• 7,000 members
• Passionate Community: Engineers, Physicians, Nurses, Researchers, HTM Professionals, Other Technology Experts, Regulators
• FDA is “sustaining” member
What Makes AAMI Unique

• **Mission:** Support HC in development, management and use of healthcare technology.
• **AAMI’s best role:** Convening diverse groups
• **Best known for:** Honest broker
AAMI Programs

- Standards Development
- Education & Training
- Patient Safety Initiatives (AAMI Foundation)
- Certification
- Publications
- Benchmarking Tools
- NO Advocacy
Examples: AAMI Standards

- Sterilization suite of standards (e.g., “Ebola” Level 4 Gowns)
- Human Factors
- Water Quality/Dialysis
- Alarms
- Risk Management
- Quality Systems
Examples: 2014 AAMI Standards Success Stories

- Cardiac implantable wireless device sensitivity to electronic surveillance gates used by retail stores
- Small bore connectors (the “Luer” connector)
- Decontamination of Ebola waste
- Cybersecurity
Why We Are Here

- **To Propose:** A consensus-based process for a risk management standard(s) for Health IT
- **To Show:** Why it’s needed
- **To Illustrate:** What will be different in the future state
- **To Discuss:** How to make it happen
HIT Safety: Current State

- No UI standardization
- Little actual UCD
- Not enough human factors engineering (HFE)
- No formal risk management
- No systems approach
- Proprietary features
- No HDO standardization
- No clear governance
- **Successes occur one hospital at a time**

(Courtesy of Luis Melendez, Partners Healthcare, FDA Interoperability Workshop, 2010.01.25, www.MDPnP.org)
Many complex engineered systems are generally reliable (e.g., bridges, power plants).

It took many years to understand and iteratively mitigate the myriad hazards of these systems.

Digital technology is relatively new.

The deployment of complex software in safety critical environments poses significant risk of harm to humans.
Software is Fallible

• *Across most industries*, humans are not yet able to design and deploy complex software systems that are on time, within budget, meet specified requirements, satisfy their users, are reliable, maintainable, and safe!

• HIT failures are particularly problematic because they can:
  – Be unpredictable
  – Have interactive or multiplicative effects
  – Be difficult to identify and diagnose
  – Be challenging to mitigate
  – **HARM PEOPLE!**
Software Reliability & Safety

• A 2007 National Academy of Science (NAS) report concluded:
  – Software systems should be considered “guilty until proven innocent”
  – It should not be the responsibility of the customer to prove that the software is unsafe
  – “The burden of proof should fall on the vendor to demonstrate to an independent certifier or regulator that a system is safe”
HIT-Specific Issues

• HIT has often been developed from erroneous or incomplete design specifications
  – see our 2011 JAMIA paper, *Health Information Technology: Fallacies and Sober Truths.*
• HIT often relies on hardware and operating systems not intended for safety critical systems
• Each implementation is a “custom job” (little standardization)
• Highly context dependent – if different context or organization, system can be unsafe or fail (emergent properties)
Product Safety in High Hazard Industries

- Safety is the top priority
- Safety is considered throughout the product life cycle from initial concept to end-of-product-life management
- Product development is governed by industry wide standards of practice
- Both processes and outcomes of these industries have some type of oversight

Figure courtesy of Bruce Hallbert, INL
**UCD – Important but Insufficient**

- User-centered design (UCD) is a critical contributor to safe and usable software.
- UCD is a way of design thinking and a structured way of working.
- UCD is but one part of a HFE process.
- **Risk management** is another part of the overall HFE process needed to attain safety & reliability.
- It has taken almost 20 years for the medical device industry to reach its current state of HFE implementation.

Figure courtesy of Matthew B Weinger, CRISS, Vanderbilt University
Risk Management (RM) Process

The process should be:

- Useful to the organization
- Integral to organizational processes
- Integral to important decisions
- Address assumptions & uncertainty
- **Structured and systematic**
- Tailorable and scalable
- Transparent & Auditable
- Iterative & responsive to change
- Continually reassessed & improved

*After ISO 31000-2009*
Managing HIT Risk

• No other hazardous industry deploys safety critical software without a formal risk management process!
• HIT risk is not just related to direct user interactions but includes data integrity, cybersecurity, etc.
• *It is time to include risk management in ONC’s required processes to assure HIT safety & reliability*
• AAMI recommends an evidence-based approach to developing and implementing a standardized risk management process for HIT safety
We Can Learn From Other Industries

Examples:

- ISO 31000 – risk management
- IEC 80001 – RM in IT networks
- IEC 14971 – medical device RM
- ISO 62304 – software RM
- IEC 27005 – IT security RM

Figure courtesy of Steve Grimes
HIT Safety – What’s Missing?

• PSOs, ECRI and The Joint Commission → Learning from Adverse Incidents
• The FDA → high risk software
• The ONC → best practices/safer guides
• **What no one is doing yet:** Establishing a standardized comprehensive risk management (RM) process for HIT safety and reliability
What RM Standards Are Needed

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What RM Standards are Needed

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Why Standardize the RM Process for HIT Safety

- One vendor at a time doesn’t work
- One hospital at a time doesn’t work
- Too many moving targets
- Best path: A systems approach to complex socio-technical challenges
- Proven from other industries
What If the RM Process for HIT Is Not Standardized

- HIT progress will be like “dream airplanes”
- HC will not be safer
- Big adverse incidents
- Net cost higher
- Finger pointing
- Won’t learn from each other or from mistakes
How to Get From Here to There

- Consensus-based standards development by ANSI-accredited SDO (AAMI)
- Start in the US
- EHR Vendor and Provider Co-chairs
- Committee membership balance
- Longer-term: integrate with international efforts
- **Key Question: What will get vendors to the table?**
Steps to Get Started

• AAMI submits paperwork to ANSI to get started
• Committee is formed (key: getting the right multi-disciplinary people who want to participate)
• Industry must pay AAMI participation or membership fees/no fee for providers
• Committee develops work plan
Desired Future State of HIT

• Vendors and providers working together
• Efficient Processes
• $$ freed up for innovation
Desired Future State of HIT

- Governance clarity
- A systems approach to complex socio-technical challenges
- Full life cycle view
- Healthcare will be safer
Analogy: Evolution of ATM Technology

1969: First cash machine
1970s: Refinement of the technology
1980s: ATM networks localized
1990s: U.S. ATM card works in Europe but only easy to find in big cities
2000s: Cash anywhere/everywhere
Today: ATM is a highly secure mini-bank
Why AAMI?

- Leader in healthcare tech-oriented consensus-based problem solving in areas of complexity
- Federal government preference for private consensus-based standards to fulfill government aims*
- Long track record of working with all stakeholders to develop consensus standards (ANSI-accredited; global through ISO and IEC)

Why AAMI?

• “AAMI is Switzerland” for working on complex problems; not an advocacy organization; no agenda or positions

• Expertise in promulgating American standards first that grow into international standards

• Expertise in the right areas: risk management; human factors; quality systems; deep knowledge of patient safety;

• This is our core competency

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"The future is already here, it just hasn’t been evenly distributed yet"

– William Gibson