have the screening rather than rely on instincts telling them that something wasn't quite right. I therefore urge you to recommend that pulse oximetry is included as part of regular neonatal checks, and am happy to discuss my experience with you further.

Kind regards,

**XXXX XXXX**

**111.** XXXX XXXX

I believe that the pulse Oximetry should be on the newborn screening to ensure more children survive earlier from heart defects. My XXXX XXXX who is nearly 8 is waiting for a Ross Konno procedure which is due to XXXX XXXX heart defect - aortic stenosis. XXXX XXXX wasn't dignosed until XXXX XXXX was 3.5years old and had open heart surgery 2 weeks after we was told about XXXX XXXX condition or XXXX XXXX of had 6 months to live.

Congenital heart defect has no cure which I know but to have better understanding and earlier diagnosis would have meant a little bit of a better life to the run up of XXXX XXXX open heart surgery.

XXXX XXXX

112. Hazel Greig-Midlane

<b>Name:</b>	Hazel Greig-Midlane	<b>Email address:</b>	xxxx xxxx
<b>Organisation (if appropriate):</b>	Heartline Families		
<b>Role:</b>	Representative		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">Yes <input checked="" type="checkbox"/>      No <input type="checkbox"/></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
5.	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.	<p>The harm and stress to the parents of a young baby going into heart failure at home, and the difficulty of getting a diagnosis, need to be put into this equation – the outcome depends on a lay person identifying symptoms as being serious enough to seek urgent medical help, As the parent of a young child whose heart failure was not identified by health visitor and GP, I cannot describe the stress in desperately seeking help, and later in suffering the flashbacks of that period of time when we could have lost xxxx xxxx.</p> <p>The ‘false positives’ included babies with serious and life-threatening conditions who were identified – these should not be excluded</p>	
22	Because the review was unable to assess the benefits and harms of pulse oximetry compared to routine	If the review was unable to reach a conclusion it is illogical to make a recommendation at this time.	



	screening alone, the review recommended against the introduction of pulse oximetry as an additional test in routine screening.	The comparison with routine screening excludes babies identified with serious infections – any further review should look at all positive screenings.
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,	<p>1. If the current evidence is insufficient to make a judgement then no recommendation should have been made at this time. As the number of hospitals using PO machines continues to rise, the recommendation against may undermine current practice. Similarly, those hospitals not introducing it may be seen as failing in their duty of care and actionable should a baby's cardiac condition be overlooked.</p> <p>2. As I understand the outcome of previous research, less than half of chds are identified in utero and 30% of babies are sent home undiagnosed. Diagnosis rises to over 90% with PO.</p> <p>3. Positive but healthy babies are rarely detained more than a few hours, so parental anxieties are quickly laid to rest.</p>
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).	The evidence is insufficient to make a judgement, and the interpretation of 'harm' and 'false positives' has avoided this being a strategic judgement – ie providing the best possible diagnoses and best possible outcomes as a result.

113. Dr Cath Harrison

<b>Name:</b>	Dr Cath Harrison, Consultant Neonatologist,	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	Leeds Teaching Hospitals NHS Trust		
<b>Role:</b>	Representative		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">Yes x</p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<p><i>Please use a new row for each comment and add extra rows as required.</i></p> <p>Current available evidence which if understood correctly by the NCS, should have led to a recommendation for universal pulse oximetry screening (POS).</p> <p>There are inaccuracies in the consultation document :</p> <p style="text-align: center;"><i>There were 8 babies who had no diagnosis and the remaining 135 babies that were identified as hypoxic were healthy on investigation.</i></p> <p>The majority of these babies would have had a repeat saturation screen only.</p>	

The false positive rate of this screen is low and the consultation document describes babies having to undergo “*further investigations*”. In fact only 0.08% cases were admitted, investigated and ultimately found not to have benefitted from identification. Correct practice is to recheck the saturations, which I would not consider an investigation and not harmful in line with the Expert group.

We have been using POS in our hospital for over 5 years alongside the newborn examination. Not only have we detected case of congenital heart disease (CHD) but we have picked up babies with severe infection and lung diseases allowing earlier treatment and resolution of their conditions.

Without POS these babies would almost certainly have presented later and been critically sick with a high mortality rate.

It is well described that the use of POS increases the detection rate of critical or life-threatening CHDs at the newborn screening opportunity. POS is a reliable and easy bedside test to be done and is now integrated into our routine practice.

Without POS half of CHD cases remain undetected by clinical examination under existing screening procedures.

Mortality rates are rising in the neonatal population in the UK, and the lack of support for using POS by the NSC will allow the mortality to increase further. Early detection of CHD and other important pathologies using POS, can only help to reduce this.

114. XXXX XXXX

<b>Name:</b>	XXXX XXXX XXXX XXXX XXXX XXXX XXXX XXXX XXXX XXXX	<b>Email address:</b>	XXXX XXXX XXXX XXXX
<b>Organisation (if appropriate):</b>	XXXX XXXX		
<b>Role:</b>	Consultant neonatal paediatricians		
<b>Do you consent to your name being published on the UK NSC website alongside your response?</b>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Section 5	Lack of comparator data	We wish to draw the committee's attention to the newly published Northern regional data that offers 11 year comparative data from screening vs non-screening units. The reference is: <i>Pulse oximetry screening for critical congenital heart disease: a comparative study of cohorts over 11 years</i> Banait N, Ward-Platt M, Abu-Harb M, Wyllie J, Miller N, Harigopal S. <i>J Matern Fetal Neonatal Med.</i> 2019 Jan 4:1-5. doi: 10.1080/14767058.2018.1538348.	

		<p>The rate of post-discharge diagnosis in the screened population was 7/100,000 and 13/100,000 in the unscreened population with a relative risk of 0.52 (CI 0.2 to 1.42). In almost 140,000 infants screening did not statistically affect diagnosis rates after discharge but we acknowledge the CI is wide.</p> <p>There was no increase in mortality at 1 year of age in the unscreened population. There were more deaths within one year in the screened population.</p> <p>This study identifies a relatively high rate of antenatal detection of 60% which may be much lower in other areas. Therefore we cannot be certain of the effect in areas with low rates of low diagnosis (AND) but would be important to look the AND rates of critical congenital heart diseases rather than looking at overall congenital heart disease.</p>
Section 23	Non-cardiac conditions – detection and impact, potential for harm, lack of sufficient evidence and need for further research	<p>We wish to support the view that pulse oximetry in neonates is a valuable adjunct tool in the detection of hypoxemia. This might be for example in cases of unrecognised sepsis or PPHN. There need to be clear pathways to minimise the number of infants separated from their mothers. This may have the following potential impacts:</p> <ul style="list-style-type: none"> <li>• Reduced breast feeding rates</li> <li>• Increased unnecessary precautionary antibiotic use</li> <li>• Increased transfers to cardiac centres for ECHOs.</li> </ul> <p>These are key outcomes that are currently under-prioritised and under-reported in the literature.</p>

115. XXXX XXXX

<b>Name:</b>	XXXX XXXX	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>			
<b>Role:</b>	parent		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>No</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Cover note for consultation	Increased parental anxiety from false positives, and more tests	<p>As a mother of 3 children who were all offered pulse ox screening, and having two that passed and 1 that 'failed' with no serious heart problems this did not provide greater anxiety. This simple test actually gave me peace of mind-it wasn't invasive and posed no harm or threat to my child. Even with the youngest who failed the test, XXXX XXXX was re-tested and then had an x-ray and remained in hospital for anti-biotitic as XXXX XXXX developed rapid breathing and an infection. This early indicator meant this was picked up quickly-without the screening test we would have been sent home and had to be readmitted which would have been even more anxiety provoking and scary. As it was we were in a safe environment everything was explained properly and it gave us as a family peace of mind that there were no serious complications. So long as the pros/cons of the test is explained adequately to parents this is acceptable. What isn't is waiting for serious symptoms to develop and putting parents through such an unexpected experience. With any national screening measure we</p>	



UK National  
Screening Committee

		can opt out. This test is non-invasive, cheap and provides peace of mind. It should not be a postcode lottery for access!.
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116.

XXXX XXXX

Hi,

I am just responding to the public consultation on whether all new born babies should be screened for congenital heart disease by checking the oxygen saturation's of all newborns.

I am in favour of making this mandatory. The benefits of identifying babies with complex congenital heart disease much earlier and thereby improving their outcomes - far outweighs any potential problems that are being muted as a reason not to do this

Please can my views be included in this public consultation

Many thanks

XXXX XXXX

XXXX XXXX



117. XXXX XXXX

<b>Name:</b>	XXXX XXXX	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	XXXX XXXX		
<b>Role:</b>			
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>Yes      No</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
All	SaTH trialled this as a pilot some 15+ years ago and it was an effective way of screening for some neonatal heart defects (although small numbers).		

**118.** Dr Lucy Grain

<b>Name:</b>	Dr Lucy Grain	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>			
<b>Role:</b>	Consultant Paediatrician at DGH (PEC)		
<b>Do you consent to your name being published on the UK NSC website alongside your response?</b>			
Yes			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Document	Whole document	I fully support the recommendations. Screening would result in an unnecessary burden on those with ultrasound skills with little benefit and significant harm as discharge would be delayed and babies might subsequently be followed up for PFO and minor echo abnormalities of no significance.	
		Once there is a decision for an echocardiogram this has to be of high quality and if incomplete might need repeat at a later date.	
		There might also be a risk that incidental abnormalities that are rare and do not cause differential oxygen saturations are missed with governance/legal implications for those who scan at PEC rather than specialist cardiology level.	



119.

XXXX XXXX

Dear colleagues

As a consultant paediatric cardiologist since 1993, I am extremely surprised that the screening committee feel that oximetry screening should not be recommended. This is an extremely inexpensive measure that could pick up early congenital heart Disease before catastrophic collapse. In previous years we used to see frequent children arrive in a collapsed state where they sustained serious bowel, brain or kidney damage before undergoing successful Cardiac surgery. Early detection could have prevented this. Long term disability is a very expensive outcome irrespective of the major ramifications for the individual concerned and their family. I urge you to reconsider your decision.

Yours sincerely

XXXX XXXX

XXXX XXXX

XXXX XXXX

XXXX XXXX

XXXX XXXX

XXXX XXXX

120.

Dear NSC colleagues

I was dismayed to hear that the review of effectiveness of pulse oximetry in the newborn period has concluded in a recommendation not to include the test as part of the NIPE examination.

As a consultant neonatologist in a neonatal unit where we now routinely measure pulse oximetry as part of the newborn examination without any significant problems, I write to express my disagreement with this conclusion.

The evidence presented supports the effectiveness of pulse oximetry as a screening tool in many ways – mainly because these are dangerous conditions that may cause death and disability if missed by conventional NIPE examinations, but which can be treated effectively with excellent outcomes if detected early. They cause major problems in units/hospitals where there is no cardiac surgery, and undertaking a transfer of a new-born infant who has been diagnosed (or suspected) late is a major logistical challenge, and highly risky to both the baby and healthcare staff, who are often dealing with an uncertain diagnosis as well as a very sick baby. The death of even one of these babies is a tragedy for obvious reasons, but also parents will expect that these cases are detected and will often complain or take legal action against health professionals with all the consequent conflict and anxiety that this causes.

As a clinician, and in our experience as a neonatal intensive care unit, I can say (with the agreement of all my colleagues) that abnormal oxygen levels in a baby are always worth investigating – even if the majority turn out to be normal, or recover from a respiratory problem. The argument that “harm” may result from a positive result seems trite – any anxiety caused may well be appropriate for those babies who turn out to have a genuine cause for their hypoxia (be it cardiac or non-cardiac), and anxiety for those who turn out to have no identifiable cause, and whose hypoxia settles, is only transient.

As for whether presymptomatic detection has any advantage over detection in babies who are already symptomatic – again as clinicians, all would agree that the former is much better than the latter in terms of timely commencement of life-saving treatments such as prostaglandin or inhaled nitric oxide therapy. This would be very difficult to prove in a research trial.

Comparator groups will be very difficult to obtain – the numbers of babies with serious congenital heart disease are small and dividing these into late and early diagnoses based on whether or not pulse oximetry was used will need a study of very large numbers of babies.

Despite the relative lack of population studies, and in particular the lack of a comparator group, I feel that waiting until the necessary level of evidence is available will result in harm to significant numbers of babies whose congenital heart conditions are missed by the current NIPE examination

Yours sincerely,

XXXX XXXX

XXXX XXXX

XXXX XXXX

**121.** XXXX XXXX

Dear NHS

I would like you to reconsider and make it mandatory for the Pulse Oximetry test be carried out on all babies born in order to detect heart conditions earlier and more successfully.

Our own XXXX XXXX was born with a heart condition and luckily this was picked up by a nurse and then further confirmed with the above test and then a scan. So we were very lucky. Our friend XXXX XXXX had the same condition and this was not picked up and XXXX XXXX was sent home with terrible consequences.

Please reconsider and make this test mandatory.

XXXX XXXX

122. XXXX XXXX

From: Office of XXXX XXXX

Sent: 01 August 2019 14:48

To: screeninghelpdesk (PUBLIC HEALTH ENGLAND) <PHE.screeninghelpdesk@nhs.net>

Subject: (Case Ref: XXXX XXXX) Pulse Oximetry Screening

I wish to express my surprise that you are not proposing that pulse oximetry screen would occur on all new born babies.

I am aware that a pilot study showed that of 32,836 babies who had a pulse oximetry screen, there were 239 babies who tested positive for hypoxaemia.

- 14 benefited from early diagnosis and subsequent treatment
- 82 other conditions were identified
- 8 with no diagnosis
- 135 babies identified as hypoxic on further investigation

As a parent myself I would much prefer that low oxygen levels in my child were picked up as early as possible. I appreciate that there is a risk of unnecessary concern for some parents but provided parental anxiety is managed well by empowering them with information, surely the benefit of the early diagnosis for those who have conditions outweighs potential anxiety?

I understand that Most babies are picked up by the test and are healthy are correctly identified within an hour or two and are not admitted to the neonatal unit so there is not significant unnecessary pressure on the Neonatal unit. Indeed the pilot indicates that less than one in a thousand of those screen with an incorrect positive are actually admitted to the unit and are usually discharged within 12 hours

I therefore would ask that Pulse Oximetry Screening should occur for new born babies.

Regards

XXXX XXXX

XXXX XXXX

XXXX XXXX

(XXXX XXXX)

I wish to submit my comments regarding the above noted consultation and stress my disappointment in the recent decision to approve the recommendation against using pulse oximetry testing in the newborn and infant physical exam.

My position on this comes from being a parent whose baby was born with with a previously undiagnosed CHD and the fact that my XXXX XXXX very nearly died because opportunities were missed on the maternity unit and XXXX XXXX ended up being rushed the following day to a cardiac unit 30 miles away.

XXXX XXXX was born in our local hospital maternity unit at 5.35pm. Due to suffering a previous stillbirth with my first pregnancy and then pre-eclampsia with my second pregnancy, I was consultant- led throughout my pregnancy. My labour was straightforward and easy, and XXXX XXXX had a quiet and peaceful entry into the world. We were overjoyed - XXXX XXXX was the final piece of our family jigsaw and was everything we both loved and wanted immensely, importantly XXXX XXXX was a very welcome little XXXX XXXX for our first XXXX XXXX.

At 10pm that evening, I was nursing XXXX XXXX when a midwife came in. I expressed my concerns - XXXX XXXX had barely woken, hadn't really fed, felt cold and looked purple. My midwife actually berated me, chastising me that as a second time mum I should know better that to fuss, that XXXX XXXX was tired from delivery that XXXX XXXX just needed mummy cuddles. It turns out that I actually did know better - I knew my little XXXX XXXX wasn't alert and didn't seem right, my instincts were spot on. I didn't sleep all night, watching XXXX XXXX and holding XXXX XXXX, trying to get XXXX XXXX to wake a little and feed.

My husband and XXXX XXXX arrived the next morning around 9.30am to bring us home. A new midwife came in and I said I had some concerns to which she again said XXXX XXXX was fine, I was overthinking things and we'd do ok once we were home. Shortly afterward, a medical student on XXXX XXXX last day of placement before rotation came to do the final clinical examination so that we could take XXXX XXXX home. As the midwives filled in discharge notes, XXXX XXXX began XXXX XXXX checks. When XXXX XXXX listened to XXXX XXXX heart - then listened again and then repeatedly checked for XXXX XXXX femoral pulses, I knew I was right. Within moments, XXXX XXXX turned to us and said ' your baby has a heart murmur, we need to do more checks.' When I said how XXXX XXXX had been since the night before, XXXX XXXX simply shook XXXX XXXX head and said it should've been investigated then. When XXXX XXXX became suddenly symptomatic it was apparent that my concerns were well founded and the transport arrangements and plans to get XXXX XXXX to the nearest paediatric cardiac unit took so long that as soon as we arrived, my husband and I were taken into a side room and given the devastating news that our little XXXX XXXX had Critical Aortic Stenosis and would only live a few hours.

Unless you are a parent who has suffered such a loss, I doubt you can imagine the immense and overwhelming grief and agony which enfolds you in such a situation.

I understand from the consultation notes that a pulse oximetry test can give a false positive result in the first 24 hours of birth - however, given my concerns within those first 5 hours, this test would have been a very quick & simple method of checking such a vital sign in XXXX XXXX health. A small and simple way of joining the dots, - low oxygen saturation, with cold, purple skin, exceptionally

tired, not feeding. Instead, a further eleven hours passed by. Eleven hours whereby xxxx xxxx could have been transferred to xxxx xxxx and received some intervention. xxxx xxxx eventually made it to the LGI by transfer from the xxxx xxxx, around 7pm that night, 25 hours after xxxx xxxx birth. At this point, as above, as soon as we arrived, my husband and I were taken into a side room and given the devastating news that our little xxxx xxxx had Critical Aortic Stenosis and would only live a few hours.

Pain, agony, devastation. Our world has never been the same.

My husband and I stayed with xxxx xxxx all night, xxxx xxxx was given prostaglandin to keep xxxx xxxx arterial duct open but we were told this was merely buying xxxx xxxx time with us, that nothing further could be done for xxxx xxxx. However, the following morning a new consultant arrived on the xxxx xxxx. xxxx xxxx offered to try to do a balloon valvoplasty on xxxx xxxx, stressing the odds were stacked against xxxx xxxx but it was the only hope for xxxx xxxx. In 2007, this procedure was quite new but we knew we had no option.

Thanks to this consultant being willing to try, we still have xxxx xxxx to this day - xxxx xxxx is 12 years old, at secondary school, living a happy life and is very much loved.

However - the rush to get xxxx xxxx across from our local maternity unit to the xxxx xxxx, the immense drop in xxxx xxxx health as xxxx xxxx went into heart failure, the missed opportunities to react earlier - all of these have had a monumental impact on us as a family.

When we have so many trained monographers now in our maternity units, able to identify early on some heart defects so that planned care can be put in place, why is this not the next step post-delivery for all babies? We are friends and are in touch with countless other heart-parents, all of whom can't understand why this is not being carried out. It's quick, it's not invasive, it's painless and if the initial results of the oxygen levels don't rise in those first few hours - it's an opportunity to look for the reasons why. A chance to check for other signs - weak femoral pulses, lethargy, unable to feed, cold, mottled skin. This is surely a step in making the right decisions to prevent last minute dashes to cardiac units, or worse still - sending a baby home to die unexpectedly.

Parents want this. It's another opportunity to add to gold-standard care and a first class health service. It shouldn't be being discussed, it needs to be implemented fast.

I know from past health-consultations that frequently decisions are made in advance and the process pays lip-service only to the cause, without a willingness to engage fully to the opinions held. I implore you to really listen to the parents that live envy day with their children who have CHD. This is not a normal life for us or our children - but the right care and the right treatment at the right time can make all the difference. Lives can be improved and saved. It's that simple.

Thank you for taking the time to read my statement, I would be more than happy to discuss this further if you wished to.

Kind regards,

xxxx xxxx



124. Chris Gale

<b>Name:</b>	Chris Gale	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	Imperial College London/Chelsea and Westminster Hospital NHS Trust – this is not an official response from these organisations		
<b>Role:</b>	Clinical Senior Lecturer and Consultant Neonatologist		
<b>Do you consent to your name being published on the UK NSC website alongside your response?</b>			
Yes			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Covernote page 1, points 4 and 5	“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.”	This statement is incorrect and misleading - There is high quality randomised controlled trial evidence from the UK, and internationally of benefit following the introduction of pulse oximetry screening	
Covernote page 1, points 4 and 5	<p>“It is also noted that there are harms associated with screening and the further investigations following a positive screening result.”</p> <p>“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.”</p> <p>“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.”</p>	<p>This is misleading – many of the conditions that are deemed to be a “false positive” of pulse oximetry screening, are actually clinically important conditions (such as sepsis) that we as neonatologists and paediatricians want to know about as early as possible – early detection in these cases may lead to additional benefit.</p> <p>Furthermore there is a far higher rate of “false positives” and the harms associated with further investigations with the current clinical examination based screening programme for congenital cardiac disease. This is not reflected here. Although pulse oximetry screening is not perfect, it is far superior to the current screening examination that it would replace/augment.</p>	

125. [REDACTED]

Pulse oximetry can help us provide immediate help to babies who are undiagnosed with hear conditions. As a sonographer I am fully aware that we are not able to diagnose every heart anomaly in scan and the results can be devastating for parents. A baby can can be born well and die within days suddenly, what is more tragic than that.

A simple test, non invasive can help us help them.

[REDACTED]

Principal sonographer

[REDACTED]

126.

XXXX XXXX

Dear Sir,

With regards to the public consultation on newborn pulse oximetry screening, it is my belief that all babies should be tested.

My youngest XXXX XXXX was born with no diagnosed heart defects, though XXXX XXXX did have a four-limb blood pressures test as one doctor thought XXXX XXXX could hear a murmur. We were discharged as usual but we became concerned after a day that XXXX XXXX breathing was laboured. XXXX XXXX was subsequently diagnosed with an evolving coarctation of the aorta and had a successful repair a week later.

Although the test may not have picked up our XXXX XXXX condition any sooner, we know that it is non-invasive and unthreatening. As parents of three we would have had no issue with this test being carried out as part of the newborn checks for any of our children. Indeed it is much less distressing than the heel-prick tests!

We are grateful for the medical care our XXXX XXXX received and support the proposed screening (pardon the pun) wholeheartedly.

Yours faithfully,

XXXX XXXX



127.

XXXX XXXX

Hello

I have just heard that this will not be included in newborn screening.

My friend is a paediatric nurse in America and list her baby to heart problems. She thinks it shouod be.

Many thanks

128. Claire Evans

<b>Name:</b>	Claire Evans		<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	Warrington and Halton Hospitals NHS Foundation Trust			
<b>Role:</b>	Antenatal and Newborn Screening Midwife			
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">Yes</p>				
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>		<b>Comment</b>	
			<i>Please use a new row for each comment and add extra rows as required.</i>	
Screening for Congenital Heart Defects  External review against programme appraisal criteria for the UK NSC.	Complete document		This review although very pertinent is now 5 years old. An additional more contemporary review should also have been included as the global landscape for pulse oximetry screening has changed.	
Screening for Congenital Heart Defects	In around one quarter of newborns with CHDs the diagnosis was not made until after discharge home from hospital		Prevalence of critical congenital cardiac defects are much higher than many of the other conditions screened for as part of the current NHS England Screening Programmes.	

<p>External review against programme appraisal criteria for the UK NSC. Pg. 3</p>		
<p>External review against programme appraisal criteria for the UK NSC. Pg. 5</p>	<p>CHDs are responsible for up to 40% of all deaths from congenital anomalies<sup>2 3</sup> and 3.0–7.5% of infant deaths.</p> <p>Most infants born with CHDs in the UK are diagnosed before one year of age, although around 25% of infants born with CHDs are not diagnosed before discharge and up to 15% of CHDs may remain undiagnosed at death.</p>	<p>Very significant and powerful evidence about the impact of undetected congenital heart defects.</p>
<p>External review against programme appraisal criteria for the UK NSC. Pg. 9</p>	<p>Clinical examination/Pulse oximetry – Cyanosis: Life-threatening CHDs which are likely to be associated with cyanosis are most often those in Group B (TGA), Group C (pulmonary valve abnormalities), and also in Group A (HLH, interrupted aortic arch) and Group D (obstructed TAPVC).</p>	<p>No mention of the poor detection of CCHD as part of the Fetal Anomaly Screening Programme fetal anomaly scan performed at 18+0 – 20+6 weeks of pregnancy nor the combined poor detection of CCHDS from the fetal anomaly scan and the newborn examination (NIPE) both of which are existing screening programmes</p>
<p>External review against programme appraisal criteria for the UK NSC. Pg. 10</p>	<p>CHDs with a short presymptomatic interval can be considered life-threatening and the benefits of newborn screening include the: <input type="checkbox"/> Avoidance of collapse, shock or critical cyanosis, with associated risk of death or hypoxic insult, leading to longer-term neurological or renal sequelae. <input type="checkbox"/> Early diagnosis, to allow timely and prompt access to appropriate management. <input type="checkbox"/> Reduction of perioperative morbidity and mortality through early identification before clinical deterioration.</p>	<p>Clinical evidence in support of early detection of CHDs and importance of detection before clinical collapse ensues. Very important information and evidence that has been largely ignored by the UK NSC.</p>
<p>External review against programme appraisal criteria for the UK NSC. Pg. 15</p>	<p>The three possible candidate tests for newborn screening are: clinical examination alone (current practice); pulse oximetry and screening echocardiography..... and are therefore more likely to be considered as adjuncts to clinical examination.</p>	<p>The clinical newborn examination as an independent screening tool for CCHD has already been proven as a poor detector of CCHD. The use of pulse oximetry screening would be an adjunct to the existing suite of screening programmes.</p>

<p>External review against programme appraisal criteria for the UK NSC. Pg. 17</p>	<p>In the newborn screening model developed for the NHS HTA Programme2 70, it was estimated that 68% of CHDs may be detected by combining pulse oximetry and newborn clinical examination compared with 32% detected by clinical examination alone.</p>	<p>Evidence has already demonstrated that the combination of the fetal anomaly scan, newborn examination (NIPE) and the addition of pulse oximetry would increase the detection rate to over CCHD to over <b>90%</b>.</p>
<p>External review against programme appraisal criteria for the UK NSC. Pg. 19</p>	<p>As around 20% of all life-threatening CHDs present at birth may become clinically symptomatic between 24 and 48 hours after birth, pulse oximetry performed within 24 hours of birth will have greater potential for preclinical detection than at a later timepoint, however the false positive rate is higher with an earlier screen.</p>	<p>See overall comment section in relation to the UK NSC considering a possible evaluative rollout process instead of dismissing a newborn pulse oximetry screening programme completely.</p>
<p>External review against programme appraisal criteria for the UK NSC. Pg. 20</p>	<p>Pulse Ox study..... Evaluation of mothers, using standardised psychological instruments, suggested that they found pulse oximetry acceptable and that false positive results did not increase anxiety significantly.</p>	<p>This is positive evidence that parents found pulse oximetry did not cause parental anxiety as suggested in the cost effectiveness analysis. The cost effectiveness analysis negatively suggest that parental anxiety is generated by pulse oximetry screening with a screen positive result.</p>
<p>External review against programme appraisal criteria for the UK NSC. Pg. 27</p>	<p>Summary: Criterion 16 The existing evidence strongly suggests that pulse oximetry in conjunction with clinical examination is more cost-effective than clinical examination alone. Further evidence, .....identified by pulse oximetry if screening occurs at birth (88 cases per 100,000 live births) compared to at 24 hours (65 cases per 100,000 live births) at an additional cost per case detected of £3,409, however the false positive rate is also higher at birth.</p>	<p>Important evidence that was not considered by the UK NSC. It seems evident that the UK NSC have not considered any of the external evidence review when making their decision.</p>
<p>External review against programme appraisal criteria for the UK NSC. Pg. 32</p>	<p><b>Routine pulse oximetry for newborn screening</b>  A staged introduction could address important uncertainties relating to optimisation of the screening and referral pathways, investigation of false positive screen results and implementing monitoring and</p>	<p>See comment regarding a possible evaluative rollout in overall comments section.</p>

	audit to ascertain false negative results and screening performance. Key issues to be addressed in a pilot would include: .....	
UK National Screening Committee Consultation on the use of pulse oximetry as an additional test in the Newborn and Infant Physical	<b>Consultation covernote</b>	Very little mention of the actual Newborn Pulse Oximetry Screening Pilot within this document and the positive aspects of newborn pulse oximetry screening being implemented by Trusts.
UK National Screening Committee Consultation on the use of pulse oximetry as an additional test in the Newborn and Infant Physical. Pg 1	<b>Current position Point 3</b> The review informed.....(NIPE)	This comment suggests that the decision by the UK National screening committee (UK NSC) not to recommend pulse oximetry screening was based on the cost effectiveness analysis alone. This statement is misleading and heavy weighted in favour of the recommendation by the UK NSC.
	<b>Current position Point 5</b> 'from the research' .....	This statement is not clear in terms of what 'research' it is referring to. Is this the cost effectiveness analysis work or the pilot? The later points imply it is the cost effectiveness analysis. There are no positive aspects or benefits of newborn pulse oximetry mentioned.
	<b>Current position Point 5</b> 'A positive result from pulse oximetry.....for non-symptomatic conditions'	This statement is too generalised, and the cost effectiveness analysis did not prove this to be the case and is only making the assumptions. It is vitally important that a screen positive result from any screening test must be put into context. A screen positive result will cause concern to parents. However, parents would



		want their baby to be investigated to exclude any anomaly. This concept applies to every screening test in every screening programme offered across the antenatal and newborn continuum. A screen positive outcome will prompt further investigation towards a diagnosis. Explanation of the pulse oximetry test and why it is offered and performed is key to what parents understand about this test and its possible outcomes. Equally parents can refuse the pulse oximetry screening.
	<b>Current position Point 5</b>  'For babies .....baby becomes symptomatic'	A wealth of global evidence exists that clearly demonstrates the adverse outcomes including increased mortality and morbidity in those infant. who suffer respiratory collapse from a CCHD or indeed other serious pathologies particularly early onset sepsis /infection in the newborn
UK National Screening Committee Consultation on the use of pulse oximetry as an additional test in the Newborn and Infant Physical Exam. Pg. 3	<b>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).</b>	I would refute this statement. The UK NSC undoubtedly have not considered all the evidence currently available in making their decision. The impression given from the public consultation documents reviewed the UK NSC have made their decision from the cost effectiveness analysis alone which in itself is unsound.
Newborn Pulse Oximetry Screening Pilot End Project Report	<b>Full report</b>	The report clearly states the results from the pilot. The recommendations do reflect the findings. Some results particularly the timing of the pulse oximetry screen by the pilot Trusts and non-adherence to the pilot screening pathway by some Trusts the overall outcome from the pilot was positive in relation to the aim and objectives of this work.
Comparison of Admission rates to Neonatal Units		A summary to clearly describe the comparative data results from this report would have been helpful.

<p>between pulse oximetry screening and non-pulse oximetry screening units. Statistical Report.</p>		<p>Interpretation of this report is difficult but it would appear that no significant statistical trends were demonstrated from this comparator data.</p> <p>This statistical report obtained the data from the national BadgerNet neonatal unit data collection system via the NDAU. If all neonatal units nationally are reporting accurate data to this system, then it is unlikely that any further comparator studies using this method would glean any more significant statistical data than already presented. To collect specific comparator data a designated data clerk would be required in each assigned neonatal unit to collate these data. The practicalities of such a method ultimately may not provide the answer to the question and evidence for a comparator arm for pulse oximetry screening as necessitated in the cost-effectiveness analysis.</p>
<p>Newborn and Infant Physical Examination (NIPE) Screening Programme Newborn Pulse Oximetry Screening. Pg 9</p>	<p><b>Conclusions on benefits and harm</b></p>	<p>It was agreed by the clinicians on the Working Party Meeting in 2018 that newborn pulse oximetry screening <b>was of benefit</b> in detecting hypoxaemia in <b>7 out of 9</b> clinical conditions discussed.</p>
<p>Pulse oximetry as a screening test for critical congenital heart effects and other significant diagnoses in newborn infants. A cost-effectiveness analysis</p>	<p><b>Full report</b></p>	<p>From the evidence presented to this public consultation the assumption can be made that the UK National Screening Committee have made the decision not to introduce pulse oximetry screening based mainly on the inconclusive findings from this cost- effectiveness analysis alone. This is an unsound decision.</p>

		<p>This cost-effectiveness evaluation report is a complex analysis and models used did not clearly explain the pulse oximetry screening and the routine NIPE arm.</p> <p>The results from the pulse oximetry pilot seem to be unjustly represented within this health economics analysis. For example, the design of the pilot was to evaluate the feasibility of implementing newborn pulse oximetry screening on NHS services. It was not a research project therefore a strict comparator arm was not included.</p> <p>The newborn pulse oximetry pilot report clearly demonstrates that it is not about the test efficacy of pulse oximetry screening. This has already been quantified from an existing wide evidence base. Not all screen positive cases had a cardiac echo performed nor was it indicated within this report that all screen positive cases should have an echo.</p> <p>It could be assumed that there is a misinterpretation of what the newborn pulse oximetry pilot set out to achieve and what was expected in relation to the cost-effectiveness analysis.</p>
Overall comments	<b>Summarised overall comments from all evidence presented as part of the public consultation</b>	1.The newborn pulse oximetry pilot report demonstrates that pulse oximetry could be implemented within the NHS without significantly impacting upon current NHS neonatal resources and services.
		2. A remodelling of a national pulse oximetry screening pathway to incorporate an extension to the timing of the first screen was acknowledged to be considered in both the pilot recommendations and that of the UK NSC pulse oximetry screening workshop. An extended first screen window to 12 hours may reduce the number of false screen positive particularly those newborns with a delayed transition – transitional circulation. This would be a more realistic



		screening window although ultimately a pulse oximetry screen before discharge is more beneficial than none at all.
		3. The conclusions from the cost-effective analysis raise more questions than answers in relation to newborn pulse oximetry screening. This represents a negative perspective on pulse oximetry screening overall. Would it not be prudent to follow on from the newborn pulse oximetry pilot work and introduce an evaluative rollout programme that would collect data on screening outcomes rather than dismiss any pulse oximetry screening programme?
		4. The experiences of the pilot Trusts with implementing pulse oximetry screening was overall positive except for just one Trust that reported higher admissions to the neonatal unit from screen positive cases. This was only one Trust's experience. This Trust was a tertiary centre with a substantially larger annual birth rate.
		5. There appears to be a misinterpretation of what the newborn pulse oximetry pilot set out to achieve and what was expected in relation to the cost-effective analysis. The pilot was not a research study.
		6. All Trusts in the newborn pulse oximetry pilot have continued to offer and perform pulse oximetry screening on newborns. The Trusts that had not done pulse oximetry screening before clearly worked hard to implement the service and believed it to be of benefit in detecting hypoxaemia in newborns.
		7. Recent evidence suggests that almost 50% of maternity units in England already offer and perform pulse oximetry screening on newborns irrespective of no national guidance.
		8. The UK NSC need to review the evidence used to support their decision not to implement newborn pulse oximetry screening. An evaluative rollout programme is achievable from the suggestions made above.



		<p>9. The criteria used for any national screening programme to be implemented must understandably be specific and strictly regulated. However, to recap on the screening principles –</p> <ul style="list-style-type: none"><li><b>a.</b> a screening test must be simple and acceptable – newborn pulse oximetry fits both criteria</li><li><b>b.</b> the nature of screening will always pick up false positive cases – the false positive rate reported in the pilot work was relatively low</li><li><b>c.</b> no screening test is 100% perfect</li><li><b>d.</b> ethically and morally screening should cause no harm</li><li><b>e.</b> screening is about making a difference</li></ul> <p>Without a constructive nation newborn pulse oximetry screening programme newborns will continue to suffer significant respiratory insults, substantial morbidities and co-morbidities and ultimately cause death. Early detection of critical congenital cardiac defects before collapse is preventable. In addition, the diagnosis of other pathologies from the use of pulse oximetry can only serve to improve outcomes for newborns and their families.</p>
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129.

XXXX XXXX

Dear Sir/Madam, according to the workshop document on this subject there is evidence that pulse oximetry is a useful tool in newborns and that it should be part of NIPE. Regards, XXXX XXXX

To whom it may concern,

I am writing to discuss with you the consultation regarding using pulse oximetry as an additional test in the Newborn and Infant Physical Exam.

As a prospective parent of the future I feel strongly that I would want my children to have the pulse ox screening included in their newborn testing.

I do not feel the 'harms' outweigh the benefit of detecting a potentially fatal condition and being able to treat any conditions sooner and avoid further complications.

I would much rather my baby have tests that may wield a false positive result and induce further testing than have my child sent home with a life threatening condition that had not been identified.

I hope you will consider the voice of prospective parents, as I am certain a huge percentage would consider the 'harms' listed as a completely worthwhile minor risk of a potentially life saving assessment tool.

Yours sincerely,

XXXX XXXX (NHS Physiotherapist, BSc Hons, MCSP)

131. XXXX XXXX

Good Evening,

Regarding the pulse oximetry post my name is XXXX XXXX. My XXXX XXXX XXXX XXXX was born on the XXXX XXXX 2016 natural birth with induction.

XXXX XXXX was a healthy weight 7lb 8.5oz and was a couple of weeks early. We got XXXX XXXX home and XXXX XXXX put on weight well for the first few checkups and when XXXX XXXX was taking XXXX XXXX bottle XXXX XXXX would go straight back to sleep. I thought it was wonderful, how easy is my child going back to sleep. When XXXX XXXX was 3 weeks old XXXX XXXX had a cough which we were unhappy about but doctors diagnosed XXXX XXXX with bronchiolitis. We were absolutely distraught to think or XXXX XXXX was ill with this viral infection.

XXXX XXXX was later released and then when XXXX XXXX was 8 weeks old XXXX XXXX had the same persistent cough, XXXX XXXX was now a grey colour and very sweaty for it being January. I took XXXX XXXX to the out of hours gp who was concerned about XXXX XXXX blood oxygen (first time it was checked) and sent us straight to hospital to be told once again that it was bronchiolitis.

That evening the doctors rounds changed and a nightshift doctor examined my XXXX XXXX, she was unhappy with the sound of XXXX XXXX heart and was transferred to the XXXX XXXX in XXXX XXXX for an echo urgently. It was there and then XXXX XXXX was diagnosed with complete atrioventricular septal defect, patent ductus arteriosus and which would later lead to pulmonary vein stenosis. XXXX XXXX is lucky to be alive and a simple pulse oximetry test would have possibly raised the alarm a lot quicker.

If it hadn't been for our constant persistent approach our XXXX XXXX would have been in heart failure in a fairly quick time.

Kindest Regards,

XXXX XXXX



132. Dr Heather Durward

<b>Name:</b>	Heather Durward	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	Chesterfield Royal Hospital		
<b>Role:</b>	Associate Specialist in Paediatrics		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>Yes</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Covernote section 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).	We have found pulse oximetry has helped to identify babies with PPHN & undiagnosed coarctation in addition to other abnormalities and would advocate it's continuing use	
Covernote section 5	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	Surely a minor degree of parent anxiety and/or delay in discharge outweighs the death of a baby with coarctation	

133. Professor Dominic Wilkinson

<b>Name:</b>	Professor Dominic Wilkinson	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	University of Oxford		
<b>Role:</b>	Consultant Neonatologist, Professor of Medical ethics		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">Yes</p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
	<p>A critical decision: Failure to introduce pulse-oximetry screening in the UK would be an ethical mistake.</p> <p>Professor Dominic Wilkinson Consultant neonatologist Professor of Medical Ethics</p> <p>Screening tests in medicine have the potential to benefit patients by allowing early detection of important, treatable conditions. However, they can also cause harm in several ways – by leading to large numbers of false positive results with unnecessary or harmful further testing and treatment as well as patient/parental anxiety, and by consuming limited health care resources that could have been better used for other interventions.</p> <p>The UK screening committee and Public Health England are therefore to be commended for carefully considering the evidence on pulse oximetry for screening newborn infants for congenital heart disease, as well as for opening up their decision-making to wider community consultation.</p>		

However, I will argue that the recent decision by the UK NSC not to recommend routine pulse oximetry screening (POS) is ethically flawed, and it would be a serious ethical mistake for the UK to not introduce this simple, potentially life-saving screening test. Why do I make this claim?

1. Decisions about screening tests involve ethical as well as scientific reasoning. There are three key elements to evaluating the scientific evidence that involve ethical values, and are not simple scientific questions.
  - a. What level of evidence is sufficient to warrant introducing a test? There is a continuum of scientific certainty from very uncertain to very certain. Where we draw the line and say that we are sufficiently certain to act or not act is a value judgement.
  - b. How should the benefits of a test be weighed against the harms? The benefits of POS are potentially identifying critical congenital heart disease – preventing death from undetected duct-dependent illness, or preventing serious deterioration prior to diagnosis. The harms are unnecessary admission to neonatal units and parental anxiety. These benefits and harms are of different magnitude and probability. There is no scientific way to say that one of these is greater or lesser – that is an ethical judgement
  - c. What should we do in the face of relative uncertainty about benefits and harms? Should we continue current screening only (antenatal ultrasound plus clinical examination), which we know misses a significant number of cases of critical congenital heart disease, or should we introduce the test with the possibility of leading to false positive results? A decision to screen or not screen in the face of uncertainty again involves ethical values, since it involves considering the ethical consequences of an act or omission.

Given the above, one glaring absence in the material prepared by the UK NSC on pulse oximetry is the lack of any ethical evaluation or discussion. There is a large amount of material on the scientific evidence on POS, there is evidence of most-effectiveness modelling, and there is discussion of the harms and benefits of screening. Yet, there is no explicit discussion of the ethics of evaluating that evidence, those harms and benefits or of acting/failing to act.

3. The decision not to introduce routine pulse oximetry screening appears to be based on an evaluation that the potential harms of screening outweigh the benefits. The consultation cover note lists the former as ‘parental anxiety, a longer stay in hospital, possible transfer to the neonatal unit, further tests to assess for non-symptomatic conditions.’ The principal benefits are prevention of collapse at home of infants with duct-dependent congenital heart disease leading to acute life-threatening illness, worse outcome from surgery, and, most concerning, to death. It is important to quantify the risks of harms or benefits from a screening test. The evidence on POS summarised in previous Cochrane reviews, and in the material assembled by the NSC attempts to do just that. However, it is also important to ethically weigh up the harms and benefits. In doing so, it is important to assess the magnitude as well as the frequency of the harms/benefits. The NSC appears to be very concerned about the possibility of unnecessary admission to the neonatal unit, identification of mild transient respiratory conditions that did not actually require treatment, and causing greater parental anxiety. However, from an ethical perspective, these harms are much lesser harms than the harm of missing a child with critical congenital heart disease who goes home and collapses. As an ethicist, but also as a neonatologist, while I am very concerned not to cause unnecessary stress for parents, not to separate babies from mothers without cause, and to avoid overtreatment, I am much more

concerned to avoid missing serious life-threatening potentially treatable illness. As a parent, myself, I know that I would wish decisions about screening tests to pay attention to the listed harms of false positive tests, but would be much more worried if screening missed important, treatable conditions in my own children.

4. Finally, the decision not to introduce pulse oximetry screening appears to be based on a determination that in the face of relative uncertainty about the harms and benefits of screening that the UK should continue current practice and not introduce the test. However, this decision may reflect undue conservatism and status quo bias. Status quo bias is a well-recognised cognitive bias in favour of the status quo. It is a flaw in our psychology that all of us are vulnerable to – it leads us to often prefer to leave things as they are rather than make a change, even where there are good reasons to make a change. Consider, for example, that 40% of UK hospitals have already introduced some form of pulse oximetry screening for newborns. If the UK NSC were correct to suggest that the evidence is uncertain, that the harms and costs outweigh the benefits of screening, then its recommendation against screening would be logical and defensible. However, the NSC should also logically recommend that those hospitals currently employing screening should also stop screening. There is no good ethical reason for recommending against screening nationally, but allowing those already screening to continue.

However, there would be, I suggest, a strong backlash if the NSC were to make such a recommendation. That is because, even if there is some uncertainty about POS, there is clear evidence that existing screening is inadequate: clinical examination and antenatal ultrasound miss more than half of critical congenital heart disease. There is no good quality evidence that clinical examination is preferable to combined clinical examination/POS. The recommendation in favour of the status quo (no POS) is not because there is evidence that this is better – it is simply because it is the current standard, and those who made the recommendation elected not to change practice in the light of evidence.

There is, of course, good reason not to harm patients by introducing unnecessary tests. Doctors and policy makers sometimes refer to the ethical principle of non-maleficence, and may even refer to this as meaning “first do no harm”. The idea is that health professionals should pay particular attention to the potential harms of medical treatments or interventions, and be wary of doing more harm than good. However, from an ethical perspective, the principle of non-maleficence must always be coupled with that of beneficence. We have to weigh both the benefits and the potential harms of medical interventions. It is an ethical mistake to only consider the risks of acting. We must also weigh up the risks of inaction. To put it most starkly, failure to introduce oximetry screening for newborn infants will mean that over the coming years in the UK some newborn infants who could have been identified by POS will be discharged home, will collapse at home and re-present to hospital critically ill. Some of those infants will be much sicker than they would otherwise be, and have a more complicated course. Some of those infants will die, who could have been saved. The UK NSC is, rightly, worried about the consequences of introducing screening, and feels responsible for the possible harms that may be caused by introducing this additional test. However, the NSC is also ethically responsible for the cases that are missed if screening is not introduced in the face of current evidence.

I have argued that decisions about introducing neonatal screening tests are dependent on ethical evaluation as well scientific facts. This is an important reason why there can be different perspectives on screening, and varying policies by different countries. Even when everyone is looking at the same evidence, they may come to different ethical conclusions about the level of certainty, the balance of risks and benefits and the best course of action given the current state of knowledge.

I have also argued that the UK NSC decision about POS is potentially ethically flawed. While there are risks as well as benefits to weigh up, and uncertainties about pulse oximetry screening, there is an important asymmetry in the risks and benefits. There are much more serious harms by failing to detect critical congenital heart disease than by erroneously detecting some newborn infants with low oxygen levels in the newborn period. There is the possibility of leading to some parental distress and anxiety by false positive results of screening. However, that distress and anxiety, I would argue is unquestionably substantially lower than the distress and anxiety of parents whose newborn infant has collapsed at home, or even, in the worst case scenario, died from a condition that could have been identified and treated.

Failing to introduce screening would be a serious ethical mistake. For that reason it is important that the NSC re-consider its recommendation against pulse-oximetry.

	Ethical considerations in decision to not recommend pulse oximetry	See attached file
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134.

XXXX XXXX

I am writing to add my voice to the call to reconsider the decision of not including the pulse oximetry test as part of the routine testing to newborns.

After seeing the anguish that friends suffered when their baby was born with a heart defect if just one baby is saved and receives the urgent timely treatment for undergoing a simple test, this decision beggars belief.

Baby XXXX XXXX was lucky XXXX XXXX had XXXX XXXX defect picked up on XXXX XXXX scan and now a beautiful toddler enjoying a healthy life, currently on heart foundation fund raising tv advert.

Only 50% of defects are picked up at the scan, the other 50% are sent home a ticking time bomb and many will not grow up to be a healthy little girl or boy as Ivy is now.

For the children of the future, please please make this part of the newborn routine testing.

The skill of the surgeons and the success I've witnessed following XXXX XXXX treatment was fantastic but this was with the team work of neonatal intensive care after XXXX XXXX was born and operated on after a couple of days. Those poor babies sent home may not be so lucky

Please reconsider

XXXX XXXX

XXXX XXXX



UK National Screening Committee

135. British Association of Perinatal Medicine



XXXX XXXX

UK National Screening Committee  
PHE Screening  
Floor 5  
Wellington House  
133-155 Waterloo Road  
London  
SE1 8UG

08 August 2019

Dear UKNSC,

**Re: Public consultation on the UKNSC's decision not to include pulse oximetry screening in the newborn and infant physical exam screening programme**

The British Association of Perinatal Medicine (BAPM) is a professional organisation helping to improve standards of perinatal care by supporting all those involved in perinatal care to optimise their skills and knowledge, deliver and share high quality safe and innovative practice, undertake research, and promote the needs of babies and their families. With almost 1000 members including neonatologists, paediatricians, nurses, midwives, trainees, network managers and other healthcare professionals dedicated to shaping the delivery and improving the standard of perinatal care in the UK, BAPM leads on standards of care in perinatal practice through its Frameworks for Practice.

The BAPM invited comments from its members about UKNSC's recommendation. We have received individual comments from our members, a combined response on behalf of the National Neonatal Grid trainees, Paediatricians with Expertise in Cardiology Special Interest Group (PECSIG) and the British Congenital Cardiac Association (BCCA). These responses uniformly disagreed with the current recommendation and urged UKNSC to reconsider its recommendation. Many of these respondents have experience of having implemented routine pulse oximetry screening locally typically coupled with Newborn Infant Physical Examination (NIPE) for years and they shared their experiences of both detection of serious CHD as well as the management of 'false positives'.

**1. Identification of babies with Congenital Heart diseases (CHD)**

The limitations of both antenatal fetal ultrasound scanning (which detects only 43% of CHD) and Newborn Infant Physical Examination (NIPE) (which fails to detect 45% of infants with CHD) are well known. Research has shown that

XXXX XXXX

XXXX XXXX



adding pulseox screening as adjunct to the antenatal screening and NIPE can identify 75-92% of critical CHD<sup>1,2</sup>.

Routine pulseox screening has been successfully and effectively implemented in a number of countries in the developed world including USA and recent reports from USA demonstrated decreased rates of deaths from critical CHD in states that have implemented routine pulseox screening<sup>3</sup>.

Our members shared a number of anecdotal stories of infants with critical CHD detected early through pulseox screening who might have otherwise been discharged home with the condition undiagnosed.

2. 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

BAPM was represented at the Expert Working Group convened by the UKNSC in June 2018 to consider the harms and benefits of the 'false positives' detected by pulseox screening. Using the data from the NSC UK PulseOx Pilot Study, of the 114 babies with positive test (from a cohort of 32,597 screened babies, 0.35%) who were admitted to the neonatal units, 82 (72% of admitted infants with screen positive) had one of eight distinct significant non-cardiac illnesses. In 6 of these conditions (persistent pulmonary hypertension of the newborn, congenital pneumonia, sepsis, meconium aspiration syndrome, transient tachypnoea of newborn and respiratory distress syndrome), the benefits of earlier detection and hence targeted treatment far outweigh any possible harms. It was only for 23 babies (22 with transient circulation and 1 with minor pneumothorax) that there was any inconvenience of delayed discharge and overtreatment, accounting for 0.07% of all screened infants. Putting it in perspective, 0.27% of screened infants were found to have a condition requiring urgent treatment which has serious implications if left undetected or detected late.

Our members have also shared instances of early detection of non-cardiac illnesses in their real life practice through pulseox screening, particularly pulmonary hypertension and sepsis.

#### Parental anxiety

Studies of anxiety scores among mothers of babies with false-positive results and those with true-negative results have not shown any significant differences. Our members who have implemented routine pulseox screening have not experienced parental anxiety. Instead, members have highlighted the need to balance the possible increased parental anxiety for a very small number of screened infants against the parental reassurance for vast majority of screened infants that their baby has normal oxygen saturations.



#### Longer Stay in hospital and unnecessary investigations

The maximum stay for babies with false-positive tests (in the absence of any significant non-cardiac illness) was 12 hours and the unnecessary investigations, which were with hindsight unnecessary, typically consisted of blood cultures and x-rays. Viewed against the huge benefits of earlier and pre-collapse detection of critical CHD through pulseox screening and timely intervention for those babies with significant non-cardiac illnesses, we do not believe that these considerations should deter the NSC from recommending a potentially lifesaving screening test.

Our members have shared their experience of a repeat pulse oximetry being the most common step following the initial positive screen test. In majority of cases, this simple step was all that was required and the families were reassured by a normal oxygen saturation before their baby being discharged home.

In summary, the current screening strategies fail to identify over half of the babies with critical CHD. The ease and high specificity of pulseox screening affords a simple yet effective and well accepted tool for earlier detection and timely intervention for babies with this potentially life-threatening health condition. Based on interpretation of the evidence and our members' shared experiences of screening thousands of babies over many years, BAPM urges the UKNSC to reconsider its recommendation against offering routine pulseox screening in the UK.

Yours sincerely,

XXXX XXXX

XXXX XXXX

XXXX XXXX

Dr Helen Mactier  
Acting President

Dr Stephen Wardle  
Hon Secretary

Dr Sanjeev Deshpande  
Hon Treasurer

1. Ewer AK, Middleton LJ, Furnston AT, et al. Pulse oximetry screening for congenital heart defects in newborn infants (PulseOx): a test accuracy study. *Lancet* 2011; 378: 785–94.
2. Zhao Q-m, Ma X-j, Ge X-l, et al. Pulse oximetry with clinical assessment to screen for congenital heart disease in neonates in China: a prospective study. *Lancet* 2014; 384: 747–54.
3. 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: 2111–18.

136. Tarak Desai

<b>Name:</b>	Tarak Desai	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	Birmingham Women's and Children's hospital		
<b>Role:</b>	Consultant Paediatric and Fetal Cardiologist		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">Yes</p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
Overall report		<p>In our practice as Paediatric Cardiologist we have seen many CCHD patients diagnosed after pulse oximetry prior to discharge preventing severe cardiovascular collapse after discharge. Early and appropriate cardiac intervention has been crucial in these cases for improved outcomes.</p> <p>Additional diagnosis of non-cardiac problems have been additional benefit of the pulse oximetry.</p> <p>We as Cardiac department feel very strongly that the pulse oximetry screening in newborn prior to discharge is extremely useful and in some cases life saving and should be continued on a national basis.</p>	

137.

XXXX XXXX

My XXXX XXXX was born with a heart defect which went undetected before leaving Hospital. Two weeks later XXXX XXXX was rushed into Hospital by blue light and was put on a life support machine. We very nearly lost XXXX XXXX. If it wasn't for the Heart Surgeons XXXX XXXX wouldn't be here today. XXXX XXXX had to under go major heart surgery. All this heart break we all went threw as a family could of been avoided had XXXX XXXX had tests before leaving Hospital. Any test heart related should be performed after birth to save lives. We were very lucky and my XXXX XXXX survived. Many babies DO NOT! So in my opinion money should be spent on doing what ever test are necessary and buying whatever equipment is necessary to do this in order to save babies lives.

Thank you. XXXX XXXX.

Sent from my iPad



138.

XXXX XXXX

Dear NSC,

I am a midwife who is NIPE trained at **xxxx xxxx**. We feel strongly that the pulse oximetry screening is a vital tool in detecting congenital heart disease in newborns and occasionally detects neonatal early onset infections and respiratory conditions too. The women at our hospital feel reassured when their baby has this screening as we explain at the NIPE examination that approximately only 42% babies with CHD are detected antenatally and the NIPE fails to detect approximately 45% of babies with congenital heart disease, with 30% of those being sent home without diagnosis or treatment. We know that by ensuring the pulse oximetry is made a mandatory part of the NIPE screening, we can detect up to 95% of babies with congenital heart disease. Therefore, it seems completely baffling that we would revoke our current practice and this could potentially lead to more babies being sent home and deteriorating with congenital heart disease that was undetected. Please reconsider your recommendations regarding pulse oximetry in the UK, making this a routine part of the newborn examination prior to discharge.

Thank you for taking the time to read my email.

Regards,

**xxxx xxxx**

Midwife at **xxxx xxxx**

139.      XXXX XXXX

<b>Name:</b> XXXX XXXX		<b>Email address:</b> XXXX XXXX
<b>Organisation (if appropriate):</b> XXXX XXXX		
<b>Role:</b> XXXX XXXX		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">Yes      No</p>		
Section and / or page number	Text or issue to which comments relate	Comment
		<i>Please use a new row for each comment and add extra rows as required.</i>
Newborn PO Screening Pilot, End Project Report	Comment with regard coincidental finding of sepsis on screening	<p>Anecdotal comment:</p> <p>We are a small rural DGH (1800 births/year), and have used PO screening for just a few years. However, we have treated at least XXXX XXXX new-born patients for likely sepsis following an initial concern detected on PO screening alone (with normal SpO2 right hand). In XXXX XXXX cases the patients were/became clinically unwell/ had significantly raised CRP despite normal observations + assigned 'low risk for sepsis' prior to PO screening. I'd be surprised if anecdotally this was not a widespread finding</p>

140. XXXX XXXX

Good morning,

I read about the consultation process with regard to the pulse oximetry screening in babies before leaving the hospital and I think this should be carried out on every child before leaving the hospital.

I had my first child in 2008 XXXX XXXX was born very healthy as we thought no problems. We learned at the age of 6 XXXX XXXX had two holes in XXXX XXXX heart and a defective heart valve. The reason we found out about XXXX XXXX condition was because XXXX XXXX kept telling me XXXX XXXX heart was sore and was breaking. I thought nothing of it until XXXX XXXX said it a few more times. I took XXXX XXXX to my gp who advised us to go see a consultant privately just in case as XXXX XXXX was so young. I arranged the appointment for a few days later and was told at that appointment our XXXX XXXX needed open heart surgery and it would be done within the next six months. As u can imagine we were not expecting that news but after talking to our doctor many things made sense like stopping playing as XXXX XXXX was so tired, was unable to keep up with a half hour swimming lesson, the blue purple colour XXXX XXXX would turn when playing I thought it was because XXXX XXXX was running about so much and other things I could list.

If I had not of listened to my XXXX XXXX telling me there was something wrong then who knows what could have happened.

If the test was done on every child then then no one can be missed and everyone can get the care needed from birth.

Many thanks

XXXX XXXX



141. XXXX XXXX

Dear National Screening Committee,

I have read that you have recommended that the pulse oximetry is not added to the mandatory new born screenings. I please urge that you re consider this.

My XXXX XXXX was taken to hospital when XXXX XXXX was 3 days old with suspected dehydration- within 2 hours of being in hospital XXXX XXXX was in complete heart failure and peri arrest. XXXX XXXX was resuscitated and nearly died. Because of XXXX XXXX late diagnosis XXXX XXXX now has lots of scar tissue on XXXX XXXX heart - something that bugs me to this day that it could have been prevented. I have to live with this and so does my XXXX XXXX. Please, help other babies. This could change the lives of so many family's.

I really hope you reconsider,

Kindest regards,

XXXX XXXX

142. XXXX XXXX

<b>Name:</b>	XXXX XXXX	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	XXXX XXXX		
<b>Role:</b>	Communications Manager		
<p>Do you consent to your name being published on the UK NSC website alongside your response?</p> <p style="text-align: center;">Yes      <b>No</b></p>			
Section and / or page number	Text or issue to which comments relate	Comment	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
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).	This is a non-invasive test that has proven to save the lives of babies with heart defects. This test would save the NHS money by eliminating emergency surgeries and admissions as cardiac problems would be picked up before the baby is discharged from hospital. It would also save the unnecessary distress to the family.	





5<sup>th</sup> July 2019

### Response to the UK Screening Committee consultation on Pulse Oximetry Screening

We are writing to you as a group of senior clinicians, working for the Leicester Neonatal Service to put forward our concerns about your recent decision not to support routine pulse oximetry screening for all newborn infants.

The Leicester Neonatal Service is a large tertiary centre with links to the East Midlands Congenital Heart Centre at Glenfield hospital. We were a pilot site for NHS England during the evaluation of the screening program and have extensive experience of the practicalities of the test and its impact on families, having provided screening to thousands of families.

Antenatal ultrasound screening will only identify 42% of babies with congenital heart disease and the Newborn Infant Physical Examination fails to identify 45% of babies before collapse. Pulse oximetry screening is a simple way to increase the early detection of clinically significant congenital heart disease.

In your consultation you describe the 'harms' of screening- we feel that these have been overemphasised and are not as much of a problem as you describe. The harms listed include:

- 1) Parental anxiety: This has not been a significant problem over the years that we have been screening. Many babies who have a borderline result pass a repeat test and if this is explained properly does not seem to cause anxiety. Many of the positive results we have seen have led to an earlier diagnosis of non-cardiac pathology, particularly pulmonary hypertension and sepsis and this is backed up by data from other centres suggesting that 80% of infants who fail the screening test have significant pathology. Parental anxiety needs to be offset against the large numbers of families that get reassurance that their baby has normal saturations before discharge
  - 2) Longer stay in hospital: Again this has not been our experience. The great majority of babies pass the test and those that have a repeat, often only have discharge delayed by a couple of hours. When we discuss this with families, they are usually reassured that their baby is not being discharged home with low saturations. The argument that it would be better not to screen the saturations and therefore allow babies to go home with unrecognised hypoxia does not seem logical.
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- 
- 3) Unnecessary investigations: When we planned to implement pulse oximetry screening, we arranged provision to provide an increased number of echocardiograms. This has not been needed and we have not seen a significant increase in the numbers of echocardiograms provided.

Most babies with a borderline result do not need any initial investigations and babies admitted with low saturations would only need an echocardiogram if the clinical features suggested congenital heart disease. We have not experienced a significant increase in normal echocardiograms since implementing screening.

We would strongly recommend reconsidering the national position on screening. This test is simple, painless and easy to implement. Published data suggests that picking up unrecognised congenital heart disease before the infant collapses is important and leads to significantly improved outcomes for this group of babies

Yours faithfully,

XXXX XXXX

XXXX XXXX

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XXXX XXXX

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XXXX XXXX

XXXX XXXX

XXXX XXXX

144. Royal College of Paediatrics and Child Health

<b>Name:</b>	Royal College of Paediatrics and Child Health	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>			
<b>Role:</b>			
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">Yes No</p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
General	Insufficient justification of NSC recommendation	As outlined in all the rows below, the review questioned the justification as to why the NSC is discounting the conclusions of the external review and the pilot programme, which are both positive about the introduction of screening and present multiple lines of evidence related to benefits and harms. However, if the recommendation results in high quality research that will better inform the decision this is better than nothing.	
External review Page 5-8 and 22	Disconnect between external review, stating that screening criteria are fulfilled by oximetry + examination, and subsequent NSC recommendation against any	The cover note says that "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." Yet the external review states "Cardiovascular collapse,	

	<p>introduction (in relation to benefit of screening to outcome of CCHD)</p>	<p>characterised by severe hypoxaemia, shock and acidosis, can have significant long-term effects as a consequence of significant multi-organ insults, including hypoxic-ischaemic brain injury. Poor clinical status at the time of intervention increases interventional mortality and has an adverse effect on outcome” and “outcomes after surgery are likely to be improved if an infant undergoes a procedure prior to clinical deterioration.” And “There is evidence to suggest that recognition and treatment of these infants prior to cardiovascular collapse positively influences outcomes after surgery” and “Earlier detection of CHDs would avoid a significant proportion of the complications and mortality associated with cardiovascular collapse subsequent to delayed diagnosis and treatment of CHD”. The evidence in relation to the benefit of oximetry does not appear to be any weaker than that related to existing antenatal cardiac screening. The summary conclusion therefore does not appear to follow the evidence presented.</p>
<p>External review P17-18</p>	<p>Disconnect between external review, stating that screening criteria are fulfilled by oximetry + examination, and subsequent NSC recommendation against any introduction (in relation to comparing oximetry + examination to oximetry alone)</p>	<p>External review states “Wennerholm reviewed routine pulse oximetry for the Swedish health technology programme and concluded that, as a newborn screening test for critical CHDs, combined screening with pulse oximetry and physical examination had better diagnostic accuracy (sensitivity 83-89%, specificity 98- 99%) than... physical examination alone (sensitivity 62%, specificity 98%).” And “An HTA model developed based on published evidence and data from the northern region, estimated that clinical examination alone could detect 32% of life-threatening CHDs, whereas 68% of life-threatening CHDs could be detected by adding pulse oximetry to the newborn clinical examination.” However, the</p>

		cover note states that it was not possible to compare oximetry and examination to examination alone. It is unclear why this conclusion followed from the evidence presented.
PHE pilot report P137-140	Disconnect between pilot outcomes and NSC recommendation	The PHE pilot report states, “The rate of true false positives i.e. babies who were completely healthy and were admitted to NNU was very low” and “There was little evidence of additional significant harm to the majority of babies who had a screen positive outcome.” And “Most screen positive babies who are admitted to NNU have a non-cardiac condition. (i.e. not the target condition) In the majority, the early identification of these conditions is of clinical benefit and a potentially important additional benefit of screening”. The NSC recommendation is concerned about a high rate of harm that does not follow from the evidence presented.
External review P20	Disconnect between external review, stating that screening criteria are fulfilled by oximetry + examination, and subsequent NSC recommendation against any introduction (in relation to the effect of false positive and negatives)	External review states “Evaluation of mothers, using standardised psychological instruments, suggested that they found pulse oximetry acceptable and that false positive results did not increase anxiety significantly.” Presumably this is reference to <a href="https://www.ncbi.nlm.nih.gov/pubmed/22611113">https://www.ncbi.nlm.nih.gov/pubmed/22611113</a> . However, the cover note states that there is insufficient evidence related to anxiety over false positives. This issue could be addressed in a staged introduction and the likelihood of overwhelming anxiety over false positives (different to other established screening tests and different to the existing evidence available) seems unlikely. In addition, the idea that false negatives would reassure parents such that they would be less likely to present to medical care with their collapsed, cyanotic baby is

		not sufficiently plausible for this to be a reason against introduction with monitoring.
External review P30	Disconnect between external review, stating that screening criteria are fulfilled by oximetry + examination, and subsequent NSC recommendation against any introduction (in relation to false positive rate)	External review states “Recent evidence reviews demonstrate that pulse oximetry and clinical examination used in combination have high specificity (>99%), moderate sensitivity (60-80%) and an acceptable false positive rate”. It is unclear why NSC concludes differently.
All especially p3	All however for ease of understanding I have linked my comments to Screening for Congenital Heart Defects External review against programme appraisal criteria for the UK NSC Version 4.0, April 2014	Reviewing the usefulness of using pulse oximetry against screening criteria is helpful but needs to be interpreted in context. They have been used strictly and therefore made conclusions invalid. Pulse oximetry does not just screen for congenital heart disease (CHD) or other serious neonatal conditions. It is an objective improvement to the newborn examination. Newborn examination is performed in most hospitals by inexperienced junior doctors. Feedback from these doctors, peers and personal experiences are that newborn femoral pulses are not easy to examine. The use of oximetry on the lower limbs adds objectivity to the examination and can actually save time. Thus, assessment of these tools using the correct diagnosis of CHD is inappropriate and invalid.
Section 3	As above	This states; “All the cost-effective prevention measures should have been implemented as far as practice: Not Applicable” However, the reviewer stated that pulse oximetry is a cost effective measure and has not been implemented as far as possible.

Section 7 page 20		Acceptable to the population. The reviewer noted that as a consultant paediatrician, they were contacted through their department director because a local newspaper wanted to know if they were using pulse oximetry (PO). Their article was asking why some hospitals had introduced this and others not. They saw this as an article which people would buy their paper for, out of outrage that PO was not used universally in the NHS. The press is a useful barometer of public opinion and would not campaign for things that the majority of their readers disagree with.
Section 13 page 24		Randomised Controlled Trials are not applicable to an intervention that improves and compliments examination technique. Were there RCTs of stethoscopes, US, CT, x-rays and MRI?
Section 14 page 24		Please see comment on section 7 above. The public want it and think it is unacceptable not to do it. In the reviewer's experience in County Durham and Darlington, staff doing examinations want it because it aids the accuracy of their examination. Cardiologists and neonatologists want it because contrary to expectations they have not been swamped with unnecessary cases.
Section 15 page 25		The benefit is early diagnosis of critically ill children. In the reviewer's experience no parent or staff involved have objected or felt the degree of anxiety generated was inappropriate or a delay in discharge unwarranted.
Section 16 p 16		Training costs are minimal. Staff already use pulse oximetry routinely. The machines are the main cost. This is capital and a few hundred pounds each.



<p>Section 21 page 28</p>		<p>Training costs are minimal. Staff already use pulse oximetry routinely. The machines are the main cost. This is capital and a few hundred pounds each.</p>
<p><a href="https://legacyscreening.phe.org.uk/documents/pulse-oximetry/PO%20Research%20Review.pdf">https://legacyscreening.phe.org.uk/documents/pulse-oximetry/PO%20Research%20Review.pdf</a> page 13 and elsewhere</p>	<p>to note that pulse oximetry will identify hypoxaemia which is indicated for CCHD and other, non-cardiac, conditions</p>	<p>It is sensible to include the other, non-cardiac conditions now. The reviewer noted that PO as a screening tool purely for CCHD may not make sense statistically as it doesn't pick up the main critical anomalies of CoA and critical aortic stenosis in the first few hours of life. However, parents as well as clinicians are relieved to have sepsis potentially picked up a bit earlier. It might be this that pushes the argument in favour of PO as part of NIPE in the end.</p>
<p><a href="https://legacyscreening.phe.org.uk/documents/pulse-oximetry/PO%20Research%20Review.pdf">https://legacyscreening.phe.org.uk/documents/pulse-oximetry/PO%20Research%20Review.pdf</a> last page but also elsewhere in the documentation</p>	<p>Future studies should also include qualitative information from parents about their concerns regarding unnecessary invasive tests.</p>	<p>This is a salient point and the qualitative work that needs to be done before deciding for or against universal screening.</p>
<p><a href="https://legacyscreening.phe.org.uk/documents/pulse-oximetry/NPOSP%20End%20Project%20Report.pdf">https://legacyscreening.phe.org.uk/documents/pulse-oximetry/NPOSP%20End%20Project%20Report.pdf</a> Appendix 1, p 142</p>	<p>2 screens 2 hours apart in the amber boxes.</p>	<p>There is room for a third screen here. If the first screen was at 4 hours of age, the baby will only be 6 hours old at the second screen. Babies with murmurs have to stay in for 24 hours in most units. The reviewer suggested a pilot study with babies with sats 90-94% having them checked every 2 hours until 24 hours of age if otherwise well. It would reduce invasive tests, keep the baby safe, and hopefully reassure parents in equal measure as scaring them. 2 hourly sats monitoring might not be practically possible either, 4 hourly might be sufficient after 12 hours of life.</p>
<p><a href="https://legacyscreening.phe.org.uk/documents/pulse-oximetry/NPOSP%20End%20Project%20Report.pdf">https://legacyscreening.phe.org.uk/documents/pulse-oximetry/NPOSP%20End%20Project%20Report.pdf</a> page 133</p>	<p>All Trusts agreed that they wished to continue with PO screening post pilot and have continued to do so.</p>	<p>The unit in Brighton has continued with PO screening after their involvement in this pilot. More and more units are now doing PO screening and it may be that</p>



		clinical practice overtakes national recommendations anyway.
P7, section 4	1st bullet point	The data does not support the conclusion. The pilot study shows that the time period needs to be defined as to allow screening to form part of the usual workflow (not that it is challenging to implement).
P7, section 4	3rd bullet point	This is irrelevant, as it is not the purpose of the screening. It may well increase it, through identification of hypoxaemia pre-discharge.
P7	6th bullet point	This is phrased in an extremely biased way. "Mildly hypoxic" is a meaningless term. Would the authors advise that it is good practice for older children and adults to be "mildly hypoxic" and left un-investigated and untreated?
Page 10	Test result data from the pilot, 4th bullet point	Transitional circulation (healthy) is a misleading term to use. These are babies with delayed, or failed transition. They are hypoxic. That is not a healthy state, and babies who develop persistent pulmonary hypertension are amongst the sickest neonates in intensive care units. Picking up these early prevents them being in the "false positive but probably beneficial findings" group. (Again "probably beneficial" is a biased phrase. Would older children and adults "probably" be better if we knew that they were hypoxaemic and could investigate and treat them appropriately?)
Whole report	Whole report	Much is made of the "harms" caused. This seems to be the rationale for rejecting this effective, safe, painless, cheap, quick, objective test which can be done as part of the routine workflow for all babies born in the UK, when they have their newborn examination (or before discharge, whichever is sooner). However, no data is supplied to support this

		claim of “harm”. In fact, the only reference to it is on page 13, section 5.3 which concludes that the “harm” of delayed discharge and worry are “likely to be broadly acceptable” and “balanced by the serious nature of late identification”. The reviewer questioned whether public consultations being carried out on this and whether the results will be used in decision making.
Pilot findings	Pilot findings	67% screen positive admitted to NNU stayed more than 24 hours (i.e. not healthy), 47% required high dependency or intensive care (i.e. not healthy), 58 required oxygen, 18 required positive pressure ventilator support.
Pilot findings	Pilot findings	“Echocardiography does not appear to be necessary for all screen positive cases with use of clinical judgement resulting in a minority requiring this test.” Based on only 10% of all screen positives undergoing echocardiography.
2014 report	2014 report	<p>Conclusion:</p> <ul style="list-style-type: none"> <li>• Routine pulse oximetry is probably the most promising additional newborn screening modality, particularly for duct-dependent defects obstructing the pulmonary circulation. Recent evidence reviews demonstrate that pulse oximetry and clinical examination used in combination have high specificity (&gt;99%), moderate sensitivity (60-80%) and an acceptable false positive rate (&lt;2%) for newborn screening for critical CHDs.</li> <li>• The addition of pulse oximetry as a newborn screening test is likely to reduce the number of infants with CHDs who experience severe acidosis before intervention and the number</li> </ul>



		<p>of infants discharged from hospital before CHD is recognised</p> <ul style="list-style-type: none"><li>• This review confirms that antenatal and newborn screening for CHDs meets NSC criteria</li><li>• Overall 25-30% of babies born with serious CHDs may remain undiagnosed at hospital discharge. The current programmes are cost-effective and highly acceptable to a low-risk population and no evidence was identified during the review to support their cessation.</li></ul>
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Hi,

I think the Pulse Oximetry needs to be mandatory for newborns I feel strongly about this because my little **XXXX XXXX** who is 13 months old had a major defect and **XXXX XXXX** had to have major open heart surgery at 6 days old! There are babies that are born with defects and aren't picked up and sometimes because it hasn't been picked up it's ended up fatal for the baby where as if you make the Pulse oximetry mandatory it could save so many babies where a defect hasn't been picked up before the baby was born. This could save families going through the awful trauma of loosing their precious babies.

Thank you

**XXXX XXXX**

146. Claire Stokes

<b>Name:</b>	Claire Stokes	<b>Email address:</b>	xxxx xxxx
<b>Organisation (if appropriate):</b>			
<b>Role:</b>			
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>Yes</b>      <b>No</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
	Making pulse oximetry tests mandatory	<p><i>Please use a new row for each comment and add extra rows as required.</i></p> <p>I believe that pulse oximetry should become a mandatory part of newborn screening across all hospitals. We nearly lost our baby xxxx xxxx as he wasn't diagnosed with CHD until xxxx xxxx was 9/10 days old. We saw several midwives who all felt our little one was just suffering from cold symptoms having had a water birth. xxxx xxxx was born on the 95<sup>th</sup> centile and within weeks was tracking against the 5<sup>th</sup>. We saw a number of medical professionals during xxxx xxxx first week of life and it was only on our day 9 midwife check-up/sign off that we put our foot down and said our xxxx xxxx respiratory did not seem right. We were then rushed to A&amp;E and then after 5 hours of tests and examinations it was picked up that xxxx xxxx had a huge ASD and VSD. To think that this could have been picked up so much sooner and prevented xxxx xxxx condition from <b>deteriorating so rapidly is madness. I can't even</b> contemplate what would have happened had we been signed off and sent home on that day. As first time <b>parents whist we knew something wasn't quite right we weren't sure if we were</b> just being overly worried.</p>	



*UK National  
Screening Committee*

147. Claire Wickett

<b>Name:</b>	Claire Wickett	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>			
<b>Role:</b>			
<b>Do you consent to your name being published on the UK NSC website alongside your response?</b>			
		<b>Yes</b>	<b>No</b>
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b> <i>Please use a new row for each comment and add extra rows as required.</i>	
Consultation covernote – page 1	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	But the research has shown that this has prevented death in some babies. This is reason enough for the screening to be compulsory.	
As above	It is also noted that there are harms associated with screening and the further investigations following a positive screening result	This is a pain free test, what harm can it bring to the baby. If very occasionally this may mean a false positive then that is better to detect the real problems and occasionally have to deal with false positives. Any of the other harms can only be seen as necessary if it means that babies lives are saved. I would absolutely have wanted both of my children tested for this, even if it meant some anxiety, a longer stay in hospital etc.	
As above	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.	If this has been adopted in other countries, there should be no reason that this can't be done in the UK also.	

I've not read the full consultation documents, but feel I should share my experience and opinion on oximetry screening.

XXXX XXXX years ago I was blessed with a set of twins, both had health issues, some picked up in the womb, but many more discovered after birth, some even weeks after. We were 'lucky' that twin 1 had his heart condition spotted in utero at the anomaly scan, and while they could not see twin 2, the specialist we were referred to persevered until he could check twin 2, thus spotting XXXX XXXX heart conditions. This was very important as after birth XXXX XXXX did not display typical symptoms of XXXX XXXX heart conditions. The Only typical outward symptom was a low oxygen level that was only picked up by oximetry screening. XXXX XXXX remained in intensive care for a number of weeks, during this time we were often told "thank goodness XXXX XXXX was already in the intensive care unit." If many of the incidents occurred at home we would not have made it to hospital in time to save XXXX XXXX life. I only live a ten-minute drive from XXXX XXXX hospital, but XXXX XXXX would not have survived if these things happened at home. XXXX XXXX is now five years old and thanks to multiple life saving surgeries, in XXXX XXXX, XXXX XXXX, XXXX XXXX and XXXX XXXX, XXXX XXXX is doing extremely well with the ability to lead a full life. XXXX XXXX still requires frequent check-ups to ensure everything is working as it should, this includes weekly blood pressure and oximetry screenings, so we know how quick, painless and easy this is.

The blood prick test and hearing checks are much more distressing than the pulse oximetry testing.

The pulse oximetry screening could easily be carried out when baby is first weighed immediately after birth.

Having spoken to other parents, in parent and toddler groups and at school, none would be alarmed at this extra screening measure, they all say they would be relieved to know their baby has been checked.

I honestly believe adding oximetry screening to post birth check ups would benefit many and cannot understand why it is not already part of the process.

Sincerely,

XXXX XXXX, a concerned parent.



149. Chris Maloney

<b>Name:</b>	Christopher Maloney	<b>Email address:</b>	xxxx xxxx
<b>Organisation (if appropriate):</b>			
<b>Role:</b>	Third year student nurse – Adult Field / patient with HLHS		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">Yes I consent /      No</p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<p><i>Please use a new row for each comment and add extra rows as required.</i></p>	
	Harm caused by pulse oximetry, specifically overdiagnosis and overtreatment.	<p>Whilst admitting that some harm can come from pulse oximetry it seems there is overwhelming evidence that harm is only likely in 1 in every 32,000 babies screened. However, compared with the harm of not reaching a diagnosis for babies with CCHD this seems negligible. The BHF have published an online resource claiming that 1 in 100 births are affected by CCHD <a href="https://www.bhf.org.uk/information-support/conditions/congenital-heart-disease">https://www.bhf.org.uk/information-support/conditions/congenital-heart-disease</a> with the children's heart foundation stating this is 1 in every 133 <a href="http://www.chfed.org.uk/how-we-help/information-service/heart-conditions/">http://www.chfed.org.uk/how-we-help/information-service/heart-conditions/</a></p> <p>Even if this were one in every 150 babies (6.66 recurring per thousand) current evidence shows that 42% of these babies will be identified in the womb. This leaves 3.8 per thousand undiagnosed at birth. Only 55% of these babies will be identified as having CCHD on post-natal examination leaving 1.7 per</p>	



		<p>thousand undiagnosed with 1.15 of these babies being sent home undiagnosed. With efficacy rates of 90% or above when pulse oximetry tests are introduced the number of missed babies reduces to 0.38 babies per 1,000.</p> <p><a href="https://www.birmingham.ac.uk/research/activity/metabolism-systems/Pulse-oximetry-screening-saving-babies-lives.aspx#nsc">https://www.birmingham.ac.uk/research/activity/metabolism-systems/Pulse-oximetry-screening-saving-babies-lives.aspx#nsc</a></p> <p>Mathematical workings drawn from statistics available on UOB (link above)</p> <p>Currently:</p> <p>A. 54 babies per 32,000 currently go undiagnosed at post-natal stage</p> <p>B. 37.11 babies per 32,000 are currently sent home with no diagnosis</p> <p>With pulse oximetry introduced on a national basis:</p> <p>A. 12.16 babies in every 32,000 would continue to be missed with pulse oximetry</p> <p>B. 41.84 babies per 32,000 would receive a diagnosis of CCHD that would not have been possible without pulse oximetry.</p> <p>C. 1 baby in every 32,000 will be put in harm's way by this examination.</p> <p>I therefore feel that the risks and potential harm of pulse oximetry is massively outweighed by the benefits received by those babies. This is drawn from the math I have equated above and due to the fact that other benefits, not pertaining to CCHD, such as the diagnosis of respiratory disease or infection could also be improved with standardised pulse oximetry screening.</p>
	Cost of services.	<p>Cost implications, such as admission to Neonatal units show that in healthy babies less than 1 in 1,000 babies will be admitted falsely, with discharge usually occurring in less than 12 hours.</p> <p><a href="https://www.birmingham.ac.uk/research/activity/metabolism-systems/Pulse-oximetry-screening-saving-babies-lives.aspx#nsc">https://www.birmingham.ac.uk/research/activity/metabolism-systems/Pulse-oximetry-screening-saving-babies-lives.aspx#nsc</a></p>



		<p>Evidence continually shows that poor diagnosis and late intervention increases the length of hospital stay. Using figures above 1.68 babies per thousand will go undiagnosed at post-natal stage and 1.15 babies per thousand will go home without diagnosis. Therefore, upon diagnosis/ re-admission to hospital are likely to need a lot more time in hospital to recover. Certainly, more than 12 hours.</p> <p>Comparatively you have: A. 1.68 babies per 1,000 requiring hospital stays likely &gt; 12hrs B. 1 baby per 1,000 requiring hospital stays of likely &lt; 12hrs</p> <p>Whilst not a completely accurate picture of the financial implications (those diagnosed would still require hospital care &gt;12hrs) patients diagnosed with a pulse oximetry screen are likely to stay in for less time than their undiagnosed/ late diagnosis counterparts who, as evidence shows, are likely to require increased stays in hospital.</p>
	Quality of life	<p>Whilst not an obvious consideration of the National Screening Committees later diagnosis, especially with critical and chronic conditions can have a severe impact on a person's quality of life. Whilst I have no direct evidence from which to make this claim it is my personal belief (and I am sure there will be supporting evidence out there) that by diagnosing earlier and by extension generating a speedier intervention these babies will experience a greater quality of life. This means that they would be able to depend less on NHS, Social and welfare services. Again, saving money and improving lives.</p> <p>As someone who studies and will soon be working within the health profession AND as a patient with a CCHD it makes perfect sense to me that the quicker interventions are made, the better a patient's quality of life and the reduced risk of further complications.</p>



	Personal level	<p>When learning that pulse oximetry was not already included nationally within the neonatal screening programme, I was shocked. It is one of the first things that comes to mind for me when I admit a patient whilst on placements as it generates an important aspect of someone's medical condition.</p> <p>It also shocks me that whilst trying to eradicate health inequalities a simple and quick screening such as this is not delivered in some parts of the country. I feel this would be an important step towards reducing health inequalities in this nation and potentially even globally.</p>

To whom it may concern,

I have recently read that “ The NHS has recommended that the pulse oximetry test is NOT added to the mandatory and routine testing of newborns”

I think this decision should be reconsidered as I am a heart parent myself and had I not been one of the “lucky” ones that had my XXXX XXXX diagnosis picked up before XXXX XXXX was born, I couldn’t even begin to imagine what the outcome might of been, as this test is not a routine test. I know for a fact as I have read up on so many past cases that not all heart defects have been picked up during pregnancy and this has resulted in a sick baby being sent home to later be readmitted into hospital for intervention that is not always diagnosed fast enough. It really is a life or death situation and I strongly believe offering this as a routine test will save so many lives. I don’t understand how you can justify offering a something like the hearing test to check on hearing but not a test that checks if the body’s vital organ is working. I urge that you please, please reconsider this decision.

Thank you and Regards

XXXX XXXX - Mother of a heart patient. (Shone’s Syndrome)

151. XXXX XXXX

Dear sirs,

In agreement with the many concerns voiced in the media, prominently summarised by both Profs. Andrew Ewer and Keith Barrington, i would like to echo their strong sentiments and suggest that the NSC Committee reviews it's suggestions and opts to INCLUDE pulse oximetry screening in the neonatal discharge process, please.

Reasons brilliantly laid out here:

<https://neonatalresearch.org/2019/06/20/pulse-oximetry-screening-a-bizarre-decision-in-the-uk/>

Thank you

XXXX XXXX

Neonatologist

XXXX XXXX UK

Dear NHS Screening Team

I understand that the NHS has recommended that the pulse oximetry test is NOT added to the mandatory & routine testing of newborns. I would like the NHS to consider reversing this decision.

As a parent of a toddler with a heart condition (under the XXXX XXXX), I believe that anything that can be done at birth to pick a heart issue up early saves potential complications and additional medical intervention, at significant cost to the NHS - not to mention the trauma that parents and children have to go through at a later stage.

With kind regards,

XXXX XXXX

To whom it may concern,

I am deeply saddened to hear that you have chosen not to make the pulse oximetry test part of the mandatory baby checks.

Heart defects that have been undetected during pregnancy can be discovered and treated following this test, without it many babies are sent home and their heart defect is not discovered until they are seriously ill or have lost their lives. It baffles me that despite the evidence and campaigning from the small charity Tiny Tickers you have ruled against saving lives. I do hope you will reconsider your decision to the right one.

Kind Regards

XXXX XXXX

Mother of a heart warrior





154.

XXXX XXXX

Dear Sir/Madam,

I write with regard to the aforementioned, further to concerns raised by constituents that the National Screening Committee has launched a public consultation on its decision not to recommend pulse oximetry screening to all newborn babies in the UK.

This test is simple, safe and painless; and has already proven to be successful in diagnosing heart conditions developed in the womb. I understand only 40% of maternity units currently use this test, yet around 1400 babies are born each year with a critical congenital heart defect; with less than half of these conditions diagnosed before birth. Therefore early identification can be life-saving.

I write to support my constituent's in their urge to have the National Screening Committee reconsider their recommendation.

Many thanks

XXXX XXXX

**on behalf** XXXX XXXX

155. Sebastian Brown

<b>Name:</b>	Sebastian Brown	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	Birmingham Women's and Children's Hospital NHS Foundation Trust via HEE West Midlands		
<b>Role:</b>	Paediatric ST5 Trainee		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><u>Yes</u>      No</p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
		<b>Please see summary below with reference to documents as appropriate</b>	
<p><b>Thoughts:</b></p> <p>As a still relatively 'junior' registrar I feel that I am unlikely to add objective further academic evidence or 'professional expertise' to the current screening consultation. However, I felt obliged to share the experiences of a paediatric trainee who has worked in units which both use and do not use routine Pulse Ox screening in addition to routine NIPE, and a brief overview of what I have gleaned from speaking to colleagues, background reading, and information I have come across at local, regional and international teaching/lectures/conferences.</p> <p>Having read the consultation documents I see that the outline for how Pulse Oximetry Screening meets the key criteria for a screening test (Consultation Document 2) have been explored in depth and extensively referenced (albeit back in 2014), and modelling for cost-effectiveness has been updated since then (Consultation Document 4) to aim to estimate the added benefit of the non-CCHD serious conditions that have traditionally been considered as part of the 'false positives' group. Although I understand there are reservations as to the</p>			

assumptions upon which the modelling is based, from reading the Consultation Documents (1, 5), there has been no clear argument that this should be the limiting factor to the acceptance of Pulse Oximetry Screening.

If I have understood the summaries correctly, the primary reservation is that there is currently insufficient evidence that the benefits outweigh the harms of adding Pulse Ox screening to current screening methods. Whilst there have been many more-qualified opinions than mine assess the specifics of this and pore over the cases of false positives and false negatives, I view the problem as an ethical challenge of trying to balance:

- i) The proportionally higher risk of the harms of blood tests, chest X-ray, standard antibiotics (in essence) and the associated delay in discharge from hospital at a time when new mothers are often desperate to get home, coupled with the anxiety of new parents over their potentially unwell baby (despite how well counselled or supported they are by midwifery/neonatal staff)

against

- ii) The proportionally lower risk of missing a case of CCHD or other serious condition, that runs the risk of a later presentation once symptomatic potentially resulting in death / post-natal collapse with attendant risk of subsequent lifelong neurological impairment.

With case ii) I think it is reasonable to presume it is likely to be coupled with a degree of parental anxiety/distress far beyond that expected from i). When weighing up acceptable harms, I think this public consultation will be a vital barometer for the views of parents and families as to what they feel is an acceptable balance. I would not prejudge where public opinion would lie, but I would be more comfortable continuing to inflict excess blood tests on neonates to offset the risk of post-natal collapse.

Leading to my next thought, we already culturally run an extremely low threshold for doing blood tests and starting antibiotics in babies, due to the risk of missing/undertreating a potential case of sepsis. It appears that as things currently stand (not wishing to comment on future directions) we accept this as a balanced risk for a large number of babies we see in delivery suites and post-natal wards.

Considering our existing risk-averse approach to potential neonatal early onset sepsis, this may well mean that when considering future public opinion with regards Pulse Oximetry Screening, I wonder if once the 'other serious conditions' get reframed as 'conditions *including sepsis*' there will be an inevitable increase in pressure from the public/politicians/media. One of the potential difficulties that I worry about is the issue of both geographical health inequalities (potentially arising/becoming exacerbated) and the relation of this to a so-called 'postcode lottery' for screening. From what I have seen the units that currently perform Pulse Ox Screening have worked this into routine practice with the added 'softer' benefits of this and are unlikely to stop offering it. This may give rise to neighbouring trusts being perceived to offer different levels of care, and where funding is already tighter, struggling units are less likely to be supported to take up this additional screening method. And, from a more global perspective, given the increasing uptake throughout the developed world, eventually the UK may see itself

as an outlier rather than a world leader in pulse oximetry screening. Bearing in mind current concerns over infant mortality in the UK, this gives a relatively small topic in Public Health a slightly grander context.

From my experience of seeing babies on delivery suites or labour wards, I have understood that both fetal anomaly ultrasound screening and the Newborn Physical Examination (NIPE) are operator/clinician dependent to variable degrees. With the greatest respect, but pragmatic acceptance, a first-year doctor or midwife runs a greater risk of misinterpreting/missing clinical signs on examination than a midwife or neonatal consultant with many years training. Even these experienced clinicians are also unlikely to be able to perform at their 100% best throughout every examination. The addition of the third layer of Pulse Oximetry screening to detect CCHD (or other potentially serious conditions) adds a last objective measurement to the screening process. One that may well still have its attendant false positives/false negatives, but one which shows much less intra- and inter- observer variability. Obviously, this clinician variability feeds back to the point of ensuring that protocols for the next steps after a 'failed pulse ox' are standardised and escalated to appropriate levels.

I have noted some 'softer' benefits to units that use routine pulse oximetry screening compared to those that don't. Although paediatric and midwifery training is constantly updating to new technologies, in the units where screening is routine, the availability and comfort of the staff in testing a baby's oxygen saturations is greater. From my personal perspective, this seems to have added an extra tool to the midwives' assessments of babies about whom they are concerned on the wards, and allows faster and safer triaging of calls for paediatric reviews. This is becoming an increasingly important consideration with the number of rota gaps across paediatric and neonatal rotas, and the ongoing recruitment/retention crisis in paediatric training. I accept though that this is balanced against the increased calls to review babies who have 'failed their pulse ox' and continuing to prioritise calls effectively.

Overall, as you can tell, I have been convinced that the arguments and the data support the use of Pulse Oximetry. I think this has less to do with any scientific naivety and more to do with being able to balance any controversies in the literature against the pragmatic approach that Neonatal Medicine has to take within the ethical limits of research in our population.

156. Elspeth Brown

<b>Name:</b>	Elspeth Brown		<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	Yorkshire and Humber Congenital Heart Disease Network			
<b>Role:</b>	Clinical Director			
<b>Do you consent to your name being published on the UK NSC website alongside your response?</b>				
<b>Yes</b>				
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>		
		<i>Please use a new row for each comment and add extra rows as required.</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, further tests to assess for non-symptomatic conditions’	Data from the NSC UK pilot in reporting from 2015 showed that the positive test rate was between 0.7 and 0.8%. Up to 80 % of those without a cardiac condition have a significant illness requiring treatment such as sepsis or pneumonia, so although the test may not have picked up congenital heart disease it has picked up significant illness. The measured anxiety scores in mothers with false positive results were not significantly higher than true negatives.		
	‘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.’	Neonates still present acutely unwell due to CCHD which has not been detected on antenatal scans. Although ante-natal detection is improving, it still only detects around 43% of CCHD in the UK. A US study clearly demonstrated that those states who implemented routine newborn screening using pulse oximetry was associated with a significant decrease in infant cardiac deaths of 33% between 2007 and 2013 when compared to states without these policies. Routine pulse oximetry is the norm throughout the Yorkshire and Humber CHD network and will continue to be used. We urge the committee to reverse it’s decision. We also note that the panel which made this recommendation had no paediatric cardiology representation		

To whom it may concern,

I will start off by saying I'm an American, but I recently heard of the decision by the NHS to not add the pulse oximetry screening to the mandatory and routine testing of newborns. Though obviously this doesn't affect me personally, I am deeply concerned with this decision.

My XXXX XXXX was born at home in 2016 in the US. Our healthcare system is vastly different than that of the UK, but I was still able to have all routine prenatal screenings, including blood tests and ultrasounds. My pregnancy was considered to be "low risk" and my XXXX XXXX was expected to be healthy. The anatomy scan ultrasound performed at 20 weeks gestation showed no abnormalities. XXXX XXXX birth was an uncomplicated vaginal delivery, and post-birth XXXX XXXX acted like a typical newborn: nursing, crying, and waking at regular intervals. At 30 hours old, my midwives returned to do a few tests, the first of which was the pulse oximetry screening. XXXX XXXX oxygen level read 67%. My midwife did not believe XXXX XXXX looked as critical as the screening indicated, so she changed the batteries in the machine, tried again, and called a representative from the company in case she was performing the test wrong (she had been trained to use it and was using it correctly). At that point we were instructed to drive to the emergency room. There, at 31 hours old, a cardiologist saw XXXX XXXX and performed an echocardiogram, and XXXX XXXX was diagnosed with Transposition of the Great Arteries. XXXX XXXX was immediately taken to the Neonatal Intensive Care Unit to await surgery. XXXX XXXX had open heart surgery at 4 days old and came home about a week later. XXXX XXXX is now a happy, healthy, wild 3 year old.

I don't believe XXXX XXXX would be here if my midwife didn't do the pulse oximetry screening. XXXX XXXX wasn't blue. XXXX XXXX wasn't lethargic. XXXX XXXX wasn't acting out of the ordinary. XXXX XXXX very well could have passed away in XXXX XXXX sleep, but because of the screening, XXXX XXXX defect was caught in time.

Not mandating the pulse oximetry screening will have drastic and traumatic effects on children who are born with congenital heart disease and their families. Congenital heart disease affects 1 in 110 people worldwide, and many of these will be overlooked in the absence of this life-saving, noninvasive, and fairly easy-to-perform screening. Some children whose defects are not caught by other methods (ultrasound or recognizing cyanosis after birth) may die.

I urge you to reconsider your decision to not require the pulse oximetry screening for every birth in the UK. It can mean life or death for babies born with undiagnosed critical congenital heart disease.

Thank you for your time,

XXXX XXXX

**158. THE COMMITTEE OF THE NEONATAL SOCIETY**

<b>Name:</b>	Professor James Boardman, president of the Neonatal Society Professor Howard Clark, immediate past president Professor Helen Budge, treasurer Professor Andrew Ewer, general secretary Dr Karen Luyt, meetings secretary Dr Chris Gale, committee member Dr Ela Chakkarapani, committee member Professor Lucy Chappell, committee member Dr Kevin Goss, committee member	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	The committee of the Neonatal Society		
<b>Role:</b>	President of the Neonatal Society		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><b>Yes</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
Consultation cover note, page 1	The UK NSC lists the following main reasons to support of its decision not to recommend using pulse oximetry as an additional test in the newborn and infant physical exam:  “A positive result from pulse oximetry will generate some harms, including: parental anxiety, a longer stay in hospital, possible transfer to the neonatal	<p><i>Please use a new row for each comment and add extra rows as required.</i></p> <p>The NSC decision document does not appear to take account of all information available from the NSC PulseOx study, which assessed the nature, scale and harms of false positive results leading to Neonatal Unit admission. Specifically:</p> <ol style="list-style-type: none"> <li>1. 114 of 32,597 (0.35%) babies who tested positive were admitted to NNU. Of these 114 babies: <ul style="list-style-type: none"> <li>• Eight had critical congenital heart disease</li> </ul> </li> </ol>	

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.”

- Eighty-two (72% of all those admitted) had a significant non-cardiac illness (congenital pneumonia, persistent pulmonary hypertension of the newborn [PPHN], early onset sepsis, meconium aspiration, pneumothorax, transient tachypnoea of the newborn [TTN], and respiratory distress syndrome [RDS]).
2. Only 22 of 114 (19%) babies admitted to NNU (0.07% of all those screened) had a transitional circulation and were healthy i.e. were true false positives.

Early detection of congenital pneumonia, PPHN, sepsis, meconium aspiration and RDS is highly desirable because early intervention (investigation and treatment) is one of the levers for preventing serious harm associated with these diseases, and it can be life-saving. This conclusion was reached by the Expert working group set up by the NSC (Document 7, NSC Notes of workshop June 2018.pdf), and we agree with it.

We accept that some babies with transitional circulation or minor pneumothoraces were exposed to unnecessary investigations and delayed discharge of up to 12 hours, but these harms are relatively minor and only 0.07% of all babies screened were affected.

The NSC concern that parental anxiety is increased by a positive result is not supported by data, which show that maternal anxiety is not increased among mothers of babies with false positive results compared to mothers of babies with true negative results (Ewer et al HTA 2012; Narayen et al Eur J Paeds. 2017).





		<p>We disagree with the statement “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.” Experience from the United States shows that implementation of POS for CCHD was associated with a 33.4% (95% CI 10.6%-50.3%) reduction in early infant death from CHD, and a 21.4% (95% CI 6.9%-33.7%) reduction in early infant death from other/unspecified causes (Abouk et al JAMA 2017).</p> <p>We conclude that false positive results in the context of newborn pulse oximetry screening have high clinical value because the majority are due to diseases that require early detection and intervention for optimal outcome. We consider that the benefit of detecting these diseases outweighs the modest harms of unnecessary investigation and delayed discharge that is expected to affect 0.07% of screened individuals who are healthy (true false positive results).</p> <p>We urge the NSC to reconsider its decision taking account of the significant non-cardiac disease burden that contributes to positive results, and the unequivocal benefits of early investigation and treatment of these conditions.</p>
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159.

XXXX XXXX

<b>Name:</b>	XXXX XXXX	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>			
<b>Role:</b>	Consultant Paediatric Cardiologist		
<p>Do you consent to your name being published on the UK NSC website alongside your response?</p> <p style="text-align: center;"><b>No</b></p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>	
		<p><i>Please use a new row for each comment and add extra rows as required.</i></p> <p>Overall comments:</p> <ul style="list-style-type: none"> <li>• Impact on cardiac infrastructure with high demand for echocardiography that in current system may not be able to be delivered</li> <li>• False reassurance in coarctation of the aorta, particularly when screening done early</li> <li>• Agree useful in detecting respiratory pathology too</li> </ul>	

160. Cheryl Battersby

<b>Name:</b>	Cheryl Battersby	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>			
<b>Role:</b>	Clinical Senior Lecturer and Honorary Consultant Neonatologist		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;"><u>Yes</u>      No</p>			
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>		<b>Comment</b>
	<p><i>Please use a new row for each comment and add extra rows as required.</i></p> <p>I urge the screening committee to reconsider their decision. Universal screening is recommended in North American and several European countries, and is already in use in over 40% of hospitals in the UK.</p> <p>In the UK, antenatal screening only detects around 43% of congenital heart disease, and routine newborn examination also misses up to 45% of congenital heart disease. This results in preventable acute collapse.</p> <p>The NSC decided against recommendation as a national screening test on the grounds of insufficient evidence that outcomes are improved, of high false positive rates, with concerns of increased parental anxiety, delayed discharge and unnecessary investigations.</p> <p>1) However, a study in the USA showed that in a birth cohort of 26 million infants, overall mortality from CHD reduced by 33% after introduction of screening in individual states.</p>		



- 2) POS false-positive rates are ten times less frequent than clinical examination alone, and in those who screen false positive, the majority have non-cardiac conditions that will benefit from early detection and intervention.

In the UK pilot study, including the 2015 NSC pilot study, the positive test rate was between 0.7-0.8% and up to 80% of these babies who were admitted had a non-cardiac condition such as pneumonia or sepsis, and potentially life threatening if delayed. Data suggests that 70 in every 10,000 babies screened with POS will test positive and 35 will be admitted to a neonatal unit for further investigations. Of these, 28 will have a condition that requires treatment and only seven will be healthy.

It is clear that most infants admitted to a neonatal unit after a positive test will benefit and avoid potential harm related to delayed diagnosis. Only a small proportion will have a delayed diagnosis and unnecessary investigations.

- 3) Postnatal wards are busy, understaffed, and babies are increasingly being discharged earlier. Relying simply on clinical examination by busy staff and parents to identify infants with hypoxaemia is increasingly difficult.
- 4) As a senior clinician, I have seen the detrimental consequences of undiagnosed congenital heart disease and non-cardiac conditions, resulting in acute collapse on the postnatal ward. Some have been missed despite a newborn examination and observations (without pulse oximetry). Detecting these earlier would have improved care and outcomes; and I am sure parents of these children would argue for a screening test to avoid another family going through similar experiences.

Newborn pulse oximetry screening (POS) is a simple, non-invasive, cost effective tool to objectively assess these babies. It meets the criteria for a screening test and I respectfully urge the committee to reconsider their decision and adopt it as a national screening test.

161. Maxine Heather Barrow

<b>Name:</b>	Maxine Heather Barrow	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	XXXX XXXX		
<b>Role:</b>	Grandparent of baby born and screened 2015, and NNU Research Nurse.		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p><u>Yes</u></p>			
Section and / or page number	Text or issue to which comments relate <i>Please use a new row for each comment and add extra rows as required.</i>	Comment	
	<p>As a grandparent and health professional, I was happy and keen to take part and this did not cause any increased anxiety in my XXXX XXXX parents. I feel that this is a very important screening test and the benefits to the babies that are picked up and treated early, outweigh the anxiety and procedures carried out unnecessarily, that may result from being screened, in the small number of babies that are found to have been screened unnecessarily. On a personal level, I had blood tests for downs in a pregnancy that came back as increased risk and was recommended to have an amniocentesis, which then came back negative, which I was grateful for the screening, but I did have increased anxiety and it did bring about the question for me that if I had been picked out, was there someone else who wasn't and their baby did have the condition.</p> <p>Screening tests are never 100% accurate, and are always going to increase anxiety, but I feel the benefits for the babies do outweigh the parental anxiety and this will be less and forgotten as time goes by, so would advocate that the pulse oximetry is rolled out as a national programme.</p>		



*UK National  
Screening Committee*

162. XXXX XXXX

If it weren't for the pulse oximetry test at 24 hours old my XXXX XXXX would not be here. XXXX XXXX multiple heart defects (tetralogy of fallot and pulmonary atresia) were not detected in utero. The pulse oximetry test showed O<sub>2</sub> at 80. When XXXX XXXX got to the XXXX XXXX hospital 3 hrs away, XXXX XXXX would spend 6 weeks in the NICU and have two open heart surgeries by 8 months old.

Please make this mandatory. It saved my XXXX XXXX life... it can save others for very cheaply!



August 8, 2019

UK National Screening Committee  
Public Health England  
National Health Service

**RE: Consultation on the Use of Pulse Oximetry as an Additional Test in the Newborn and Infant Physical Exam**

Dear NSC Representatives,

Please accept the following consultation on the recent review of newborn pulse oximetry as a screening test for earlier identification of otherwise asymptomatic babies.

The Newborn Foundation and its partners have spent the better part of the past decade working on key implementation methods and quality improvement surrounding newborn CCHD (pulse oximetry) screening in the United States and in more than a dozen countries around the world. We appreciate the time and dedication of the committee in researching and reviewing this important public health issue

However, we believe the evidence provided to justify the committee recent decision does not meet the threshold for withholding this screening as part of the NIPE for babies born in the UK.

In your own position statement, UK NSC states that its review focused on the harms and benefits of potential for over-diagnosis, over-treatment, false positives, false reassurance, uncertain findings, and complications. This is, of course an important component of any evidence review. It should not, however have been the primary focus of the review or weighted disproportionately against the economic or clinical evidence of efficacy, feasibility and improved outcomes.

1. The evidence is simply not there to support the notion that appropriate use of pulse oximetry in the newborn period leads to “over-diagnosis” or over-treatment. In fact, multiple studies have shown the addition of pulse oximetry screening to physical exam may avert additional tests or time in the unit.<sup>1</sup> This includes one of the most robust international studies conducted in Birmingham, which demonstrated the opportunity to actually avert unnecessary referrals and echocardiograms by adding pulse oximetry to routine exam.
2. Treatment of a newborn based on a pulse oximetry measurement is left to the expert discretion of the primary care provider – and protocols for hypoxemia and identification of causes of hypoxemia have been well-established in both the literature and in practice. There are, in fact, only a fraction of a percent of newborns with abnormal SpO<sub>2</sub> that result in NO need for clinical action.<sup>2</sup>
3. The false positive rate for newborn pulse oximetry screening may be slightly higher in UK birth settings due to the early discharge of mothers and babies from the unit. This slightly higher FP rate has been determined to be acceptable from a public health screening standpoint – and may be considered to be “offset” by the number of babies earlier identified with important heart and respiratory conditions These babies have the benefit of



being properly referred and treated in a timely fashion, whereas screening after 24 hours of age can result in newborns already presenting with signs and symptoms, potentially putting them at risk for distance-transport or the most effective interventions. <sup>3,4,5,6</sup>

4. It is very important to note that the sensitivity of pulse oximetry screening for critical congenital heart disease (CCHD) of approximately 76.3% (specificity is 99.9% and a false positive rate of less than .14%), is based exclusively on detection of “critical” heart defects, and does not take into account the other “categories” of CHD, including serious cardiac defects. It also does not take into account the other important non-cardiac conditions that are picked up earlier through screening, including serious but asymptomatic lung and respiratory conditions and infections. <sup>7</sup> Widely disseminated training for screeners and parents alike provides the necessary education and understanding that not ALL cardiac defects can be detected with this screening method, and that signs and symptoms should not be ignored – and CHD not automatically ruled out, if a baby presents with these following screening and discharge from the birth setting.<sup>8</sup> This issue has also been addressed in numerous studies exploring parental attitudes toward pulse oximetry screening.
5. The reports offer little concrete evidence surrounding “uncertain findings”. Clearly, no infant with an abnormal oxygen saturation should be summarily discharged from a clinical setting without some confidence that the cause of the abnormal reading has been determined. In the 8 years since routine implementation in the United States, there have been few, if any instances of harm to a newborn occurring based “uncertainty” following the addition of screening. These cases are addressed through protocol-based follow up of the infant, both in the unit and post-discharge. In Newborn Foundation studies spanning a cohort of more than a 154,000 newborns, there have been no documented cases of harm to a newborn based on screening alone. <sup>9,10,11</sup>
6. It is an overwhelming body of evidence to suggest significant benefit to babies by including pulse oximetry screening over physical exam alone. While “complications” are mentioned in the report, there are few details or actual data cited to support this. One cannot assume that a longer stay in the unit following a positive pulse oximetry screen is a harm. Studies would show that instead of “many” of these babies having unnecessary further investigation only to be identified as healthy – the statistics show this number is actually very, very few. <sup>12</sup>
7. For babies with CHD and other non-cardiac lesions it is absolutely clear that earlier identification will lead to improved ability to manage the condition and a better, more informed process for treatment – whatever that may be. It was never the purpose of routine newborn pulse oximetry screening to accelerate critical interventions. It was to provide the opportunity to better manage identified conditions at the most optimal time. <sup>3,4,5,6</sup>

There is a clear body of evidence to show that babies are AT RISK of a poorer outcome if they are not identified until after signs and symptoms present. These risks include:  
symptoms that manifest as a result of rapid decompensation or multi-organ failure,  
lack of immediate access to confirmatory testing or echocardiography,  
lack of immediate access to PGE1 or other types of stabilization,  
and challenges with medical transport of medically fragile infants.

Babies with non-cardiac conditions that are commonly detected through pulse oximetry screening, including pneumonia and sepsis are also shown to benefit from earlier detection. Additionally, the early discharge policy in the UK puts babies at greater risk of complications from delayed identification of serious medical conditions that will not be

picked up until after families are back at home, and potentially far from a facility that can promptly diagnose and treat.

Given the similarities in burden of disease and economic stratification, it seems abundantly clear that the findings following the U.S. implementation of newborn CCHD (pulse oximetry) screening would yield similar results in the UK. In an observational study conducted between 2007 and 2013 including approximately 27 million US births, state adoption of a mandatory screening policy was associated with a statistically significant decline of 33.4% in the death rate due to critical congenital heart disease compared with states without such policies.<sup>13, 14</sup>

Congenital heart disease is the most common birth defect, affecting at least 8 in every 1,000 babies born in the UK. Given the approximate annual births of 680,000 per year, it can be assumed around 5,400 children will be born each year with congenital heart disease. One-half to on-third of those babies will have critical defects (CCHD), requiring surgical intervention in the first months of life. If even 800 babies remain undiagnosed prior to birth, this pool of newborns runs the risk of leaving the hospital nursery without a diagnosis of a potentially deadly heart condition.

In real terms, the cost of having one of these babies return to the hospital already in circulatory collapse would negate the annual cost of screening altogether. The cost of one malpractice suit following a preventable death from a missed diagnosis (or misdiagnosis by GPs post-discharge) would equate to several years of screening costs.

No matter how you slice the data there will be babies missed with the existing methods: prenatal screening + physical exam alone.

The committee relied heavily on an article by Banait et al. that used data from three tertiary hospitals in the Newcastle area in northern England to conclude that pulse ox screening (POS) did not appreciably improve CCHD outcomes, but also said the same conclusion cannot be made for regions with lower antenatal detection rates. Following the public health model – the target condition of CHD or CCHD was identified, knowing that we may indeed find numerous other important conditions associated with hypoxemia in the newborn. That has born itself out in the data. Backtracking now to “rename” the screening as one that searches for hypoxemia alone (not the related conditions) does little other than delay access to a vital screening tool for babies and those who care for them.

Even in the U.S. the impact of screening varies between states and regions. Tertiary care hospitals or areas with high levels of prenatal identification of cardiac defects, would naturally report less impact from screening on timely CCHD diagnoses. Prior to the introduction of universal POS in the US, there were large disparities in timely CCHD diagnosis, and the primary benefit of screening is likely to have been infants who were not born in tertiary care institutions or in high volume centers with nearby access to pediatric cardiac services or life-saving surgical interventions. As such, we are concerned that the committee and reviewers may not have fully understood or appreciated the population health argument for universal screening.

In the U.S. we have a very robust evidence review process at the federal level to consider and evaluate any conditions that might be ready for inclusion in the Routine Uniform Screening Panel (RUSP). This includes a full literature review – domestic and international, along with program and economic modeling, interviews with relevant clinical and public health experts and interim reports to the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC). Your conclusions cite a lack of comparator data that made is impossible to model cost effectiveness of pulse oximetry for cCHD and the other conditions identified. Yet, a large body of data is indeed available to inform this decision.<sup>14,15,16</sup> All the UK NSC needed to is look outside its own borders to see the evidence, including cost-effectiveness, timeliness impact on outcomes, parental anxiety, and implementation feasibility for a routine screening program.

Even countries on the World Bank list of Low and Middle-Income nations (LMICs) are investing in pulse oximetry for newborn screening. Even in places where resources are exponentially more stretched than the UK or the U.S., clinicians and public health leaders alike understand the proven value of routine newborn pulse oximetry screening. The UK is also among 193 member states having signed on to the UN Sustainable Development Goals. The NHS and agencies should understand that by denying this simple, low-cost and effective screening to all babies, it defies the principals of the UN SDGs #3 (good health and wellbeing) and #10 (reduce inequalities). Access to only a select, privileged few, in the right geographic locations, is not equitable or ethical. Nor does it make an attempt to reduce the burden of preventable deaths among children under-5 from non-communicable diseases.

F the addition of CCHD screening to the U.S. Routine Uniform Screening Panel, we had several productive meetings with Dr. Mackie's office. After 6 years, this result is indeed unexpected. We had confidence that the slower, thoughtful approach in the UK would result in a recommendation to screen all babies for critical CHD. Have you been in touch with Dr. Barrington? How can we collaborate on a response?

Following the addition of CCHD screening to the U.S. Routine Uniform Screening Panel, the Newborn Foundation had had several productive meetings with the NSC. We had confidence that the slower, thoughtful approach in the UK would result in a recommendation. Instead it was a devastating, unexpected result – not supported by science, the public health community, or the dozens of nations that have already implemented universal pulse oximetry screening to save and improve fragile lives.

As the mother of a child diagnosed with critical congenital heart disease at 3 days old – I hope the committee carefully considers the important consultations they receive. Lives like my own daughter's are at stake. We are available for questions or collaboration at your request.

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Respectfully,

Annamarie Saarinen  
Chief Executive Officer, Newborn Foundation  
<https://www.linkedin.com/in/annamariesaarinen/>  
Eve's Story: <https://bit.ly/2Hh7njH>

1. Andrew K. Ewer. Pulse Oximetry Screening for Critical Congenital Heart Defects: A Life-Saving Test for All Newborn Babies. *International Journal of Neonatal Screening*.
2. Oster ME, Aucott SW, Glidewell J, Hackell J, Kochilas L, Martin GR, Phillippi J, Pinto N, Saarinen A, Sontag M, Kemper A. Lessons learned from newborn screening for critical congenital heart defects. *Pediatrics*. 2016;137(5):e20154573. *This report from an expert panel reviews the lessons learned thus far in CCHD screening and identifies opportunities for further study and improvement.* [Google Scholar](#)
3. Eckersley L, Sadler L, Parry E, Finucane K, Gentles TL. Timing of diagnosis affects mortality in critical congenital heart disease. *Arch Dis Child*. 2015;1–5. doi: [10.1136/archdischild-2014-307691](https://doi.org/10.1136/archdischild-2014-307691). *Identifies the scope of and impact of late diagnosis in New Zealand, focusing on excess mortality and the need for intervention particularly for d-TGA.*
4. Liberman RF, Getz KD, Lin AE, Higgins CA, Sekhvat S, Markenson GR, Anderka M. Delayed diagnosis of critical congenital heart defects: trends and associated factors. *Pediatrics*. 2014;134:e373–81. [CrossRefPubMedGoogle Scholar](#)
5. Peterson C, Ailes E, Riehle-Colarusso T, Oster ME, Olney RS, Cassell CH, Fixler DE, Carmichael SL, Shaw GM, Gilboa SM. Late detection of critical congenital heart disease among US infants: estimation of the potential impact of proposed universal screening using pulse oximetry. *JAMA Pediatr*. 2014;168(4):361–70. *Estimates that in the U.S., 29.5% of nonsyndromic infants born with CCHD may benefit from CCHD pulse oximetry screening and identifies factors associated with late detection.*
6. Peterson C, Dawson A, Grosse SD, et al. Hospitalizations, costs, and mortality among infants with critical congenital heart disease: how important is timely detection? *Birth Defects Res A*. 2013;97(10):664–72. [CrossRefGoogle Scholar](#)
7. Plana MN<sup>1</sup>, Zamora J, Suresh G, Fernandez-Pineda L, Thangaratinam S, Ewer AK. Pulse oximetry screening for critical congenital heart defects. *Cochrane Database Syst Rev*. 2018 Mar 1;3:CD011912. <https://www.ncbi.nlm.nih.gov/pubmed/29494750>
8. U.S. Centers for Disease Control and Surveillance. Congenital Heart Defects Information for Healthcare Providers. <https://www.cdc.gov/ncbddd/heartdefects/hcp.html>
9. Zuppa AA, Riccardi R, Catenazzi P, D'Andrea V, Cavani M, D'Antuono A, Iafisco A, Romagnoli C. Clinical examination and pulse oximetry as screening for congenital heart disease in low-risk newborn. *J Matern Fetal Neonatal Med*. 2015;28(1):7–11. [CrossRefPubMedGoogle Scholar](#)
10. Lanker AM, Chowdhary J, Jeelani N, Jeelani S, Hassan AU. Effectiveness of pulse oximetry screening for congenital heart disease in asymptomatic new-borns. *Int J Res Med Sci*. 2014;2(3):1112–6. [CrossRefGoogle Scholar](#)
11. Kemper, A.R.; Mahle, W.T.; Martin, G.R.; Cooley, W.C.; Kumar, P.; Morrow, W.R. Strategies for implementing screening for critical congenital heart disease. *Pediatrics* 2011, 128, e1259–e1267. [[CrossRef](#)] [[PubMed](#)]
12. Thangaratinam, S.; Daniels, J.; Ewer, A.K.; Zamora, J.; Khan, K.S. The accuracy of pulse oximetry in screening for congenital heart disease in asymptomatic newborns: A systematic review. *Arch. Dis. Child. Fetal Neonatal*. Ed. 2007, 92, F176–F180. [[CrossRef](#)] [[PubMed](#)]

13. Rahi Abouk, PhD<sup>1</sup>; Scott D. Grosse, PhD<sup>2</sup>; Elizabeth C. Ailes, PhD, MPH<sup>2</sup>; et al. 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 <https://jamanetwork.com/journals/jama/article-abstract/2664999>
14. Ewer, A.K.; Furnston, A.T.; Middleton, L.J. Pulse oximetry as a screening test for congenital heart defects in newborn infants: A test accuracy study with evaluation of acceptability and cost-effectiveness. *Health Technol. Assess.* 2012, 16, 1–184. [CrossRef] [PubMed]
15. Zhao QM, Ma XJ, Ge XL, Liu F, Yan WL, Wu L, Ye M, Liang XC, Zhang J, Gao Y, Jia B. Pulse oximetry with clinical assessment to screen for congenital heart disease in neonates in China: a prospective study. *Lancet*. 2014;384(9945):747–54. *Largest published study to date investigating CCHD pulse oximetry screening in China.* [Google Scholar](#)
16. Kochilas LK, Lohr JL, Bruhn E, Borman-Shoap E, Gams BL, Pylipow M, Saarinen A, Gaviglio A, Thompson TR. Implementation of critical congenital heart disease screening in Minnesota. *Pediatrics*. 2013;132:e587–94. [CrossRefPubMedGoogle Scholar](#)

164. Anna Lazar

<b>Name:</b>	Anna Lazar	<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	XXXX XXXX		
<b>Role:</b>	MOTHER OF HUNOR LAZAR		
<p><b>Do you consent to your name being published on the UK NSC website alongside your response?</b></p> <p style="text-align: center;">yes</p>			
Section and / or page number	Text or issue to which comments relate	Comment	
		<i>Please use a new row for each comment and add extra rows as required.</i>	
	short presymptomatic interval: short interval between birth and presentation, i.e. these CHDs are likely to present with life threatening symptoms or signs in the first week after birth (many are	<p>My XXXX XXXX was born in XXXX XXXX, at XXXX XXXX, 2015.</p> <p>XXXX XXXX was born with CHD, HLHS!</p> <p>This heart condition was diagnosed in XXXX XXXX, close to midnight at XXXX XXXX 2015 when my XXXX XXXX, a newborn infant was already fighting hard to keep XXXX XXXX tiny body functioning and stay alive after a collapse at home, after 6 hours struggle at the local A&amp;E at XXXX XXXX, XXXX XXXX, where doctors worked hard and managed to keep XXXX XXXX alive but could not find a reason of XXXX XXXX critical state, until the point when XXXX XXXX took the risk of transporting him to XXXX XXXX. My XXXX XXXX</p>	

	<p>'duct-dependent' and present as the ductus arteriosus closes),</p>	<p>had a total organ failure by this point and [REDACTED] realistically could pass away at any second. The trauma; of witnessing this sudden episode of a "healthy baby" (according to the birth Hospital) and extreme complications which followed after (several open heart and other surgeries - first at age of 6 days old -, 6 months of continuous hospitalisation, treats of future disabilities, treats of high risk of loosing my baby) left our entire family affected by this trauma.</p> <p>Weeks after weeks, months after months by [REDACTED] just survived this immensely critical stage. At the present time in [REDACTED] school age had to be deferred a year from Reception School admission as being physically underdeveloped, still carrying over effects form [REDACTED] long and complicated hospitalisation. Overall, [REDACTED] is a success story, especially in relation of his CHD, mainly because of the exceptional works of many and many NHS professionals in my [REDACTED] [REDACTED] treatment hospital.</p> <p><b>BUT IT DOESN'T HAVE TO BE LIKE THIS!!!!</b> <b>NO MOTHER OR FATHER SHOULD SEE AND EXPERIENCE THEIR CHILD DYING, COLLAPSING OR ALMOST DYING</b></p> <p>just because an existing medical condition was not detected early enough or was not detected at all. My [REDACTED] condition was not examined and observed during pregnancy. My [REDACTED] condition was</p>
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not detected or observed after birth. After birth my [REDACTED] was not examined properly by the birth hospital paediatrician before we left hospital with [REDACTED]. However, a murmur of [REDACTED] heart was heard, blood pressure and ECG tests were carried out and we were discharged with a letter, addressed to our GP to check out my [REDACTED] [REDACTED] heart at [REDACTED] 6 weeks of routine check. We were told that the murmur was heard is due to the duct of [REDACTED] heart not being closed by itself which is normal and probably will be closed within 2 or 3 days, or even a week after birth. About 48 hours later when my baby's ductus started to close [REDACTED] started to become ill and finally collapsed at home. I think I can not stress this fact out enough; **JUST VERY FEW CHILDREN SURVIVES THE SAME ROUTE AS MY CHILD HAD SURVIVED WITH [REDACTED] CHD, HLH SYNDROME.**

Until the present time, I think about it a million times; what would help my baby, what would help us as a family, what would help me as a mother. If my [REDACTED] CHD would be detected during pregnancy still would feel traumatic, nevertheless, we still would have 20 weeks to deal with and prepare our adults mindset for the worst.

**BUT** what would happen if the birth hospital would use a PULSE OXIMETRY at their screening? I believe the answer to this is very simple; **WOULD SAVE A CHILD AND [REDACTED] FAMILY FROM EXTREME** of the trauma, extreme of treat, extreme of risk, extreme



		<p>of dying, extreme of diagnosis of a condition, extreme of complications and extreme of different affects of a diagnosed heart condition and extreme of different affects of a long and problematic hospitalisation, SIMPLY AS IT IS; WOULD SAVE HUMANS FROM EXTREME OF PAIN AND FROM EXTREME OF SUFFERING.</p> <p>Thank you for having a chance of addressing at the right place WHAT COULD HAVE BEEN USEFUL BUT WAS NOT IN PLACE at a very tragic time in our life.</p> <p>With best wishes</p> <p>XXXX XXXX</p>
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165. Andrew Ewer

UNIVERSITY OF  
BIRMINGHAM



XXXX XXXX

Tel XXXX XXXX

Email XXXX XXXX

7<sup>th</sup> August 2019

Dear UK National Screening Committee

**Re: Public consultation on the decision not to include pulse oximetry screening as an additional test in the Newborn and Infant Physical Exam programme**

I would like to thank the NSC for the opportunity to respond to this decision. I think it has provided an opportunity for all of us to reflect carefully on the evidence presented in support of the decision and indeed, the review which led to it. I believe this period of reflection will result in a crystallising of views of the key stakeholders in this decision – i.e. the parents of newborn babies and the clinical staff who care for those babies.

As you know I was present at the meeting at which the preliminary decision was discussed and I was grateful for being provided with the opportunity to respond at the time to the initial draft of the report.

My response takes the form of five separate response documents:

1. My initial response to the draft review previously submitted on 21<sup>st</sup> February 2019. This was circulated to members of the committee prior to the meeting but did not result in any change to the review document (interestingly, including the major error in reporting proportion of babies who had investigations!) . Therefore the comments still apply.
2. My response to the statements on the Consultation covernote (Doc 1 on NSC

website)

3. My response to the Research review document which formed the basis of the decision (Doc 5 on the NSC website).
4. My response to the specific concerns of the balance of benefit vs. harm which appear to have been a key factor in influencing the decision.
5. A comparison of the relative harms of pulse oximetry screening with a few of the existing UK screening tests

I realise there is a degree of repetition without some of these documents but I believe the repetitions reflect slightly different aspect of important areas of discussion and so I make no apology for this.

Just in case you were not aware of them, I have also attached two publications which came out in direct response to the public consultation which emphasise similar arguments from a wider group of individuals.

I do hope you will consider my comments carefully. They are not meant to be a criticism of the committee *per se* but they are certainly a criticism of the research review which, in my view, is inadequate and falls short of the standards one would expect from the NSC, particularly on such an important subject.

I am very happy to discuss any of my comments at any time and also for them to be made public once the review of the consultation is complete.

Thank you once again for the opportunity to respond.

Yours faithfully

XXXX XXXX

Andrew Ewer

Professor of Neonatal Medicine, University of Birmingham

Honorary Consultant Neonatologist, Birmingham Women's Hospital

**Comments on PO Research review (Doc 5)**

**Page 1**

The overview states that ‘...a discussion paper presenting recent research on PO and its value as an additional screening test was taken to the FMCH reference group’ and ‘The FMCH reviewed the evidence and the options presented [in order to make] their recommendation.’

The ‘recent research’ that was included is as follows:

- i) An external review on POS written in 2014 (**CHD and PO first review**; Doc 2)
- ii) The ‘End project report’ on the UK POS pilot from 2015 (**NPOSP End Project Report**; Doc 3)
- iii) A statistical report produced in an attempt to clarify whether the addition of POS increased the number of admissions to Neonatal Units (**PO Statistical report**; Doc 6)
- iv) A health economic report produced in an attempt to identify whether screening with pulse oximetry was cost-effective (based on data from the pilot which included patients identified in addition to those with cardiac defects (**PO Health Economics report**; Doc 4.
- v) The conclusions of the Expert Workgroup convened by the NSC to consider the benefits versus harms of POS for all babies (**Notes from Pulse oximetry Workshop 2018** (Doc 7).

No other recent research was included which is strange because there have been a number of important papers published recently which address the concerns of the NSC. *These are highlighted in my previous response to the Consultation Covernote.*

I would like to review the evidence considered and reflect how the content influenced the final decision of the NSC.

### **CHD and PO first review (Doc 2)**

This is a thorough, comprehensive and balanced review of all the evidence available at the time by two independent experts in the field. In this respect it contrasts markedly with the present Research Review (Doc 5) which in my opinion has none of these qualities.

The objective of the first review was

‘... to evaluate the current evidence against NSC screening criteria in order to

- (1) clarify the objectives of screening for CHDs pre- and postnatally,
- (2) summarise the evidence concerning screening for CHDs, particularly in relation to first trimester nuchal translucency measurement and second trimester fetal anomaly scan, and evaluate the impact of antenatal detection on newborn screening,
- (3) appraise the evidence relating to proposed additional screening tests for CHDs, in particular routine pulse oximetry in the newborn period, including screening performance and referral for further investigations
- (4) determine the gaps in evidence and the impact these may have on future decisions about screening. ‘

The report is a very detailed and inclusive summary of screening for CCHD (including using pulse oximetry screening) against the criteria for a screening programme which are set out by the National Screening Committee.

The report highlighted the potential benefits of adding POS to the National programme but also highlighted areas of uncertainty which it recommended should be addressed in a UK pilot study (which was undertaken the following year).

Although included in the evidence list, in neither the '**Consultation covernote**' (Doc 1) nor the '**Research review**' (Doc 5) is there specific reference to any of the findings or conclusions of this report.

Importantly, comments relating to the specific concerns of the NSC identified in their decision – i.e. ***the harms and benefits of potential for over-diagnosis, over-treatment, false positives, false reassurance, and complications*** are not included (see below for specific omissions)

- i) Comments from the review on the **Existing screening programme** for CCHD (Antenatal US and Clinical examination) and the additional of POS - Criterion 5

Page 13 '*Newborn clinical examination currently detects less than half of all CHDs before hospital discharge. An HTA model developed based on published evidence and data from the northern region, estimated that clinical examination alone could detect 32% of life-threatening CHDs, whereas 68% of life-threatening CHDs could be detected by adding pulse oximetry to the newborn clinical examination. Subsequently, meta-analyses of routine pulse oximetry in over 200,000 newborns have estimated moderate detection rates for critical CHDs of around 60-80% for pulse oximetry, and test specificity is high.*'

- ii) Comments from the review on Criterion 14 – **Acceptability**

Page 25 '*Antenatal ultrasound, newborn clinical examination and pulse oximetry appear acceptable as screening tests. However the acceptability of high false positive rates (which may raise anxiety) and false negative rates (leading to false reassurance) requires further exploration for all screening modalities.*'

- iii) Comments from the review on Criterion 15 - **Benefits must outweigh harms**

Page 25 '*Existing evidence suggests that the benefits of screening outweigh the harms for newborn screening using clinical examination with or without pulse oximetry as the screening test.*'

Comments from the review on Criterion 16 – **Cost effectiveness**

Page 27. '*The existing evidence strongly suggests that pulse oximetry in conjunction with clinical examination is more cost-effective than clinical examination alone.*'

### **NPOSP end project report (Doc 3)**

This report provides great detail of the process and results of the NSC pilot.

The Research review (Doc 5) describes the set-up of the pilot in some detail but mistakenly describes the two groups of Units (Group A and Group B) as '**matched**' (page 5 of research review). Details of the selection of the participating units is described on page 15 and 33 of the End project report (Doc

3) where it is stated that the units were simply divided in to the 2 subgroups to 'facilitate the analysis of different levels of feasibility and impact'. There was no intention of matching and to state this suggests a lack of understanding of the pilot set-up. [NB. This error is further conflated on page 11 of the Research review (Doc 5) where it is suggested that in the statistical report analysis (Doc 6), the comparisons are between group A and Group B units, which is incorrect. In the statistical report the comparison was between **all** units participating in the pilot (groups A and B) and a 'matched group of [units] which did not participate in the pilot study' (statistical report page 4). As the data from the statistical report were unhelpful, this error is not important but it does suggest a lack of understanding by the research review authors, of the detail of what these different analyses were trying to achieve. Any subsequent criticisms relating to poor matching (page 9 of research review), and indeed other criticisms, should be considered in this context].

It is stated in the research review that 'PHE undertook a review of the extent to which POS met the UKNSC criteria for screening, **particularly focussing on the harms and benefits of potential for over-diagnosis, over-treatment, false positives, false reassurance, and complications.**'

Much of the data required to address these issues can be found in the End project report (pages 106-118).

Unfortunately although these data are available, the research review shows a distinct lack of focus in these highly important areas with no detail about the numbers of babies who will be affected by each outcome. This makes it difficult to judge whether the potential harms might be justifiable in order to identify a baby with potential serious illness.

Using data provided in the NSC pilot it is possible to estimate the number of babies who will be affected and this is something one would have expected to be included in the research review. Absence of such an analysis is a serious oversight particularly given the unsubstantiated claims about excessive harm.

From the pilot report we can calculate the following

#### **False positives, over diagnosis, overtreatment**

- 99.3% of all babies tested will pass the test (993 out of every 1000 babies screened)
- 0.7% will not pass and be test positive (7 babies for every 1000 screened)
- **More than half of the babies (6 out of every 10 or 60%) who test positive are healthy** and they just have slow adaptation to birth. **Five out of these 6 babies** will develop normal oxygen levels very quickly **and need no investigation or treatment.**
- **Five out of every 10 babies** who test positive (3.5 out of every 1000 babies tested) will need further investigations and almost all will be admitted to the Neonatal Unit (NNU) for further assessment.

#### **Of the babies admitted to NNU:**

- **1 in 10 will have a heart problem** and they will all benefit from early diagnosis and treatment.
- **7 in 10 will have a breathing problem or infection** and most will benefit from the test by early diagnosis and treatment of a potentially serious illness (see expert working groups view on benefits to test positive babies).

- **2 in every 10 will be healthy** – these babies will have tests that were unnecessary and may have a delayed discharge but they are usually on NNU for less than 12 hours.
- Therefore **80% of babies admitted** will have a condition judged by doctors to warrant treatment and **only 20%** will be healthy
- 3 babies per thousand screened will have a significant health problem
- Less than one baby per thousand (0.07%) screened will be healthy and have unnecessary investigations and delayed discharge

It can also be seen (on page 112 on end project report) that almost half (47%) of the babies admitted following a positive screen (i.e. babies who were perceived to be asymptomatic) went on to receive either intensive care or high dependency care, which strongly suggest that these babies had a serious illness which required escalation of level of support. It is not unreasonable to predict that a delay in diagnosis for these babies might have resulted in a greater requirement for these levels of care.

### **False reassurance (false negatives)**

In the pilot 2 babies with CCHD were missed by pulse oximetry screening which means that 1 in every 16 000 babies screened had a critical heart defect which was missed by the test. This important fact is omitted in the NSC documentation (Incidentally, these babies were also missed by AN screening and the NIP exam).

### **Complications**

No complications were reported. This important fact is omitted in the NSC documentation

### **Information regarding outcomes**

Page 8 of Research review ‘...***the absence of outcome data for an unscreened comparator is a major (critical) impediment to decision making.***’ Comment

Pulse oximetry is a screening test whose primary objective is to identify babies with a critical congenital heart defect (CCHD) which has been missed by antenatal screening before the baby develops acute collapse or death.

In 2009, Granelli et al published a study<sup>1</sup> which compared outcome for newborns with CCHD in 2 regions of Sweden - one which employed PO screening and one which did not. Comparing the non-screening region to the POS region risk of leaving hospital with an undiagnosed CCHD was 28% vs. 8% (p=0.0025, RR 3.36), risk of babies leaving hospital with undiagnosed Transposition of Great Arteries [one of the commonest CCHDs] (44% vs. 0% p=0.001), risk of severe acidosis/collapse at CCHD diagnosis (33% vs. 12% p 0.0025, RR 2.8), Mortality from CCHD was 5% vs. 0% p= 0.16). The lack of statistical significance in mortality reflects an inadequate sample size to identify a difference (death is thankfully relatively rare).

However, there is **robust evidence** from the USA (analysing 27 million newborns) that shows the introduction of PO screening significantly **reduced mortality** (death rate) in newborns from CCHD **by 33%** and mortality from all cardiac causes **by 25%**.<sup>2</sup> The USA has a similar antenatal CCHD detection rate to the UK (source NICOR) and so it is disingenuous to consider that UK babies would not have a similar benefit.

Of concern is that POS also detects babies with other non-cardiac conditions (including breathing problem, infections etc.) some of which may be relatively mild and some which are potentially life-threatening but there is a lack of a gold standard diagnostic test in many cases.

The NSC pilot was designed with the specific aim of testing feasibility of introducing POS and the effect on clinical services. It was not designed to investigate outcomes. However in view of the concerns regarding the additional non-cardiac diagnoses and the lack of comparator data, the NSC convened a workgroup of senior UK Neonatologists and Key Opinion Leaders in the field.

The report of the Workgroup was considered as evidence in the review and a short summary of the views of the group is recorded (page 13).

*'The group were clear that for 6 of the 8 additional [non-cardiac] conditions there would be some clinical benefit to earlier diagnosis, in one condition (pneumothorax) no clinical benefit and in one condition (culture negative sepsis) there are some harms and some benefits. For the healthy babies, there is some harm from unnecessary investigations and delayed discharge.*

*Additional research and discussions at this workshop suggest that the harms described... are likely to be broadly acceptable to parents and are balanced by the potentially serious nature of a late identification of the incidental conditions.*

The clinical members of the Workgroup were clear in their opinions and of the unanimous view that for the majority of non-cardiac condition babies would benefit and modest and acceptable harms would occur in a small minority. This view is not reflected in the NSC decision and the reasons why an alternative view is taken is not clearly documented in the research review. The clinical members of the workgroup re-iterated their concerns about this in a letter to Archives of Disease in Childhood (attached)<sup>3</sup>

## **Summary**

In my opinion the Research review is inadequate and potentially biased. Important conclusions from extant literature and from the included research have not been considered and there is very little evidence to support the claims made in support of the decision. I urge the NSC to consider these comments and to review the decision in light of them.

**A K Ewer**

## **References**

1. Granelli AW, Wennergren M, Sandberg K, et al. Impact of pulse oximetry screening on the detection of duct dependent congenital heart disease: a Swedish prospective screening study in 39 821 newborns. *BMJ* 2009; **338**: a3037.
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**: 2111–18.
3. Ewer AK, Deshpande SA, Gale C, Stenson BJ, Upton M, Evans C, Oddie SJ. Potential benefits and harms of universal newborn pulse oximetry screening: response to the UK National Screening Committee public consultation. *Arch Dis Child* published online 11<sup>th</sup> July 2019, doi: 10.1136/archdischild-2019-317859.



## **Comparison of harms of pulse oximetry screening with harms of established screening tests**

The following comparisons are based on published patient information produced by the UK NSC.

### **Harms of pulse oximetry screening**

For every 10 000 babies screened, 73 will test positive, 35 will be admitted to NNU, 28 will have a condition which requires treatment and 7 healthy babies will be harmed by slightly delayed discharge, unnecessary blood tests and x-rays. *Possible* parental anxiety although confirmatory test results are available within a few hours

### **Harms of bowel scope screening for bowel cancer**

For every 10 000 patients screened, 500 will test positive (anxiety until test result is reported after at least 1 week), 500 will experience embarrassment, 2000 will experience pain greater than mild pain and 300 will have severe pain), 3 will have rectal bleeding which requires admission to hospital and some (unspecified) will have bowel perforation requiring surgery. 200 will say they were not glad they had the procedure. 33 cancers will be detected.

### **Harms of breast screening**

For every 10 000 patients screened, 400 will test positive and require further invasive investigation. 100 will have cancer and 300 will not (anxiety and unnecessary invasive testing in 300).

### **Harms of newborn hearing screening**

For every 10 000 patients screened, 220 will test positive and 7 will have hearing loss. Parental anxiety waiting for definitive test result (for at least a week) in 213 cases.

### **Harms of antenatal testing for aneuploidy**

For every 10 000 patients screened, 200 will test positive and have amniocentesis and 2 (potentially healthy) babies will die as a result of miscarriage.

In comparative populations (10 000 screens), for established screening tests, up to hundreds and sometimes thousands of screened patients are harmed in some way. Importantly, the risks of somescreening involves major complications including requiring emergency surgery or even death. Given this perspective the possibility of delayed discharge, unnecessary blood tests and x-rays in 7 babies does seem comparatively benign.

I would be interested in the NSC's explanation as to why these specific harms are deemed unacceptable but other much more serious harms are not.

**A K Ewer**

## Specific comments regarding harms and benefits of pulse oximetry screening (POS) in the NSC decision documentation.

The NSC decision covernote (Doc 1) makes a number of statements regarding the balance of harms and benefits which **form the crux of the NSC decision** not to recommend POS.

Page 1.

### Section 2

*'PHE undertook a review... focusing on the harms and benefits...'*

### Section 4

*'...there is currently insufficient evidence to suggest that there is greater benefit...than that afforded by current screening programme alone. ... there are also harms associated with screening...following a positive screening result.'*

### Section 5

*'A positive result will generate some harms, incl. parental anxiety, a longer stay in hospital, possible transfer to NNU, further tests to assess for non-symptomatic conditions.'*

*'For babies with CHD or other non-cardiac conditions it is not clear that investigations and identification of these conditions will lead to any better outcome than a diagnosis at a time the baby becomes asymptomatic.'*

## Comment

The NSC's strong narrative in the covernote is that current newborn screening for CCHD is adequate and effective; that POS does not improve outcome; and it harms more babies than it benefits. However, **the evidence to support these claims is not presented** in the Research review. Specifically: there is no clear indication of the numbers of babies that might be harmed; there are unsupported claims and a claim that is incorrect; importantly, there is **no acknowledgement of the benefits** to babies from POS.

This makes the covernote unbalanced and misleading.

In the Research review (Doc 5) there are the similar comments on harms and benefits with similar inadequacies.

Additionally, there are statements within the Research review that are not reflected in the subsequent narrative in the covernote regarding the final decision.

For example:

Page 2, para 5

*'The 2016 pilot study findings supported those of the 2014 review which presented evidence to demonstrate that pulse oximetry... increases the detection rate of CCHDs...'*

Page 7 3rd box on left

*'Clinical experts agree that early diagnosis of sepsis and respiratory conditions is beneficial'.*

Page 8 para 1

*'That POS identifies hypoxaemia which triggers further investigations and can lead to the identification of CHD and other significant non-cardiac conditions is accepted.'*

Page 13 final para

*'The clinical judgement of benefit from earlier diagnosis is not disputed...'*

## **Comment**

Current UK screening for CCHD is inadequate; missing between 30 and 50% of babies, some of whom will die and many of whom will suffer acute collapse with the consequence of worse outcome.<sup>1-4</sup> One might pose the question if current screening for CCHD was acceptable why did the NSC invest so much time and money into investigating POS?

POS will identify more babies with CCHD than either examination or antenatal screening and importantly, identify them while still asymptomatic.<sup>2,4</sup> The Cochrane review<sup>4</sup> of almost half a million screened babies, has clearly demonstrated this and this is outlined in the NSC commissioned CHD and PO first review (Doc 2). Data from the US<sup>5</sup> and Sweden<sup>3</sup> has shown reduction in mortality from CCHD with POS (33% reduction in the US study). The implication that earlier identification will not improve outcome (or at least lack of acknowledgment of this fact) is absurd. This significant benefit of POS is not described in the NSC documentation and most importantly not acknowledged in the decision covernote, and this is a significant oversight.

The question of improved outcome for the non-cardiac conditions is less clear. The NSC PO pilot was not designed to address this issue and the subsequent flawed statistical report (doc 6) was not fit for purpose because of a lack of adequate comparator data

Therefore, as a result of the lack of clarity regarding outcomes for non-cardiac conditions, the NSC convened a workgroup of clinical experts to pragmatically assess the relative benefits and harms to this group of babies.

The outcome of this meeting is summarized in the research review

Page 13

*'The group considered the benefits of earlier diagnosis and the potential harms of over-diagnosis and follow-up of false positives'*

*'The group were clear that for 6 of the 8 additional conditions there would be some clinical benefit to earlier diagnosis, in one condition ... no clinical benefit and in one ...there are some harms and some benefits. For the healthy babies, there is some harm from unnecessary investigation and delayed discharge.'*

*'Additional research and discussions at this workshop suggest that the harms described ... are likely to be broadly acceptable to parents and are balanced by the potentially serious nature of a late identification of the...condition.'*

There is an important error on Page 13

*'All of these screen positive babies had further investigations.'*

This statement in the review is **false** (less than half of the test positive babies had investigations) and the **false assumption** generated by it is critical and may have influenced whole decision. In my opinion this is a serious error and is highly misleading.

### **Comment**

As a consequence of the lack of comparator data, a group of experts (who treat babies with these conditions on a daily basis) was invited by the NSC to give their opinion and were **unequivocally clear** regarding the benefits of early diagnosis for the majority of non-cardiac conditions presenting as false positives. (This clarity is highlighted in the letter to the editor of Archives of Disease in Childhood which the clinical members of the Workgroup felt necessary to write in order to correctly represent their views).<sup>6</sup>

The following statement in the Research review (page 13 final para) needs to be strongly challenged as it flies in the face of the expert opinion:

*'The clinical judgment of benefit from earlier diagnosis is not disputed, however, it is unclear from the pilot study whether pulse oximetry impacts on these outcomes for the following reasons:*

- *The protocols for using PO were not fully adhered so we do not have adequate timings data to fully understand the early nature of the referral outcomes*
- *We do not have data on the outcomes of the NIP exam*
- *The statistical report showed no apparent difference in admissions to NNU for respiratory and sepsis, but provided no health outcomes data.'*

The logic of this argument is difficult to follow and has no impact on the outcome of the experts' assessment. The suggestion is that despite what the experts agreed was clinically plausible in specific cases, these spurious points somehow allow the clinical experts' pragmatic conclusions to be discounted.

For the record, the pilot study recommended screening in the first 24 hours (ideally 6-8 hours) and 78% were screened within 12 hours and 92% within 24 hours. The protocol demanded that all babies were deemed to be asymptomatic at the time of POS. The NIP exam usually takes place after 24 hours of age, but if the NIPE had taken place and the baby was found to have symptoms POS screening would not have occurred. In my opinion, the rationale for questioning the expert workgroup's conclusion is not based on fact.

The suggested 'harms' to the healthy babies need to be quantified and put into perspective before it is possible to weigh up the relative benefits and harms for all babies screened. This has not been undertaken in the NSC review and this is a serious omission.

It is explicit in the POS pilot report (Doc 3) that **less than half** of the babies who tested positive were admitted to NNU and/or had investigations. On page 111 of the pilot report it can be clearly seen that of the 239 babies who tested positive, 114 (48%) were admitted to NNU and 110 (46%) had any investigations. Of the babies who turned out to be healthy only 22 were admitted and only 18 had investigations. All healthy babies were discharged from NNU within 12 hours.

Putting these figures into perspective is important so that the reader can make a judgment about whether the assertions made in the decision document are justified and evidence-based. In the Research review (page 11) it states:

*'It is fundamental in implementing a national programme, where we potentially lead a non-symptomatic person through investigations and tests, to understand the harms and benefits of the screening intervention and to ensure **that the benefits outweigh the harms.**'*

Given the NSC decision, the implication is that they consider the harms to outweigh the benefits. In my opinion the evidence does not support this conclusion nor does the NSC documentation. I would make the following specific comments:

- i) In the NSC POS pilot 32 836 babies were screened, out of which 239 (0.7% of all babies screened) tested positive. 114 (0.35%) were admitted to NNU and 110 (0.33%) had investigations.
- ii) Of the babies admitted 90 (79% of all babies admitted) had a significant clinical illness of which all but one would have overall clinical benefit from early diagnosis (according to the expert workgroup)
- iii) Of the babies who had investigations 92 (84%) had a significant clinical illness of which all but one would have overall clinical benefit from early diagnosis (according to the expert workgroup)
- iv) This leaves 24 babies (0.07% of all babies screened) who were harmed by unnecessary tests and/or unnecessary admission.
- v) Therefore, 32 597 babies were neither harmed nor benefitted (test negative), 91 babies benefitted from early diagnosis and 24 were harmed (by harms which were considered '*broadly acceptable*' by the expert group). So almost 4 babies benefitted for every baby who had minor acceptable harm. The potential harm of discharge without diagnosis is **disproportionate** in comparison and alarmingly, has not been considered by the NSC.
- vi) The claim that parents will undergo anxiety is not based on any data and directly contradicts published evidence.<sup>1</sup>

Based on this assessment it is difficult to see how the statements on outcome and benefit versus harm that are made in the NSC documentation can be justified based on the evidence that is presented. I urge the committee to review the decision in the light of these comments.

A K Ewer

## References

- 4. Ewer AK, Furnston AT, Middleton LJ, et al. Pulse oximetry as a screening test for congenital heart defects in newborn infants: a test accuracy study with evaluation of acceptability and cost-effectiveness. *Health Technol Assess* 2012; 16: 1–184.
- 5. National Institute For Cardiovascular Outcomes Research. Activity and 30-day outcomes by age group for all procedures 2014–17 (not risk stratified). 2017. [https://nicor4.nicor.org.uk/chd/an\\_paeds.nsf/vwContent/NCHDA%20Report%20Analyses%202014-17?Opendocument](https://nicor4.nicor.org.uk/chd/an_paeds.nsf/vwContent/NCHDA%20Report%20Analyses%202014-17?Opendocument) (accessed June 27, 2019).
- 6. Granelli AW, Wennergren M, Sandberg K, et al. Impact of pulse oximetry screening on the detection of duct dependent congenital heart disease: a Swedish prospective screening study in 39 821 newborns. *BMJ* 2009; 338: a3037.
- 7. Plana MN, Zamora J, Suresh G, Fernandez-Pineda L, Thangaratinam S, Ewer AK. Pulse oximetry screening for critical congenital heart defects.

*Cochrane Database Syst Rev* 2018; 3: CD011912.

8. 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: 2111–18.
9. Ewer AK, Deshpande SA, Gale C, Stenson BJ, Upton M, Evans C, Oddie SJ. Potential benefits and harms of universal newborn pulse oximetry screening: response to the UK National Screening Committee public consultation. *Arch Dis Child* published online 11<sup>th</sup> July 2019, doi: 10.1136/archdischild-2019-317859.

## Comments on Consultation covernote 2019 (Doc 1).

### 1. Aim of the consultation (page1)

The **Aim** of this consultation is described as follows

*‘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).’*

### Comments

In my opinion the NSC evidence review is inadequate for the following reasons: i) important recent evidence has not been considered in the final conclusion ii) important details from the evidence presented (and by implication the evidence considered) have not been considered in the final conclusion iii) inappropriate, poor quality evidence appears to have had a disproportionate influence on the decision and iv) there are no data to support the main claims against pulse oximetry screening which led to the decision.

Addressing each of these comments in more detail

#### i) Important recent evidence has not been considered

- The 2018 paper published in *JAMA*<sup>1</sup> which showed conclusively that the introduction of POS in US states **reduced mortality from CCHD by 33%** and all **other cardiac deaths in newborns by 20%** and the 2009 paper from Sweden<sup>2</sup> which showed **risk of discharge with undiagnosed CCHD was 28% (non-POS) vs. 8% (POS)**, risk of discharge with undiagnosed Transposition of Great Arteries [one of the commonest CCHDs] was **44% (non-POS) vs. 0% (POS)**, risk of severe acidosis/collapse at CCHD diagnosis (**33% vs. 12%**) and mortality from CCHD (**5% vs. 0%**).
- The 2014 paper from Birmingham<sup>3</sup> which showed great consistency with the NSC UK Pilot in terms of proportion of test positives (0.7% - 0.8%) and proportion of test positives admitted

to a neonatal unit (NNU) who had a significant clinical diagnosis (~80%) indicating the consistency of the screen in a UK setting.

- The 2012 paper from Birmingham which concluded unequivocally (following rigorous psychometric testing) that **mothers found POS acceptable** and a **false positive test did not increase anxiety**.<sup>4</sup>
- The 2017 Cochrane review of the test accuracy of POS<sup>5</sup> - which included almost half a million babies screened with POS in research studies and confirmed a test accuracy which was remarkably consistent with a previous (2012) systematic review<sup>6</sup> are mentioned only in passing with no description of the findings or conclusions.

**ii) and iii) Important details from the evidence presented have not been considered and inappropriate poor quality evidence, appears to have had a disproportionate influence on the decision**

The Research review included the **CHD and PO first review** (Doc 2) and **Notes from Pulse Oximetry Workshop (2018)** [Doc 7] but there is scant reference to the contents and conclusions of either of these important documents (see below). In contrast, the review has analysed the **statistical review** (Doc 6; an attempt to answer questions posed by the NSC regarding number of admissions to NNU) *in some detail*. This piece of work was 'not fit for purpose' (and this inadequacy was clearly conveyed to the NSC by the authors). This additional question was not included in the aims of the UK pilot and there were insufficient comparator data to answer it satisfactorily. The inclusion in the research review is confusing and unhelpful. In order to address the former question the NSC convened the Expert workgroup (Doc 7 see below).

**iv) There are no data to support the main claims against pulse oximetry screening which led to the decision**

The evidence review **includes no meaningful data** on important concerns such as harms or benefits in order to support the decision that has been made. Without giving any detail of the numbers of babies who might be affected by the relative benefits or harms, it is difficult for the reader to make any assessment of the balance of risk and to see how the NSC was able to do this on the evidence presented. Important evidence from the pilot (Doc 3) and other sources (see above) plus the opinions stated in the 2014 Comprehensive review (Doc 2) and the Conclusions of the 2018 Expert Workgroup (Doc 7) have, at best, not been included and at worst, ignored.

**In summary, I would strongly argue that the evidence considered by the NSC is insufficient to support the decision made. The arguments against are not evidence-based, and conflict with the published evidence and the views of senior neonatal clinicians and parents who are familiar with the test.**

**Comments on the Current position (page 1)**

The current position is stated as follows:



*‘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. ‘*

## **Comments**

### **i) Statements 2 and 5**

With regard to statement 2 - there are 22 criteria by which the UK NSC judge the suitability of screening for a particular condition. These are highlighted and discussed, in great detail, with respect to POS for CCHD, in the excellent report by Knowles and Hunter (CHD and PO first review Doc 2).

Of the 22 criteria, it appears that the NSC review has focussed mainly on only one – criterion 15; *‘The benefit from the screening programme should outweigh the physical and psychological harm (caused by the test, diagnostic procedures and treatment).’*

In statement 5 of the covernote there are a number of robust, but unsubstantiated, statements which are critical of POS such as:

*‘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.’*

In their comprehensive review (CHD and PO first review, Doc 2), which was commissioned by the NSC and included in the evidence review, Knowles and Hunter in their evaluation of criterion 15 conclude as follows:

*‘Existing evidence suggests that the benefits outweigh the harms for newborn screening, when the screening test is clinical examination with or without pulse oximetry, and for antenatal screening, when the screening test is antenatal ultrasound.’*

However the conclusion reached by the NSC does not take this view into account, nor does it take into account the conclusions of the expert workgroup (convened by the NSC) which are found in ‘Notes from pulse oximetry workshop (2018)’ [Doc 7]. This group concluded that POS was ‘*of clinical benefit*’ in 6 out of the 9 non-cardiac conditions which were identified as false positives by the test. In one condition (culture negative sepsis) the condition was ‘*Probably over treated*’... [but]... *it is better to treat suspected cases as the outcome of non-treatment of sepsis is serious.*’ In the 2 remaining conditions, (pneumothorax and transitional circulation) the group concluded that there was ‘*no clinical benefit*’. However they also noted that this accounted for only 23 babies out of the total 32 597 screened (0.07% of screened population). Therefore, of the test positive babies, 51 babies definitely benefitted and in 43, the benefit outweighed the harm. Incidentally, the workgroup also identified the harms which were from unnecessary investigations (blood tests and x-ray) and delayed discharge and deemed these to be ‘broadly acceptable’ to parents.

As the pilot study clearly demonstrates only 0.35% of all screened babies are admitted to NNU and 80% of those admitted have a condition which requires treatment and the majority will benefit. It is difficult to see how ‘harm’ outweighs the benefit given these facts and the NSC has not explained why they think this is the case. *This argument is explored in more detail in a separate document relating to my specific comments on harms and benefits.*

The NSC has stated that POS will increase parental anxiety but has presented no evidence to support this assertion and surprisingly has not considered evidence that shows that anxiety is not increased (see above). It is difficult to see how this assertion can be justified. The anxiety created by the risk of a baby being discharged with an undiagnosed life-threatening condition is not considered, which in my opinion, is a serious oversight.

The statement ‘*for many of these babies further investigations will be unnecessary*’ is unquantified and misleading – as stated above, this occurs in 0.07% of all screened babies.

#### **ii) Statement 4**

With regard to statement 4 – ‘*...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.*’

This statement implies that the current screening programme for CCHD is performing well (i.e. appropriate numbers of babies with CCHD are detected before acute collapse or death) and no additional babies will be detected (by POS). I would argue that neither of these implications is correct.

The current average UK pick-up rate for antenatal screening for serious heart defects is 42% (NICOR) with regional variation of 33% to 62% suggesting a wide disparity in practice and increased risk for

babies in areas with a low detection rate. For the NIPE examination there are no UK data on its sensitivity and specificity for detecting CHD despite it being in place for many years. Evidence from Europe and parts of the UK indicate that up to 45% of babies with CCHD<sup>2</sup> are not diagnosed before acute collapse and up to on third are discharged home without diagnosis.<sup>8</sup> The inadequacies of the current screening system are explored in detail by Knowles and Hunter (CHD and PO first review, Doc 2) *and discussed in a separate document submitted by me on the Research review.*

Death from CHD and infections are the two commonest single causes of death in term infants and the UK neonatal mortality rate is currently rising after many years of steady decline.<sup>9</sup> In 2015 the UK was ranked 19<sup>th</sup> out of 28 European countries in terms of Neonatal Mortality - a fall from 7<sup>th</sup> place in 1990. So, more newborn babies are dying and the death rate is worse compared with other European countries. This suggests that current screening is missing babies who subsequently die and that POS, which undisputedly identifies babies at risk of CCHD and sepsis (and other additional non-cardiac conditions) may have a role to play to improve outcomes for babies (see below).

The statement *'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.'* is incorrect and fails to acknowledge the seminal work by Abouk *et al*<sup>1</sup> (published in JAMA in 2017) which examined a cohort of 27 million births and unequivocally showed a 33% reduction in mortality for CCHD in states which had introduced POS. In addition there was a 20% reduction in death from other cardiac causes. Granelli *et al* showed increased risk of the following in regions of Sweden not using POS compared with those that used POS i) leaving hospital with an undiagnosed CCHD 28% vs. 8%, ii) risk of babies leaving hospital with undiagnosed Transposition of Great Arteries [one of the commonest CCHDs] (44% vs. 0%), iii) risk of severe acidosis/collapse at CCHD diagnosis (33% vs. 12%), iv) mortality from CCHD (5% vs. 0%). For the other non-cardiac conditions identified, the expert Workgroup clearly indicated their view that early diagnosis of majority of the non-cardiac illnesses by POS was beneficial and by implication that this would lead to better outcome. This evidence and opinion has not been considered by the NSC review and it is difficult to see why the opposite view has been taken.

### iii) Statement 5

In statement 5 there are the following additional assertions:

- *'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.'*

The argument that a lack of comparator data has influenced the NSC's decision does not hold water in my opinion. As I have already stated, there is strong evidence to support the benefit,

acceptability<sup>7</sup> and cost-effectiveness<sup>7</sup> of using POS for detecting CCHD screening, including in the NSC commissioned report by Knowles and Hunter (Document 2).

These evaluations focussed exclusively on CCHD screening and identified that all babies who did not have the target condition as false positives. As we know from subsequent work this is not the case; other non-cardiac conditions (many of which may be fatal if diagnosed late), are also identified. Whether the outcome for these babies is improved following early detection has not been demonstrated in a research study but it is totally illogical to assume that the outcome would be worse (with the exception of the tiny minority who have modest harms (see previous comments). At worst for the 80% of test positive babies who are admitted to NNU the outcome might be the same (although the view of the expert workgroup was that the outcome would be improved for the majority). So previous studies showing acceptable false positive rates and a cost-effective test can only be better and more cost-effective if in many of the false positive cases an alternative benefit is achieved. The idea that more research (at great expense) is required to precisely define how many more babies would die in the comparator arm would require a huge population (c.f. the 27 million in the US study by Abouk)<sup>1</sup> - because death is thankfully, relatively rare - is unlikely to be funded and highly likely to be deemed unacceptable to parents.

**In summary, the NSC review is inadequate in its assessment of harms and benefits. It makes statements which are unquantified and misleading, has considered evidence which is not fit for purpose while failing to include evidence from published literature and sources whose opinion the NSC invited. I do not think that the evidence presented is sufficient to support the conclusion and I urge the committee to reconsider its decision.**

**A K Ewer**

## **References**

10. 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: 2111–18.
11. Granelli AW, Wennergren M, Sandberg K, et al. Impact of pulse oximetry screening on the detection of duct dependent congenital heart disease: a Swedish prospective screening study in 39 821 newborns. *BMJ* 2009; 338: a3037.
12. Singh AS, Rasiah SV, Ewer AK. The impact of routine pre-discharge pulse oximetry screening in a regional neonatal unit. *Arch Dis Child Fetal and Neonatal Ed* 2014; 99:F297-F302. Published Online First: 19 March 2014 doi:10.1136/archdischild-2013-305657.
13. Powell R, Pattison HM, Bhojar A, Furmston AT, Middleton LJ, Daniels JP, Ewer AK. Pulse oximetry as a screening test for congenital heart defects in newborn infants: an evaluation of acceptability to mothers. *Arch Dis Child Fetal and Neonatal Ed* 2013;98:F59-F63.
14. Plana MN, Zamora J, Suresh G, Fernandez-Pineda L, Thangaratinam S, Ewer AK. Pulse oximetry screening for critical congenital heart defects. *Cochrane Database Syst Rev* 2018; 3: CD011912.
15. Thangaratinam S, Brown K, Zamora J, Khan KS, Ewer AK. Pulse oximetry screening for critical congenital heart defects in asymptomatic newborns: a systematic review and meta-analysis. *Lancet* 2012;379:2459-2464.

16. Ewer AK, Furnston AT, Middleton LJ, et al. Pulse oximetry as a screening test for congenital heart defects in newborn infants: a test accuracy study with evaluation of acceptability and cost-effectiveness. *Health Technol Assess* 2012;16: 1–184.
17. Office for National Statistics. UK drops in European child mortality rankings. 2017. <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/childhealth/articles/ukdropsineuropeanchildmortalityrankings/2017-10-13> (accessed June 11, 2019).

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XXXX XXXX

Email [xxxx@birmingham.ac.uk](mailto:xxxx@birmingham.ac.uk)

21<sup>st</sup> February 2019

Dear [xxxx@birmingham.ac.uk](#)

Thank you for sending me the documents relating to Pulse Oximetry Screening (POS) which will be discussed at the NSC meeting next week.

I appreciate the time and effort that has gone into producing these reports and I am grateful for the opportunity to respond.

I have tried to keep my responses as brief as possible and I would be grateful if they could be circulated to the committee before the meeting.

I would like to challenge some of the assertions made in the FMCH review and provide evidence to support my arguments. I realise there is limited time to discuss this issue in the meeting but in view of the significant amount of public money that has been spent gathering this evidence I think it is important consider all sides of the argument before making a decision.

The recommendation that pulse oximetry screening should not be introduced in the UK is based specifically on a review of the UK NSC PulseOx pilot study and the subsequent analyses (which were attempts to address questions raised by the pilot).

The recommendation was based on 3 screening criteria which were considered not to have been met. These were:

- i) 11. Evidence of improved outcome
- ii) 13. Evidence of benefit over harm
- iii) 14. Evidence of cost-effectiveness.

I would like to make the following comments

## 1. The Pilot study and the subsequent analyses

As stated in the FMCH review (page 9) the main aims of the pilot was **to demonstrate feasibility and impact on clinical services**. This was achieved, in that the pilot demonstrated that introduction of POS was feasible and did not significantly increase the clinical workload. All 15 participating units continue routine POS to this day.

In my view the concerns about adherence to the algorithm are overstated. In the pathway we *recommended* screening at 4-8 hours but *mandated* that it be performed before discharge (see End of Pilot report p 27). Pre-discharge screening was achieved in at least 90% and 91% of those were screened within 24 hours.

The subsequent analyses (using data from the Neonatal Data Analysis Unit and other sources) were a post-hoc attempt to address 2 specific questions raised by the pilot

- i) Did the introduction of PO screening significantly increase admission to Neonatal units?
- ii) What was the cost-effectiveness of PO screening if the non-cardiac conditions were included?

It is clear in hindsight that the data sources we used to try to answer these questions were inadequate and so neither report is fit for purpose. Any study to adequately address these specific questions is likely to be expensive and unlikely to be funded.

## 2. Concerns about unmet screening criteria

### i) Evidence of improved outcome and ii) benefits vs. harms

The pilot study and the subsequent analyses were **not designed to show improved outcome** for any of the conditions identified (CHD and non-cardiac) and this requirement was not stipulated by the NSC at the time of setting up the pilot or additional requests for further analyses.

However, in the USA, POS for CCHD is mandatory and performed in all states since July 2018. Introduction of POS in the US occurred from 2011 onwards, in a state-by-state manner and a recent analysis from the Centre for Disease Control (CDC) published in JAMA (Abouk *et al* 2017) clearly showed a significant (33%) reduction in mortality from CCHD in states which had initiated POS compared with those states that had not. In addition, they demonstrated a reduction in mortality of 21% from other cardiac conditions. As the US has a similar antenatal detection rate to the UK it is not unreasonable to suggest that a similar reduction in mortality is likely in a UK setting.

Regarding outcomes for the non-cardiac conditions - **there are no data**. As these babies are technically false positives the outcome as a result of screening is not essential to the screening criteria, however evidence of harm in these babies is vital. **That is the reason the NSC set up the expert workgroup to provide a consensus opinion on whether such babies would benefit or be harmed from identification by POS**; to quote the FMCH review (p 13):

*'The workshop was set up by the UK NSC Secretariat, chaired by Graham Shortland to develop an expert clinical view on the net effect to babies and their families of a screen positive result.'*

*'The workgroup explored the implications resulting from positive test results for healthy babies, and babies with significant other non-cardiac conditions. The group considered the benefits of earlier diagnosis and potential harms of over-diagnosis and follow up of false positives.'*

Thus, the remit of the workgroup was to establish the likely number of babies of false positives who would benefit and the number who would be harmed.

When considering benefits, the group were clear that in 6 of the 8 non-cardiac conditions identified by POS there was benefit to earlier diagnosis and in one (culture negative sepsis) there were some benefits and harms but the view of the group was **'better to treat suspected cases as the outcome of non-treatment of sepsis is serious'**. Given that all babies were asymptomatic at the time of screening early diagnosis by POS is clearly the case.

#### **Extracting data from the pilot study (page 110 of End Pilot Report):**

##### **Out of 239 babies who tested positive**

14 had CHD – benefit

38 had a non-cardiac condition **which the workgroup considered would benefit from POS**

43 had culture negative sepsis – see above

1 had pneumothorax - harmed by unnecessary investigations

##### **So, out of 239 babies**

52 would definitely benefit,

43 some would benefit, some be harmed but overall considered better to treat than not

1 would definitely be harmed

##### **Of the remaining 143 test positive babies who had no significant diagnosis (healthy)**

117 - had *no investigations* (**the statement in the review that all test positive babies underwent investigations [p 13] is incorrect**)

18 – were harmed by unnecessary investigations.

Thus, the pilot showed that 19 out of 239 babies (**8% of test positives and 0.05% of total screened population**) were harmed by unnecessary investigations. Given the agreed potential seriousness of some of the conditions detected the benefits would appear to outweigh the harms regardless of ultimate clinical outcomes and this was the view of the expert workgroup.

#### **iii) Evidence of cost-effectiveness**

**POS for CCHD has been shown to be cost-effective** both in a UK setting (Roberts *et al* 2012), the US (Peterson *et al* and in other countries (Grosse *et al* 2018). No study has shown that POS for CCHD is not cost-effective. The additional question posed by the NSC was ‘what is the cost-effectiveness if we include both CCHD and the non-cardiac conditions?’ and the recent cost-effectiveness analysis referred to the review was an attempt to answer this question. It is clear that such an analysis was not possible because of a lack of appropriate comparator data.

**However, this does not mean that cost-effectiveness data are unavailable.**

In Roberts (2012) the cost-effectiveness of screening for CCHD in 20 000 babies in the UK PulseOx study was reported. The proportions of test positives were virtually identical to the NSC pilot but in this analysis **all non-CHD test positives were considered ‘false positives’**. The cost of managing and investigating these were included in the analysis and the cost per timely diagnosis related to CHD only. In any subsequent analysis (i.e. Roberts 2019) which would consider a proportion of the false positives to be true positives (i.e. the non-cardiac conditions) the cost per case diagnosed is likely to go down. Although this could not be demonstrated because of a lack of data it is logical to assume this scenario. It is highly unlikely that the cost would increase.

As stated in the 2019 Cost-effectiveness Report by Roberts:

*‘Given our previous study (4) suggested that POS was likely to be considered cost-effective and should be implemented, it should be intuitively acceptable that if the same test can be revealed to have additional benefits with fewer false positives because of the benefit of identifying other significant conditions, then it can be intuitively anticipated that the results are likely to be even more favourable on cost-effectiveness grounds. However, it was considered appropriate to try and quantify the additional benefit.’*

In summary, I would argue that the 3 screening conditions, identified as unmet by the review, have been met for detecting CCHD by POS and overall, benefits outweigh harms for the non-cardiac conditions that are also detected. A small minority of healthy babies (0.05%) will be harmed by unnecessary investigations.

I would value the opportunity to discuss these observations at the meeting.

Yours sincerely

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## References

About 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

Peterson, C, Grosse SD, OsterME, Olney RS, Cassell CH Cost-effectiveness of routine screening for critical congenital heart disease in US newborns. *Pediatrics* 2013, 132, e595–e603.



Grosse SD, Peterson C, Abouk R, Glidewell J, Oster ME. Cost and cost-effectiveness assessments of newborn screening for critical congenital heart disease using pulse oximetry: a review. *Int J Neonatal Screen* 2017, 3, 34; doi:10.3390/ijns3040034

Roberts TE, Barton P, Auguste P, Middleton LJ, Furnston AT, Ewer AK. Pulse oximetry as a screening test for congenital heart disease in newborn infants: a cost effectiveness analysis. *Arch Dis Child* 2012;97:221-226.

### **Comparison of harms of pulse oximetry screening with harms of established screening tests**

The following comparisons are based on published patient information produced by the UK NSC.

#### **Harms of pulse oximetry screening**

For every 10 000 babies screened, 73 will test positive, 35 will be admitted to NNU, 28 will have a condition which requires treatment and 7 healthy babies will be harmed by slightly delayed discharge, unnecessary blood tests and x-rays. *Possible* parental anxiety although confirmatory test results are available within a few hours

#### **Harms of bowel scope screening for bowel cancer**

For every 10 000 patients screened, 500 will test positive (anxiety until test result is reported after at least 1 week), 500 will experience embarrassment, 2000 will experience pain greater than mild pain and 300 will have severe pain), 3 will have rectal bleeding which requires admission to hospital and some (unspecified) will have bowel perforation requiring surgery. 200 will say they were not glad they had the procedure. 33 cancers will be detected.

#### **Harms of breast screening**

For every 10 000 patients screened, 400 will test positive and require further invasive investigation. 100 will have cancer and 300 will not (anxiety and unnecessary invasive testing in 300).

#### **Harms of newborn hearing screening**

For every 10 000 patients screened, 220 will test positive and 7 will have hearing loss. Parental anxiety waiting for definitive test result (for at least a week) in 213 cases.

#### **Harms of antenatal testing for aneuploidy**

For every 10 000 patients screened, 200 will test positive and have amniocentesis and 2 (potentially healthy) babies will die as a result of miscarriage.

In comparative populations (10 000 screens), for established screening tests, up to hundreds and sometimes thousands of screened patients are harmed in some way. Importantly, the risks of somescreening involves major complications including requiring emergency surgery or even death. Given this perspective the possibility of delayed discharge, unnecessary blood tests and x-rays in 7 babies does seem comparatively benign.

I would be interested in the NSC's explanation as to why these specific harms are deemed unacceptable but other much more serious harms are not.

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## 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,<sup>1</sup> meets the criteria for a universal screening test<sup>1</sup> and reduces mortality.<sup>2</sup>

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.<sup>1</sup>

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<sup>3</sup> 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,<sup>4</sup> 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'.<sup>3</sup>

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)<sup>3</sup>—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)).<sup>4</sup>

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.<sup>4</sup>

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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Christopher Gale,<sup>4,5</sup> Benjamin J Stenson,<sup>6,7</sup> Michele Upton,<sup>8</sup> Claire Evans,<sup>9</sup> Sam J Oddie<sup>10,11</sup>

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**Contributors** AKE wrote the first draft. All authors edited and approved subsequent drafts.

**Competing interests** AKE was a clinical adviser to the NSC regarding POS and the clinical lead on the PHE pulse oximetry pilot. SAD is Hon. Treasurer, British Association of Perinatal Medicine (BAPM). MU is Patient Safety Lead for NHS England, CE was project lead for the PHE pulse oximetry pilot. SJO is the Clinical Lead for the National Neonatal Audit Project (NNAP).

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### REFERENCES

- 1 Plana MN, Zamora J, Suresh G, *et al*. Pulse oximetry screening for critical congenital heart defects. *Cochrane Database Syst Rev* 2018;3:CD011912.
- 2 Abouk R, Grosse SD, Ailes EC, *et al*. Association of US State Implementation of Newborn Screening Policies for Critical Congenital Heart Disease With Early Infant Cardiac Deaths. *JAMA* 2017;318:2111–8.
- 3 Legacy Screening Portal. UK NSC consultation: pulse oximetry as an additional test in the Newborn and Infant Physical Exam. 2019. <https://legacyscreening.phe.org.uk/pulse-oximetry>
- 4 Public Health England. Newborn Pulse Oximetry Screening Pilot End Project Report. 2016. <https://legacyscreening.phe.org.uk/documents/pulse-oximetry/NPOSP%20End%20Project%20Report.pdf>
- 5 Public Health England. Newborn and Infant Physical Examination (NIPE) Screening Programme Newborn Pulse Oximetry Screening. <https://legacyscreening.phe.org.uk/documents/pulse-oximetry/Notes%20of%20workshop%20June%202018.pdf>.

## UK consultation on pulse oximetry screening for critical congenital heart defects in newborns



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Universal screening allows potentially life-threatening diseases to be detected while presymptomatic. UK neonatal mortality is rising and in 2015 was ranked 19th out of 28 European countries.<sup>1</sup> Congenital anomalies and infections are the main causes of UK term neonatal mortality, and most deaths from congenital anomalies are from cardiac defects.<sup>2</sup> Critical congenital heart defects (CCHD) occur in two per 1000 livebirths and, if undetected, can result in collapse and death following closure of the ductus arteriosus.<sup>2</sup> Most such defects are amenable to surgical or transcatheter intervention, but survivors of acute collapse have worse outcomes.<sup>2</sup>

In the UK, antenatal screening detects only 43% of CCHD, with wide regional variation.<sup>3</sup> Routine newborn clinical examination fails to identify up to 45% of CCHD before acute collapse<sup>4</sup> and up to a third of cases present after hospital discharge.<sup>2</sup>

Newborn pulse oximetry screening (POS) detects babies with CCHD before clinical deterioration, is cost-effective,<sup>2</sup> and meets criteria for a screening test.<sup>2,5,6</sup> In 2017, 40% of UK hospitals used some form of POS<sup>7</sup> and more have begun screening since then.

In February, 2019, the UK National Screening Committee (NSC) decided not to recommend routine POS in the UK, citing insufficient evidence of overall improvement in newborn outcomes, concerns about parental anxiety following a positive test, and that harms (delayed discharge and unnecessary investigations and treatment) outweighed benefits. Importantly, they have invited a public consultation on this decision until Aug 9, 2019.<sup>8</sup>

POS improves detection of CCHD compared with examination alone.<sup>4,9</sup> Meta-analysis of 437 000 screened babies showed consistent test accuracy with a sensitivity of 76.3% and a specificity of 99.9% for detection of CCHD.<sup>5</sup> Studies suggest that overall detection of CCHD rises to over 92% with the addition of POS to existing screening tests.<sup>6,9</sup>

The low prevalence of CCHD means large implementation studies are needed to show statistically significant improvements in newborn outcomes. POS is mandatory for all babies in the USA,<sup>10</sup> and in a birth cohort of over 26 million infants, overall mortality from

CCHD was reduced by 33% after introduction of POS in individual states.<sup>11</sup>

POS does generate false-positive results, but these occur ten times less frequently than with clinical examination alone.<sup>9</sup> The rate of false positives with POS varies according to the time of screening.<sup>5</sup> Screening later than 24 h after birth leads to fewer false positives, but up to half of CCHD cases can present before screening.<sup>4</sup> Early discharge from hospital is commonplace in the UK and other countries, so screening in the first 24 h is pragmatic and reduces the risk of acute collapse prior to screening,<sup>4</sup> which is the outcome screening aims to prevent.

In UK studies,<sup>2,6,12</sup> including the 2015 NSC pilot study,<sup>13</sup> the positive test rate was consistently between 0.7% and 0.8%. Importantly, up to 80% of babies who are admitted to a neonatal unit after a positive test have a non-cardiac condition, such as pneumonia or sepsis, that required treatment<sup>8,12</sup> and some of these conditions are potentially life-threatening if treatment is delayed. Concerns about an increase in the demand for echocardiography following a positive test have not been realised, with less than a third of babies with a positive test undergoing this investigation.<sup>8,12,13</sup>

Data from the NSC UK pilot<sup>13</sup> suggest that 70 in every 10 000 babies screened with POS will test positive and 35 will be admitted to a neonatal unit for further investigations. Of these, 28 will have a condition that



requires treatment and only seven will be healthy (true false positive).<sup>8</sup>

Despite these reassuring data, the NSC is concerned about potential overdiagnosis and overtreatment of infants with false-positive screening tests, and therefore convened a workgroup of neonatologists and other health professionals to consider the balance between benefit and risk of POS for these babies. The group concluded that most infants admitted to a neonatal unit after a positive test would benefit and there would be moderate harms relating to delayed discharge and unnecessary investigations and treatment in a minority of babies.<sup>8</sup> The question of whether parental anxiety is unnecessarily increased when a baby has a positive test on screening is important. Psychometric analysis has shown no significant increase in anxiety among mothers of babies with false-positive results compared with mothers of babies with true-negative results.<sup>2,14</sup>

Moreover, it will never be possible to assess the detrimental effect of discharging non-cardiac, hypoxaemic babies who might benefit from early treatment. However, parents should be aware of the potential risk for newborn babies who might be discharged home with suboptimal oxygen levels.

We believe there is clear evidence that early diagnosis of CCHD with POS is beneficial and cost-effective and that potential harms associated with false-positive tests are not serious or common.<sup>2,5,8,12,13</sup> Universal screening is recommended in North America and some European countries<sup>15</sup> and is already used in over 40% of UK hospitals.<sup>7</sup> We think that routine POS should be recommended in the UK. We urge parents, patients, and health professionals to voice their views on this important consultation.

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SO, BS, and AKE were all part of an expert group, convened by the UK NSC in 2018 to review aspects of implementation of possible POS for CCHD. AKE was a clinical adviser to the NSC regarding POS and the clinical lead on the NSC pulse oximetry pilot.<sup>13</sup> None of us have a direct role on the NSC, but we have reported to the committee. We were not involved in the decision not to recommend screening, but our submissions were used as part of the evidence considered in the NSC recommendation that is discussed in this Comment. AKE has received travel and accommodation expenses to speak at scientific meetings from Masimo and Medtronic. JW was an originator of the idea that gave rise to POS and is President of the Resuscitation Council and Vice Chair of the Neonatal Task Force, International Liaison Committee on Resuscitation.

- Office for National Statistics. UK drops in European child mortality rankings. 2017. <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/childhealth/articles/ukdropsineuropeanchildmortalityrankings/2017-10-13> (accessed June 11, 2019).
- Ewer AK, Furnston AT, Middleton LJ, et al. Pulse oximetry as a screening test for congenital heart defects in newborn infants: a test accuracy study with evaluation of acceptability and cost-effectiveness. *Health Technol Assess* 2012; **16**: 1-184.
- National Institute For Cardiovascular Outcomes Research. Activity and 30-day outcomes by age group for all procedures 2014-17 (not risk-stratified). 2017. [https://nicor4.nicor.org.uk/chd/an\\_paeds.nsf/vwContent/NCHDA%20Report%20Analyses%202014-17?OpenDocument](https://nicor4.nicor.org.uk/chd/an_paeds.nsf/vwContent/NCHDA%20Report%20Analyses%202014-17?OpenDocument) (accessed June 27, 2019).
- Graneli AW, Wennergren M, Sandberg K, et al. Impact of pulse oximetry screening on the detection of duct dependent congenital heart disease: a Swedish prospective screening study in 39 821 newborns. *BMJ* 2009; **338**: a3037.
- Plana MN, Zamora J, Suresh G, Fernandez-Pineda L, Thangaratnam S, Ewer AK. Pulse oximetry screening for critical congenital heart defects. *Cochrane Database Syst Rev* 2018; **3**: CD011912.
- Ewer AK, Middleton LJ, Furnston AT, et al. Pulse oximetry screening for congenital heart defects in newborn infants (PulseOx): a test accuracy study. *Lancet* 2011; **378**: 785-94.
- Mikrou P, Singh A, Ewer AK. Pulse oximetry screening for critical congenital heart defects: a repeat UK national survey. *Arch Dis Childhood Fetal Neonatal Ed* 2017; **102**: F558.
- Public Health England. UK NSC consultation: pulse oximetry as an additional test in the newborn and infant physical exam. 2019. <https://legacyscreening.phe.org.uk/pulse-oximetry> (accessed June 25, 2019).
- Zhao Q-m, Ma X-j, Ge X-l, et al. Pulse oximetry with clinical assessment to screen for congenital heart disease in neonates in China: a prospective study. *Lancet* 2014; **384**: 747-54.
- Mahle WT, Martin GR, Beekman III RH, et al. Endorsement of Health and Human Services Recommendation for pulse oximetry screening for critical congenital heart disease. *Pediatrics* 2012; **129**: 190-92.
- 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**: 2111-18.
- Singh A, Rasiah SV, Ewer AK. The impact of routine pre-discharge pulse oximetry screening in a regional neonatal unit. *Arch Dis Child Fetal Neonatal Ed* 2014; **99**: F297-302.
- Public Health England. Newborn Pulse Oximetry Screening Pilot End Project Report. May, 2016. <https://legacyscreening.phe.org.uk/documents/pulse-oximetry/NPOSP%20End%20Project%20Report.pdf> (accessed June 25, 2019).
- Ilona C, Narayan IC, Adrian A, et al. Maternal acceptability of pulse oximetry screening at home after home birth or very early discharge. *Eur J Pediatr* 2017; **176**: 669-72.
- Manzoni P, Martin GR, Sanchez Luna M, et al, for the European Pulse Oximetry Screening Workgroup. Pulse oximetry screening for critical congenital heart defects: a European consensus statement. *Lancet Child Adolesc Health* 2017; **1**: 88-90.

166. xxxx xxxx

Professor Ewer and his team looked after my daughter in the Neonatal unit at xxxx xxxx and their integrity and work is outstanding. I also work at the University so am aware of the excellence of his research within the academic community.

I am therefore writing to show support for the pulse oximetry test he has developed for newborns which is used throughout the US and which I believe should be implemented across all UK hospitals given the simplicity of the test, its positive impact in supporting the diagnosis of babies with heart defects and fact that the national screening committee's findings were that the benefits of the test outweigh the harms.

I would strongly urge the screening committee to review its findings and decision

Best wishes

xxxx xxxx





		PEADIATRIAN PRIOR TO DISCHARGE
		DESPITE w PURPLE COLOUR, MIDWIVES
		INSISTED xxx WAS 'JUST BRUISED'

Please return to the Evidence Team at [screening.evidence@nhs.net](mailto:screening.evidence@nhs.net) by 9<sup>th</sup> August 2019

DUE TO A DIFFICULT BIRTH, xxx WAS MY 3RD CHILD. I KNEW SOMETHING WAS WRONG + xxxx WAS BREATHING TOO FAST. HAD I NOT BEEN A FORCEFUL CHARACTER OR HAD THIS BEEN MY FIRST CHILD, WE WOULD HAVE BEEN SENT HOME TO THE MERCY OF THE MIDWIVES, HEALTH VISITORS + GP. (THE LATTER TWO OF WHOM TOTALLY FAILED TO DIAGNOSE A ~~PO~~ SCOLIOSIS SIX MONTHS LATER - AGAIN DESPITE ME REPEATEDLY DRAWING IT TO THEIR ATTENTION). THE CONSULTATION'S FAITH IN THE COMMUNITY MEDICAL FACILITIES IS TOUCHING BUT MISPLACED. AND RISKS LIVES AND OUTCOMES. PULSE OXIMETRY IS SIMPLE, NON INVASIVE + HAS SAVED LIVES + IMPROVED OUTCOMES. ~~THAT~~ THIS SHOULD BE MORE IMPORTANT THAN PARENTAL ANXIETY, AND ANY PARENT WILL CONFORM THIS!



168. [REDACTED]

Good afternoon

My [REDACTED] was 2 days old when [REDACTED] was given the Pulse Oximetry test at [REDACTED] Hospital. After using 2 machines, [REDACTED] was blue lighted to [REDACTED] in [REDACTED], and diagnosed the next day with Coarctation of the Aorta. At 8 days old [REDACTED] had heart surgery then needed open heart surgery when [REDACTED] was 13 months old.

Had it not been for the Pulse Oximetry Test, we would have taken [REDACTED] home not knowing that [REDACTED] was seriously ill and could have died.

I've been amazed since I was told, about 3 years ago, that not every health board carries out this simple, non evasive test. Something so simple that could ultimately save a child's life. And stop unnecessary heartache.

I have emailed [REDACTED] on this matter before, but got a very standard non committal response.

As a parent of a now thriving 4 year old, I would ask that this matter is reconsidered seriously before another family has to go through hell.

Kind regards

[REDACTED]

169. [REDACTED]

Good evening

It is my understanding that you are seeking the public's views on the introduction of the pulse oximetry as part of newborn baby screening.

My [REDACTED] was born in 2015 and thanks to [REDACTED] having this test [REDACTED] life threatening heart condition (TGA) was detected. [REDACTED] had open heart surgery and we are blessed to have a lively, healthy [REDACTED] today. Without this test this would not be the case and I beg authorities to consider this essential in the screening of new born babies.

Regards

[REDACTED]

**170. Aideen O'Hanlon**

<b>Name:</b>	Aideen O'Hanlon		<b>Email address:</b>	XXXX XXXX
<b>Organisation (if appropriate):</b>	Local Government			
<b>Role:</b>	Data Analyst			
Do you consent to your name being published on the UK NSC website alongside your response? Yes <del>No</del>				
<b>Section and / or page number</b>	<b>Text or issue to which comments relate</b>	<b>Comment</b>		
		<b>Please use a new row for each comment and add extra rows as required.</b>		
External review against programme appraisal criteria for the UK NSC Page 19 Page 20 Page 25	This risk of discharge home without a diagnosis or of severe acidosis has been estimated to be reduced by around 60% with pulse oximetry.	Considering the risk of discharge without diagnosis can be reduced by 60%, that a mother would accept a false positive to ensure their <b>child's wellbeing before</b> leaving the hospital and that overall, knowledge of fetal wellbeing out ways the harm of extra tests and false positive tests, pulse oximetry should not be questioned as to whether or not the pros outweigh the cons.		
	Evaluation of mothers, using standardised psychological instruments, suggested that they found pulse oximetry acceptable and that false positive results did not increase anxiety significantly.			
	Current evidence reviews suggest that visual confirmation of fetal wellbeing is the primary reason why women seek ultrasound during pregnancy, and that the benefits of fetal anomaly scanning outweigh the harms.			
Pg 14	Findings from an HTA review suggest a second-trimester scan is the most cost-effective strategy for screening for all fetal anomalies. However,	As so many issues/implications can arise at this stage when detecting CHD, a new practice is required.		

	<p>existing evidence also suggests that antenatal screening technologies have variable success in recognising fetuses with serious CHDs and that this is dependent on the type of defect, expertise of the person scanning , standard of equipment, gestation and maternal body mass index (BMI).</p>	<p>As CHD is one of the most common types of birth defects, why are there so many issues during diagnosis?</p> <p>On a personal note, a transposition of the greater arteries was missed when <b>xxxx xxxx</b> was scanned. Only that a <b>xxxx xxxx</b> funded by <b>xxxx xxxx</b> and <b>xxxx xxxx</b>, working with the <b>xxxx xxxx</b> was conducting a pilot study of pulse oximetry as an additional test at NIPE (<b>xxxx xxxx</b>), this would have been missed (April 2018).</p>
Pg 19	<p>Non-cardiac conditions leading to low oxygen saturation, such as respiratory or infective illness, may be found in infants with low oxygen saturations (false positive screening results).</p>	<p>Another illness maybe found, can this really be seen as a bad result, as an issue has be found?</p> <p>Is the test the only used for one purpose? Can adapters not be added for infants to the current machines? - Help with cost effectiveness issues</p>
		<p>This research does not include Wales, Scotland or Northern Ireland. Considering 2/1000 babies are born in NI with CHD, a quarter of the UKs rate, whilst we are only 2.7% of the UK population, maybe more consideration should be given to NI within pilot tests and research.</p>

171.

XXXX XXXX



UK National Screening Committee  
PHE Screening  
Floor 5  
Wellington House  
133-155 Waterloo Road  
London  
SE1 8UG

6<sup>th</sup> August 2019

Dear National Screening Committee,

**Re: NSC Public Consultation on pulse-oximetry screening for critical congenital heart defects**

We are writing on behalf of the Congenital Cardiac Nurses Association (CCNA) in response to the UK National Screening Committee Consultation on pulse oximetry as an additional screening test in the Newborn & Infant Physical Examination.

The CCNA is the only UK association dedicated to representing the voice of children's cardiac nurses throughout the UK and Southern Ireland. As an association we are dedicated to improving outcomes for babies with congenital heart disease and in our daily work we see the benefits of early detection for those babies with the most severe defects.

We were disappointed to hear that the NSC reviewed pulse oximetry and decided not to introduce routine pulse oximetry for the detection of critical congenital heart disease (CCHD) in the newborn.

We feel that this will disadvantage babies across the UK because the current UK antenatal screening programme has a widely variable detection rate and clinical examination for heart defects misses a significant proportion.

In our daily work we see the consequences of late diagnosis and we feel the addition of pulse oximetry screening will help reduce this and improve outcomes for these babies. Evidence from the USA, where pulse oximetry screening is available for all babies indicates that many lives will be saved.

Reviewing the evidence presented on the NSC website we do not feel that the harms outlined are as serious or as frequent as the potential harms of a missed diagnosis. It is our view that parents will find the harms of pulse oximetry favourable compared to the alternatives of collapse or possible death.

Newborns are still presenting with late diagnosis of CCHD, this has significant implications for the outcome for these babies. We think that pulse oximetry will reduce the likelihood of this happening and we would ask the NSC to reconsider their decision not to recommend routine screening for CCHD.

Yours sincerely

XXXX XXXX

XXXX XXXX

XXXX XXXX

XXXX XXXX

XXXX XXXX

XXXX XXXX

**172.** [REDACTED]

On [REDACTED] 2012 our [REDACTED] child was born. On [REDACTED] 2012 [REDACTED] died. [REDACTED] had been born with transposition of the great arteries but this had not been detected before [REDACTED] birth, and only was by the time [REDACTED] was 24hours old, by which time it was too late to save [REDACTED]. Despite valiant efforts at [REDACTED] by the team there and a team from [REDACTED] children's hospital [REDACTED] died a few hours later.

We had a beautiful home birth, which obviously if [REDACTED] condition had been detected during pregnancy would not have happened. [REDACTED] condition was only detected following the use of pulse oximetry once after we had been referred back into hospital following a newborn check from our gp. If we had had [REDACTED] in hospital I know there are no guarantees [REDACTED] condition would have been detected sooner, but it may have been, and our story would be different.

The following February we had another little [REDACTED]. [REDACTED] blood saturation levels were checked after birth at [REDACTED] due to the loss of [REDACTED] [REDACTED], [REDACTED] was fine.

It just seems a no brainer that this test is not given to all newborns rather than it being down to luck of where your baby is born or previous bad luck.

Many thanks for taking time to read this.

[REDACTED]

173. xxxx xxxx

Dear Sirs,

Please reconsider the decision and add the pulse oximetry test to the mandatory and routine testing of newborns.

This would save so much angst and stress for parents already being dealt a difficult blow.

Thank you,

xxxx xxxx