

Review Article

Newborn Screening for Critical Congenital Heart Disease Using Pulse Oximetry: A Quality Improvement Project Proposal

Khairy G. Gad*

Consultant paediatrician, North Cumbria NHS Trust, Carlisle, England

***Corresponding Author:** Dr. Khairy G. Gad, Consultant paediatrician, North Cumbria NHS Trust, Carlisle, England, E-mail: khairygad@gmail.com

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Abstract

Critical congenital heart disease (CCHD) is a leading cause of death in the neonatal period. It accounts for approximately one-third of the cases of mortality due to birth defects [1]. Some infants with CCHD may initially be asymptomatic and look healthy. There is an increasing body of evidence that CCHD could be missed in the first few days, therefore, resulting in increased morbidity and mortality. In the US, the CDC estimates the number of infants where the diagnosis of CCHD is delayed at 1755 cases per annum. Half of those cases would have been diagnosed earlier by Pulse Oximetry [2]. Figures from New Zealand estimate that 1 in 5 babies with undiagnosed CCHD are discharged home [3]. Routine use of pulse oximetry has been recommended recently in the UK by PECSIG to help improve the detection rates of CCHD [4]. In this project, a proposal to adopt routine Pulse Oximetry at DGH level is discussed.

Keywords: Newborn Screening; Congenital Heart Disease; Antenatal scanning

Abbreviations and definitions: AAP: American Academy of Pediatrics; CCHD: Critical congenital heart disease is a type of congenital heart disease which requires intervention or results in death in infancy; CCGs: Clinical Commissioning Groups; CDC: Centers for Disease Control and Prevention; Hypoxaemia: Low measured blood Oxygen saturations; Neonatal period: first 28 days after birth; Pulse Oximetry screening (PO): involves measuring oxygen saturations in the right hand (pre-ductal) and either foot (post-ductal) in the neonatal period; NIPE: Newborn Infant Physical Examination; NICE: The National Institute for Health and Care Excellence; NICU: Neonatal Intensive Care Unit; PECSIG: Paediatricians with Expertise in Cardiology Special Interest Group; RCPCH: The Royal College of Paediatrics and Child Health; SCBU: Special Care Baby Unit

1. Introduction

Prenatal scans helped improve the early diagnosis of congenital heart disease and subsequently lead to appropriate referrals and management of cases identified. Nevertheless, antenatal scans do not detect all the complex congenital heart disease cases and only have approximately 40% accuracy rate at best [5]. A systematic review (Pulse Ox Study) published in 2011 showed that antenatal scanning detected 50% of the CCHD cases (twelve out of twenty-four cases) [6]. Other studies showed that PO can miss some cases i.e. false negative or can infrequently be false positive [7]. PO has false positive rates of 0.14% (95% confidence interval of 0.06-0.33) [8]. A combination of prenatal scans, thorough NIPE and PO would be essential for higher detection rates.

There is a national drive to take this forward and to ensure that PO is performed before discharge from the hospital. Ewer et al reported that PO screening has 99.1% specificity and 58.3% sensitivity for the detection of CCHD [9]. They surveyed the use of pulse oximetry in the UK. The surveys showed that the number of neonatal units using PO to screen for CCHD has doubled over 4 years' period. In 2012 approximately 1 in 5 neonatal units used PO as a screening tool compared to 4 in 10 units in 2016 [10]. The surveys concluded that more units have adopted this practice over time and other units are considering as a tool to screen for CCHD [10].

AAP has published recommendations for the use of PO as a screening tool for CCHD [11]. The procedure is painless, safe and simple to undertake, nevertheless, parents need to be explained and an informed consent should be obtained. Parents also should be explained what happens if the screen is failed (positive) i.e. results are abnormal. A pilot of newborn PO screening is recommended by the National Screening Committee in the UK [12]. In the United States, the reported cost of neonatal PO is around \$14 /case [13].

Local policies for screening should be developed detailing indications and contraindications for screening and the age at which the PO screen is undertaken. This should be based on regional and national evidence based-guidance. Clear policies for obtaining parental informed consent should be available.

2. Proposal

To introduce PO screening for newborn infants as a routine practice before discharge from postnatal wards or SCBU. In addition, there is currently a plan to further train echocardiography technicians to perform paediatric heart scans (echocardiograms) at both hospital sites in the trust rather than one hospital site. This will take place at a planned monthly visiting paediatric cardiology consultant clinic.

3. Objectives

1. To improve the quality of newborn infant care.
2. Introduction of pulse oximetry (PO) as part of the routine NIPE to improve the outcomes of CCHD cases.
3. Develop a local care pathway for PO screening based on national and regional recommendations.
4. Collaborate with maternity to develop local policies for newborn screening using pulse oximetry

5. To collaborate with regional NICU, Northern Neonatal Network and regional paediatric and neonatal cardiology network.

4. Proposal Action Plan

1. The opinions of parents, paediatricians, neonatal nursing staff, midwifery and obstetric colleagues will be sought out via the maternity governance group or joint meetings with maternity platforms.
2. Draft a written guidance on newborn PO screening using up to date published evidence, national and international research findings.
3. Develop a toolkit for neonatal PO screening
4. Develop a business case for routine PO screening. This will involve working with the operational service manager on a business case to analyse anticipated costs and benefits. Potential costs will include the cost of training staff and costs of additional equipment.
5. Parents' views and consent will be required for such screening. A parent information leaflets to explain the screening process and further necessary actions/referrals if the result is abnormal.
6. Liaise with tertiary paediatric cardiologists on developing an algorithm for referrals or discussion of cases who have a positive screen.
7. Utilise ongoing staff feedback and collaborate with maternity services on drawing plans for PO screening.
8. Infants requiring an echocardiogram will have it performed locally by technicians and the images could be linked using telemedicine for review by paediatric cardiologists.
9. Training of midwifery and SCBU staff to undertake the test, interpret and act on the results

5. Parental/Service User Involvement

Close liaison with the families to develop this service would be essential. Parents' views are to be sought out ideally during antenatal visits. A consent form is to be developed explaining the pros and cons of using PO as a screening tool for CCHD. If parents were to deny consent, a meeting to see a paediatrician would be arranged and if consent is still denied, this has to be clearly documented in the maternal case notes. This information will have to be shared with SCBU and paediatric teams. Service user representation is essential at both national and regional level when screening policies are developed. Written information leaflets should explain what the PO screening entails.

6. Potential Benefits to the Service Users

1. Early identification of potential cases of CCHD
2. Reduction of morbidity and mortality
3. Reduction of unnecessary travel to tertiary centres for echocardiography scan
4. Timely management and transfer to specialist services

7. Potential Benefits to the Service Provider

1. Improved clinical governance through reducing harm to patients
2. Improved staff training through attendance of visiting tertiary paediatric cardiologist clinics

3. Improved service user's experience
4. Improved staff morale by avoidance of near misses or delayed diagnosis of CCHD. Such late diagnosis may result in long-term sequelae or even death.

8. Challenges and Proposed Solutions

1. A proportion of infants are delivered at home or discharged home early. These are usually low- risk deliveries and the NIPE is performed later after discharge by the community midwives or the GP. Clear pathways for screening these infants in the community will be required.
2. Cost implications: the cost of PO machines, reusable probes, disinfectants etc should be included in the cost-effectiveness analysis as well as staff time, training of staff etc.
3. There are significant inconsistencies of existing screening policies and a national policy e.g. RCPCH or NICE is required.
4. Funding for the screening: Would it be from the CCGs or Public Health England as the latter is concerned with screening programmes? This remains to be debated at local, regional and national levels. Funding is probably the biggest barrier esp. with limited resources available for the NHS.
5. Staffing: Trained midwifery or neonatal nursing staff could do the PO screening. Alternatively a dedicated trained team could do the PO screen and refer as appropriate if the screen is positive i.e. abnormal.

9. Retrospective Audit

A retrospective audit of infants diagnosed with congenital heart disease including CCHD in the preceding year before the proposal will be carried out. Aims of the audit are to identify the number of infants diagnosed with congenital heart disease in infancy where prenatal scans and routine NIPE were reported as normal. Identify cases discharged home then readmitted with significant or critical heart disease. Audit of the process: referral pathways, patients required urgent transfer for a paediatric cardiology review and/or an echocardiogram. Audit of the outcomes: any intervention required the length of hospital stay and associated morbidity or mortality if any. Parent/carer's survey could be designed as a questionnaire to explore the service user views both pre and postnatally.

10. Evaluation

We will aim to pilot the newborn PO screening for 6 months as a tool to screen for CCHD as per the National Screening Committee recommendations. A prospective audit will be undertaken to evaluate the perceived benefits and barriers encountered. Cases identified on PO screening where prenatal scans and routine NIPE were normal would indicate the potential benefits of screening. In the long-term regional or national data collected would be more representative as the local numbers may not be large enough. False positive, false negative, missed or declined screens will also be identified. Collaboration with community midwives and GPs would be essential to identify missed screens. The audit would identify cases where local policy was not followed. Service users will have to be part of the whole process, ensuring adequate representation on guidance developed at local level. The community midwives, SCBU and the obstetric teams would be able to explore service users' wishes. At the regional level

representation from BLISS may help to convey parental views. Caldicott guardians input would be required if data are to be collected at regional or national level.

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