INCOSE Healthcare Working Group

4th Annual Systems Engineering in Healthcare Conference

Balancing Safety, Security and Usability in the Design of Secure Medical Devices

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Agenda

- Safety
- Safety & Usability
- Safety & Security
- Safety, Usability & Security
- System of Systems & Emergent Properties

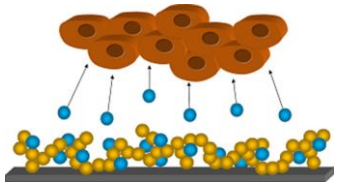
Medical Device Safety

Comets???

Usability

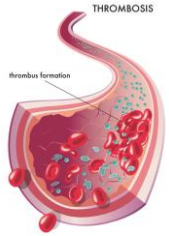
System Security

Electrical Shock

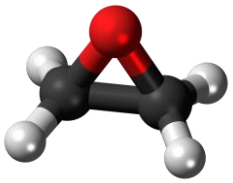


Biocompatibility

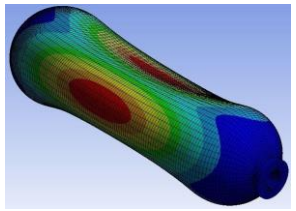
EMI



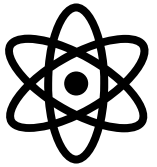
Thrombosis



Sterilization



Mechanical Failure



Radiation

14971 and 60601

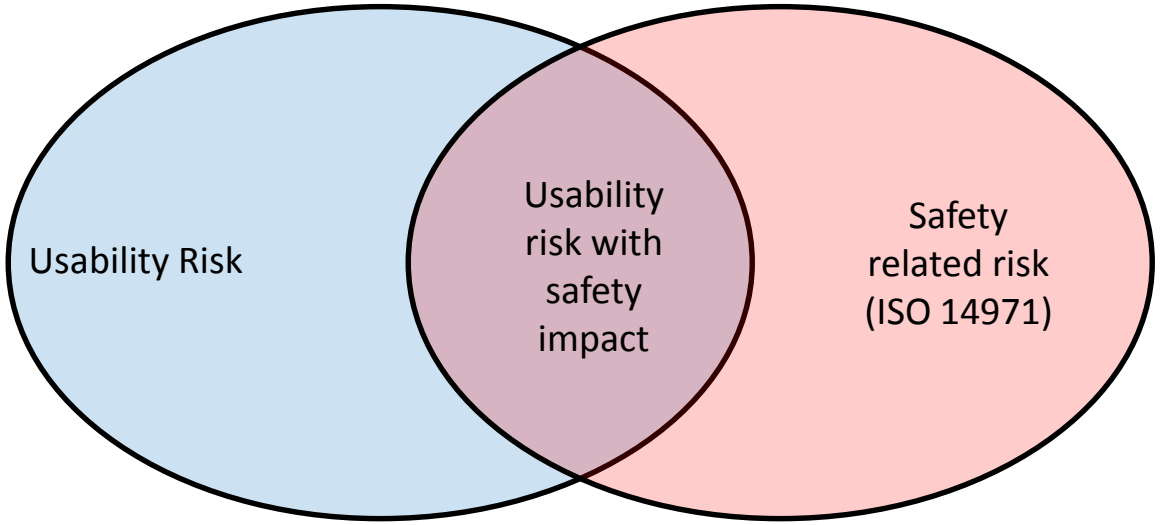
- 14971 defines the process for (safety) risk management
  - Defines harm, hazard and hazardous situation
  - Defines a process to evaluate risk, with or without protective measures
  - Documents means to assess acceptable residual risk
  - Establishes monitoring process requirements
  - Auditable but not testable
- 60601 defines “basic safety and essential performance”
  - Broadly and for individual device classes
  - Explicitly addresses usability
  - Addresses device response to failure
  - Generally testable

Usability recognized as a source of patient harm

- Order entry system confusion
- Surgery in the wrong location
- Ventilators left off accidentally (post X-ray)
- Tubing confusion in hospitals
- Alarm confusion/fatigue
- Similar device/different user interface designs

Usability and Safety Risks

- Usability risks that impact safety
  - User confusion leads to wrong pump setting
- Usability risks that don't impact safety
  - Wordiness, spelling errors
- Safety risks unassociated with usability
  - Power supply failure



Usability Analysis/62366

- Usability Engineering Process
  1. Specify application of device – Intended use & user
  2. Identify frequently used functions
  3. Identify hazards and hazardous situation related to usability – ISO 14971 – foreseeable misuse
  4. Identify device primary op. functions
  5. Develop usability specification
  6. Prepare usability validation plan
  7. Design & implement user interface
  8. Usability verification
  9. Validate usability of medical device

- Lifecycle stages
  - Concept development
  - User needs/requirements
  - Risk management
  - Verification and Validation
  - Post-market monitoring

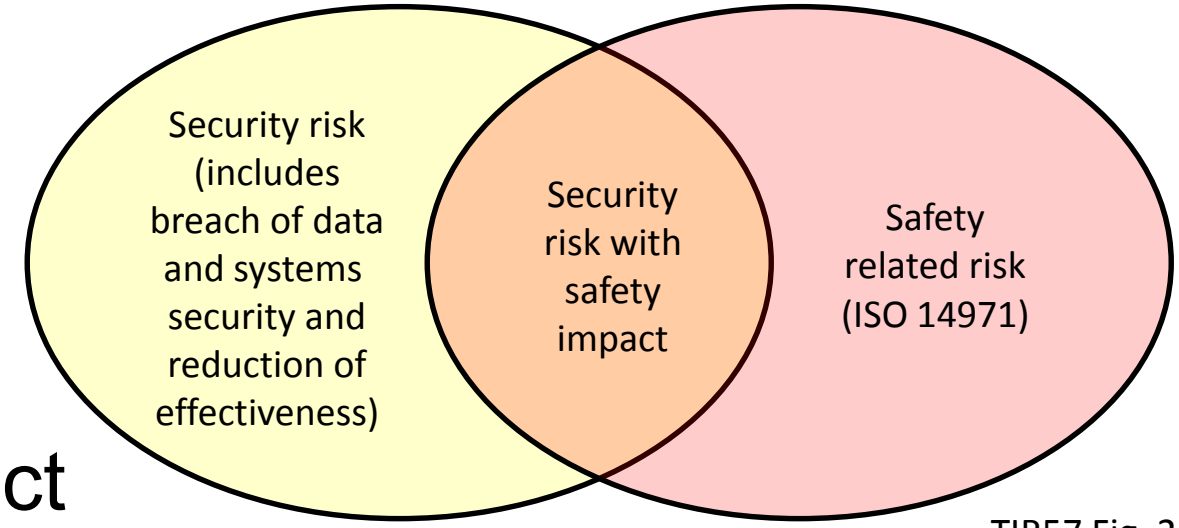
- No explicit references to “Usable security”

Security recognized as a source of patient harm

- Implantable Defibrillator hacking demonstrations (2008+)
- Wearable insulin pump hacking demonstrations (2010+)
- Cardiac company short sell (2016)
- WannaCry impacts on devices and hospital operations (2017)
- Ransomware hits hospitals (2017+)

Security and Safety Risks

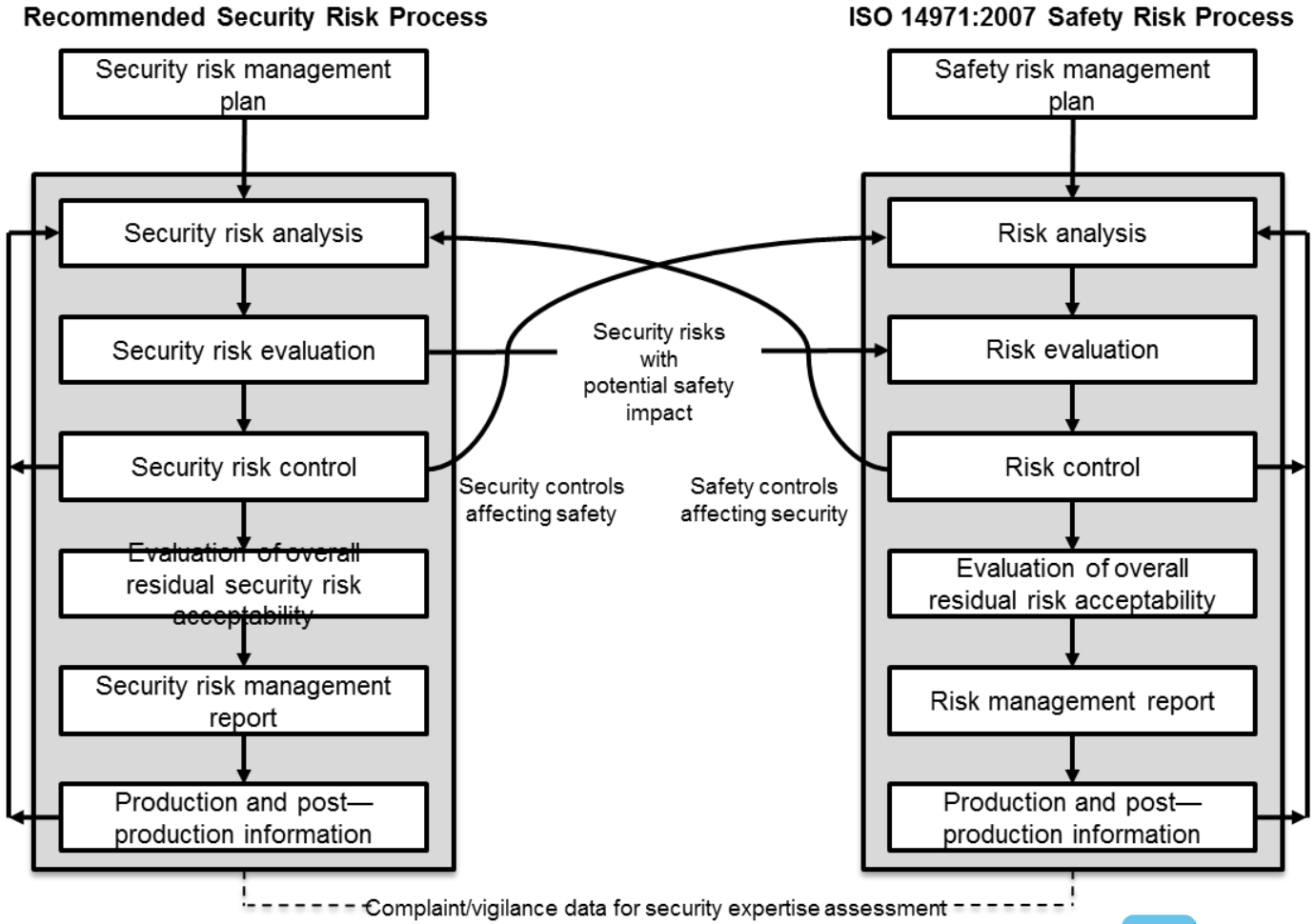
- Security risks that impact safety
  - Hacked pump changes drug flow rate
- Security risks that don't impact safety
  - PHI exposed
- Safety risks unassociated with security
  - Power supply failure



TIR57 Fig. 2

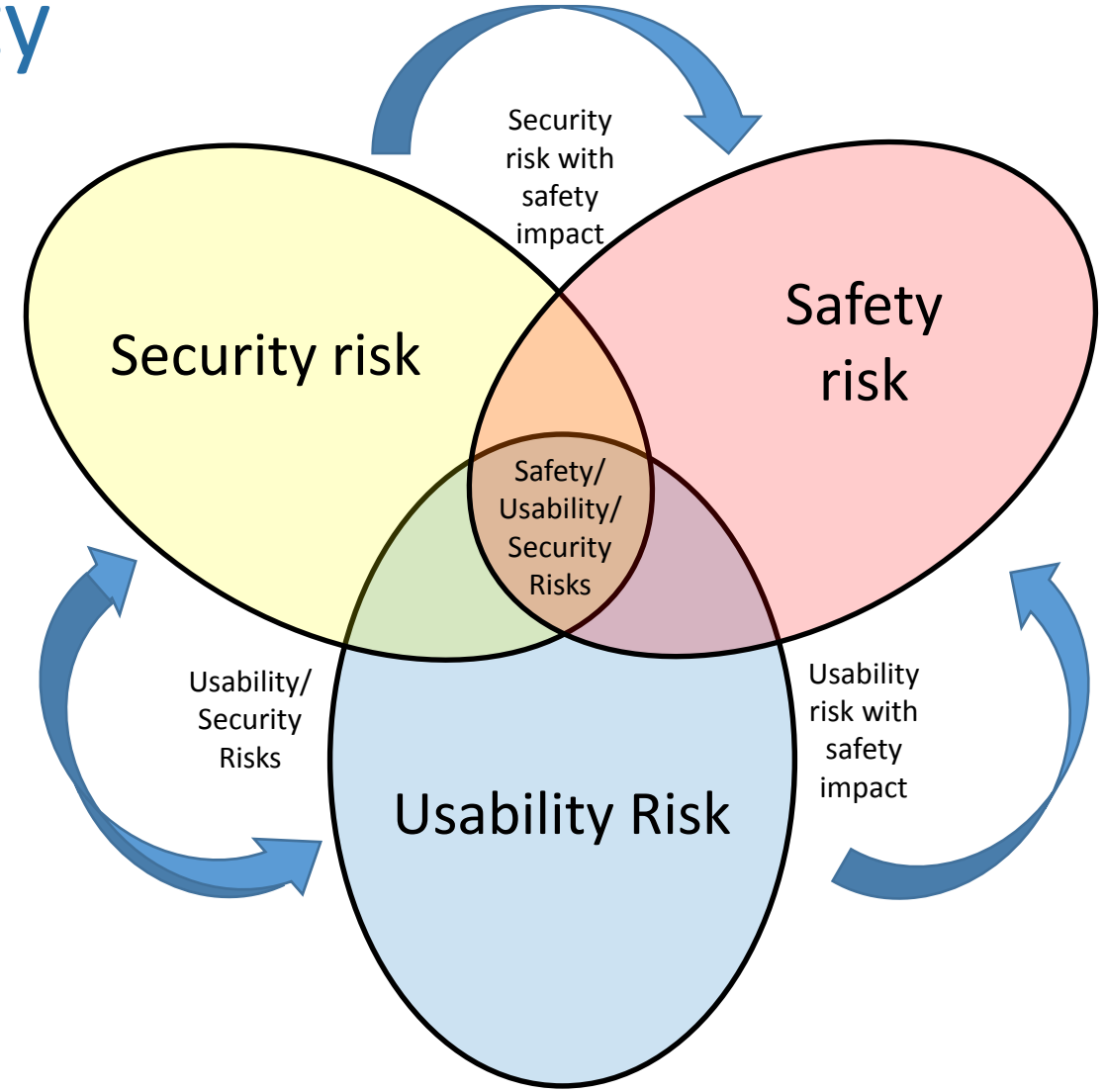
AAMI TIR57

- Addresses security risk management in the context of 14971.
- Creates clear linkages between the consideration of safety and security.
- Recognized by the FDA and referenced in their recent post-market guidance.



Safety, Usability and Security

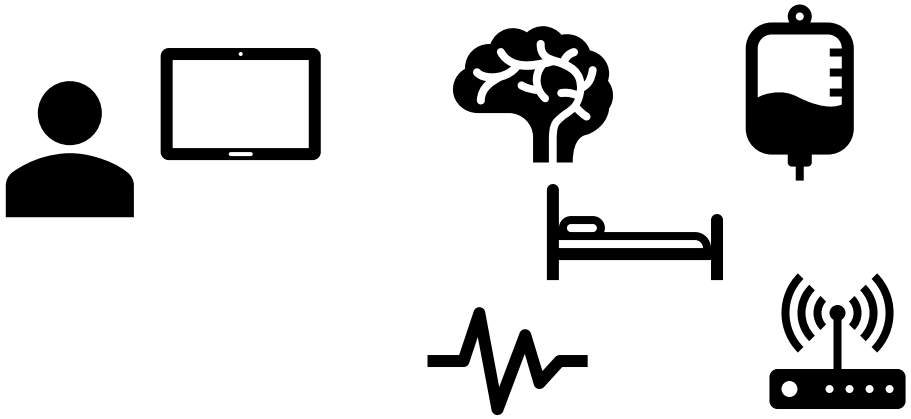
- All three can interact
  - Positively – good usable security can enhance safety
  - Negatively – elimination of a security control for fast access



Development Implications

- Early usability and security analysis must be done interactively
  - Early prototype assessment needs to have planned security controls in place
- Complete set of stakeholders/users need assessment
  - End user
  - Network/Device administrator (e.g. BMET department)
- Post-market monitoring and response to cyber-vulnerabilities needs to include usability analysis
  - Added controls to close a security hole might introduce user issues

System of Systems & Emergent Properties



- Safety, Usability and Security are all emergent systems properties
  - Can construct a system with property X from components without it
  - And vice-versa
- Regulatory processes encourage consideration of these properties only at a single device level.
- When integrated into a network, is the property preserved??

Healthcare System Implications

- Who serves the role of “systems integrator” in the creation of a network of heterogeneous medical devices?
- What new standards are needed will reduce the integration effort?
- What tools and methods can support ad hoc integrators?
  - E.g. Small to mid-sized hospitals with less experienced staff?

Conclusions

- Achieving system safety depends on a balance of supporting properties
  - Usability and Security need to be considered together

- Work is needed to better understand how to ensure safety, security and usability in networks of integrated heterogeneous devices

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