Balancing the Tension Between Hyperoxia Prevention and Alarm Fatigue in the NICU

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\textbf{abstract}

**BACKGROUND:** After the implementation of narrowed oxygen saturation alarms, alarm frequency increased in the C.S. Mott Children’s Hospital NICU which could have a negative impact on patient safety. The Joint Commission on the Accreditation of Healthcare Organizations issued a Sentinel Event Alert for hospitals in 2013 to improve alarm safety, resulting in a 2014 National Patient Safety Goal requiring institutional policies and procedures to be in place to manage alarms.

**METHODS:** A multidisciplinary improvement team developed an alarm management bundle applying strategies to decrease alarm frequency, which included evaluating existing strategies and developing patient care–based and systems-based interventions. The total number of delivered and detected saturation alarms and high saturation alarms and the total time spent within a targeted saturation range were quantitatively tracked. Nursing morale was assessed qualitatively.

**RESULTS:** SpO\textsubscript{2} alarms per monitored patient-day increased from 78 to 105 after the narrowing of alarm limits. Modification of the high saturation alarm algorithm substantially decreased the delivery and escalation of high pulse oxygen saturation (SpO\textsubscript{2}) alarms. During a pilot period, using histogram technology to individually customize alarm limits resulted in increased time spent within the targeted saturation range and fewer alarms per day. Qualitatively, nurses reported improved satisfaction when not assigned >1 infant with frequent alarms, as identified by an alarm frequency tool.

**CONCLUSIONS:** Alarm fatigue may detrimentally affect patient care and safety. Alarm management strategies should coincide with oxygen management within a NICU, especially in single-patient-bed units.

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The ECRI Institute defines alarm fatigue as a condition of sensory overload for staff members who are exposed to an excessive number of alarms.\textsuperscript{1} Excessive false alarms can lead to nursing desensitization\textsuperscript{2} and burnout,\textsuperscript{3} resulting in complacency toward alarm response,\textsuperscript{4} which can ultimately result in patient harm. The importance of alarm safety and management was publicized by a 2013 Sentinel Event Alert from the Joint Commission after 80 alarm-related deaths were directly reported in the Joint Commission database between 2009 and 2012\textsuperscript{5} and the Food and Drug Administration’s Manufacturer and User Facility Device Experience database reported 566 alarm-related deaths between 2005 and 2008.\textsuperscript{6} The Sentinel Event Alert called for hospitals to improve medical device alarm safety,\textsuperscript{7} resulting in the 2014 National Patient Safety Goal (NPSG), which states that institutional policies and procedures for alarm safety are to be in place by 2016\textsuperscript{8} (Fig 1).
Alarm frequency became a significant challenge in the C.S. Mott Children’s Hospital NICU at the University of Michigan during implementation of new oxygen management guidelines that focused on oxygen targeting to reduce severe retinopathy of prematurity (ROP). The guidelines included narrowing of oxygen saturation alarms measured by pulse oximetry (SpO2) to maximize time spent within a target range. Bedside SpO2 alarms and signals from our secondary alert notification system (SANS) escalated during initial evaluation. This increase in both primary and secondary alarms detrimentally affected nursing morale and created concern for patient safety, impeding further work on the original quality improvement (QI) effort to reduce ROP through oxygen targeting.

The goal of the QI effort described here was to identify and implement alarm management strategies that would reduce the burden of tightened alarms to levels commensurate with preintervention data. It was anticipated that attention to and improvement in alarm frequency would improve patient care by returning focus of patient care to oxygen targeting rather than alarm management.

METHODS
Setting
The level IV NICU consists of 46 single-patient rooms over 19 580 square feet of patient care space. Bedside cardiorespiratory monitoring is achieved by use of GE Solar 8000i monitors (GE Healthcare, Wauwatosa, Wisconsin) from time of admission through discharge. Default SpO2 alarm parameters were 80% to 97%, and the default averaging time was 16 seconds based on preexisting unit guidelines. A new institution-wide addition to workflow with the single-patient room layout was SANS technology through Connexall Middleware System (Globestar Systems, Toronto, Ontario, Canada), which escalates alarms detected at the bedside monitor to a nurse’s phone through a modifiable algorithm. The initial SANS escalation algorithm was based on benchmarking, opinion, and manufacturer recommendations (Fig 2A) and transmitted high saturation alarms, low saturation alarms, and low heart rate alarms through the same algorithm to the nurse’s phone after 20 seconds. An alarm was considered detected if the SpO2 value breached the set high or low parameter limits on the bedside monitor.

FIGURE 2
A. Original SANS escalation algorithm for high and low SpO2 and heart rate. If the bedside alarm is not acknowledged by the primary nurse within 40 seconds, it is escalated to a predetermined secondary nurse, and then to a backup team. B. Modified SANS escalation algorithm for high SpO2 only. The signal to the primary nurse was delayed by an additional 25 seconds to allow for autocorrection. The primary nurse now has 60 seconds to acknowledge the bedside alarm before escalation to the secondary nurse.
monitor. Institutional review board approval was not sought for this QI effort, as our focus was on activities (alarms) rather than human subjects, thereby not meeting the definition of human subjects research requiring institutional review board approval (per Code of Federal Regulations 45§46 and 21§56).

A multidisciplinary task force consisting of physicians, nurses, and respiratory therapists (dubbed the “Sat Pack”) reviewed results from randomized controlled trials on oxygen targeting. Among many changes, narrowed alarm parameters based on gestational age were adopted. SpO2 alarm frequency was a predetermined balancing measure, with prospective data collection of SpO2 alarms beginning in May 2012 and retrospectively available from December 2011. Informal staff education through e-mail began in February 2013, with formal training starting in April 2013. In May 2013, we conducted a small-scale pilot to study the impact and usability of the guidelines. Narrowed SpO2 alarm limits were introduced methodically to include more labile infants, allowing staff to garner skill in oxygen management strategies. Concerns regarding patient safety and nursing morale were voiced, along with a parent-voiced “near miss,” which redirected the team to shift focus to meet the urgent needs of alarm management and delay the unitwide implementation of the oxygen management guidelines until August 1, 2013.

Planning the Initiative

The Sat Pack expanded to include biomedical engineering and an information technologist. Patient care practices and systems/operational practices were determined to be key drivers of alarm frequency (Fig 3). Processes to affect these key drivers were identified, and appropriate measures were selected and modified to align with those recommended by the Joint Commission (Fig 1).

Patient Care Practices

1. Develop processes for safe alarm management and response. The Sat Pack guidelines included algorithms about when and how to respond to SpO2 alarms. Real-time support for staff regarding alarm safety was provided throughout the improvement process, and

![Alarm Management Driver Diagram](image)

**FIGURE 3**

Driver diagram of alarm management strategies demonstrating primary and secondary drivers and process measures. No changes were made to signal averaging time after initial assessment, so no process measure was identified.
safety reports were retrospectively reviewed for patient harm related to alarm strategies.

2. Tailor alarm settings for individual patients. Premature neonates are notorious for fluctuations in SpO\textsubscript{2}, and the ability to keep an infant’s SpO\textsubscript{2} within target range is variable\textsuperscript{10} (from 16% to 64% in 1 study\textsuperscript{11}). We theorized that the absolute number of alarms does not provide the quantitative data to determine the time spent above or below a certain target range, and that perhaps a better tool for targeting oxygen therapy existed. Histogram technology was identified as a possible tool, as it quantifies the time spent within, above, and below the prespecified target range\textsuperscript{10,12} (Adams KK, Goldstein M, Ninnis J, Hopper A, Deming D, unpublished observations) and provides visual display of this data. In September 2013, a pulse oximeter with histogram technology (Masimo Radical-7, Masimo Corp., Irvine, California) was piloted on 7 infants who were identified to have the most alarms. Histogram data were monitored by the care team at least every 4 to 8 hours. Individualized (usually broadened) saturation alarm limits were granted to patients who rarely required intervention for their alarms or who showed improved time within their target saturation range. The number of SpO\textsubscript{2} alarms and time spent within target range were collected at baseline and throughout the pilot. After the pilot, equipment resources allowed a maximum of 10 patients to be monitored with histogram technology at any point.

Technology Interventions

1. Ensure clear guidelines for alarm settings. Guidelines for alarm settings were standard practice in our NICU, and the Sat Pack modified them to incorporate gestational age and degree of respiratory support. Electronic order sets and nursing documentation were customized to ensure clarity during physician ordering and patient charting, respectively. Oxygen targets and alarms were displayed visually at the bedside and were expected to be reviewed daily during medical rounds. The daily review was informally audited by the Sat Pack and formalized in May 2014.

2. Incorporate alarm data in patient care assignments. Review of SpO\textsubscript{2} data showed that 10% of patients were responsible for >65% of alarms, providing a new measure of acuity for nursing assignments. The information technologist translated individual patient alarm frequency data into a “patient alarm barometer.” This barometer color-codes the number of SpO\textsubscript{2} alarms from a 24-hour period in a unitwide summary view. Charge nurses used this tool in constructing daily nurse-patient assignments, with instructions to avoid pairing patients having frequent alarms with the same nurse. The barometer was reviewed with the on-service medical teams during the daily multidisciplinary morning report. Nurse opinions and all provider opinions were surveyed to assess the utility of this tool in October 2013 and April 2014, respectively.

3. Evaluate and modify SANS escalation algorithms. Although both high and low SpO\textsubscript{2} are quantitatively associated with harm in vulnerable populations over time,\textsuperscript{7–9} the immediate need to decrease false alarms required careful consideration of the secondary notification system algorithms. Because low SpO\textsubscript{2} and heart rate changes can be immediately associated with poor patient outcome (ie, death), and because the intervals for escalation are arbitrarily determined, changes were first made to the high SpO\textsubscript{2} alarm escalation algorithm. Working with our information technologist, the algorithm for high saturation alarms was modified (Fig 2B). The total number of alarms detected at the bedside monitor and the number of alarms delivered through SANS were measured. Severe ROP was tracked as a balancing measure.

4. Evaluate signal averaging time on a primary monitor. Pulse oximeters average the detectable signal over time, and previous studies have shown that short averaging times result in more alarms but longer averaging times can result in falsely lengthened events, since an average of multiple short events may appear as 1 long event.\textsuperscript{13} An averaging time of 16 seconds was an existing alarm intervention, and small tests were made with different averaging times. We maintained the 16-second averaging time to prevent an unnecessary increase in alarms, and the importance of averaging time for bedside care providers in clinical decision making was included in educational materials.

Data Collection and Analysis

Alarm data were collected with the Connexall Middleware System and the data stored in a structured query language (SQL) server database (Microsoft, Redmond, Washington). Inbound alarm data were processed by redundant application components and archived to a SQL server database with data located on a storage area network. Data were extracted via standard SQL queries. Data presentation was achieved through a combination of Excel charts and SQL server reporting services.

Weekly alarm rates were rationally subgrouped (detection, escalation to secondary nurse, and escalation to regional team), then plotted on annotated control charts with QI-Charts version 2.0.22 (Process Improvement Products, Austin, Texas). Because large denominators...
created overdispersion in $u$ charts, $u$-prime ($u'$) charts were used when appropriate. Statistical process control was used, and natural break points were identified through special-cause variation using the 4 conventional rules. Thirty-five data points were used to establish baseline rates and initial control limits, during which time special-cause variation rules were not applied. After interventions began, if special-cause variation was sustained, mean lines were adjusted to reflect the new steady-state rates. Spurious signals (e.g., isolated data points outside the control limits in the absence of attributable causes) did not result in mean line adjustments. Alarm data were not case-mix adjusted to account for periods of higher and lower aggregate acuity in the NICU. For the purposes of this analysis, the alarm rates of 4 epochs were defined and analyzed: baseline period (August 26, 2012, to May 4, 2013: 36 weeks), narrowed SpO$_2$ period (May 5, 2013, to July 20, 2013: 11 weeks), revised escalation period (July 21, 2013, to February 22, 2014: 31 weeks), and histogram period (February 23, 2014, to August 16, 2014: 25 weeks) (Table 1), although the histogram intervention applied to only 20% to 25% of the unit census. Wilcoxon rank sum was used as appropriate to generate traditional $P$ values (StatCrunch, Integrated Analytics, Great Falls, Virginia).

Although not designed for statistical power, the number of alarms and percentage of time spent within the target range from the histogram technology pilot were compared by using a nonparametric repeated measures ANOVA (Friedman test) (GraphPad InStat, La Jolla, California). Nursing and physician opinions surrounding interventions were assessed in October 2013 and again in April 2014 using Qualtrics software (Qualtrics, Provo, Utah). The Sat Pack monitored and responded to patient safety concerns prospectively, and deidentified voluntary patient safety reports were retrospectively queried for reference to “alarm” and individually reviewed to determine whether resuscitation was required, and if so, the incident’s relevance to SpO$_2$ alarm management. The diagnosis of ROP was tracked through the Vermont Oxford Network that is queried quarterly for quality improvement review. ROP stages before and after narrowed limits (January 2012 to April 2013 and May 201 to October 2014, respectively) were compared using Wilcoxon rank sum to test for significance. Results

In a 32-month monitoring period, 3,459,637 saturation alarms were detected, and 9,031,344 total alarms were detected at the bedside monitor (Fig 4). Natural fluctuation in data is present and is attributed to unit acuity, patient characteristics, and compliance with alarm settings. The average number of SpO$_2$ alarms per monitored patient-day increased from 78 before narrowing of alarms to 105 after intervention. Informal discussions and education led to an initial increase in alarm frequency, followed by a sustained increase with the pilot of narrowed alarms (Fig 4). The modified SANS algorithm for high SpO$_2$ delivery resulted in an immediate and sustained decrease in the escalation of high SpO$_2$ alarms to nursing phones (Fig 5). Reorientation to histogram technology in early 2014 was temporally associated with a decrease in high SpO$_2$ alarms (Fig 5A). The histogram technology pilot for 7 patients resulted in a 7.2% maximum increase in time spent within the targeted saturation range and a maximum reduction of 120 alarms per monitored patient ($P = .13$ and $P = .34$, respectively). The pilot was not designed for statistical significance, but the staff reported that histogram technology was a helpful tool in oxygen targeting (Fig 6), even though we could only monitor one-quarter of the unit with this technology at any time point. The October 2013 survey showed that 94% of responding charge nurses reported the patient alarm barometer to be at least a somewhat helpful tool in directing nursing.

### Table 1: High SpO$_2$ Alarms and Escalations During Intervention Periods

<table>
<thead>
<tr>
<th>Monitor and Primary Registered Nurse</th>
<th>Escalation to Secondary Registered Nurse</th>
<th>Escalation to Team</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aggregate high SpO$_2$ alarms</td>
<td>633,338</td>
<td>22,768</td>
</tr>
<tr>
<td>Aggregate monitored patient-days</td>
<td>28,003</td>
<td>28,003</td>
</tr>
<tr>
<td>Aggregate alarm rate per monitored patient-day</td>
<td>22.69</td>
<td>0.81</td>
</tr>
<tr>
<td>Baseline alarm rate per monitored patient-day</td>
<td>16.78</td>
<td>0.95</td>
</tr>
<tr>
<td>Narrowed SpO$_2$ period alarm rate per monitored patient-day</td>
<td>38.64</td>
<td>2.19</td>
</tr>
<tr>
<td>Alarm rate change compared with baseline, %</td>
<td>131</td>
<td>132</td>
</tr>
<tr>
<td>$P$ compared with baseline rate</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Revised escalation period alarm rate per monitored patient-day</td>
<td>25.45</td>
<td>0.51</td>
</tr>
<tr>
<td>Alarm rate change compared with baseline, %</td>
<td>52</td>
<td>−46</td>
</tr>
<tr>
<td>$P$ compared with baseline rate</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Histogram period alarm rate per monitored patient-day</td>
<td>20.35</td>
<td>0.40</td>
</tr>
<tr>
<td>Alarm rate change compared with baseline, %</td>
<td>21</td>
<td>−58</td>
</tr>
<tr>
<td>$P$ compared with baseline rate</td>
<td>&lt;.033</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>
assignments, and 100% of fellows and attending physicians found it to be somewhat helpful in medical decision making on subsequent survey. Figure 6 displays the results of the multidisciplinary survey in April 2014 (n = 69) regarding attitudes and perceptions in alarm frequency, demonstrating that most respondents felt that alarm frequency had improved and alarm fatigue was being addressed.

Patient safety reporting identified no serious events requiring resuscitation secondary to alarm management. Although the study was not powered to detect the impact of narrowed SpO2 alarms on ROP at a single institution in this time period, these data were nevertheless reviewed. Reductions in incidence and severity were noted, although they did not meet statistical significance.

**DISCUSSION**

This report emphasizes the importance of selecting appropriate balancing measures for QI efforts. Alarm frequency was a predetermined balancing measure for the Sat Pack oxygen management guidelines, ultimately allowing the team to respond to increasing alarm frequency before full-scale implementation of the new guidelines. Measuring alarms also quantified the unfortunate burden of using pulse oximetry alarms as a tool for oxygen targeting. The number of pulse oximetry alarms is staggering, but pulse oximetry alarms are only 1 source of alarms in an intensive care setting, with additional signals coming from cardiac monitoring, respiratory support devices, and medication delivery devices. Because not all alarms require intervention, the sheer number of false alarms is of concern. False alarms contribute to alarm fatigue; it has also been demonstrated that as alarm reliability decreases, response to the alarms also decreases. Bliss and Dunn demonstrated that the reliability of the alarm system becomes more important in situations with increasing workload, which certainly has implications when caring for critically ill patients. Other reports have identified the number of false-positive alarms and inappropriately set alarms to be key factors in alarm desensitization.

Acknowledging that alarm management must be a collaborative effort among disciplines was a pivotal first step in this initiative. A cultural change was necessary throughout our unit, transitioning from excessive alarm frequency being solely a nursing concern to everyone taking ownership of the problem. It was only by engaging multiple diverse skill sets that we were able to develop strategies to address unnecessary alarm frequency.

We demonstrate the importance of determining key drivers of alarm frequency to develop improvement strategies. The development of clear strategies and guidelines for alarm settings and training of personnel can minimize alarms and was included in our Sat Pack guidelines. Gross et al emphasized the increasing need to customize alarm limits in health care facilities, as individualizing alarm thresholds has been shown to decrease alarms, resulting in less nursing distraction and alarm fatigue. By collaborating with our information technologists, we were able to maximize data collection to aid us in customizing the SpO2 alarm limits for some of our most challenging patients while still targeting specific SpO2 goals.

The goal for reduced hyperoxia/ROP can cause unintended secondary quality metrics to deteriorate (alarms), but this process can be mitigated and even improved with the modification of technology. We have shown that the modification of technology applications (ie, a secondary alert notification system delivery algorithm) can affect alarm frequency and that evaluation of equipment is essential to alarm system design. We have demonstrated the potential application of an alarm frequency monitoring tool to heighten awareness and engage multiple team members in the problem-solving effort of alarm management. Finally, our data support that individualization of alarms combined with histogram technology can
FIGURE 5
Three u’ control charts demonstrate high SpO₂ alarm rates, with steady-state means represented as solid lines and control limits as dashed lines. A (dots), alarms detected by the monitor, including those automatically sent to the primary nurse’s phone after a short delay. B (diamonds), subset of alarms from panel A that were delivered to a secondary nurse’s phone, either from automatic time delay or purposeful escalation by the primary nurse. C (triangles), subset of alarms from panel B that were escalated to the phones of the regional care team, either from automatic time delay or purposeful escalation by the primary or secondary nurse. Narrowed SpO₂ alarm criteria significantly increased detected alarms as well as alarms escalated to secondary nurses and broader teams. Redesign work on the alarm delivery and escalation algorithms maintained above-baseline high SpO₂ detection but reduced alarm escalations to below baseline rates.
contribute to decreasing alarm frequency and improved patient outcomes and staff satisfaction.

**Strengths**

This report provides numerical data to support the concerns raised by the Joint Commission. The ability to quantify the volume of alarms and use this data to test strategies for alarm system design improvement is unique. This initiative outlines potential alarm management strategies focused on both understanding and integrating technology and patient individualization that could aid other ICUs in complying with the 2014 NPSG. Our strategies heighten awareness of the potential risks associated with clinical alarms (NPSG phase 1) while also identifying different means to mitigate those risks (NPSG phase 2). The Joint Commission aims for health care facilities to identify which alarms need to be targeted for better management based on input from medical staff, the potential risks for patient harm if not appropriately attended, and which alarms contribute most significantly to unnecessary alarm frequency. In the NICU, saturation alarms were readily identified as the most appropriate alarms to be targeted owing to their frequency. Our alarm management strategies address how to determine clinically appropriate values for alarm limits, when to individualize settings, and how to monitor alarm frequency along with false-alarm frequency.

**Limitations**

The Sat Pack oxygen management guidelines and subsequent alarm management strategies are predicated on current best evidence for oxygen targeting that itself has controversies. After its development, pulse oximetry quickly became a standard of care in medicine, yet the application to mitigate morbidity and mortality has remained elusive. Results from recent oxygen targeting trials in extremely premature neonates further emphasize this point.

Acknowledging the effect of alarm settings on the time spent within the target range, we elected to use the SpO₂ alarm limits of 85% to 95% that were used in the Surfactant, Positive Pressure, and Oxygenation Randomized Trial (SUPPORT) as an initial step in narrowing our limits from 80% to 97%. A second limitation is that our auditing process for alarm and target compliance was informal and insufficient. We have since developed processes to better audit alarm compliance. Last, despite the strategies implemented to manage alarms, we have not achieved a full return to baseline (Fig 5). We believe that increased emphasis on oxygen targeting, application of histogram technology to a minority of the unit, and the process for alarm individualization contribute to this. Individualization of patient alarms is not an automated system, and it may take several days of evaluation and adjustments to set new limits, accumulating alarms in the meantime. Most importantly, providers believe that alarm management has improved in the NICU.

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**FIGURE 6**

Perception and attitudes of NICU nurses, respiratory therapists, nurse practitioners, and physicians in April 2014 regarding alarm frequency and interventions to improve alarm fatigue.
Future Directions

We are securing histogram technology for all patients. We anticipate that by standardizing the use of this technology, we will be able to better identify time within the target range and individualize alarm settings when needed, resulting in fewer overall alarms while maintaining target saturation goals.12 Our multidisciplinary improvement task force will continue to monitor alarm data as we return focus to the original QI efforts of reducing severe ROP. We are merging our oxygen management and alarm management guidelines to have a unified algorithm, emphasizing how the two are interdependent. We have identified and implemented several strategies in an initial phase to improve alarm frequency, but alarm management continues to be a struggle in our unit and will require future multidisciplinary collaborative efforts in addition to cultural practice changes to achieve significant quality improvement.

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ABBREVIATIONS

QI: quality improvement
ROP: retinopathy of prematurity
SANS: secondary alert notification system
SpO2: pulse oxygen saturation
SQL: structured query language

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