VIGILANCE Study: Vital sign monitoring with continuous pulse oximetry and wireless clinician notification after surgery

James Paul MD MSc FRCPC
Outline

- Background
- Rationale
- Methods
vigilance |ˈvɪjələns|
noun
the action or state of keeping careful watch for possible danger or difficulties.
ORIGIN late 16th cent.: from French, or from Latin vigilantia, from vigilare ‘keep awake,’ from vigil (see vigil).

Study definition: ‘Keeping careful watch over our patients’
Opioid Analgesia

- Oral and parental opioids administered by nurses are effective but are often given in larger dosages at infrequent intervals
- PCA opioids provide better analgesia with better patient satisfaction
- Epidural analgesia provides better analgesia than PCA opioids

**BUT..**

- All opioids can be sedating and lead to respiratory depression
## Incidence of respiratory depression

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>N</th>
<th>Methodology</th>
<th>Definition</th>
<th>Epidural</th>
<th>PCA</th>
<th>PCA + Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schug</td>
<td>1993</td>
<td>2636</td>
<td>Prospective cohort</td>
<td>Naloxone</td>
<td>0.4%</td>
<td>0.3%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Sidebotham</td>
<td>1997</td>
<td>6035</td>
<td>Prospective cohort</td>
<td>RR&lt;8 SpO$_2$&lt;90%</td>
<td></td>
<td>0.2%</td>
<td></td>
</tr>
<tr>
<td>Walder</td>
<td>2001</td>
<td>414</td>
<td>Systematic review</td>
<td>RR&lt;10 SpO$_2$&lt;90%</td>
<td></td>
<td></td>
<td>4.6%</td>
</tr>
<tr>
<td>Shapiro</td>
<td>2005</td>
<td>4500</td>
<td>Prospective cohort</td>
<td>RR&lt;10</td>
<td>0.6%</td>
<td>1.9%</td>
<td></td>
</tr>
<tr>
<td>Overdyk</td>
<td>2007</td>
<td>178</td>
<td>Continuous monitoring</td>
<td>SpO$_2$&lt;90%</td>
<td></td>
<td>12%</td>
<td></td>
</tr>
<tr>
<td>Popping</td>
<td>2008</td>
<td>18925</td>
<td>Prospective cohort</td>
<td>RR&lt;8</td>
<td>1.1%</td>
<td>0.7%</td>
<td></td>
</tr>
<tr>
<td>Paul</td>
<td>2010</td>
<td>35384</td>
<td>Prospective cohort</td>
<td>Naloxone</td>
<td>0.5%</td>
<td>0.6%</td>
<td>1.46%</td>
</tr>
</tbody>
</table>
Hamilton Acute Pain Safety Study

- Does root cause analysis reduce the incidence of adverse events on the Acute Pain Service?

- 4 RCAs (out of 10) investigated cases of respiratory depression, 1 resulted in a cardiac arrest and death

- 8 of the RCAs identified serious gaps in vital signs assessments: sedation scores - 9h; resp rate - 5h

- The resulting recommendations included a trial of a wireless respiratory monitoring system
The obstructive sleep apnea problem

- Incidence is high: 24% of men; 9% of women (AHI ≥ 5)
- Adherence to CPAP is poor = 30-60%
- Patients with moderate-severe OSA presenting for major surgery require continuous pulse oximeter monitoring if they are noncompliant with CPAP
What we already know

- Early recognition of respiratory depression is essential to prevent cardiorespiratory arrest.
- Universal surveillance with pulse oximetry in the postoperative period reduces the number of respiratory rescue events and ICU transfers.
  - 36 bed orthopedic unit over a 11 month period
  - Rescue events down from 3.4 to 1.2 per 1000 patients
  - ICU transfers down from 5.6 to 2.9 per 1000 patients
  - No reductions on two other comparison surgical units

Impact of Pulse Oximetry Surveillance on Rescue Events and Intensive Care Unit Transfers

A Before-and-After Concurrence Study

Andreas H. Taenzer, M.D., F.A.A.P.,* Joshua B. Pyke, B.E.,† Susan P. McGrath, Ph.D.,‡ George T. Bilke, M.D.§
What this study hopes to determine

- Will continuous pulse oximetry be effective on two general surgical wards at Juravinski?
- Will monitoring reduce the incidence of Naloxone administration, transfers to the observation ward, code blues and ICU transfers?
- What is the incidence of respiratory events and what is their timing relative to surgery?
- What are the risk factors for respiratory events?
- What is the impact of a respiratory monitoring system on nursing workflow and patient care?
<table>
<thead>
<tr>
<th></th>
<th>6 South</th>
<th>6 West</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>General Surgery/Oncology</td>
<td>General Surgery/Oncology</td>
</tr>
<tr>
<td>Beds</td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td>Nurse:Patient ratio</td>
<td>1:4</td>
<td>1:4</td>
</tr>
<tr>
<td>Discharges per year</td>
<td>1100</td>
<td></td>
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</tbody>
</table>
Population

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
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<tr>
<td><strong>ALL</strong> surgical admission to E4 and F4</td>
<td>Patient refusal to be monitored</td>
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Sample Size

Sample size calculation (for the comparison of two independent proportions) = 2000

Assuming:
1. Baseline respiratory rescue event rate of 2%
2. 50% reduction in rescue events with monitoring
3. Alpha error = 5%
4. Beta error = 20%
<table>
<thead>
<tr>
<th>Intervention</th>
<th>6 South</th>
</tr>
</thead>
<tbody>
<tr>
<td>After cohort (9 months)</td>
<td>Spring 2013 to Spring 2015</td>
</tr>
</tbody>
</table>
| Monitoring system | Covidien  
N600X Monitors  
Alarm Management System |
| Alarm thresholds | **SpO₂ < 90%**  
**HR < 40 OR > 130**  
Bedside audio alarm delay = 15 seconds  
Pager notification delay = 15 seconds |
Impact of duration on incidence

- Overdyk results

- Incidence decreases with duration
- 83% of events less than 30 seconds
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Analysis</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Respiratory resuscitations: Naloxone, Observation room transfers,</td>
<td>Box plot &amp; Odds ratio</td>
<td>Alarm/Event form</td>
</tr>
<tr>
<td>Code blues</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. ICU Transfers</td>
<td>Box plot &amp; Odds ratio</td>
<td>Alarm/Event form</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Admin data</td>
</tr>
<tr>
<td>3. Alarm types and duration</td>
<td>Descriptive stats</td>
<td>Download from monitor server?</td>
</tr>
<tr>
<td>4. Alarms per patient &amp; false vs real alarms</td>
<td>Descriptive stats</td>
<td>Download from monitor server?</td>
</tr>
<tr>
<td>5. Risk factors for respiratory events?</td>
<td>Multivariable regression analysis</td>
<td>Chart review (after cohort) - research</td>
</tr>
<tr>
<td></td>
<td></td>
<td>coordinator</td>
</tr>
<tr>
<td>6. Nursing impact</td>
<td>Descriptive stats</td>
<td>Questionnaire</td>
</tr>
</tbody>
</table>
Randomization form

VIGILANCE STUDY

Vital sign monitoring with continuous pulse oximetry and wireless clinician notification after surgery

This patient is part of the VIGILANCE STUDY which involves using either standard vital signs monitoring or the wireless respiratory monitoring system for 3 days after surgery.

To determine which monitoring protocol this patient is to receive please call the RANDOMIZATION CENTER at 905-524-1487

The patient was randomized to the following monitor regimen:

☐ Standard vital signs monitoring as per the surgeons orders

☐ Wireless respiratory monitoring in addition to the vital signs monitoring ordered by the surgeon

Was the prescribed monitoring regimen started at the time of admission to the ward?

☐ Yes
☐ No

If no, please explain:

☒ Wireless monitor not available
☒ Probe not available
☒ Patient refused wireless monitor
☒ Other:

If you have any questions regarding this study please call Toni Tidy at 21737 from 8:00 to 16:00 on weekdays, or Dr. James Paul at 905-972-3597 after hours and on weekends.
Study orders

VIGILANCE STUDY ORDERS:

1. At the time of admission to the ward, call the randomization number (805-594-1407) to determine the monitoring regimen for the patient.

2. Record the randomized monitoring regimen (wireless OR standard) on the Randomization Form.

3. If the patient is randomized to the wireless monitoring system, register them with their name and room number on the central monitor at the nursing desk.

4. Continue the randomized monitoring regimen for 3 days and then use the vital signs orders as per the surgeon.

5. If you are unable to use the randomized monitoring regimen, record the reason why on the Randomization Form.

6. If the patient alarm goes off, respond and record the necessary action on the Alarm Documentation Form.

7. If the patient requires Naloxone (for respiratory depression), is transferred to the ICU or a Code Blue is called, record this on the Alarm Documentation Form.

8. At the end of the 3-day monitoring period place the Alarm Documentation Forms in the Vigilance Study box, located at the nursing desk.

If you have any questions regarding this study please call Tony Tidy at 217-37 from 8:00 to 16:00 on weekdays, or Dr. James Paul at 905-972-3597 after hours and on weekends.
HHS Wireless Respiratory Monitoring System Trial Survey

Please take the time to complete this questionnaire and give feedback on the wireless respiratory monitoring system. Your feedback will be anonymous. When completed please place the questionnaire in the study box on the ward front desk.

1. Did you care for patients that were monitored with either the Philips or Covidien wireless respiratory monitoring systems?
   - Yes
   - No

   If no, then you don’t have to complete the remaining questions.

2. On which ward do you work and are you a part-time or full-time staff?
   - 6 South
   - 6 West

   - Part time
   - Full time

3. How long have you been working on this ward?
   - More than 2 years
   - 1 to 2 years
   - Less than a year

4. The monitoring system was easy and intuitive to operate?
   - Strongly disagree
   - Disagree
   - Neither agree nor disagree
   - Agree
   - Strongly agree

5. The monitoring system generated too many false alarms?
   - Strongly disagree
   - Disagree
   - Neither agree nor disagree
   - Agree
   - Strongly agree

6. The alarm triggers were set at the appropriate values for SpO2 and heart rate?
   - Strongly disagree
   - Disagree
   - Neither agree nor disagree
   - Agree
   - Strongly agree

7. The pager notification system worked reliably?
   - Strongly disagree
   - Disagree
   - Neither agree nor disagree
   - Agree
   - Strongly agree

8. The pager messages clearly identify the type of alarms?
   - Strongly disagree
   - Disagree
   - Neither agree nor disagree
   - Agree
   - Strongly agree

9. The pulse oximetry monitoring system was helpful in caring for your patients?
   - Strongly disagree
   - Disagree
   - Neither agree nor disagree
   - Agree
   - Strongly agree
Methodological Issues

- Study is limited by looking at historical controls.
  - The period effect would have to be addressed by looking at a couple of “control” surgical wards that don’t get a monitoring system.

- Is it worth the 500+ days of chart review time to identify risk factors of respiratory depression?
  - The VISION study addresses a similar question but without a monitoring system and therefore the risk of respiratory depression is underestimated by a factor of 10.

- Do we need to get individual patient consent?
  - Before cohort timeframe has already passed. Previous studies of monitoring systems got REB approval but not patient consent.
## Respiratory Monitoring Study Summary

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>Does continuous monitoring with pulse oximetry with wireless clinician notification on a orthopedic and general surgery ward reduce the incidence or respiratory resuscitations with Naloxone, observation room transfers, code blues and ICU transfers?</th>
</tr>
</thead>
<tbody>
<tr>
<td>DESIGN</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>POPULATION</td>
<td>N = 2000 (?2 yrs)</td>
</tr>
<tr>
<td></td>
<td>All elective surgical admissions to E4 and F4</td>
</tr>
<tr>
<td>INTERVENTION</td>
<td>STANDARD Monitoring</td>
</tr>
<tr>
<td></td>
<td>Vital sign monitoring as per the surgeon’s orders</td>
</tr>
<tr>
<td></td>
<td>1. Respiratory resuscitation events: Naloxone, Observation ward transfers, Code Blues and ICU transfers</td>
</tr>
<tr>
<td></td>
<td>2. Alarm types and duration</td>
</tr>
<tr>
<td></td>
<td>3. Alarms per patient and real vs false</td>
</tr>
<tr>
<td></td>
<td>4. Risk factors for respiratory events</td>
</tr>
<tr>
<td></td>
<td>5. Nursing impact - questionnaire survey</td>
</tr>
<tr>
<td>OUTCOMES</td>
<td></td>
</tr>
</tbody>
</table>
THANKS