Actionable Patient Safety Solution (APSS) #7:
SUB-OPTIMAL NEONATAL OXYGEN TARGETING

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Executive Summary Checklist

Hypoxia in pre-term infants can result in mortality. Supplemental oxygen administration helps avoid hypoxia but hyperoxia can cause retinopathy of prematurity and increase risk for other conditions. Implementing an optimal oxygen targeting policy 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 policy for neonates.

☐ Select technologies that have been shown to improve neonatal outcomes, including but not limited to: blenders, pulse oximetry, and heated humidifiers.

☐ Determine the oxygen targeting policy that healthcare providers should implement:
  ☐ The SpO₂ for a pre-term baby breathing supplemental oxygen should not exceed 95%.
  ☐ The SpO₂ 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 SpO₂ 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.
  ☐ The high SpO₂ alarm should be set to 95%, depending on the infant. The low SpO₂ alarm should be set to 85%.
  ☐ Alarms signaling should receive attention from the nurse/doctor.
  ☐ When a baby is not breathing supplemental oxygen but is being monitored for desaturations, the low SpO₂ 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 and for this reason hypoxia should be avoided. However, 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 not recognized in newborn patients and cannot be fully eradicated. However, evidence shows that eliminating inappropriate oxygen administration and increasing the use of oxygen monitoring can lead to significantly decreased rates of these preventable conditions (7,8).\(^7\)\(^8\)

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 improvement in the quality and safety of healthcare as well as cost savings.\(^9\)

Hospital practices for oxygen monitoring are variable with many delivery rooms and neonatal intensive care units worldwide adhering to outdated or otherwise inappropriate protocols. Even though several studies have shown that excessive oxygen administration during the first few minutes of life is noxious 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,

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there is an opportunity to prevent many adverse effects through education on appropriate oxygen management and dosing approaches, such as the measurement of oxygen dose 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 competing pulse oximetry, both centers simultaneously changed their neonatal oxygen targeting policy, and one of the centers switched to Signal Extraction 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.

Additional studies have shown there was neither increased mortality nor serious brain injuries as a result of avoiding hyperoxia in preterm infants.15,16,18 Additionally, a recent large study found no significant differences in the composite outcome of death or neurodevelopmental impairment among extremely premature infants randomly assigned to a lower target oxygen-saturation range (85 to 89%) or higher target SpO₂ range (91 to 95%).19 However, recent randomized prospective trials have shown that targeting SpO₂ at less than 90% increases mortality rate, and therefore targeting SpO₂ to 85-89% should be avoided.19,20,21 However, several issues that suggest extreme caution with the findings of these reports

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20 Castillo A, Sola A. 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. 2008 May;121(5):882-9
have been published in peer reviewed journals.\textsuperscript{22,23,24} Additionally, narrow ranges are difficult to be maintained for more than 50-60\% of the time.\textsuperscript{13,25} To date the “perfect” SpO\textsubscript{2} target range is still not known for all newborns at all times.\textsuperscript{26,27} The appropriate SpO\textsubscript{2} range for an individual infant will depend on the type of SpO\textsubscript{2} monitors used, gestational age, postnatal age, and the clinical diagnosis and severity of the condition.\textsuperscript{28} Despite this variability, it is clear that in order to improve clinical outcomes some clinical practices must be eradicated and replaced with protocols of clinical care aimed to avoid both hyperoxia and hypoxia by avoiding sub-optimal neonatal oxygen targeting.

In summary, 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. To close 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.

**Leadership Plan**

- Implement a plan that includes fundamentals of change outlined in the National Quality Forum safe practices, including awareness, accountability, ability, and action.\textsuperscript{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.”\textsuperscript{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

\textsuperscript{26} Castillo A, Sola A. 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. 2008 May;121(5):882-9.
\textsuperscript{27} Saugstad OD. Why are we still using oxygen to resuscitate term infants? J Perinatol. 2010; 30(546-50).
\textsuperscript{29} NQF Safe Practices for Healthcare. 2010 Update.
• 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 policy for neonates.
   ☐ The SpO₂ for a pre-term baby breathing supplemental oxygen should not exceed 95%.

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   ☐ When a baby is not breathing supplemental oxygen but is being monitored for desaturations, the low SpO₂ 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.

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@patientsafetysummit.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.
• Use heated humidifiers when using CPAP and in all circumstances where the infant is intubated even for a few minutes.
• 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) is proven effective for neonatal oxygen targeting.
  o Signal Extraction Technology (SET) pulse oximetry

**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 SpO₂ 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 SpO₂ 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 SpO₂ range (%) \_\_\_baseline \_\_\_Median & Mean \_\_\_ – Percent of time outside of optimal SpO₂ range (%) \_\_\_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

**Chair:**

Augusto Sola, MD, Vice President of Medical Affairs for Neonatology, Masimo

**Members:**

Jim Bialick, President, Patient Safety Movement Foundation  
Paul Jansen, Executive Vice President of Business Development, Masimo  
Ariana Longley, MPH, Deputy to the President, Patient Safety Movement Foundation  
Annamarie Saarinen, Co-founder and CEO, Newborn Foundation

**Metrics Integrity:**

Nathan Barton, Statistical Data Analyst, Intermountain Healthcare  
Robin Betts, RN, Assistant Vice President of Quality and Patient Safety, Intermountain Healthcare  
Jan Orton, RN, MS, Clinical Operations Data Manager, Intermountain Healthcare

### Revision History

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<th>Primary Author(s)</th>
<th>Description of Version</th>
<th>Date Completed</th>
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<tr>
<td>Version 1</td>
<td>Augusto Sola, Paul Jansen</td>
<td>Initial Release</td>
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<tr>
<td>Version 3</td>
<td>Augusto Sola, Michael Ramsay, Steven Barker, Paul Jansen, Joe Kiani, Ariana Longley</td>
<td>Executive Review</td>
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