A Business & Clinical Case for Continuous Surveillance

Session 209, February 14, 2019

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John Zaleski, PhD, CAP, CPHIMS, Chief Analytics Officer, Bernoulli Health
Conflict of Interest

Leah Baron, MD

Principal investigator and clinical lead of study.
Conflict of Interest

John Zaleski, PhD

Employed by Bernoulli Health – developer and manufacturer of software & hardware for data capture employed in the study.
Agenda

- The Challenge
- Capnography for Continuous Monitoring
- The Pilot
- Alarm Fatigue
- IRB Study Findings
- Summary
Learning Objectives

• Identify the perioperative care challenges from technical, clinical, and workflow perspectives associated with monitoring and identifying patients either at-risk for or experiencing respiratory depression

• Analyze the use of continuous monitoring to detect potential signs of respiratory depression while differentiating non-actionable from actionable alarm signals, and understand the impact on clinical alarm fatigue

• Assess the creation and use of multivariate alarm signals using real-time data to generate more clinically actionable notifications to clinical staff

• Investigate the strategies, technologies and workflow processes required for continuous patient monitoring and remote patient surveillance in a general care floor setting

• Identify opportunities and challenges associated with scaling continuous patient monitoring and surveillance across the enterprise
Questions

• Please complete online session evaluation

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General Acknowledgement

What follows and the studies conducted could only have been performed with the contributions of multiple individuals and departments within the health system. The names are many, and roles include nursing and nurses aids, telemetry technicians, respiratory therapy, physicians, information technology, biomedical/clinical engineering, & vendors.
The Challenge

Improving patient safety for post-operative, at-risk patients
The Challenge

- Improving post-operative patient safety
  - Caring for increasingly complex, co-morbid patients
    - Bariatrics, joint replacements, etc.
    - Co-morbidities: apnea, COPD, diabetes, heart failure, etc.
- Improving clinical oversight of post-operative quality of care
  - Reduce incidents of Opioid-Induced Respiratory Depression (OIRD) on general care floor
- Seeking ways to improve clinical oversight of at-risk patients
  - Continuous surveillance of key parameters
  - Notification paradigm to clinical stakeholders
Background

Pain management in the post-operative general care environment
“Clinical deterioration on the general hospital wards is common ... all too often results in patients progressing to cardiopulmonary arrest, which carries significant morbidity and mortality…

“Surgical patients may be prone to cardiopulmonary arrest due to their underlying diseases (especially conditions such as obstructive sleep apnea and cardiac disease)…

“This is a major concern for anesthesia professionals who help determine if the patient is safe to go to an unmonitored floor or should request a monitored bed which may be a limited resource…

“…the frequency of vital sign acquisition on the wards may be insufficient to allow detection of clinical deterioration…

“…Electronic health records (EHRs) do little to improve this situation as their performance is dependent on the intermittently and sometimes inaccurately collected data points…”

“Surveillance monitoring may be a better way to collect and act on clinical data for a patient who is deteriorating on a general ward…

“…vital-sign data collection should be continuous, since use of intermittently collected data may miss early signs of deterioration.”

Carbon Dioxide Narcosis

• Up to 14% of patients using opioids suffer from respiratory depression. ¹

• 50% of CODE BLUE events involve patients who receive opioid analgesia ²

• Respiratory failure caused by acute hypercapnia can occur in a matter of minutes. ³

Postoperative Opioid-induced Respiratory Depression

A Closed Claims Analysis

Lorri A. Lee, M.D., Robert A. Caplan, M.D., Linda S. Stephens, Ph.D., Karen L. Posner, Ph.D.,
Gregory W. Terman, M.D., Ph.D., Terri Voepel-Lewis, Ph.D., R.N., Karen B. Domino, M.D., M.P.H.

ABSTRACT

Background: Postoperative opioid-induced respiratory depression (RD) is a significant cause of death and brain damage in the perioperative period. The authors examined anesthesia closed malpractice claims associated with RD to determine whether patterns of injuries could guide preventative strategies.

Methods: From the Anesthesia Closed Claims Project database of 9,799 claims, three authors reviewed 357 acute pain claims that occurred between 1990 and 2009 for the likelihood of RD using literature-based criteria. Previously cited patient risk factors for RD, clinical management, nursing assessments, and timing of events were abstracted from claim narratives to identify recurrent patterns.

Results: RD was judged as possible, probable, or definite in 92 claims ($\kappa = 0.690$) of which 77% resulted in severe brain damage or death. The vast majority of RD events (88%) occurred within 24 h of surgery, and 97% were judged as preventable with better monitoring and response. Contributing and potentially actionable factors included multiple prescribers (33%), concurrent administration of nonopioid sedating medications (34%), and inadequate nursing assessments or response (31%). The time between the last nursing check and the discovery of a patient with RD was within 2 h in 42% and within 15 min in 16% of claims. Somnolence was noted in 62% of patients before the event.

Conclusions: This claims review supports a growing consensus that opioid-related adverse events are multifactorial and potentially preventable with improvements in assessment of sedation level, monitoring of oxygenation and ventilation, and early response and intervention, particularly within the first 24 h postoperatively. (Anesthesiology 2015; 122:659-65)
A substantial number of preventable deaths and other adverse events are associated with opioid-induced ventilatory impairment (OIVI). In fact, opioids are the most common category of drugs prescribed in U.S. hospitals today and the second most common category (hormone and synthetic substitutes being the first) associated with serious patient adverse outcomes. While the exact incidence of OIVI in hospitals is difficult to quantify, one study suggested that it may occur in as many as 1 in 200 postoperative patients. Unfortunately, risk stratification and heightened awareness of risk factors does not identify all patients who develop postoperative OIVI.

The APSF’s mission is the ongoing improvement of patient safety through advancement of research, education, and quality improvement programs that stimulate ideas for positive safety change. As one step toward fulfilling that mission, the APSF has sponsored two multidisciplinary conferences: the first one in October 2006 in San Francisco and the most recent one in June 2011 in Phoenix. The Phoenix conference was titled, “Essential Monitoring Strategies to Detect Clinically Significant Drug-Induced Respiratory Depression in the Postoperative Period.” The premise of the conferences was summarized by the statement that, “No patient shall be harmed by opioid-induced respiratory depression in the postoperative period.” The consensus of the 136 conference participants was that continuous electronic monitoring should be utilized for postoperative patients receiving opioids. At that time, pulse oximetry was determined to be the most reliable and readily available monitor in those patients not receiving supplemental oxygen. In addition, if supplemental oxygen is being used, the consensus was to use monitors of gas exchange (i.e., capnography) to detect hypventilation. Although participating recognized that the lack of local resources may thwart universal continuous monitoring, they hoped to see a period when all patients receiving opioids would be monitored for OIVI. As part of its ongoing efforts in this area, the APSF developed an innovative educational video with real-life patient and family experiences involving OIVI (https://www.apsf.org/resources/oivi/). Experts in this field, with the support of APSF, have continued to promote the use of continuous electronic monitoring for those patients receiving postoperative opioids. In addition, several research projects involving OIVI have been funded by the APSF to advance this patient safety topic.
Monitoring for Opioid-Induced Respiratory Depression

by Rajnish K. Gupta, MD, and David A. Edwards, MD, PhD

interruption, interference with nursing workflow, and staffing expenditures. For postoperative patients, the first four hours after post-anesthesia care unit (PACU) discharge is the time period associated with the highest rates of sedation, and the first 12 hours after surgery are when over half of OIVI events occur. In addition, 75% of all OIVI events occur within the first 24 hours after surgery. Based on the timing of postoperative OIVI, a greater emphasis on monitoring the first 24 hours is likely to be helpful in reducing adverse events from opioids.

method of alerting health care professionals when these events occur must be addressed in order to ensure an effective system. Establishing an evidence-base of monitoring alerts that are useful for detecting OIVI is a critical need. Inadequately established alert thresholds lead to alarm fatigue, patient and staff irritation, and complacency; all of which can make even the most effective monitoring system completely ineffective in achieving the desired outcome. Ideally, monitoring systems should use multiple parameters in concert to detect whichever indicator of respiratory depression may arise first and employ combinations of measures to accurately identify an impending event. In the past, threshold alarms have been fairly simplistic and prone to error.
### Table 1. APSF Perioperative Patient Safety Priorities*

<table>
<thead>
<tr>
<th></th>
<th>Safety Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Preventing, detecting, and mitigating clinical deterioration in the perioperative period</td>
</tr>
<tr>
<td>2</td>
<td>Safety in non-operating room locations</td>
</tr>
<tr>
<td>3</td>
<td>Culture of safety</td>
</tr>
<tr>
<td>4</td>
<td>Medication safety</td>
</tr>
<tr>
<td>5</td>
<td>Perioperative delirium, cognitive dysfunction, and brain health</td>
</tr>
<tr>
<td>6</td>
<td>Hospital-acquired infections and environmental microbial contamination and transmission</td>
</tr>
<tr>
<td>7</td>
<td>Patient-related communication issues, handoffs, and transitions of care</td>
</tr>
<tr>
<td>8</td>
<td>Airway management difficulties, skills, and equipment</td>
</tr>
<tr>
<td>9</td>
<td>Cost-effective protocols and monitoring that have a positive impact on safety</td>
</tr>
<tr>
<td>10</td>
<td>Integration of safety into process implementation and continuous improvement</td>
</tr>
<tr>
<td>11</td>
<td>Burnout</td>
</tr>
<tr>
<td>12</td>
<td>Distractions in procedural areas</td>
</tr>
</tbody>
</table>

*Published on the APSF website: [https://www.apsf.org/patient-safety-initiatives/](https://www.apsf.org/patient-safety-initiatives/)
A critical assessment of monitoring practices, patient deterioration, and alarm fatigue on inpatient wards: a review

J Paul Curry* and Carla R Jungquist²

Abstract

Approximately forty million surgeries take place annually in the United States, many of them requiring overnight or lengthier post operative stays in the over five thousand hospitals that comprise our acute healthcare system. Leading up to this Century, it was common for most hospitalized patients and their families to believe that being surrounded by well-trained nurses and physicians assured their safety. That bubble burst with the Institute of Medicine’s 1999 report: To Err Is Human, followed closely by its 2001 report: Crossing the Quality Chasm. This review article discusses unexpected, potentially lethal respiratory complications known for being difficult to detect early, especially in postoperative patients recovering on hospital general care floors (GCF). We have designed our physiologic explanations and simplified cognitive framework to give our front line clinical nurses a thorough, easy-to-recall understanding of just how these events evolve, and how to detect them early when most amenable to treatment. Our review will also discuss currently available practices in general care floor monitoring that can both improve patient safety and significantly reduce monitor associated alarm fatigue.
Figure 3 RECC Type II pattern of respiratory dysfunction (CO₂ Narcosis).
Capnography for Continuous Monitoring (Virtua Project)

Ventilation monitoring using capnography to detect immediate changes in respiratory issues
Patient Assessment for Patients Receiving Narcotics

- Sedation Level
  - Use modified POSS
  - Monitor
    - q ½ hour x 2 on initiation of therapy
    - q 1 hour until stable as indicated by achievement of comfort
    - q 4 hours once stable

- Respiration Rate
  - count for a full minute
  - assess rhythm and depth of chest excursion
  - assess for pauses in breathing pattern

- Oxygenation: Pulse oximetry
  - Do not rely on pulse oximetry alone because pulse oximetry can suggest adequate oxygenation in patients who are actively experiencing respiratory depression, especially when supplemental oxygen is being used.

- Ventilation: Capnography
  - Measures carbon dioxide in the exhaled breath

Source: “Preparing to Use Capnography: Pre-Capnography Class Nursing Education September, 2013”
Difference Between Capnography & Pulse Oximetry

Important but Different Measurements

**Capnography**
- EtCO₂
- Reflects ventilation
- Hypoventilation and apnea detected immediately

**Pulse oximetry**
- SpO₂
- Reflects oxygenation
- Values lag with hypoventilation and apnea

“Cases of respiratory depression were 28 times as likely to be detected, if they were monitored by capnography, as those who were not monitored.”

“...end-tidal carbon dioxide monitoring is an important addition to oximetry for detecting respiratory depression...”

Source: “Preparing to Use Capnography: Pre-Capnography Class Nursing Education September, 2013”


Capnography Applications

Medical surgical units
- Monitoring patients who are receiving PCA or epidural opioid medications; detecting respiratory depression
- Aids in decision making for clinical staff

Procedural sedation
- Effectively monitors the patient’s airway providing the earliest indication of airway compromise

Critical care unit
- Detects apnea immediately, regardless of supplemental oxygen administration, and provides an earlier warning than pulse oximetry
- Provides a continuum of care of ventilation monitoring from intubated patients during mechanical ventilation to monitoring the weaning of the patient from the ventilator

Pre-hospital and emergency department
- Detects airway obstruction, ventilation problems, endotracheal tube placement and verification
- Provides continuous feedback on airway, breathing and ventilatory status for non-intubated patients

Source: “Preparing to Use Capnography: Pre-Capnography Class Nursing Education September, 2013”
Initial Rollout...2013

Employ capnography to detect opioid-related respiratory insufficiency in post-operative patients, using remote telemetry monitoring
Pilot Overview

• Description
  – 2 hospital sites Memorial and Marlton
  – 4NE, 4N
    – 2 weeks- Mon- Fri (controlled environment)
• Patient association in the PACU, via bar-coding
• Transferred patients to floor
• Remote monitoring to tele room for ~ 24 hours
• Disassociation in Central Processing
Initial Pilot Rollout

• Target population for capnography:
  – ≥ 60 YOA
  – Significant:
    • COPD
    • Heart Failure
    • Cardiomyopathy
    • Emphysema
    • $O_2$ – dependence
    • OSA presence
  – Concomitant use of CNS depressant meds (benzodiazepines)
  – Persistent hypoxemia
  – Patients requiring escalating doses of PCA, bolus or basal
  – Patients with known increased sensitivity to narcotics
  – Patients with history of chronic high doses of narcotics
  – Prolonged anesthesia times > 5 hours
# STOP-BANG CRITERIA

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>YES/NO</th>
</tr>
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<tbody>
<tr>
<td>S</td>
<td>(Snore) Have you been told that you snore?</td>
<td></td>
</tr>
<tr>
<td>T</td>
<td>(Tired) Are you often tired during the day?</td>
<td></td>
</tr>
<tr>
<td>O</td>
<td>(Obstruction) Do you know if you stop breathing or has anyone else</td>
<td></td>
</tr>
<tr>
<td></td>
<td>witnessed you stop breathing while you were asleep?</td>
<td></td>
</tr>
<tr>
<td>P</td>
<td>(Pressure) Do you have high blood pressure or are you on medication to</td>
<td></td>
</tr>
<tr>
<td></td>
<td>control high blood pressure?</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>(BMI) Is your body mass index greater than 35?</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>(Age) Are you 50 years old or older?</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>(Neck) Are you a male with a neck circumference greater than 17 inches</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(43 cm), or a female with a neck circumference greater than 16 inches</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(40 cm)?</td>
<td></td>
</tr>
<tr>
<td>G</td>
<td>(Gender) Are you a male?</td>
<td></td>
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</table>
## Vital Signs Limit Thresholds

### Monitoring Alarm Signal Limit Settings

<table>
<thead>
<tr>
<th></th>
<th>Urgent</th>
<th>Caution</th>
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<tr>
<td>ETCO2 High</td>
<td>50</td>
<td>45</td>
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<tr>
<td>ETCO2 Low</td>
<td>29</td>
<td>35</td>
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<tr>
<td>FiCO2 High</td>
<td>8</td>
<td>2</td>
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<tr>
<td>RR High</td>
<td>24</td>
<td>21</td>
</tr>
<tr>
<td>RR Low</td>
<td>6</td>
<td>8-10</td>
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<tr>
<td>No Breath Sec</td>
<td>30</td>
<td></td>
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<tr>
<td>SpO2 High</td>
<td>100</td>
<td>100</td>
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<tr>
<td>SpO2 Low</td>
<td>91</td>
<td>95</td>
</tr>
<tr>
<td>PR High</td>
<td>110</td>
<td>100</td>
</tr>
<tr>
<td>PR Low</td>
<td>54</td>
<td>60</td>
</tr>
<tr>
<td>SAT Sec</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>IPI Low</td>
<td>3</td>
<td>5</td>
</tr>
</tbody>
</table>
Capnostream 20 Capnography Monitor

Capnogram: Wave form

Capnometer: Numeric measurement of End-tidal CO₂

awRR: Airway Respiratory Rate

Oxygen Saturation

Heart Rate

Sampling Line

IPI-Integrated Pulmonary Index: a single number that describes the patient’s respiratory status

Source: “Preparing to Use Capnography: Pre-Capnography Class Nursing Education September, 2013”
Tele-Tech Role:
 Workflow
 Decrease variation
 Assessment and impact
Pop-Up Notifications: Bed-Board View
**Urgent Alert**

<table>
<thead>
<tr>
<th>CAP01</th>
<th>ICU01</th>
<th>ICU02</th>
<th>ICU03</th>
<th>ICU04</th>
<th>ICU05</th>
<th>PACU02</th>
<th>PACU03</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**URGENT ALERT with SOUND**

- **Saturation (% SpO2):** 99
- **Temperature (°F):** 55

Minimum threshold integrated pulmonary index exceeded (4 < 5) on 10/09/2013 (2 report)

Maximum threshold respiratory rate exceeded (55/min > 22 min) on 10/09/2013 (2 report)

Respiratory-Rate-Maximum triggered (Rsop = 55) on 10/09/2013 (2 report)

IPI-Minimum triggered (Pulmonary_Index = 4) on 10/09/2013 (2 report)
CO2 Pump Paused

Pump Paused
Cautionary Alert
Alarm Print For Tele Workflow
Data Continuously Measured

![Graph showing CO2-EX (mmHg) and SPO2 (%) over time](image-url)
Data Continuously Measured

RR (breath/min)

etCO2 (mmHg)
Significant Alarm Signals

Signal threshold breaches for individual measurements became overwhelming.
Some Improvement: Sustained Signal Delays

- Raw data may have aberrations leading to false alarms—these would cause notifications to be communicated when thresholds are exceeded.
- Running 30-sec average establishes trend over 5 measurements (each measurement 6 seconds apart) so that when a threshold is exceeded, is occurring on basis of multiple values—more indicative of a real trend.
• Communication of monitoring alarms directly to telemetry technicians impractical
  – Overwhelming quantities of non-actionable notifications
  – Signals interleaved with artifact made identifying truly actionable events next to impossible
    • Aside: No industry-standard alarm recommendations for adoption at the time
• Decision: explore the field of “combinatorial” machine alarms to help reduce non-actionable alarm load
  – Tightly-controlled environment, with institutional oversight
  – With assistance from research nurses to add a layer of safety to our patients
Alarm Fatigue

Non-actionable notifications that have no clinically-relevant cause
Default machine-issued alarms are not very skillful in identifying adverse events.

350 cardiac alarms / patient / day (ICU)

False Alarm Rate as high as 99%!

In addition, the U.S. Food and Drug Administration’s (FDA) Manufacturer and User Facility Device Experience (MAUDE) database reveals that 566 alarm-related patient deaths were reported between January 2005 and June 2010, a figure that is considered by industry experts to underrepresent the actual number of incidents.
Retrospective analysis of pulse oximeter alarm settings in an intensive care unit patient population

Krystal Lansdowne, David G. Strauss, and Christopher G. Scully

Abstract

Background

The cacophony of alerts and alarms in a hospital produced by medical devices results in alarm fatigue. The pulse oximeter is one of the most common sources of alarms. One of the ways to reduce alarm rates is to adjust alarm settings at the bedside. This study is aimed to retrospectively examine individual pulse oximeter alarm settings on alarm rates and inter- and intra-patient variability.

Results

Decreasing SpO2 thresholds and increasing delay times resulted in decreased alarm rates. A limited number of patient records accounted for most alarms, and this number increased as alarm settings loosened (the top 10% of patient records were responsible for 57.4% of all alarms at an SpO2 threshold of 90% and 15 s delay and 81.6% at an SpO2 threshold of 84% and 45 s delay). Alarm rates were not consistent over time for individual patients with periods of high and low alarms for all alarm settings.

Conclusion

Pulse oximeter SpO2 alarm rates are variable between patients and over time, and the alarm rate and the extent of inter- and intra-patient variability can be affected by the alarm settings. Personalized alarm settings for a patient’s current status may help to reduce alarm fatigue for nurses.
IRB Study...2015

Evaluate the use of smart rules in the environment on a smaller cohort of patients & evaluate outcomes
Study Parameters

- Conducted with IRB oversight
- Limit to a specific hospital general medical surgical unit
- Obtain patient consent prior to surgery
- Identify patients particularly at-risk for respiratory depression
Study System Architecture

10x per minute:
- etCO2
- PR
- SpO2
- RR
- Device-issued alarms

Rules Engine & Alarm Communication

Upon event:
- Threshold breaches
- Technical Alarms

Dashboard Display:
Alarms shown graphically in grid view

Data Storage & Rules Library

Hospital System ADT Feed

Barcode used for patient-to-device association (Initial pilot only)
Alarm Notifications via VoIP Phone

Sources: Supe et al. 2017; photos by author
Alarm Signals Based on Threshold Breaches

Non-consecutive etCO2 measurements which exceed threshold
## Limit Threshold Alarm Annunciations Were Significant

<table>
<thead>
<tr>
<th>Alarm Condition</th>
<th>Frequency of Occurrence</th>
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<tbody>
<tr>
<td>ALR-DISC-SPO2</td>
<td>8527</td>
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<tr>
<td>ALR-LO-BAT</td>
<td>8301</td>
</tr>
<tr>
<td>ALR-NO-BREATHE</td>
<td>7065</td>
</tr>
<tr>
<td>ALR-LO-IPI</td>
<td>5153</td>
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<tr>
<td>ALR-LO-CO2EX</td>
<td>3065</td>
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<tr>
<td>ALR-FL-DISC-CO2</td>
<td>3051</td>
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<tr>
<td>ALR-PR-NF</td>
<td>1925</td>
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<tr>
<td>ALR-HI-RR</td>
<td>2173</td>
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<td>ALR-CO2-PUMP-OFF</td>
<td>1768</td>
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<td>ALR-LO-PR</td>
<td>1637</td>
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<td>ALR-OFF-SPO2</td>
<td>1318</td>
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<td>ALR-LO-RR</td>
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<td>ALR-LO-SPO2</td>
<td>873</td>
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<td>ALR-CO2-CHK-CAL</td>
<td>331</td>
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<tr>
<td>FL-BLOCK</td>
<td>308</td>
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<td>ALR-STBY-CO2</td>
<td>264</td>
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<td>ALR-CO2-CHK-FLW</td>
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<tr>
<td>CO2-MLFNC</td>
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<td>SPO2-MLFNC</td>
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<td>ALR-HI-CO2EX</td>
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<td>ALR-HI-SPO2</td>
<td>0</td>
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<tr>
<td>ALR-STBY-SPO2</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>47021</td>
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<table>
<thead>
<tr>
<th>Parameter Type</th>
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<td>Respiratory rate</td>
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<tr>
<td>≤6 breaths/minute</td>
<td>7,947</td>
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<tr>
<td>≥28 breaths/minute</td>
<td>6,750</td>
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<tr>
<td>SpO₂</td>
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<tr>
<td>≤85%</td>
<td>880</td>
</tr>
<tr>
<td>Pulse rate</td>
<td></td>
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<tr>
<td>≤40 bpm</td>
<td>10</td>
</tr>
<tr>
<td>≥150 bpm</td>
<td>0</td>
</tr>
<tr>
<td>etCO₂</td>
<td></td>
</tr>
<tr>
<td>≤15 mmHg</td>
<td>7,221</td>
</tr>
<tr>
<td>≥65 mmHg</td>
<td>4</td>
</tr>
<tr>
<td>Total data points per parameter</td>
<td>193,177</td>
</tr>
</tbody>
</table>
Alarm Signals Based on Sustained Behavior (non-self-correcting)

Consecutive parameter measurements which exceed threshold
Combinatorial Parameter Alarm Annunciations Proved to be Most Effective
Example: Pulse versus time
Example: Oxygen Saturation v. Time
Example: Respirations & etCO2 v. Time

- $etCO2 \leq 15 \text{ mmHg}$
- $f_R \leq 6 \text{ breaths/minute}$
Use of Measurements to Create Combination Alarm Signals: etCO2

Hypocapnia Alarm Limit (CO2-EX < 15 mmHg)

Instantaneous & sustained occurrences of CO2-EX < 15 mmHg
Use of Measurements to Create Combination Alarm Signals: Resp

Bradypnea Alarm Limit ($f_R < 6$ rpm)

Instantaneous & sustained occurrences of $f_R < 6$ rpm
Use of Measurements to Create Combination Alarm Signals: SpO2

Hypoxia Alarm Limit (SpO2 < 90%)

Instantaneous & sustained occurrences of SpO2 < 90%
Single Combination Alarm

Possible instances of central or obstructive sleep apnea: $\text{etCO}_2 = 0 \& f_R = 0$, with valid measurements

(i.e., no technical alarm thrown & cannula properly in place on patient)

Reference:

13 individual alarms translate into 2 combined sustained alarms
Alarm Threshold Limits Considered

Alarm level changes or policies to reduce alarms must be validated for clinical efficacy & safety.
Correlations Among Machine-Reported Alarm Signals

Low expired carbon dioxide (<15 mmHg)
Low respirations (< 6 per minute)
Low hemoglobin oxygen saturation (< 90%)

<table>
<thead>
<tr>
<th></th>
<th>Low etCO2</th>
<th>Low Respirations</th>
<th>Low SpO2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low etCO2</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Respirations</td>
<td>0.987</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Low SpO2</td>
<td>0.892</td>
<td>0.885</td>
<td>1</td>
</tr>
</tbody>
</table>
Combination Alarms per Study

<table>
<thead>
<tr>
<th>Sustained Alarm Signal Delay (seconds)</th>
<th>Hypopneic Hypoventilation with Hypoxia* (no.)</th>
<th>Hypopneic Hypoventilation† (no.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>106</td>
<td>4,852</td>
</tr>
<tr>
<td>12</td>
<td>59</td>
<td>4,522</td>
</tr>
<tr>
<td>18</td>
<td>0</td>
<td>209</td>
</tr>
<tr>
<td>24</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Combination of low respirations, oxygen saturation & end-tidal carbon dioxide were chiefly correlated with patients who required active interventions: truly apneic patients
### 3-Parameter Sensitivity & Specificity (Small Patient Sample)

- Limited data based on not identifying patients with condition due to cuffs off patient.
- No patient who truly required intervention was not correctly identified.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>0.800</td>
</tr>
<tr>
<td>Specificity*</td>
<td>0.750</td>
</tr>
<tr>
<td>PPV</td>
<td>0.364</td>
</tr>
<tr>
<td>NPV*</td>
<td>0.955</td>
</tr>
</tbody>
</table>

- **Sensitivity** = \(100 \times \frac{TP}{TP + FN}\) | **Sensitivity**: probability or fraction indicating that condition is present among those having the condition.

- **Specificity** = \(100 \times \frac{TN}{TN + FP}\) | **Specificity**: probability or fraction indicating a negative result in those not having the condition.

Positive Predictive Value (PPV): What is the probability that a patient with a positive result truly has condition?

Negative Predictive Value (NPV): What is the probability that a patient with a negative result truly does not have the condition?

- **PPV** = \(100 \times \frac{TP}{TP + FP}\)
- **NPV** = \(100 \times \frac{TN}{TN + FN}\)
1. Patients receiving parenteral opioids should be monitored continuously regardless of location in the hospital.

2. Minimal set of continuous data should include pulse, oxygen saturation, respirations and expiratory carbon dioxide.

3. Monitoring should be a team effort involving floor nursing, respiratory therapy and physicians, and all should be trained in the workflows and technologies associated with continuous ventilation monitoring.

4. Notifications for clinical alarms related to hypoventilation concurrent with hypoxia should be directed to nursing AND respiratory therapy.

5. Clinical or biomedical engineering should be part of the notification chain for machine-specific alarms and errors that indicate possibility of false readings.

6. When continuous surveillance is used, smart alarms using multiple parameters that identify hypoventilation together with declining oxygenation provide the best indicator of impending respiratory distress.

“The 6 Rights of OIRD Surveillance”
A Business & Clinical Case for Continuous Surveillance

Thank you!

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