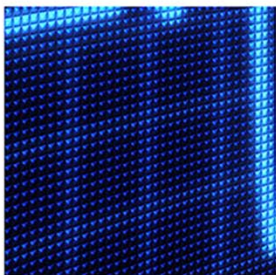
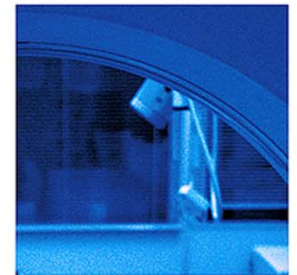


Clinical Alarm Effectiveness: Recognizing & Mitigating Risk to Patient Care

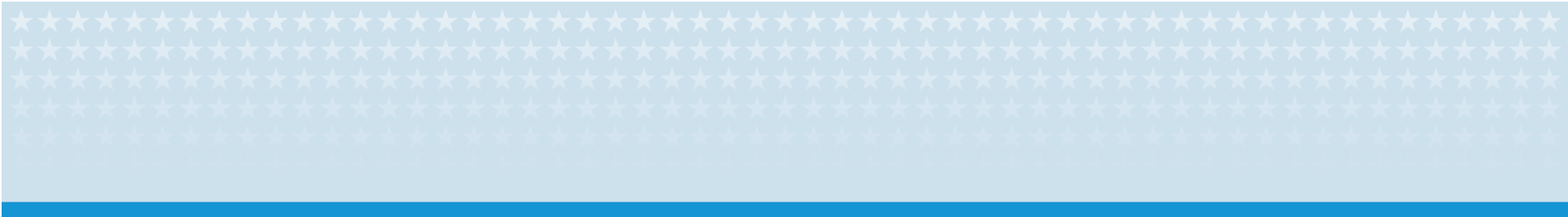


Thomas Bauld, PhD, CCE, Biomedical Engineer
National Center for Patient Safety (NCPS)

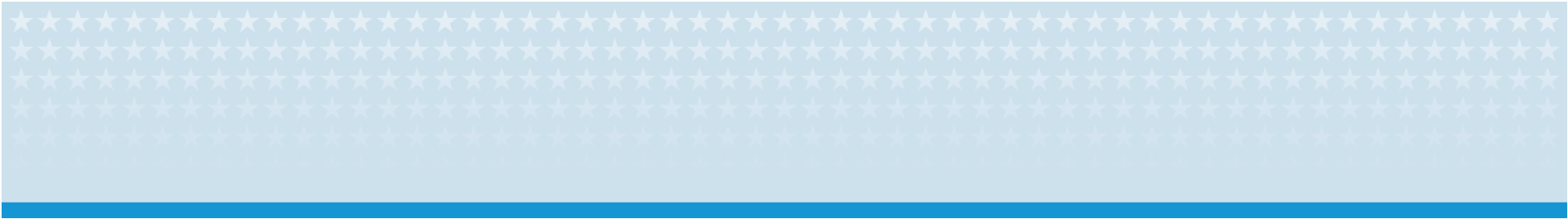
Elena Simoncini, Clinical Engineer
VA Boston Healthcare System



Veterans Health Administration
 Healthcare Technology Management

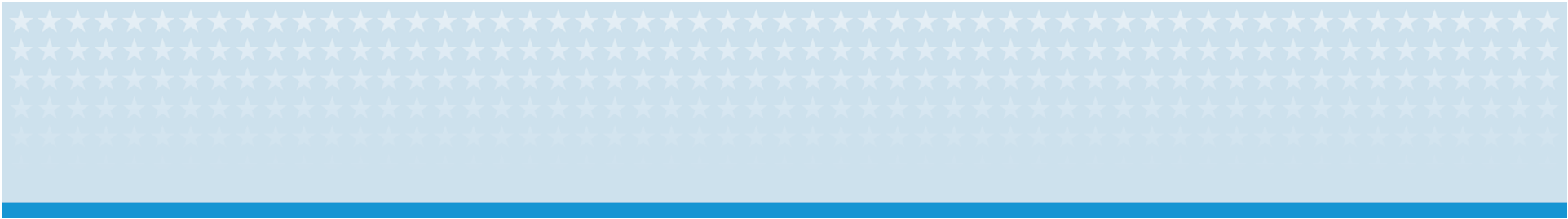


- **Clinical Alarms**: alarm systems that are either built in or attached to medical equipment and monitoring systems, and that are triggered by physiological changes in the patient, by variations in measured parameters or by system problems.
- **Alarm Fatigue**: the psychological effect produced by too many alarms occurring in a clinical environment, causing clinicians to miss true clinically significant alarms.
- **Non-Actionable (“nuisance”) Alarms**: alarms that are not clinically relevant and are not treated.

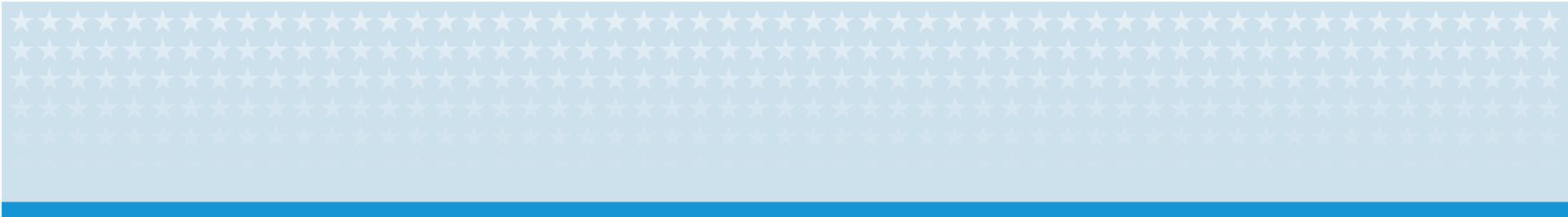


“The Joint Commission’s Sentinel Event database includes reports of **98 alarm-related events** between January 2009 and June 2012. Of the 98 reported events, **80 resulted in death**, 13 in permanent loss of function, and five in unexpected additional care or extended stay.”

-The Joint Commission Sentinel Event Alert



A study in 2011 involving a patient monitor in an operating room recorded a total of 124 hours of intra-operative monitoring and measured 8,975 alarms during that timeframe, with an average of 1.2 alarms per minute. This study concluded that nearly **80%** of the 8,975 alarms had no clinical consequences.



Section 1:

Joint Commission Sentinel Event Alert

Medical Device Alarm Safety in Hospitals

Factors Contributing to Alarm-Related Sentinel Events:

- Absent or inadequate alarm systems
- Improper alarm settings
- Alarm signals not audible
- Alarm settings inappropriately turned off
- Alarm fatigue
- Alarm settings that are not customized to the individual
- Inadequate staff training on proper use of equipment
- Inadequate staffing
- Lack of integration of alarms between medical devices
- Equipment malfunctions and failures

Devices with Alarms

- Physiological monitors
- Telemetry monitors
- Ventilators
- Infusion Pumps
- Anesthesia Machines
- Compression Pumps
- Feeding Pumps
- Nurse Call System
- Bed Alarms

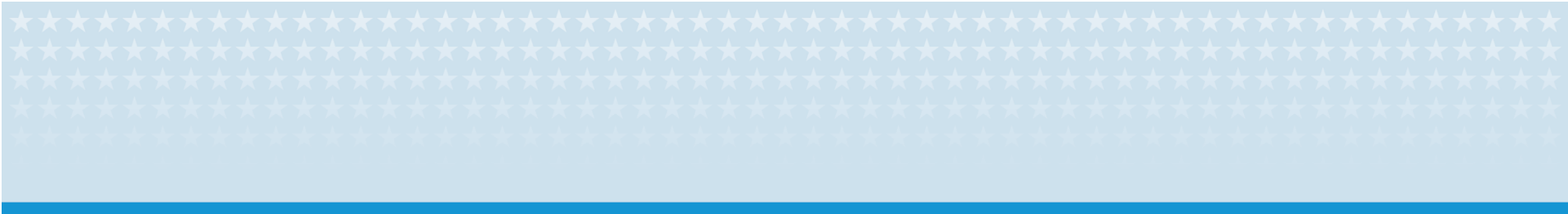
(just to name a few...)



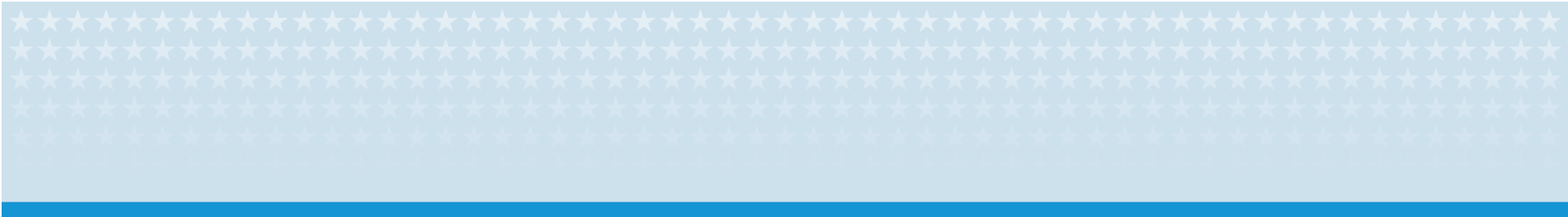
Overview of Joint Commission Sentinel Event Alert (SEA)#50

SEA Recommendation	Process for Implementation
1. Leadership ensures that there is a process for safe alarm management and response in high-risk areas.	<ul style="list-style-type: none">• Create or update Medical Center Policy & Standard Operating Procedure (SOP)
2. Prepare an inventory of alarm-equipped medical devices and identify the default alarm settings and the limits appropriate for each care area.	<ul style="list-style-type: none">• Collaborate & Define• Alarm data gathering• Team sets standards
3. Establish guidelines for alarm settings on alarm-equipped medical devices.	<ul style="list-style-type: none">• Establish guidelines• Create cognitive aid

1 of 3



SEA Recommendation	Process for Implementation
4. Establish guidelines for tailoring alarm settings and limits for individual patients.	<ul style="list-style-type: none">• Establish guidelines• Create cognitive aid
5. Inspect, check, and maintain alarm-equipped devices to provide for accurate and appropriate alarm settings, proper operation, and detectability.	<ul style="list-style-type: none">• Ensure clinical users and Biomed staff have & follow policies
6. Provide all members of the clinical care team with training on the organization’s process for safe alarm management and response.	<ul style="list-style-type: none">• Training and education• Create cognitive aid
7. Change single-use sensors (ex. ECG leads) according to manufacturer’s recommendations, unless contraindicated.	<ul style="list-style-type: none">• Process change



SEA Recommendation	Process for Implementation
8. Assess whether the acoustics in patient care areas allow critical alarm signals to be audible.	<ul style="list-style-type: none">• Investigate physical environment
9. Re-establish priorities for the adoption of alarm technology.	<ul style="list-style-type: none">• Leadership / organizational planning
10. Establish a cross-disciplinary team to address alarm safety and the potential impact of alarm fatigue in all patient care areas.	<ul style="list-style-type: none">• Form facility committee• Create Policy and SOP• Investigation and analysis• Act on findings
11. Share information about alarm-related incidents, prevention strategies, and lessons learned.	<ul style="list-style-type: none">• Communication

Facility Level Workgroup Formation

- Members:
 1. Clinicians
 2. Clinical Engineering/Biomedical Engineering
 3. Information Technology
 4. Risk management
 5. Patient Safety
- Goals:
 1. Establish process for improvement of alarm policies and configurations
 2. Review trends and patterns in alarm-related events
 3. Implement alarm system management policy



Section 2:

Veterans Healthcare Administration (VHA) Clinical Alarms Committee

Members

- Team formed following the AAMI Alarms Summit in October 2011
- Representatives from:
 - Office of Nursing Service (ONS)
 - Healthcare Technology Management (HTM) Group
 - National Center for Patient Safety (NCPS)
 - VHA Office of Health Information - Product Effectiveness



Veterans Health Administration
Healthcare Technology Management



**U.S. Department
of Veterans Affairs**



Goals

- Research current best practices inside and outside of VHA
 - Supported through a VHA survey administered in 2013
- Share those best practices with VHA team
- Increase risk awareness of clinical alarm fatigue
- Provide education on the latest technological developments
- Communicate best practices to help manage The Joint Commission Sentinel Event “Medical device alarm safety in hospitals”
- Ultimate Goal: improve care, safety, and reduce risk of adverse events for our veteran patients

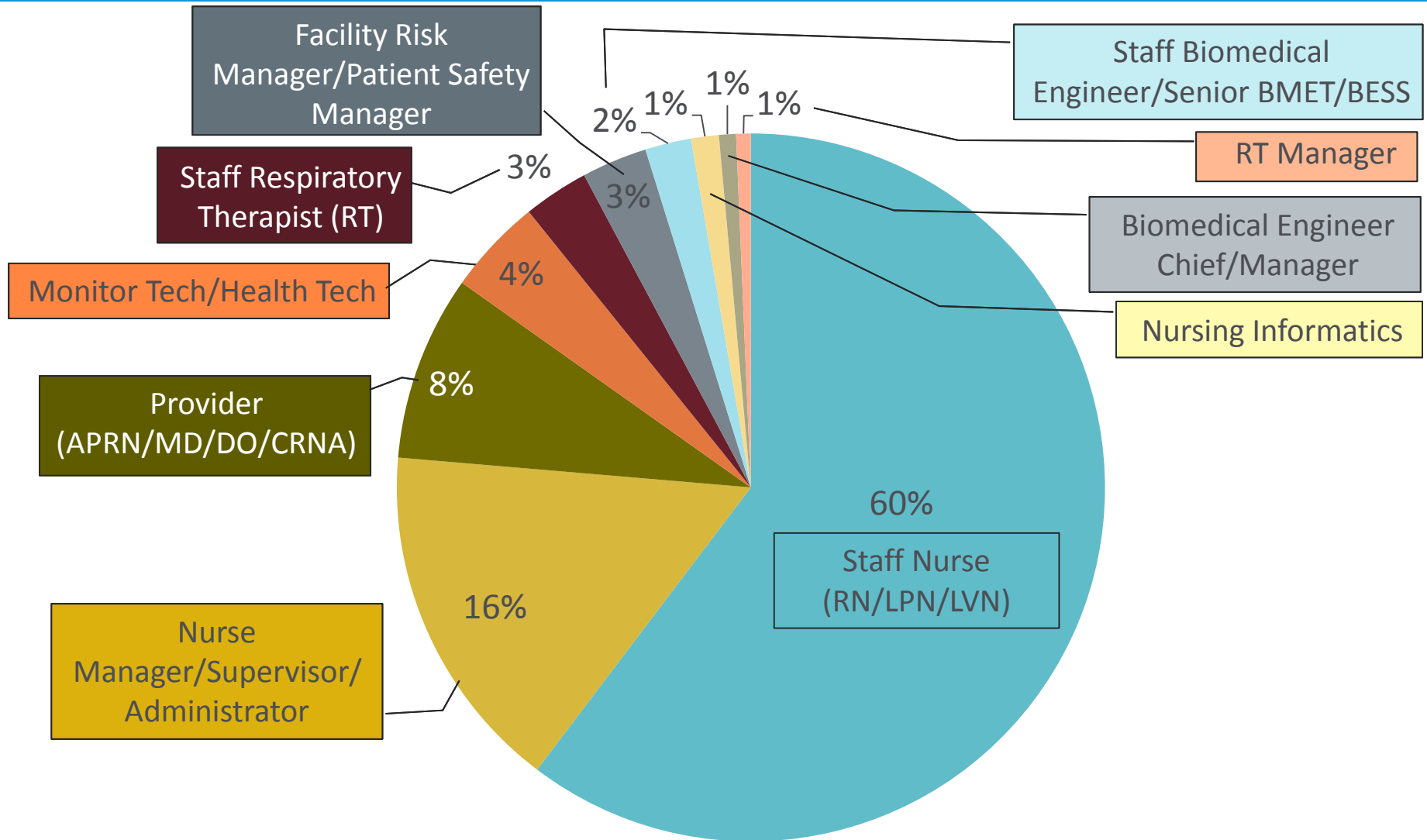


Section 3:

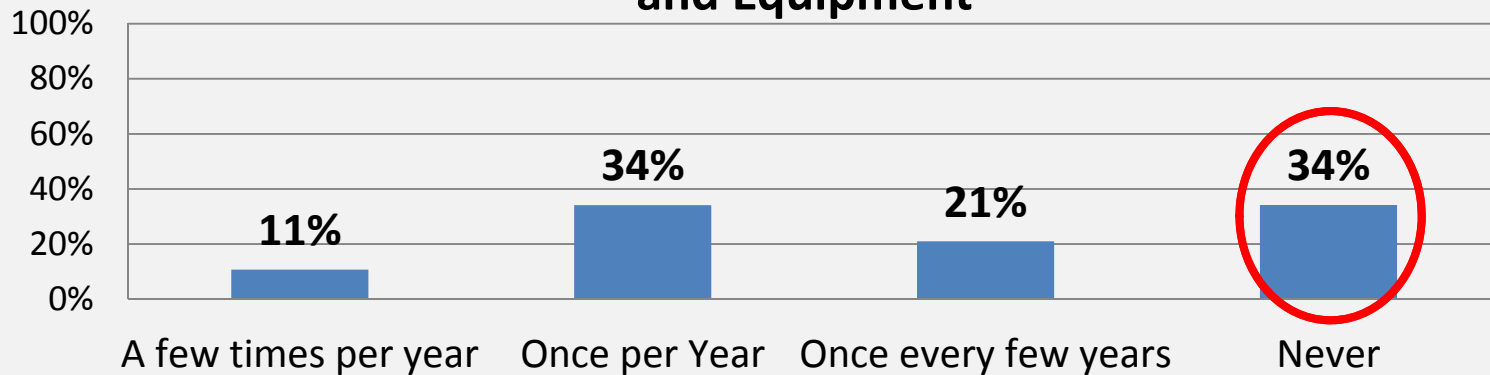
Preliminary Findings from VHA National Clinical Alarm Survey Results

Overview

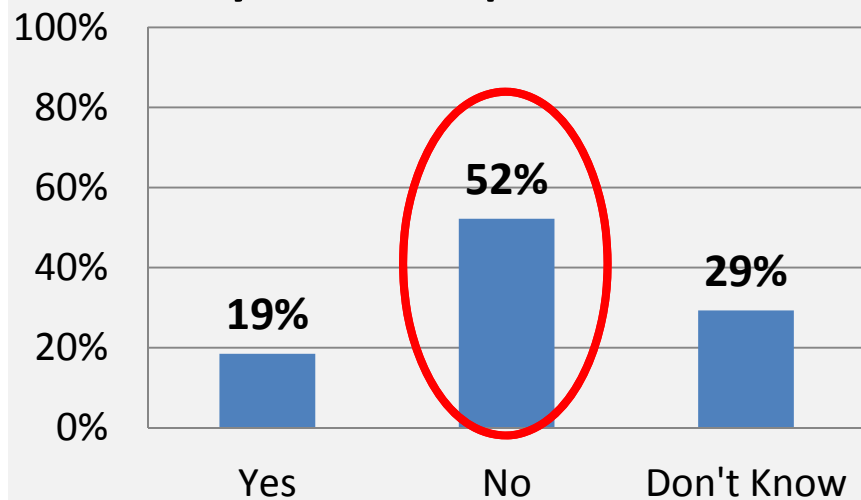
43 VHAs surveyed
– 2,845 responses



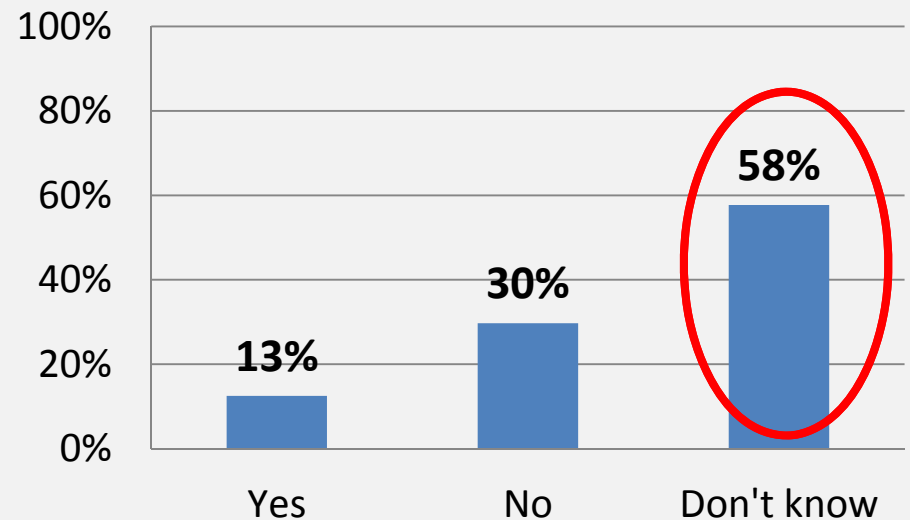
Frequency of Training on Use of Clinical Alarm Monitors and Equipment



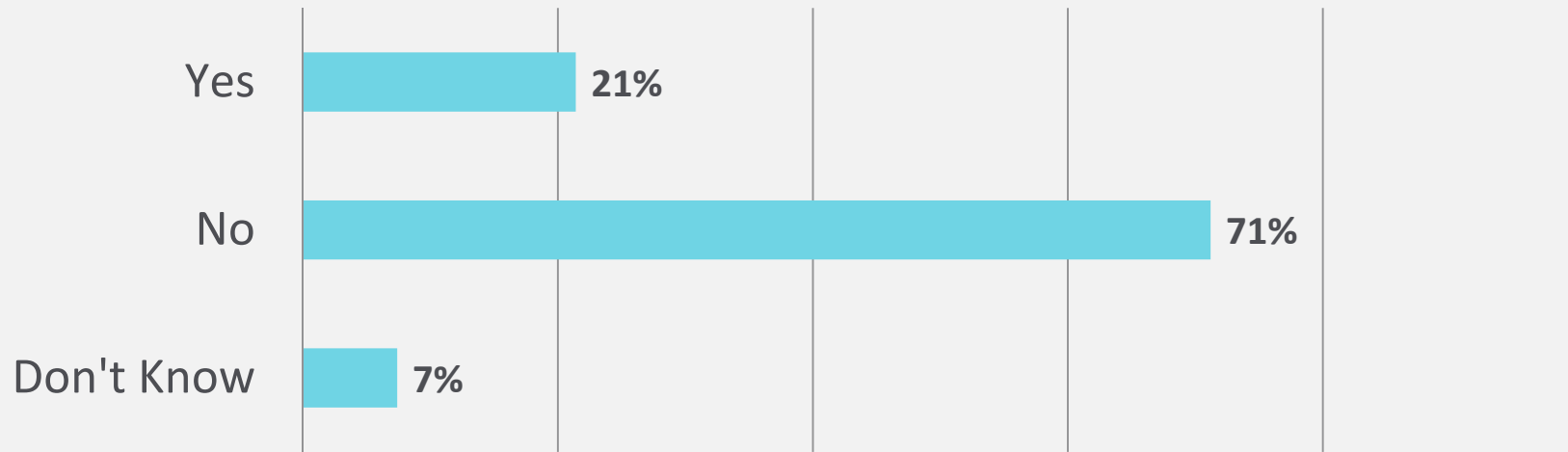
Would you be able to sleep if you were a patient?



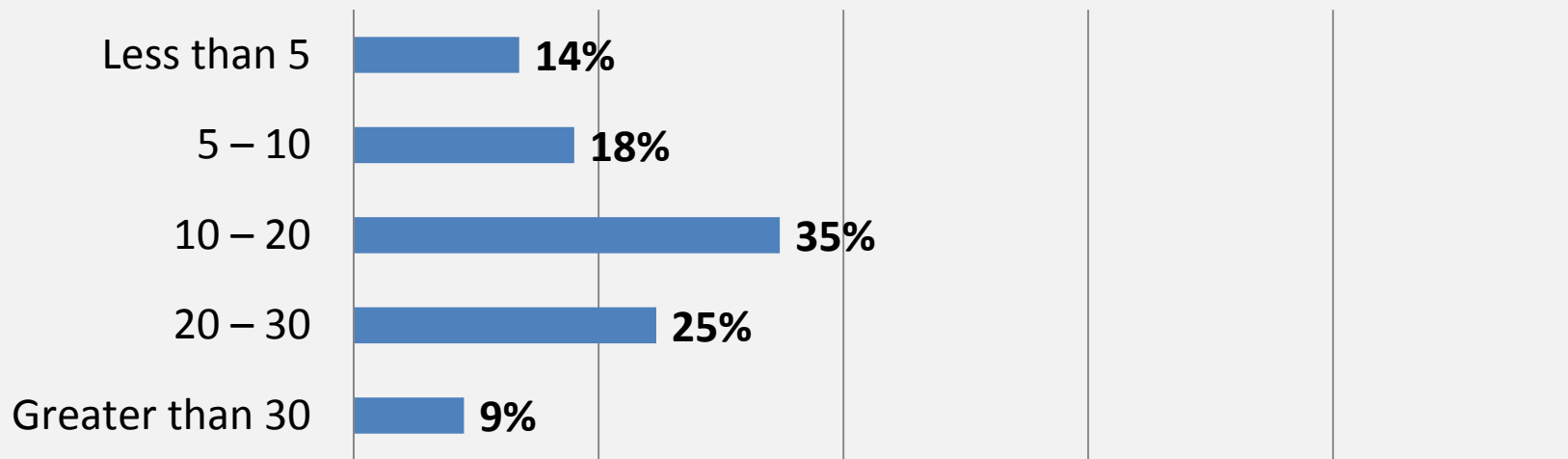
Developed Clinical Alarm Policy in Past Year?



VHA's Employing Monitor Techs



Number of Patients Observed by Each Monitor Tech



Question	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Patients find the noise and frequency of clinical alarms to be distracting during the nighttime .	4%	9%	18%	35%	35%
Patients find the noise and frequency of clinical alarms to be distracting during the daytime .	5%	14%	20%	38%	23%

The large number of clinical alarms that staff is required to respond to is causing alarm fatigue.	7%	24%	23%	26%	20%
False alarms or non-actionable/nuisance alarms are taking away from my ability to administer patient care.	10%	28%	22%	29%	10%
The number of clinical alarm sounds and signals makes it difficult for me to identify the actionable alarms.	9%	35%	19%	24%	13%
On an average shift, environmental background noise interferes with my ability to recognize clinical alarms.	12%	36%	17%	26%	10%
False alarms or non-actionable/nuisance alarms sometimes influence me to either turn off (disable) the alarm or turn down its volume.	24%	32%	14%	24%	6%

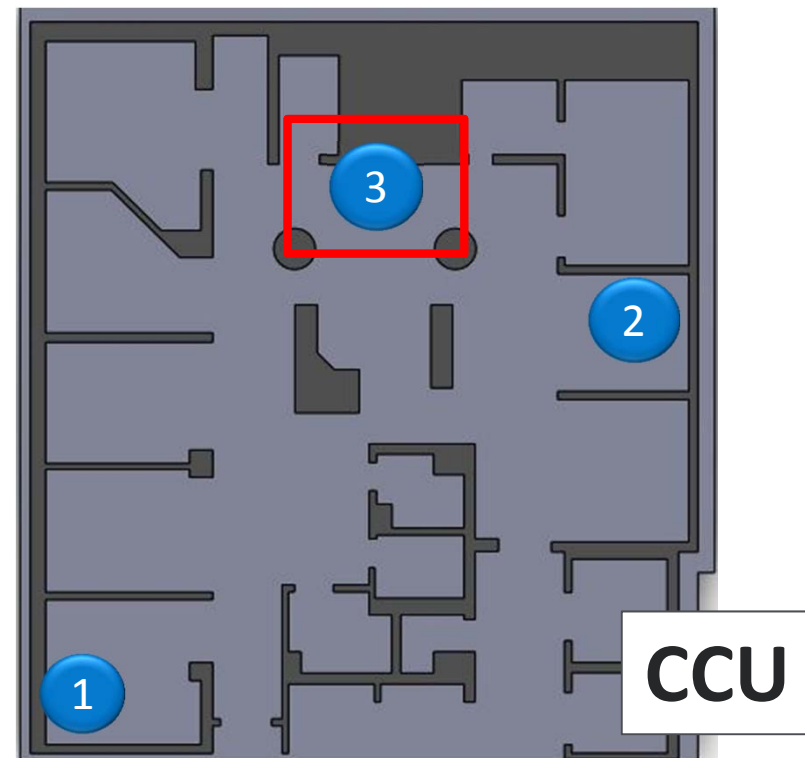
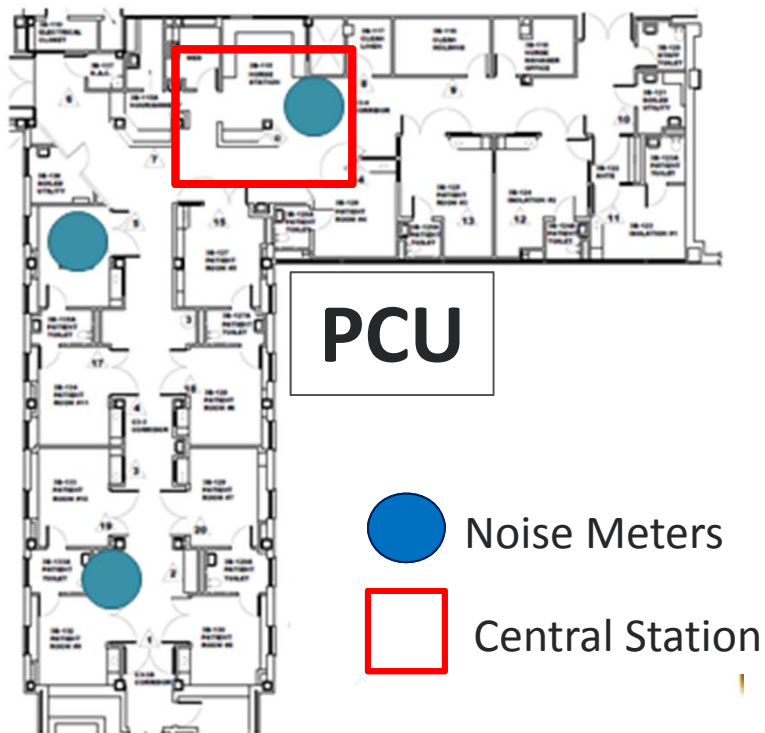


Goals in Action:

VA Boston Healthcare System Alarms Project

Project Overview

- Two Intensive Care Units observed:
 - Progressive Care Unit (PCU): 9 beds, 3:1 patient to nurse ratio
 - Cardiac Care Unit (CCU): 8 beds, 2:1 patient to nurse ratio



Methods

PCU

- Sound level sampled once every 5 seconds recording in decibels (dB)
- Developed EXCEL formulas to filter and analyze data



SoundEar Data Logging
Noise Sign

CCU

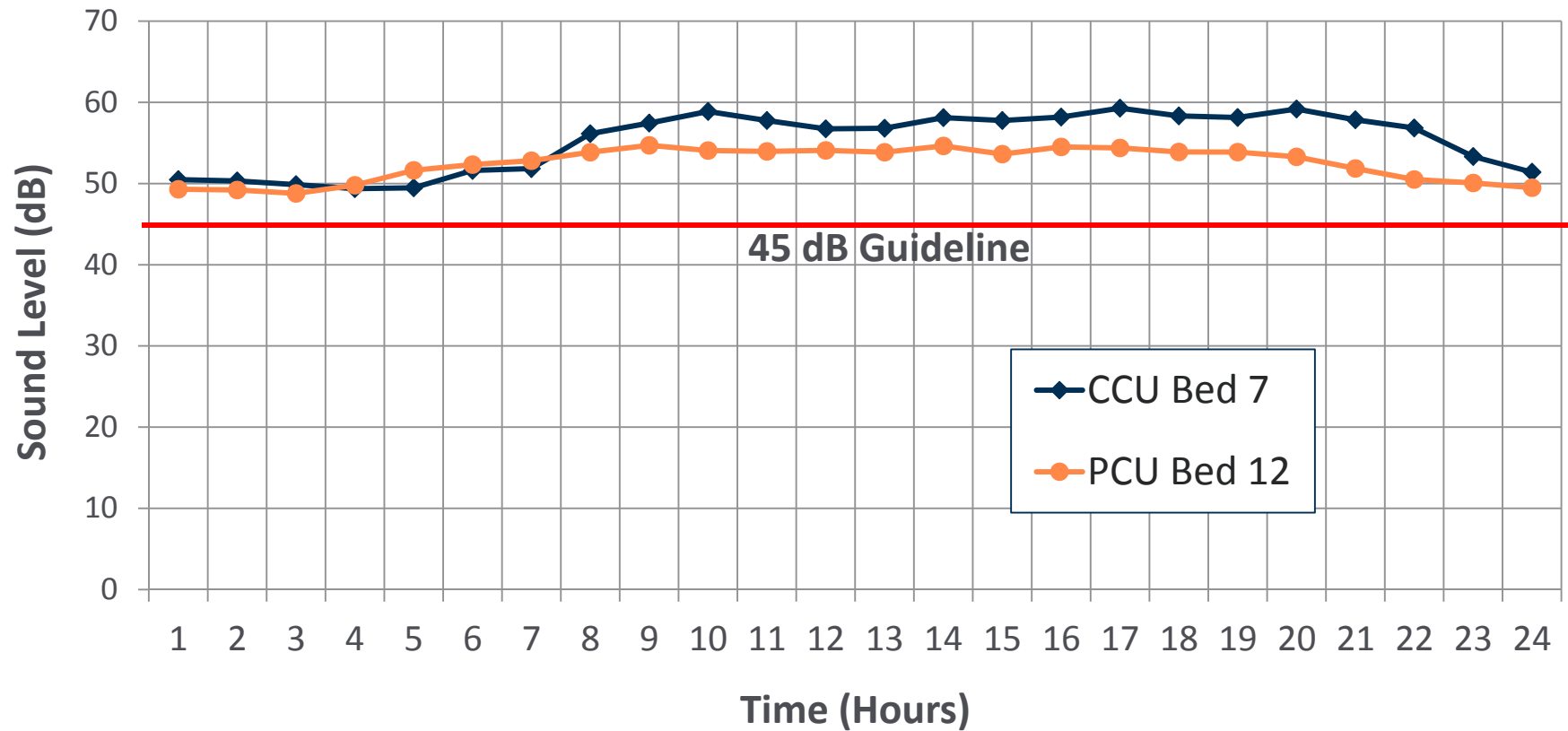
- Sound level recorded once per second recording in decibels (dB)
- Developed EXCEL formulas to filter and analyze data
- Used Philips Research Data Export (RDE) tool to record medium (yellow) and high (red) priority alarms (**CCU only**)



Extech SDL600
Soundlogger

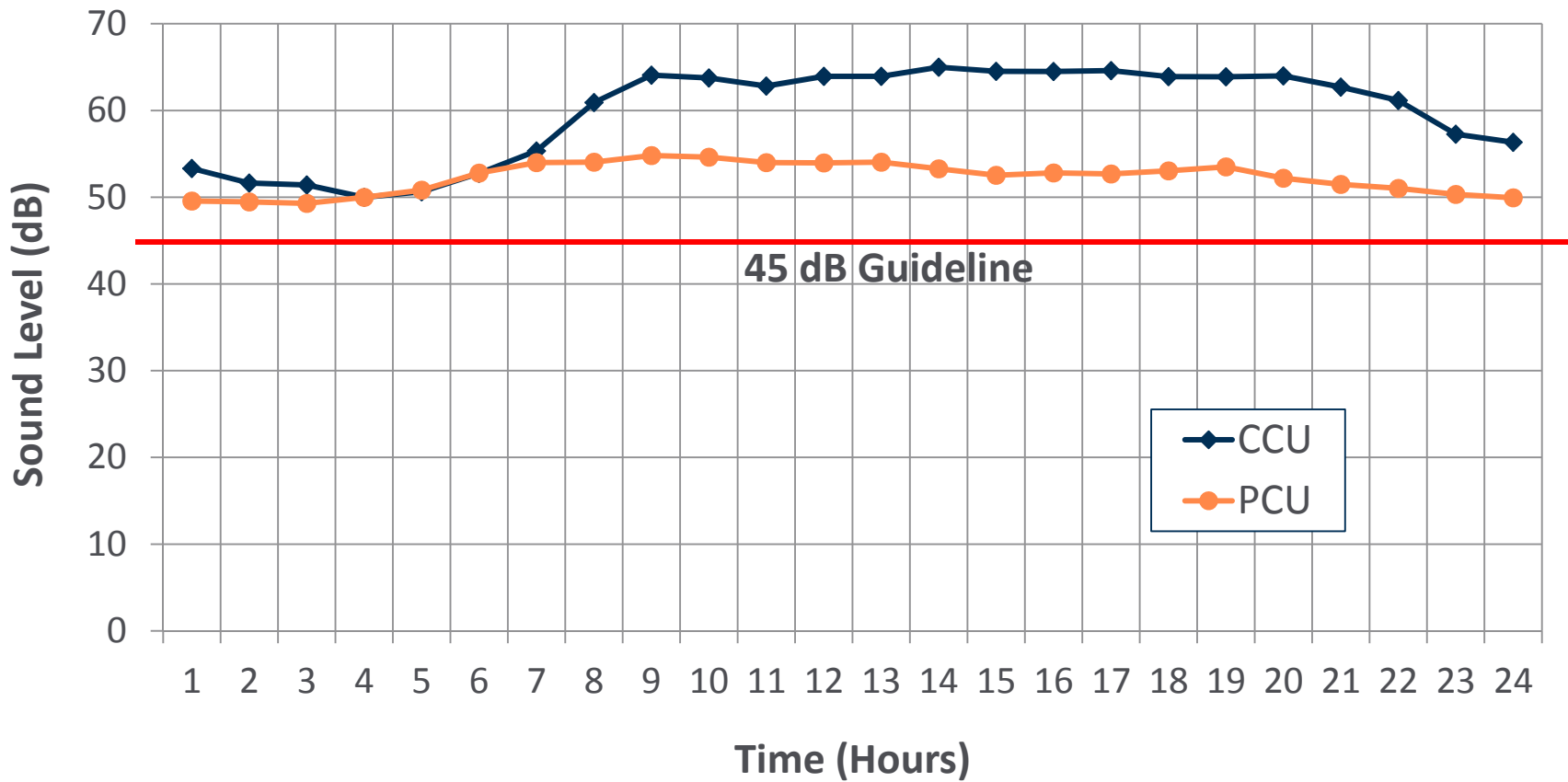
Noise Levels

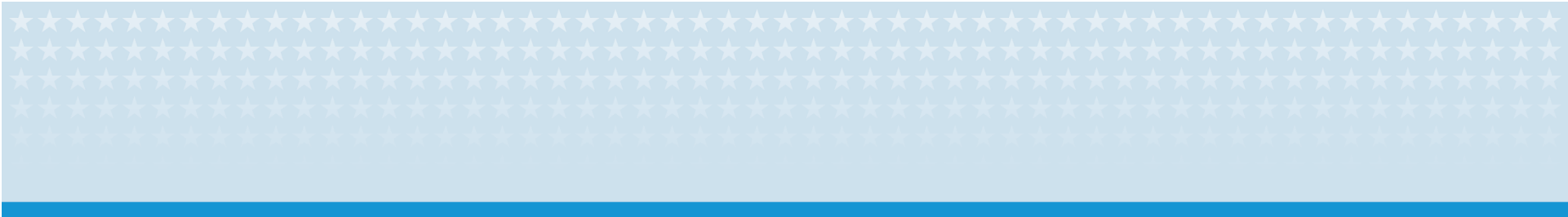
Patient Room Comparison



Noise Levels Continued

Central Station Comparison

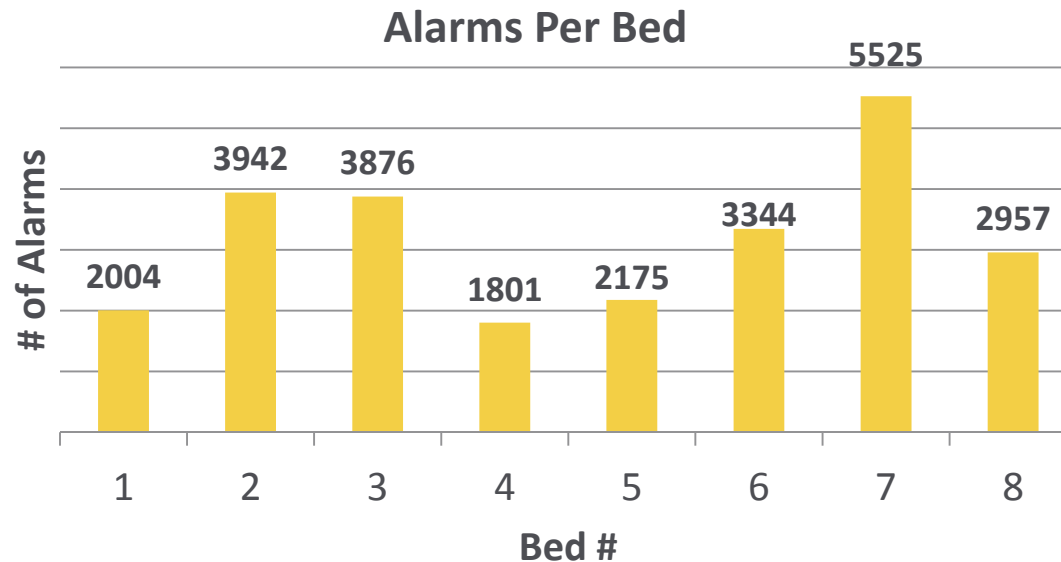




Location	Percentage of Time Spent Above 45 dB (10pm-7am)	Sample Size (# Readings)
CCU Room #1	52 %	489,682
CCU Room #7	99 %	361,081

CCU Alarms Study

- Total # Alarms: **25640 (38 days)**
- Avg. # Alarms/ bed / day: **85**
- For the 3 patients with the most alarms, each elicited:
 - Consecutive alarms of the same type within a 5 minute span of each other for 3 hours
 - These alarms were usually either PVCs, Pauses, or SpO2 related (32%)



	A	B	C
1	Name	Time	Priority
2	**NBP 88 < 90	3/14/2013 1:05:52 PM	Medium
3	**NBP 86 < 90	3/14/2013 1:00:58 PM	Medium
4	* PACER NT PACING	3/14/2013 1:00:23 PM	Medium
5	*** DESAT 82 < 85	3/14/2013 12:01:11 PM	High
6	**SpO2 85 < 90	3/14/2013 12:00:44 PM	Medium
7	*** DESAT 76 < 85	3/14/2013 11:59:34 AM	High
8	**SpO2 85 < 90	3/14/2013 9:52:35 AM	Medium
9	** RR HIGH	3/14/2013 9:50:57 AM	Medium
10	* PAIR PVCs	3/14/2013 9:40:00 AM	Medium
11	* PAIR PVCs	3/14/2013 8:26:30 AM	Medium
12	* PAIR PVCs	3/14/2013 8:02:30 AM	Medium
13	**SpO2 83 < 90	3/14/2013 7:01:03 AM	Medium
14	* PAIR PVCs	3/14/2013 6:29:41 AM	Medium
15	* VENT TRIGEMINY	3/14/2013 6:25:12 AM	Medium
16	* PVCs/min HIGH	3/14/2013 6:25:07 AM	Medium
17	* PAIR PVCs	3/14/2013 6:19:35 AM	Medium
18	* PAIR PVCs	3/14/2013 6:15:13 AM	Medium
19	* PVCs/min HIGH	3/14/2013 6:14:50 AM	Medium
20	* PAIR PVCs	3/14/2013 6:11:44 AM	Medium
21	* PAIR PVCs	3/14/2013 6:05:41 AM	Medium
22	* PVCs/min HIGH	3/14/2013 6:01:36 AM	Medium
23	* PACER NT PACING	3/14/2013 5:56:21 AM	Medium

Outcomes of VA Boston Study

- Implemented an alarms committee to:
 - Analyze alarm burden
 - Strategize ways to follow advice put forth by AAMI, the ECRI Institute and the Joint Commission in the 2013 Sentinel Event
 - Implement Standard Operating Procedures (SOPs) for all hospital employees on managing all high priority medical device alarms
- Implemented a noise committee
 - Brainstorm and implement ways to counteract noise on high acuity units
- Using Research Data Export tool to study alarm burden on general patient floors and ICU's.
 - Creating protocols to adjust alarm parameter limits, specifically SpO2 and PVC alarms to reduce un-actionable alarms.

Conclusions

- Alarm fatigue is a real and serious problem in all areas of the hospital.
- The Joint Commission Sentinel Event shows ways to reduce alarm burden in high acuity areas by:
 - Creating alarm task force
 - Writing standard operating procedures
 - Establishing guidelines
 - Creating cognitive aids for staff
- Can use data from the VHA Alarms Committee survey and the VA Boston Healthcare System to make changes which better tailor alarms to patients and reduce false alarms.

Acknowledgements

- VHA Office of Health Information - Product Effectiveness Team
- All members of the Veterans Healthcare Administration (VHA) Clinical Alarms Committee
- Staff at the VHA Boston Healthcare System:
 - Lisa Bradley, *Clinical Engineering Supervisor*
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 - Maria Rivera, *CCU Assistant Nurse Manager*
 - Helen Muller, *PCU Acting Nurse Manager*
 - Rebecca Shultz, *PCC RN Supervisor*
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 - Brad Mello, Tyler Hanna, Matthew Gagnon, William Pinette



Questions?

