NHS

Screening Programmes

Newborn and Infant Physical Examination

Pulse Oximeter Specification

	Author	Date published
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Background

Following publication of an HTA report on newborn pulse oximetry screening in 2012 a UK National Screening Committee (UK NSC) review was undertaken. The NIPE Programme commissioned work on the cost effectiveness of adding pulse oximetry to the screening pathway for the detection of critical congenital heart defects (CCHD).

Public consultation took place between September/ December 2013 and the evidence presented to the UK NSC in March 2014.

The review concluded that there was value in using pulse oximetry for the detection of CCHD as an adjunct to the existing newborn screening programmes for CHD (newborn and infant physical examination and antenatal fetal anomaly ultrasound screening) and found it to be cost effective.

Decision made by the UK NSC to undertake an 18 month pilot project for pulse oximetry screening in the newborn.

Decision ratified by ministers in May 2014.

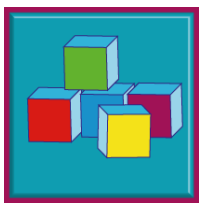
Aim

The aim of the pilot is to evaluate the impact of implementing newborn pulse oximetry screening on NHS services and to establish feasibility for future national roll out as an addition to the existing suite of screening tests undertaken as part of the newborn NIPE examination (<72 hrs).

Pilot Methodology

Newborn pulse oximetry screening is already in place in a number of Trusts across England but there is currently no national guidance or standards in place to support practice. Local pathways have been developed and outcomes of newborn pulse oximetry screening are not collated at national level.

The Project Board therefore considered that, as part of the pilot and introduction of newborn pulse oximetry as a new screening test, it is important to understand existing practice in a representative number of Trusts already undertaking newborn pulse oximetry screening.



The pilot will therefore be conducted in two phases collating data from two distinct groups.

Phase one will:

- Undertake baseline assessment and data collection in selected Trusts already undertaking newborn pulse oximetry to assess the current service provision (group A).

- Undertake baseline assessment and data collection in selected Trusts who have expressed an interest in implementing newborn pulse oximetry screening as part of the pilot project (group B).

Phase two will:

- introduce or assure the agreed national screening pathway in those Trusts already undertaking newborn pulse oximetry and collect data to record impact of any change (group A)

- introduce pulse oximetry screening as a new element of the NIPE examination in selected pilot Trusts and collect data to record impact of any change (Group B)

Data collected in phase 2 will therefore offer information on the impact of change in introducing the new screening test and those who are aligning to the national protocol

In line with the pilot project methodology there will be a requirement for additional more detailed local data collection, in particular for screen positive cases and those babies who are admitted to neonatal units or readmitted to hospital with a suspected CCHD. The exact data set for this is under development.

Funding

Central funding (via the NIPE Programme) to support local data collection will be available. In addition, it will be available for pilot trusts to procure equipment (pulse oximeters) in agreement with the NIPE programme and to the defined standard specification.

General description.

The equipment must be suitable for use on newborn babies at the cot-side or in the home. It should be stand-alone (not multi-parameter) and hand held.

Scope

This specification is for pulse oximeters to be used in the NIPE Pilot for 10 months starting in May 2015. Winning the contract for the pilot does not guarantee those a place on the contract for the full national rollout.

Price and price variation

Commitment Price - Prices are dependent on the total quantity of units committed to during a mutually agreed period, between the NIPE Programme/NHS Trust/NHS Logistics/Health Authority and the , not exceeding XX months, and shall be applicable for any combination of units detailed on a single purchase order. The NHS NIPE/NHS Trust/NHS Logistics/Health Authority should submit detailed ordering schedules, including full delivery address and named contact person to the at the time of ordering.

Quantity bandings.

The number of pulse oximeters that will be needed for the pilot is 131.

Delivery

Suppliers are required to detail their delivery timescales for all products offered, including calibration and repairs, in working days from receipt of order. Suppliers should stipulate whether this lead time would increase for large orders.

Warranty period

Suppliers are required to state the warranty period for each product offered. A minimum period of twelve months warranty, inclusive of parts and labour is expected. Suppliers should provide details of their policy regarding replacement of a product under the standard warranty period, for example, new for old, loan equipment provided whilst faulty product is repaired, etc.
Suppliers may also submit prices for extensions to the warranty period .
Warranties are to commence when equipment is delivered and full details of serial number and despatch date forwarded to the NHS NIPE Programme.

Service and Maintenance

This contract is not for the on-going service and maintenance of the equipment offered, however Suppliers are required to detail the service and maintenance requirements for each piece of equipment offered.
Suppliers should state whether there is any service and maintenance provision for the equipment whilst it is under manufacturer's warranty.
Suppliers are also required to state the manufacturers recommendation for frequency of calibration and the standards to which equipment should be calibrated.
Suppliers should detail their policy and procedure to be followed by NHS Trusts with regard to equipment which fails during the warranty period and for equipment which fails outside of the warranty period.
Suppliers are required to state whether service and maintenance information is available to provide sufficient calibration information to NHS trusts who wish to undertake calibration and service and maintenance 'in-house'.

Training

The pulse oximeter device training must be provided by the manufacturer. The device training must be delivered to all identified trusts within the specified time.
A competency checklist for the device should be available for use by trusts to assess staff competency in the use of the device. Any additional training and educational resources for the device should be made available.

CE marking

All products, including software, must be CE marked under the Medical Devices Directive. Evidence of which level and how certification was achieved must be provided. Contractors must provide details of the notified body with whom they are registered. Software must comply with DSCN 14/2009Patient Safety Risk Management System-Manufacture of Health Software as well as DSCN 18/2009 Patient Safety Risk Management System-Deployment and use of Health Software.

Environmental

Equipment must be suitable for use within NHS e.g. be resilient to hygiene procedures and be suitable for use at the cot-side or in the home. It must comply with IT configurations used in the NHS e.g. Windows and Internet explorer versions and operate within NHS Information Governance constraints The Suppliers will comply with all obligations imposed on them by the Waste Electrical and Electronic Equipment Regulations 2013 in relation to products that are subject of the contract.

Product history

Suppliers should detail the product history up to the current issue / revision level, in terms of detail of upgrade, from when equipment was launched. History must be relevant to the neonatal population.

Provision of spare/maintenance

Calibration and repairs must be carried out promptly, minimising screening down time. Suppliers must state the time frame for replacement of parts, for repairs and calibration whether they be carried out on site or require a return to the factory. Costs for the various options must be stated.
Suppliers are required to guarantee the supply of spare parts and the provision of maintenance and repair services for minimally five years from the expiry of this agreement or the withdrawal from sale.

Product Literature

Suppliers are required to submit a user manual and technical manual, in English, for each item of equipment offered and must accompany this offer. The user manual must include the manufactures recommended hygiene control procedures.

Technical specification

The following gives a framework of essential and desirable features/functions of the equipment to be used. The desirable features will be considered during the evaluation / award process on a value for money basis.

Where contractors are asked to provide test results that "can be independently verified" these may take the form of peer review articles in journals, independent reports carried out on the contractor's behalf or summary data that the company submits for inspection by the designated evaluation team.

All articles, test results and data should explicitly describe the protocol used to achieve the results and the name(s) of the person(s) who can be contacted to verify the protocol used. If the journal articles do not include sufficient information on protocol, then an additional submission detailing the protocol should accompany the article.

We appreciate that for many screening devices 'desirable features' are a luxury or indeed an encumbrance in some instances. However, in this section, part of what we wish to explore is the flexibility that the offered equipment has to respond to future changes in protocol that may be deemed desirable or beneficial in the light of experience and research evidence.

Product compliance

Essential

E1 Must be suitable for use on neonates including those with low perfusion states

E2 Must be motion tolerant

E3 Hand held pulse oximeter device that displays the record results and is intended to be held in the hand in normal use. Probes are connected to the unit via a cable.

E4 Accuracy of SpO_2 must comply with standard BS EN ISO 99199:2009. It states that SpO_2 must be less than ±4% over the range of 70% to 100%. To demonstrate compliance evidence from population specific neonatal clinical trials and comparison with SaO_2 must be provided.

E5 Accuracy of pulse or heart rate must comply with standard BS EN ISO 99199:2009. It states that accuracy should be supported by evidence of comparison with a reference method of measuring heart rate e.g. electronic pulse simulator of ECG heart rate specific to the neonatal population.

E6 Display must be visible in low and artificial light conditions which would be expected on maternity wards or in NICUs.

E7 Must have removable, rechargeable batteries so that it can be used at the cot-side or in the home and have sufficient capacity for use throughout typical working day.

E8 Sensors should be re-usable and resilient to frequent cleaning.

E9 A suitable carry case must be provided for safe transportation of the equipment between clinical situations and community.

Desirable

D1 Methods and products recommended for the securement of the sensor to babies' limbs must be cost effective to encourage best practice with is one use only. The options must be described.

Participating trusts

1. Brighton & Sussex University Hospitals NHS Trust
2. East Cheshire NHS Trust
3. Hull & East Yorkshire Hospitals NHS Trust
4. Liverpool Women's NHS Foundation Trust
5. United Lincolnshire Hospitals NHS Trust
6. University Hospitals of Leicester
7. Wye valley NHS Trust
8. York Teaching Hospital NHS Foundation Trust