Planning and implementation of a pulse oximetry screening programme

Pulse oximetry fulfils the acceptance criteria for universal screening for detection of critical congenital heart defects and is currently being piloted by the UK National Screening Committee for feasibility and impact on resources. Establishing a quality improvement programme presents many challenges and in this article the authors present their suggestions for success and lessons learnt from planning and implementing a pulse oximetry screening programme.

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Key points

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1. The addition of pulse oximetry screening to existing fetal anomaly screening ultrasound and physical examination of the newborn, may increase detection rates for CCHD to over 90%.
2. A structured programme for planning, implementation and surveillance is the key to success and should involve all stakeholders and the multidisciplinary team.

Background

Congenital heart defects are the most common type of congenital anomalies with an incidence of 8-9 per 1,000 live births. The estimated incidence of ductal-dependent critical congenital heart defects (CCHD) is between two and three per 1,000 live births. CCHD are defined as congenital heart conditions that require invasive intervention within 28 days of life or lead to death. The current screening tools for detection of CCHD are fetal anomaly screening ultrasound at 18-20 weeks of gestation and routine examination of the newborn infant. Both have a relatively low detection rate and it is estimated that up to a third of infants may be discharged with an undiagnosed CCHD, which carries a high risk of death or poor outcome.[1-4] Early detection of CCHD reduces the risk of acute cardiovascular collapse, acidosis and death, and improves outcome.

Pulse oximetry as a screening tool for CCHD

The concept of using pulse oximetry as a screening tool to detect undiagnosed CCHD in asymptomatic newborn infants was first explored almost two decades ago. Since then it has been extensively evaluated in many well-designed studies and randomised controlled trials involving over 230,000 infants.[1,5-8] Pulse oximetry is a simple, well-established, accurate, non-invasive test for objective quantification of hypoxaemia that is often clinically undetectable in asymptomatic infants but present to some degree in most cases of CCHD. A systematic review and meta-analysis published in 2012 reported that pulse oximetry screening has a high specificity, moderate sensitivity and a low false positive rate.[1] This meta-analysis identified 13 studies of over a quarter of a million infants, investigating the use of pulse oximetry screening in detection of CCHD. The overall sensitivity for pulse oximetry screening was 76.5%, the specificity 99.9%, and the false positive rate 0.14%. This review concluded that pulse oximetry meets the criteria for universal screening for detection of CCHD.[1]

Other studies have established its cost-effectiveness, acceptability to parents and staff, and feasibility of implementing screening outside the research context.[9-12]

In addition, the detection of non-critical congenital heart defects and significant non-cardiac conditions such as respiratory problems or early-onset sepsis (**TABLE 1**) is reported as an additional benefit of pulse oximetry screening when performed early.[1,3,5-6,13] These clinically important conditions contribute to up to two thirds of the reported false positive group, which reduces the clinically non-significant false positivity by half. The non-cardiac conditions that are clinically undetectable but identified through pulse oximetry screening could be a result of low oxygen

Sepsis
Pneumonia
Persistent pulmonary hypertension of the newborn (PPHN)
Pneumothorax

TABLE 1 Non-cardiac conditions that can be detected with pulse oximetry screening.

Detection likely	Detection less likely
Dextro-transposition of the great arteries (d-TGA)	Coarctation of the aorta
Hypoplastic left heart syndrome	Interrupted aortic arch
Pulmonary atresia (with intact septum)	Mild Ebstein anomaly
Tetralogy of Fallot	Double-outlet right ventricle
Total anomalous pulmonary venous return	Single ventricle
Tricuspid atresia	Pink tetralogy of Fallot
Truncus arteriosus	

TABLE 2 The likelihood of critical congenital heart defect detection by pulse oximetry screening.

saturation from an underlying pathological condition or delay in adaptation to neonatal circulation, leading to hypoxaemia.

It is important to note that not all CCHD are detected with pulse oximetry screening (**TABLE 2**). However, the addition of pulse oximetry to existing screening tools may increase detection rates for CCHD to over 90%.[1-2]

Planning and implementation of a pulse oximetry screening programme

Research studies provide compelling evidence for the introduction of pulse oximetry screening into routine clinical practice.[1,14] Although pulse oximetry screening has been reported as fulfilling the criteria for universal screening, careful consideration should be given to various aspects of implementation to make the quality improvement programme successful.

Like many other quality improvement programmes, a pulse oximetry screening programme has its own challenges. The authors' team at Cambridge University Hospitals adopted a structured approach involving a multidisciplinary team with a programme leader, a midwifery lead for practice development and educators for cascading the training for midwives, maternity support workers and neonatal medical staff. A guideline was developed along with a parent information leaflet and a competency document for the staff performing the pulse oximetry screening. The information was disseminated via email and posters in the clinical areas before the launch in January 2014. There is an active clinical audit programme to review clinical practice regularly. The lessons learnt are reflected in a change in practice. The following ten steps programme (as summarised in **TABLE 3**) should be helpful for any other organisations considering establishing a pulse oximetry screening programme.

1. Multidisciplinary team input

The planning process should involve a multidisciplinary team comprising a neonatologist/paediatrician, managers, midwives, midwifery support workers, community midwives, neonatal nurses and ancillary staff. There should be a designated programme leader and coordinator to facilitate planning and implementation of the screening programme. All stakeholders should be involved in multiple planning sessions to facilitate brainstorming, education, communication and decision making.

2. Pulse oximetry screening guideline

A clear, comprehensive and concise evidence-based guideline with a visual flow diagram should be developed, including guidance on documentation, reporting and making decisions about normal and abnormal results. This would be slightly different for home births in comparison to hospital births. The pathway for the management of infants requiring further evaluation should be clear to avoid any ambiguity or confusion.

The guideline should identify the necessary action in cases where the opportunity to offer the screening test is missed. It should be made clear who would take responsibility for ensuring that the infant is swiftly followed up.

3. Timing of screening

Timing of screening in the reported studies has varied, with an average time ranging from four to 38 hours. There is no doubt that later screening (>24 hours) has a lower rate of false positive results than earlier screening (<24 hours). This has been a consistent finding in most of the published reviews, although a recent Polish study screening infants at an average age of seven hours reported one of the lowest false positive rates.[5]

It is worth considering the timing of screening carefully as most of the non-cardiac conditions are more likely to present in the first 24 hours and early identification of these problems may reduce morbidity and mortality. Nevertheless a high false positive rate could potentially impact on clinical services,

1. Establish a multidisciplinary team and designate a leader and coordinator to facilitate planning and implementation of the programme.
2. Develop an evidence-based guideline with a visual flow diagram. Include documentation for reporting and decision-making for normal and abnormal results. Develop a clear pathway for management of infants requiring further evaluation.
3. Consider the timing of screening carefully.
4. Post-ductal or pre- and post-ductal saturation measurement?
5. Decide who will perform the pulse oximetry screening (eg midwifery staff, midwifery support workers, paediatric doctors, etc).
6. Choose the right equipment: a pulse oximeter with motion-resistance and approved for use in neonates, preferably with documented accuracy and reliability.
7. Staff training and support: establish a mechanism for robust staff training with competency achievement documentation and ongoing support.
8. Develop a parent information leaflet about the practical aspects of testing, the benefits and limitations and the option to decline screening.
9. Schedule multiple planning sessions to facilitate brainstorming, education, communication and decision making. Regular communication is essential: provide feedback to all staff members on uptake, any identified cases, any missed cases, etc.
10. Establish robust plans for audit and surveillance of the programme results and outcomes.

TABLE 3 A structured programme for the planning and implementation of pulse oximetry screening.

hence the need to strike a balance between timely diagnosis of life-threatening conditions and an excess of false positives. It is noteworthy that half of reported false positive cases have non-cardiac conditions leading to hypoxaemia; no infant should have persistent unexplained hypoxemia.

Home births may have to be considered separately.[15] For example, an early screening between four and eight hours has the benefit of timely detection of CCHD and other potentially life threatening non-cardiac conditions but may not be feasible for all home births; in many instances the midwifery staff will have left before four hours post birth. Given the relatively low number of babies born at home, perhaps it is worth examining screening at two hours of age (prior to staff leaving the home).

Also relevant is the momentum within an institution regarding discharging mothers and their infants. A lengthy stay on the premise that pulse oximetry needs to be performed may lead to bed blocking and a likely increase in overall cost.

4. Post-ductal or pre- and post-ductal saturation measurement?

In the 2012 meta-analysis, more than half of the studies (60%) used post-ductal measurements alone.[1] There was no difference in sensitivity between post-ductal testing alone and combined pre- and post-ductal testing. However, two of the recent large studies using pre-ductal and post-ductal testing reported that a small proportion of infants with CCHD (three babies in one study and one in another) would have been missed if post-ductal testing alone had been used.[1-3] In Cambridge, both pre- and post-ductal oxygen saturation levels are measured between four and eight hours for hospital births, and at two hours for home births.

5. Who should perform pulse oximetry screening?

This decision should be made early on in the planning process for hospital and community births. It may vary between and within organisations. Pulse oximetry screening could be performed by the midwifery staff (midwives or midwifery support workers) or by neonatal or paediatric doctors who perform routine examinations of the newborn. Other screening staff (eg those performing hearing screening) could be an option. Benefits and limitations, cost implications, impact on staff resources and training should be carefully considered. The authors found that screening by midwifery support workers supported by midwives was the best way forward, especially when aiming to implement early pulse oximetry screening within four and eight hours of birth.

6. Equipment

Ensure that the equipment is fit for purpose. Equipment for pulse oximetry screening should be approved for use in neonates with a motion-resistant ability, ideally with documented accuracy and reliability. New generation pulse oximeters have improved motion-resistance and faster signal detection making them suitable for infants who often move during screening. Equipment should be easily cleanable with products readily available to avoid any unnecessary additional cost.

7. Staff training and support

Staff training is critical. All staff performing the test should be able to demonstrate proficiency in undertaking pulse oximetry screening including knowledge of a screening guideline. Completion of defined competencies prior to participation might also be recognised through a certificate of achievement of competency. Booster sessions could be offered regularly to provide an opportunity to re-educate staff and answer any questions that may have arisen during practice.

Initial training could be given to key personnel who can then help in cascading to all staff. The medical representative from the company supplying the pulse oximeters should be involved in the training sessions. It would be useful to identify a key person during the introduction phase to act as a 'champion', offering support with equipment, training, education resources, etc.

8. Parent/carer information leaflet

Verbal consent from parents should be taken before performing pulse oximetry. A parent information leaflet describing the procedure, its benefits and limitations should be developed and given to all parents. Clear documentation regarding the discussion and information provided should be recorded for those parents who decline pulse oximetry screening.

9. Communication

Like any other quality improvement programme in neonatal medicine, regular communication is essential, not only with the key personnel involved in planning and implementation but also with all multidisciplinary team members involved in the process. Regular feedback is the key; all staff members involved in pulse oximetry screening should receive updates on the uptake of screening and any cases identified on screening (both cardiac and non-cardiac). Feedback on any missed cases of a congenital heart defect is equally important for shared learning.

Communicating the importance and benefit of such a tool should improve 'buy in' from healthcare professionals. Frequent updates regarding the success of the intervention should motivate staff to robustly support its use.

10. Audit and surveillance

A rigorous clinical audit and surveillance programme should be agreed as part of the planning process. It is necessary to ensure that screening is offered to all eligible infants and that the organisational guideline is being followed. The following points should be considered:

- Uptake of pulse oximetry screening
- True positive and false positive cases
- Outcome of positive cases
- Impact on echocardiography and cardiology services
- Missed opportunities for pulse oximetry screening and the subsequent actions taken.

Conclusions

Pulse oximetry screening is increasingly endorsed by a large number of professional bodies and national institutions and currently being piloted by the UK National Screening Committee for its feasibility as a universal screening tool. The key to success for this quality improvement programme is careful planning and implementation. Involvement from the multidisciplinary team who will undertake the screening, effective communication, a concise guideline with a clear pathway, robust staff training and mechanisms for regular surveillance will help ensure success.

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