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The European Pulse Oximetry Screening Workgroup

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Pulse oximetry screening for critical congenital heart defects: a European consensus statement

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Life-threatening critical congenital heart defects (CCHD), which require intervention in the first few weeks of life, occur in about 2 per 1000 livebirths and are an important cause of neonatal mortality and morbidity.[1-3] Surgical and catheter interventions now provide excellent results for most CCHD but timely detection is essential for optimal outcomes.[3] Current newborn screening strategies, such as antenatal ultrasound and postnatal examination, fail to detect up to one third of infants with CCHD before discharge from the place of birth and many of these will either collapse or die prior to diagnosis.[1-3]

Pulse oximetry screening (POS) has been shown to improve early detection of babies with CCHD by identifying those with low oxygen saturations.[1-7] POS is simple, quick and painless with a consistent test accuracy which increases detection of CCHD.[1-3] In addition POS has been shown to be cost-effective and acceptable to both staff and parents for screening.[3]

In the USA, POS for CCHD was added to the recommended uniform screening panel in 2011.[8] In Europe, POS has been adopted by an increasing number of hospitals and pilot studies are currently underway in several countries;[9] but to-date, only a few (including Poland, Ireland and Switzerland) have issued national guidelines recommending universal screening.[2]

In order to implement strategies to address these gaps, neonatologists, experts in CCHD screening and representatives from major European scientific paediatric societies came together to create this European recommendation. *Full details of the membership and methodology leading to this consensus statement can be found at http://*

POS is based on the concept that the majority of babies with CCHD have lower oxygen saturations and this was first described over 20 years ago. However, initial small studies were too imprecise to establish test accuracy.[1-3]

Between 2008 and 2014 several large well designed studies, mainly from Europe[3-5] but also from China,[6] consistently demonstrated that POS was a highly specific, moderately sensitive test which met the criteria for universal screening.

All studies showed that addition of POS (with new generation 'motion tolerant' software) to existing screening methods (i.e. antenatal ultrasound and newborn examination) increased the overall detection rate to between 90 and 96% irrespective of the detection rates of the other screening

methods.[2,7] Most studies also reported that important non-cardiac conditions, such as respiratory and infective disorders and pulmonary hypertension, were also identified as well as the target conditions which may be an important additional benefit of POS.[4,5,7,10]

There is some heterogeneity of screening algorithms adopted in the published studies.[4-7, 10,11] These differences can be broadly categorised as follows: i) timing of initial screening; ii) use of single or dual sites for measuring saturations (post-ductal only or pre and post-ductal); iii) cut-off saturation values for a positive test. *A full review of the evidence considered by the group can be found at http://*

Earlier screening (i.e. within 24 hours of birth) is associated with a higher false positive (FP) rate than screening after 24 hours.[2,7,11] However, up to 50% of babies with CCHD may present with symptoms (including cardiovascular collapse) before 24 hours of age; the same may be true for the non-cardiac conditions identified by POS.[2] In addition, many countries discharge mother and baby from hospital before 24 hours making later screening impracticable.[2] The group gave careful consideration to the concept of achieving a timely diagnosis even if this was at the expense of a slightly higher false positive rate.[11] *Full details can be found at http://*

When evaluating different screening algorithms it is important to consider sensitivity, specificity, FP and false negative rate. It is also vital that screening results in timely diagnosis – i.e. before presentation with acute collapse.[11] Most PO screening studies report high specificities of >99% and FP rates <1% which means that most healthy babies will test negative; however when considering national screening programmes a higher FP rate may involve a considerable number of babies.[7,11] This requires careful consideration in order to achieve a balance, both in clinical and economic terms, between test sensitivity and FPs. The issue of detection of non-cardiac diagnoses makes this more complex although this is generally seen as a potential advantage to screening by clinicians.[10,11]

In order for a screening test to work in practice it has to be acceptable to the group agreeing to the screening (in this case the parents of babies) and to the clinical staff who have to perform the test and manage the consequences of the result. The large numbers of babies recruited into studies suggests this is acceptable, but a formal assessment of acceptability to parents and staff was undertaken as part of the UK PulseOx study.[3,5] In addition to assessing acceptability, the anxiety created by the test - particularly in mothers of FP babies - was reported.[3] Satisfaction with, and perceptions of, the test and anxiety and depression following screening were quantified using

validated questionnaires on samples of mothers whose babies were true positive, FP and true negative. All participants were predominantly satisfied with screening and there was no significant difference in anxiety in mothers of FPs compared with true negatives.[3] Staff perceptions of testing were also assessed by focus groups and questionnaires and POS was widely regarded as worthwhile and effective across all staff groups.[3]

Almost all the previous studies screened babies in well baby nurseries in a hospital setting.[1] Consideration of screening in other settings such as babies born out of hospital and those admitted to NICU is also important.[1]

With regard to PO screening, homebirths are different from hospital births as the midwife usually leaves the mother and baby after 2 hours. This means screening would either have to be performed very early or delayed until the following day. Studies from the Netherlands and the UK both demonstrate that screening at 2 hours in homebirths is feasible and although the test positive rate is slightly higher, it was reported as clinically acceptable.[1]

The situation in the NICU is different; babies are usually admitted because they are unwell and/or premature and this may affect oxygen saturations. Additionally, NICU babies usually undergo continuously PO monitoring. The majority of published screening studies excluded babies admitted to the NICU for these reasons; however if national screening programmes are to include all babies then it is important to consider whom, how and when to screen. The best approach has yet to be determined.

In all published studies, babies who tested positive had a diagnostic echocardiogram to establish any CHD and to define test accuracy. This has led to the assumption that during routine screening all test positives need an urgent echocardiogram. This is not unreasonable as the consequences of missing a CCHD are potentially disastrous. However, it is clear from many reports that the majority of false positives (FPs) have an alternative non-cardiac condition determining the test positivity i.e. a secondary condition that requires medical attention and prompt management.[10,11] As a significant proportion of these FPs have a respiratory or infective problem, it may often be that the correct diagnosis is made following blood tests or radiographs prior to performing echocardiography and echocardiography may be limited to those babies in whom the diagnosis is unclear.[10,11]

The recommendations of our international workgroup which included clinicians from 11 countries, CCHD POS experts and senior representatives of major European Paediatric, Neonatal and Perinatal Scientific Societies (EAPM, ESPR, EPA-UNEPSA, and UENPS [see below for details]) are shown in Figure 1.

We have tried to create common, shared, reasonable scientific recommendations for using POS for early detection of CCHD in Europe. We believe that we have created an evidence-based, and importantly, flexible framework for adoption, implementation and standardisation of CCHD screening with PO practices across Europe. These recommendations should be considered at a national level across Europe, providing an additional tool better to identify these potentially life-threatening conditions.

Societies represented: European Association of Perinatal Medicine (EAPM) – Umberto Simeoni (President) and Luc J.I. Zimmermann (council member)
European Society for Pediatric Research (ESPR) – Luc J.I. Zimmermann (President) and Daniele De Luca (Council member)
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Figure 1. Recommendations of the European pulse oximetry screening workgroup

1. Pulse oximetry screening should be recommended for all European countries.
2. Pulse oximetry screening should be performed using new generation equipment that is motion tolerant.
3. Screening should occur after 6 hours of life or before discharge (preferably before 24 hours of life) from the birthing centre.
4. Screening should be performed in two extremities; the right hand and either foot.
5. Each European country should consider pros and cons of the Nordic and UK protocols and adopt which best suits their population.