

REGULAR ARTICLE

Nordic pulse oximetry screening – implementation status and proposal for uniform guidelines

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Keywords

Congenital heart disease, Guidelines, Newborn screening, Pulse oximetry

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Received

28 February 2014; revised 13 July 2013; accepted 21 July 2014.

DOI:10.1111/apa.12758

The copyright line for this article was changed on 7 May 2015 after original online publication.

ABSTRACT**Aim:** Pulse oximetry screening of newborn infants increases early detection of critical congenital heart disease and minimises the risk of circulatory collapse before surgery. This study provides an update on the implementation of pulse oximetry screening in the Nordic countries and proposes standardised guidelines.**Methods:** A questionnaire exploring pulse oximetry screening, clinical examination routines and availability of echocardiography was distributed to all 157 delivery units in the Nordic countries in June 2013.**Results:** We received responses from 156 of the 157 delivery units, and 116 (74%) were using pulse oximetry screening by September 2013. Preductal and postductal screening were both used in 59 of 116 units (51%), with just postductal screening in 51 of 116 (44%) and just preductal screening alone in 6 of 116 (5%). Screening was performed before 24 h in 105 of 116 units (91%). The implementation of screening was highest in Finland (29/30, 97%), Sweden (42/46, 91%) and Norway (43/48, 90%) and lowest in Denmark (2/24, 8%) and Iceland (0/8 units).**Conclusion:** In Sweden, Norway and Finland, the implementation of pulse oximetry screening is currently the highest in the world and coverage will be close to 100% in 2014. We propose uniform Nordic guidelines using preductal and postductal screening before 24 h of age.**INTRODUCTION**

If newborns with critical congenital heart defects (CCHD) are left untreated, they will develop circulatory collapse and die, usually within a few days or weeks after birth. Although foetal heart screening has the potential to detect a substantial proportion of such defects, the majority of cases of CCHD are still left for postnatal diagnosis in large populations (1–3). Because symptoms and signs may be subtle or lacking, CCHD may be missed in the routine clinical examination of newborns (4,5). Subnormal arterial oxygen saturation, which is present in most cases of CCHD, is often clinically undetectable (6).

In a Swedish study, 26% of newborns with CCHD were discharged without a diagnosis (5). A UK study reported that one-third of infants with potentially life-threatening cardiac defects were discharged home with the disease undetected and 5% of them died before receiving a diagnosis (7). The trend towards earlier discharge after birth may increase the risk of this happening (5). A recent U.S. study estimated that 30% of newborns with CCHD had

a late diagnosis and would have benefitted from CCHD screening (8).

Large prospective, population-based multicentre studies from Norway (9), Sweden (1), Germany (10), the United Kingdom (11) and Poland (12) have confirmed the test accuracy of universal pulse oximetry screening. In 2012, a large meta-analysis of 13 high-quality studies comprising nearly 230 000 infants came to the same conclusion (13).

Key notes

- Pulse oximetry screening of newborn infants increases early detection of critical congenital heart disease and minimises the risk of circulatory collapse before surgery.
- In Sweden, Norway and Finland, the implementation of pulse oximetry screening is currently the highest in the world and coverage will be close to 100% in 2014.
- We propose uniform Nordic guidelines using preductal and postductal screening before 24 h of age.

The most recent contribution to the evidence is also the largest. A Chinese multicentre study screened 122 738 newborns, confirming the significant improvement in the detection of CCHD by adding pulse oximetry screening and proving that this also works in a developing country (14).

In the United States, the Secretary of Health and Human Services recommended pulse oximetry screening of all newborns in 2011 (15). The strategy for implementing screening, endorsed by the American College of Cardiology Foundation, the American Heart Association and the American Academy of Paediatrics, was that screening should be:

- 1 performed using motion-tolerant oximeters cleared by the Food and Drug Administration for reporting functional oxygen saturation;
- 2 based on the Swedish screening algorithm (1) and performed by qualified personnel educated in the use of the algorithm and trained in pulse oximetry monitoring of newborns (16); and
- 3 performed between 24 and 48 h of age or shortly before discharge if <24 h of age.

To stress the importance of using proper equipment for screening, the recommendation states the use of a pulse oximeter that can read through motion and low perfusion. There are currently only four U.S. States that have not yet taken any action to implement screening. A paper addressing the challenges and opportunities of the implementation process in the United States was published in 2013 (17).

In the United Kingdom, a shift in opinion has been noted since 2010 and the vast majority of neonatologists are now in favour of screening (18).

Only four European countries (Switzerland, Ireland, Poland and Norway) have a national recommendation to screen despite the fact that all but one of the largest published multicentre studies were conducted in Europe (1,9–12).

Recently, at a meeting in Turin, steps were taken by an international group of neonatologists, paediatric cardiologists and screening experts to promote CCHD screening across Europe (19).

The purpose of this study was to examine the extent of pulse oximetry screening in the Nordic countries, as well as details of the screening methods used, and to discuss whether the results could provide a basis for uniform Nordic guidelines.

PATIENTS AND METHODS

A form containing 28 questions exploring pulse oximetry screening, clinical examination routines and availability of echocardiography was distributed to all 157 delivery units in the Nordic countries in June 2013. The results were presented at the Nordic Paediatric Cardiology meeting in Copenhagen in September 2013 and describe the situation at that point in time. Following this, a proposal for uniform Nordic guidelines was agreed by the authors.

Descriptive statistics are presented as numbers and percentages. No statistical comparisons were made.

RESULTS

We received responses to the questionnaire from 156 of the 157 delivery units (Table 1). The number of delivery units and live births, routines for clinical examination of newborns and access to echocardiography in each country are shown in Table 1. It can be seen that Sweden, Finland and Denmark have a centralised birth pattern, while in Norway, births are more decentralised. In Iceland, 73% of the 4500 deliveries per year are centralised to Reykjavik, but the remaining deliveries are distributed between seven units.

In all Nordic countries, with the notable exception of Denmark, newborns are routinely examined, at least once, by a physician before discharge. In Sweden and Finland, the newborn examination is always performed by a paediatric consultant or resident, whereas in some units in Norway and Iceland, nonpaediatric physicians undertake this clinical screening. In Denmark, the physical examination of newborns by a physician was cancelled in most units in 2007, because it was considered that there was not enough scientific evidence of its benefits (20). Instead, newborns are examined by a midwife in 75% of units. Auscultation of the heart and palpation of femoral pulses, however, are not part of this examination.

Urgent echocardiography 24 h a day is available for all newborns in the Nordic countries, but sometimes only after transport. This is especially so in Norway, where 25 of the 48 delivery units have to transport a baby to another hospital for echocardiography (Table 1).

Local guidelines regarding investigation of cardiac malformations in newborns are in use in 85% of all delivery units in Sweden, 77% in Norway, 87% in Finland and 76% in Denmark. In Iceland, there are no written guidelines.

Pulse oximetry screening

In total, 116 of the 156 (74%) responding delivery units have implemented pulse oximetry screening for CCHD (Table 1). The implementation of screening is highest in Finland, Sweden and Norway and lowest in Denmark and Iceland (Table 1).

There were no national guidelines for pulse oximetry screening in any of the Nordic countries when the questionnaire was distributed (June 2013). However, during that month, the Norwegian Directorate of Health endorsed universal pulse oximetry screening (21). Regardless of the lack of guidelines, screening was gradually implemented in Sweden, Norway and Finland from 2004. A high prenatal detection rate was cited as the main reason for not screening in Denmark and a high prenatal detection rate combined with a very low neonatal mortality rate in Iceland. This was the lowest in Europe for 3 years in a row at 0.9–1.1 per 1000 in 2010–2012. Other reasons mentioned by units for not screening were

Table 1 Number of delivery hospitals and live births, newborn examination routines, access to echocardiography and pulse oximetry screening routines in the Nordic countries in September 2013. Percentages were calculated based on the number of responding units unless otherwise stated

	Sweden	Norway	Finland	Denmark	Iceland	Total
Number of delivery units	46	48	30	25	8	157
Number of responding units	46	48	30	24	8	156
Live births 2012	113 137	61 149	59 038	59 527 ^a	4 450	297 301
Number of units with						
<500 deliveries	2 (4.3%)	24 (50.0%)	5 (16.7%)	2 (8.3%)	7 (87.5%)	40 (25.6%)
500–1500	12 (26.1%)	11 (22.9%)	11 (36.7%)	6 (25.0%)	0	40 (25.6%)
>1500	32 (69.6%)	13 (27.1%)	14 (46.7%)	16 (66.7%)	1 (12.5%)	76 (48.7%)
Number of examinations by physician ^b						
0	0	0	0	24 (100.0%)	0	24 (15.4%)
1	37 (80.4%)	43 (89.6%)	26 (86.7%)	0	0	106 (67.9%)
2	9 (19.6%)	5 (10.4%)	4 (13.3%)	0	8 (100.0%)	26 (16.7%)
Transport always needed for echo	4 (8.7%)	25 (52.1%)	5 (16.7%)	16 (66.7%)	6 (75.0%)	56 (35.9%)
Pulse oximetry screening status						
Screening by September 2013	42 (91.3%)	43 (89.6%)	29 (96.7%)	2 (8.3%)	0	116 (74.4%)
Will start during 2013	4 (8.7%)	3 (6.3%)	0	0	0	7 (4.5%)
Will start during 2014	0	2 (4.2%)	1 (3.3%)	2 (8.3%)	0	5 (3.2%)
Proportion of neonates screened ^c	95%	89%	99%	≈10%	0	≈76%
Units screening at <24 h ^d	32 (76.2%)	42 (97.7%)	29 (100.0%)	2 (100.0%)	–	105 (90.5%)
Screening method ^d						
Measuring in right hand and one foot	42 (100.0%)	7 (16.3%)	10 (34.5%)	0	–	59 (50.9%)
Measuring in right hand only	0	5 (11.6%)	1 (3.4%)	0	–	6 (5.2%)
Measuring in one foot only	0	31 (72.1%)	18 (62.1%)	2 (100.0%)	–	51 (44.0%)

^a2011.^bSecond examination before discharge or at follow-up.^cEstimated based on birth rates 2012 (2011 for Denmark) and screening policy in September 2013.^dPercentages were calculated based on number of units screening by September 2013.

lack of national guidelines and concerns about false positives.

Table 1 shows data for pulse oximetry screening routines. In Sweden, all units use the Granelli protocol, which calls for preductal and postductal screening (1), whereas in Norway, most units use only postductal screening (9). In Finland, there is a mixture of both protocols. The majority of units in all three countries screen before 24 h of age and most use motion-tolerant oximeters. In both Sweden and Norway, 95% of the screening units use reusable sensors in contrast to Finland, where 55% use disposable sensors. A mix of midwives and nurses perform the screening, with midwives making up the majority.

The result of screening is stored electronically in all Swedish units (17% also keep paper records), 88% in Norway (17% paper records) and 80% in Finland (12% paper records). However, none of the units in the Nordic countries store the results in a digital database enabling retrieval of data for research purposes, without having to check each individual patient file.

Uniform guidelines

We propose uniform Nordic guidelines (Table 2) based on the Swedish algorithm with the modification to always screen within 24 h of birth. This algorithm is presented in Figure 1.

Table 2 The proposed uniform Nordic pulse oximetry screening guidelines

Screening should be done with a motion-tolerant pulse oximeter reading through low perfusion and reporting functional oxygen saturation
Screening should be based on the endorsed screening algorithm and performed by qualified personnel who have been educated in the use of the algorithm and trained in pulse oximetry monitoring of newborns
A positive screen occurs when
One oxygen saturation value is <90%
Oxygen saturation is <95% in both right hand and one foot or there is a >3% absolute difference in oxygen saturation between the right hand and one foot on three repeated measurements. Any measurement that is >95% in either extremity with <3% absolute difference in oxygen saturation between the upper and lower extremity would be considered a pass and screening would end
The screening should be conducted within the first 24 h of life
Standards should be developed for digital reporting of the screening result that can be retrieved for follow-up

DISCUSSION

In this update on pulse oximetry screening routines in the five Nordic countries, we found that screening had been successfully implemented in three of them (Sweden, Norway and Finland). This has occurred as a bottom-up approach, in the absence of national recommendations,

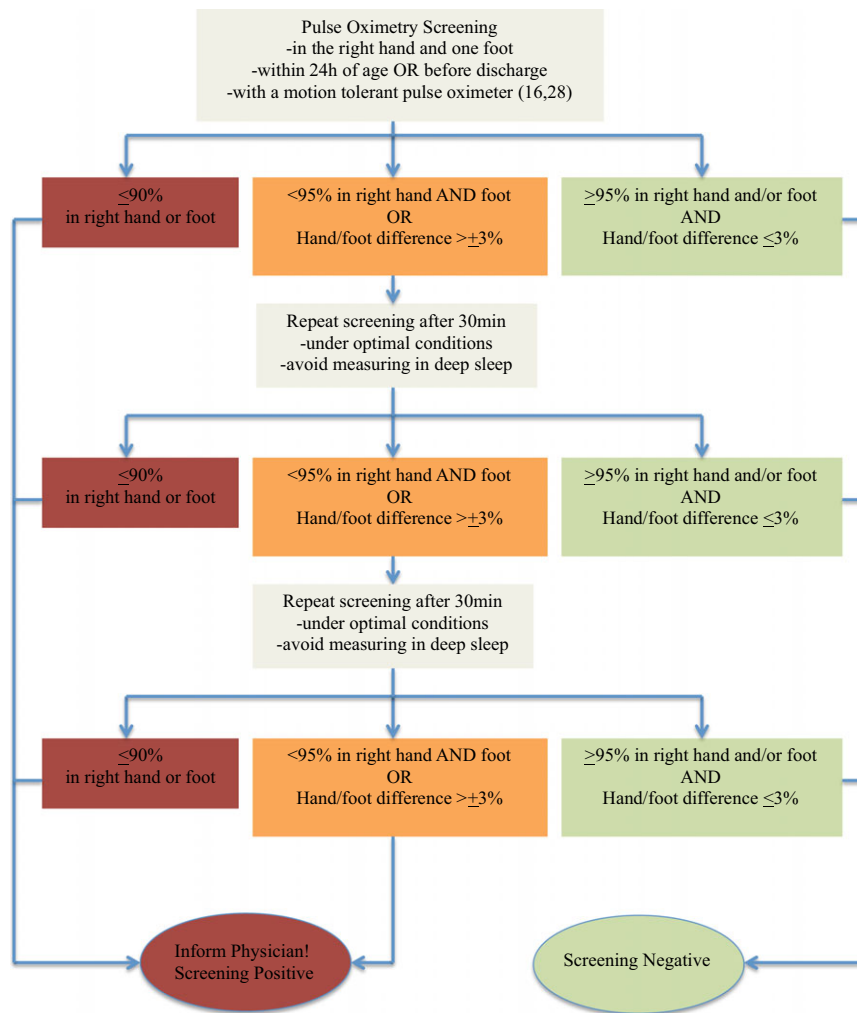


Figure 1 Proposed screening algorithm for the Nordic countries.

special funding or training. Screening has reached over 90% coverage across these three countries, currently the greatest proportion in the world. This shows the feasibility of the method and clearly dismisses concerns that this method only works in large research settings with dedicated staff and funding (22).

In Denmark, the general belief has been that prenatal detection rates are so high that screening would not be cost-effective, although actual detection rates have not been widely acknowledged. In Iceland, an active decision was made not to screen on the same grounds. We did not examine prenatal detection rates. However, all five countries have programmes for foetal heart screening in the second trimester. These programmes always include the four-chamber view and in a majority of units also outflow views and the three-vessel view. The effectiveness of prenatal screening programmes is, however, highly variable within countries as well as between countries (2,23,24). Some areas in Sweden, for example, report more than 75% prenatal detection of CCHD, whereas

other areas detect <25% (personal communications, unpublished data). The situation in the United Kingdom is similar, with a wide variation in detection rates (3). In Denmark, the general assumption has been that the prenatal detection rate is high, but at the annual Danish neonatology meeting in 2011, it was reported that the prenatal detection of CCHD was 34% in 2008–2009 (25). Partly as a result of the present study, at least two Danish units are now planning to start pulse oximetry screening, with a bottom-up approach, while waiting for a national recommendation.

When employing pulse oximetry screening on national levels, the diagnostic yield may be lower in areas served by large university hospitals with effective prenatal screening programmes compared to other areas, but screening should be promoted on all levels to optimise the diagnostic yield on a national level. We encourage a combined approach with effective prenatal screening according to International Society of Ultrasound in Obstetrics and Gynaecology guidelines (26) and postnatal pulse oximetry screening

using the algorithm presented here to optimise perinatal care of foetuses and newborns with CCHD.

Differences between recommended screening algorithms

One of the main obstacles preventing or delaying implementation of pulse oximetry screening, reported by physicians in the United Kingdom and the Nordic countries, has been a lack of national recommendations and/or guidelines. When the Norwegian Directorate of Health endorsed universal pulse oximetry screening in June 2013 (21), it recommended postductal screening after 24 h of age, thus diverging both from the United States (preductal and postductal, 24–48 h of age) and our proposal for common Nordic recommendations (preductal and postductal before 24 h). We believe screening within the first 24 h after birth is justified despite a higher proportion of false positives (11), because the majority of the false positives resulting from pulse oximetry screening have true hypoxia requiring special or intensive care (early infections, pulmonary hypertension and other pulmonary disorders), and thus can be considered as secondary targets and an additional advantage with screening (1,9,11,12,14). In a recent study, Singh et al. (27) evaluated the impact of CCHD screening before 24 h of age and found that of 208 (0.8%) who screened positive, 17 had CHD and 148 had other clinical conditions requiring further intervention, confirming the additional benefit of screening confirming this additional benefit of screening. In a hypothetical future situation, with close to 100% prenatal detection rate of CCHD across all delivery units in a country, including small delivery units in decentralised organisations, such as in Norway, there may still therefore be a place for postnatal pulse oximetry screening. Another justification for this recommendation is that the screening is already performed within 24 h in nearly all units in Sweden, Norway and Finland. Screening may take place either in the delivery unit before discharge if very early discharge is planned or before transfer to the nursery, or in the nursery before 24 h of age.

The recommendation to screen both preductally and postductally is based on the fact that this increases the chances of detecting some types of CCHD. In transposition of the great arteries, with or without aortic arch obstruction, only postductal screening may miss the hypoxia as these babies can have a higher, and sometimes normal, postductal saturation with concomitant critically low preductal saturation (28). Newborns with coarctation of the aorta sometimes have a lower postductal than preductal saturation and will then be detected by screening if it is performed in both the right hand and a foot (28). However, most newborns with coarctation of the aorta have normal saturations both pre- and postductally and will therefore be missed by pulse oximetry screening (1). The reason for this is presumably a large left-to-right shunt across the foramen ovale of fully saturated blood and a large pulmonary blood flow resulting in a normal or near-normal saturation in the blood shunted right to left across the ductus arteriosus. Another mechanism could be that in some neonates, the coarctation may

be mild initially, when pulse oximetry screening is performed, with a pure left-to-right shunt through the ductus arteriosus. This is an important limitation of the method as coarctation of the aorta is the CCHD most commonly overlooked in the newborn examination (5). Careful examination of the newborn, including palpation of the femoral pulses and echocardiography before discharge in all neonates with weak or absent femoral pulses, should therefore be mandatory also in units employing pulse oximetry screening.

To improve quality in screening for CCHD, the use of a computer-based tool to interpret the algorithm was recently proposed (29). The authors found the manual algorithm to be susceptible to human error. Their findings underline the importance of proper training of the personnel to understand the algorithm for CCHD screening and to make correct interpretations of their measurements.

Limitations

One limitation of this study was that we lacked up-to-date data on prenatal detection rates for duct-dependent cardiac defects in all areas of all Nordic countries. Such data would have been of value to analyse the role of postnatal pulse oximetry screening routines and recommendations in the complete perspective of pre- and postnatal detection of CCHD.

Another limitation was that none of the Nordic countries employing pulse oximetry screening store the screening results in a way that data can be retrieved for whole populations. When such data are available for all newborns, together with data on whether there was a prenatal diagnosis or not, a detailed analysis of the relative contributions of the two screening methods on a national level will be possible.

Challenges for the future

Coarctation of the aorta is the duct-dependent cardiac defect most often missed on clinical examination of the newborn, as well as by pulse oximetry screening. Coarctation is also often overlooked in prenatal ultrasound screening programmes (3). It is therefore an important research objective to try to improve pre- and postnatal detection of coarctation. There is some promise that the additional use of perfusion index may improve the detection of aortic arch obstructions after birth (30).

It is hoped that a consensus can be reached by the respective organisations in the Nordic countries to endorse uniform guidelines for pulse oximetry screening based on our proposal. An important next step will be to stimulate also other countries to consider national recommendations for pulse oximetry screening of all newborns.

ACKNOWLEDGEMENTS

The authors thank Nils-Gunnar Pehrsson for statistical support. We also thank the Nordic colleagues who answered the questionnaire. Special thanks to Karl Viktor

Perminow, Oslo University Hospital, Oslo, Norway; Lars Björklund, Skane University Hospital, Lund, Sweden; Gunnar Bergman, Karolinska Institutet, Stockholm, Sweden; and Olli Pitkänen, Hospital for Children and Adolescents, University of Helsinki, Helsinki, Finland, for valuable advice and support.

FINANCIAL DISCLOSURE

This study was made possible by funding from the Swedish Heart-Lung Foundation (Mats Mellander).

CONFLICT OF INTEREST

The authors declare no conflict of interest in relation to the manuscript.

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