Health Policy Advisory Committee on Technology

Technology Brief

Pulse oximetry for detecting heart defects in newborns

November 2012
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This brief was prepared by Dr. Vicki Foerster and Ms. Stefanie Gurgacz for the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).
Pulse oximetry for detecting heart defects in newborns: November 2012

TECHNOLOGY BRIEF

Register ID: WP134

Name of Technology: Pulse oximetry

Purpose and target group: Newborns with critical congenital heart defects

Speciality: Paediatrics and neonatology

Technology type: Device

Setting: General Hospital

Stage of development in Australia:

☐ Yet to emerge
☐ Experimental
☐ Investigational
☒ Nearly established

☐ Established
☐ Established but changed indication or modification of technique
☐ Should be taken out of use

Australian Therapeutic Goods Administration approval:

☒ Yes
☐ No
☐ Not applicable

ARTG number: Multiple devices

International utilisation:

<table>
<thead>
<tr>
<th>Country</th>
<th>Level of use</th>
<th>Trials underway or completed</th>
<th>Limited use</th>
<th>Widely diffused&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td></td>
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<td></td>
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<tr>
<td>Egypt</td>
<td></td>
<td>☒</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germany</td>
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<tr>
<td>Norway</td>
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<tr>
<td>Poland</td>
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<tr>
<td>Sweden</td>
<td></td>
<td></td>
<td></td>
<td>☒&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>United Kingdom</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td></td>
<td></td>
<td></td>
<td>☒&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup> A report from 1 May 2012 states that the USA is the only country to show mandatory jurisdictional uptake of the test (http://www.theheart.org/article/1392703.do).

<sup>b</sup> Recommended by the Ministry of Health for use nationwide in 2010<sup>1</sup>.

<sup>c</sup> 10 states have indicated engagement in pulse oximetry screening for critical congenital heart defects,<sup>2</sup> with universal screening required by law in eight states, a ninth offers the test to select populations, or by request only.<sup>3, 4</sup>

Impact summary:

Pulse oximetry is a rapid, painless, non-invasive way to measure oxygen (O<sub>2</sub>) saturation in the blood. In newborns it can be used to screen for critical congenital heart defects (CHDs) which are potentially lethal malformations that may miss
detection via antenatal ultrasound and newborn clinical examinations. A number of manufacturers produce the small devices with several being registered for use in Australia. The testing can be done by trained staff such as nurses, midwives and midwife assistants. As a potential screening manoeuvre, parameters such as sensitivity and specificity are important and, along with economic analyses, can aid decision-makers in choosing whether or not to provide a screening service.

**Background**

A CHD is defined as ‘a gross structural abnormality of the heart or intrathoracic great vessels that is actually or potentially of functional significance’. Congenital heart defects have been subdivided into many types with ‘critical CHDs’ (15-25% of all CHDs) generally referring to ‘all potentially life-threatening duct-dependent conditions plus infants dying or undergoing invasive procedures (surgery or cardiac catheterisation) within the first 28 days of life (death from undiagnosed CHDs can also occur after that)’. Although there is some variation in the anatomical conditions included in the critical CHD category, examples are: hypoplastic left heart syndrome, pulmonary atresia with intact ventricular septum, simple transposition of the great arteries, interruption of the aortic arch, coarctation of the aorta, aortic valve stenosis, pulmonary valve stenosis, tetralogy of Fallot, pulmonary atresia with ventricular septal defect and total anomalous pulmonary venous connection. Some CHDs are detected during a mid-trimester anomaly ultrasound that visualises the heart chambers, and others are detected via clinical examination assessing the cardiovascular system at birth; however, some go undetected despite these two manoeuvres. If defects are not detected early, there is a risk of circulatory collapse, with a substantial adverse effect on prognosis. Poor clinical status at the time of operation increases surgical mortality; thus timely diagnosis improves outcomes. The evaluation of screening strategies to enhance early detection of CHDs is of great importance.

Primary prevention is not possible; therefore, early detection before the onset of symptoms is important, particularly for critical CHDs. Postnatal echocardiography is the gold standard for diagnosis but is unsuitable as a screening tool for a number of reasons, including diagnosis of abnormalities of no clinical significance (false-positives), need for operator expertise and cost. Clinical examination shortly after birth and again at six to eight weeks involves listening for heart murmurs and additional sounds, palpation of the peripheral pulses, and observation for cyanosis, but detection rate of CHDs is low.

Use of pulse oximetry in newborns for the detection of CHDs has been explored for several decades, but thus far has not seen wide uptake as a screening tool. The procedure is performed within the first few hours after birth (preferably within 3–6
hours), although some centres have delayed the test until the baby is 24–48 hours old. During a bedside test, a sensor is placed on one of the baby’s legs and, in some cases, another on the right arm. Oxygen saturation and pulse are measured with testing taking a mean of five minutes in one study (range 1–30 minutes) but as little as 45 seconds in another reference.

Figure 1  Example of a baby being fitted with a pulse oximetry device

Clinical need and burden of disease

Congenital heart defects are a leading cause of infant death in the developed world with an incidence of 4 to 10 per 1,000 live births (1 to 1.8 per 1,000 for critical CHDs). One source cited the incidence in Australia as 8 per 1,000. Congenital heart defects lead to more deaths than any other type of malformation; up to 40 per cent of deaths from congenital defects and about seven per cent of infant deaths are due to CHDs. Surgery greatly improves survival, particularly for infants with potentially life-threatening critical disorders. A report from the National Perinatal Epidemiology and Statistics Unit on congenital malformations in Australia between 1981 and 1992 collected data from each state and territory regarding the number and nature of congenital malformations among newborns, using perinatal data systems, birth defects registers and hospital records.

The report included data on congenital malformations of the heart including transposition of great vessels, ventricular septal defect, hypoplastic left heart and coarctation of the aorta. In 1981–1992 there were 2.85 million births and 8,123 notifications of congenital malformations of the heart; this equates to a rate of 28.5 notifications per 10,000 births.
The Australian Institute of Health and Welfare (AIHW) reported 2,866 hospital separations for procedures on the cardiovascular system (ICD classification 600-693) and 1,592 separations according to principal diagnosis of congenital malformations of the circulatory system (Q20-24) in children under the age of one in 2009-10.\textsuperscript{12}

**Table 1** AIHW hospital separations data for congenital malformations of the circulatory system (Q20-24) in children under the age of one\textsuperscript{12}

<table>
<thead>
<tr>
<th>Congenital malformations of the circulatory system (Q20-24) in children under the age of one\textsuperscript{12}</th>
<th>Separations in children under the age of one, 2009-10</th>
<th>All separations, 2009-10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital malformations of cardiac chambers and connections</td>
<td>236</td>
<td>425</td>
</tr>
<tr>
<td>Congenital malformations of cardiac septa</td>
<td>654</td>
<td>2,490</td>
</tr>
<tr>
<td>Congenital malformations of pulmonary and tricuspid valves</td>
<td>112</td>
<td>264</td>
</tr>
<tr>
<td>Congenital malformations of aortic and mitral valve</td>
<td>131</td>
<td>491</td>
</tr>
<tr>
<td>Other congenital malformations of heart</td>
<td>96</td>
<td>280</td>
</tr>
<tr>
<td>Congenital malformations of great arteries</td>
<td>363</td>
<td>791</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,592</strong></td>
<td><strong>4,741</strong></td>
</tr>
</tbody>
</table>

AIHW: Australian Institute of Health and Welfare.

**Diffusion of technology in Australia**

Pulse oximetry screening in newborns is not universal in Australia, although it may be offered in some centres.

A media report from 2 May 2012\textsuperscript{7} described the systematic review included below and quoted Dr Dominic Wilkinson, Associate Professor of Neonatal Medicine and Bioethics at the University of Adelaide, who said it was just a matter of time before pulse oximetry became a routine procedure for newborns in most countries:

In Australia at the moment, there are only one or two centres doing this, but it’s not common at all ... on the face of it, the evidence is now pretty convincing that this testing is able to identify infants who have a risk of becoming seriously unwell and dying, without a huge number of false-positives ... there are some reservations about extrapolating the data to an Australian setting, but even accepting those reservations, if this test was introduced here, it would identify infants who would otherwise be missed and potentially save their lives, and it wouldn’t pose a great cost.\textsuperscript{13}

Similarly, a media report from 8 May 2012 quoted Dr Christoph Camphausen, Head of the Cardiology Department at Sydney Children’s Hospital, as saying that the method was already in use in major Australian population centres:

The research convincingly reminds health authorities to provide the necessary funds and infrastructure for this important and simple test in newborn babies.\textsuperscript{10}
The article goes on to state that the Paediatric Congenital Cardiac Council of the Cardiac Society of Australia and New Zealand does not currently have an agreed stance on the widespread use of the screening, but is expected to discuss the issue at its next conference.¹⁰

Comparators

Current routine screening for CHDs relies on a mid-trimester anomaly ultrasound scan in pregnant women involving imaging of the heart chambers, and a postnatal clinical examination that assesses the cardiovascular system. Both have relatively low detection rates and a number of babies are discharged from hospital before a CHD is diagnosed. A proportion of these may die or present in such a poor clinical condition that the outcome, despite treatment, is compromised.⁵

Safety and effectiveness

Four studies have been selected for evidence of the safety and effectiveness of pulse oximetry testing in newborns, including a systematic review and meta-analysis assessing 13 studies that reported on pulse oximetry screening in newborns,⁷ a subsequent primary observational study from Poland,¹ detail about a primary study that was reported in the systematic review and accompanied by an economic analysis⁵ and an evaluation of acceptability of testing to mothers.¹⁴

Thangaratinam et al⁷

Researchers from the United Kingdom (UK) performed a systematic review that focussed on the use of pulse oximetry screening in asymptomatic newborns to detect critical CHDs. Four databases were searched up to 2011 with no language restrictions. Ultimately, 13 studies (12 cohort and one case-control) were included, reporting on nearly 230,000 babies. Studies were assessed for quality. There was no funding source for this research.

Authors’ observations about the 13 studies (Table 2) include:

- Studies verified positive test results via echocardiography and negative results via interrogation of congenital anomaly registers, mortality data or clinical follow-up.
- Studies varied in several ways including:
  - antenatal diagnosis of CHD. Four studies allowed this.
  - timing of pulse oximetry. Six studies performed the test less than 24 hours after birth.
  - positioning of pulse oximetry monitoring. Eight studies used the foot alone (postductal readings) and five utilised both the right hand and foot (preductal and postductal readings).
Table 2  Characteristics of studies included in the Thangaratinam et al review

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Country</th>
<th>n</th>
<th>Limb</th>
<th>Antenatal Dx CHD</th>
<th>Test Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hoke et al</td>
<td>2002</td>
<td>USA</td>
<td>2,876</td>
<td>Foot &amp; right hand</td>
<td>Included</td>
<td>&lt; 24 hours</td>
</tr>
<tr>
<td>Richmond et al</td>
<td>2002</td>
<td>UK</td>
<td>5,626</td>
<td>Foot only</td>
<td>Included</td>
<td>&lt; 24 hours</td>
</tr>
<tr>
<td>Koppel et al</td>
<td>2003</td>
<td>USA</td>
<td>5,626</td>
<td>Foot only</td>
<td>Excluded</td>
<td>&gt; 24 hours</td>
</tr>
<tr>
<td>Reich et al</td>
<td>2003</td>
<td>USA</td>
<td>2,114</td>
<td>Foot &amp; right hand</td>
<td>Excluded</td>
<td>&gt; 24 hours</td>
</tr>
<tr>
<td>Bakr et al</td>
<td>2005</td>
<td>Egypt</td>
<td>5,211</td>
<td>Foot &amp; right hand</td>
<td>Excluded</td>
<td>&gt; 24 hours</td>
</tr>
<tr>
<td>Rosati et al</td>
<td>2005</td>
<td>Italy</td>
<td>5,292</td>
<td>Foot only</td>
<td>Excluded</td>
<td>&gt; 24 hours</td>
</tr>
<tr>
<td>Arlettaz et al</td>
<td>2006</td>
<td>Switzerland</td>
<td>3,262</td>
<td>Foot only</td>
<td>Included</td>
<td>&lt; 24 hours</td>
</tr>
<tr>
<td>Kawalec et al</td>
<td>2006</td>
<td>Poland</td>
<td>27,200</td>
<td>Foot only</td>
<td>Excluded</td>
<td>&gt; 24 hours</td>
</tr>
<tr>
<td>Meberg et al</td>
<td>2008</td>
<td>Norway</td>
<td>50,008</td>
<td>Foot only</td>
<td>Excluded</td>
<td>&gt; 24 hours</td>
</tr>
<tr>
<td>Sendelbach et al</td>
<td>2008</td>
<td>USA</td>
<td>15,233</td>
<td>Foot only</td>
<td>Excluded</td>
<td>&gt; 24 hours</td>
</tr>
<tr>
<td>De Wahl Granelli et al</td>
<td>2009</td>
<td>Sweden</td>
<td>39,821</td>
<td>Foot &amp; right hand</td>
<td>Excluded</td>
<td>&gt; 24 hours</td>
</tr>
<tr>
<td>Riede</td>
<td>2010</td>
<td>Germany</td>
<td>41,442</td>
<td>Foot only</td>
<td>Excluded</td>
<td>&gt; 24 hours</td>
</tr>
<tr>
<td>Ewer et al</td>
<td>2011</td>
<td>UK</td>
<td>20,055</td>
<td>Foot &amp; right hand</td>
<td>Included</td>
<td>&lt; 24 hours</td>
</tr>
</tbody>
</table>

TOTAL 229,421

N: number of patients; CHD: congenital heart defect.

With respect to study quality, most included studies were deemed to be of good quality based on prospective design and adequate descriptions of the population, test and reference standard. Follow-up was considered to be adequate in 10 of 13 studies. The authors noted that precision of findings had improved since a previous review.

The researchers calculated sensitivity, specificity and corresponding 95 per cent confidence intervals (CIs). From the individual studies they noted the numbers of true-positive, false-positive, true-negative and false-negative results and then calculated an overall false-positive rate. Two of the 13 studies were not included in the analyses as one was a case-control study and one detected no critical CHDs.

Safety

No safety data was reported.

Effectiveness

The results calculated from data available from the 11 (of the 13) studies reporting relevant data showed that:
the overall sensitivity of pulse oximetry for detecting critical CHDs is 77 per cent, 95% CI [67.7, 83.5]

- specificity was 99.9 per cent, 95% CI [99.7, 99.9]
- the false-positive rate was 0.1 per cent, 95% CI [0.06, 0.33].

The researchers noted that the false-positive rate for detection of critical CHDs was lower when testing was done more than 24 hours after birth versus less than 24 hours (0.05%, 95% CI [0.02, 0.12] versus 0.50, 95% CI [0.29, 0.6]; \( p = 0.0017 \)), although the sensitivity of the test did not change significantly \( (p = 0.36) \). Differences were not statistically significant if testing involved the foot only versus a foot and the right hand \( (p = 0.22) \). Inclusion of newborns who were antenatally suspected to have CHDs resulted in a significant increase in the false-positive rate \( (p<0.0001) \).

Detail from the included studies reveals that, as is common with screening manoeuvres, many positive results from pulse oximetry testing are false-positives. For example, in a large included study from Norway \( (n=50,008) \), 324 tests were positive but only 27 proved to be true positives with the other 297 being false-positives. Similarly, in a large UK study \( (n=20,055) \), 18 positive tests were true positives with 177 being false-positives.

**Ewer et al**

A large pulse oximetry study from the UK, the PulseOX study, was included in the systematic review; however, it was subsequently published in a detailed health technology assessment (HTA) accompanied by considerations related to acceptability of the test to stakeholders and an economics analysis, and therefore is presented here.

For 11 months in 2008, pulse oximetry screening was performed in six maternity units on 20,055 newborns prior to their discharge from hospital. All pregnant women booked for delivery at the six units were approached for consent to be recruited into the study and 76% agreeing to participate in the study. Study inclusion criteria are detailed in Table 3 below.

Babies were assessed by routine antenatal screening and clinical examination, in addition to pulse oximetry. Abnormal results for pulse oximetry were defined as \( O_2 \) saturation less than 95 per cent in either limb or a difference of greater than 2 per cent between the limb readings. For those with abnormal results, an expedited clinical examination was performed. If this was normal, pulse oximetry was repeated within one to two hours. Babies with continuing abnormal results underwent echocardiography (the reference standard) as soon as possible within 72 hours. Others were followed up for one year through cardiac registries and clinical follow-up (delayed verification).
Table 3  Inclusion criteria

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population</strong></td>
<td>Apparently healthy asymptomatic newborn infants of gestation ≥ 35 weeks prior to discharge from hospital, including babies who were suspected antenatally of having a CHD.</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>O₂ saturations from pulse oximetry readings (the device employed was the Radical-7R pulse oximeter [Masimo⁷, Irvine, CA]) from the right hand and either foot, ideally within 3–6 hours of birth, performed by a trained midwife or midwifery assistant</td>
</tr>
<tr>
<td><strong>Comparator</strong></td>
<td>Reference standard echocardiography, clinical follow-up and follow-up through interrogation of regional and national clinical databases.</td>
</tr>
<tr>
<td><strong>Outcome</strong></td>
<td>Detection of major CHDs.</td>
</tr>
</tbody>
</table>

CHD: congenital heart defect

**Safety**

No safety data were reported.

**Effectiveness**

In this study, major CHDs were subdivided into critical (causing death or requiring invasive intervention before 28 days) and serious (causing death or requiring invasive intervention at one to 12 months of age). Results showed that there were 53 cases of major CHDs (24 critical, 29 serious). Of those with an abnormal result following pulse oximetry (n=195), 26 (13%; 95% CI 9-19%) had major CHDs (18 critical, 8 serious). Of those with normal pulse oximetry (n=19,860), 27 (0.1%; 95% CI 0.1% to 0.2%) had major CHDs (6 critical and 21 serious).

For the full cohort, the test had a sensitivity of 75 per cent (95% CI 53-90%) for critical cases and 49 per cent (95% CI 35-63%) for critical plus serious cases combined. For the cohort where CHDs were not suspected following antenatal ultrasound, pulse oximetry had a sensitivity of 58 per cent (95% CI 28-85%) for critical cases (12 babies) and 29 per cent (95% CI 15-46%) for critical plus serious cases combined (35 babies). One in 119 babies (0.8%) without serious or critical CHDs had a false-positive result (specificity 99%).

While pulse oximetry screening identified 26 cases of CHDs, of these, 17 were identified by antenatal ultrasound scanning. Of the remaining nine cases, seven displayed abnormalities during clinical examination. In this study, pulse oximetry screening enabled an additional two diagnoses for every 20,000 babies screened over antenatal screening and clinical examination.

Turska–Kmieć et al¹

In the Polish province of Mazovia, pulse oximetry was performed on 52,993 babies (95% of total births) born in 51 neonatal units over 12 months in 2007–08. Babies with and without symptoms were enrolled. The study analysed the groups separately.
and only the latter group is discussed here to assure consistency with the other evidence presented in this brief.

Specially trained nurses conducted the two to three minute test on infants less than 24-hours-old. Devices from three manufacturers were employed. Positive results were defined as $O_2$ saturation less than 95 per cent. Positive results were verified via clinical exam and echocardiography and negative results were verified via hospital readmissions or public health data.

**Safety**

No safety data was reported.

**Effectiveness**

The data for nearly 53,000 newborns were assessed separately according to the presence of pre-testing symptoms: Group A (symptomatic) included 1,295 newborns and Group B (asymptomatic) included 51,698 newborns (Figure 2). The focus in this study is on Group B as this group is most useful for determining the accuracy of pulse oximetry for screening asymptomatic newborns.

Pulse oximetry was performed, on average, 7.3 hours after birth. Among 51,698 asymptomatic newborns, a positive result was obtained in 29 cases, of which 15 proved to have critical CHD while 14 were false-positive results. Of the 51,669 newborns with negative test results, four were subsequently found to have critical CHDs (only one was discharged without a diagnosis). In total, of the 82 newborns found to have critical CHD in the entire study, the 15 true positives comprised 18 per cent of the total and the four false-negatives comprised five per cent of the total.

Statistical analysis revealed the following:

- sensitivity of pulse oximetry for detecting critical CHD of 78.9 per cent
- specificity of 99.9 per cent
- positive predictive value of 51.7 per cent
- negative predictive value of 99.9 per cent.
Cost impact

A model-based economic evaluation was performed as part of the included HTA, it was performed on the results from the PulseOx clinical study. The timeline was one year. The objective of the evaluation was to compare the cost and cost-effectiveness of pulse oximetry as an adjunct to current practice compared with current practice alone based on an outcome of cost per timely diagnosis. Current practice was defined in this study as clinical examination plus further testing as needed. The model drew heavily on an earlier UK economic analysis published in 2005. Cost data were based on UK costs in 2009.

Results of the analysis indicated that the main cost for initial testing was due to equipment and staff time to perform the test. It was assumed a midwife would do the testing. A pulse oximetry machine purchase price of £1,100 (A$1,712 on 29/9/12) plus 10 per cent for maintenance costs, were built into the model assumptions. In addition, the lifecycle of the technology was assumed to be five years with an annual discounting rate of four per cent. The price of disposable probes was £150 (A$224) and these were assumed to last six months. Based on actual data, testing time took a mean of 6.9 minutes (median 5, range 1–30 minutes), with the cost of staff time being £5.64 (A$8.78). Employing these estimates, the total cost of carrying out the pulse oximetry test in 2009 was £6.24 (A$9.71). Additionally, follow-up clinical exam for those with positive results cost £5.43 (A$8.45) and the cost of follow-up echocardiography performed by a paediatric cardiologist was estimated at £115.57 (A$179.92).
The model predicted that, for asymptomatic newborns diagnosed with critical CHDs, the incremental cost-effectiveness ratio (ICER) would be £24,900 (A$38,764) per timely diagnosis. This ICER was defined as the additional cost per additional case of timely diagnosis of clinically significant CHDs, a surrogate outcome, rather than per QALY. This analysis does not allow for a fair comparison with other economic assessments of healthcare interventions and therefore should not be used as a basis to guide decision making.

Costs were also considered in a position paper from the American Heart Association and American Academy of Pediatrics. The paper quotes an economic assessment that calculated a cost per test of US$1 per asymptomatic newborn (including the cost of diagnostic evaluations) in hospitals with moderate obstetric volume and ready access to paediatric echocardiography. However, the authors note that more work is needed to assess the cost and yield of the test in a wider range of settings.

**Ethical, cultural or religious considerations**

Attitudes towards testing were examined in two studies. In the first recent study conducted in Poland, mothers were asked two questions at time of consent signing (i.e., before actual testing occurred), including: ‘Was it easy for you to decide for your child to have the saturation measurement?’ and ‘Do you think such a test should be performed in all newborns in Poland?’ Affirmative answers were received from 91 per cent of those surveyed. However, the study did not indicate whether mothers understood the screening test and implications of a positive result, in addition to whether they felt enough information had been provided to give informed consent.

The second study was the included HTA, in which mothers as well as healthcare staff were questioned. The researchers were particularly concerned about whether maternal anxiety is increased by a false-positive result and whether this persists over time.

Participating mothers received a baseline cross-sectional questionnaire (13 questions rated on a 5-point scale) with a one-year follow-up survey for those with false-positive results (response rate 43%, median 385 days after birth). Mothers of newborns who received true-positive results were approached when they were felt to be ready (response rate 71%, median 20 days after birth). The response rate for mothers of true-negative results was 33 per cent. Mothers of newborns with false-negative results were not asked to complete a follow-up survey. Results showed that mothers given false-positive results were not more anxious after participating than those given true-negative results, although they were less satisfied with the test and had slightly higher depression scores. White British/Irish mothers were more likely to participate in the study (5% declined), and were less anxious and more satisfied than
those of other ethnicities. Black African mothers were the most likely to decline participation (21%).

Mothers with more than one baby were also more likely to decline. Generally, pulse oximetry was well received, being seen as useful, quick, safe, non-invasive, painless and non-distressing for the baby, and reassuring for parents. The PulseOx results for mothers were also reported separately.¹⁴

Healthcare staff who were involved in requesting consent for the test or conducted the testing (midwives and nurses) as well as physicians or nurse practitioners were surveyed. Healthcare staff members involved in the consent or testing were queried via focus groups, and physicians and nurse practitioners were surveyed using open-ended format email questionnaires. The response rate was 26 of the 199 (13%) individuals questioned. For the midwife group, sentiments were predominantly positive with suggestions for process improvements, including revision of the complex consent process. For the physician group, most were very positive about pulse oximetry testing becoming routine, although there was concern about the resources required.

Other issues

Currently a 12-month pilot study is taking place in a number of Perth hospitals and will screen about 50 per cent of newborns via pulse oximetry and evaluate the feasibility of setting up a program in Western Australia. It appears there will be an economic assessment as well. The study is led by Dr Jim Ramsay, Princess Margaret Hospital, Perth, and funded by HeartKids Grants in Aid.¹⁶

In addition, another study of interest is registered at clinicaltrials.gov. The observational cohort study in Fudan, China (NCT01665261) is currently recruiting and aims to enrol 3000 consecutive symptomatic and asymptomatic babies at ages six to 72 hours.¹⁷ The objective is to assess the diagnostic accuracy of seven indicators of CHD, including pulse oximetry reading less than 95, family history of CHD, tachypnoea, heart murmurs and cyanosis. Patients who test positive will be assessed via echocardiography and a single investigator will perform all the testing.

Any proposal to establish a nation screening program requires referral to the Standing Committee of the Community Care and Population Health Principal Committee for assessment against the AHMAC-endorsed Australian Population Based Screening Framework.

Summary of findings

Pulse oximetry for the detection of critical CHDs in asymptomatic newborns may be on the cusp of use as a screening tool, in the United States it has been added to the Recommended Uniform Screening Panel and had been mandated in eight states.³⁴ In Australia, there appears to be pressure to consider the same. The bedside test is
quick and painless, and positive results are followed up via clinical examination and echocardiography. A recent UK systematic review of 13 studies from various countries included results for nearly 230,000 newborns and reported an overall sensitivity of 77 per cent and specificity of 99.9 per cent with a false-positive rate of 0.14 per cent (dropping to 0.05% if the test was delayed until age greater than 24 hours). As with all screening tests, some babies will receive false-positive results and will be further assessed needlessly. Likewise, false-negatives will also occur. While the assessment procedures following a positive result are not invasive, psychosocial effects require consideration; prior to testing, parents should be provided with sufficient information to understand the outcomes of testing, with counselling provided following a positive result.

A UK economic analysis calculated an ICER for asymptomatic babies diagnosed with critical CHDs at £24,900 (A$38,764) per timely diagnosis, rather than per quality adjusted life year. As such, this ICER is not comparable to other economic analyses of healthcare interventions and should not be used to guide policy.

The overall sensitivity of pulse oximetry screening ranged between 75-79 per cent in the studies reported, indicating a relatively high false-negative rate; furthermore, the benefits of pulse oximetry screening over current practice of antenatal screening and clinical examination may be small, and may decrease with further improvements to antenatal screening.¹⁸

**HealthPACT assessment**

While screening for CHDs in newborns may have some merit, the feasibility and value of mandatory pulse oximetry screening remains uncertain, given the low sensitivity and high rates of false-negative results observed. Consequently, HealthPACT recommend that further research on this technology is not warranted.

**Number of studies included**

All evidence included for assessment in this Technology Brief has been assessed according to the revised NHMRC levels of evidence. A document summarising these levels may be accessed via the HealthPACT web site: [HealthPACT web site](#).

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**References**


Search criteria to be used

pulse oximetry, oximetry [MeSH Terms], newborn, infant, newborn [MeSH Terms], screening, mass screening [MeSH Terms]