PULSE OXIMETRY SCREENING OF NEWBORNS

An investigation into the challenges and limitations of implementing universal pulse oximetry screening for critical congenital heart disease in asymptomatic newborns

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ABSTRACT

Neonatal pulse oximetry has been identified as an important screening tool for critical congenital heart disease. This oximetry screening, although mandatory in many developed countries, is not routinely implemented in South African hospitals.

The objective of this study was therefore to determine the feasibility of implementing pulse oximetry in a typical level 2 hospital in the province of KwaZulu-Natal. Challenges and limitations experienced in implementing the screening were documented.

The study was an observational analytical descriptive study which was conducted in the postnatal ward of Addington Hospital, Durban. Nursing staff were educated regarding the importance of pulse oximetry screening and were subsequently trained to perform the procedure.

A total of 2 453 newborns were admitted to the hospital from January to August 2016 with 599 of these being eligible for enrolment in the study. Consent and screening were initially performed by participating nursing staff. During the last 4 months, consent was obtained by a dedicated research assistant. Of the 599 eligible newborns, 22 were excluded resulting in 577 being available for analysis. There were 29 newborns who fulfilled criteria for a second screening, however, in 21 of these newborns, the protocol was not appropriately followed.

This study suggests that while routine neonatal saturation monitoring appears to be a simple, cost-effective tool to detect critical congenital heart disease, several barriers to its implementation were detected. The main barriers were inadequate staffing and infrastructure. This, in turn, highlighted the need for appropriate human resource provision and training as well as adequate infrastructure. These may not be easily achievable in a resource constrained environment.

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INTRODUCTION

A congenital heart defect (CHD) is the most common birth defect leading to infant mortality.[1,2] In developing countries, practitioners have noted that the diagnosis of CHD is either entirely missed, misdiagnosed or identified at an advanced stage, i.e. too late for repair.[3] A mid trimester anomaly scan may be used to screen for congenital heart disease. This involves imaging of the heart chambers and thereafter a postnatal systemic cardiovascular examination.[4]

Congenital heart disease is present in approximately 9 of every 1 000 live births.[5] However, in South Africa there is an estimated 11 000 children (resulting in 0.6 - 0.8/1 000) children born annually with congenital heart disease. The majority of these children do not receive appropriate care, often due to late, or non-diagnosis.[6,7] This is as a result of inefficiencies in the public health sector, in particular, limited mechanisms and training for early detection of congenital heart defects.[7] Some of the contributing factors were noted to be poor infrastructure and inadequately trained staff as well as staff shortages at different referral hospitals.[7]

Life threatening cardiac abnormalities presenting at, or soon after, birth are referred to as critical congenital heart defects (CCHD) with a reported incidence of 2 - 3/1 000 live births.[5] Less than 50% of cases of CCHD are recognised when foetal ultrasound is done[8] and approximately 25% of children will have CCHD, requiring surgery or catheter intervention, in their first year of life.[9] Most newborns are discharged early if they appear asymptomatic and well. This is often the case with CCHD as the features of their condition are masked during the transition from foetal to "adult" circulation. There are approximately 20% of CHD cases presenting with life threatening illness in the neonatal period, but only a fraction of these newborns are referred for intervention, thus highlighting the importance of timely diagnosis, management and referral for survival.[6,10] Late detection is associated with circulatory collapse, resulting in shock and acidosis with an adverse effect

on prognosis and an increased risk of surgical mortality. Early diagnosis, therefore, is critical.[11]

In September 2010, critical congenital cyanotic heart disease was approved to be included in a uniform newborn screening panel on the basis of findings from a comprehensive evidence review by the United States Health and Human Services (HHS) Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC).[12] The objective of this approval was to recognise those newborns with structural heart defects commonly associated with hypoxia in the newborn period who can have significant morbidity, or mortality, with closure of the ductus arteriosus or other physiological changes early in life.[12] Hypoxaemia is a common feature of CHD resulting from mixing of systemic and venous circulations. Central cyanosis occurs when 5g of haemoglobin is deoxygenated.[13] However, most congenital heart defects have low levels of hypoxaemia, which would not result in visible cyanosis, and it is with these infants where the need for pulse oximetry to detect potentially life threatening cardiac defects becomes crucial.[11] Many newborns with the targeted congenital heart defects do not develop clinically significant cyanosis until after nursery discharge. Some lesions (e.g. hypoplastic left heart syndrome) may present with substantial cardiovascular compromise without obvious cyanosis. Therefore, the working group advised renaming the target conditions "critical congenital heart disease" (omitting the word "cyanotic").[12]

Pulse oximetry is a non-invasive method to measure oxygen saturation. Studies have shown that if pulse oximetry is performed too early in the neonate (<6 hours old), congenital heart defects are missed as a result of the transition from foetal to neonatal circulation resulting in excessive false positive results.[12] It is recommended that pulse oximetry screening be performed after 24 hours, thus ensuring that the false positive rate is much lower.[14] Screening should be done using the right hand and any foot, in which case one is monitoring the preductal (right hand) and post ductal (any foot) oxygen saturation. It is recommended that a diagnostic echocardiography is performed in all suspected positive cases.[8]

In a recent systematic review and meta-analysis it was found that pulse oximetry was highly specific (99.9%) and moderately sensitive (76.5%) when the screen was performed before vs. after 24 hours. It revealed a low false positive rate (0.14%) for the detection of critical congenital heart disease when the screen was performed after 24 hours of birth, thus meeting the standard threshold for universal screening as an adjunct investigation.[11]

The main costs for a pulse oximetry screening programme commonly relates to staff time for screening, obtaining results and communicating with the parents, purchasing and maintenance of screening equipment, the consumables associated with screening (saturation probes, adhesive wraps, cleaning materials) and the cost accompanying a positive result and treatment.[12] Overall, the cost of pulse oximetry screening is considered much less than the associated morbidity and mortality when CHD is missed entirely or presents late in advanced disease.

Many developing countries in Africa lack the infrastructure and human resources to establish well-coordinated cardiac services. In South Africa there have been some advances in paediatric cardiac services, such as regionalisation of cardiac services. However, hospitals remain understaffed with increasing waiting lists for cardiac surgery.[7,15] A recent audit of paediatric cardiac services revealed that only 25% of children in South Africa with CHD received the care that they needed from public health services.[16] These same authors subsequently reported that there is an accumulated backlog of untreated CHD and every year over 3 000 children either die, or become disabled, from their specific congenital heart condition.[6] The Medical Research Council of South Africa's statistics revealed that cardiac abnormalities accounted for 1.2% of under 5 mortality.[7]

Untreated CHD has significant costs due to increased need for hospital admissions. There are additional physical, emotional and psychological burdens on families and caregivers, especially for those who are already disadvantaged by their socio-economic status. It is an added frustration to health care professionals and families to know that they are precluded from available treatment due to their geographical and economic situation.[6] There is a major short fall for screening neonates with congenital heart disease in South Africa that hampers survival which depends mainly on early detection and intervention within the first year of life.[17]

Universal pulse oximetry screening is not routinely performed in the district and regional hospitals in KwaZulu-Natal (KZN). Implementing universal pulse oximetry screening for CCHD in asymptomatic newborn babies in the KZN district and regional hospitals would enable early detection and management of these cardiac defects.

This study was therefore undertaken to document the challenges and limitations of implementing pulse oximetry screening at Addington Hospital, a busy regional hospital in Durban, KwaZulu-Natal. The outcomes of the screening were also documented. It was envisaged that the information obtained would provide data regarding the feasibility of implementing routine pulse oximetry screening in other hospitals in KZN.

METHODS

An observational, analytical descriptive study was undertaken. A cohort of newborns, delivered at Addington Hospital

Complex, was screened using pulse oximetry for possible CHD within 12 - 48 hours of their delivery in the postnatal ward. In South African public hospitals, infants from uncomplicated deliveries are often discharged within 6 -12 hours. To allow for these earlier discharge times, the recommended 24 hours age for screening was reduced to 12 hours in this study. The observational method was chosen since a wide range of information can be obtained in order to describe the challenges, and the limitations, while implementing universal pulse oximetry on a small scale and then using the information to scale up to provincial level. The study period was January - August 2016. Ethics approval was obtained from the University of KwaZulu-Natal Biomedical Research Ethics Committee (BREC reference Number - BE171/15) and from the Head of Department of the KwaZulu-Natal Department of Health, the District Health Manager of the eThekwini District and Hospital and Medical Managers of Addington Hospital.

INCLUSION AND EXCLUSION CRITERIA

All well, asymptomatic newborn babies in the postnatal ward who were awake and calm, as well as any newborn who had been admitted to the low- and intermediate-care nursery that had no respiratory distress and did not require oxygen therapy, were included in the study. Newborns were excluded from the study if they had dysmorphic features, had been admitted to the nursery with severe respiratory distress or sepsis and/or had a cardiac murmur or condition previously detected.

STUDY SITE

Addington hospital is a regional level maternal and child health hospital. It provides medical support to numerous local clinics and a district hospital. There are on average 300 deliveries per month at Addington Hospital. There is one postnatal ward which has a bed capacity of 37 and therefore a high patient turnover. The uncomplicated, stable normal vaginal deliveries are discharged within 6 hours of delivery and the post caesarean section stable patients are discharged after 72 hours. During the study period the ward had an average of 5 staff members on duty per 12 hour shift (1 sister, 2 staff nurses and 2 enrolled nursing assistants).

PROCEDURES

During study training (which lasted approximately 1 hour), all the nursing staff of the postnatal ward, regardless of nursing categories, received a power point presentation which provided them with education regarding the need for pulse oximetry. The training was done personally by the principal investigator (PI) for both day and night staff. During the study period the PI was informed if there were any new staff and they were individually trained. They were also provided with practical training and were evaluated by the PI on their competency in performing the pulse oximetry on the newborn. The operational manager of the postnatal ward was equipped as a trainer and she, together with the PI, were responsible for responding to queries/problems with the methodology. In cases were protocol errors were identified, the training was repeated by the operational manager and principle investigator. Information was made available which included a leaflet with the algorithm for screening as well as a leaflet on inclusion and exclusion criteria.

An information sheet was given to the mothers and their written consent was obtained after every aspect of the study had been explained. The information sheet was in English but was translated into IsiZulu by the nursing staff and/or research assistant if the mother's primary language was IsiZulu. Approximately half way through the study, it was noted that the study sample numbers were slow, due to nurses not having enough time to take informed consent and complete the data sheet in addition to their regular duties. As a result, a research assistant was employed who received in-service training on the need for the study and how to complete the data sheet as well as the consent form. The pulse oximetry, however, was always performed by the nursing staff.

The pulse oximetry screening was performed on alert, calm newborns between 12 and 48 hours of age on the right hand and foot, one immediately after the other. The Mindray VS-800 was used with the reusable paediatric finger clip SpO2 sensor – Nellcor Nursing staff ensured that there was a good pulse waveform. The screening test was considered negative if the pulse oximetry was ≥95% on the right hand and foot with a ≤3% difference between the right hand and foot readings. No further screening was required and the parents were reassured that their newborn's screening test for cyanotic cardiac defect was negative. The screening test was considered positive if pulse oximetry was <90% on the right hand or foot at any stage of screening. The screening test was also considered positive if there was >3% absolute difference in oxygen saturation between the right hand and foot. Newborns with a positive result were to be referred to an appropriate health facility for further assessment and investigations such as chest radiograph, electrocardiogram and echocardiogram. Indeterminate screening tests (≥90%, <95% readings on right hand or foot or >3% difference between the readings) required a second or third test as per algorithm (Figure 1).

ANALYSIS OF DATA

The data was captured on a data sheet and then transferred to an Excel spread sheet with all the parameters on the data sheet. A statistician was involved in analysing the data. Descriptive statistics were used to summarise the demographic and clinical characteristics of the newborns. Frequencies and percents were used for categorical data. Frequency distributions of age and birth weight were not normally distributed using

Shapiro Wilk test for normality, so medians and interquartile ranges are reported. The flow chart shows the results of the screens and number of newborns at each point. The statistical software used was Stata V13.

RESULTS

A total of 2 453 newborns were admitted to postnatal ward from January - August 2016. Of these 2 453 infants admitted, only 545 sick newborns were admitted to the nursery and hence were not eligible for the study. Of these 545 newborns which were excluded from the study, 14 were newborns with suspected cardiac problems. A further 1 319 were not approached for inclusion in study because of early discharge – newborns born via normal vaginal delivery where both mum and infant were clinically well, were discharged within 6 hours of delivery as per the standard protocol.

The remaining 599 infants were screened and enrolled in the study. The nursing staff was able to consent and screen 249 newborns during the time frame January - April 2016. A further 350 were screened from May - August with the consents, however, being obtained by the research assistant. A total of 22 newborns were excluded from the study, resulting in a total of 577 patients. The 22 newborns were excluded for the following reasons: 14 were either less than 12 hours old or more than 48 hours old; 3 newborns had no age documented; and 5 newborns had consent taken but were not screened.

In 29 (5% of the total) newborns re-screening was required. Protocol deviations occurred in 21 patients. These deviations were: 1 patient who had a second screening done on the right hand but not on the right foot, and 20 who had no second or third screening done, as required. In only 8 cases was a second screening appropriately performed and these were all noted as negative.

Three (0.5%) newborns were suspected positive screens as pulse oximetry readings were less than 90% and, according to the protocol, they should have been considered as positive and

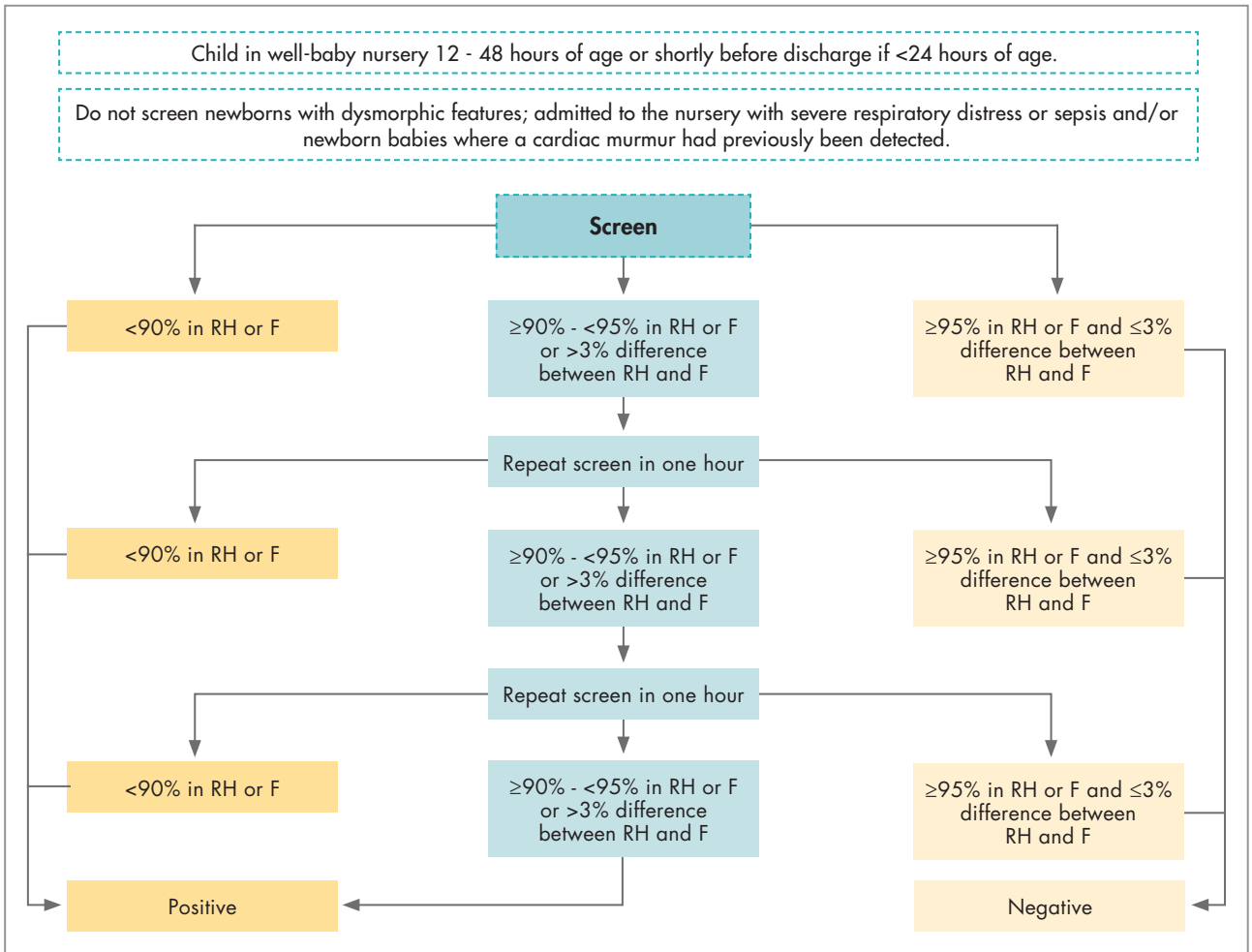

FIGURE 1: Congenital Heart Disease (CHD) Assessment.
Pulse oximetry screening protocol based on results from right (RH) and foot (F). (Adapted from proposed protocol in Kemper, et al.)[12]

referred for further investigation. A protocol deviation occurred and a second screening was performed on all 3 newborns and a third screening on 2 of them. The subsequent screens for the 2 newborns were negative but were not referred for further investigations. One of these 2 newborns was subsequently found to have low oxygen saturation secondary to hypothermia, the oxygen saturation was within the normal clinical range on warming the newborn and the chest radiograph was normal.

Patients were screened between 12 and 48 hours of age. The majority of the newborns were between 18 - 24 hours old with a percentage of 40%, there was 25% who were less than 18 hours old and 35% between 25 - 48 hours old. There was a predominance of male newborns being screened with 54% being male and 46% female newborns. A total of 420 were caesarean sections (73%) and 157 were normal vaginal deliveries (27%). The majority of the patients screened were post caesarean section newborns. The newborns born via normal vaginal delivery who were clinically stable with no risk factors and complications were discharged within a 6 hour period, and therefore they were not included in the study population. There was a wide range of caesarean section indications; predominant indications were having a previous history of a caesarean section (35%) and foetal distress (25%).

NURSING STAFF FEEDBACK

A total of 22 nurses were trained. The nurses were given a questionnaire to evaluate the study and their understanding of it. Only 12 nurses were available to complete the questionnaire since 5 were transferred and 5 were on leave at the time the questionnaire was performed. Of the 12, 6 had no difficulties, and the remaining 6 reported experiencing difficulties especially highlighting: staff shortages; dealing with a crying, restless newborn and the excessive time taken to perform the consent and screening. Six of the nurses reported a cleaning time for the oxygen saturation probes of between 3 - 5 minutes while the other 6 nurses reported it took less than 2 minutes. Five of the nurses said it took them 8 - 10 minutes to obtain the oxygen saturation on the newborns, 3 reported taking 5 - 7 minutes, another 3 took less than 5 minutes and one took 14 - 15 minutes. The 12 nurses said that a crying, moving and cold newborn were the reasons it took long to obtain the

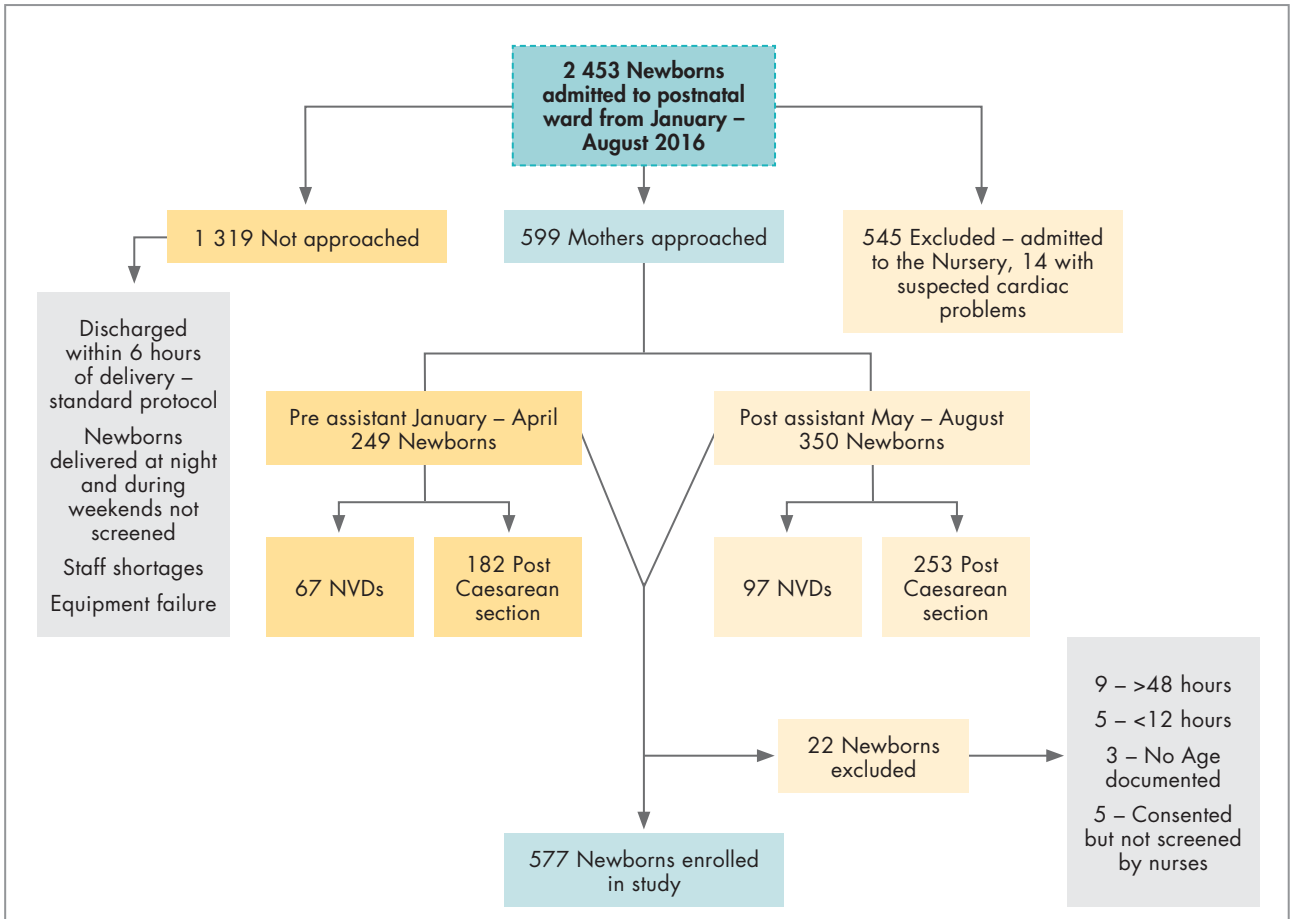

FIGURE 2: Cohort profile.

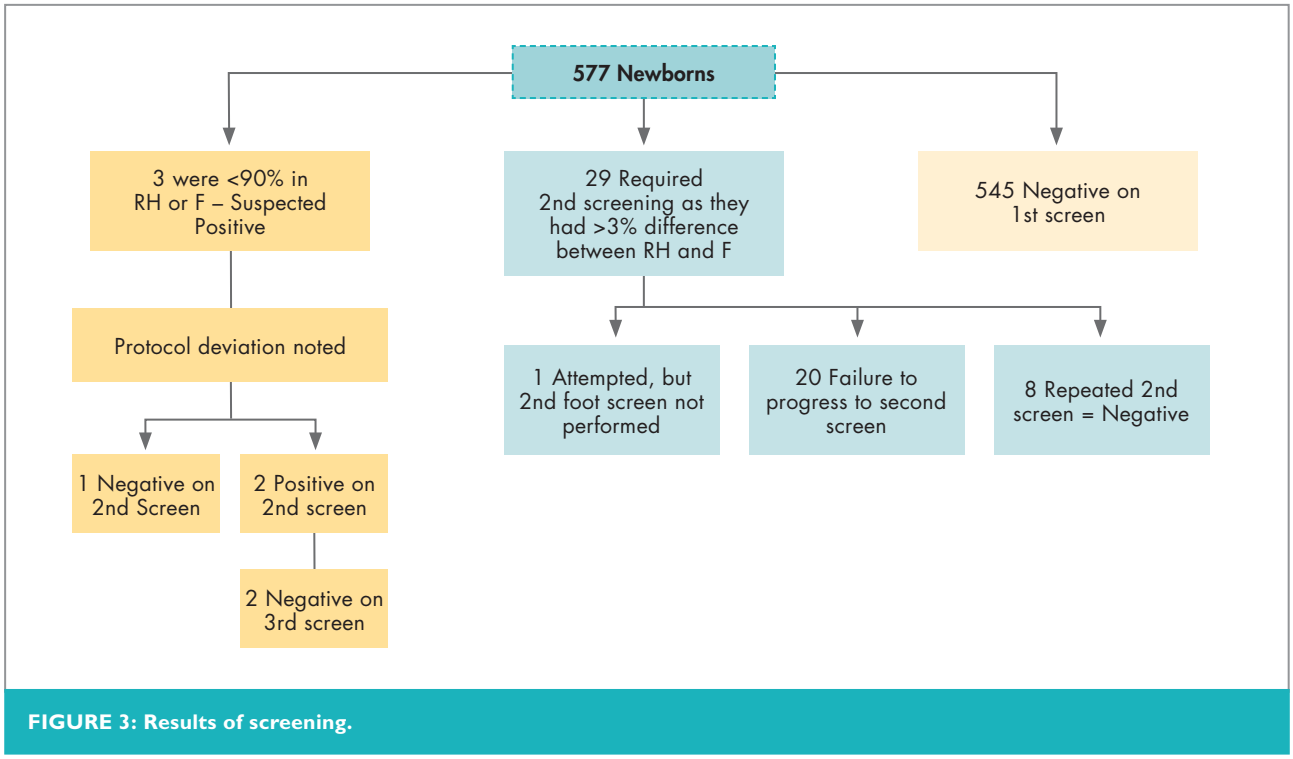

FIGURE 3: Results of screening.

oxygen saturations. Ten of the nurses advised that the hospital was not yet ready to perform routine oxygen saturations as they were critically short staffed with limited equipment and advised the employment of more staff and/or appointing someone as a separate entity to perform the screening. The 2 that had said yes did not validate their answer. All the nurses suggested that in order to perform routine screening, and for it to be a success, one should employ more nurses, obtain more pulse oximetry machines and perform the screening as part of their daily routine work.

CHALLENGES IDENTIFIED

This study proved to have several challenges, mainly related to staff and infrastructure.

STAFF CHALLENGES

Despite training all nursing staff, only enrolled nurses were allocated to the study which highlighted the hierarchy and limitations. Public sector hospitals in KZN experience staff shortages and work in a resource limited environment. The large number of staff shortages during the study period contributed, in part, to the deficiency of the number of newborns screened and the prolonging of the study time. The nursing staff were only allocated time to screen these newborns once the more important and pertinent tasks had been done. Nurses noted that taking the consent and filling in the data sheet took up most of the time, which also decreased the number of newborns enrolled in the study by delaying the actual screening. Thus leaving them with little time to complete their routine ward allocated duties.

Despite the staff shortages, it was also noted that the nurses may not understand the critical need for routine pulse oximetry screening. This was clearly evident, especially after training them and educating them on the inclusion and exclusion criteria, and following the algorithm on screening. We found that when the nursing staff took the consent they occasionally screened newborns that did not meet the inclusion criteria, especially with reference to age in hours. They also did not clearly understand the positive and negative screen algorithm. It was noted that 29 newborns had a more than 3% difference between the 2 readings which required a second or third screening, as outlined in the algorithm, resulting in an inappropriate screen. The parents of newborns, that had a more than 3% difference, were contacted to have the screen repeated. However, most of the contact numbers were unavailable and only one mum returned with her babies and this turned out to be a negative screen. These were identified as a protocol deviation and those nurses involved in the study were retrained.

Most nurses felt that they should not be the ones performing the study and that it should be the responsibility of a third party, despite having been informed that the purpose of the study was to understand whether it was feasible to roll out the study in a hospital setting in South Africa.

After the research assistant was appointed to assist with the taking of consent and filling in the data sheet, the number of

newborns approached were slightly higher than when the nurses performed it. It did alleviate some strain from the nursing staff. In spite of this there continued to be protocol deviations when the nurses were performing the pulse oximetry screening as some of them did not understand the algorithm, especially when there was a more than 3% difference in the right arm and right leg, hence no second or third screening was performed when required. However, despite the research assistant taking the consent and filling in the data sheet, some patients were not screened.

HOSPITAL INFRASTRUCTURE

The postnatal ward was constantly short staffed which created challenges in obtaining the expected sample of about 600 within a 3 month period, hence the study was extended to 8 months. During the times of staff shortages there was no contingency plan in place to assist with staff shortages.

In Addington Hospital it was found that, for the entire postnatal ward, there was only 1 oxygen saturation monitor which was also used to monitor mothers' blood pressure and pulses post-delivery. This added a lot of strain to the study as the monitor was only available to the newborns after a certain time of the day. During the study period, the only monitor that the ward had malfunctioned and no newborns were screened for 2 weeks. The monitor was sent in for repairs which were estimated to take several months, therefore a monitor borrowed from another ward was subsequently used to complete the study.

Addington hospital has only 1 postnatal ward, and due to bed numbers in the ward, well babies were discharged within 6 hours of delivery provided mum and baby were well post vaginal delivery. Hence, many newborns were lost to screening as they were not hospitalised long enough. The majority of the newborns screened (72.5%) were from the post caesarean section babies.

DISCUSSION

This study suggested that in a significantly resource restrained environment, as exists in most of South Africa and Africa, significant investment in training, human resources and equipment would be necessary before an oxygen saturation screening programme could become feasible. Additional issues that require investigation are the capacity to timeously and appropriately refer patients for diagnosis and management of their cardiac condition.

A recent review of universal pulse oximetry screening implementation suggested that it is cost effective and feasible since no additional staff is required and the burden on clinical services is limited.[8] This would suggest that for situations where there are staff shortages, routine screening would impose too much of a burden on the staff and additional specially trained assistants would be needed to introduce such screening.

Public health screening programmes can only be implemented successfully through a comprehensive educational method that includes public health officials, providers and families. The staff, required to perform the test, need to be thoroughly trained in the screening procedures, interpretation of results and knowing how to respond to babies with failed screens.[18]

KZN and other resource limited provinces encounter numerous barriers to implementing routine oxygen saturation screening. These barriers include poorly funded health services in the public sector caring for an enormous patient load. This results in limited staff and equipment available which is required for the well-deserved clinical services.[19]

Results from this study suggest that if the screening is routine, and not part of a study, it will result in less time spent on explanations, consenting and tedious paperwork by the nursing staff and hence there would most probably be an opportunity for screening all newborns admitted to the postnatal ward. Oxygen saturation training would obviously be essential for all nursing staff in all hospitals. Resources were also shown to play a key factor in the study and it is clear that having only 1 monitor for the entire postnatal ward is sub-optimal. The study depicted the real-life situation experienced in this regional hospital where, at times, adequate available equipment is in short supply. Sufficient oxygen saturation monitors need to be readily available in all hospitals for routine screening.

Although there have been many studies that have documented the feasibility and benefits of oxygen saturation screening in developed countries,[6] only 1 study in South Africa[19] ascertained the feasibility of this type of screening. This study, in 1 of the better-resourced secondary level public sector hospitals in South Africa, highlighted the practical feasibility of oxygen pulse oximetry screening for critical congenital heart disease with overall acceptance from both nurses and the parents.[19] This hospital, although having the same average staff complement as the study hospital, had a higher percentage of senior nurses compared to the study hospital, which at any given time only had 1 senior nurse on duty.

LIMITATIONS TO THE STUDY

The study was performed in only 1 regional hospital in KZN. This is not representative as resources, staffing and equipment may be different in other hospitals. A major limiting factor during the study period was staff shortages. Additionally, infants delivered after hours (when routine screening was not available) were not screened. Staff shortages during routine working hours also hindered newborns from being screened. Nursing staff may not have understood the critical need for routine

pulse oximetry screening, as well as the algorithm, as many protocol deviations were noted. The training may have been inadequate in terms of time and not specifically geared to each different category of nursing staff. The staff may have performed better if more discussions and time had been spent in understanding their concerns regarding the study. A pilot study would have been beneficial, as we then would have noted the misunderstandings and protocol deviations, and found a solution to gain optimum results and bolster staff enthusiasm. The questionnaire should have perhaps been beneficial directly after the pilot study. The other major limiting factor was equipment failure, or the absence of essential equipment. One available functioning oxygen saturation monitor for the entire postnatal ward was a major limiting factor. The study would have benefited in having more oxygen saturation monitors with a back-up monitor readily available should there be malfunctioning equipment.

CONCLUSION

This study suggests that, while routine neonatal saturation monitoring appears to be a simple cost-effective tool to detect critical congenital heart disease, several barriers to its implementation were detected. The need for appropriate human resource provision and training, as well as adequate infrastructure, was highlighted. These may not be easily achievable in a resource constrained environment. Universal routine pulse oximetry screening remains an important crucial step in the development of a comprehensive health care system that prioritises the early detection and treatment of disease.

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Conflict of interest: none declared.

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APPENDIX A

Pulse Oximetry Screening of New-borns Study (POSON study)

Questionnaire for the screening team

1. While performing the Oxygen Saturation of the new-born babies what difficulties did you experience?
   ☐ No difficulties ☐ Yes the following difficulties

2. While performing the Oxygen Saturation of the new-born babies what were the concerns of some of mothers?
   ☐ No concerns ☐ Yes followings were the concerns

3. How long did it take to obtain consent from the mothers? Estimate the time correctly.
   ☐ Less than 5 minutes ☐ 5-7 minutes ☐ 8- 10 minutes
   ☐ 11-13 minutes ☐ 14-15 minutes ☐ More than 15 minutes

4. How long did it take for you to clean the oxygen saturation probe before checking the oxygen saturation? Estimate the time correctly.
   ☐ Less than 2 minutes ☐ 3-5 minutes ☐ 6-8
   ☐ 9-10 ☐ More than 10 minutes

5. How long did it take to obtain oxygen saturation reading of a baby? Estimate the time correctly.
   ☐ Less than 5 minutes ☐ 5-7 minutes ☐ 8- 10 minutes
   ☐ 11-13 minutes ☐ 14-15 minutes ☐ More than 15 minutes

6. If measurement of oxygen saturation took longer than you expected what you think were the reasons of this delay?
   6.1 _____
   6.2 _____
   6.3 _____
   6.4 _____
   6.5 _____

7. What are some of your suggestions to ensure that every new-born baby gets oxygen saturation done before discharge?
   7.1 _____
   7.2 _____
   7.3 _____
   7.4 _____
   7.5 _____

8. In your opinion do you think that our hospital is ready to do oxygen saturation of all the new-born babies and why?
   ☐ No Why? _____
   ☐ Yes Why? _____

9. Are you satisfied that the purpose and aims of the study were easy to understand and was the algorithm easy to follow?
   ☐ No Why? _____
   ☐ Yes Why? _____

10. After the training sessions how confident you were to be able to explain the purpose and limitations of pulse oximetry screening of new-born babies.
    ☐ Not confident at all ☐ Confident ☐ Very confident

Thanks for your participation