



# Respiratory Volume Monitoring to Predict & Prevent Respiratory Compromise

A presentation for HealthTrust members  
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# Today's Presenters



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# Speaker Disclosures

- Hans Tillmann Hein, M.D., is a Shareholder in Respiratory Motion, Inc.
- Donna Lee Armaignac, PhD, APRN, CCNS, CCRN, has no interests to disclose.
- Note: This program may contain the mention of suppliers, brands, products, services or drugs presented in a case study or comparative format using evidence-based research. Such examples are intended for educational and informational purposes and should not be perceived as an endorsement of any particular supplier, brand, product, service or drug.



# Learning Objectives:

1. Recall contemporary guidelines driving new practices in respiratory monitoring
2. Discuss pathophysiologic responses that contribute to respiratory decompensation
3. Identify methods and technologies for respiratory assessment
4. Visualize respiratory volume monitoring (RVM) as a new clinical tool for respiratory assessment
5. Outline an implementation plan of respiratory solutions



# Objective 1: Recall contemporary guidelines driving new practices in respiratory monitoring



“.....even admitting to the full extent the great value of the hospital improvements in recent years, a vast deal of the suffering, and some at least of the mortality, in these establishments is avoidable.”

~Florence Nightingale 1863



# Respiratory Failure is One of the Largest Patient Safety Problems... Further Exacerbated by the Growing Opioid Crisis

- Patients with respiratory compromise are **29x more likely** to die vs. the rest of patients
  - **30%** of post-op patients have respiratory compromise
  - Respiratory complication
  - **3<sup>rd</sup>** most rapidly increasing inpatient cost in the US
  - **2<sup>nd</sup>** leading avoidable patient safety issue in US
- ➔ **350,000 respiratory deaths** per year
  - ➔ **~1 million patients** a year with 5 million extra hospital days
  - ➔ Costs an average of **\$53,000** per patient
  - ➔ Inpatient stays associated with respiratory compromise will exceed **\$37 billion by 2019\***
  - ➔ **Over 60% of respiratory arrests are potentially avoidable due to delayed intervention**



Source: [www.respiratorycompromise.org](http://www.respiratorycompromise.org); Agarwal, SJ, Erslon, MG, Bloom, JD. Projected incidence and cost of respiratory failure, insufficiency and arrest in Medicare population, 2019. Abstract presented at Academy Health Congress.



# 2018 Standards, Guidelines & Requirements Drive Improved Respiratory Monitoring: Society Recommendations Address Respiratory Failure and Patient Safety

**2011** – APSF: No Patient Shall Be Harmed by Opioid Induced Respiratory Depression (OIRD)

**2012** -- The Joint Commission of Hospital Accreditation: Sentinel Event Alert

**2013** – ASA Practice Guidelines for Postanesthetic Care

**2014** – CMS Requirements for Post Operative Care of Patients

**2015** – Multicenter Closed Claims Analysis, Anesthesiology Journal

**2016** – ASA Practice Guidelines: Prevention, Detection and Management of Respiratory Depression

**2018** – The Joint Commission: Pain Assessment and Management Standards for Hospitals

- “Continuous electronic monitoring of oxygenation and/or ventilation should be available and considered for all patients.”
- “.....causes for adverse events associated with opioid use are: ...inadequate monitoring of patients on opioids.”
- “Particular attention should be given to monitoring oxygenation, ventilation, circulation,...”
- “OIRD has resulted in patient deaths that might have been prevented with appropriate risk assessment for adverse events as well as frequent monitoring”
- “The vast majority of Respiratory Depression events (88%) occurred within 24h of surgery, and 97% were judged as preventable with better monitoring and response... particularly in the first 24 hours postoperatively.”
- “Monitor all patients receiving neuraxial opioids for adequacy of ventilation (e.g., respiratory rate, depth of respiration, [assessed without disturbing a sleeping patient]), oxygenation...”
- “Promoting safe opioid use by identifying high risk patients... monitoring high risk patients.”



American Society of  
Anesthesiologists 



apsf<sup>®</sup>

The Joint  
Commission

  
CENTERS FOR MEDICARE & MEDICAID SERVICES

## Objective 2:

Discuss pathophysiologic responses that contribute to respiratory decompensation

- Identify patients at risk.
- Identify factors leading to respiratory compromise.

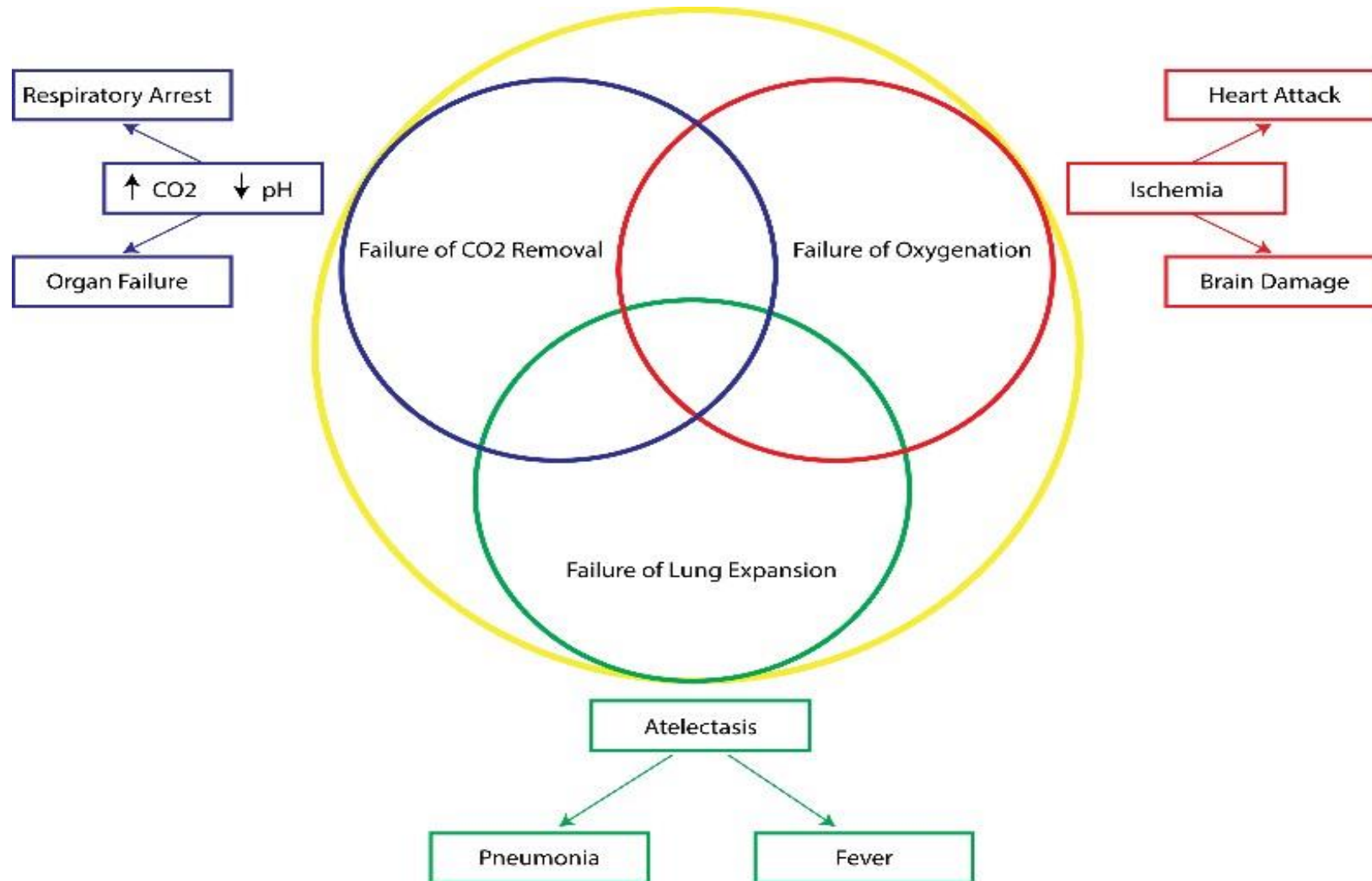




# Who is at Risk for Respiratory Compromise?

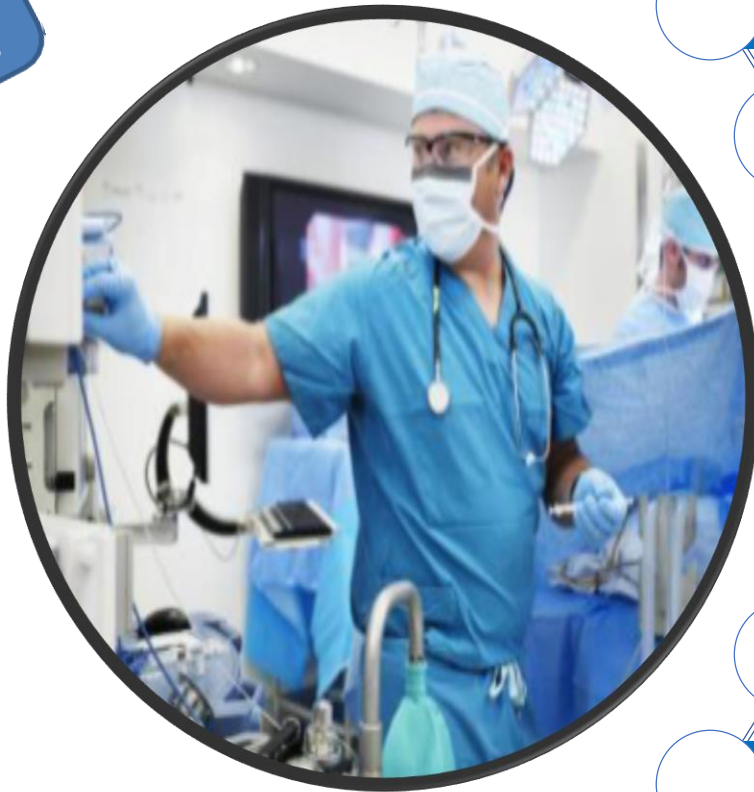


# Respiratory Compromise and Respiratory Failure – Not Just Oxygenation....



# Where are Patients at Risk for Respiratory Compromise? Hospital Wide

Anyone,  
Anytime,  
Anywhere



Emergency Room

Post-Anesthesia Recovery

Critical Care

Transport

Procedural Sedation

General Hospital Floor

Surgery Centers & Remote Sites

Patients are at risk for respiratory compromise at any point during their stay



## Objective 3: Identify methods and technologies for respiratory assessment

- What parameters we monitored historically?
- What technology do you use?
- How effective are your tools?



# The Evolution of Respiratory Monitoring Parameters

1970s

1980s

1990s

2000s

## Clinical Observation

- ✗ Intermittent
- ✗ Subjective
- ✗ Assessment scores miss risk (Aldrete, STOP-Bang)

## Blood Gas

- ✗ Invasive
- ✗ Intermittent
- ✗ Delayed
- ✗ Requires staff time

## Pulse Oximetry (SpO<sub>2</sub>)

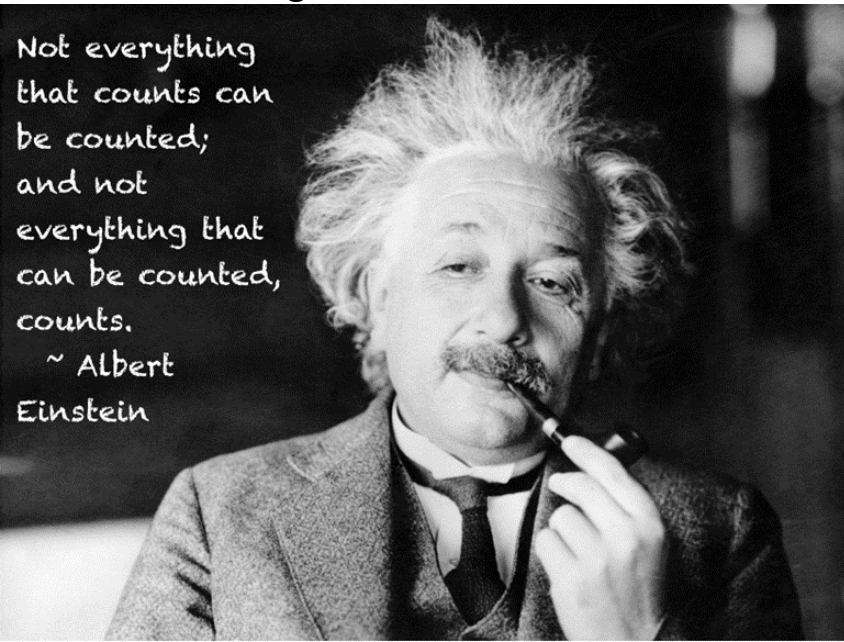
- ✗ Late indicator
- ✗ Excessive false alarms
- ✗ Motion artifact
- ✗ Not predictive of decline
- ✗ Challenged by low perfusion

## End-Tidal CO<sub>2</sub>

- ✗ Challenging and error prone on non-intubated patients
- ✗ Excessive false alarms
- ✗ Incompatible with CPAP, BiPAP, Mask
- ✗ Depends on sensor position, often leads to dislodgement
- ✗ Complex interpretation

## Respiratory Rate

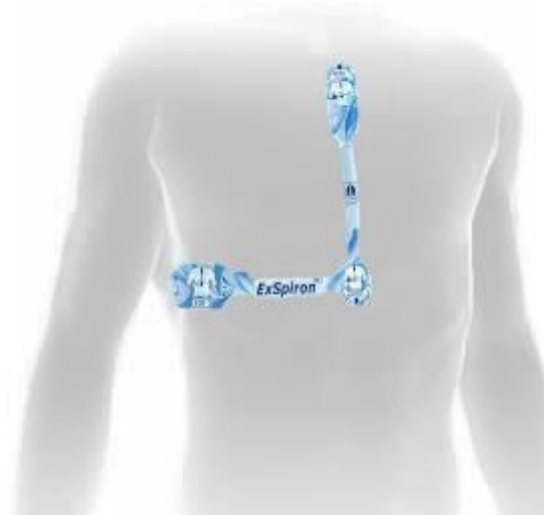
- ✗ Misses 80% of respiratory depression
- ✗ Misses shallow/stressed breathing
- ✗ Does not report volume; small part of the picture
- ✗ Excessive false alarms
- ✗ Inconsistent lead placement impacts accuracy



Not everything that counts can be counted, and not everything that can be counted, counts.  
~ Albert Einstein

"Closer to ideal would be a respiratory minute volume monitor, which does not yet exist as a bedside monitor."

# Consensus – Continuous, Reliable Respiratory Monitoring is Necessary



- Respiratory Ventilation Monitoring (RVM)
- Monitors Minute Ventilation (MV) for non-intubated patients
- MV - Fundamental unit of breathing

$$MV = TV \times RR$$





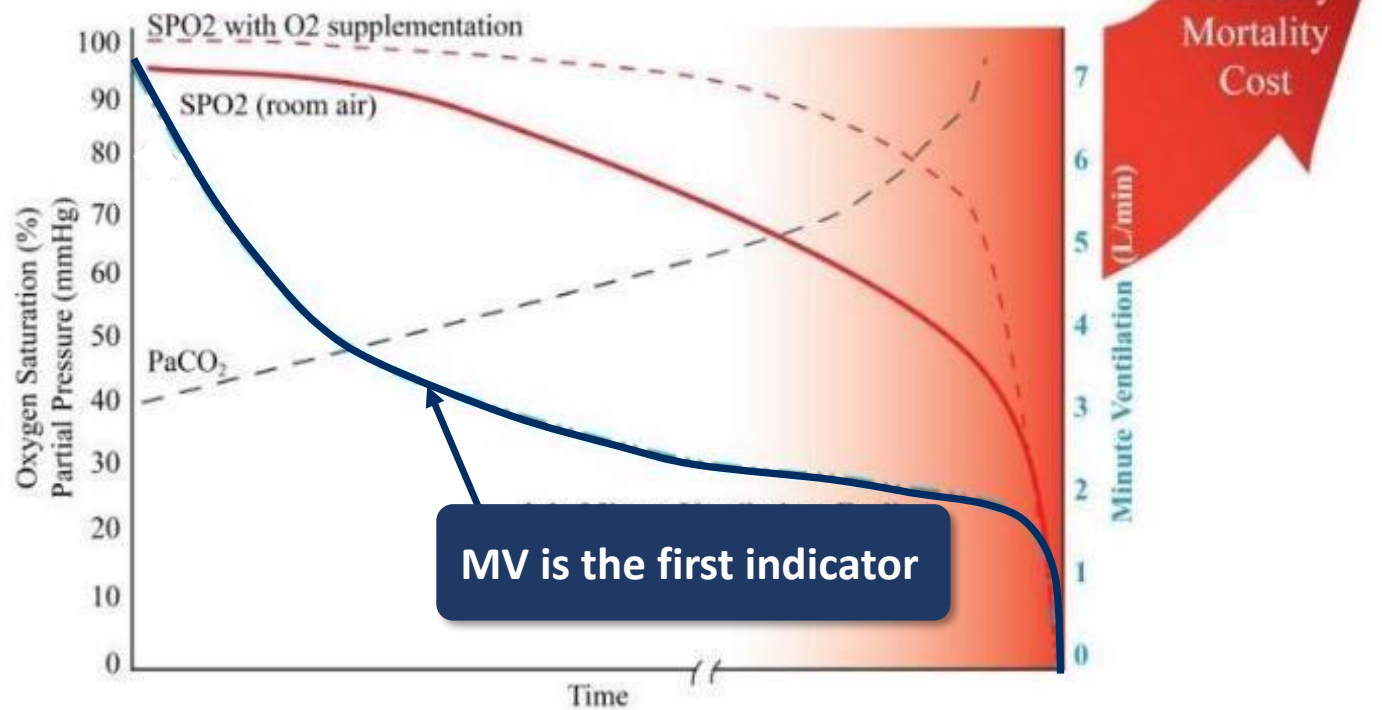
# How Do They Compare?

	Assess Ventilation	Quantitative	Continuous	Easy to Use	Early Warning	Low False Alarms	Sensitivity	Reliability
<b>Blood Gas</b>	✓	✓	✗	✗	✓/✗	✗	High	High
<b>Respiratory Rate</b>	✗	✓	✗	✓	✗	✗	Low	Low
<b>Capnography (extubated)</b>	✓	✓	✓	✗	✗	✗	Low	Low
<b>Pulse Oximetry</b>	✗	✓	✓	✗	✗✗	✗	Low	Low
<b>Clinical Assessment</b>	✓	✗	✗	✗	✗	✓	Low/Mid	Mid
<b>Ventilator</b>	✓	✓	✓	✗	✓/✗	✓	High	High
<b>RVM</b>	✓	✓	✓	✓	✓	✓	High	High



# MV is the Earliest and Most Comprehensive Indicator of Change in Respiratory Status

## Pattern of Unexpected Hospital Deaths: <sup>1</sup>



- Low MV is on average 71 minutes earlier than low SpO<sub>2</sub><sup>4</sup>
- Respiratory rate misses > 80% of hypoventilation<sup>2</sup>
- RVM's MV is more reliable and clinically relevant than EtCO<sub>2</sub> in non-intubated patients<sup>3</sup>
- Hypoventilation (↓MV) is common postoperatively and with opioids

1. Lynn and Curry: Patterns of unexpected in-hospital deaths: a root cause analysis. *Patient Safety in Surgery* 2011 5:3

2. Holley K, et al. Monitoring minute ventilation versus respiratory rate to measure the adequacy of ventilation in patients undergoing upper endoscopic procedures. *J Clinical Monitoring and Computing* 2016;30:3, Fletcher Allen Hospital, University of Vermont

3. Mehta, J, The relationship between minute ventilation and end tidal CO<sub>2</sub> in intubated and spontaneously breathing patients undergoing procedural sedation. June 29, 2017: <https://doi.org/10.1371/journal.pone.0180187>, Massachusetts General Hospital, Harvard University, University of Texas at Houston

4. Galvagno S, et al. Evaluation of Respiratory Volume Monitoring (RVM) to Detect Respiratory Compromise in Advance of Pulse Oximetry and Help Minimize False Desaturation Alarms. *J Trauma Acute Care Surgery* 2016;81(5 Suppl 2) S162-S170., Massachusetts General Hospital, Harvard University



# ECRI—Evaluated Monitors Detecting Respiratory Depression

*ECRI Institute. Evaluation background: monitors for detecting respiratory depression—recommended for patients on opioids. Health Devices 2016 Oct 5.*

## Evaluation Criteria

- Timeliness
- Accuracy
- Actionable
- Real-world work flow

- **Independent third party organization** that evaluates and rates medical devices
- 4 out of every 5 U.S. hospitals rely on ECRI to guide their operational and strategic decisions
- **“Consumer Reports” for medical devices**
- 3,000+ hospitals commissioned ECRI to evaluate respiratory monitoring devices

## Evaluation Results

### Monitors for Detecting Respiratory Depression

Model	Overall Rating
RVM	★★★★
ETCO2	★★★
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Capnography	★★★

## Evaluation Summary

### Requirements:

- Pulse ox too late – not considered
- Respiratory rate insufficient – not considered
- Need connectivity to central station

### Findings for RVM:

- **Comprehensive indicator** of respiratory failure
- **Outperforms** other devices
- **Ease of use** in clinical settings

[www.ecri.org](http://www.ecri.org)



## Risk Stratification

- Several specialty groups in the perioperative arena have developed a standard risk stratification system. Each has its own limitations.
- Opioids remain the foundation of pain management.
- Intermittent monitoring is inadequate.
- Continuous monitoring is supported by multiple agencies in all post operative patients.**

Sources: 1. A Risk Stratification Algorithm Using Non-Invasive Respiratory Volume Monitoring to Improve Safety When Using Post-Operative Opioids in the PACU. Voscopoulos C, Theos K, Tillmann Hein HA, George F. J Clin Monit Comput 2017;31(2):417-426. doi: 10.1007/s10877-016-9841-9.

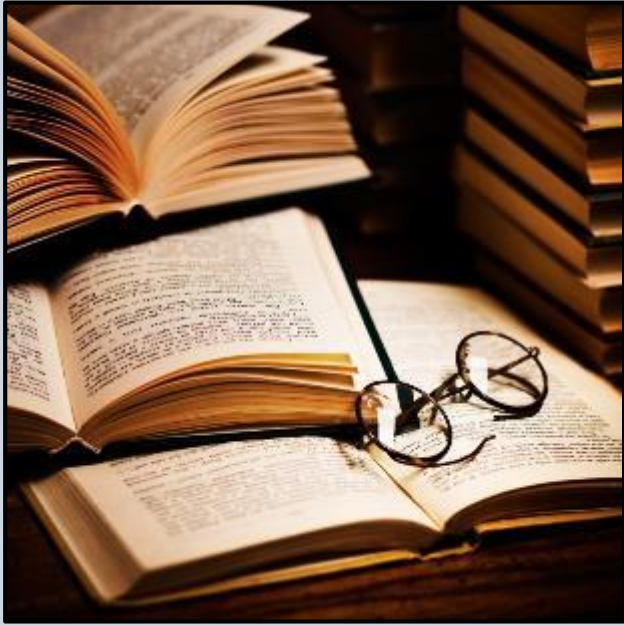
2. Postoperative Respiratory Impairment is a Real Risk for Our Patients: The Intensivist's Perspective. Rao VK, Khanna AK. Anesthesiol Res Pract 2018;3215923. doi: 10.1155/2018/3215923.

3. Development and Validation of a Score for Prediction of Postoperative Respiratory Complications Brueckmann B, Villa-Urbe JL, Bateman BT, Grosse-Sundrup M, Hess DR, Schlett CL, Eikermann M. 2013; 118(6):1276-85.



## Objective 4:

# Visualize respiratory volume monitoring (RVM) as a New Clinical Tool for Respiratory Assessment



- What do we know?
- What are the facts?

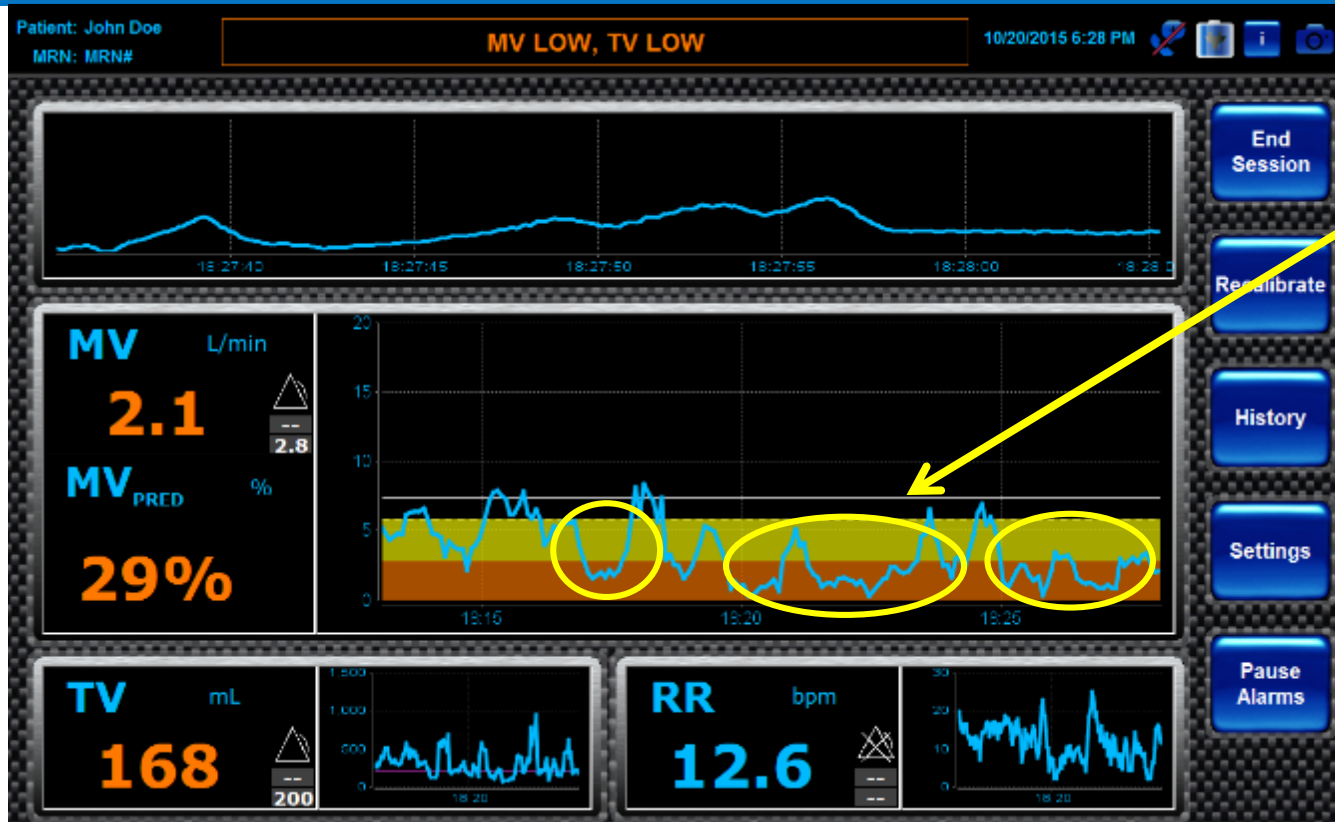




# Establishment of RVM as Earliest & Most Comprehensive Indicator of Change in Respiratory Status

## Single threshold:

- 100% normal
- <40% Low MV alarm
- Non-invasive, real-time, continuous, shows trends
- Communicates objective quantifiable information
- Very few false alarms
- Remote monitoring capability



Low MV

Normal!

Earliest indicator: when other measurements show *NO* sign of respiratory depression

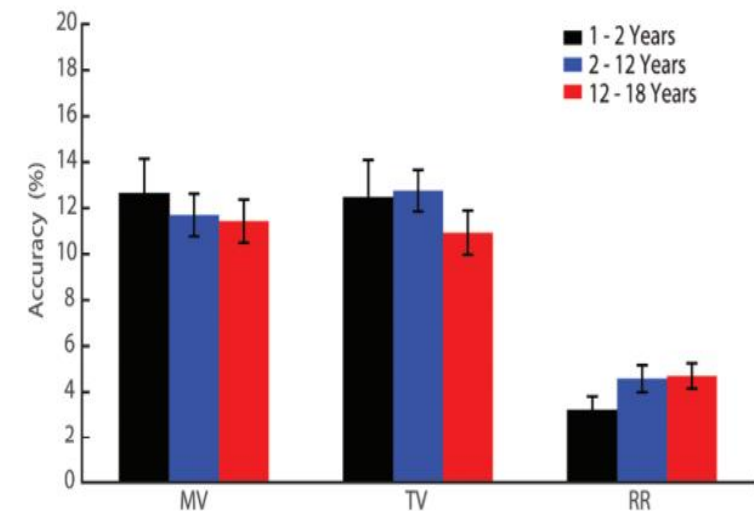
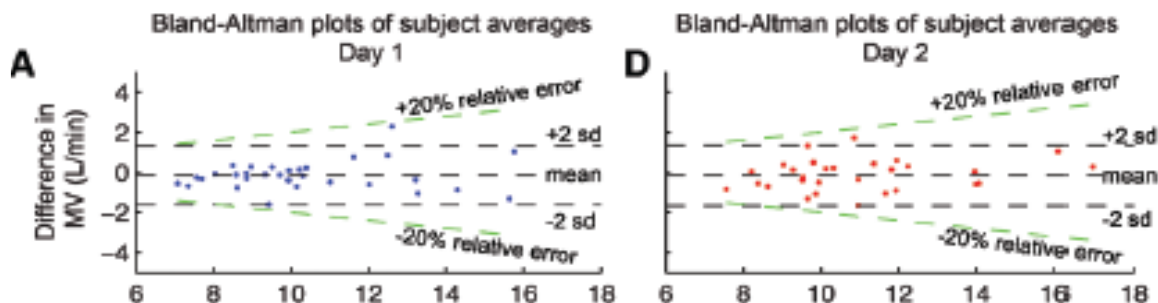
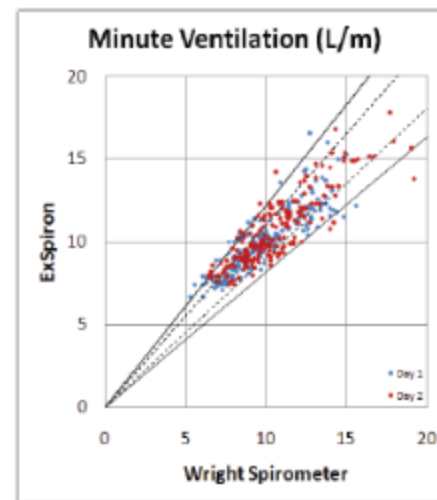
O<sub>2</sub> Sat: 98%  
EtCO<sub>2</sub>: N/A  
RR: 13





# Minute Ventilation (MV)—Known Measurement with Long Standing Clinical Use

- MV, TV and RR used every day on ventilators, so we know what the values mean
- RVM has excellent accuracy ~90%



Sources:

1. Voscopoulos C, Brayonov J, Ladd D, Lalli M, Panasyuk A, Freeman J. Special article: evaluation of a novel noninvasive respiration monitor providing continuous measurement of minute ventilation in ambulatory subjects in a variety of clinical scenarios. *Anesth. Analg.* 2013;117:91–100.
2. Voscopoulos C, MacNabb C, Brayonov J, Freeman J, Qin L, George E. The evaluation of a non-invasive respiratory volume monitor in surgical patients undergoing elective surgery under general anesthesia. *Anesth. Analg.* 2014;119:97.
3. Gomez-Morad AD, Cravero JP, Harvey BC, Bernier R, Halpin E, Walsh B, Nasr VG. The Evaluation of a Noninvasive Respiratory Volume Monitor in Pediatric Patients Undergoing General Anesthesia. *Anesth Analg.* 2017 Dec;125(6):1913-1919.



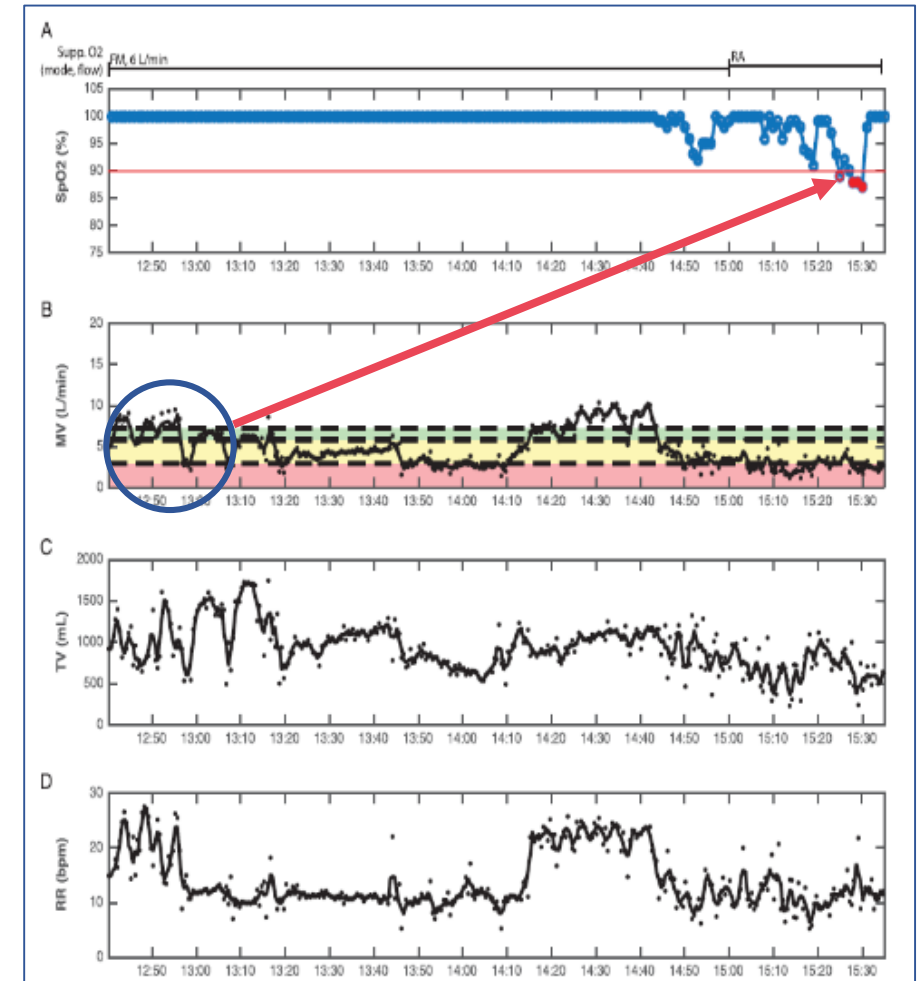
## RVM—Supported by Clinical Evidence from Multiple Care Areas

- 30+ peer-reviewed papers, 300+ presentations, 6,000+ patients, 1 million+ data sets
  - Protocols for clinical use, use across clinical environments, accuracy
  - More than a decade in testing and analytical product development
  - Definitive clinical information far in advance of others in the space
- PACU, general floor
  - ICU
  - Procedural sedation
  - Endoscopy
  - Orthopedics, obesity
  - Obstetric
  - Pediatric
  - Cardiac surgery
  - Pain management
  - Monitoring of therapeutics
  - Difficult airway
  - CPAP, BiPAP, High-flow



# Evaluation of Respiratory Volume Monitoring (RVM) to Detect Respiratory Compromise in Advance of Pulse Oximetry & Help Minimize False Desaturation Alarms

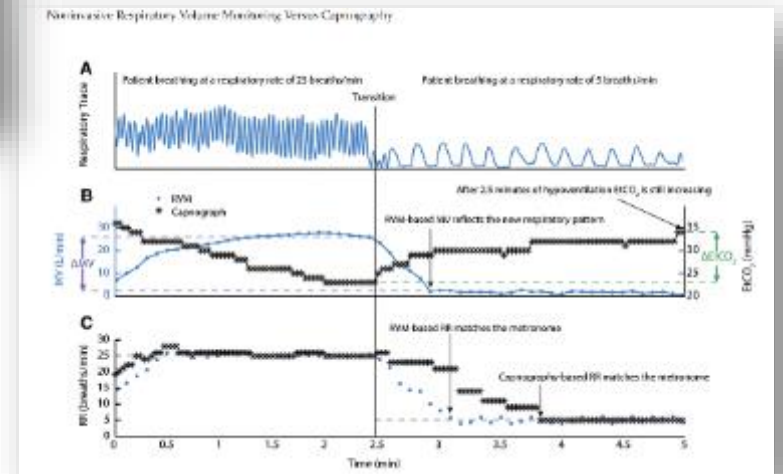
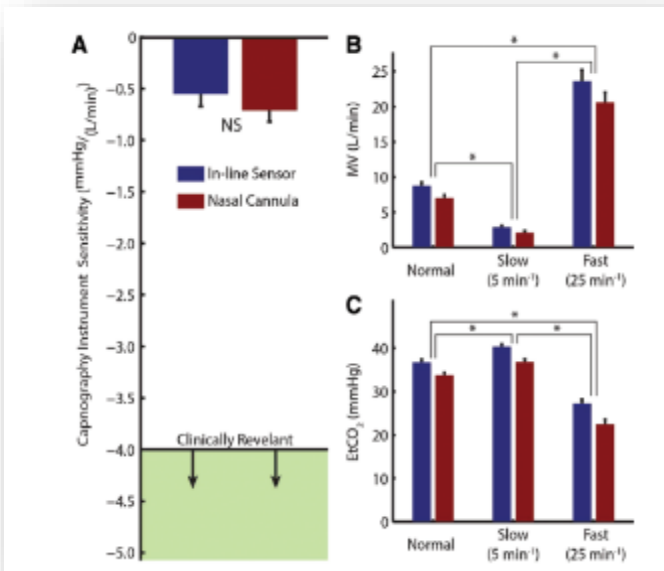
- 259 PACU patients / joint replacement surgery – MGH observational study
- 93% of recorded SpO<sub>2</sub> alarms were considered false alarms
- Repeated Low MV alarms began an average of 71.4 minutes before true desaturation measured by SpO<sub>2</sub>
- Patients with Low MV had 1 hour longer Length of Stay in the PACU compared to patients with “adequate” MV



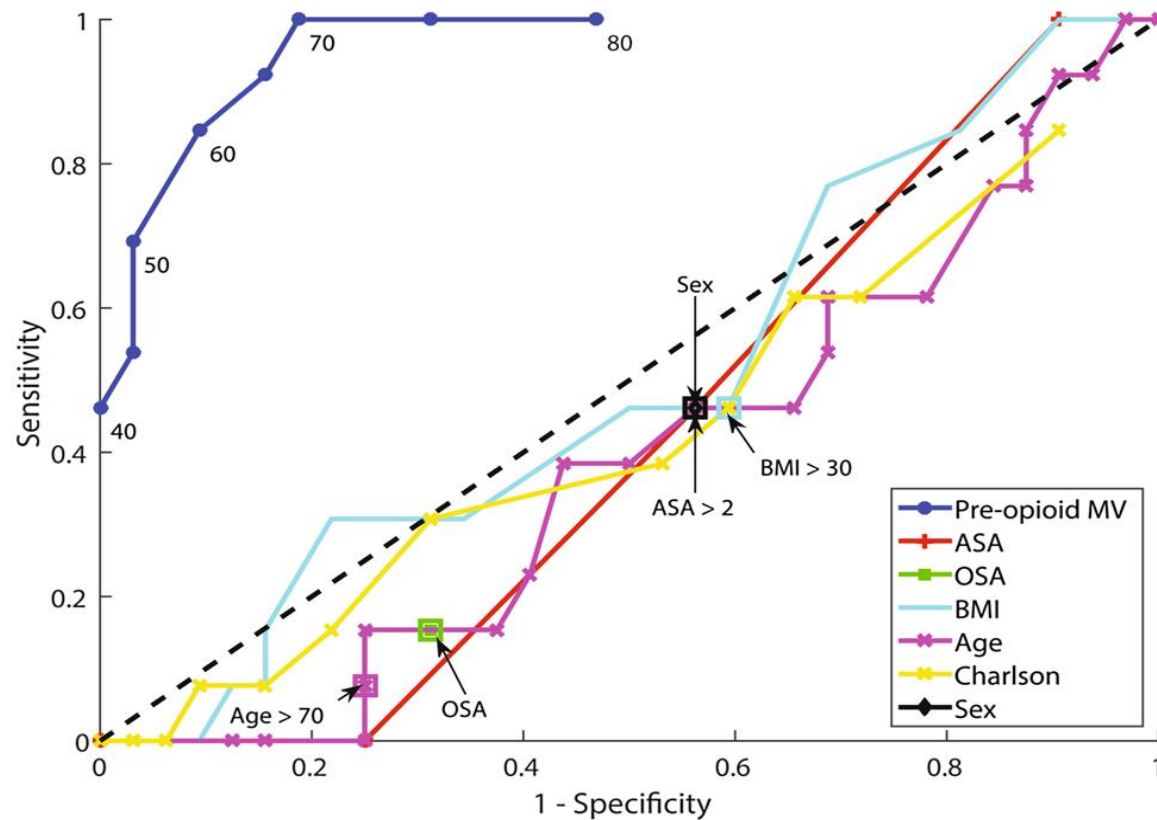
# Capnography Does Not Work Well in Non-intubated Patients

- 48 non-intubated subjects
- Sensitivity of capnography to even large changes in MV in non-intubated patients is not clinically relevant

- MV measurements change more rapidly and by a greater degree than capnography in response to respiratory changes in non-intubated patients



# Pre-opioid MV, the Only Way to Risk Stratify Patients “At Risk” for Respiratory Depression



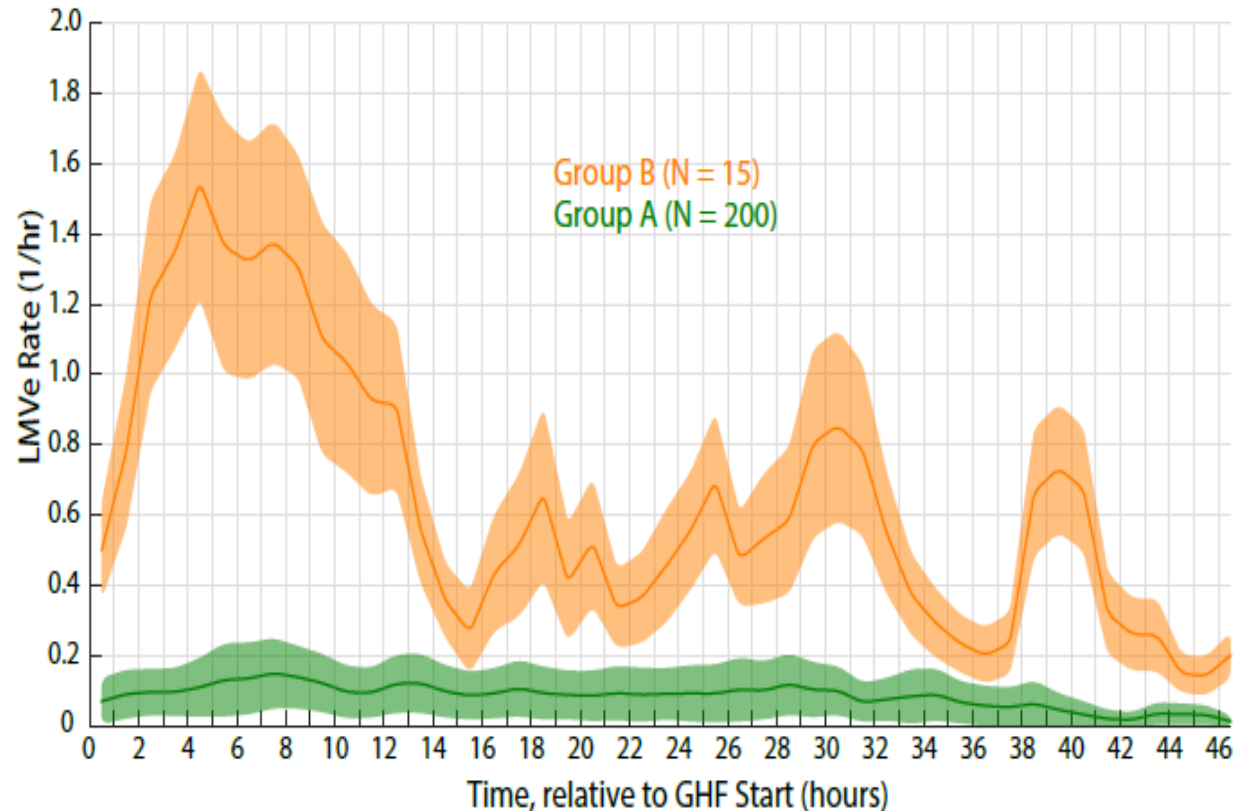
- 107 PACU patients s/p intraperitoneal surgical procedures
- Risk Stratification: RVM identifies patients at RISK!
- Using RR alone, 88.2% of all respiratory depression would be missed

Source: Low Minute Ventilation Episodes During Anesthesia Recovery Following Intraperitoneal Surgery as Detected by a Non-invasive Respiratory Volume Monitor. Cavalcante AN, Martin YN, Sprung J, Imsirovic J, Weingarten TN. *J Clin Monit Comput.* 2017 Dec 20. doi: 10.1007/s10877-017-0093-0. [Epub ahead of print] \*Mayo Clinic Rochester MN.\*



## PACU Triage Criteria

- 215 patients PACU/floor
- 48hr observational study
- 7% of patients had hypoventilation during last half hour in PACU and then hypoventilation on the floor
- Maximum respiratory depression not in PACU but 3-13 hours after surgery
- RVM identifies patients in the PACU who went on to have significant hypoventilation on the floor





# Colon Resection - Post-Operative



## Case

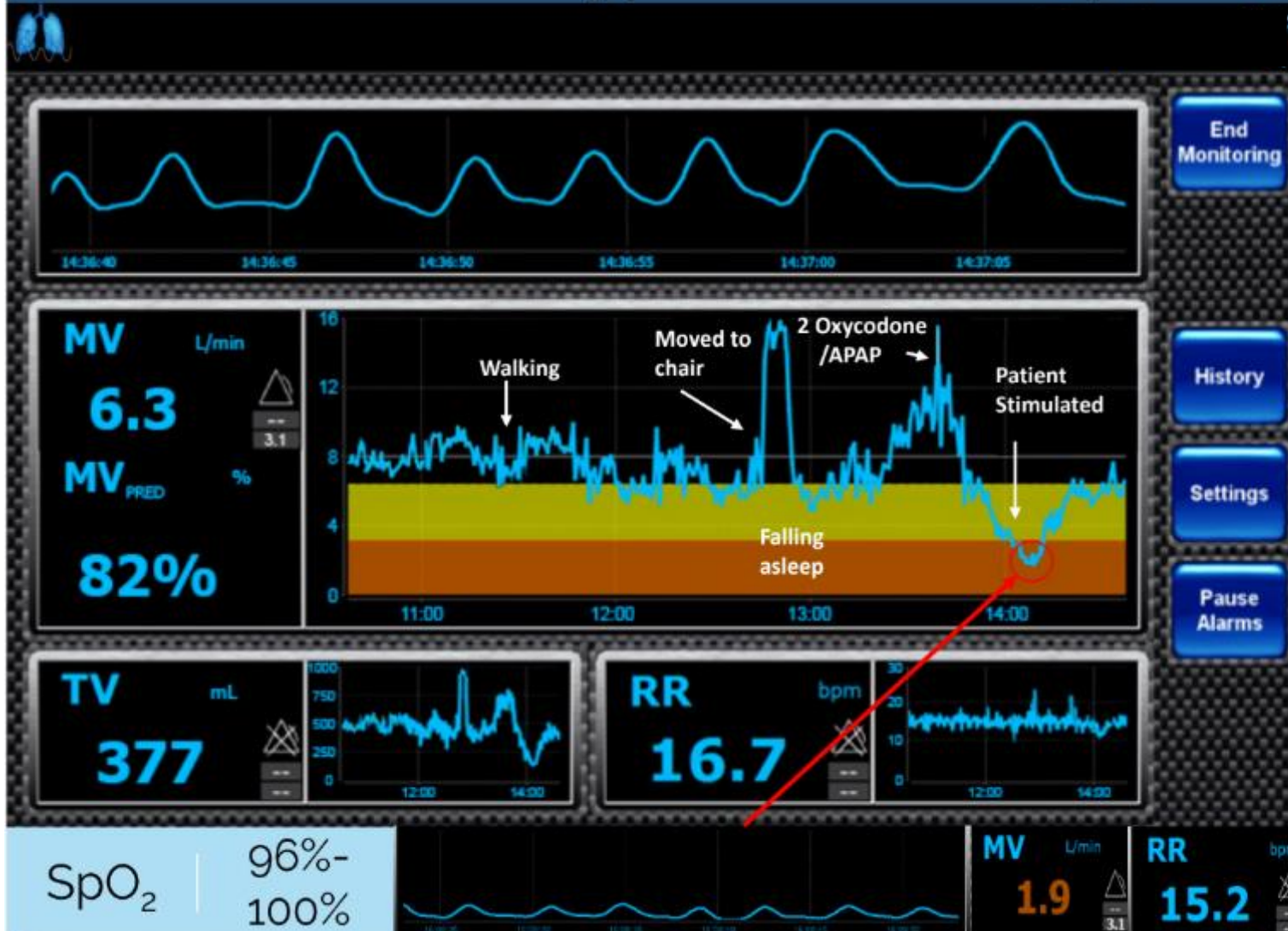
- PCA opioid led to hypoventilation
- Patient stimulated based on real-time low MV
- PCA dose cut in half

## Take Away

- Patient both safe and comfortable
- Avoid the need to rescue

Monitoring Minute Ventilation (MV) provides indication of hypoventilation post operatively

# Gastric Bypass – Post-Operative



## Case

- Oral opioids caused "Unsafe" hypoventilation
- TV low, with normal RR

## Take Away

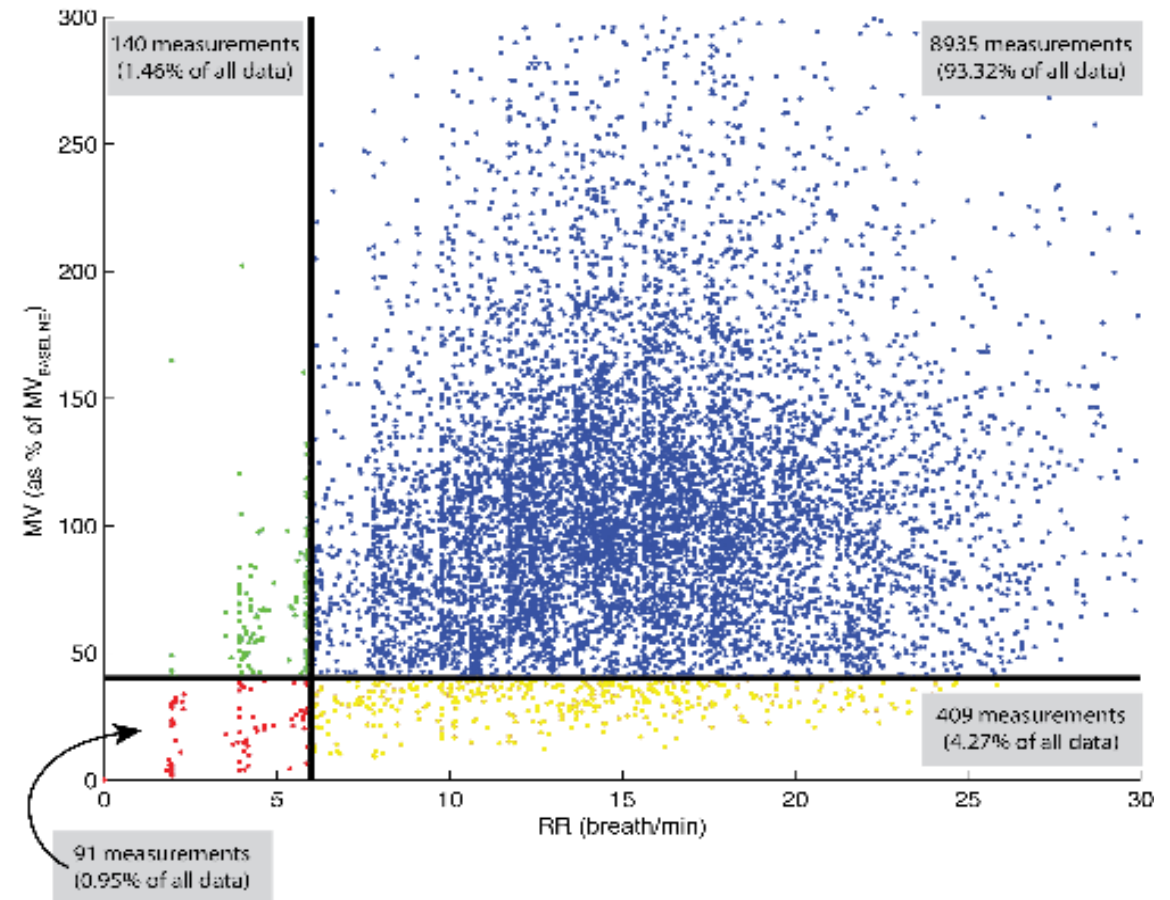
- Measuring RR alone misses >80% of hypoventilation

Low MV measurements help clinicians make objective decisions around patient care



# Adequacy of RVM during Upper Endoscopy Procedures

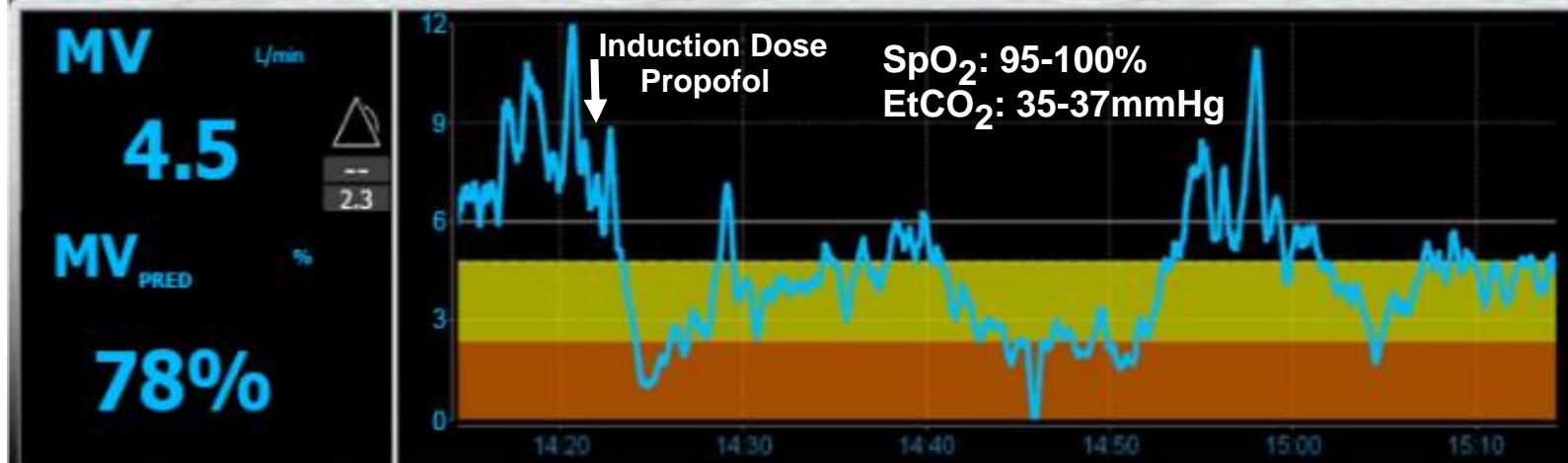
- 51 patients
- 9,575 respiratory epochs
- There is very weak correlation MV and the corresponding RR ( $r=0.05$ )
- RR alarm set at 6 bpm would miss > 82% of respiratory depression
- RR alone has only an 18.2% sensitivity – for predicting Low MV
- MV indicates respiratory performance; RR is not an adequate proxy.



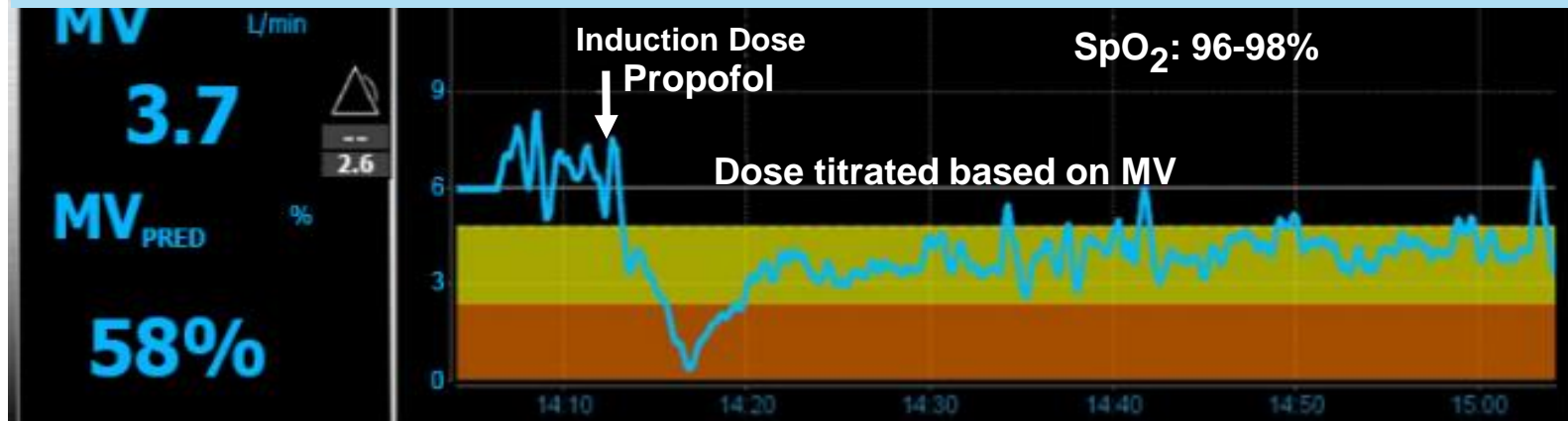
Source: Holley K, MacNabb CM, Georgiadis P, Minasyan H, Shukla A, Mathews D. Monitoring minute ventilation versus respiratory rate to measure the adequacy of ventilation inpatients undergoing upper endoscopic procedures. J Clin Monit Comput. 2016 Feb;30(1):33–9. doi: 10.1007/s10877-015-9674-y. Epub 2015 Mar 4.

# Upper Endoscopy/Procedural Sedation - RCT

## Blinded: not using *RVM*



## Unblinded: using *RVM*



## Cases

- EtCO<sub>2</sub> & SpO<sub>2</sub> measurements in normal range despite hypoventilation
- When RVM data available, CRNA is able to guide propofol, opioids, sedatives to avoid hypoventilation and decrease variations in level of sedation

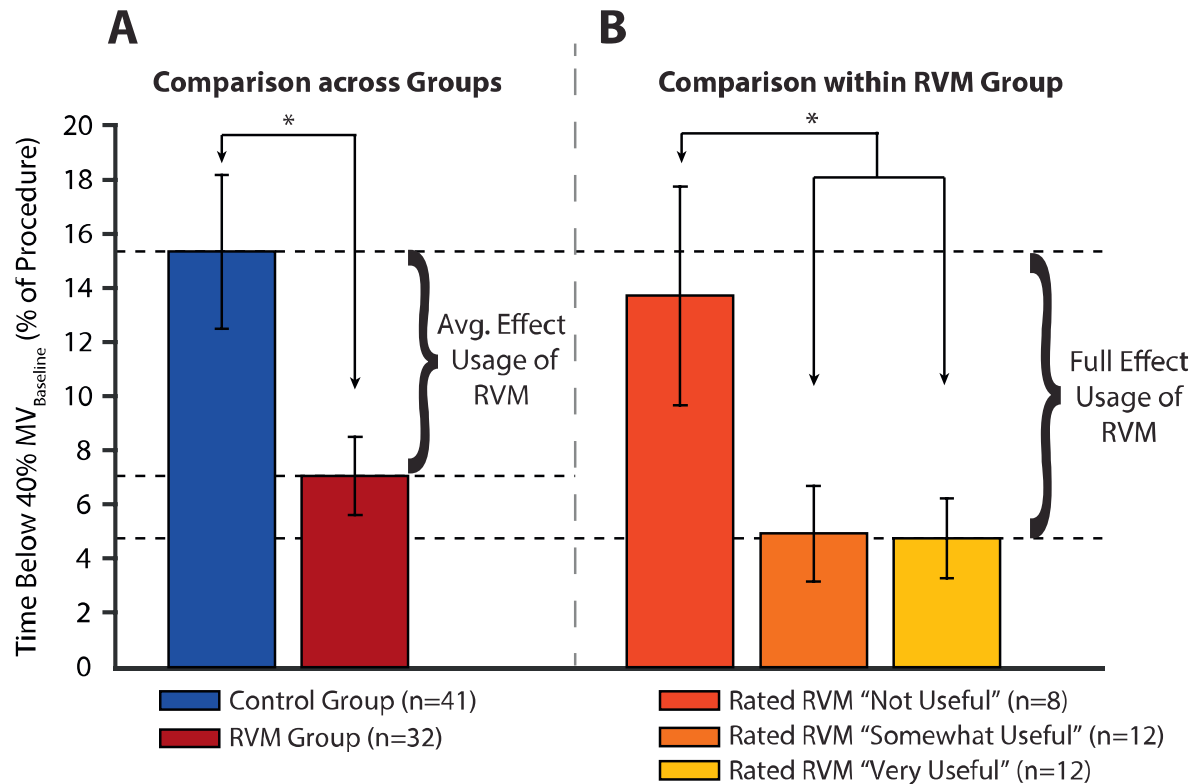
## Take Away

- MV measurement ensures both safety and comfort

Real time measurement of MV provides early, ongoing and actionable insight into patient respiratory status



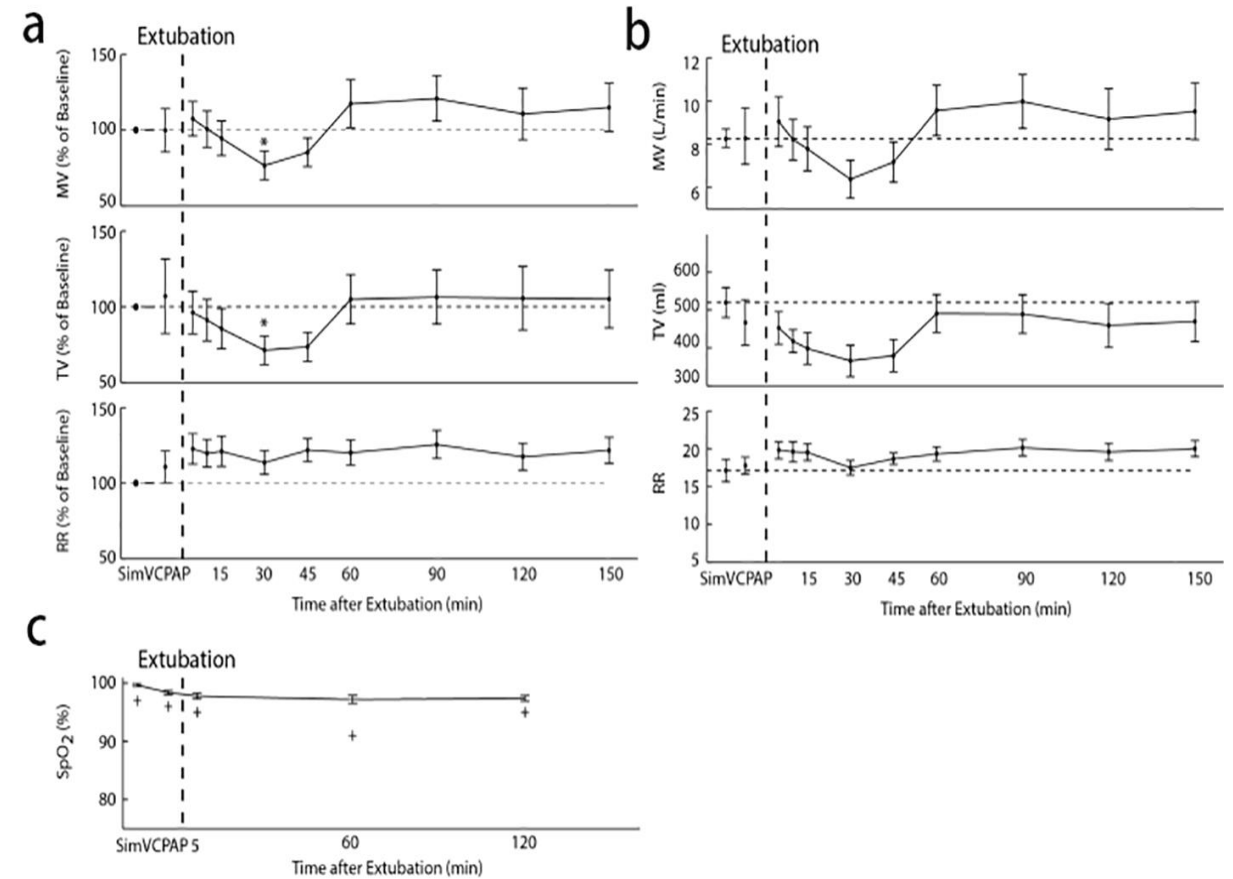
# Improving Safety during Procedural Sedation using RVM



- RCT of 73 patients undergoing upper complex endoscopy (Blinded to RVM data vs using RVM data to manage patients)
- 3x LESS respiratory depression when RVM used to manage sedation compared to blinded group

# Using RVM to Assess Respiratory Status Post Cardiac Surgery

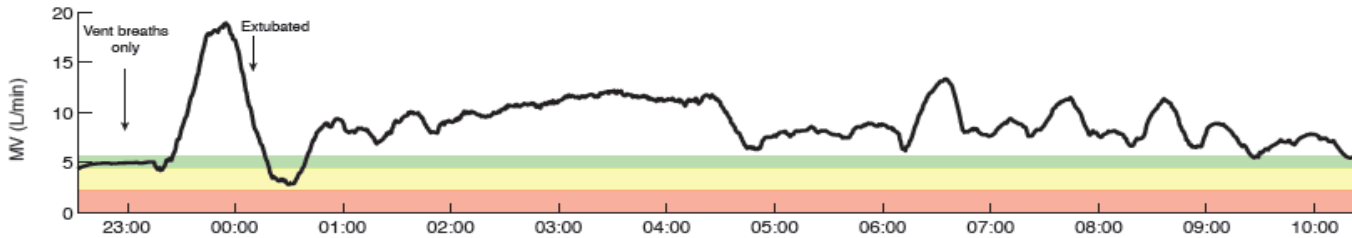
- Patients successfully extubated have a reproducible dip in MV post-extubation
  - maximum dip at 30 min. returns to baseline after 60 min.
- SpO<sub>2</sub> fails to report initial drop in respiration and return to baseline





# ICU Extubation: s/p CABG

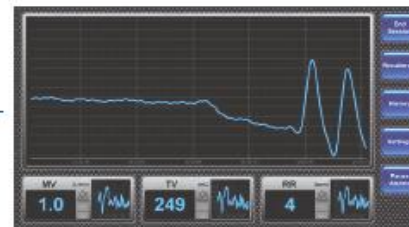
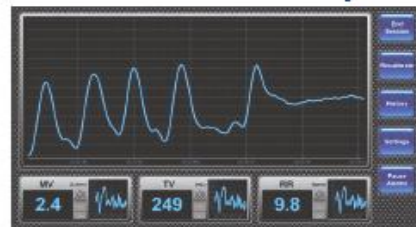
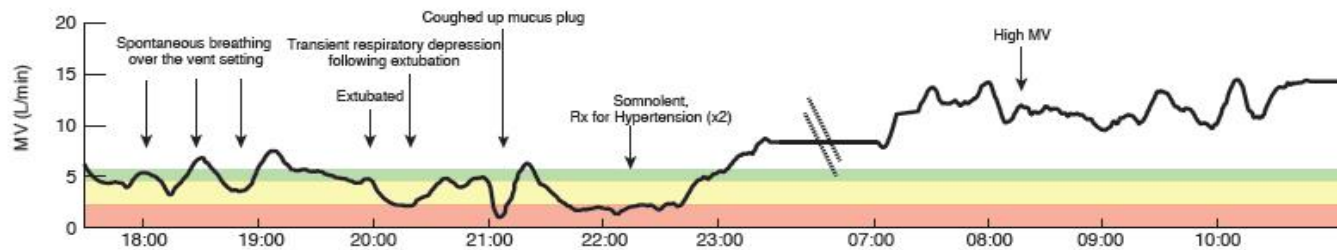
## Patient 1



## Patient 1 – Usual Course

- Usual 25% dip in MV post-extubation with return to normal in 90 min

## Patient 2



## Patient 2 – Hypoventilation

- Abnormally large dip in MV post-extubation
- Marked hypertension at change of shift
- Patient asleep
- Nurse treated twice with Lopressor
- Unsafe hypoventilation
- Hypertension likely due to hypercarbia
- Standard bedside monitor and pulse-ox did not alert nurse
- Arrest would have been considered cardiac in origin

Hypoventilation can be the unrecognized cause of rapid response teams or code blue events



# ► Objective 5: Outline an implementation plan of respiratory solutions

- What do we need to address?
- How can we improve patient care based on what we've processed?



# Clinical Protocols Can Lead to Success – but Complexity Limits Implementation

Chung F., Davidson T., Benumof J.L., Davis D., Ebert, T., Eikermann M., Gay P.C., Hillman D., Isono S., and Overdyk F. (Oct. 2010) *Perioperative management of OSA patients – Practical solutions and care strategies. University of California San Diego and University of Toronto*

## Prolonged Stay in PACU (> 30-60 min after modified Aldrete criteria met)

Known OSA

- Non-compliant with PAP Tx
- Severe OSA – (AHI >30), or
- Recurrent PACU Respiratory Event (30min block)
  - O<sub>2</sub>Sat < 90% (3 episodes)
  - Bradypnea <8 breaths / min (3 episodes)
  - Apnea ≥10 sec (1 episode)
  - Pain sedation mismatch

No

Moderate OSA (AHI > 16-30),  
Postoperative parenteral or oral opioids required  
(> codeine 60 mg q4h or equivalent)

No

Discharge to home if  
minor surgery

Yes

Postoperative care on  
surgical ward

Suspected OSA  
(≥2 on STOP, 3 STOP-bang)

- Recurrent PACU Respiratory Event (30min block)
  - O<sub>2</sub> Sat < 90% (3 episodes)
  - Bradypnea <8 breaths / min (3 episodes)
  - Apnea ≥10 sec (1 episode)
  - Pain sedation mismatch

Yes

Postoperative PAP  
therapy and care in a  
monitored bed with  
continuous oximetry

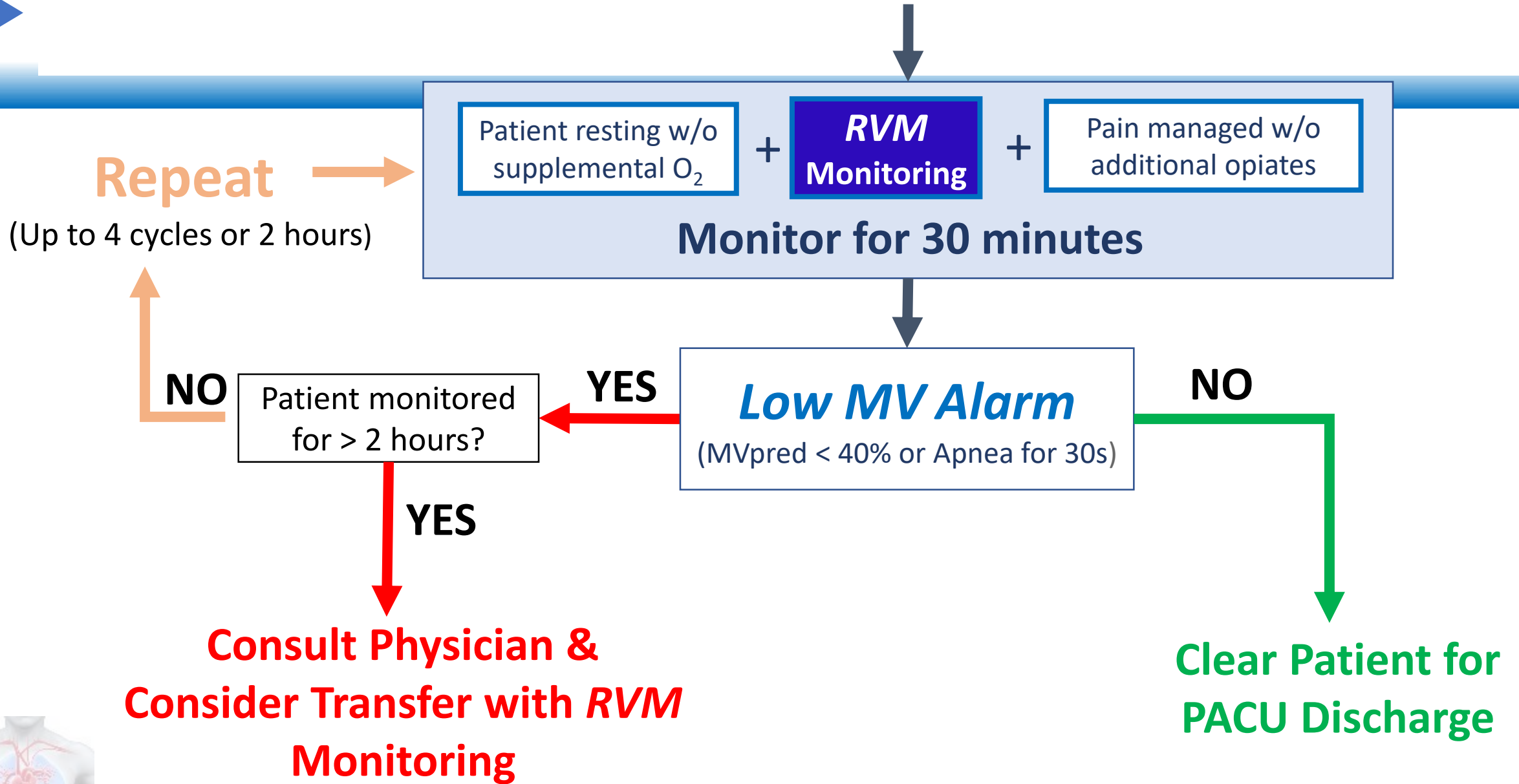
No

Discharge to home if  
minor surgery or  
postoperative care on  
the surgical ward

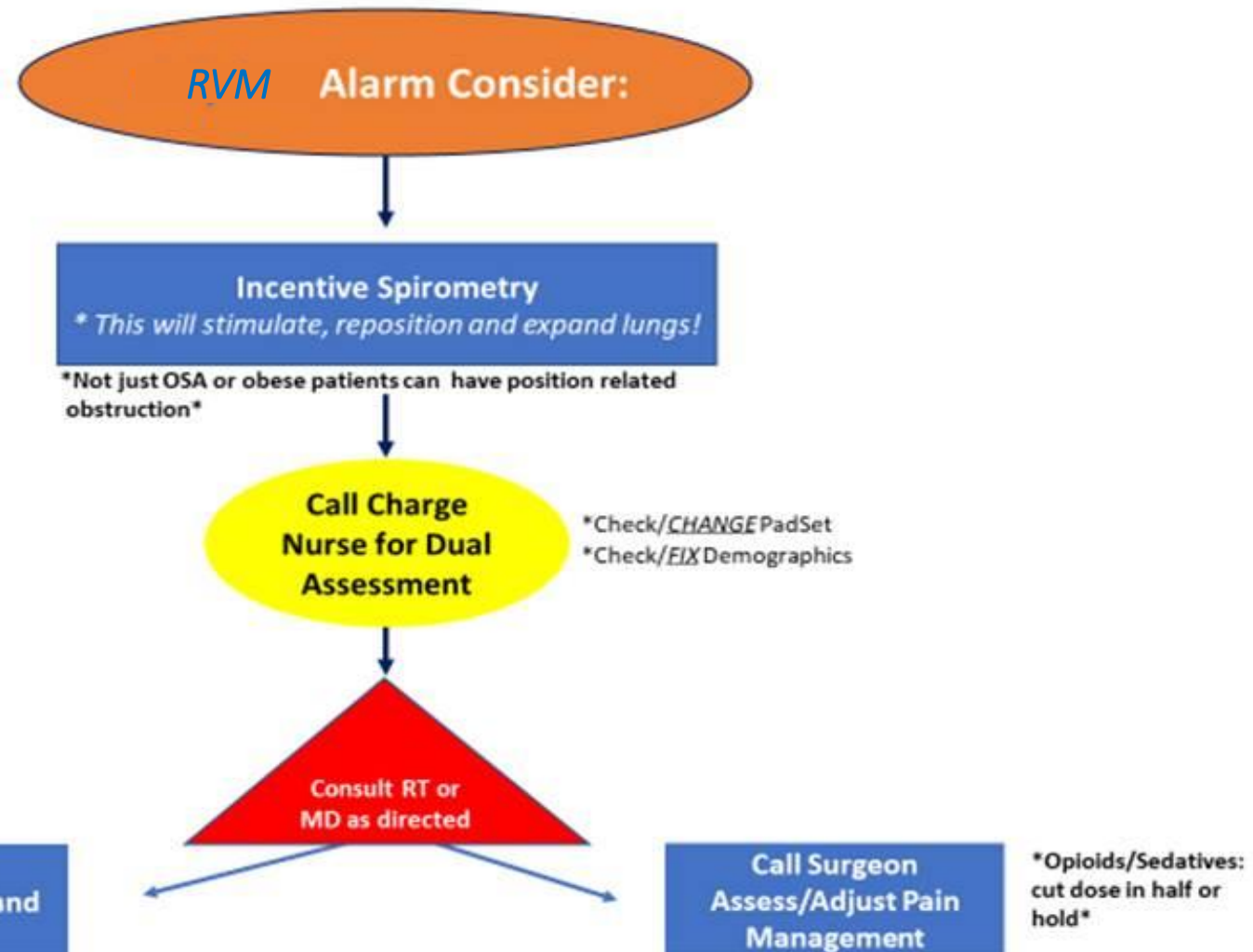
EXAMPLE



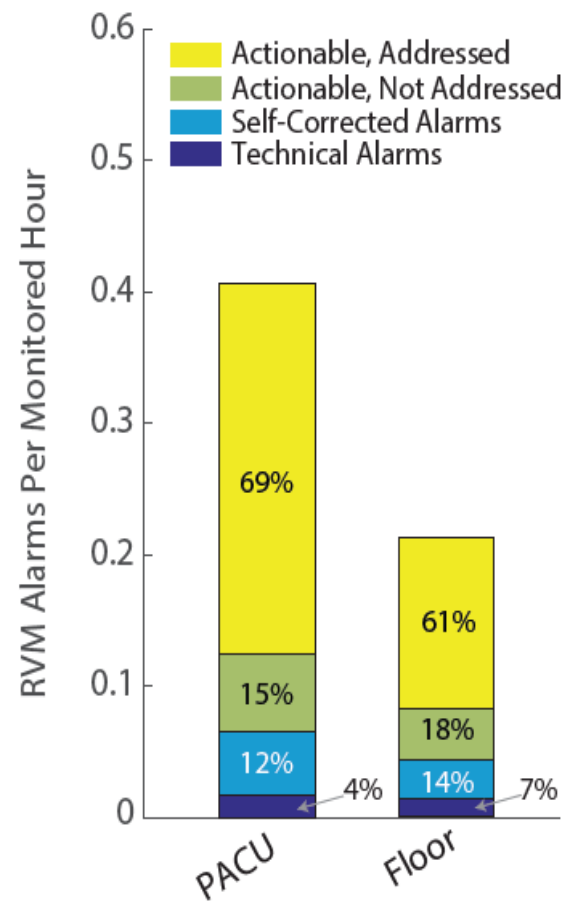
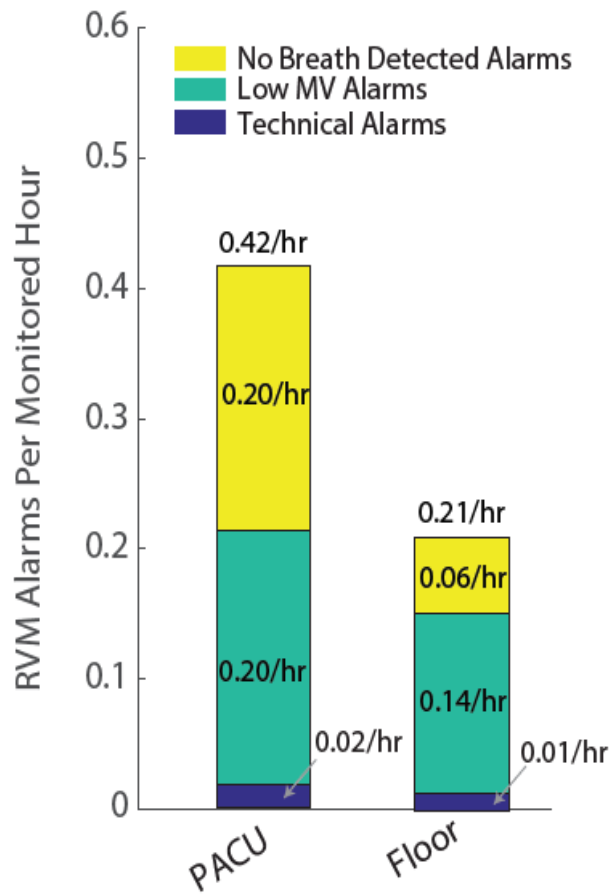
# Begin OSA MONITORING on PACU Arrival



# Devices and Alarms don't Improve Safety – A Plan Improves Safety



# Minute Ventilation (MV) – in the Perioperative setting



95% of alarms were “actionable”

### Clinical Interventions:

- 72% Stimulation
- 4% Change in opioids
- 2% Change in other meds
- 3% Patient repositioning
- 3% CPAP / BiPAP
- 2% MD / RT alerted
- 2% Change in LOS
- 1% Change in level of care
- 1% Avoided intubation

RVM provides an early warning. Due to RVM alarms triggering clinical interventions there were no respiratory related negative events.

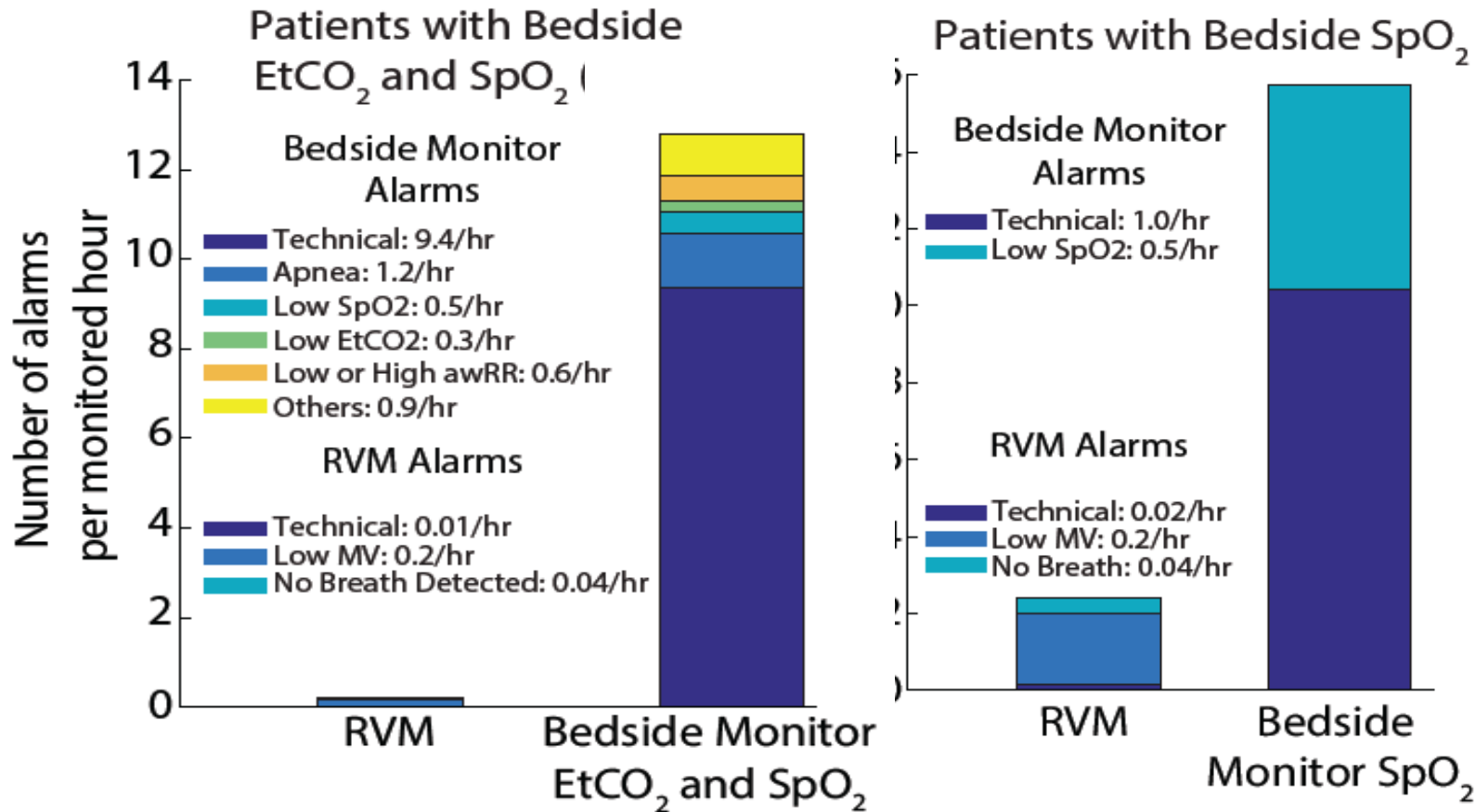
**RVM generates actionable alarms, with a high intervention-to-false-alarm ratio.**

**No RVM alarms provides confidence in respiratory status despite false alarms from other monitors.**





# Comparison of RVM, SPO2 and ETCO2 Alarms on the Hospital Floor



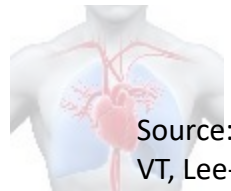
ASA 2018

RVM had 0.01 false alarms/hour

- For a nurse with five patients, they would hear **2 false alarms** per week with RVM

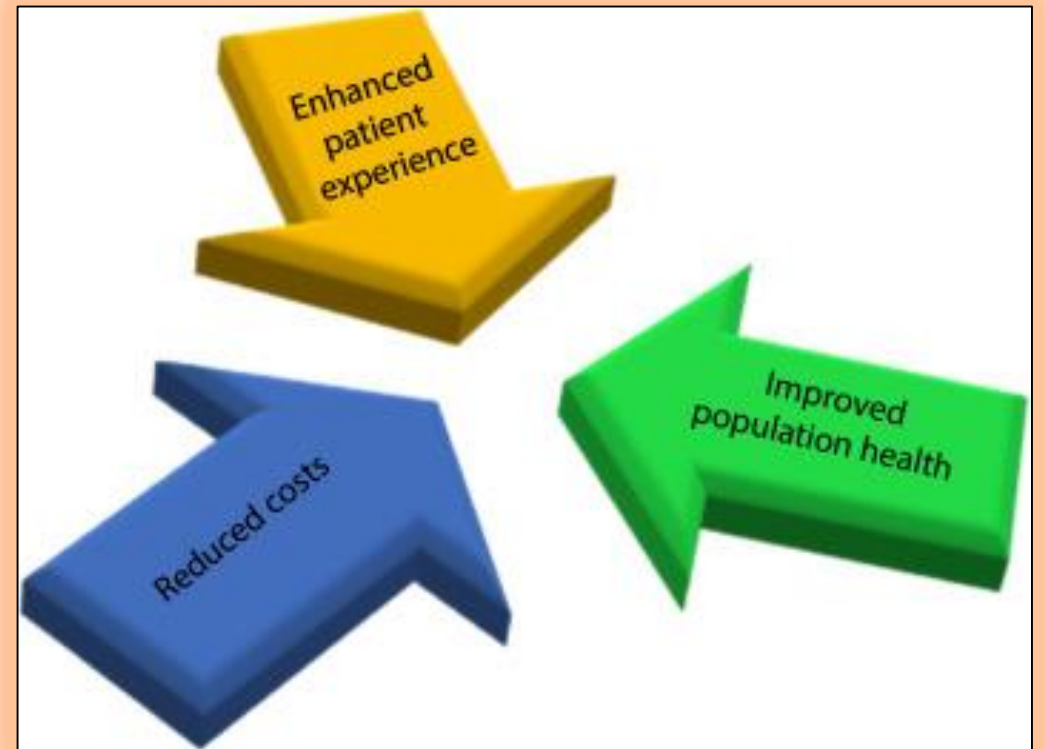
VERSUS:

- 200 false alarms** per week with oximetry
- 2000 false alarms** per week with capnography

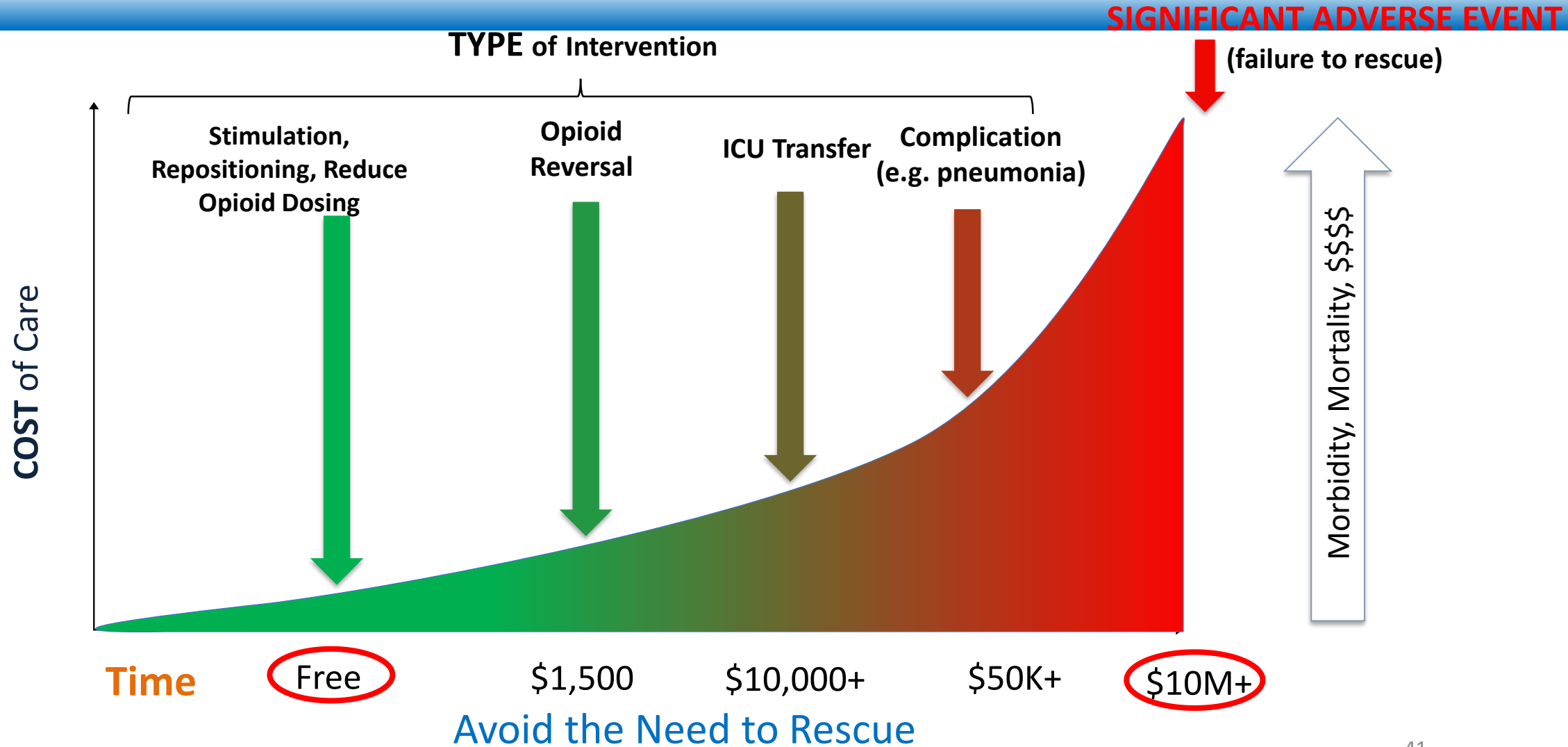


## Objective 5: Outline an implementation plan of respiratory solutions, *continued*

- Which clinical, financial, and operational actions need to be taken to achieve success?
- How will these changes achieve better healthcare?



# RVM—Early Intervention Increases Safety & Decreases Cost of Care



Source: Projected Incidence and Cost of Respiratory Failure, Insufficiency and Arrest in Medicare Population, 2019. Agarwal SJ, Erslon MG, Bloom JD. Academy Health Congress, June 2011. University of North Carolina

# RVM—Early, Predictive & Cost Effective

## Clinical Excellence that pays for itself

- Superior **Patient Safety**
- Standardized language for respiratory status
- Low staff burden
- Rapid financial return justifies implementation

## National Leadership in Standard of Care Improvement

- Drive and exceed **Patient Care Standards** to differentiate patient care
- Manage risk and efficiency across clinical environments, across institutions in systems
- Better information for clinician feedback: guide, standardize and evaluate

## Provide Enhanced, Proactive, Preventative Clinical Care to Patients

- Better patient management: enhances **Patient Experience** promotes **Patient Satisfaction**
- Short term patient management benefits
- Long term patient satisfaction increasing:
  - Patient referral
  - Physician referral
  - Reputation of institution



# RVM — “The EKG of the Lungs”

Supports Our Philosophy to Predict & Prevent Versus Recognize & Respond

## Cardiac



- ✓ Diagnostics
- ✓ Monitoring
- ✓ Compromised Cardiac Function
- ✓ Multiple Sites of Care
- ✓ Advanced therapeutics
- ✓ Closed loop  
(pacemakers, defibrillators, etc.)

## Respiration Ventilation



- ✓ Real Time Diagnostics
- ✓ Continuous Monitoring
- ✓ Compromised Ventilation Function
- ✓ Multiple Sites of Care
- ✓ Advanced Warning
- ✓ Therapeutic Monitoring
- ✓ Closed loop (PCA, BiPAP)

## RVM



- ✓ Fundamental unit of breathing
- ✓ MV: Leading Indicator of Respiratory Depression
- ✓ SpO<sub>2</sub>, EtCO<sub>2</sub>, RR provide false assurance and false alarms
- ✓ Adrenergic and Non-adrenergic medications mask or falsify perfusion... limits SpO<sub>2</sub>
- ✓ Trend of depth and rate of ventilation
- ✓ Enables personalized medicine





# Thank you!

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# Appendix





## References

[Respiratory Volume Monitoring Library](#)

[Minute Ventilation Monitoring Guidelines](#)

<https://www.ecri.org/components/HDJournal/Pages/Eval-Background-Monitors-Respiratory-Depression.aspx#>



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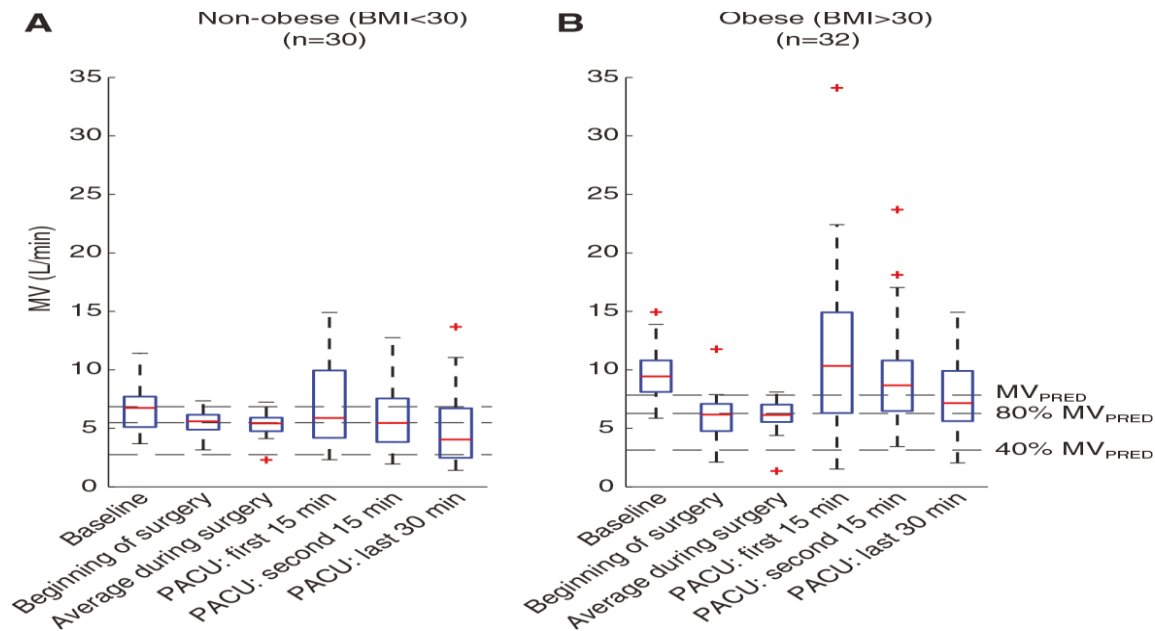


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  - **University of North Carolina**



# Assessment of obese vs. non-obese patients using RVM



- 62 PACU patients after elective joint replacement
- Obese patients have greater variability in ventilation post-op than non-obese patients
- RVM may be especially useful in obese patients