Advanced Medical Technology Training and the APSF Recommendations: Perspectives from my Vantage Point

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Why are we here?
Improve patient care by ...

• Better utilizing advanced device capabilities
• Reducing equipment misuse
• Decreasing stress and cognitive burden on anesthesia caregivers

• Challenge is not “what” to do or “why” to do it, but “how” to effect change
Observations from MGH

• New anesthesia faculty are trained by biomed (clinical) engineers and monitoring nurses
• Often hire MGH-trained fellows, residents – that helps reduce knowledge gap
• Entire department has access to intermittent hands on “skill sessions” – e.g. Belmont Rapid Infuser, Infusion pumps, Hemocue
• Expert help is readily available (staff, anesthesia technicians, BME/Clinical Eng)
MGH - challenges

• Not enough time/opportunity to learn
• Not possible for everyone to participate in skill sessions
• If online – when?
  – Personal time?
  – Adequate without hands on?
  – Taken seriously or just “check the box”?
Recommendation #1
Reduce the need for lengthy training

• Through better design and monitoring device use/performance
• Example - AED concept. Once device has two modes of operation:
  – “Public” mode with voice assist
  – “Expert” mode with manual control
Will training alone ever be sufficient?

Ideal state – minimal to no training should be required

Standards recognize the complexity of modern equipment:

Symbol on the medical device that means “read the manual”

“Caution” per ISO 7000-0434A

New symbol on the medical device

Per ISO 7010-M002

Mandatory action safety sign: (It is a mandatory action to) Refer to instruction manual/booklet
Note: on me equipment “Follow instructions for use”

How can we read instruction manuals that we can’t find?
(Do YOU still read manuals for new consumer electronics?)
Example: Belmont Rapid Infuser

- Pelvic fracture at 0300
- Belmont (or equivalent) could be life-saving
- Do I remember how to set it up?

NB: This is an example of the need for better access to device information. It is NOT intended to single-out Belmont or any manufacturer.
I would start with the Belmont web site.

The Belmont Rapid Infuser

The Belmont® Rapid Infuser has become the standard of care for rapid blood transfusion, by allowing precise control of intravascular volume while preventing hypothermia, air embolus and vessel trauma. The Belmont® Rapid Infuser uses patented electromagnetic induction heating to heat to target temperature in a single pass while intelligent software monitors and controls infusion. The touch screen allows for flow rate infusion from 2.5 to 1000ml/min with the touch of a button. The screen continuously displays total volume infused, infusion rate, fluid temperature and system pressure. The disposable set is designed for easy set up and active air evacuation.

There are more than 3,000 systems in use in more than 30 countries throughout the world. Widely used in major medical centers, community hospitals, and children's hospitals, The Belmont® Rapid Infuser is a proven life saver.
To Request Product Information, complete this form:
Still looking ...
Next, I try YouTube ...
Without success

Video does not Depict device setup
The need to educate users is a challenge for manufacturers and users:

“I have had problems loading the Belmont ...”
“rep came to our institution and gave me tips on how to properly load the cassette ...”
What if the device or cassette package had a “QR Code” that linked to information?

Audience: Read this QR code with your smartphone now

Note – there are many free smartphone apps to read or create QR codes
What if QR code showed this?

Or this ...

Interactive Ventilator Simulator (www)
QR Codes are widely used

• Invented 1994
• ISO standard
• Fast readability

QR App

Ticket number and date
Recommendation #2
Improve access to training material

• Consider QR Code or similar approach for point-of-care access to key information
  – Point-of-care specific instructions
  – Informational web site
  – Current/updated warnings/cautions/recalls
  – Form to report problem, ask questions
Recommendation #3

Improve the **usability** of training material

• Recognize learning styles or “types” and diverse device features to be learned. Consider:

1. Static Documents
2. Videos/animations
3. Interactive computer/web animations
4. Hands-on training fairs
5. Critical device setup information
6. Devices can have “training” mode
Recognize that device are used within a **system**, not in isolation. Manufacturers and **regulators** must understand the use environment.
Recommendation #4: A system perspective is needed
Automated data logging

How will we know if training was effective? Was training the appropriate approach vs improved design?

• How can we identify equipment design improvement opportunities (use errors)?

• What if we could record/monitor device(s) in use
  – Button presses
  – Find confusing menus/submenus
  – Capture other contextual information from the SYSTEM of devices + patient
  – *Concept of black box recorder or system data logger – more than device-level logging]*

*See standard ASTM F2761-09, and project on ICE data logger funded by DoD [http://mdpn.org/MD_PnP_Program_DataLogger.html]
Manual reporting of device/system issues:

Documenting the gaps and opportunities: **Clinical Scenario Repository Project at MGH**

- **Clinical Scenario**: A brief description of a clinical situation or event. The purpose is to inform of the need for development of technical solutions.
- **Clinical Scenario Repository**: A web portal to allow clinicians, clinical engineers and other users to enter, revise and annotate clinical scenarios.

A place to document and share these scenarios will help to identify clinical and technical challenges, address healthcare needs to guide improvements in patient safety and quality of healthcare delivery.

Development supported by DoD – pilot go live in 2013. Check [www.mdpnlp.org](http://www.mdpnlp.org) for updated info.
Manual reporting of device/system issues:

- Enter clinicians, clinical environments and equipment.
- Choose from a preselected array of options, or input your own.

Project information will be posted on www.mdpnp.org
Add a **clinical concept of operations** to show the improvement in safety and effectiveness via a specific solution implementing the proposed state.

Describe the benefits of the proposed process and analyze its potential risks.

*Project information will be posted on [www.mdpmnp.org](http://www.mdpmnp.org)*
FDASIA

The Food and Drug Administration Safety Innovation Act (FDASIA) Workgroup is charged with providing expert input on issues and concepts identified by the Food and Drug Administration (FDA), Office of the National Coordinator for Health IT (ONC), and the Federal Communications Commission (FCC) to inform the development of a report on an appropriate, risk-based regulatory framework pertaining to health information technology including mobile medical applications that promotes innovation, protects patient safety, and avoids regulatory duplication.

The FDASIA Workgroup is expected to build on prior work such as the Institute of Medicine (IOM) report, *Health IT and Patient Safety: Building Safer Systems for Better Care and ONC's Health IT Patient Safety Action and Surveillance Plan*; FDA’s mobile medical applications guidance and *Medical Device Data Systems Rule*; FCC’s *National Broadband plan* and other relevant work. Specifically the three agencies will seek input on issues relevant to the report, which include:

http://www.healthit.gov/policy-researchers-implementers/federal-advisory-committees-facas/fdasia
Recommendation #5
Must align national patient safety interests with the use of clinical technology: consider “HITSA”

• Need - a national approach for evolving the safety and capabilities of healthcare system technologies
• Centralized reporting, analysis, recommendations, shared solutions. Regulatory enforcement + Market incentives
• Health IT Safety Administration or Board (HITSA) modeled on other national reporting initiatives (NHTSA, ASRS, MedSun, NTSB, ASTERD, PSO, etc.):
  – Adverse event reporting (expanded definition)
  – Include FDA Regulated and non-regulated (IT) devices
  – Multi-stakeholder
    • Regulators, clinical representatives, manufacturers, etc.

http://www.mdpnp.org/HITSA.html
Essential elements for success:

- **Data** is required on equipment use/*misuse/training effectiveness (ongoing basis)
- **Technology** should assist in its safe and effective use of devices; reduce training needs; support use information
- **Research** must be performed using above
- **Policy** is needed to align healthcare incentives
- **Training** should be effective and efficient
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