Acute Care and Wearable Technology

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- Director Perioperative Outcomes and Informatics Collaborative
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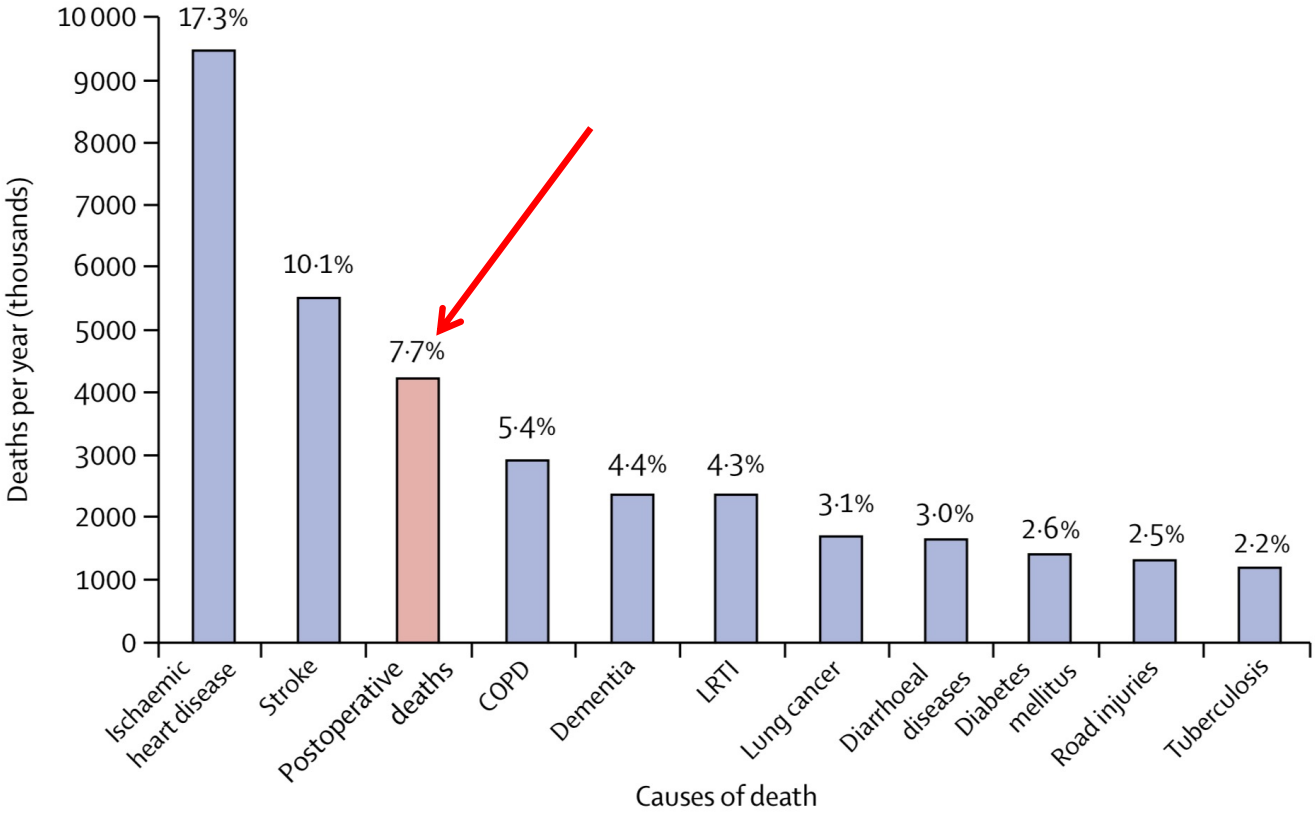
- Wake Forest Hypertension and Vascular Research Cardiovascular Sciences Center
- Critical Illness, Injury and Recovery Research Center (CIIRRC)
- Outcomes Research Consortium, Cleveland, OH

Disclosures

- Edwards Lifesciences – consultant, key opinion leader, grant funding
- Caretaker Medical – consultant, grant funding
- Retia Medical – advisory board, grant funding
- Potrero Medical – consultant, grant funding
- GE Healthcare – consultant
- Philips Research North America – consultant
- Medtronic – executive advisory board, grant funding to previous institution
- Fifth Eye Inc. – consultant

- NIH/NCATS KL2 Wake Forest CTSI “ A pilot trial of continuous portable postoperative hemodynamic and saturation monitoring on the general care floor ”
- BrainX LLC – founding partner

The postoperative period - major cause of death



Nepogodiev D, et al. Lancet 2019

Look beyond the ICU – we leave our patients under monitored

- Three quarters of patients who died in the hospital **were not admitted to an ICU at any stage** after surgery - EuSOS study

- About **half of all adverse events** in hospitalized patients occur on the general care ward
- Responsible for **85% of post-operative mortality**

Pearse R et al. Lancet 2021
Andersen, et al. Resuscitation 2016

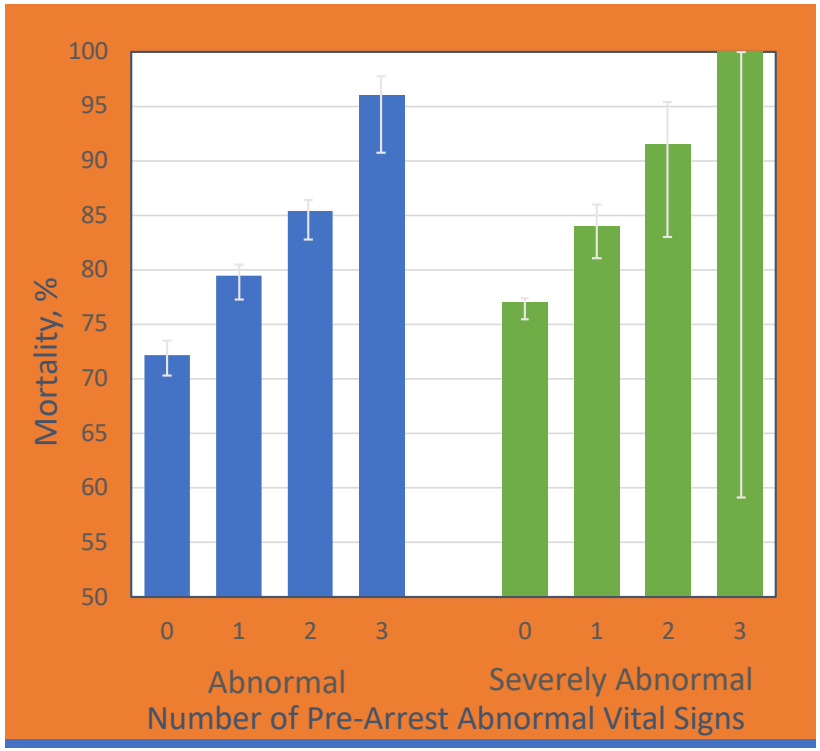
Perman, et al. JAHA 2016

Why Monitoring? Why wearables?

Do code blues occur out of the blue?

- **60%** patients had **at least one** abnormal vital sign 1–*4 hours before* cardiorespiratory arrest

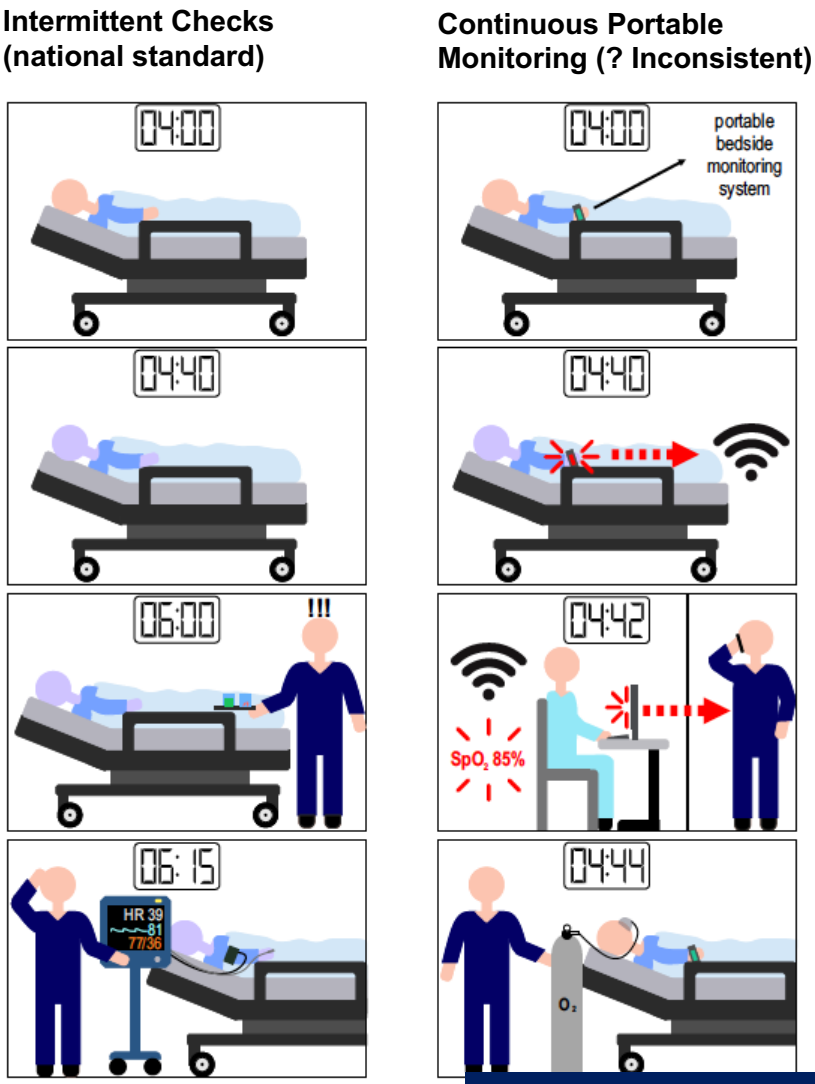
- Step-wise increase in mortality with increasing number of abnormal vital signs



Andersen, et al. Resuscitation 2016

Ward monitoring is critical

- Spot-checks miss prolonged periods of hypotension, hypoxemia and hypoventilation
- Events (cardiac/respiratory) preceded by 4-6 hours of a change in patterns of vital signs



Khanna AK et al. Crit Care 2019

Falling off the monitoring cliff….

Average surgical time 130 mins

BP every 5 mins (usually more)

26 times/ 2 hrs.

Hospital LOS is 2-4 (3) days

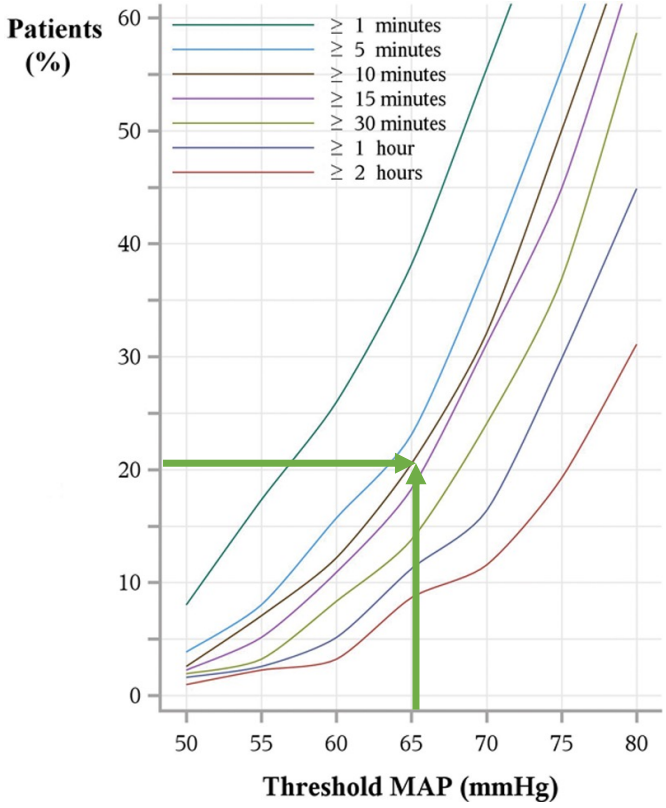
BP every 4 hrs.

18 times/3 days

Home …..Never to be checked again?

Thoughts courtesy Dr.Alparslan Turan

Postoperative Hypotension – common & undetected



MAP Threshold for Hypotension (mm Hg)	N, Detected by Continuous Monitoring, %*	Patients Missed by Routine Assessments among Those Detected by Continuous Monitoring: No. Missed by Routine Assessment/ No. Detected by Continuous Monitoring	Proportion (95% CI)	N, Detected by Routine Vital-sign Assessments, %†
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< 75	140 (45%)	14/140	10% (6, 16)	212 (68%)
< 80	204 (65%)	6/204	2.9% (1.1, 6.3)	258 (83%)

*Continuous monitor detected at least one contiguous episode (without gap greater than or equal to 5 min) for at least 15 min below thresholds. †Defined by single measurements.

Spot checks missed about 50% of episodes of MAP<65mmHg detected by continuous monitoring

Turan A, Khanna AK et al. Anesthesiology 2019

Postoperative Respiratory Depression – common & undetected

PRediction of Opioid-induced respiratory Depression on Inpatient wards using continuous capnoGraphY and Oximetry: An International Prospective, Observational Trial

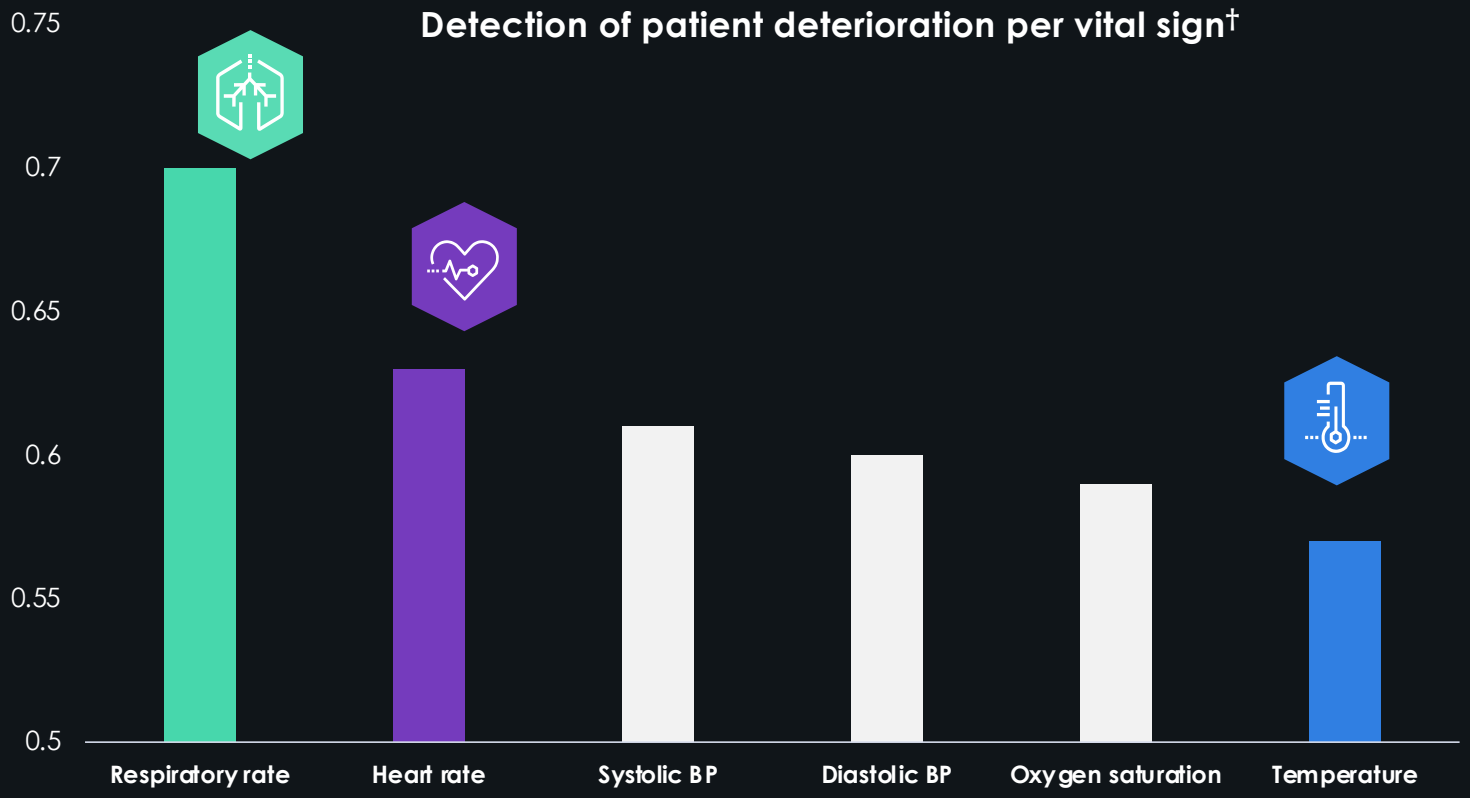
The PRODIGY Study

Monitoring tethered!

- ✓ **614/1381 (46%) patients with at least one RD episode**
- ✓ **RD episodes – detected with continuous silenced/blinded monitoring**

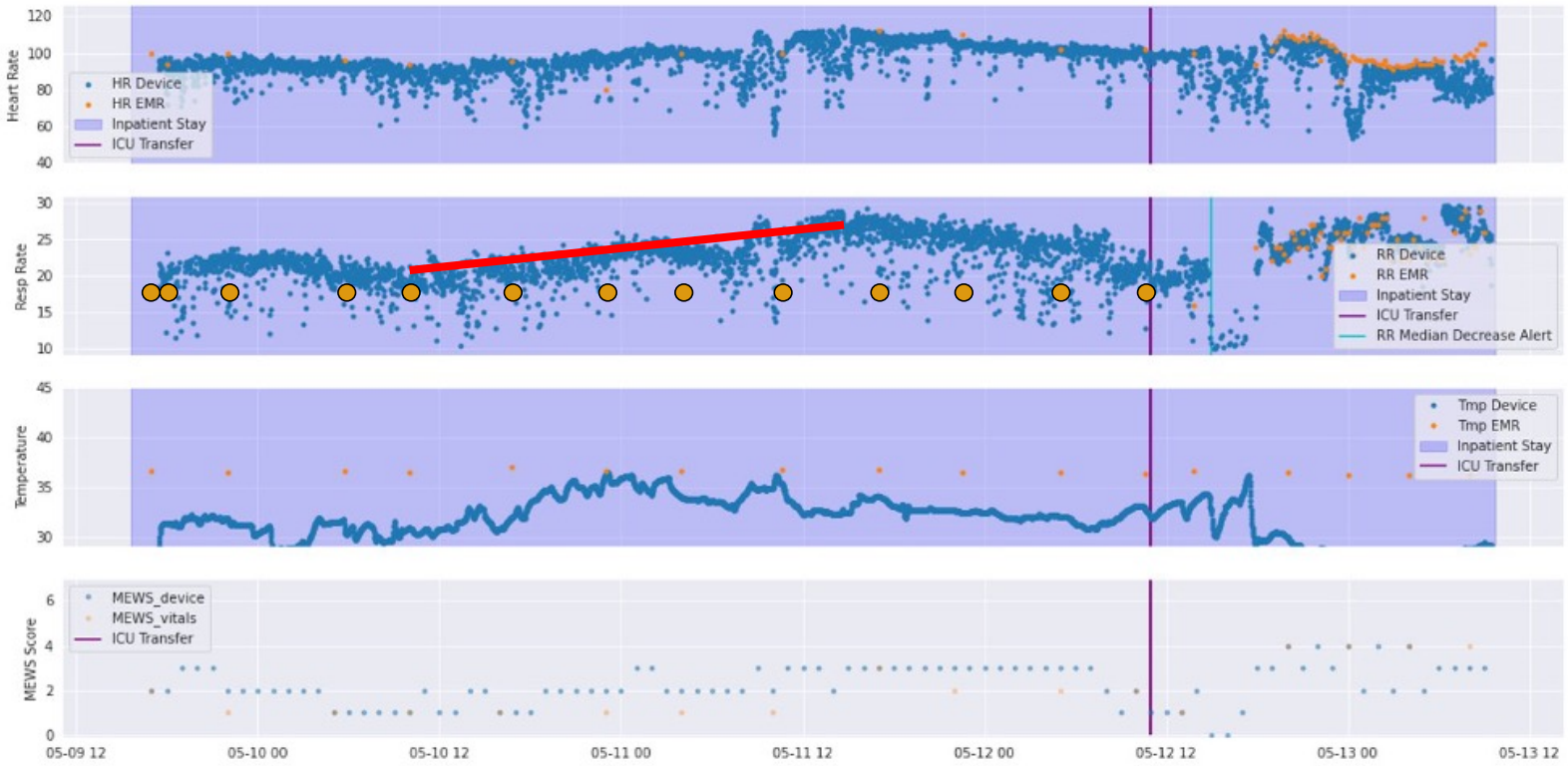
Khanna AK, et al. A&A 2020

What vital signs trends?

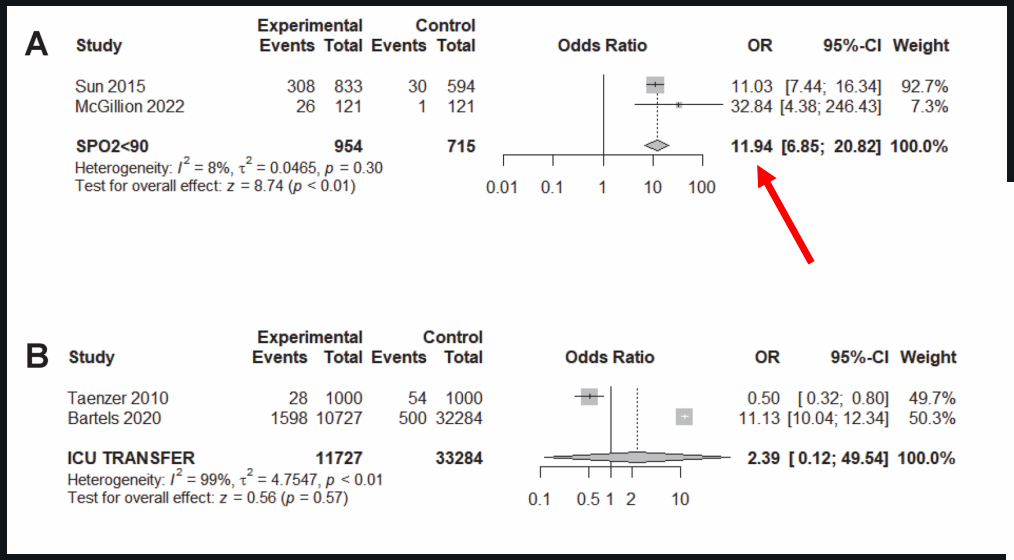


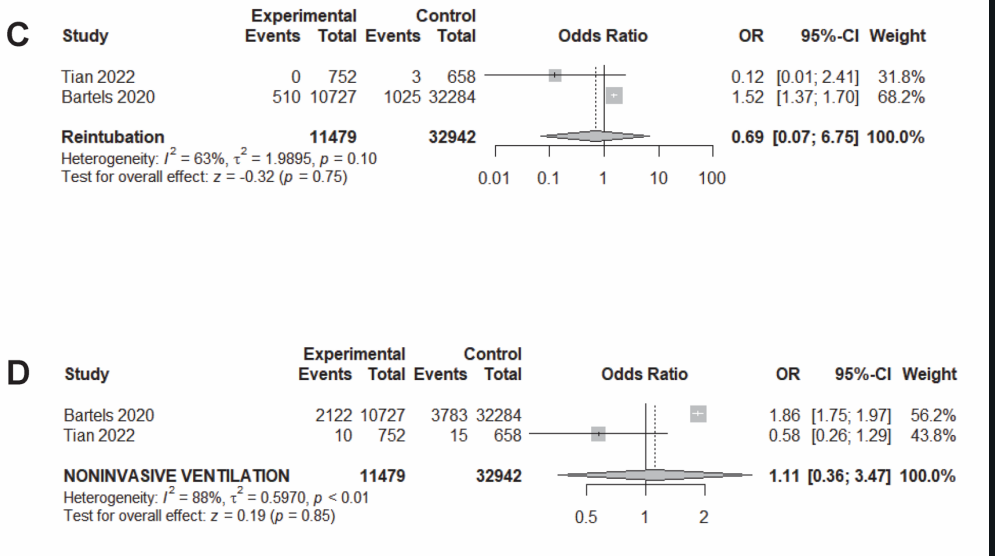
Churpek M, et al. Resuscitation 2016

Do wearables improve the accuracy of measurement of RR?



Role of Continuous Pulse Oximetry and Capnography Monitoring in the Prevention of Postoperative Respiratory Failure





Khanna AK, Kaw R et al. [Unpublished]

There is a ‘smart monitoring patch’ for nearly everything

Michard F, et al. JCMC 2022

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Continuous Monitoring Beyond the ICU

The rise of mobile solutions

Post-ICU patients are at high-risk of clinical deterioration. Continuous and mot monitoring on hospital wards is useful to detect clinical deterioration at an eart stage. It may help to prevent serious adverse events and ICU readmission.

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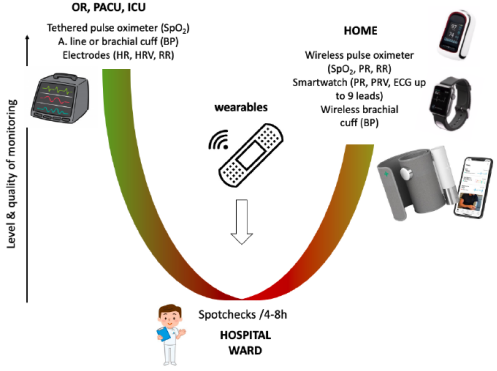
monitoring of vital signs has been shown to be associated with a decrease in calls for rescue interventions and cardiac arrest, in ICU transfer and in hospital mortality (Taenzer et al. 2010; Bellomo et al. 2012; Brown et al. 2014; Subbe et al. 2017). However, until

saturation and blood pressure from vi monitoring (Luo et al. 2019), but vali tion studies done in real hospital conditi are lacking. Contact free solutions are v appealing for patients because they do need to be connected to any device



EDITORIAL

Automated Continuous Noninvasive Ward Monitoring

Validation of Measurement Systems Is the Real Challenge

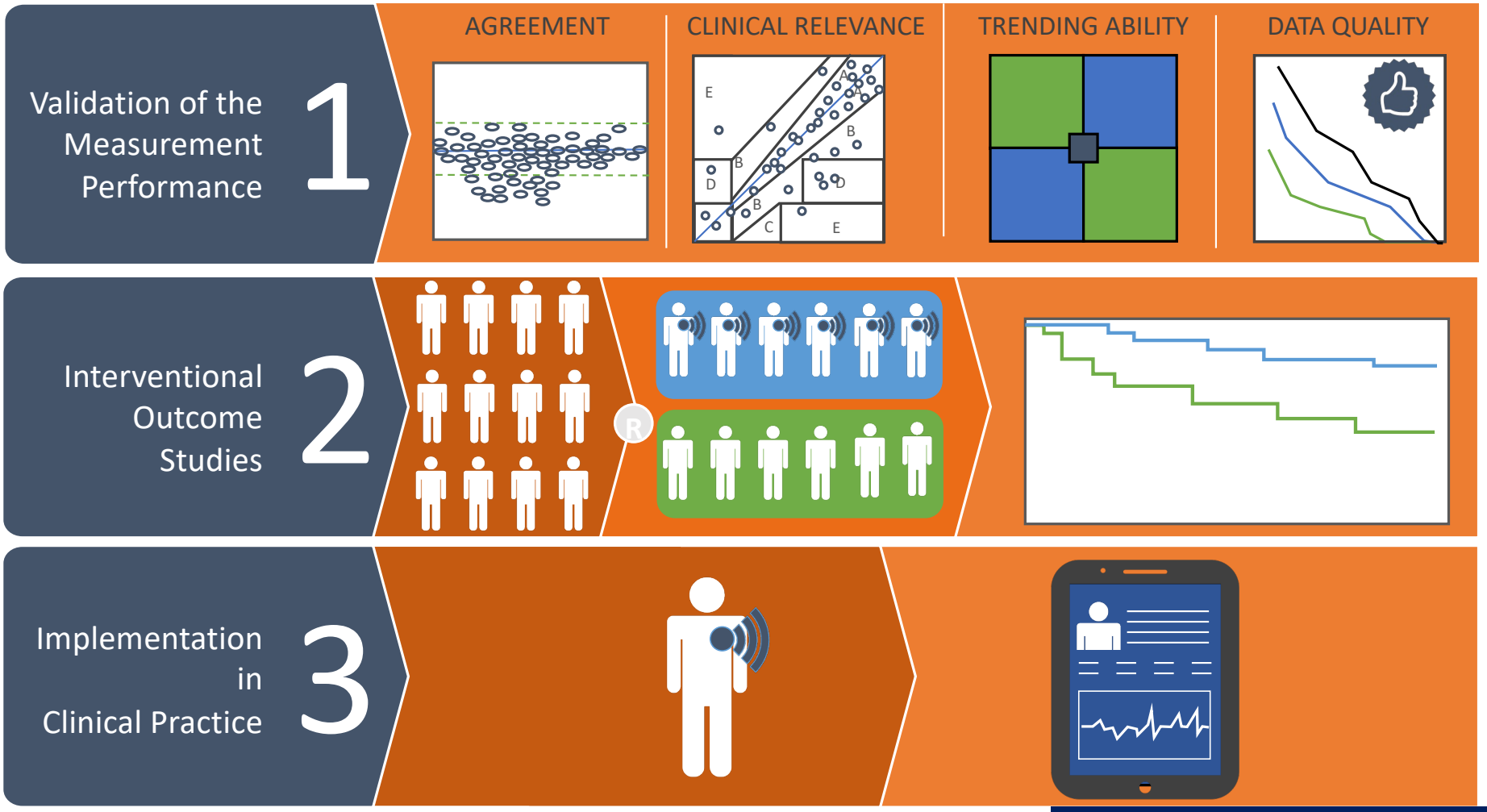
Bernd Saugel, M.D., Phillip Hoppe, M.D., Ashish K. Khanna, M.D., F.C.C.P., F.C.C.M.

About half of all adverse events in hospitalized patients occur on the general care ward.[1] However, acute cardiorespiratory events do not occur out of the blue. Up to 60% of patients have at least one or more abnormal vital signs as early as 4 to 6 h before a cardiac arrest.[2] Early detection of changes in cardiorespiratory physiology therefore is critical for preventative or therapeutic measures to be effective and to eventually improve patient outcomes. Automated continuous noninvasive ward monitoring may be a promising approach for improving surveillance of general care ward patients at risk for cardiorespiratory events. With numerous continuous ward monitoring devices flooding the healthcare market, it becomes crucial to rigorously test

"[T]he impact of continuous ward monitoring on patient-centered outcomes needs to be investigated in large interventional clinical trials."

and the reference method. By using Bland–Altman analysis accounting for repeated measurements within subjects, the authors assessed the mean of the differences and the limits of agreement. A clinically acceptable agreement was defined as ±10%, ±5 beats/min, or ±3 breaths/min in comparison with the reference method. Although the mean of the differences (often termed "bias") was low, the relatively wide limits of agreement indicate that the precision of agreement of the test methods in comparison with the reference method still need to be improved.

In addition, as a secondary endpoint, the clinical relevance of measurement differences was assessed using error-grid analysis that provides information about the consequences of incorrect treatment decisions triggered by measurements with the test



Saugel B, Hoppe P, Khanna AK et al.
Anesthesiology 2021

BJA Open

BJA Open, 1 (C): 100002 (2022)

doi: 10.1016/j.bjao.2022.100002
Original Research Article

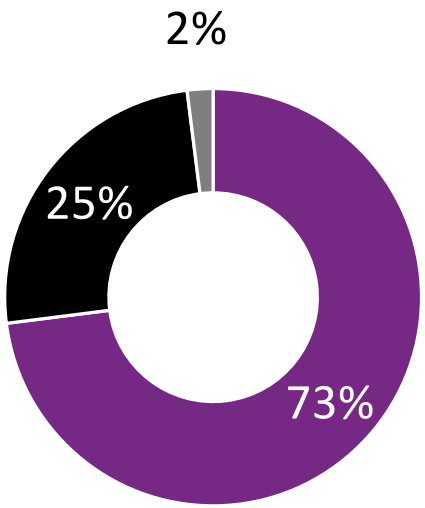
ORIGINAL RESEARCH ARTICLE

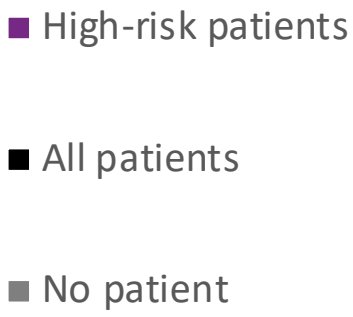
Wireless wearables for postoperative surveillance on surgical wards: a survey of 1158 anaesthesiologists in Western Europe and the USA

Frederic Michard[1,*], Robert H. Thiele[2], Bernd Saugel[3,4], Alexandre Joosten[5], Moritz Flick[3], Ashish K. Khanna[4,6], and Collaborators[†]

[1]MiCo, Denens, Switzerland, [2]Department of Anesthesiology, University of Virginia, Charlottesville, VA, USA, [3]Department of Anesthesiology, Center of Anesthesiology and Intensive Care Medicine, University Medical Center Hamburg–Eppendorf, Hamburg, Germany, [4]Outcomes Research Consortium, Cleveland, OH, USA, [5]Department of Anesthesiology, University Paris Saclay, Paul Brousse Hospital, Villejuif, France and [6]Department of Anesthesiology, Wake Forest School of Medicine, Winston-Salem, NC, USA

Which patients should be monitored continuously ?





EU	US
81%	63%
17%	35%
2%	2%

→ risk stratification tools or scores

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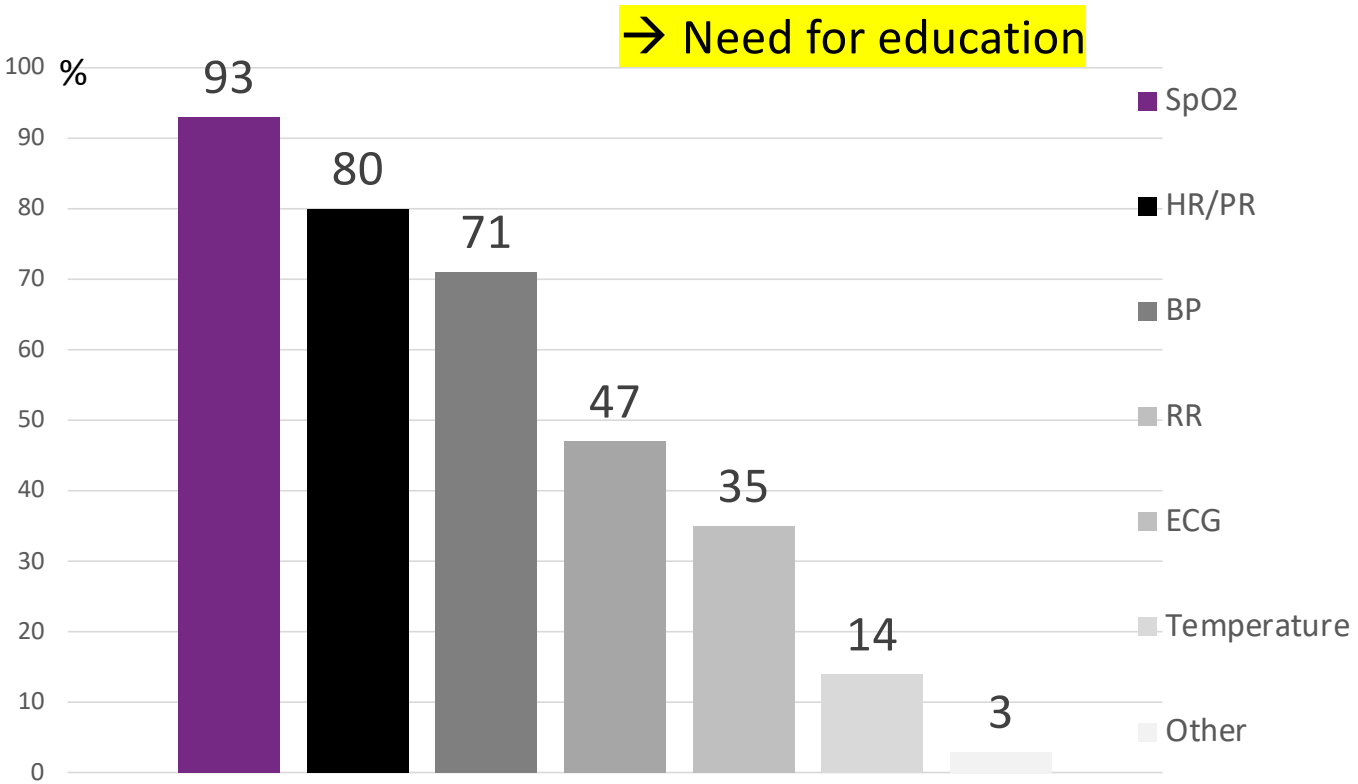
Which variables would you monitor continuously?



EU	US
93%	94%
83%	77%
71%	70%
51%	41%
30%	42%
17%	11%
2%	4%

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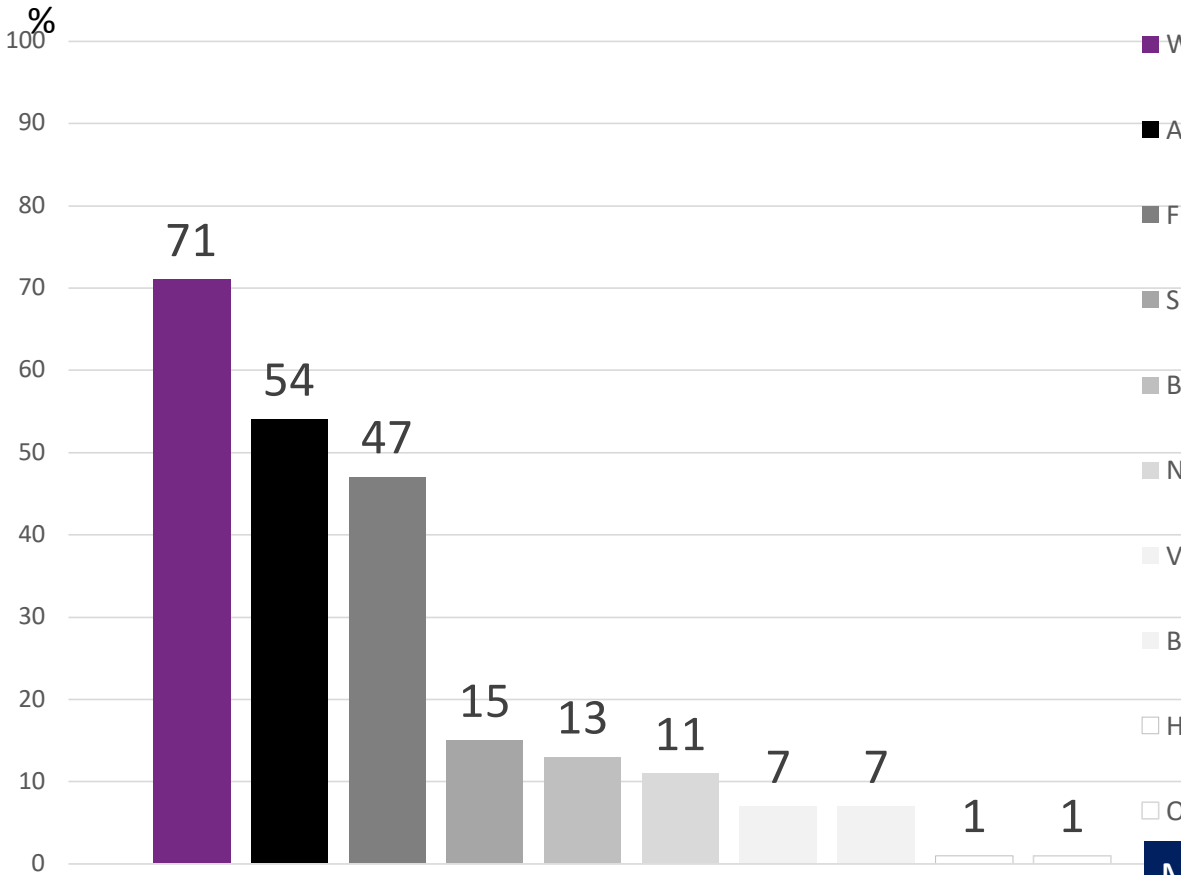
Which sensor would be ideal for continuous monitoring?



	EU	US
Wrist device or bracelet	69%	72%
Adhesive patch	56%	51%
Finger sensor or ring	49%	45%
Shirt or pyjama	18%	12%
Bed sensor	16%	9%
Necklace	12%	11%
Video	3%	11%
Belt	9%	4%
Headband or helmet	1%	2%
Other	0%	1%

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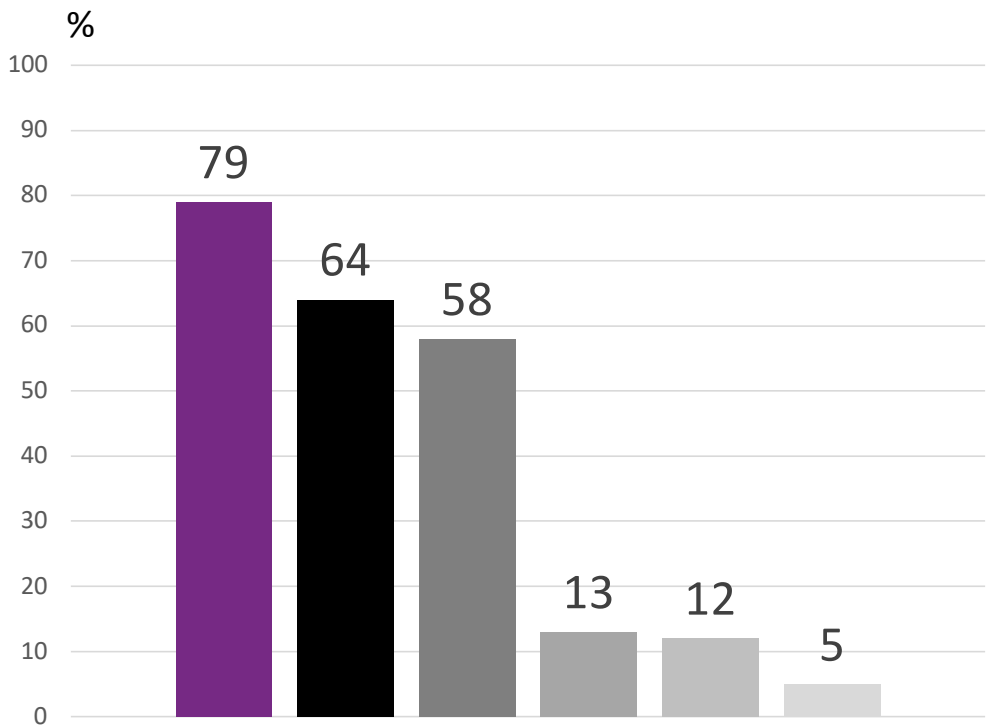
What are the main implementation challenges?



	EU	US
Economic	75%	84%
Connectivity/IT	66%	62%
Nurse pushback	57%	59%
Ward physician pushback	14%	12%
Patient pushback	14%	10%
Other	5%	5%

→ ROI estimation

→ Connectivity robustness

→ Alarm management strategies

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Our experiences at Wake Forest – dense data, patterns, alarms and more…

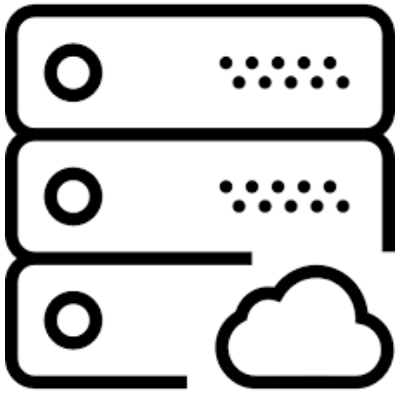
- FDA cleared for continuous ECG, Heart Rate, SpO_2, Blood Pressure (cuff-based and cuffless on beat-to-beat basis), Respiration Rate and Skin Temperature
- Completely wireless technology

Wake Forest Ward Monitoring Data Flow

Continuous Vital Sign Monitoring & Data Collection

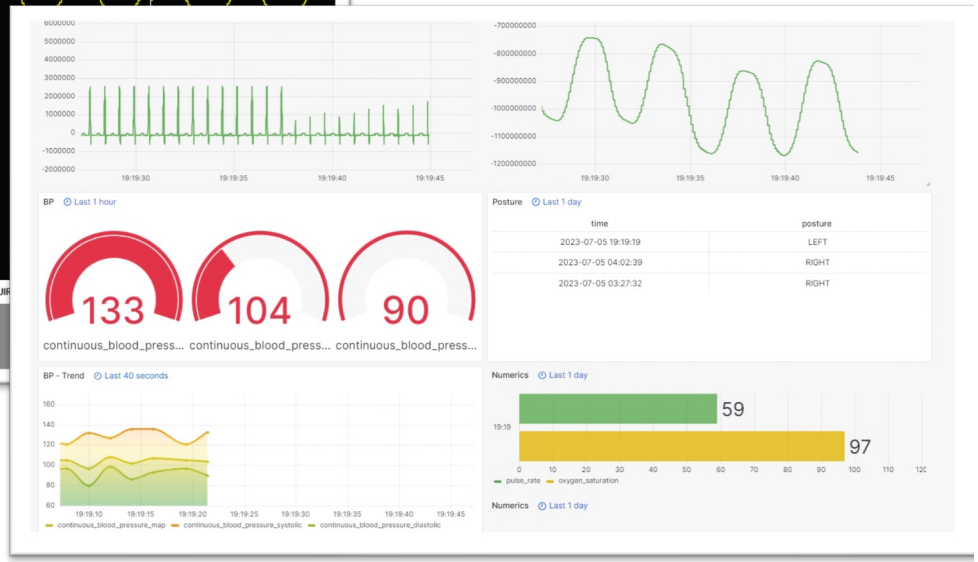
Patient Worn Device (PWD)

Patient Data Server (PDS)

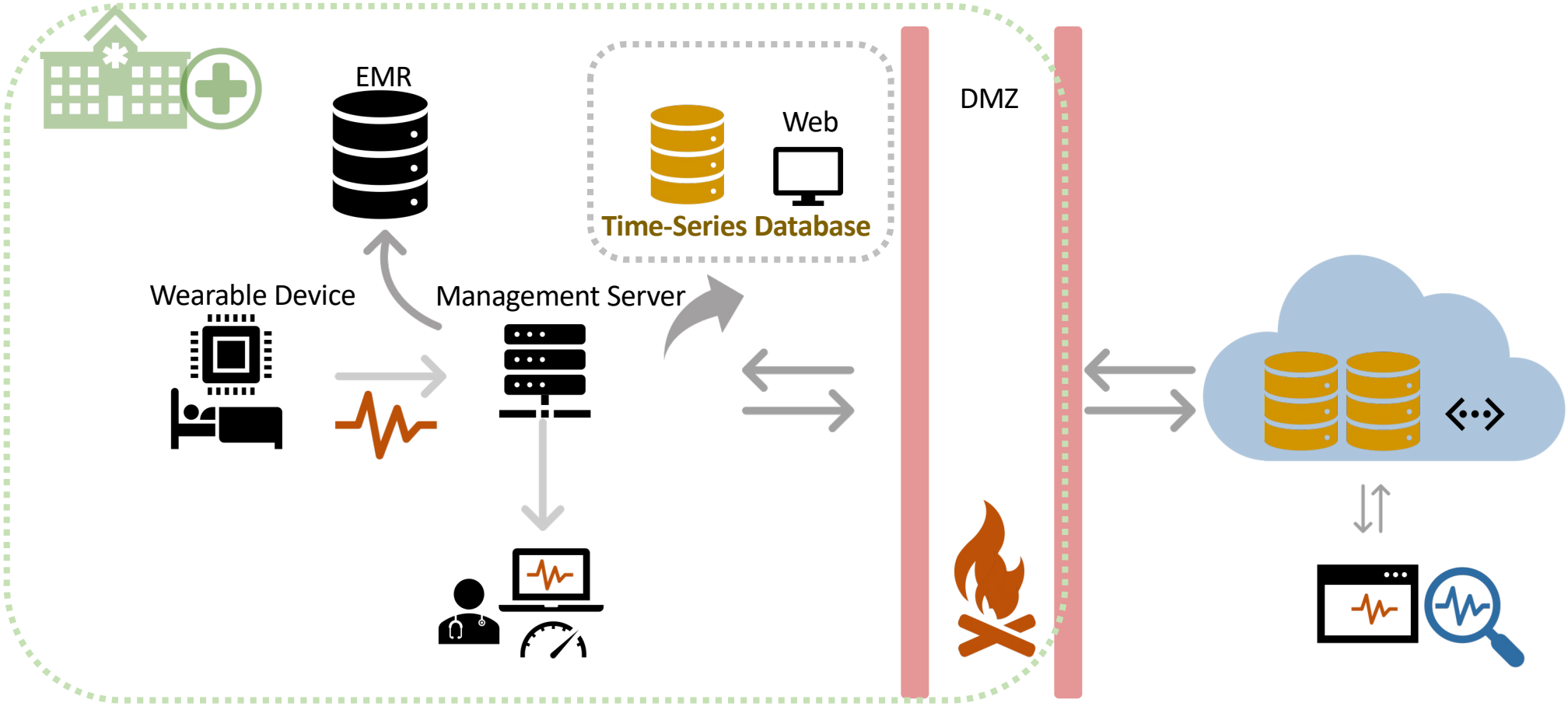


Remote Cloud Storage (RCS)

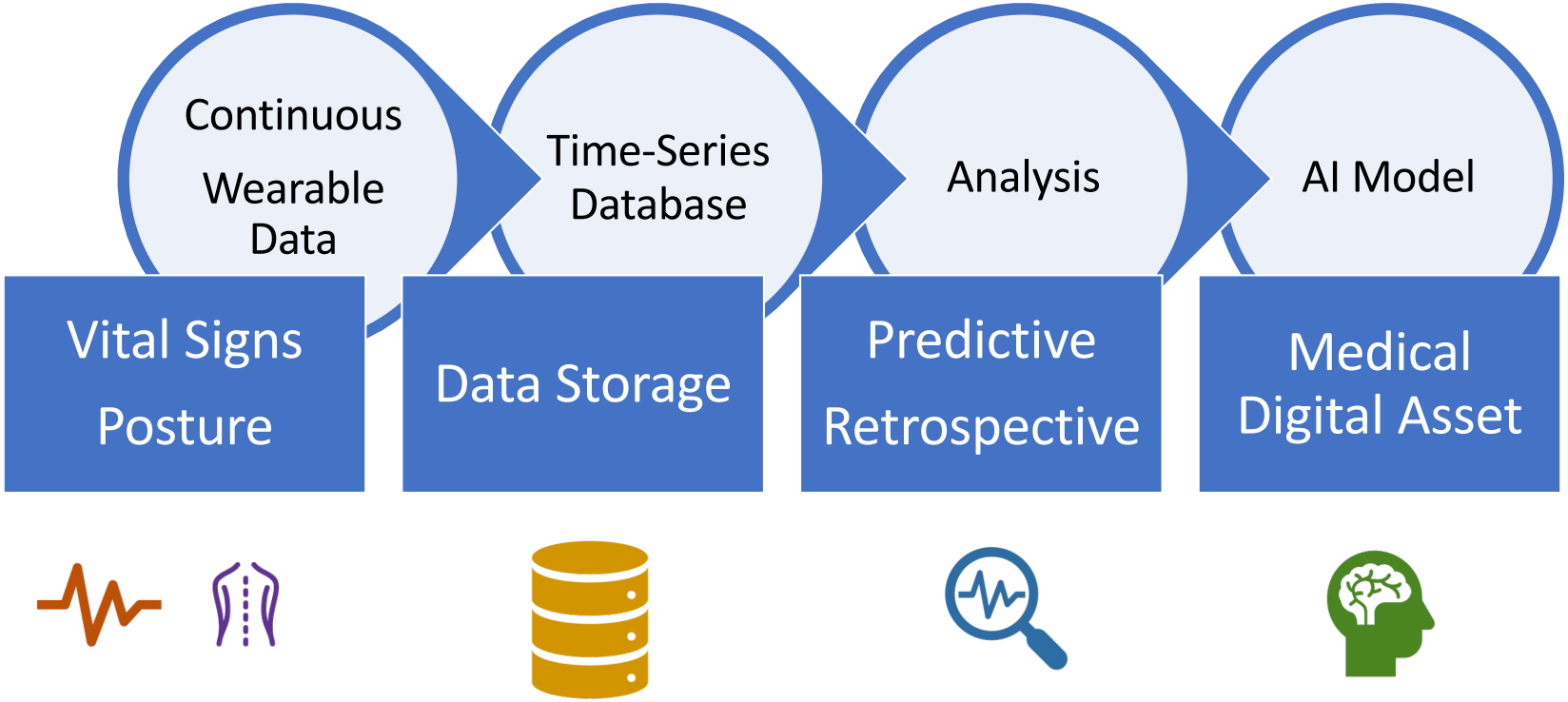
Wake Forest Ward Monitoring Data Display



The vision – EMR and analytics



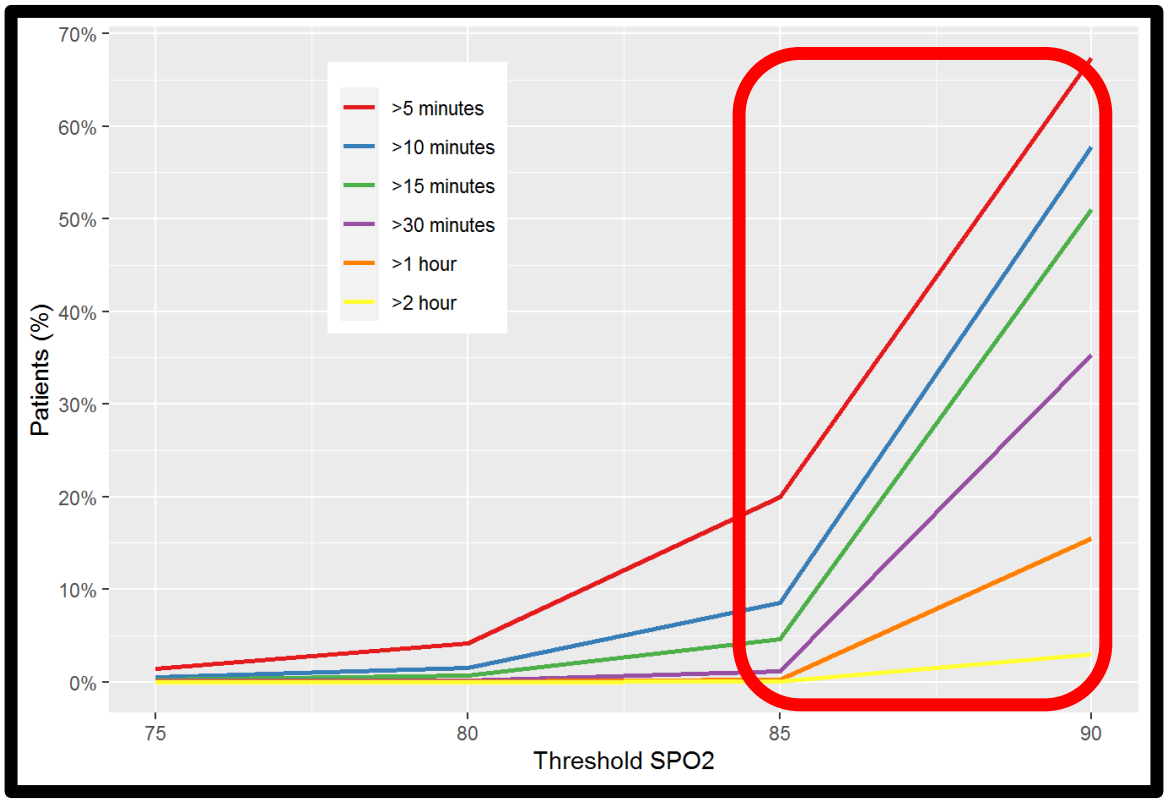
Monitoring Data Computation Opportunities



Wake Forest experience postoperative – hypoxemia

- >100,000 + monitoring sessions
- Continuous portable monitoring **with central alarms and alerts**

- Current investigation via NIH/NCATS KL2



Khanna AK – personal data

Wake Forest experience postoperative – bradypnea

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- Continuous portable monitoring with **central alarms and alerts**

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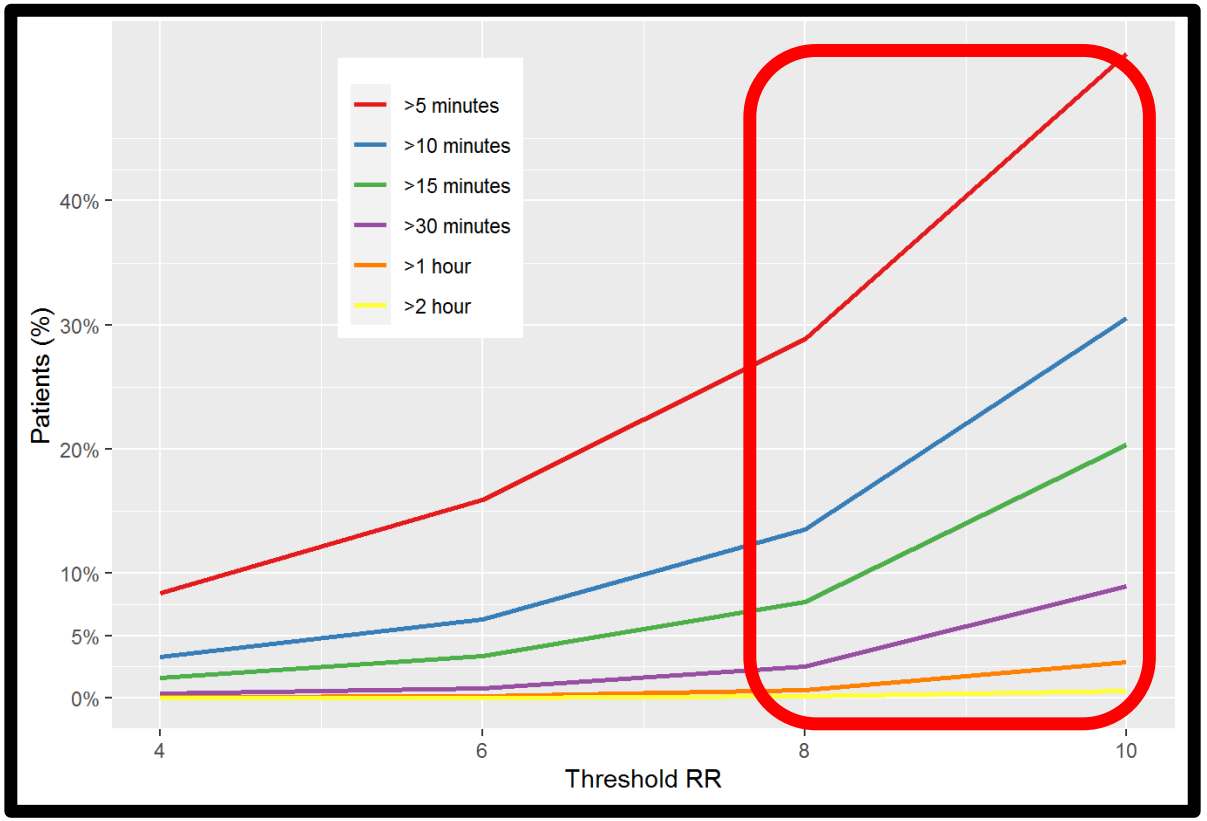
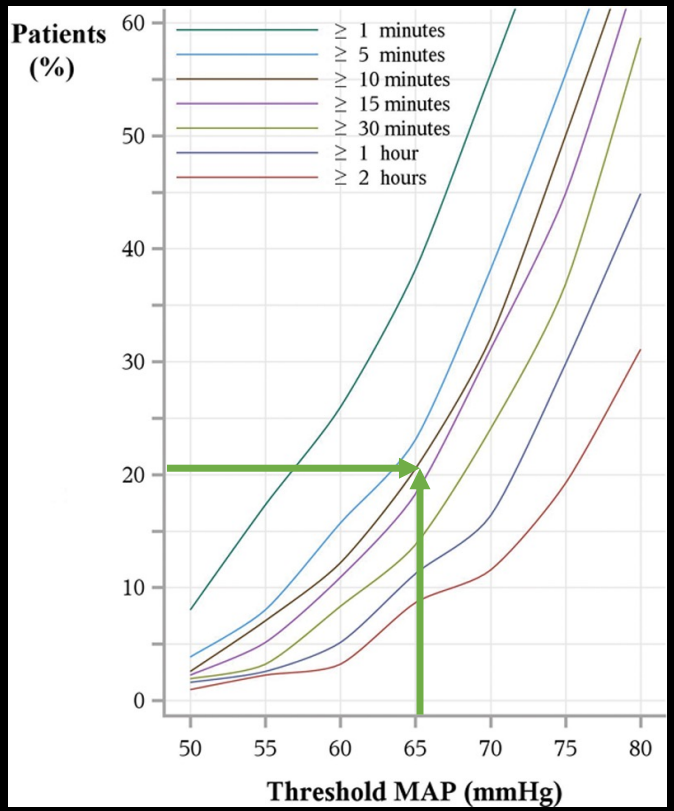


Khanna AK – personal data

Postoperative Hypotension – common & undetected



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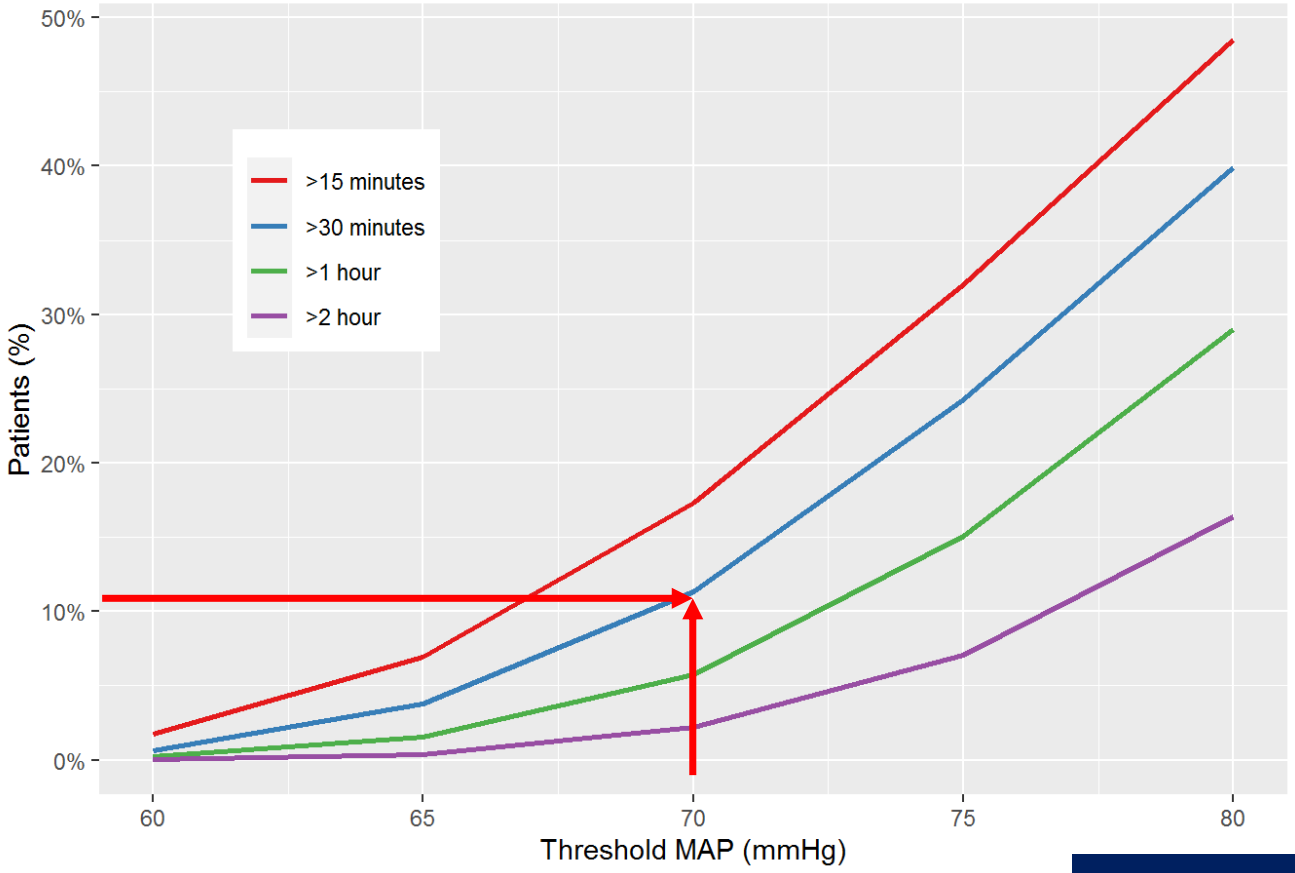
Spot checks missed <u>about 50%</u> of episodes of MAP<65mmHg detected by continuous monitoring

Turan A, Khanna AK et al. Anesthesiology 2019

Postop Hypotension – not as common at WF



Turan et al.

1. N = 500
2. Post hoc analysis of prospective study – monitor silenced (no alarms)

25% MAP<70mmHg 30 minutes

Wake Forest, Khanna et al.

1. N = 15,000
2. Real world data – monitors and alarms **active with interventions**

10% MAP<70mmHg 30minutes

✓ **Alarms and interventions help decrease the burden of post operative vital signs changes**

Khanna AK, et al. JCA 2023

Proportion of episodes detected by continuous monitoring that would have been captured by intermittent monitoring.

	Number of Patients with at Least 1 Episode(s) Detected by Continuous Monitoring (%)	Intermittent Monitoring Detection Rate	Proportion (%) Detected with Intermittent Monitoring (95% CI)
Bradycardia for > 3 min (beats/min)			
HR < 50	1975 (12.76%)	1111 / 1975	56.3% (54.1%, 58.4%)
HR < 45	671 (4.34%)	292 / 671	43.5% (39.8%, 47.3%)
HR < 40	258 (1.67%)	85 / 258	32.9% (27.5%, 38.9%)
HR < 35	149 (0.96%)	39 / 149	26.2% (19.8%, 33.8%)
HR < 30	99 (0.64%)	24 / 99	24.2% (16.9%, 33.5%)

Contents lists available at ScienceDirect

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journal homepage: www.elsevier.com/locate/jclinane

Original Contribution

Incidence, severity and detection of blood pressure and heart rate perturbations in postoperative ward patients after noncardiac surgery

Ashish K. Khanna, (MD,MS,FCCP,FCCM,FASA) [a,b,c,*], Nathaniel S. O'Connell, (PhD) [d], Sanchit Ahuja, (MD) [c,e], Amit K. Saha, (PhD) [a,b], Lynnette Harris, (BSN) [a,b], Bruce D. Cusson, (RN) [a], Ann Faris, (MSN) [b,f], Carolyn S. Huffman, (PhD) [b,f], Saraschandra Vallabhajosyula, (MD, MSc) [b,g], Clancy J. Clark, (MD) [h], Scott Segal, (MD) [a,b], Brian J. Wells, (MD, PhD) [i,j], Eric S. Kirkendall, (MD) [k,l], Daniel I. Sessler, (MD) [m]

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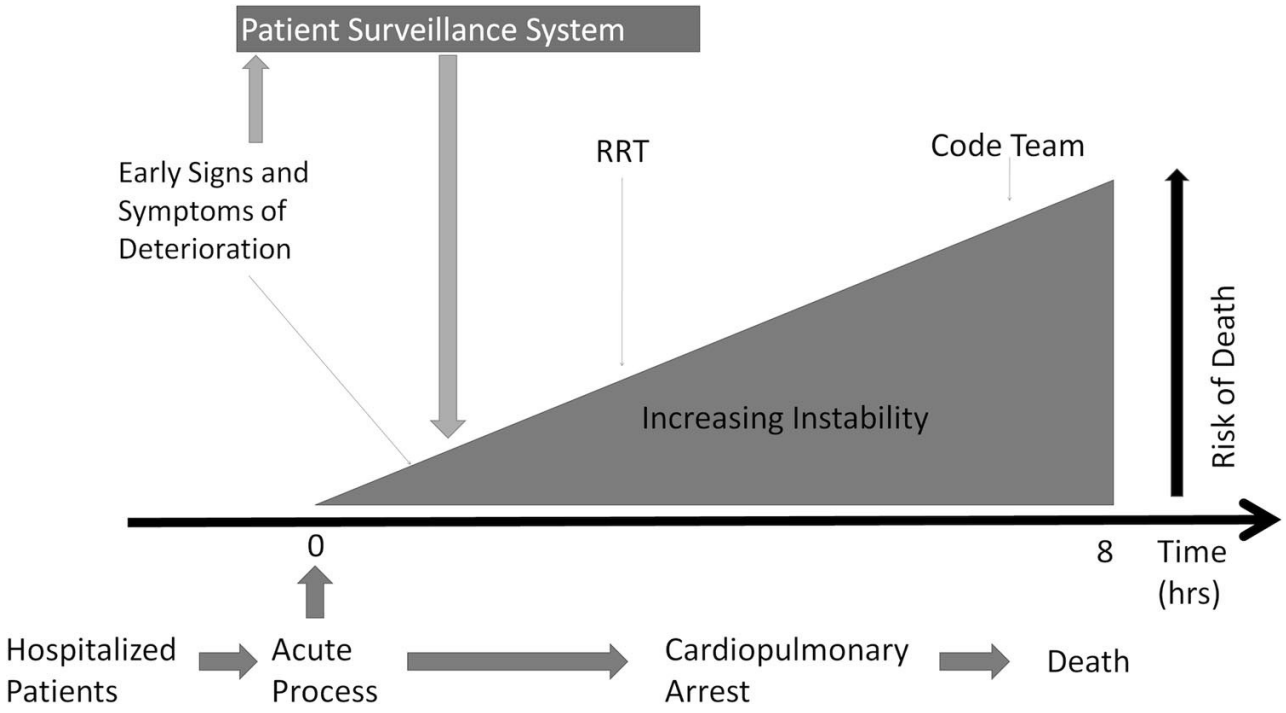
Continuous (wireless) monitoring is (not) an obvious answer ?



- ✓ **Evidence**
- ✓ **Implementation Science**
- ✓ **Alarm Fatigue**
- ✓ **ROI**

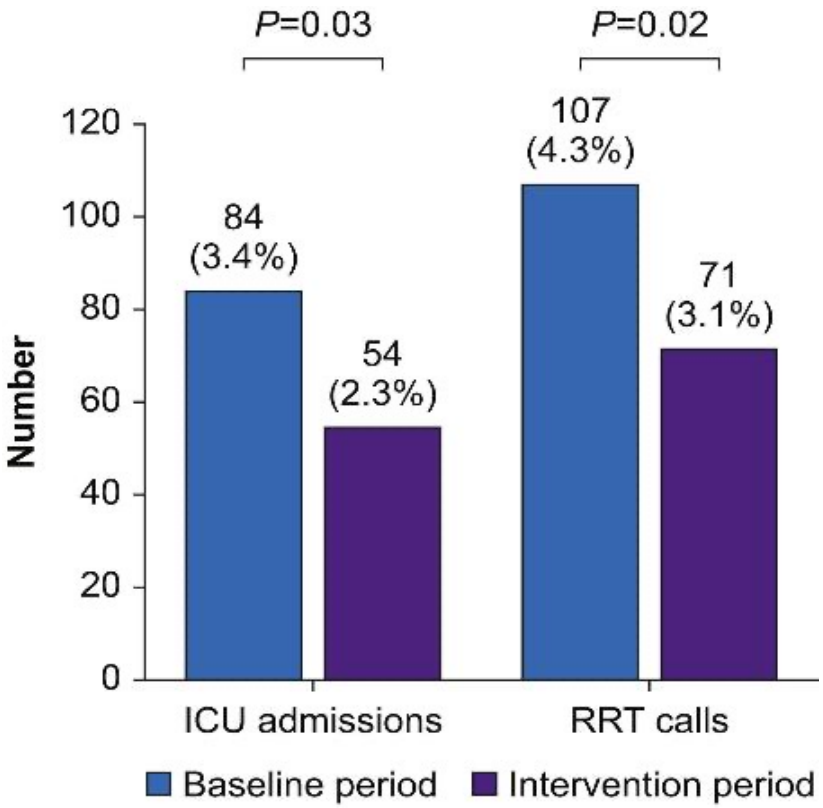
Taenzer, et al. Anesthesiology 2011

Evidence lacks interventional studies !!

Patients, n	Study Type	Monitoring Sensors	Continuous Monitoring	Wireless System	Outcome Benefits	Reference
Postoperative 5,959	Prospective before–after	Pulse oximeter	Spo_2, pulse rate	No	Decrease in rescue events and ICU transfers	Taenzer *et al.*[36]
General 3,747	Prospective before–after	Piezoelectric bed sensor	Heart rate, RR	Yes	Decrease in calls for cardiac arrest and hospital length of stay	Brown *et al.*[37]
Postoperative 128,111	Retrospective before–after	Capnography	RR	No	Decrease in rapid response team events	Stites *et al.*[38]
Medical 4,402	Prospective before–after	Abdominal patch, brachial cuff, pulse oximeter	Heart rate, RR, blood pressure, Spo_2	Yes	Decrease in cardiac arrest, ICU and hospital mortality	Subbe *et al.*[39]
Neurologic and neuro-surgical 1,958	Prospective before–after	Electrodes, brachial cuff, pulse oximeter	Heart rate, RR, blood pressure, Spo_2	Yes	Decrease in rapid response team events	Weller *et al.*[40]

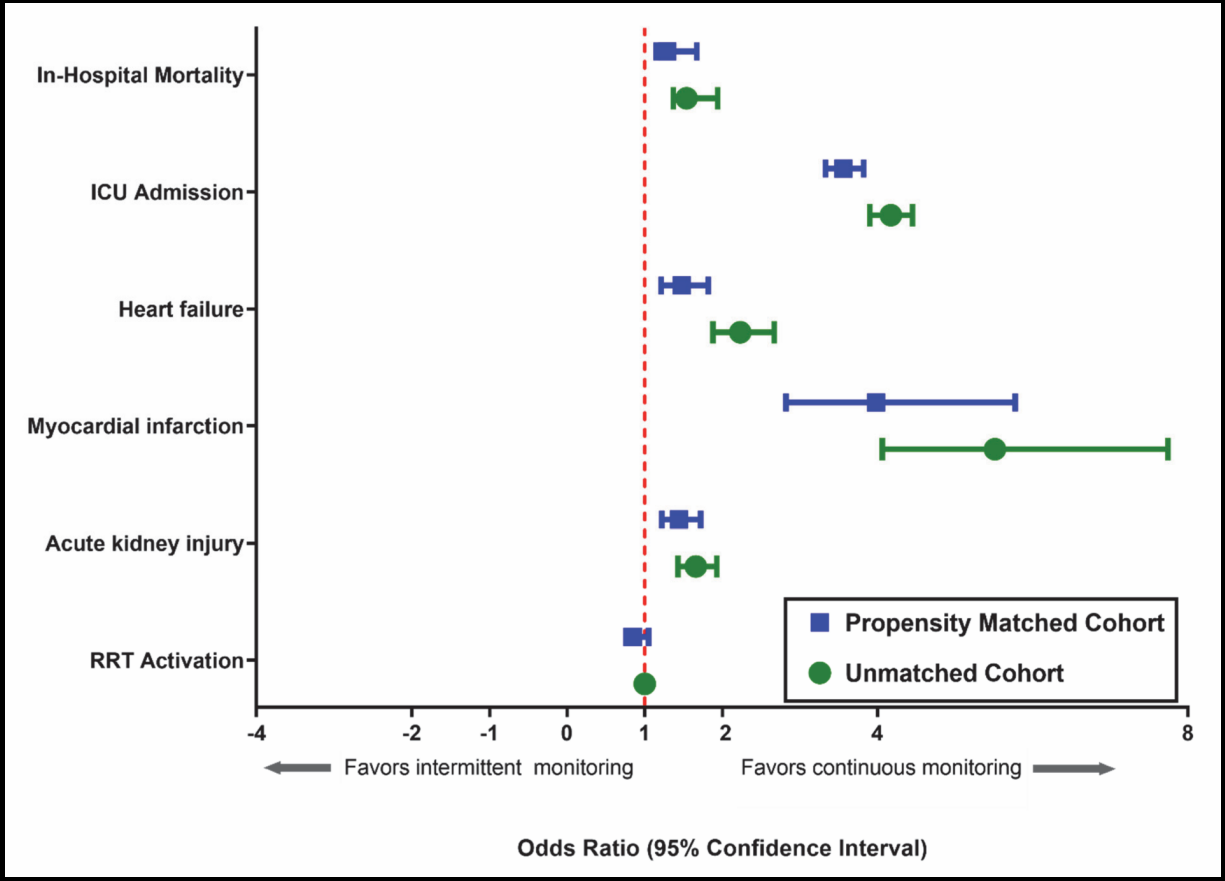
Michard F, et al. Anesthesiology 2021

Effect of Continuous Wireless Vital Sign Monitoring on Unplanned ICU Admissions and Rapid Response Team Calls: A Before-and-After Study



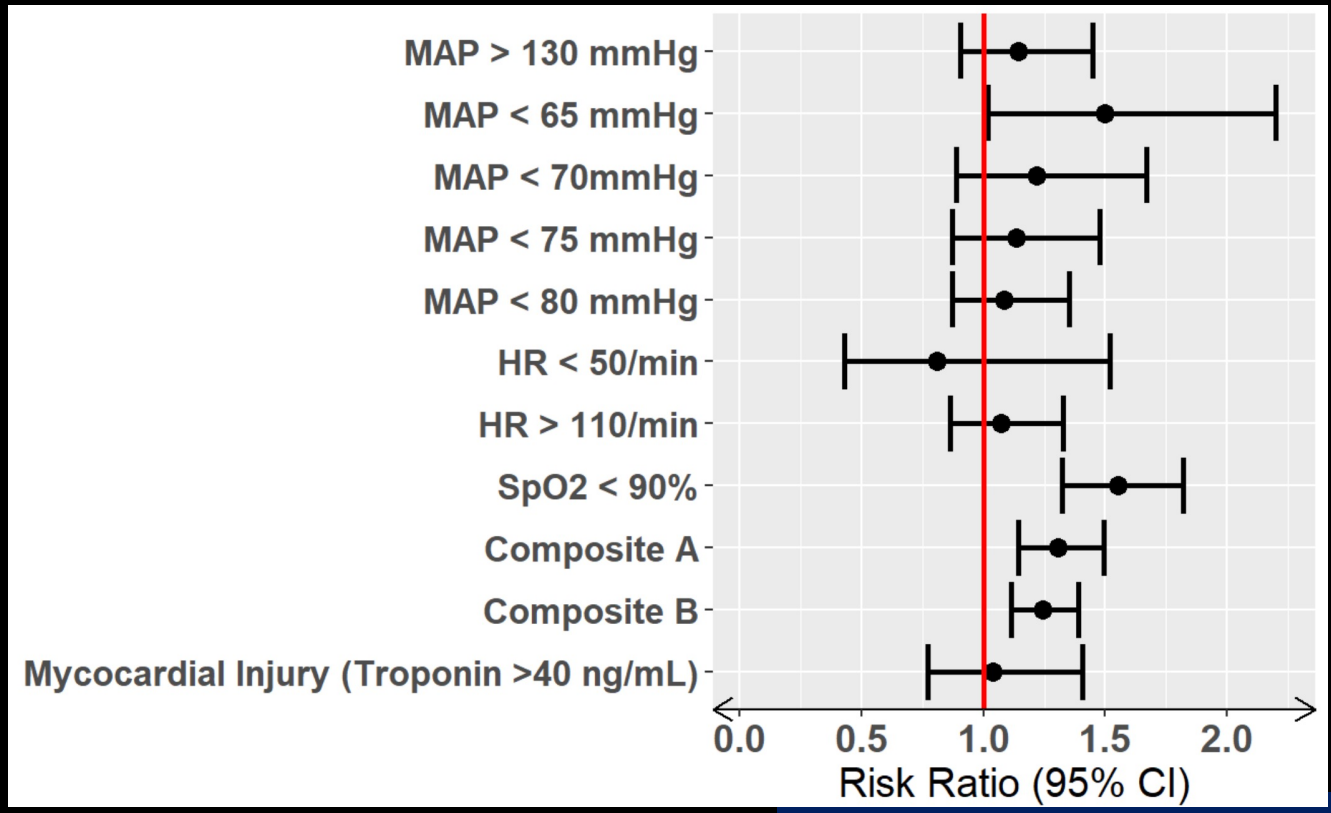
Eddahchouri Y, et al. BJA 2022

Continuous Wireless Vital Sign Monitoring on Clinical Outcomes: Propensity matched 36,000 patients



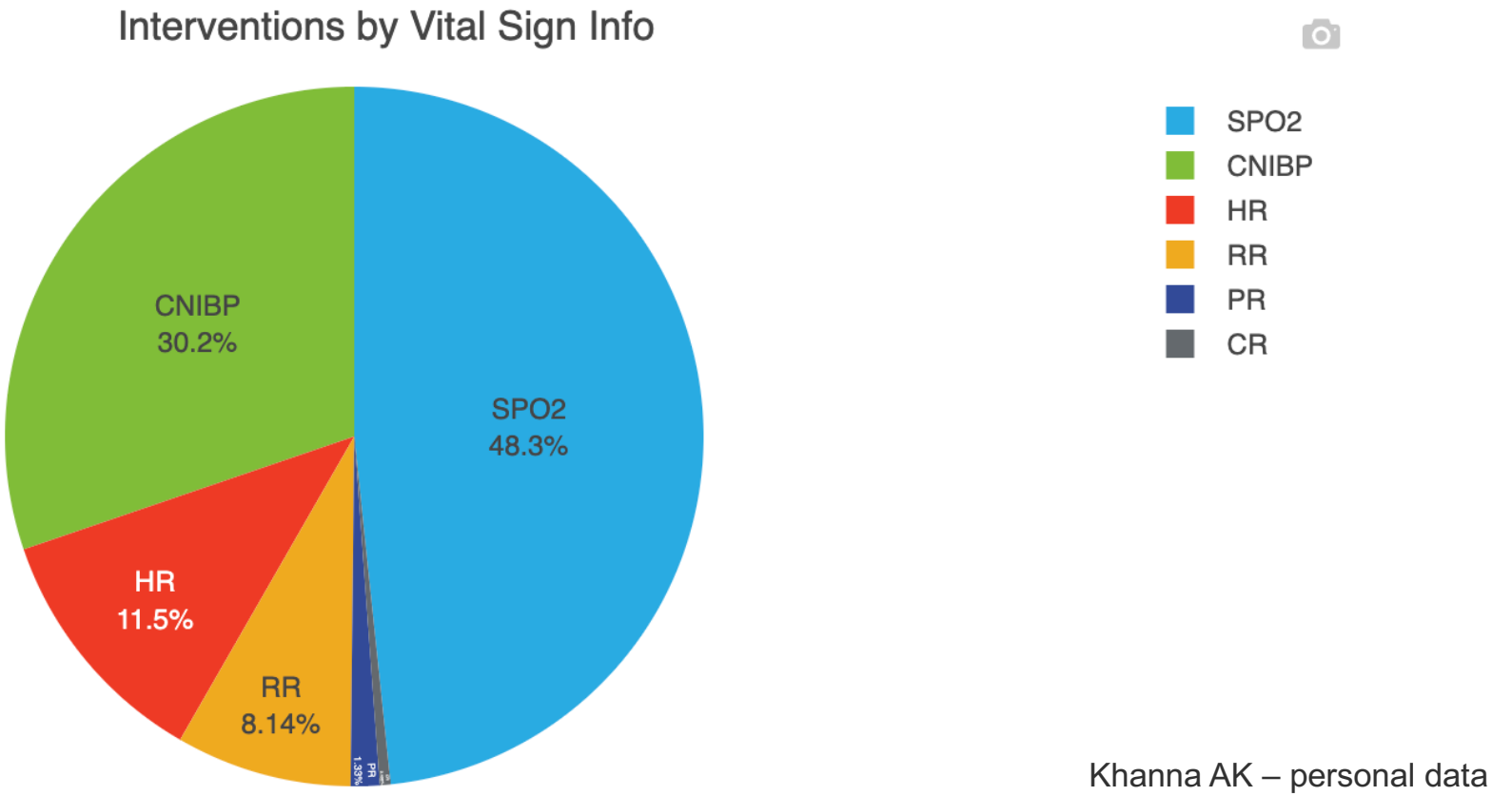
Khanna AK, et al. [unpublished]

Risk Of Spending Time Beyond Each Critical Threshold In The Intermittent Monitoring Group Relative To Continuous Monitoring Group *(Cluster randomized pragmatic RCT)*



Khanna AK, et al. [Unpublished Data]

Understanding perceptions around vital signs



Khanna AK – personal data

Understanding (nursing) perceptions around wireless wearable monitoring

	Which alarm is most often a false alarm			I get most concerned when I get an alarm for…			I am least concerned when I receive an alarm for			I receive the most alarms for		
				NRes N=133	Res n=20	Total N=153				NRes n=131	Res n=22	Total N=153
Low heart rate		17.4%	11.5%	24.8%	5%	22.2%				8.4%	13.6%	9.2%
High heart rate				7.5%	20%	9.2%		16.7%		4.6%	45.5%	10.5%
Low pulse rate	3.8%		3.2%	2.3%	10%	3.3%	3.4%			2.3%	4.5%	2.6%
High pulse rate				8%	15%	2.6%		5.6		3.1%	4.5%	3.3%
Low respiratory rate	**17.3%**	**30.4%**	**19.2%**	**4.5%**		**3.9%**	**31.9%**	**22.2%**	**30.7%**	**11.5 %**	**18.2%**	**12.2%**
High respiratory rate	**14.3%**	**13%**	**14.1%**	**14.3%**	**5%**	**13.1%**	**16.8%**	**16.7%**	**16.8%**	**19.1 %**	**13.6%**	**18.3%**
Low SpO_2	11.3%	26.1%	13.5%	35.3%	35%	35.3%	3.4%			31.3%		26.8%
Low systolic blood pressure		4.3%		7.7%	10%	7.8%	1.7%		1.5%	4.6%		3.9%
High systolic blood pressure	14.3%			3%		2.6%	23.5%	11.1%	21.9%	15.3%		13.1%

Khanna AK, et al. [Personal Data]

Understanding (patient) perceptions around wireless wearable monitoring

Were continuous vital signs monitoring using a monitoring device important to you?

Was intermittent nursing checks (provider in the room) to check on your vital signs important to you?

Was the type of devices that were used to monitor your vital signs important to you?

Were you inconvenienced with the portable monitoring device on your wrist?

Were you inconvenienced with the intermittent nursing checks (provider in the room) to check on your vital signs?

Did alarms inconvenience you?

Would you feel safer with a continuous monitoring device strapped to you all the time while you recover in the hospital?

Is the size of the continuous monitoring device important for you?

Is the ability to ambulate/walk around freely while being monitored important for you?

Would it be a good idea to continue to monitor your vital signs remotely even after you go home?

Khanna AK, et al. [Personal Data]

Not all about hypotension and hypoxemia

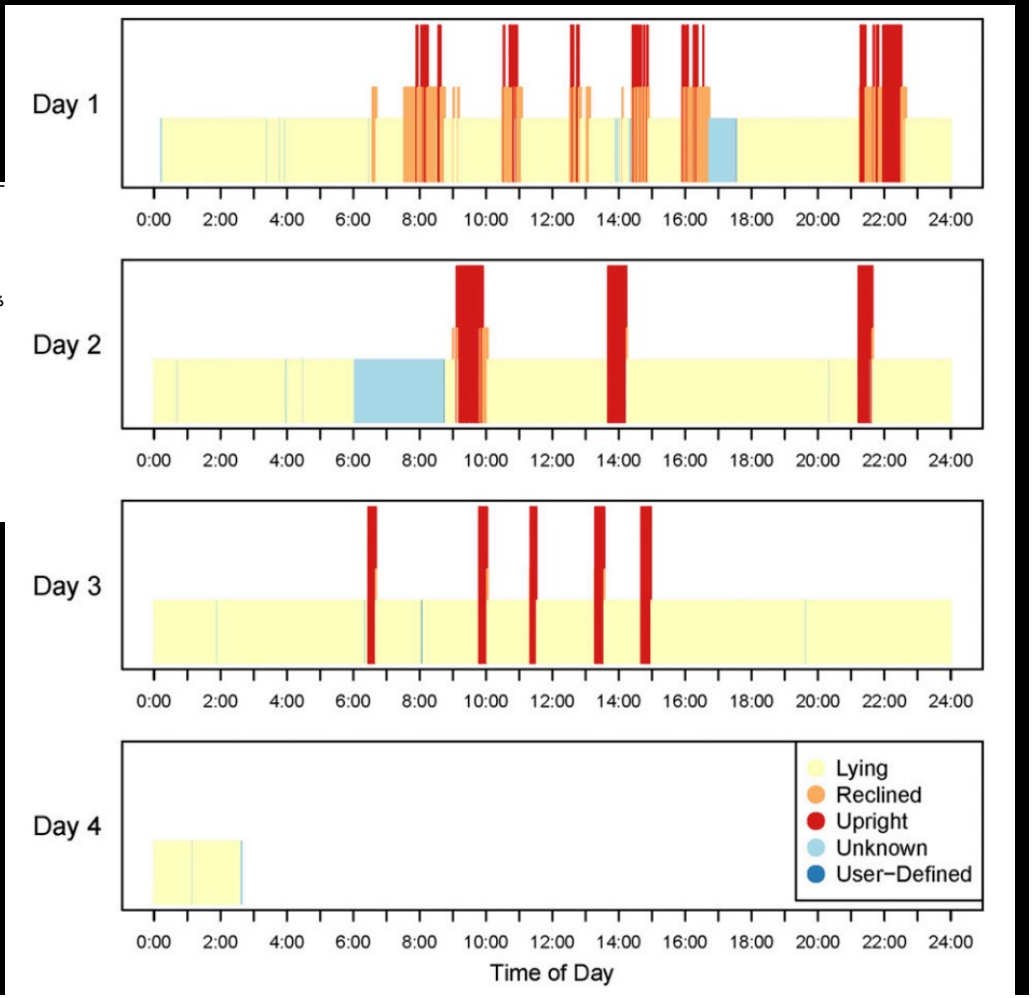
Use of a Multi-Sensor Monitoring Device in an Early Post-operative Mobilization Program

Alexis Restrepo, BS[1], Amit K. Saha, MS, PhD[2], Ashish K. Khanna, MD[3,4], Emily Huang, PhD[5], and Clancy J. Clark, MD[6]

The American Surgeon
2022, Vol. 0(0) 1–7

DOI: 10.1177/00031348221087196
journals.sagepub.com/home/asu
SAGE

>10 million posture readings
>43,000 postoperative hours of monitoring time



Research

JAMA Surgery | Original Investigation

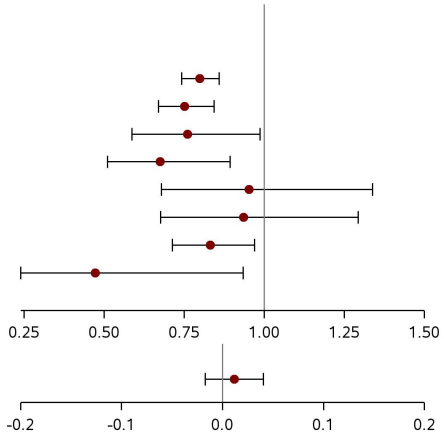
Association Between Mobilization and Composite Postoperative Complications Following Major Elective Surgery

Alparslan Turan, MD; Ashish K. Khanna, MD, MS; Jack Brooker, MD; Amit K. Saha, PhD; Clancy J. Clark, MD; Anusha Samant, BS; Elif Ozcimen, MD; Xuan Pu, MS; Kurt Ruetzler, MD; Daniel I. Sessler, MD

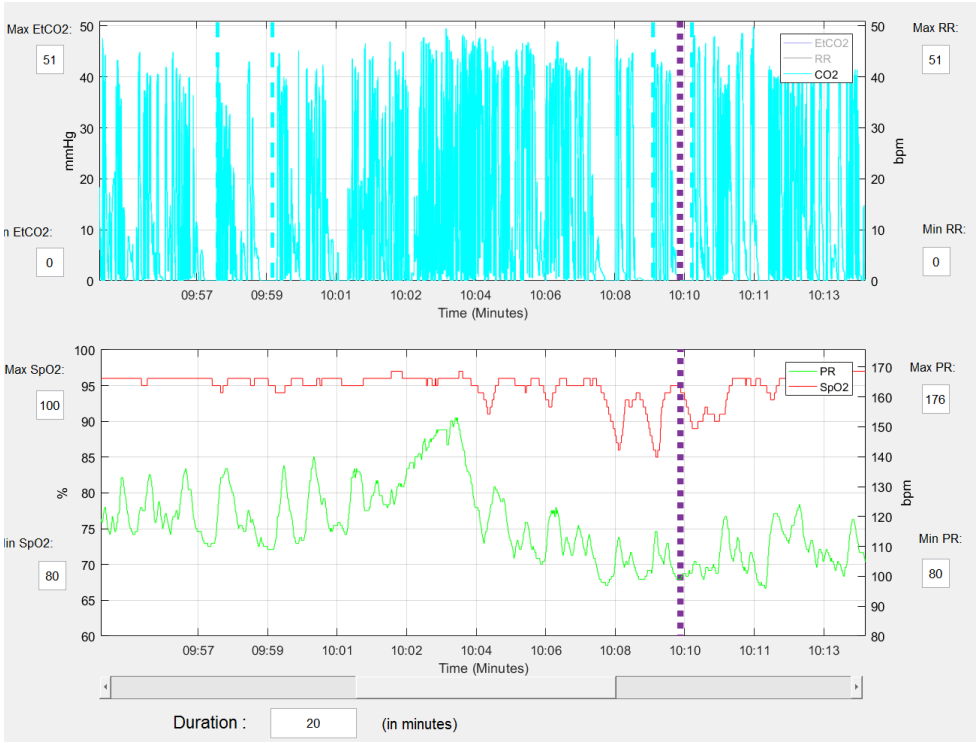
Nearly 9,000 patients at Wake Forest

Mobility data from wireless wearable technology

	Mobilization (min/hour)		
Primary outcomes	**≤4 min (N=4379)**	**>4 min (N=4274)**	**Odds ratio (CI)**
Common effect	412	221	0.80 (0.74, 0.86)
Average relative effect			0.75 (0.67, 0.84)
- Myocardial injury	88	42	0.76 (0.59, 0.99)
- Ileus	98	33	0.68 (0.51, 0.89)
- Stroke	17	11	0.95 (0.68, 1.34)
- Venous thromboembolism	21	14	0.94 (0.68, 1.29)
- Pulmonary complication	209	121	0.83 (0.71, 0.97)
- Mortality	24	6	0.47 (0.24, 0.93)
Secondary outcome	**N=4284**	**N=4204**	**Mean change (CI)**
TWA pain score	3.8(2)	3.7(2)	0.01 (-0.02, 0.04)



What's the future? Pattern detection



Khanna AK, et al. PRODIGY Dataset

Respiration and Sleep Medicine
ORIGINAL CLINICAL RESEARCH REPORT

OPEN

Prediction of Opioid-Induced Respiratory Depression on Inpatient Wards Using Continuous Capnography and Oximetry: An International Prospective, Observational Trial

Ashish K. Khanna, MD,*† Sergio D. Bergese, MD,‡§ Carla R. Jungquist, NP, PhD,‖ Hiroshi Morimatsu, MD, PhD,¶ Shoichi Uezono, MD,# Simon Lee, MD,** Lian Kah Ti, MBBS, MMed,†† Richard D. Urman, MD,‡‡ Robert McIntyre Jr, MD,§§ Carlos Tornero, MD, PhD,‖‖ Albert Dahan, MD, PhD,¶¶ Leif Saager, Dr Med,##*** Toby N. Weingarten, MD,††† Maria Wittmann, MD,‡‡‡ Dennis Auckley, MD,§§§ Luca Brazzi, MD, PhD,‖‖‖ Morgan Le Guen, MD, PhD,¶¶¶ Roy Soto, MD,### Frank Schramm, MD,**** Sabry Ayad, MD,†††† Roop Kaw, MD,†††† Paola Di Stefano, MSc,‡‡‡‡ Daniel I. Sessler, MD,§§§§ Alberto Uribe, MD,‡ Vanessa Moll, MD, PhD,** Susan J. Dempsey, MN,§§‖‖‖‖ Wolfgang Buhre, MD,¶¶¶¶ and Frank J. Overdyk, MD,#### on behalf of the PRediction of Opioid-induced respiratory Depression In patients monitored by capnoGraphY (PRODIGY) Group Collaborators

Clinical Characteristic	Estimate	OR (95% CI)	Pr > |t|	Points if Clinical Characteristic = 'Yes'
Age (≥60 - <70)	0.8077	2.243	<0.0001	8
Age (≥70 - <80)	1.2323	3.429	<0.0001	12
Age (≥80)	1.5647	4.781	<0.0001	16
Sex (M)	0.7550	2.128	<0.0001	8
Opioid Naïve	0.2912	1.338	0.0782	3
Sleep Disorders	0.4755	1.609	0.0175	5
Chronic Heart Failure	0.7494	2.116	0.0668	7
				Sum = PRODIGY Score

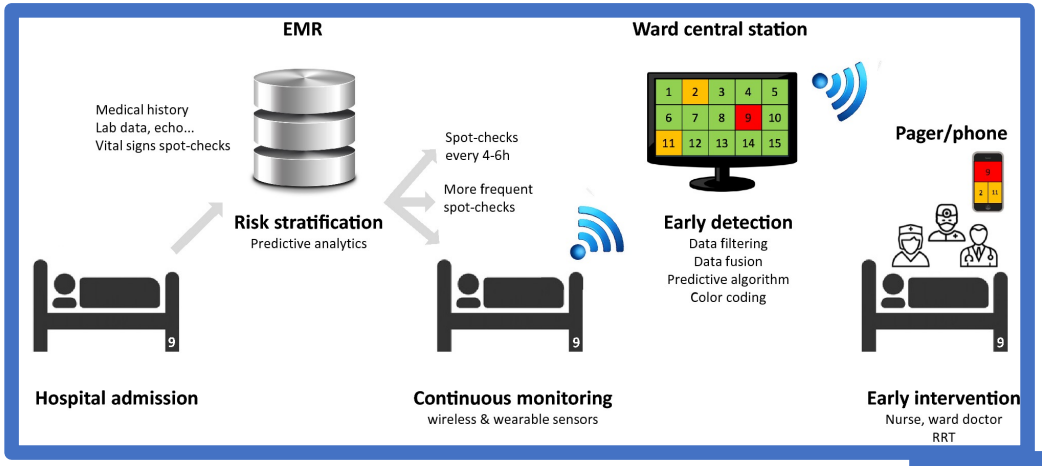
PRODIGY Score Distribution

	Low-Risk	Intermediate-Risk	High-Risk	*p* value
PRODIGY Score	<8 points	≥8 & <15 points	≥15 points	
% Pts with RD in Risk Category	24%	42%	65%	<0.0001
Sensitivity	—	0.86	0.52	
Specificity	—	0.39	0.77	
OR (p value)	OR_{IL} = 2.34; p<0.001 OR_{HL} = 6.07; p<0.001	ORHI = 2.6; p<0.001		

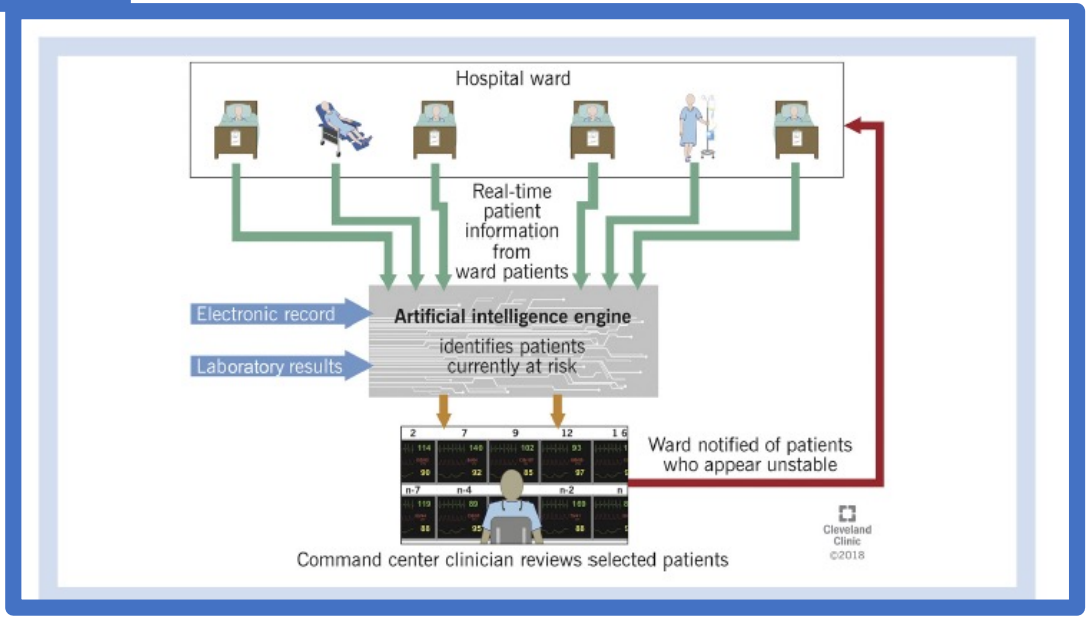
What's the future? Early diagnosis

	Heart rate	Heart rate variability	Blood pressure	Respiratory rate	Oxygen saturation	Tempera-ture	Numerical pattern
No event/alarm							333333
Cardiac arrhythmia	↑	↑↑	↓				452333
Shock	↑↑		↓↓	↑		↑*	531433/531434*
Respiratory depression				↓↓	↓		333123
Respiratory failure	↑			↑↑	↓↓	↑**	433513/433514**
Sepsis	↑		↓	↑		↑↑	432435
Bleeding	↑		↓				432333

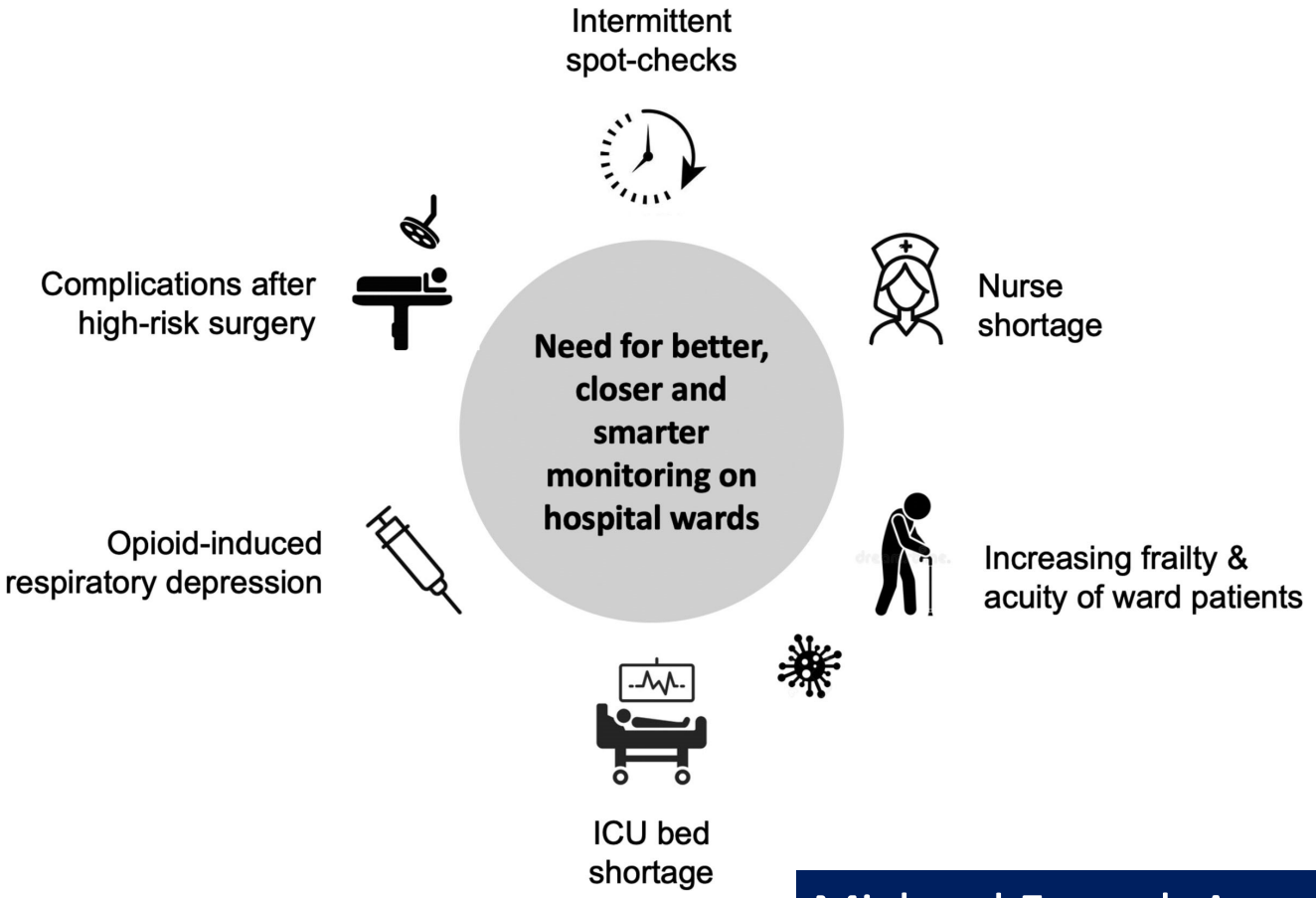
Michard F, et al. Anesthesiology 2021



Coming soon to a hospital near you…



Need ‘more reasons’ for continuous wireless monitoring?



Michard F, et al. Anesthesiology 2021

Next steps …..

- Appropriate trial design examining 'patient centric outcomes'
- Rich repository of vital signs data – AI & ML based algorithms to predict patient deterioration early
- Effective analysis of alarm fatigue with modelling of alarm thresholds and delay periods
- Postoperative patient safety guidelines
- Patient monitoring consortium
- **Anyone want to help me?**

Perioperative Outcomes and Informatics Collaborative (POIC)

Wake Forest®
School of Medicine

FEATURE - PROFILE

Discovery for All: Innovative Research Monitors Vital Signs of Patients in the ICU

Ashish Khanna, MD, merges his research to improve clinical care with his digital expertise in wireless monitoring technology, hemodynamics, vasopressors and artificial intelligence with a touch of amateur podcasting.

for perioperative outcomes research and aims to be a hub for collaborative research trials, data analytics and quality improvement.

Learn More

Perioperative Outcomes and Informatics Collaborative (POIC)

The Perioperative Outcomes and Informatics Collaborative (POIC) is a multidisciplinary research center housed within the Atrium Health Enterprise that provides an intellectual home for perioperative outcomes research and aims to be a hub for collaborative research trials, data analytics, and quality improvement.

POIC Questions?

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akhanna@wakehealth.edu