Patient Safety MOVEMENT
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Actionable Patient Safety Solution (APSS) #7A:
SUBOPTIMAL NEONATAL OXYGEN TARGETING

Executive Summary Checklist

Hypoxia in preterm infants can result in severe morbidity and mortality. Supplemental oxygen administration helps avoid hypoxia but hyperoxia can cause retinopathy of prematurity and increased risk for other conditions. Implementing an optimal oxygen targeting guideline can improve neonatal outcomes. To address suboptimal oxygen targeting:

- ▢ Make an organization-wide commitment by administrative, clinical, and patient engagement leaders to address neonatal patient safety related to oxygen administration.
- ▢ Assess opportunities to improve oxygen administration and monitoring for the prevention of adverse events due to lack or excess of oxygen.
- ▢ Implement interdisciplinary strategies and develop an action plan with a timeline with concrete milestones to implement an optimal oxygen guideline for neonates.
- ▢ Select technologies that have been shown to improve neonatal outcomes, including but not limited to: blenders, pulse oximetry, and heated humidifiers.
    - Use blenders in all circumstances when administering oxygen, including the delivery room.
        - Bird, Carefusion, Precision Medical's low-flow and high-flow oxygen-air blenders
    - Use heated humidifiers when using CPAP and in all circumstances where the infant is intubated, even for a few minutes.
        - Fisher & Paykel
    - Use heated humidifiers in the delivery room.
    - For pulse oximetry, select equipment that: a) can measure through motion and low perfusion conditions to avoid inaccurate measurements/false alarms and identify true alarms; and b) has been proven effective for neonatal oxygen targeting.
        - Masimo Signal Extraction Technology (SET) pulse oximetry (until another technology is proven to be equivalent)
- ▢ Determine the oxygen targeting guideline that healthcare providers should implement:
    - The SpO_2 for a preterm baby breathing supplemental oxygen should not exceed 95%.
    - The SpO_2 for other larger infants and neonatal patients breathing supplemental oxygen should stay in the range of 88-95 or 90-96% depending on infant and condition.
    - When SpO2 dips below the desired % or when the low alarm sounds, avoid a response that results in high saturation (>95%).
    - In order to accomplish this, the monitor alarms should always be on and active when an infant is breathing supplemental oxygen.
    - Neonates in an intensive care environment should always be monitored by a pulse oximeter capable of monitoring through motion and low perfusion with appropriate alarm limits
    - The high SpO_2 alarm should be set to 95%, depending on the infant.
    - The low SpO_2 alarm should be set no lower than 85%.
    - Alarms signaling should receive attention from the nurse/doctor/respiratory therapist.
    - When a baby is not breathing supplemental oxygen, but is being monitored for desaturations, the low SpO_2 alarm should be set at 85% and the high alarm can be turned off.
- ▢ Implement your action plan for including educational activities, workshops, and tools for all members of the neonatal healthcare team.
- ▢ Develop a process for continuous improvement by communicating with staff and implementing measures to improve processes in order to meet the oxygen targeting objective.

The Performance Gap

It has been clear for many decades that avoiding hypoxia in neonatal care is associated with increased survival and lower rates of cerebral palsy. For this reason, hypoxia should be avoided; this is not to say that hyperoxia should be allowed. Supplemental oxygen in newborn infants has been over-utilized worldwide. This practice has been associated with prolonged hospitalizations, blindness for life due to retinopathy of prematurity (ROP), cancer in childhood, chronic lung disease, developmental disabilities, periventricular leukomalacia, cerebral palsy and other oxidant-stress related adverse effects including DNA damage, endocrine and renal damage, decreased myocardial contractility, alveolar collapse, infection, inflammation and fibrosis.[1,2,3,4,5,6] Most if not all of these complications are as a result of care in the newborn period and cannot be fully eradicated. However, evidence shows eliminating inappropriate oxygen administration and increasing the use of oxygen monitoring can lead to significantly decreased rates of these preventable conditions.[7,8]

The use of unnecessary oxygen and the resulting prolonged hospital stays add significantly to health care costs, not to mention the tremendous emotional costs of preventable chronic conditions. Actively addressing the administration and monitoring of oxygen in newborn infants to prevent both hypoxia and hyperoxia can realize significant improvements in the quality and safety of healthcare as well as cost savings.[9]

Hospital practices for oxygen monitoring are variable. Many delivery rooms and neonatal intensive care units worldwide adhere to outdated or otherwise inappropriate protocols. The evidence has shown that excessive oxygen administration during the first few minutes of life is noxious. Yet, in many delivery rooms worldwide, pure oxygen (100% O_2) is still administered unnecessarily, FiO_2 is not measured, and oxygen saturation (SpO_2) levels are not adequately monitored.[10,11,12,13,14,15,16] Therefore, there is an opportunity to prevent many adverse effects through

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[1] Collins, M. P., Lorenz, J. M., Jetton, J. R., & Paneth, N. (2001). Hypocapnia and other ventilation-related risk factors for cerebral palsy in low birth weight infants. Pediatric Research, 50(6), 712-719.
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[5] Sola, A. (2008). Oxygen in neonatal anesthesia: Friend or foe?. Current Opinion in Anesthesiology, 21(3), 332-339
[6] Sola, A., Saldeno, Y. P., & Favareto, V. (2008). Clinical practices in neonatal oxygenation: Where have we failed? What can we do?. Journal of Perinatology, 28, S28-S34.
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[9] Vaucher, Y. E., Peralta-Carcelen, M., Finer, N. N., Carlo, W. A., Gantz, M. G., Walsh, M. C., ... & Schibler, K. (2012). Neurodevelopmental outcomes in the early CPAP and pulse oximetry trial. New England Journal of Medicine, 367(26), 2495-2504.
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[13] Bizzarro, M. J., Li, F. Y., Katz, K., Shabanova, V., Ehrenkranz, R. A., & Bhandari, V. (2014). Temporal quantification of oxygen saturation ranges: an effort to reduce hyperoxia in the neonatal intensive care unit. Journal of Perinatology, 34(1), 33-38.

education on appropriate oxygen management, such as the measurement of oxygen titration with a blender and monitoring the infant's saturation level with pulse oximetry technology that can measure through motion and low perfusion.[10-12,17]

In a two-phased study of two centers that previously used conventional pulse oximetry, both centers simultaneously changed their neonatal oxygen targeting guideline, and one of the centers switched to Signal Extraction Technology pulse oximetry.[14] In the first phase of the study, there was no decrease in retinopathy of prematurity at the center using non-Signal Extraction Technology; but there was a 58% reduction in significant retinopathy of prematurity and a 40% reduction in the need for laser eye treatment at the center using Signal Extraction Technology. In the second phase of the study, the center still using non-Signal Extraction Technology switched to Signal Extraction Technology and it experienced similar results as the center already using Signal Extraction Technology. In the follow up study, the outcomes of 304 very low birth weight infants whose oxygen targeting was performed with non-Signal Extraction Technology pulse oximetry were compared with 396 post-initiative infants whose oxygen targeting was performed after switching to Signal Extraction Technology pulse oximetry.[13] After switching to Signal Extraction Technology, there was a 59% reduction in incidence of severe ROP and a 69% reduction in ROP requiring surgery.

A summary of recent publications on extremely premature infants randomly assigned to a lower target oxygen-saturation intention to treat (85 to 89%) or higher target SpO_2 intention to treat (91 to 95%) has shown there was neither increased mortality nor serious brain injuries as a result of avoiding hyperoxia in preterm infants.[15,16,1819,20,21,22]Also a recent presentation by Askie et al (Cochrane review) shows that there is no difference in the primary outcome of death or disability between the two intentions to treat studied, a higher (91-95%) versus a lower (85-89%) arterial oxygen saturations. Higher rate of NEC occurred with lower intention to treat (85-89%) and a higher rate of severe ROP with higher target range (91-95%). Recently the Committee on Fetus and Newborn of the AAP (Cummings JJ et al Pediatrics 2016;138(2):e20616576) have made clinical recommendations which are included in this document.

Therefore, an intention to treat with SpO_2 of 85-89% should be avoided.[20,21] There are several issues that suggest extreme caution should be used in the interpretation of these randomized controlled trials..[23,24,25] Additionally,

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[14] Chow, L. C., Wright, K. W., & Sola, A. (2003). Can changes in clinical practice decrease the incidence of severe retinopathy of prematurity in very low birth weight infants?. Pediatrics, 111(2), 339-345.
[15] Deulofeut, R., Critz, A., Adams-Chapman, I., & Sola, A. (2006). Avoiding hyperoxia in infants ⩽ 1250 g is associated with improved short-and long-term outcomes. Journal of Perinatology, 26(11), 700-705.
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[20] Castillo, A., Sola, A., Baquero, H., Neira, F., Alvis, R., Deulofeut, R., & Critz, A. (2008). Pulse oxygen saturation levels and arterial oxygen tension values in newborns receiving oxygen therapy in the neonatal intensive care unit: Is 85% to 93% an acceptable range?. Pediatrics, 121(5), 882-889.
[21] Askie, L. M., Brocklehurst, P., Darlow, B. A., Finer, N., Schmidt, B., & Tarnow-Mordi, W. (2011). NeOProM: neonatal oxygenation prospective meta-analysis collaboration study protocol. BMC Pediatrics, 11(1), 1.
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narrow ranges are difficult to maintain for more than 50-60% of the time.[13,26] To date, the "perfect" SpO_2 target range is still not known for all newborns at all times.[20,27]

In summary, in extremely low birth weight infants the ideal oxygen saturation range or intention to treat remains unknown and is a compromise among negative outcomes associated with either hyperoxemia (ROP, BPD) or hypoxemia (NEC, death). The appropriate SpO_2 range for an individual infant will depend on the type of SpO_2 monitor used, gestational age, postnatal age, hemoglobin A concentration, hemoglobin level, oxygen content, cardiac output, clinical diagnosis and illness severity.[28] Despite this variability, it is clear that in order to improve clinical outcomes, some clinical practices must be eradicated and replaced with guidelines of clinical care aimed at avoiding both hyperoxia and hypoxia.

Alarms:

- Alarms should always be operative (do not disconnect or deactivate alarms).
- Alarm limits are used to avoid harmful extremes of hyperoxemia or hypoxemia.
- Busy NICU nurses respond much better to SpO_2 alarms rather than to "mental SpO_2 target ranges or intention to treat".
- Given the limitations of SpO_2 and the uncertainty regarding the ideal SpO_2 intention to treat for infants of extremely low birth weight, wider alarm limits are easier to target.
- **The lower alarm limit** generally needs to extend somewhat below the lower SpO_2 chosen as the intention to treat. It must take into account practical and clinical considerations, as well as the steepness of the oxygen saturation curve at lower saturations. It is suggested that the low alarm for extremely low birth weight infants be set no lower than 85% (86-87% may also be appropriate)
- **The upper alarm limit s**hould not be higher than 95% for extremely low birth weight infants while the infant remains on supplemental oxygen.
- ROP and other morbidities can be exacerbated by hyperoxemia. For example, at 5 years of age, motor impairment, cognitive impairment and severe hearing loss are 3 to 4 times more common in children with than without severe ROP.

Based on these considerations, there is a need to introduce clinical measures at all institutions caring for newborn infants to close the gap between knowledge and practice. The lack of a systematic approach to prevent hypoxia and hyperoxia significantly affects patient safety, quality, and cost of care. Closing the performance gap will require hospitals, healthcare systems and all members of the neonatal health care team (RN's, RT's and MD's) to commit to action in the form of specific leadership, practice, and technology plans to improve safety for newborn infants who require oxygen supplementation.

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[28] Castillo, A., Deulofeut, R., Critz, A., & Sola, A. (2011). Prevention of retinopathy of prematurity in preterm infants through changes in clinical practice and SpO2 technology. Acta Paediatrica, 100(2), 188-192.

Leadership Plan

- Implement a plan that includes fundamentals of change outlined in the National Quality Forum safe practices, including awareness, accountability, ability, and action.[29]
- Hospital governance and senior administrative leadership commit to become aware of this major performance gap in their own healthcare system.
- Hospital governance, senior administrative leadership, and clinical/safety leadership close their own performance gap by implementing a comprehensive approach to addressing the performance gap.
- Set a goal date to implement the plan to address the gap with measurable quality indicators - "Some is not a number. Soon is not a time."[30]
- Allocate a budget for the plan to be evaluated by governance boards and senior administrative leaders.
- Clinical/safety leadership endorse the plan and drive implementation across all providers and systems.
- Collect data and perform analysis to be used for implementation and assessment of outcomes.
- Address and readdress two questions for quality improvement and to address gaps: Are we doing the right things? Are we doing things right?

Practice Plan

- Make an organization-wide commitment by administrative, clinical, and patient engagement leaders to address neonatal patient safety related to oxygen administration.
- Assess opportunities to improve oxygen administration and monitoring for the prevention of adverse events due to lack or excess of oxygen.
- Implement interdisciplinary strategies and develop an action plan with a timeline with concrete milestones to implement an optimal oxygen guideline for neonates.
    - The SpO_2 for a preterm baby breathing supplemental oxygen should not exceed 95%.
    - The SpO_2 for other larger infants and neonatal patients should stay in the range of 88-95 or 90-96% depending on infant and condition.
    - When the saturation or SpO_2 dips below 88%, avoid a response that would induce hyperoxia, or high saturation.
    - In order to accomplish this, the monitor alarms should always be on and active when an infant is breathing supplemental oxygen or in the neonatal intensive care unit..
    - The high SpO_2 alarm should be set to 95%, depending on the infant. The low SpO_2 alarm should be set to 85%.
    - Alarms signaling should receive attention from the nurse/doctor/respiratory therapist.
    - When a baby is not breathing supplemental oxygen but is being monitored for desaturations, the low SpO_2 alarm should be set at 85% and the high alarm can be turned off.
- Implement your action plan for including educational activities, workshops, and tools for all members of the neonatal healthcare team.
- Develop a process for continuous improvement by communicating with staff and implementing measures to improve processes in order to meet the oxygen targeting objective.

[29] National Quality Forum. (2010). Safe practices for better healthcare–2010 update. Retrieved from: http://www.qualityforum.org/publications/2010/04/safe_practices_for_better_healthcare_%E2%80%93_2010_update.aspx

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Technology Plan

Suggested practices and technologies are limited to those proven to show benefit or are the only known technologies with a particular capability. As other options may exist, please send information on any additional technologies, along with appropriate evidence, to info@patientsafetymovement.org.

- Select technologies that have been shown to improve neonatal outcomes, including but not limited to: blenders, pulse oximetry, and heated humidifiers.
    - Use blenders in all circumstances when administering oxygen, including the delivery room.
        - Bird, Carefusion, Precision Medical's low-flow and high-flow oxygen-air blenders
    - Use heated humidifiers when using CPAP and in all circumstances where the infant is intubated, even for a few minutes.
        - Fisher & Paykel
    - Consider using heated humidifiers in the delivery room.
    - For pulse oximetry, select equipment that:
        - a) can measure through motion and low perfusion conditions to avoid inaccurate measurements/false alarms and identify true alarms;
        - b) is proven effective for neonatal oxygen targeting.
            - Masimo Signal Extraction Technology (SET) pulse oximetry (until another technology is proven to be equivalent)

Metrics

Topic:

Neonatal Oxygen Targeting actively addresses the administration and monitoring of oxygen in newborn infants to prevent both hypoxia and hyperoxia.

Outcome Measure:

Percent of time (unit of measure: shifts, days, weeks or months) neonatal patients on supplemental oxygen are outside of the SpO_2 range or intention to treat, as defined in the NICU protocol.

Metric Recommendations:

Indirect Impact:

All neonatal patients that received supplemental oxygen

Direct Impact:

The percent of time that neonatal patients that received supplemental oxygen are kept within the accepted SpO_2 range.

Data Collection:

One approach could be at minimum, random sampling of 3-4 babies on supplemental oxygen on different shifts during one week each month. Nursing shifts range from 6 up to 12 hours across the world and nurse to patient ratios are also variable. For this reason, the data collection method should be tailored by hospital, and by unit.

Lives Spared Harm for neonatal patients on supplemental oxygen:

Percent of time outside of desired SpO_2 range (%) $_{\text{baseline}}$ [Median & Mean] – Percent of time outside of optimal SpO_2 range (%) $_{\text{after APSS implementation}}$ [Median & Mean]

Rate of severe ROP before implementation of this APSS compared to Rate of ROP 12 months after its implementation.

Workgroup

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Revision History

Version	Primary Author(s)	Description of Version	Date Completed
Version 1	Augusto Sola, Paul Jansen	Initial Release	January 2013
Version 2	Annamarie Saarinen, Jim Bialick, Paul Jansen, Ariana Longley, Augusto Sola	Workgroup Review	January 2016
Version 3	Augusto Sola, Michael Ramsay, Steven Barker, Paul Jansen, Joe Kiani, Ariana Longley	Executive Review	May 2016
Version 4	Augusto Sola, Ariana Longley, Steven Barker, Mitchell Goldstein, Michael Ramsay, Joe Kiani	Workgroup and Executive Review	January 2016

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Actionable Patient Safety Solution (APSS) for #7B:
FAILURE TO DETECT CRITICAL CONGENITAL HEART DISEASE (CCHD) IN NEWBORNS

Executive Summary Checklist

Congenital Heart Disease (CHD) is one of the most common types of birth defects. Critical Congenital Heart Disease (CCHD), including ductal-dependent lesions, represents 40% of death caused by CHD. CCHD is life threatening and typically takes place during the first year of infancy. Early intervention of CCHD is imperative and remains an important clinical challenge. Due to the absence of physical signs and difficulties in screening mild cyanosis in newborns, a third of babies are discharged unchecked. A fetal anomaly scan can identify increased structural abnormalities and proportions, however this detailed ultrasound is operator-dependent and highly inconsistent. Pulse oximetry screening is a universally accepted test that increases overall detection of CCHD to over 90% and identifies babies with non-cardiac, hypoxemic conditions such as congenital pneumonia, early-onset sepsis, and pulmonary hypertension.

To address the failure to detect CCHD in newborns, we should implement the following actionable steps:

- ▢ Make an organization-wide commitment to implement a universal pulse oximetry screening program for newborns.
- ▢ Develop an action plan to immediately implement a universal pulse oximetry screening program.
    - Select technology proven to be effective for newborn screening. *The technology must monitor and accurately read through during motion and low perfusion.* Masimo Signal Extraction Technology (SET) pulse oximetry (until another technology is proven to be equivalent)
    - Determine the screening protocol
        - Age at screening: >24 hours or prior to discharge
        - Obtain pulse oximetry measurements from preductal (right hand) and postductal (either foot) sites
        - Screening results which will be considered positive and require further investigation
            - ➢ SpO_2 <90% from any site; or
            - ➢ SpO_2 <95% from the right hand or either foot
                - If initial SpO_2 measurement is <95%, proceed with up to two additional SpO_2 measurements.
                - If the second and third SpO_2 measurements read >95% the screening is **negative**.
                - If the second and third SpO_2 measurements are <95% the screening is **positive**.
            - ➢ >3% difference in SpO_2 measurements between the right hand and either foot (repeat three times as described in the bullet above)
    - Additionally, if Perfusion Index (PI) <0.7 that should increase the need for assessment of the baby (if <0.4 the baby should be immediately assessed)
    - Educate clinical staff on proper screening, strategies for family education and engagement, follow-up protocols for positive screens, and results reporting policy
- ▢ Develop a process for continuous improvement by educating and communicating with staff and implementing measures to improve processes in order to meet the universal newborn screening objective.

The Performance Gap

Congenital heart disease (CHD) is the most common birth defect, affecting approximately 8 in 1,000 live born infants.[1,2] Nearly 40,000 infants are born with CHD per year in the US; and 1.35 million globally.[3,4] Critical congenital heart disease (CCHD), including ductal dependent lesions, affects between one-quarter and one-third of these infants.[5,6,7] CCHD represents about 40% of the deaths from congenital anomalies and the majority of the deaths due to CHD that occur in the first year of life.[3]

Antenatal ultrasound and physician examination after birth improve detection and perinatal outcomes for certain forms of CCHD.[8,9] Recent evidence shows that prenatal detection has been increasing every year (2006-2012); prenatal detection now occurs in 34% of patients.[10] The benefit of a CCHD diagnosis before birth allows for counseling and coordination of delivery at an experienced cardiac center.

The gap in patient safety is that more than 30 percent of CCHD deaths have been attributed to late or missed diagnosis.[11] It is estimated that 2,000 infants/year die or are undiagnosed in the US and some 300,000 infants/year die globally.[12] The burden of undiagnosed cases in the developing world is significant, with less than half of CHD cases diagnosed in the first week of life.[13] Several publications address these issues.[1415,16,17,18,19,20,21]

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[1] Bernier, P. L., Stefanescu, A., Samoukovic, G., & Tchervenkov, C. I. (2010, December). The challenge of congenital heart disease worldwide: Epidemiologic and demographic facts. In Seminars in Thoracic and Cardiovascular Surgery: Pediatric Cardiac Surgery Annual (Vol. 13, No. 1, pp. 26-34). WB Saunders.

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[3] Hoffman, J. I., & Kaplan, S. (2002). The incidence of congenital heart disease. Journal of the American college of Cardiology, 39(12), 1890-1900.

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[10] Quartermain, M. D., Pasquali, S. K., Hill, K. D., Goldberg, D. J., Huhta, J. C., Jacobs, J. P., ... & Ungerleider, R. M. (2015). Variation in prenatal diagnosis of congenital heart disease in infants. Pediatrics, 136(2), e378-e385.

[11] Chang, R. K. R., Gurvitz, M., & Rodriguez, S. (2008). Missed diagnosis of critical congenital heart disease. Archives of Pediatrics & Adolescent Medicine, 162(10), 969-974.

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[15] de- Wahl Granelli, A., Meberg, A., Ojala, T., Steensberg, J., Oskarsson, G., & Mellander, M. (2014). Nordic pulse oximetry screening–implementation status and proposal for uniform guidelines. Acta Paediatrica, 103(11), 1136-1142.

Pulse oximetry noninvasively measures oxygen saturation (SpO_2) and pulse rate. In 2009, de-Wahl Granelli et al published a breakthrough cohort study in which 39,821 infants were screened for CCHD by identifying abnormal SpO_2 measurements from Signal Extraction Technology (SET) pulse oximetry, which was chosen for its ability to measure through motion and low-perfusion.[22] In a separate CCHD screening study of 20,055 asymptomatic newborns, Ewer et al, confirmed the importance of utilizing SET technology of the appropriate size and specifications that can "produce accurate saturations that are stable in active neonates and in low perfusion states, making them suitable for use in the first few hours of a newborn baby's life."[23] In 2014, Zhao et al reported similarly positive results from a prospective study using SET in more than 100,000 newborns in China.[24]

The addition of pulse oximetry screening to antenatal ultrasound and physical examination may increase detection rates for CCHD to over 90%. Furthermore, the detection of non-critical CHDs and significant non-cardiac neonatal conditions, such as respiratory problems or early-onset sepsis, is reported as an additional benefit. However, clinicians need to be aware that, although combining pulse oximetry screening with other screening methods will reduce this diagnostic gap, some babies will still be missed. The Journal of Pediatrics has published a study estimating the number of infants with critical congenital heart defects (critical CHDs) potentially detected or missed through universal screening for critical CHDs using pulse oximetry.[25] CDC researchers estimated that about 1,755 infants with critical CHDs would be diagnosed late (meaning on or after the third day after birth). Of these, about half (875 infants) with a critical CHD would be detected through newborn screening using pulse oximetry, but an equal number (880 infants) might still be missed each year in the United States.

Most studies report that the lesions most often missed are those causing obstruction to aortic outflow (e.g. coarctation and interrupted arch), which may not necessarily be detected in antenatal ultrasound, physical examination, or by abnormal SpO_2 values from pulse oximetry. However, an additional SET pulse oximetry measurement may increase detection of CCHD with obstructions to aortic outflow. This measurement is called perfusion index (PI), which is an assessment of strength of perfusion at the monitored site. In a 2007 study, Granelli showed that adding abnormal PI to pulse oximetry screening may increase sensitivity to identifying CCHD with an obstruction to the aortic outflow. The authors of this study also noted that adding PI to the screening criteria may also result in an increase in false positives.

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In 2011, the federal CCHD workgroup, with members selected by the US Health and Human Services Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, the American Academy of Pediatrics, the American College of Cardiology Foundation, the Newborn Foundation, the March of Dimes, and the American Heart Association, developed a report: Strategies for Implementing Screening for Critical Congenital Heart Disease.[26] After a thorough review, the workgroup relied upon a thorough body of evidence and independent published studies to recommend that "screening be performed with motion tolerant pulse oximeters that report functional oxygen saturation, have been validated in low-perfusion conditions, have been cleared by the FDA for use in newborns, and have a 2% root mean-square accuracy."

Several domestic and international studies have shown parents are predominantly satisfied with pulse oximetry screening and those whose babies had a false positive result were no more anxious than those with true negative tests.[27] Parents generally perceived it as an important and valuable test to detect ill babies. Additionally, all staff groups (healthcare assistants, midwives, nurses and doctors) were predominantly positive about the testing procedure and perceived the test as important.

Screening for CCHD not only reduces pain and suffering of infants and families but can also reduce costs associated with severe cardiovascular and other organ or neurological compromise upon delayed admission to a cardiac unit – and has been tied to significantly reduced mortality, fewer poor surgical outcomes, and lower incidence of prolonged ventilation and potential developmental issues.[28]

Relative to the developing world, the prevalence of certain heart lesions varies significantly on the global map, as does the burden of hypoxemia-related conditions such as neonatal pneumonia, sepsis, necrotizing enterocolitis (NEC), and PPHN.[13] Every year nearly 41% of all under-five child deaths are among newborn infants, babies in their first 28 days of life or the neonatal period.[29] Three quarters of all newborn deaths occur in the first week of life, and 1/3 of these newborn deaths are from infection, such as pneumonia, tetanus, and sepsis.[30] Each of these conditions are likely to manifest with below normal oxygen saturations. Some are preventable deaths in that when diagnosed in a timely fashion, a course of antibiotics and/or supplemental oxygen therapy can save a life or improve an outcome.

Considerations regarding algorithms for screening

A recent review describes the experience of CCHD screening in the United States in reference to optimizing the algorithm for screening, educating all stakeholders and performing screening using the proper equipment.[30] There are many factors to consider when determining the optimal screening algorithm, including the balance of sensitivity and specificity, resource utilization, cost, high altitude and timing of screening. For this reason, other screening protocols have been evaluated in the United States and in other countries.[31,32]

For this reason, other screening protocols have been evaluated in the United States and in other countries. For example, infants at high altitude may have a lower oxygen saturation than those at sea level with potential implications at elevations

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over 6,800 feet. Therefore, to identify the optimal algorithm in particular settings, it may be necessary to modify the screening protocol described in this document, including the saturation cutoff points and the timing of screening.

A certain degree of controversy still remains, and debate continues regarding the most appropriate time to screen, the most effective screening pathway, what saturations are acceptable, which conditions are we trying to identify and screening outside the well-baby nursery.

When evaluating algorithms, it is important to consider sensitivity, specificity, and false-positive and false-negative rates. It is also vital that screening leads to timely diagnosis (ie, before presentation with acute collapse).

- The screening should be pre-and post-ductal as analysis of raw saturation data from infants who had both limb measurements shows that some infants with CCHD would be missed by postductal testing alone.
- False-positive rate is significantly higher with earlier testing (<24 hours). This led to recommendations that screening be performed after 24 hours of age.
- However, analysis of recent studies shows that many false-positive tests (30%–80%) have alternative non-cardiac conditions (eg, congenital pneumonia, early-onset sepsis, or pulmonary hypertension), which may be equally as life threatening as CCHD if diagnosed late.
- In published studies that adopted earlier screening (< 24 hours) the false-positive rate was higher, but more non-cardiac disease was identified.
- In some countries, mothers and infants are discharged from hospital within 24 hours after birth, and an increasing proportion is born at home. In these circumstances, screening in hospital > 24 hours is not practical.
- Additionally, infants at high altitude may have a lower oxygen saturation than those at sea level with potential implications for screening for CCHD at elevations over 6,800 feet. Therefore, to identify the optimal algorithm in particular settings, it may be necessary to modify the screening protocol described in this document, including the saturation cutoff points and the timing of screening.

Be all this as it may, if SpO_2 is < 90% in either limb the infant needs to be assessed immediately. If SpO_2 is between 90-94% in one or both limbs and the infant does not look completely healthy, clinical assessment is mandatory without delays for repeated measurements. If infant is completely healthy, measurement should be repeated as described. Finally, there is no need to do an echocardiogram immediately, as many babies with positive screening do not have CCHD.

In summary, the lack of a systematic approach to prevent failure to rescue in CCHD significantly affects patient safety, quality, and cost of care. Universal newborn screening with pulse oximetry technology has been shown to increase the detection of CCHD by identifying potential abnormalities that are not apparent in prenatal or postnatal examinations. Closing the performance gap with CCHD will require hospitals, healthcare systems and all members of the neonatal health care team (RN's, RT's and MD's) to commit to action in the form of specific leadership, practice, and technology plans for all newborn infants.

Leadership Plan

- Implement a plan that includes fundamentals of change outlined in the National Quality Forum safe practices, including awareness, accountability, and action.
- Hospital governance and senior administrative and medical and nursing leadership commit to become aware of this major performance gap in their own healthcare system.
- Hospital governance, senior administrative leadership, and clinical/safety leadership close their own performance gap by implementing a comprehensive approach to addressing the performance gap
- Set a goal date to implement the plan to address the gap with measurable quality indicators.
- Allocate a budget for the plan to be evaluated by governance boards and senior administrative leaders.
- Clinical/safety leadership endorse the plan and drive implementation across all providers and systems.
- Conduct data collection and analysis to be used for implementation and assessment of outcomes.

Practice Plan

- Evaluate guidelines[15,26,27] and reviews[16-20] and choose a screening strategy that, when implemented, is in compliance with processes described and technology used in well-designed, large published studies.[21,23-25]
- Develop an action plan with a timeline with concrete milestones to implement universal newborn screening.
    - Select technology proven to be effective for newborn screening
        - Use SET pulse oximetry screening strategy[15-21,23-27]
    - Determine the screening protocol
        - Age at screening: >24 hours or prior to discharge
        - Obtain pulse oximetry measurements from preductal (right hand) and postductal (either foot) sites
        - Screening results which will be considered positive and require further investigation[27]
            - ➢ SpO_2 <90% from any site; or
            - ➢ SpO_2 <95% from the right hand or either foot
                - If initial SpO_2 measurement is <95%, proceed with up to two additional SpO_2 measurements.
                - If the second and third SpO_2 measurements read >95% the screening is **negative**.
                - If the second and third SpO_2 measurements are <95% the screening is **positive**.
            - ➢ >3% difference in SpO_2 measurements between the right hand and either foot (repeat three times as described in the bullet above)
    - Additionally, if Perfusion Index (PI) <0.7 that should increase the need for assessment of the baby (if <0.4 the baby should be immediately assessed)
- Implement interdisciplinary strategies and educational activities for all members of the neonatal healthcare team
    - Proper screening methods
    - Strategies for family education and engagement
    - Follow-up investigation protocols for positive screens
    - Public health results reporting policy
- Implement optimization and workflow guidelines to ensure performance of adequate screening.
    - As a quality indicator, each week randomly assess the number of babies that have should have been screened but were not. Communicate with staff and, based on results, implement measures to improve processes in order to meet the goal of screening all newborns. Utilize clinical decision support tools and software whenever available to avoid misinterpretation or screening results or faulty data entry
- Report screening results per state and federal requirements

Technology Plan

Suggested practices and technologies are limited to those proven to show benefit or are the only known technologies with a particular capability. As other options may exist, please send information on any additional technologies, along with appropriate evidence, to info@patientsafetymovement.org

- Select pulse oximetry technologies have proven to be effective in helping clinicians screen for CCHD.
    - Signal Extraction Technology (SET) measure-through motion and low perfusion pulse oximetry[21,23-25] (until another technology is proven to be equivalent)
    - SET pulse oximetry is available in:
        - Standalone monitors (Rad-5, Rad-57, Radical-7, Rad-87)
        - Integrated in over 100 devices from over 50 companies including Atom, Drager, Fukuda Denshi, GE, Mindray, Nihon Koden, Philips, Spacelabs, and Welch Allyn.
- Consider utilizing a device that reduces operator induced-variability and improves efficiency by automating the screening steps, measurement selection, application of the measurements to the screening criteria chosen by the hospital, and categorization of the test as a positive or negative screen
    - Eve® app on the Radical-7 (note this device CE Marked but has not received U.S. FDA 510k)
- Consider utilizing public health reporting systems for newborn screening
    - Such as Oz® Systems newborn screening or automated reporting with Oz® BabyBundle

Metrics

Topic:

Critical Congenital Heart Defects (CCHD) is the number of patients identified with CCHD through technology-enabled newborn screening. The rate is the reflection of the number of patients diagnosed with CCHD over the total number of infants screened.

Outcome Measure Formula:

Numerator: Number of newborns identified with CCHD
Denominator: Number of patients screened

Metric Recommendations:

Indirect Impact:

All newborns that received technology-enabled newborn screening as identified through medical record

Direct Impact:

All infants who received newborn detection of CCHD via technology-enabled newborn screening

Lives Spared Harm:

Number of asymptomatic infants identified with CCHD through pulse oximetry or echocardiogram and received successful clinical intervention.

Years of Potential Life Saved
Those infants saved multiplied by average life expectancy.

Data Collection:

Both the numerator and denominator data could be collected from the medical record.

Mortality (will be calculated by the Patient Safety Movement Foundation):

Prenatal detection of CCHD has been shown to improve surgical outcome reducing neonatal morbidity and mortality,[8-10] supporting findings of neonatal studies that early detection has impact on the clinical results and morbidity and mortality rates. The Patient Safety Movement Foundation will use the mortality rates associated with the findings published in 2013 by Oster et al.[22] The Oster study found that the one-year survival of newborns screened by pulse oximetry after 24 hours of age was 82.5%. Based on these data the mortality rate of 17.5% will be used.

Workgroup

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Revision History

Version	Primary Author(s)	Description of Version	Date Completed
Version 1	Augusto Sola, Paul Jansen	Initial Release	January 2013
Version 2	Annamarie Saarinen, Augusto Sola, Rene Cortes, Paul Jansen, Alex Kemper, Anne Granelli, Ariana Longley, Jim Bialick	Workgroup Review	January 2016
Version 3	David Mayer, Michael Ramsay, Paul Jansen, Joe Kiani, Ariana Longley	Executive Review	April 2016
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