Statement on the Importance of Collaboration between Biomedical Engineering and Clinical Staff and the Simulation Laboratory Activities to Patient Safety and Reporting at Brigham & Women's Hospital (BWH)

-Mary White RN, MBA, CPHRM Risk Manager, July 22, 2013

Risk Management staff at BWH work very closely with biomedical engineering and the clinical disciplines to investigate adverse events, for both "harm" and "no harm events." With the advent of our Biomedical Liaison role, which Michael Dumais and Michael Fraai will discuss, it became much easier for us to effectively investigate those adverse events involving equipment and devices. The Liaison crosses the disciplinary boundaries that used to get in our way - the liaison speaks "nursing" and "clinical speak," while translating and communicating the clinical issues to the biomedical engineer experts in a way that the problem makes sense to them too. This role, a nurse with a strong clinical and technological background embedded on a day-to-day basis within the Biomedical Engineering Department, was created here in 2002.

Our Risk Management Department, and I think I can safely speak for our clinical colleagues as well, can't imagine going backwards to a time when we didn't have this role in place. The liaison helps our hospital ensure that we fully understand the equipment problems we encounter, identify workable solutions that make sense from both an engineering perspective AND a clinical perspective, and determine when a satisfactory clinical solution can't be devised. The liaison also helps us ensure we're reporting adverse events causing harm or with potential to cause harm quickly to FDA through MedSun.

In short, Risk Management finds this role tremendously helpful - essentially an investigator based in Biomedical Engineering, a "United Nations Ambassador" of sorts, who can speak all the required languages, helping us improve the safety of the care we provide (which automatically improves life for our clinicians) every day.

The Anesthesia Simulation Lab, The Nursing Simulation Lab, and STRATUS based in the Emergency Department:

The Anesthesia Simulation Lab has been an integral part of our physician training program for years. We have also developed a Simulation Lab for Nursing, which Carol Luppi will describe, and STRATUS, our Multidisciplinary Simulation Lab based in the Emergency Department, where clinical teams practice and hone their skills, to prepare them before they have to work on a patient. Simulation allows us to practice not only critical skills but also working well as a team, before someone's life depends on it. It also gives us an opportunity to test our proposed solutions to problems in a safe environment. These activities have proven to be extremely important to the patient safety and MedSun reporting efforts at our hospital, and we are happy to share information about them with other hospitals.

Building Relationships between Biomedical Engineering and Clinical Staff to Improve Medical Device Safety and Event Reporting

MedSun Webinar July 25, 2013

BRIGHAM AND WOMEN'S HOSPITAL

HARVARD MEDICAL SCHOOL *TEACHING AFFILIATE*

Building Relationships between Biomedical Engineering and Clinical Staff to Improve Medical Device Safety and Event Reporting

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BWH BRIGHAM AND WOMEN'S HOSPITAL

HARVARD MEDICAL SCHOOL
TEACHING AFFILIATE

Program Description: The purpose of this MedSun webinar is to discuss the collaboration between clinical staff and biomedical engineering, and how this collaboration can benefit medical device safety for patients and staff in the hospital, the quality of medical device-related reports submitted to FDA through the Medical Product Safety Network (MedSun), and patient safety nationwide. This collaboration has been successfully implemented at Brigham and Women's Hospital, and has grown in its scope and importance there. Our presenters will discuss their experiences with this collaboration and how it has benefitted their work.

Objectives:
1. Attendees will be able to describe the various roles of clinicians in Biomedical Engineering at BWH.
2. Attendees will be able to describe the role of simulation in hospital based education programs.
3. Attendees will be able to describe the investigation process utilized by Biomedical Engineering at BWH.

Disclosure

None of the presenters have any relevant financial relationships to disclose.

Brigham and Women's Hospital

- 793 bed quaternary care hospital
- Extensive scope of health care
- 18,000 employees / 5,000 employees in the Nursing Department
- Biomedical Engineering staff
  - 8 Clinical Engineers
  - 22 Biomedical Engineering Technicians
- Center for Nursing Excellence
- 350 – 400 new RN's / year
- 4 day core RN orientation every 2 weeks

Introduction

- Increasing reliance on patient care technology, mostly high risk technology, for evidence based care and evolving clinical practice

- Patient care technology introduction and its use is no longer solely a technical or purchasing decision
  - A multi-disciplinary approach with clinicians and biomed staff having critical roles
  - Technology which can be overwhelming to caregivers

- The clinical aspect (story) needs to be factored in technology introduction, training, incident investigation and MedSun reports

- ➤ Need for collaboration between these two professions is essential

Clinicians associated with BWH Biomedical Engineering

- Board Certified Electrophysiologist/Biomedical Engineer

- Nursing Bedside Technologies Specialist

- Operating Room-Board Certified Anesthesiologist/CCE

- Robust collaboration with Nursing Department

  - Nursing Education

- Closely aligned with Risk Management Department

  - Investigation of Sentinel and Non-Sentinel Events

  - Results reported to MedSun and other regulatory bodies

Roles of Clinicians in Biomedical Engineering

Liaison between Clinical Community and BWH Biomedical Engineering

- The bridge between clinicians and technical group
- The clinical perspective in project specifications, solution development and incident investigation
- Nursing Department
- Risk Management
- Vendors

BWH Nursing and Biomedical Engineering Collaboration

- **New Employee Orientation Equipment Training**
  - Ubiquitous and high-risk technology
  - Smart Infusion Pumps
  - Defibrillators
- **Hospital Wide Rollout of New Technology**
  - Change to new defibrillator vendor for inpatient and outpatient areas
  - Smart Infusion Pumps
    - Software upgrades
    - Hardware upgrades
    - Wireless infrastructure
    - IV medications
    - Epidural infusions

Why use simulation in education?

- Simulation training is gaining remarkable popularity as a method to enhance healthcare safety.

- Unique educational needs of the BWH staff practicing at the bedside of our highly sophisticated, exceptional care facility.

- BWH patients deserve staff that have state-of-the art education that provides the knowledge and skills to deliver the safest care possible.

Why Simulation?

- Participants are adult learners best engaged when education is tied to patient care (Jeffries, 2005)

- Able to combine focused practices of BWH staff in standardized, reproducible, evidence based experiences. (Larew, Lessans, Spunt, Foster, Covington, 2006)

- Simulators lead to more rapid skills acquisition. (Jeffries, 2005)

- Learn to manage unpredictability to provide safe care in current environment. (Ebright, 2004)

Initial Mission and Goals

- Our mission is to enhance patient safety and quality of healthcare while promoting Brigham and Women's Hospital's patient-focused philosophy through the use of human patient simulation.

- Goals
  - Enhance clinical competency of healthcare providers
  - Improve clinical efficiency and confidence of healthcare providers
  - Evaluate clinical competency of healthcare providers prior to entry into the patient care environment
  - Provide a safe environment for error analysis and investigation of technology-based dilemmas
  - Trial new devices and perform usability studies to facilitate new technology acquisition
  - Create and implement pedagogically sound education programs for:
    - New Employee Orientation
    - Annual Competency Validation
    - Interdisciplinary Team Building
    - Intradisciplinary and Interdisciplinary Communication Skills
    - Crisis management
    - New technology devices and software
    - Clinical and technical training of Biomedical Engineering staff

Bwhemarcnetrain,David

| 22134647 (BWH) | 12/12/1945 (62 yrs.) M | 17A 601 1 | 08/21/2007 01:35 | CL02 |

Select | OE | eMAR | Results | LMR | Resource

Pod Monitor for 17A   (Refreshed: 04/29/08 at 16:22:30)   Current OE User : Carol Luppi

| Alert | Systems | Write | View | Process Orders | Tools | Other OE Functions | Other Patients | BedUpdate |

ROOM	MRN		NAME	ORDER STATUS	eMAR	Assigned
13-2	18919027		EMARTEST,MAGGIE	X1; PENDING; Cosign		
14-1	18919035		EMARTEST,KANG	X1; PENDING; Cosign	Rx	
	18919043		EMARTEST,KODOS	Cosign		
15-1	18919050		EMARTEST,MCBAIN	Cosign		
15-2	18919068		EMARTEST,BARNEY	PENDING; Cosign		
16-1	18919076		EMARTEST,APU	Cosign		
16-2	18919084		EMARTEST,MOE			
17-1	18919092		EMARTEST,ITCHY			
17-2	18919100		EMARTEST,SCRATCHY	Cosign		
18-1	18919118		EMARTEST,KRUSTY	Cosign		
56-7	18919126		EMARTEST,FLANDERS	PENDING; Cosign		
12-2	18919134		EMARTEST,SMITHERS	X1; PENDING; Cosign		
30-1	19327139		RXTEST,MARK	X1; PENDING; Cosign		
	19327147		RXTEST,JACKIE	X1; PENDING; Cosign		
60-1	22134647		BWHEMARCNETRAIN,DAVID			MGII

94 - 328(0,110,15,0,0,203)   Local intranet

Technology in Clinical Context
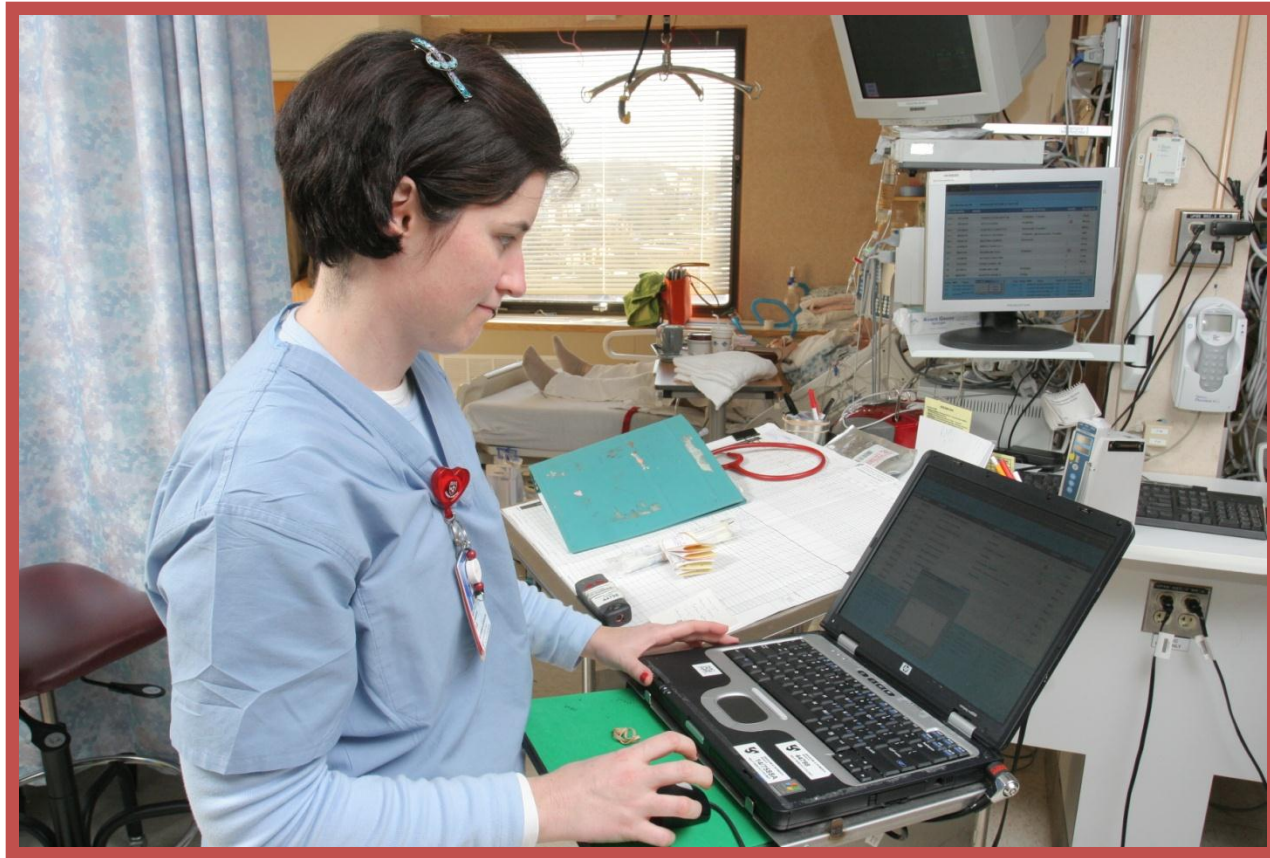
Complement Nursing Workflow not Complicate

Roles of Clinicians in Biomedical Engineering

Education

Clinical training for technical staff:
- Biomedical Engineering Technicians
- Clinical Engineers

Benefits of clinical training for technical staff:
- Increased understanding of what the device does and clinical application for the device.
- Greater understanding of clinical practice in planning installations
- Greater insight when troubleshooting

Roles of Clinicians in Biomedical Engineering

Evaluation
- Ongoing evaluation of medical devices
- New technology evaluation
- Acquisition evaluation
- Collaborate with Nursing Clinical Informatics Committee regarding recommendations for research and development for future technology enhancements

Roles of Clinicians in Biomedical Engineering

Investigation

- All sentinel and non-sentinel event investigations are performed *in-house*
- Occasional 3rd party involvement - e.g. ECRI
- Avoid vendor involvement whenever possible

Roles of Clinicians in Biomedical Engineering

Regulatory Liaison

- DPH
- FDA
  - via MedSun

Roles of Clinicians in Biomedical Engineering

Communication

- Large scale notifications of recalls, etc

- Communications of alerts or upgrades

Sentinel Event/Device Reporting Process at BWH

- Begins with a Safety Report (SR)
- All BWH staff can author SR's
- Encouraged by hospital leadership
- Can provide great detail
  - Who, Where, When, etc…
  - Precise device identification

Sentinel Event/Device Reporting Process at BWH

SR Assigned to Team Leader/Clinical Engineer

Operating Room   Med-Surg   Heme-Onc   ICU
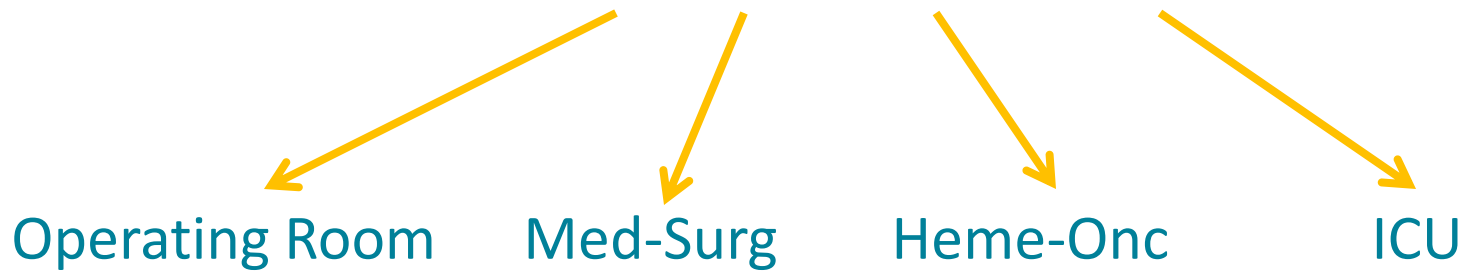
- Team has established relationship with care unit
    - Nursing Director
    - Clinical Staff
- Clear understanding of the technology

Sentinel Event/Device Reporting Process at BWH

MedSun Review

- Review prior occurrences online
- Especially helpful with **new/unusua**l events

MedSun Database
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm

MAUDE Database
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm

Sentinel Event/Device Reporting Process at BWH

Evidence Collection

- Timely **Clinician** Review-ASAP
  - Who
  - What
  - Where
  - When
  - Why

Sentinel Event/Device Reporting Process at BWH

Evidence Collection

Technical Review

- Physical Condition of Device

- Functional Testing

Sentinel Event/Device Reporting Process at BWH

Evidence Collection

Log Data Download

Event Log Report

8100 - Pump, Serial Number

| Seq	Log Date	Description	Details
0	############	AVA_EVENT_ATTACHED	SourceType=ATTACHED_UNIT; SourceContext=0;
1	############	PUMP_PRESSURE_MODE	
2	############	OCCLUSION_RETRIES_CHANGED	NewMaxOcclRetry=0
3	############	AIL_BOLUS_CHANGED	AilBolusLimit=75; AccumulatedAirEnabled=True
4	############	AVA_EVENT_ATTACHED	SourceType=USER_INTERFACE; SourceContext=0;
5	############	PUMP_PRESSURE_MODE	
6	############	OCCLUSION_RETRIES_CHANGED	NewMaxOcclRetry=1
7	############	AIL_BOLUS_CHANGED	AilBolusLimit=250; AccumulatedAirEnabled=True
8	############	PUMP_PRESSURE_MODE	
9	############	OCCLUSION_RETRIES_CHANGED	NewMaxOcclRetry=1
10	############	AIL_BOLUS_CHANGED	AilBolusLimit=250; AccumulatedAirEnabled=True
11	############	UNIT_LABEL	U
12	############	AVA_EVENT_ATTACHED	S
13	############	CENTRAL_UNIT_INFO	M
14	############	AVA_EVENT_ATTACHED	S

```
02:57:44.093  0772:1372  audio.exe Alarms silenced
02:57:51.109  0804:0812  alm_rec.exe "6D|75: SPO2 PROBE" 1,3,3,2,45,0
02:57:52.234  0772:1372  audio.exe "6D|75" (display slot 2) now SYSTEM_ALARM audio level
02:57:52.234  0772:1372  audio.exe SYSTEM_ALARM sounding - volume 70 %
02:57:52.234  0772:0796  audio.exe MCI_PLAY:SYSTEM
02:57:54.093  1296:1364  _cic.exe ALARMCOND(SLOT:0,TTX:8660,BED:6D|74,MSG(14):PVC)
02:57:55.109  0804:0812  alm_rec.exe "6D|75: PULSE SEARCH" 1,3,3,2,45,0
02:57:58.234  0772:1372  audio.exe "6D|75" (display slot 2) now NO_AUDIO_ALARM audio
02:57:58.234  0772:0796  audio.exe MCI_STOP
02:57:58.234  0772:1372  audio.exe Alarms silenced
02:58:01.062  3116:3144  fdsvr.exe get_admit_pkt::openUNITY() failed (Err = 0) to "6D|74+"
02:58:02.125  0804:0812  alm_rec.exe "6D|75: SPO2 LO 37" 1,6,6,2,45,0
02:58:02.234  0772:1372  audio.exe "6D|75" (display slot 2) now WARNING_ALARM audio 02:58:02.234
0772:1372  audio.exe WARNING_ALARM sounding - volume 70 %
```
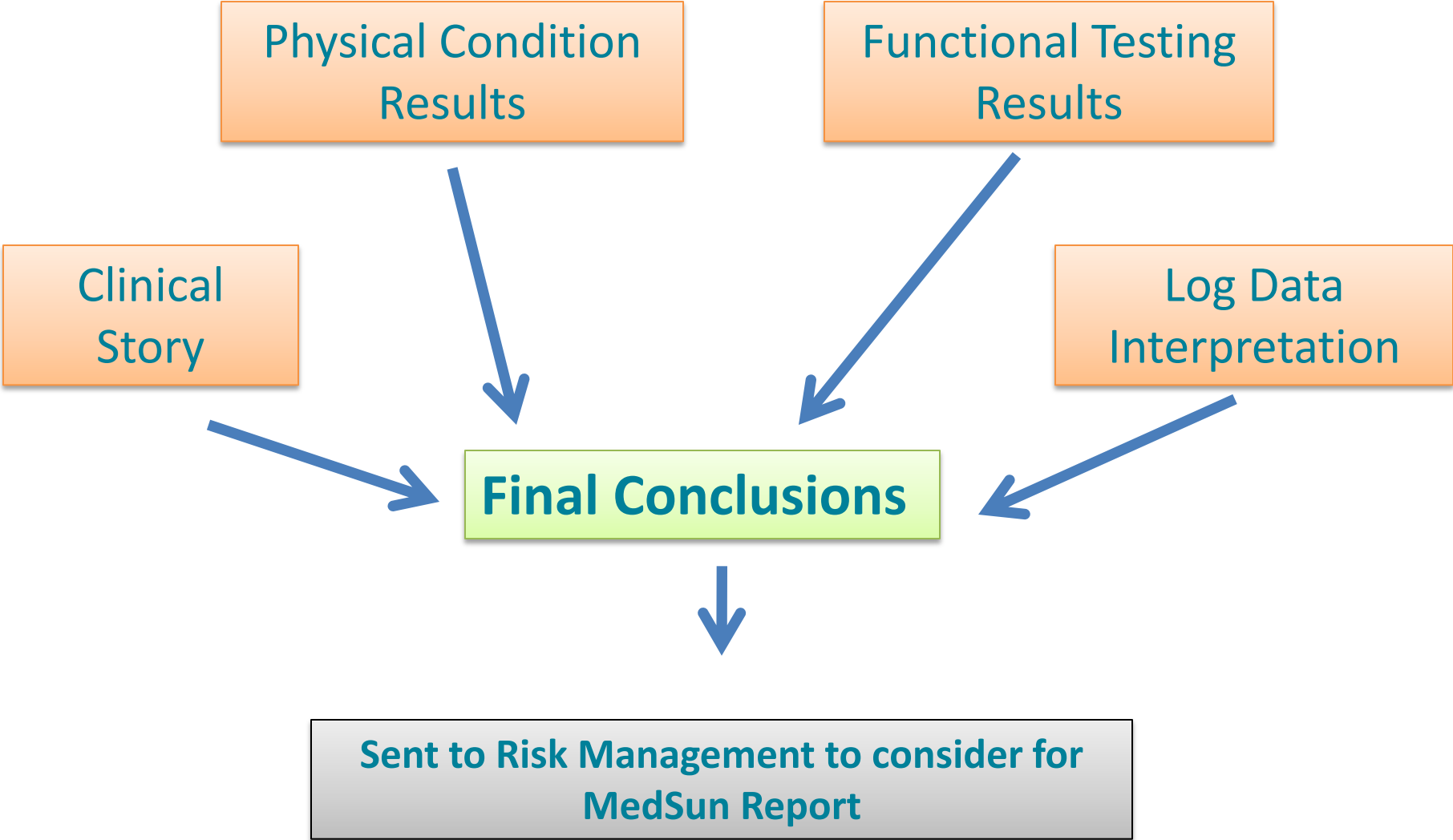
Sentinel Event/Device Reporting Process at BWH

Evidence Collection

Document, document, document…

- Images

- Video

- Text Documentation
- Supports and easily explains issue if MedSun report needs to be filed
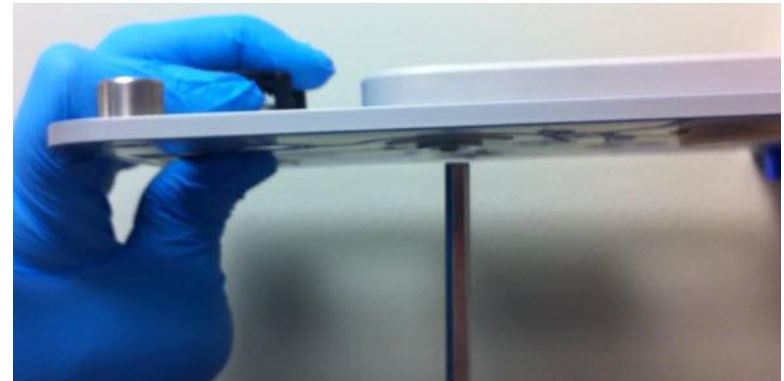
Sentinel Event/Device Reporting Process at BWH

Sentinel Event/Device Reporting Process at BWH

•Filled out per routine

•Enter as much detail as possible

•Follow-up with analyst with supporting documentation

  •Images

  •Video

  •Log data

Sentinel Event/Device Reporting Process at BWH

Feedback to Clinical Staff

- Fact based feedback only
- Clinicians sensitive to "Use Error" label
- Never place label of "Use Error" unless you can provide *evidence* of use error
  - Presence of fully functional device does not equal use error
  - Not knowing what happened does not equal use error

Summary

- Benefits of a collaborative effort between Biomedical Engineering and Nursing
  - Enhanced technology training programs
  - Incident investigation for MedSun reporting to increase patient safety with technology use not only in our hospital but nation-wide
- Simulation use to augment training programs which also will contribute to patient safety
- Enhanced results of incident investigations for MedSun reporting through a collaborative effort between Biomedical Engineering and Nursing

Questions