

# Should New Zealand introduce nationwide pulse oximetry screening for the detection of critical congenital heart disease in newborn infants?

Elza Cloete, Tom Gentles, Jane Alsweiler, Lesley Dixon, Dianne Webster, Deborah Rowe, Frank Bloomfield

Pulse oximetry has been utilised internationally as a screening tool for the detection of congenital heart defects in newborn infants for more than a decade.<sup>1-4</sup> In recent years this practice has been introduced in various jurisdictions as it became evident that the number of late-diagnosed infants can be reduced significantly when pulse oximetry is used in conjunction with other screening strategies, namely antenatal ultrasound and newborn physical examination.<sup>5-8</sup> In New Zealand, there currently is no national approach to newborn pulse oximetry screening for critical congenital heart disease (CHD). However, some district health boards have begun screening led at hospital level. Given the existing regional and demographic variation in maternity care,<sup>9,10</sup> hospital-led approaches to screening are unlikely to improve health outcomes in an equitable way.

Congenital heart defects are the most common group of congenital malformations, with an incidence of between four and 10 per 1,000 live-born infants. Surgery and cardiac catheter interventions have resulted in marked improvements in survival, particularly for those infants with life-threatening conditions.<sup>11-13</sup> Successful intervention is dependent on timely diagnosis; if such defects are not detected early, severe hypoxaemia, shock, acidosis and death are potential sequelae. Detecting infants with severe cardiac malformations before or

immediately after birth is therefore of the utmost importance.

A recent population-based study found that only 46% of New Zealand-born infants with critical CHD are diagnosed in the antenatal period. Twenty percent of critical cardiac defects are currently diagnosed after discharge from hospital. It is estimated that four babies die each year in New Zealand as a result of late-diagnosed CHD.<sup>14</sup> The impact on permanent disability, especially neurodevelopmental deficit, is likely to be greater, as late diagnosis of CHD is associated with a greater risk of hypoxaemia and acidosis, both of which are associated with neurological damage.<sup>15,16</sup>

Researchers are in agreement that the question no longer is whether pulse oximetry screening should be performed on newborn infants, but rather how best to deliver the test.<sup>17-19</sup> Pulse oximetry screening for critical CHD is highly specific, moderately sensitive and meets criteria for universal screening.<sup>20</sup> Various factors can impact on the sensitivity and specificity of this screening tool. Recent studies have demonstrated that test accuracy varies according to the healthcare setting in which screening is undertaken. Screening performed at tertiary centres located in first world settings is associated with sensitivity greater than 80%.<sup>21,22</sup> Conversely, regional hospitals and those in developing countries often report lower test sensitivity.<sup>7,23-25</sup>

The cost-effectiveness of pulse oximetry screening has been demonstrated in the US<sup>26,27</sup> and the UK,<sup>28</sup> but a recent study evaluating screening in Chinese regions with diverse socioeconomic status demonstrated cost-effectiveness only in affluent regions.<sup>29</sup> A cost-effective analysis is currently being undertaken in the Netherlands where 18% of births occur at home. A Dutch national screening programme would warrant the provision of pulse oximeters to each of the country's 1,800 community midwives, adding to the cost in this setting.<sup>30</sup>

The importance of considering region-specific factors is evident when international studies are reviewed. The American Academy of Pediatrics recommends that screening should be performed after 24 hours of age, thereby minimising the number of false-positive results. In a large Chinese study involving 122,738 newborn infants, the false-positive rate was 0.55% when screening was performed 6–24 h after birth compared to 0.29% when screening was done 25–48 h after birth.<sup>6</sup> However, in countries where newborn babies and their mothers are discharged home prior to 24 hours, a late screening strategy will not be feasible. Furthermore, it is crucial to detect critical CHD prior to cardiovascular compromise. Early screening strategies can enable early diagnosis and treatment that can ultimately result in better outcomes for these infants. The potential harm caused by false-positive results has to be weighed up against the benefits associated with early diagnosis and treatment.

The Dutch recently investigated the feasibility and accuracy of a very early screening strategy, which was necessitated by the large number of community births and early discharges from hospital following uncomplicated births in this country. In order to minimise the impact pulse oximetry screening has on the workload of community midwives, the screening protocol was designed to fit in with the times midwives are routinely present following a birth. Measurements were obtained at approximately one hour after birth and again on day two or three. Higher screening rates were achieved in the community (97%) than in hospitals (70%). This study demonstrated that it is feasible to incorporate pulse oximetry screening into the daily routine

of midwives attending home births and that very early screening does not result in significantly high false-positive rates (0.6%).<sup>30</sup>

It is important to appreciate that New Zealand will face unique challenges when implementing a new screening practice for newborn infants. The country's dispersed rural populations will pose a variety of challenges. We have a largely midwifery-led model of maternity care with the majority of primary maternity care provided by self-employed community midwives also known as the Lead Maternity Carer (LMC). The majority of women give birth at either tertiary or secondary facilities (with their midwife LMC in attendance) and may transfer either home or to a primary maternity facility for postnatal care. Many of these transfers occur between two and six hours following the birth provided that the mother and baby are well. The proportion of home births ranges from 1.3% to 7.6% (mean 3.4%) across New Zealand's 20 district health boards, and 9% of women are giving birth in one of many primary facilities predominantly located in rural settings.<sup>9</sup> According to a ministerial report on maternal health, over a quarter of all women giving birth live in the most socioeconomically deprived areas of New Zealand.<sup>9</sup> Furthermore, New Zealand has only one cardiac intervention centre located at Starship Children's Hospital in Auckland. Lack of availability and access to specialist centres can be perceived as barriers to the implementation of a nationwide pulse oximetry screening programme. Lack of availability of echocardiography services and concerns about the potential increase in workload for midwives and paediatric cardiology services have been named as the main barriers to implementation at tertiary Australasian hospitals.<sup>21</sup>

Midwives' involvement with the care of women and their babies at birth and in the first few days after birth would place them in the ideal position to carry out the screening test. A pragmatic approach would be to incorporate screening into the midwives' routine newborn health assessments. The place of birth and time at which screening is undertaken, which will be guided by the screening protocol, will likely dictate whether hospital-based midwives or self-employed community midwives are in

the best position to perform the screening test. Several groups have investigated the time taken to perform the screening process and consistently reported that approximately five minutes are required.<sup>8,21,22,31</sup> These studies were done in various countries with differing models of care, and all reported that no extra staff members were needed to perform pulse oximetry screening.

Failure to reach predetermined oxygen saturation targets should prompt clinicians to do a careful clinical examination and should not necessarily result in an echocardiogram or referral to specialist cardiac services. Approximately two-thirds of positive screening results will yield an alternative diagnosis.<sup>6,8,21,32–36</sup> Persistent hypoxaemia can be the result of other important pathologies such as sepsis, pneumonia, pulmonary hypertension or metabolic disorders. If undetected, these pathologies may also result in death that could otherwise have been prevented. An Australian review of Sudden Unexpected Early Neonatal Death and Acute Life Threatening Events found that persistent pulmonary hypertension and infection were responsible for many of these events along with cardiac disease and accidental asphyxia. The majority of infants collapsed on the first day.<sup>37</sup> Transient hypoxaemia can be seen in newborn infants with transitional circulation. False-positive results should be minimised and therefore screening protocols should recommend repeating the test in infants with borderline low oxygen saturation levels. It is expected that 4–5% of newborns screened on day one of life will require repeat testing in order to exclude healthy infants with transitional circulation.<sup>32</sup>

The majority of hypoxaemic infants can be managed at their local hospital. Echocardiography will only be warranted in infants with signs and symptoms suggestive of cardiac disease or in infants with persistent abnormal oxygen saturation levels in the absence of a non-cardiac diagnosis. An Australian study reported only five unnecessary echocardiograms over a 42-month period, during which 18,801 infants were screened.<sup>21</sup> Similarly, a Swedish study that screened 39,821 infants

reported that three unnecessary echocardiograms, demonstrating no cardiac anomaly, were performed.<sup>8</sup>

Interventions designed to improve population health can ultimately lead to greater inequality in society. Adaptation and change often occur more rapidly among groups that already have better than average health status, and although the overall health of the population improves, the gap between the affluent and deprived widens.<sup>38</sup> Pulse oximetry screening may, however, be most valuable in populations where the antenatal detection rate of CHD is low. Implementing a national screening programme will likely have the greatest benefit to the most deprived communities of New Zealand.

To date, there have been no reports in the literature of New Zealand-specific data relating to pulse oximetry that can contribute to building a business case for the implementation of a national screening programme. Undertaking a research study exploring the feasibility of pulse oximetry screening in the New Zealand maternity setting can provide valuable information in support of national implementation. Making an assessment of local patient demographics and the impact of universal pulse oximetry screening on maternity, paediatric and cardiac services in New Zealand will be an essential step towards achieving this goal.

A uniform screening programme that is governed by the country's National Screening Unit will be superior to hospital-led initiatives. First, a screening programme should be funded sufficiently to ensure the availability of resources to all regions and services involved with the screening and subsequent care of newborn infants so screening can be offered to every baby regardless of place of birth. Secondly, central governance and monitoring of the programme will enable quality improvement initiatives, further promoting equity for all New Zealand-born infants. Thirdly, the morbidity and mortality related to congenital heart disease can be reduced when pulse oximetry screening is offered to all New Zealand-born infants.

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**Author information:**

Elza Cloete, Neonatologist and Research Fellow, Liggins Institute, University of Auckland, Auckland; Thomas L Gentles, Paediatric Cardiologist and Service Clinical Director, Green Lane Paediatric and Congenital Cardiac Service, Starship Children's Health, Auckland; Jane M Alsweiler, Neonatologist and Senior Lecturer, Department of Paediatrics: Child and Youth Health, University of Auckland, Auckland; Lesley A Dixon, Midwifery Advisor, New Zealand College of Midwives, Christchurch; Dianne R Webster, Director Newborn Metabolic Screening Programme and Lead Clinical Scientist Antenatal Screening for Down Syndrome and Other Conditions, LabPlus, Auckland City Hospital, Auckland; Deborah L Rowe, Senior Lecturer, School of Nursing, University of Auckland, Auckland; Frank H Bloomfield, Professor of Neonatology and Director, Liggins Institute, University of Auckland, Auckland.

**Corresponding author:**

Dr Elza Cloete, Liggins Institute, University of Auckland, Private Bag 92019, Auckland 1142. e.cloete@auckland.ac.nz

**URL:**

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**REFERENCES:**

- Koppel RI, Druschel CM, Carter T, et al. Effectiveness of pulse oximetry screening for congenital heart disease in asymptomatic newborns. *Pediatrics*. 2003; 111(3):451–5.
- Reich JD, Miller S, Brogdon B, et al. The use of pulse oximetry to detect congenital heart disease. *J Pediatr*. 2003; 142(3):268–72.
- Bakr AF, Habib HS. Combining pulse oximetry and clinical examination in screening for congenital heart disease. *Pediatr Cardiol*. 2005; 26(6):832–5.
- Rosati E, Chitano G, Dipaola L, et al. Indications and limitations for a neonatal pulse oximetry screening of critical congenital heart disease. *J Perinat Med*. 2005; 33(5):455–7.
- Oakley JL, Soni NB, Wilson D, Sen S. Effectiveness of pulse-oximetry in addition to routine neonatal examination in detection of congenital heart disease in asymptomatic newborns. *J Matern Fetal Neonatal Med*. 2015; 28(14):1736–9.
- Zhao QM, Ma XJ, Ge XL, et al. Pulse oximetry with clinical assessment to screen for congenital heart disease in neonates in China: a prospective study. *Lancet*. 2014; 384(9945):747–54.
- Turska Kmiec A, Borszewska Kornacka MK, Blaz W, et al. Early screening for critical congenital heart defects in asymptomatic newborns in Mazovia province: experience of the POLKARD pulse oximetry programme 2006–2008 in Poland. *Kardiol Pol*. 2012; 70(4):370–6.
- de-Wahl Granelli A, 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.
- Ministry of Health. Report on Maternity 2014. Wellington: Ministry of Health; 2015. Available from: <http://www.health.govt.nz/publication/report-maternity-2014>
- Ministry of Health. New Zealand Maternity Clinical Indicators 2014. Wellington: Ministry of Health; 2016. Available

- from: <http://www.health.govt.nz/publication/new-zealand-maternity-clinical-indicators-2014>
11. Fixler DE, Xu P, Nembhard WN, Ethen MK, Canfield MA. Age at referral and mortality from critical congenital heart disease. *Pediatrics*. 2014; 134(1):e98–105.
  12. Brown KL, Ridout DA, Hoskote A, et al. Delayed diagnosis of congenital heart disease worsens preoperative condition and outcome of surgery in neonates. *Heart*. 2006; 92(9):1298–302.
  13. Tobler D, Williams WG, Jegatheeswaran A, et al. Cardiac outcomes in young adult survivors of the arterial switch operation for transposition of the great arteries. *J Am Coll Cardiol*. 2010; 56(1):58–64.
  14. Eckersley L, Sadler L, Gentles TL, et al. Timing of diagnosis affects mortality in critical congenital heart disease. *Arch Dis Child*. 2016; 101(6):516–20.
  15. Bonnet D, Coltri A, Butera G, et al. Detection of transposition of the great arteries in fetuses reduces neonatal morbidity and mortality. *Circulation*. 1999; 99(7):916–8.
  16. Calderon J, Angeard N, Moutier S, et al. Impact of prenatal diagnosis on neurocognitive outcomes in children with transposition of the great arteries. *J Pediatr*. 2012; 161(1):94–8 e1.
  17. Ewer AK. Pulse oximetry screening: do we have enough evidence now? *Lancet*. 2014; 384(9945):725–6.
  18. Mahle WT, Martin GR, Beekman RH, 3rd, Morrow WR, Section on C, Cardiac Surgery Executive C. Endorsement of Health and Human Services recommendation for pulse oximetry screening for critical congenital heart disease. *Pediatrics*. 2012; 129(1):190–2.
  19. Narayen IC, Blom NA, Ewer AK, Vento M, Manzoni P, te Pas AB. Aspects of pulse oximetry screening for critical congenital heart defects: when, how and why? *Arch Dis Child Fetal Neonatal Ed*. 2016; 101(2):F162–7.
  20. Thangaratinam S, Brown K, Zamora J, et al. Pulse oximetry screening for critical congenital heart defects in asymptomatic newborn babies: a systematic review and meta-analysis. *Lancet*. 2012; 379(9835):2459–64.
  21. Bhola K, Kluckow M, Evans N. Post-implementation review of pulse oximetry screening of well newborns in an Australian tertiary maternity hospital. *J Paediatr Child Health*. 2014; 50(11):920–5.
  22. Kochilas LK, Lohr JL, Bruhn E, et al. Implementation of critical congenital heart disease screening in Minnesota. *Pediatrics*. 2013;132(3):e587–94.
  23. Ozalkaya E, Akdag A, Sen I, et al. Early screening for critical congenital heart defects in asymptomatic newborns in Bursa province. *J Matern Fetal Neonatal Med*. 2016; 29(7):1105–7.
  24. 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(4):F297–302.
  25. Saxena A, Mehta A, Ramakrishnan S, et al. Pulse oximetry as a screening tool for detecting major congenital heart defects in Indian newborns. *Arch Dis Child Fetal Neonatal Ed*. 2015; 100(5):F416–21.
  26. Peterson C, Grosse SD, Oster ME, et al. Cost-effectiveness of routine screening for critical congenital heart disease in US newborns. *Pediatrics*. 2013; 132(3):e595–603.
  27. Reeder MR, Kim J, Nance A, Krikov S, Feldkamp ML, Randall H, et al. Evaluating cost and resource use associated with pulse oximetry screening for critical congenital heart disease: Empiric estimates and sources of variation. *Birth Defects Res A Clin Mol Teratol*. 2015; 103(11):962–71.
  28. 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(2):v-xiii, 1–184.
  29. Tobe RG, Martin GR, Li F, Mori R. Should postnatal oximetry screening be implemented nationwide in China? A cost-effectiveness analysis in three regions with different socioeconomic status. *Int J Cardiol*. 2016; 204:45–7.
  30. Narayen IC, Blom NA, Bourgonje MS, Haak MC, Smit M, Posthumus F, et al. Pulse oximetry screening for critical congenital heart disease after home birth and early discharge. *J Pediatr*. 2016; 170:188–92 e1.
  31. Bradshaw EA, Cuzzi S, Kiernan SC, et al. Feasibility of implementing pulse oximetry screening for congenital heart disease in a community hospital. *J Perinatol*. 2012; 32(9):710–5.

32. Richmond S, Reay G, Abu Harb M. Routine pulse oximetry in the asymptomatic newborn. *Arch Dis Child Fetal Neonatal Ed.* 2002; 87(2):F83–8.
33. Meberg A, Bruggmann-Pieper S, Due R Jr, et al. First day of life pulse oximetry screening to detect congenital heart defects. *J Pediatr.* 2008; 152(6):761–5.
34. Sendelbach DM, Jackson GL, Lai SS, et al. Pulse oximetry screening at 4 hours of age to detect critical congenital heart defects. *Pediatrics.* 2008; 122(4):e815–20.
35. Riede FT, Worner C, Dahnert I, et al. Effectiveness of neonatal pulse oximetry screening for detection of critical congenital heart disease in daily clinical routine—results from a prospective multicenter study. *Eur J Pediatr.* 2010; 169(8):975–81.
36. 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(9793):785–94.
37. Lutz TL, Elliott EJ, Jeffery HE. Sudden unexplained early neonatal death or collapse: a national surveillance study. *Pediatr Res.* 2016; 80(4):493–8.
38. Smith KB, Humphreys JS, Wilson MG. Addressing the health disadvantage of rural populations: how does epidemiological evidence inform rural health policies and research? *Aust J Rural Health.* 2008; 16(2):56–66.