

Lessons Learned from the Deployment of New Clinical Alarm Solutions

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MDEXPO
SoCal • October 11-13, 2022

Izabella Gieras

- Currently the Director of Clinical Engineering at Huntington Health in Pasadena and Cedars-Sinai Medical Center in Beverly Hills, CA – part of the Cedars-Sinai Health System
- Worked as the Director of Clinical Engineering with ARAMARK Healthcare/ Mount Sinai Medical Center, New York, NY; Director of Technology Management at William Beaumont Hospital in Royal Oak, MI
- Past President of ACCE (American College of Clinical Engineering)
- Fellow of ACCE, AAMI
- Certified Clinical Engineer (CCE)
- Holds a B.S. in Electrical Engineering from the University of Cape Town in South Africa, M.S. in Biomedical Engineering from the University of Connecticut and an MBA from Walsh College in MI



Michele Manzoli



- Currently Senior Clinical Systems Engineer with the Device Integration team at Cedars-Sinai
- Worked in Medical Device Regulatory Affairs in Italy, Quality Management Systems in the UK, and Clinical Engineering at Yale-New Haven Hospital in Connecticut
- Certified Clinical Engineer (CCE)
- Current Secretary of ACCE (American College of Clinical Engineering)
- Holds a M.S. in Clinical Engineering from the University of Trieste (Italy) and a M.S. in Biomedical Engineering from the University of Connecticut



Agenda

- Session Summary and Objectives
- National & Regulatory Standards
- Perspectives and Initiatives
 - Huntington Health
 - Cedars-Sinai
- Lessons Learned



Session Summary



Huntington Health and **Cedars-Sinai** embarked on deployments of new clinical alarm management strategies across various patient monitoring departments. The Teams worked closely with a diverse group of healthcare representatives to ensure successful planning, go-live, and post-implementation phases are carried out.

Keeping **The Joint Commission** standards in mind, the Teams developed robust clinical foundations to support the operational needs of the end users and the safety of the patients. The solutions encompassed the alarm management as well as the communication strategies.



Session Objectives

1. Leverage diverse team dynamics to support overall project management
2. Develop strong collaboration with the vendor of the deployed solution
3. Ensure ongoing oversight post project deployment to maximize results and customer satisfaction



National and Regulatory Standards

Joint Commission "R3 Report" Explains New Clinical Alarm National Patient Safety Goal

(Oakbrook Terrace, Ill. – December 11, 2013) The Joint Commission today released an "R3 Report" for the new National Patient Safety Goal (NPSG) that requires accredited hospitals and critical access hospitals to improve the safety of their clinical alarm systems. "R3 Report" provides accredited healthcare organizations and interested healthcare professionals in-depth information about the rationale and references that were employed in the development of the new alarm NPSG.



The alarm NPSG is being implemented in two phases. The first phase will go into effect on January 1, 2014, and heightens awareness of the potential risks associated with clinical alarms. The second phase, will be effective January 1, 2016, and introduces requirements to mitigate those risks. The goal addresses clinical alarms that can compromise patient safety if they are not properly managed. This includes alarms from equipment such as cardiac monitors, IV machines, ventilators, etc. that have visual and/or auditory components. In general, this does not include items such as nurse call systems, alerts from computerized provider order entry, or other information technology systems.



Huntington Health Perspectives & Initiatives



Affiliation – Huntington Health/Cedars-Sinai

Huntington Hospital Affiliation with Cedars-Sinai Becomes Official

Published on Wednesday, August 4, 2021 | 12:18 pm



The affiliation between [Huntington Hospital](#) and [Cedars-Sinai Health System](#) became official Wednesday, with the completion of the appropriate regulatory approvals. The affiliation will strengthen Huntington's long-term commitment to providing affordable, accessible, high-quality care to the San Gabriel Valley.

Extract from Pasadena Now, online



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Huntington Health: Clinical Technology



- Level II Trauma Center with 619 licensed beds
- Bariatric & Stroke Center
- 18 Operating Rooms
- 3 DaVinci Robotic Systems
- 6 Cath Labs & IR Suites
- 6500+ personnel
- 300+ applications
- 4500+ end user computing devices
- Affiliate of the Cedars-Sinai Health System
- Clinical Technology has 7 biomedical technicians, 3 support staff, and a director
 - Reports to Enterprise Information Services (Cedars-Sinai)



Cedars-Sinai: Clinical Engineering



- ◆ Located in Beverly Hills, part of LA
- ◆ Licensed for 889 beds
- ◆ Over 14,000 employees
- ◆ 91,014 patients seen in the ED annually
- ◆ Over 6000 births annually
- ◆ Estimated 32,000 surgeries annually
- ◆ Over 105 anesthesia locations
- ◆ Clinical Engineering:
 - 33 members strong
 - Over 33,000 devices
 - Reports to Enterprise Information Services



Problem Statement

- End of support technology
- Insufficient analytics
- Insufficient reporting options
- Interpretation of QA/QC data not user friendly



The Journey

- **Be the champion**
- Develop project management strategies
- Appropriate technology selection
- Two phased approach
- Team approach
 - VOC
 - Clinical Alarms Management Committee
- Support from the vendor



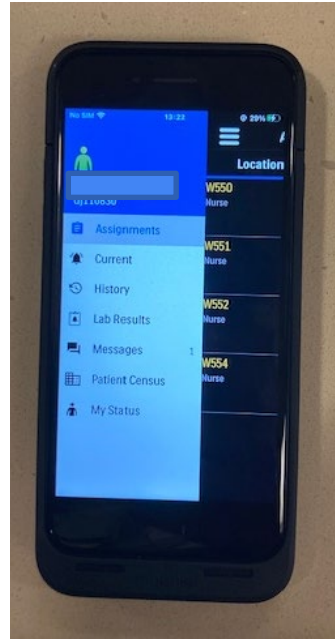
User Requirements



- Integration with patient monitoring system
- Robust design and support
- High reliability
- Delivers clinical content directly to the smartphone
 - Prioritizes and escalates alarms
- Seamless communication along with alarm mgmt. strategy
- Gains insight into alarms with data and caregiver reports
- Avails data to aid in decision-making
 - Educational initiatives
 - Investigations/RCA's



User Interfaces

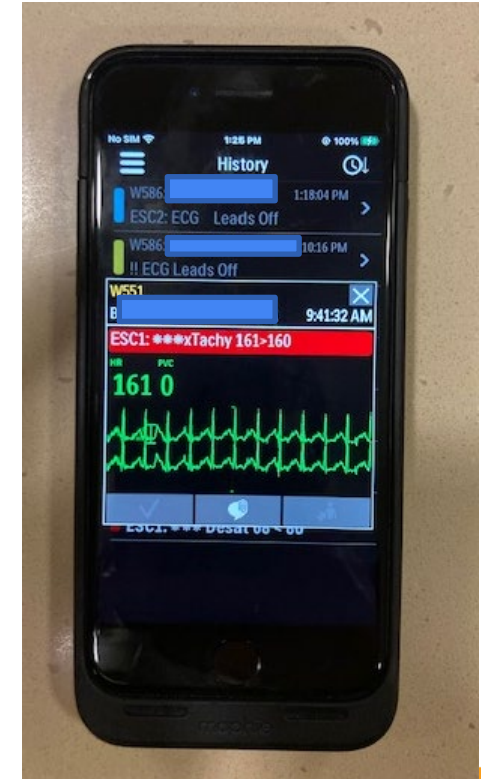
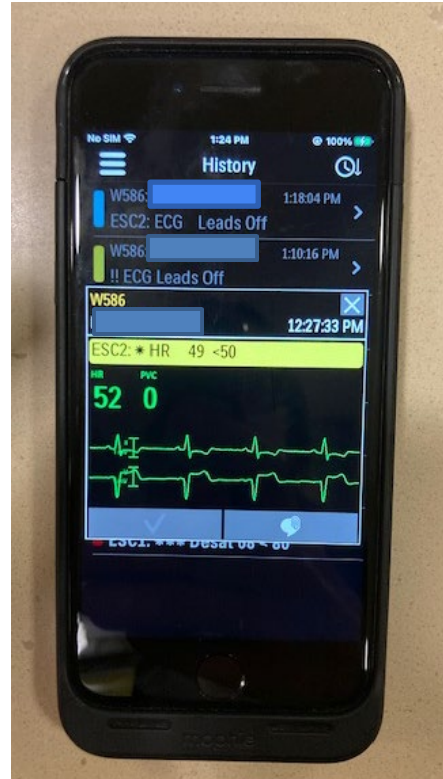


- Familiar iPhone platform
- Easy to navigate
- Potential to expand to other apps



User Interfaces (cont.)

- Selected high, medium and low alarms
- A few seconds waveform snapshot
- Ability to acknowledge alerts on the phone
- Ability to view historical alarms



Alarm Escalation Model

Alarm	Level 1	Self-escalation time	Level 2	Self-escalation time	Level 3
Asystole	Nurse + PFC	60 seconds	All Nurses + PFC	60 seconds	All Nurses + PFC
Vfib-Tach	Nurse + PFC	60 seconds	All Nurses + PFC	60 seconds	All Nurses + PFC
Vtach	Nurse + PFC	60 seconds	All Nurses + PFC	60 seconds	All Nurses + PFC
Extreme Tachy	Nurse + PFC	60 seconds	All Nurses + PFC	60 seconds	All Nurses + PFC
Extreme Brady	Nurse + PFC	60 seconds	All Nurses + PFC	60 seconds	All Nurses + PFC
Red Pressure	Nurse + PFC	60 seconds	All Nurses + PFC	60 seconds	All Nurses + PFC
Red SPO2	Nurse + PFC	60 seconds	All Nurses + PFC	60 seconds	All Nurses + PFC
Red Resp	Nurse + PFC	60 seconds	All Nurses + PFC	60 seconds	All Nurses + PFC
Red Pulse	Nurse + PFC	60 seconds	All Nurses + PFC	60 seconds	All Nurses + PFC
Red Other	Nurse + PFC	60 seconds	All Nurses + PFC	60 seconds	All Nurses + PFC
Yellow HR	Nurse	60 seconds	Nurse	60 seconds	Nurse
NonSustain VT	Nurse	60 seconds	Nurse	60 seconds	Nurse
Vent Rhythm	Nurse	60 seconds	Nurse	60 seconds	Nurse
Run PVCs	Nurse	60 seconds	Nurse	60 seconds	Nurse
Pair PVCs	Nurse	60 seconds	Nurse	60 seconds	Nurse



Reports - Sample

Event to Notification + Escalation

4/26/2022 12:00:00 AM - 4/26/2022 6:20:00 PM

Event Category	Total Events	Total Notifications	Total Escalations	Total Event Notifications First Level	Total Event Notifications Second Level	Total Event Notifications Third Level
Irregular HR	88	408	116	176	126	106
Yellow SpO2	222	954	255	444	298	212
Nurse Call	6	0	0	0	0	0
All Yellow Inops	53	138	16	106	18	14
Yellow Inop ECG Lead(s) Off	53	138	16	106	18	14
All Inops	2871	212	60	92	64	56
Inop SpO2	323	0	0	0	0	0
Inop No Pulse	333	0	0	0	0	0
Inop Battery Low	168	114	34	46	34	34
Inop Replace Battery	138	38	10	18	12	8
Inop Cannot Analyze ECG	22	0	0	0	0	0
Inop ECG Leads Off	5	8	2	4	2	2
Inop Single Lead Off	382	0	0	0	0	0
Inop No Data	227	0	0	0	0	0
Inop ECG Leads Unplugged	39	52	14	24	16	12



Lessons Learned

- Implement project management strategies
- **Collaborate, collaborate, collaborate**
- Where feasible, implement phased-in approach
 - Validate
- Secure budget early
- Plan in advance
 - Downtimes
 - Vendor and Nursing resources often need to be planned a few months in advance



Lessons Learned (cont.)

- Not all strategies work together
 - Need for alternatives
- Monitor post implementation
- Report updates
 - EOC
 - Alarms Mgmt. Committee
 - Patient Safety
 - Nursing Council
 - Others



Cedars-Sinai

Perspectives & Initiatives



Cedars-Sinai: Device Integration Team

- Supports 3 Hospitals, several outpatient clinics and procedure centers
- Team of 7 CSEs
 - BMDI (1M+ data points/day)
 - Electronic Cardiac Rhythm Strips (2k strips/day)
 - Nurse Call systems and integrations (15k activations/day)
 - Alarm integration systems (3k notifications/day)
 - Clinical Communication systems (33k texts/day)
 - RTLS (12,000+ assets tracked)
 - Environmental Monitoring (300 alerts/day)
 - Infant Protection
 - Staff Duress



Problem Statement

BiPAP machines' alarms not dispatched to a secondary notification system.

Substantial risk that their alarms are not heard and addressed in a timely fashion, especially in isolation rooms.



Different Environments...

- Intensive Care Units
 - Physiological Monitor
 - Middleware Device



Different Environments...

- Step-Down Units
 - Physiological Monitor
 - Nurse Call audio ports
- Med-Surg Units
 - Nurse Call audio ports



...required Different Solutions

- Med-Surg and Step-Down Units
 - Nurse Call system integration

- Intensive Care Units
 - Middleware integration



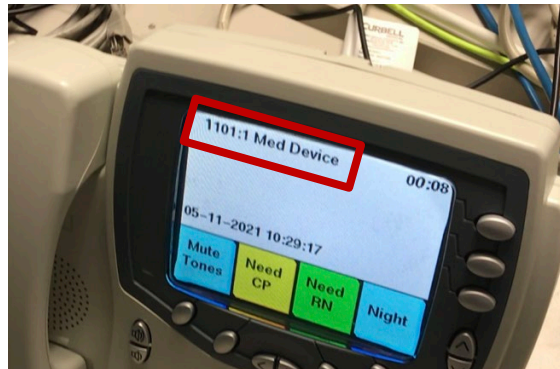
Nurse Call System integration

- Audio cable connecting the medical device to the nurse call system, leveraging the “two-jack” station
- Station used also for other purposes: chair alarm, infusion pump alarm, physiological monitor alarm. “Med Device” label was *initially* used.



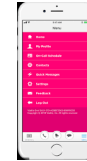
Nurse Call System integration (cont.)

- Audio cables attached to the back of all BiPAP machines. When used in a med-surg or step-down room, the connector is plugged into the Med Device outlet on the wall.
- The cable is tested before each use, to ensure correct functioning.
- A BiPAP machine triggers a High-Priority Alarm.
- The nurse console rings, displaying the room number and “Med Device”.



Nurse Call System integration (cont.)

- A notification is sent to the Primary RN's phone and assigned RT's phone
- The patient room call light flashes
- The light keeps flashing until the alert is cancelled

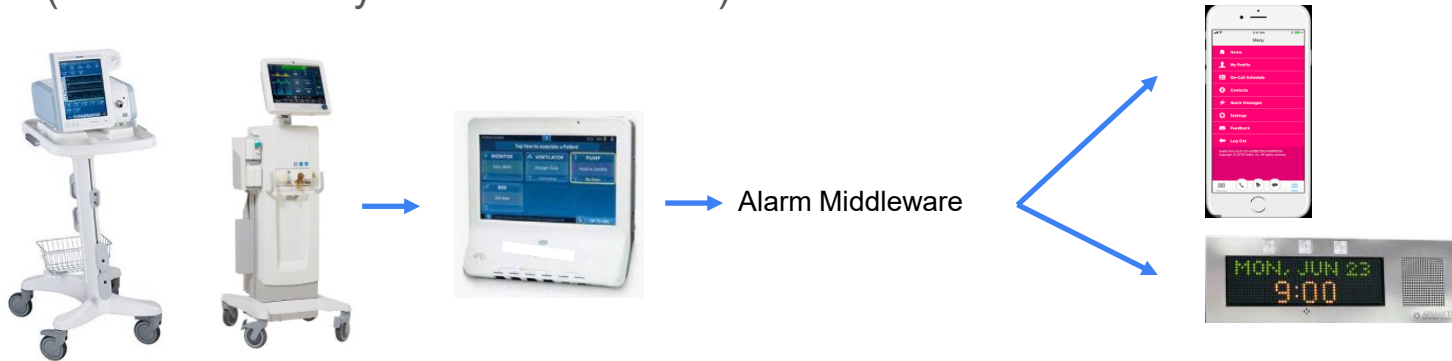


Escalation: if not resolved, notification sent to Primary RN and Charge RN after 60 seconds.



Middleware integration

- The BiPAP machines and invasive ventilators already connect to the middleware device at the bedside for vitals integration.
- We will leverage the same connection to transmit the alarms to our existing alarm middleware platform.
- From there, the alarms can be dispatched to the caregivers' phones and to scroll boards (to be installed by the nurse stations)



Middleware integration (cont.)

High-priority alarms in scope: focus on ACTIONABLE alarms

- e.g., Ppeak high (delay 15s), Patient Disconnect (no delay)
- Apnea (delay already set on the vent)

Notification at the scroll boards only initially

- Room and type of alarm, dedicated sound, lights
- New workflow: education needed

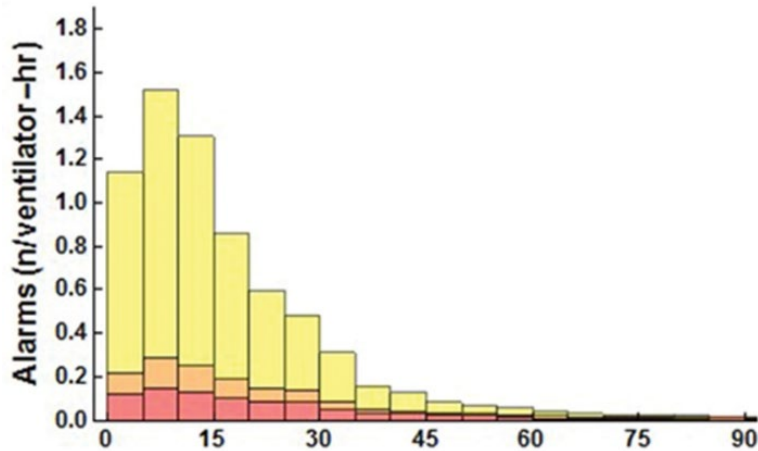
Escalation: after two minutes

- Phone notification to Primary RN and Charge RN
- New workflow: education needed

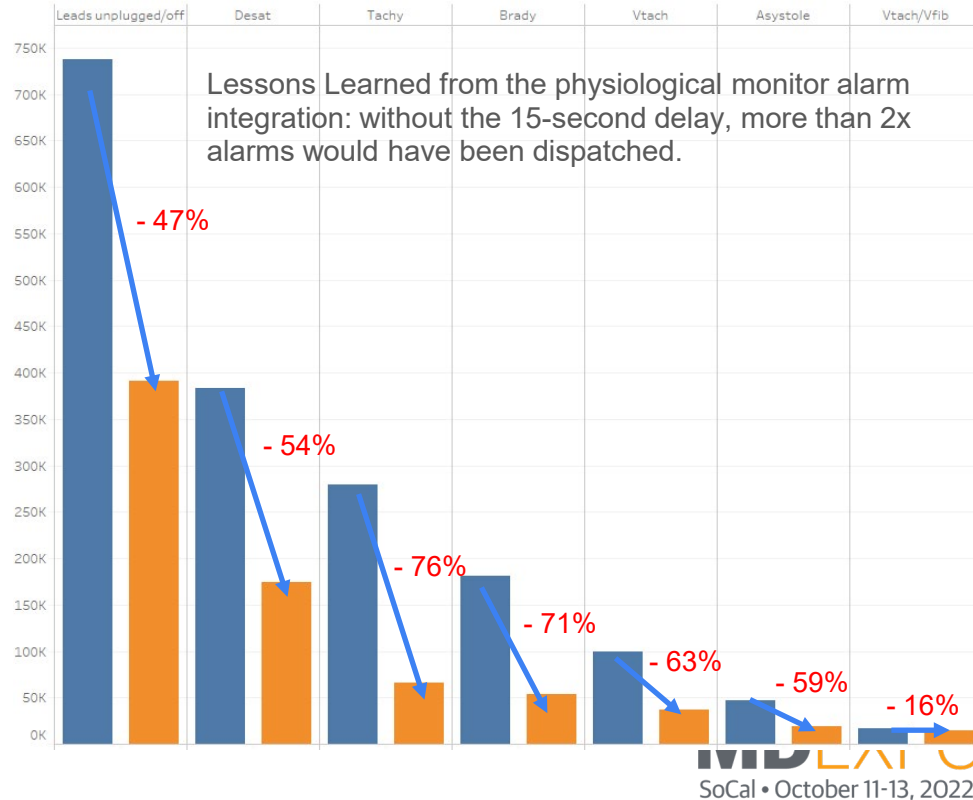


Middleware integration (cont.)

Ventilator alarm conditions **resolved within 15 seconds 60% of the time**



From: M. Cvach et al., "Ventilator Alarms in ICUs: Frequency, Duration, Priority, and Relationship to Ventilator Parameters", Anesthesia & Analgesia, Jan 2020



Lessons Learned

- Not technical, rather on the human factor side
- Initial inconsistency (not always plugged in)
- Improve education process: include demonstration (not just tip sheet) and frequent follow-ups on the unit
- Precise labeling to prevent erroneous connections and to prevent confusion
- Set clear expectations from the beginning
- Focus more on RT/RN collaboration: be on the same page on responsibilities
- Post-implementation monitoring



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