The Application of Systems Engineering in Medicine

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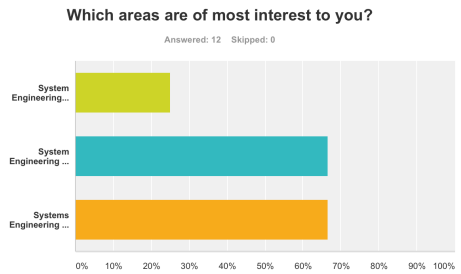
The HWG integrates SE perspectives across the Healthcare Domain



INCOSE International Council on Systems Engineering

VSE

INCOSE International Council on Systems Engineering

Risk

INCOSE International Council on Systems Engineering

MBSE

INCOSE International Council on Systems Engineering

HWG

INCOSE International Council on Systems Engineering

LEAN

ACCE AMERICAN COLLEGE OF CLINICAL ENGINEERING

AAMI Advancing Safety in Healthcare Technology

DEPARTMENT OF VETERANS AFFAIRS UNITED STATES OF AMERICA

These are just a few examples, there are many more!

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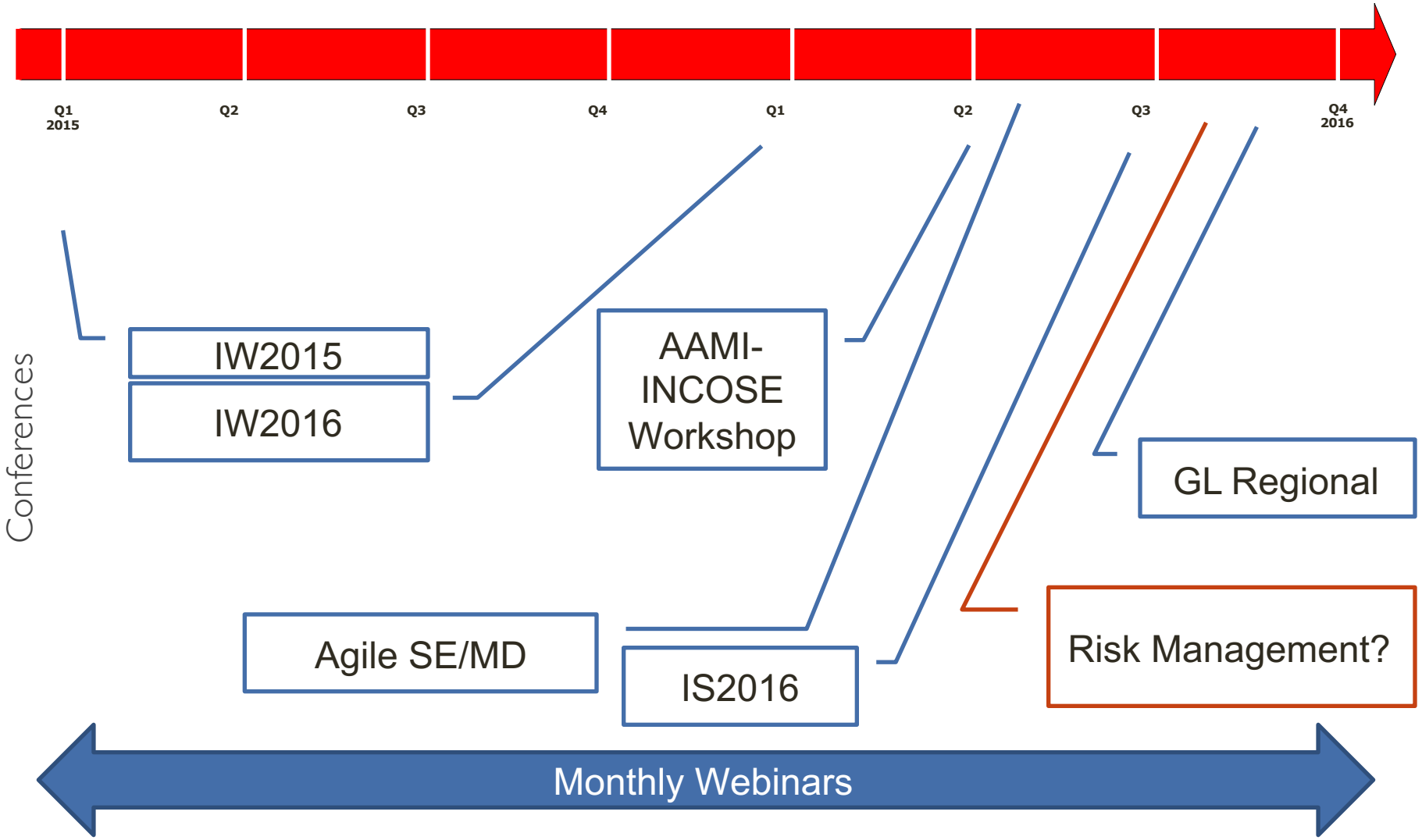
Activity Timeline



These are just a few examples, there are many more!

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Why System Engineering?

- Reduction to **cost, risk, and timelines**
- Improved **integration** across internal functions and external vendors
- Increased **reliability**
- Increased **efficiency**

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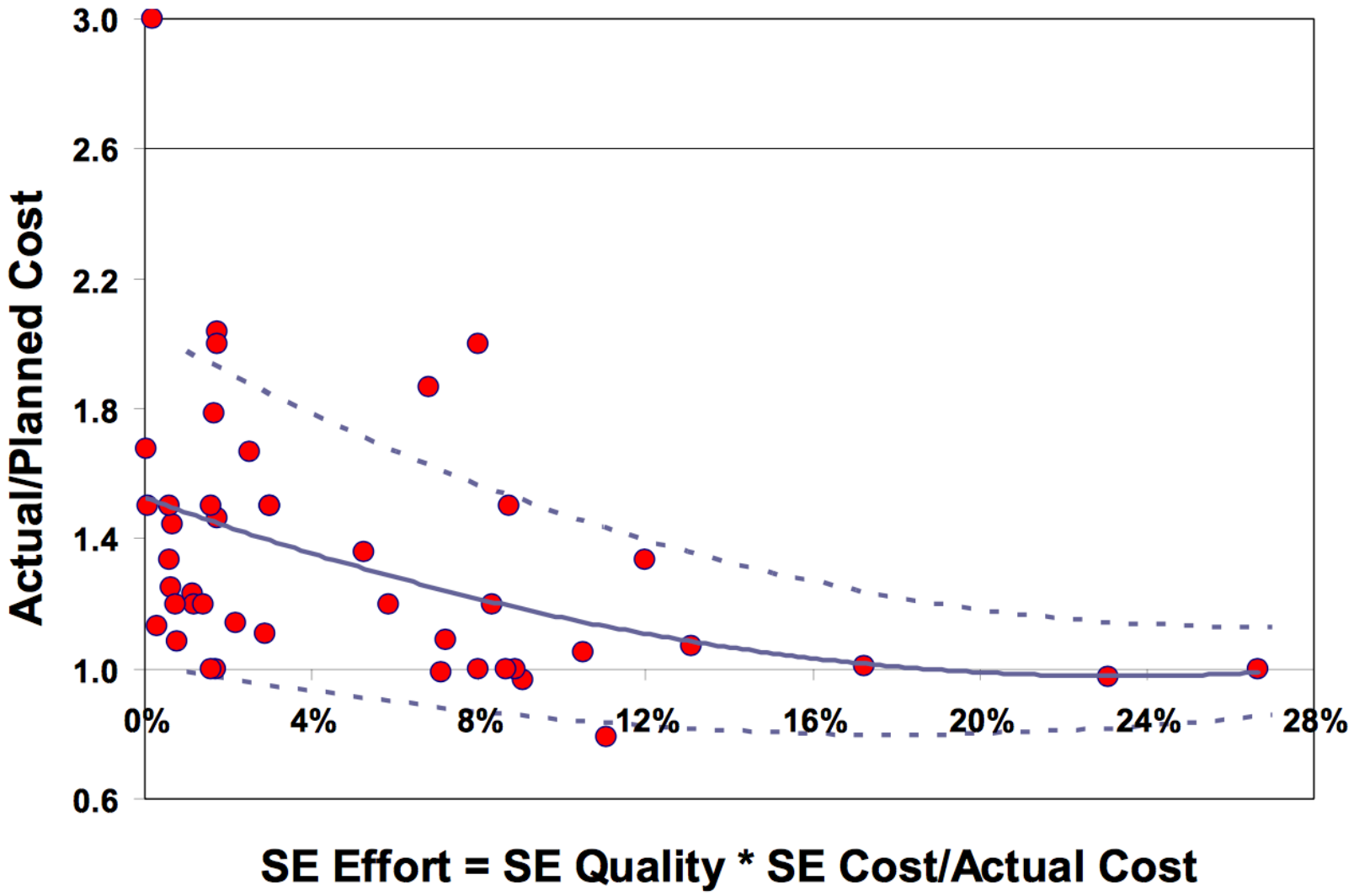
SE pays significant ROI on Cost.



Source: Honor, 2009

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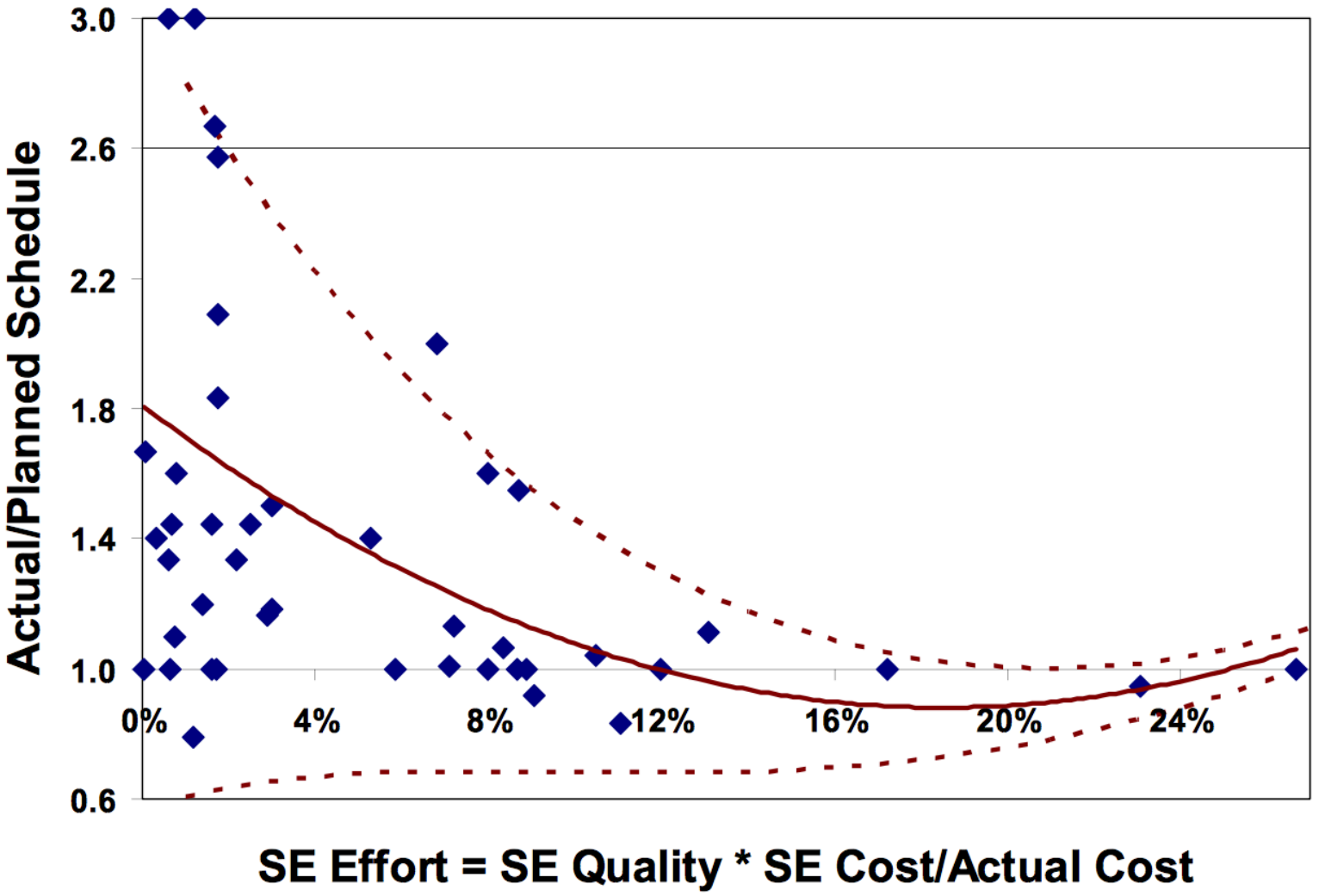
SE pays significant ROI on Schedule.



Source: Honor, 2009

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Past Successes at SCI using SE Approaches

- A recent client process update demonstrated a cost-savings of greater than $150M USD.
- Mean of $2.3M savings in the first month of engagement with new clients
- Improving program execution to save over 50% on development costs
- Providing solutions that save over 60% on execution schedules
- Resolving warning letters and improving execution to avoid them in the future
- Integrating the largest on-body connectivity hardware/software solution in med-tech.
- Delivering programs ahead of schedule when they were originally 30% behind

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Our Agenda

- SE in this Domain versus others
- Medical Devices, Medical Technology - Medtech
- Biotech - Biotechnology
- Hospitals – the next frontier

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SYSTEM ENGINEERING: SUCCESS IN BIOTECH!

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SE in MedTech versus others domains

- Not as mature… (opportunity for you!)
- Needs to be scaled to the efforts (Class I versus Class III)
- The Medtech industry is more fragmented
- More and more startups… multiple varied technologies…
- Required per regulations (Did you do your SE homework?)
- Does not follow the standard defense acquisition models

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Translating for a new domain:

- Say NO to “Missions”… say “Outcomes” instead
- Understand that defining your inputs will be different!
- An SE Role is still poorly understood, talk about
  - Team Leads
  - People who understand the big picture
  - People who can integrate
- Recognize that an SE role might be split differently across multiple “functions”

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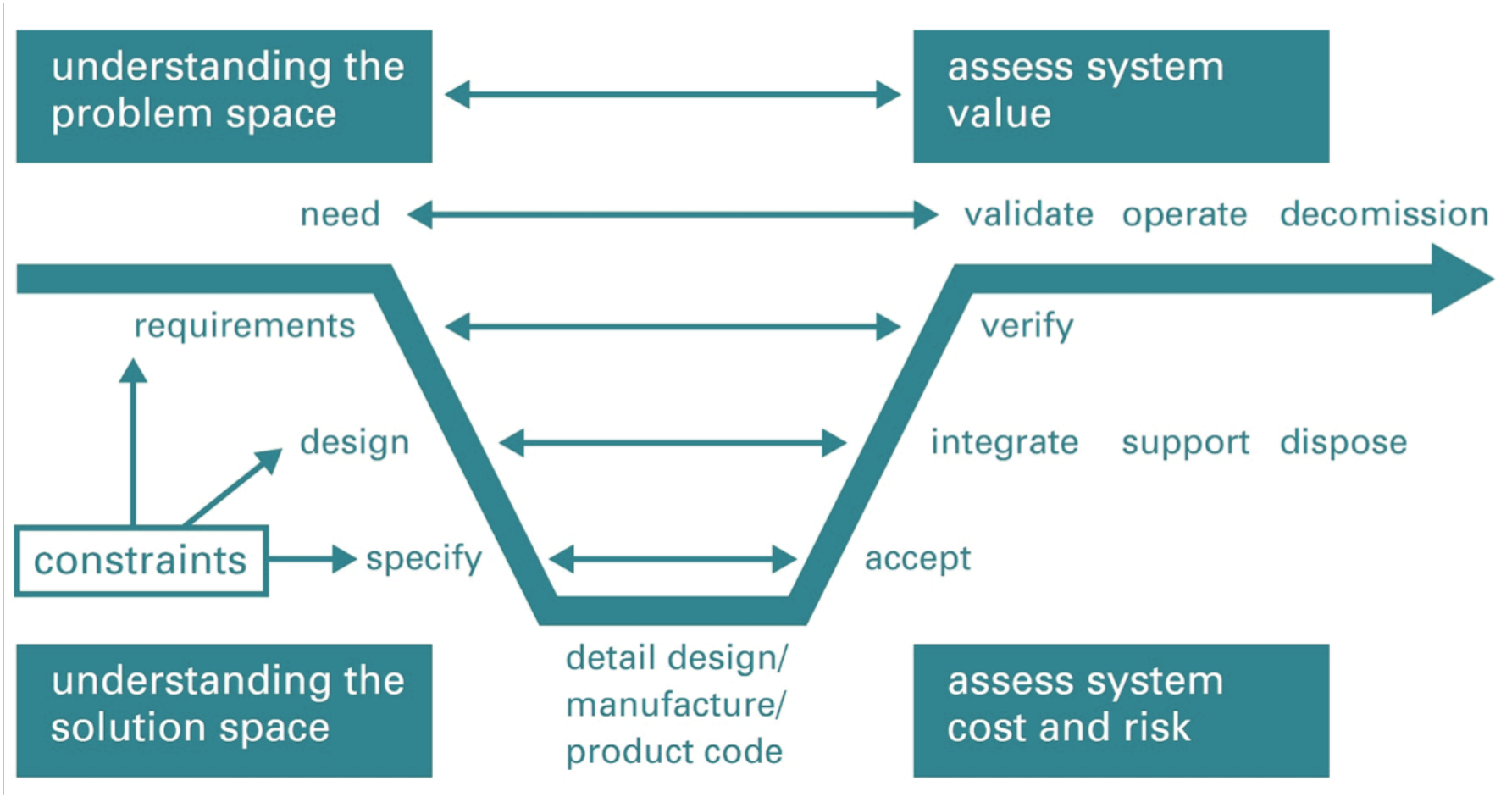
SE integrates functions and sites with consistent, integrated processes.



Beasly, 2012

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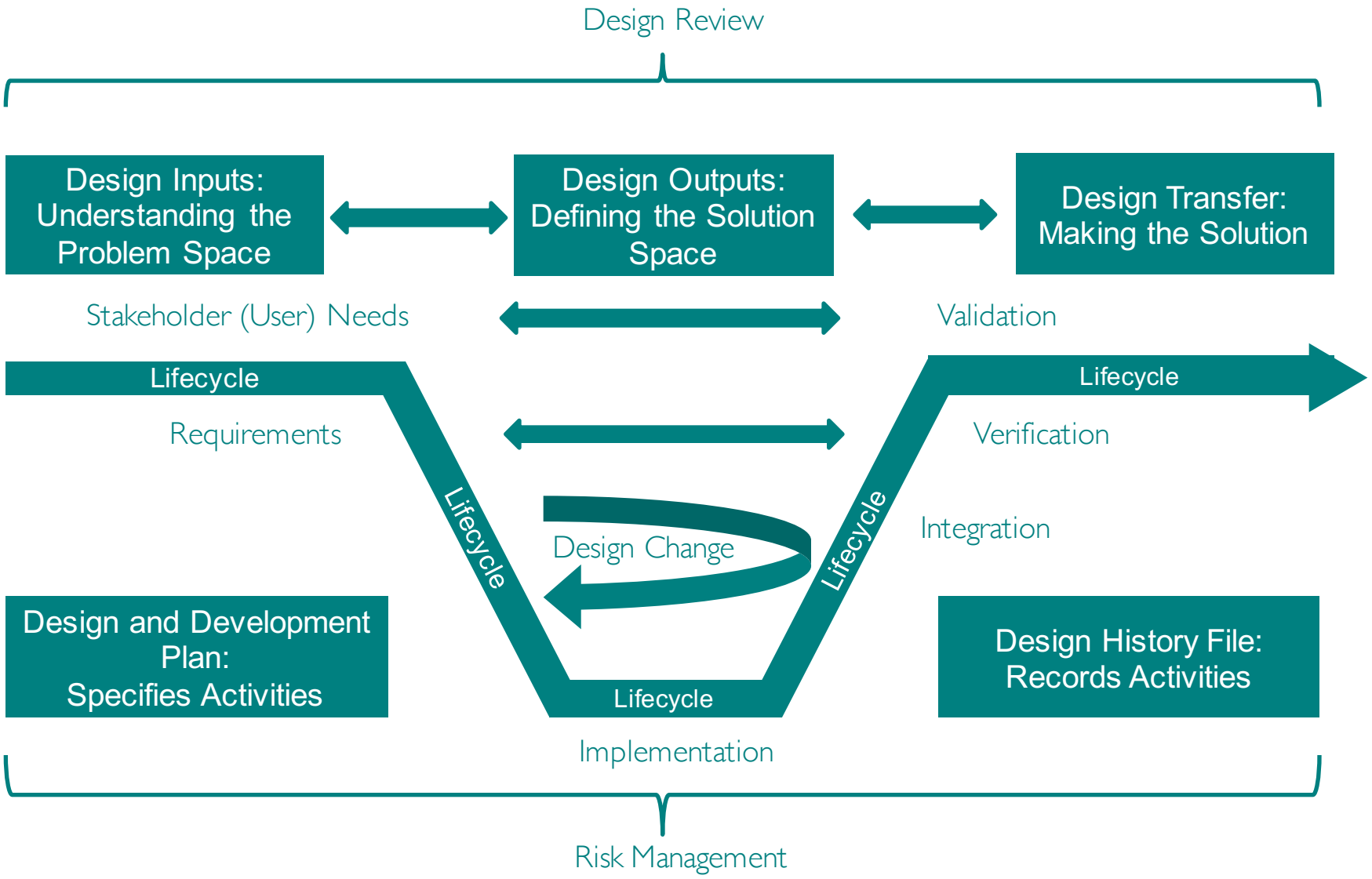
Systems Engineering integrates functions, teams, and design controls into the product development process.



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Examples of Medical Devices

- Imaging systems (CAT, PET, MRI, Xray)
- Combination products
- Diabetes systems
- Holter monitors
- Pacemakers
- Glucose sensors
- Connected care systems
- Autoinjectors
- Electro-mechanical injection systems
- Defibrillators
- Infusion pumps
- Blood glucose meters
- Implantable neurostimulators
- Transcutaneous stimulators
- Ophthalmology equipment
- And …
- Tounge depressors, contact lenses

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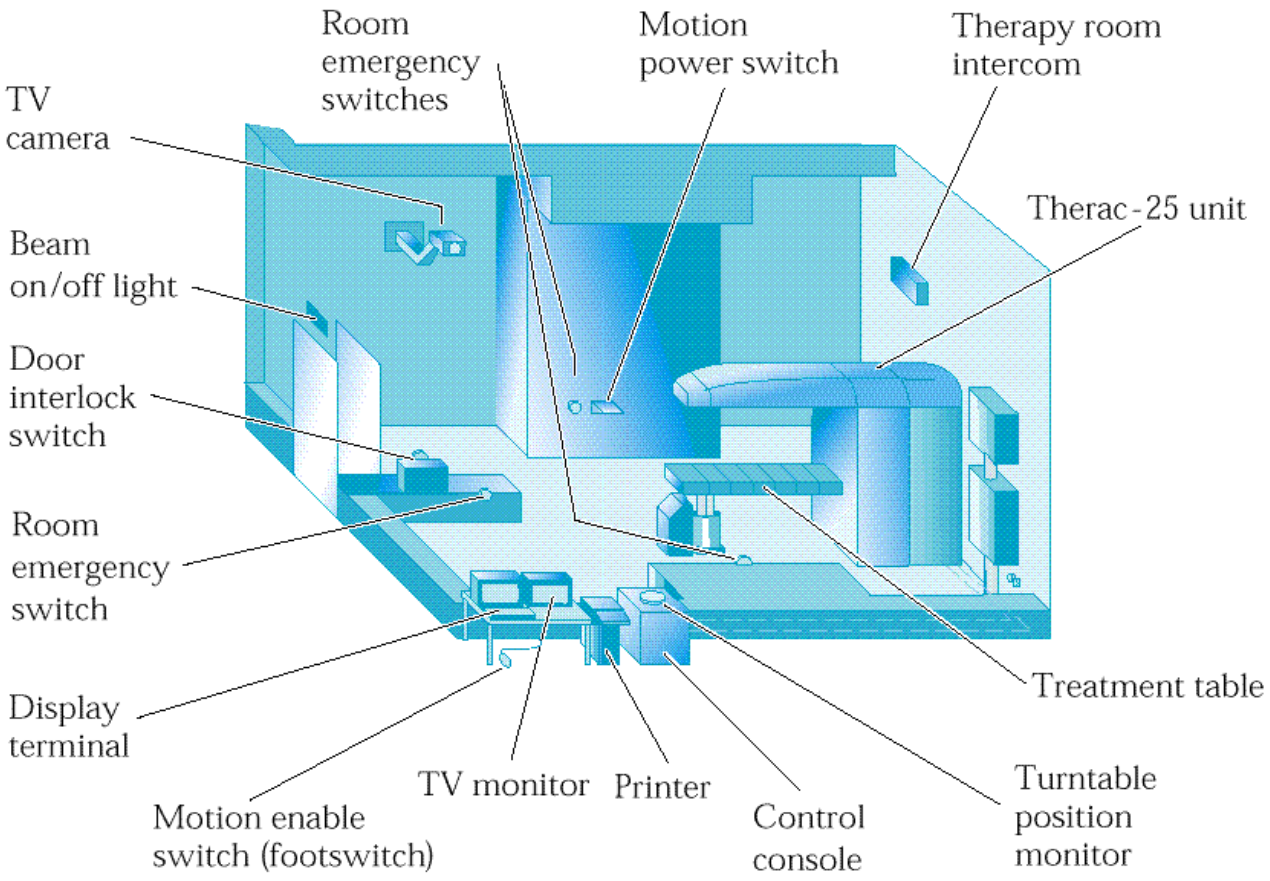
Therac-25 Malfunction 54



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Therac-25 Malfunction 54

```
PATIENT NAME    : JOHN DOE
TREATMENT MODE : FIX      BEAM TYPE: X      ENERGY (MeV): 25

                           ACTUAL      PRESCRIBED
    UNIT RATE/MINUTE           0             200
    MONITOR UNITS          50  50             200
    TIME (MIN)              0.27            1.00

GANTRY ROTATION (DEG)        0.0              0      VERIFIED
COLLIMATOR ROTATION (DEG)  359.2             359      VERIFIED
COLLIMATOR X (CM)           14.2            14.3      VERIFIED
COLLIMATOR Y (CM)           27.2            27.3      VERIFIED
WEDGE NUMBER                   1               1      VERIFIED
ACCESSORY NUMBER               0               0      VERIFIED

DATE    : 84-OCT-26    SYSTEM : BEAM READY    OP.MODE: TREAT AUTO
TIME    : 12:55. 8     TREAT  : TREAT PAUSE             X-RAY 173777
OPR ID : T25VO2-RO3    REASON : OPERATOR      COMMAND:
```

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What criteria would you apply to select this connector?

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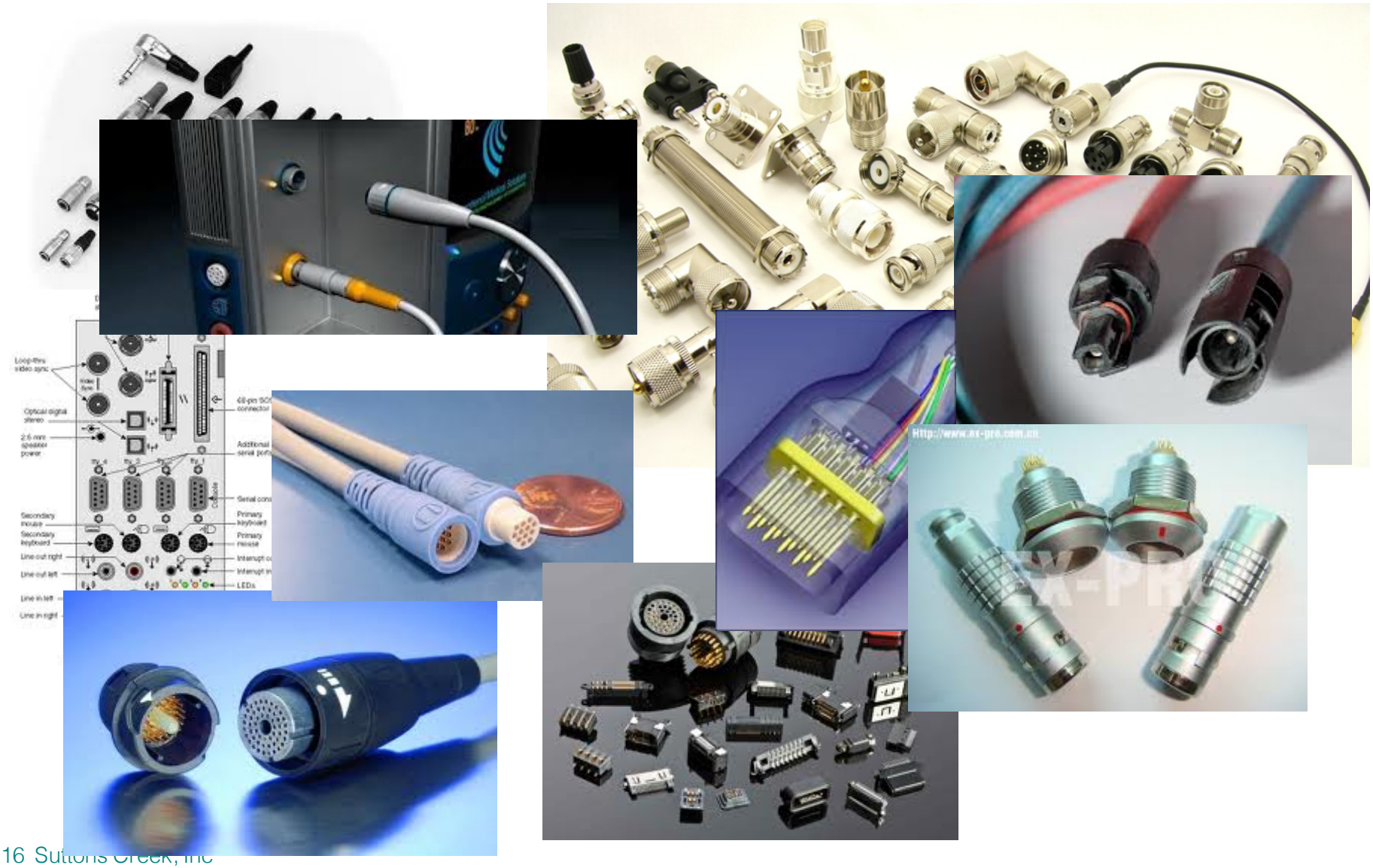
What criteria would you apply to select this connector?



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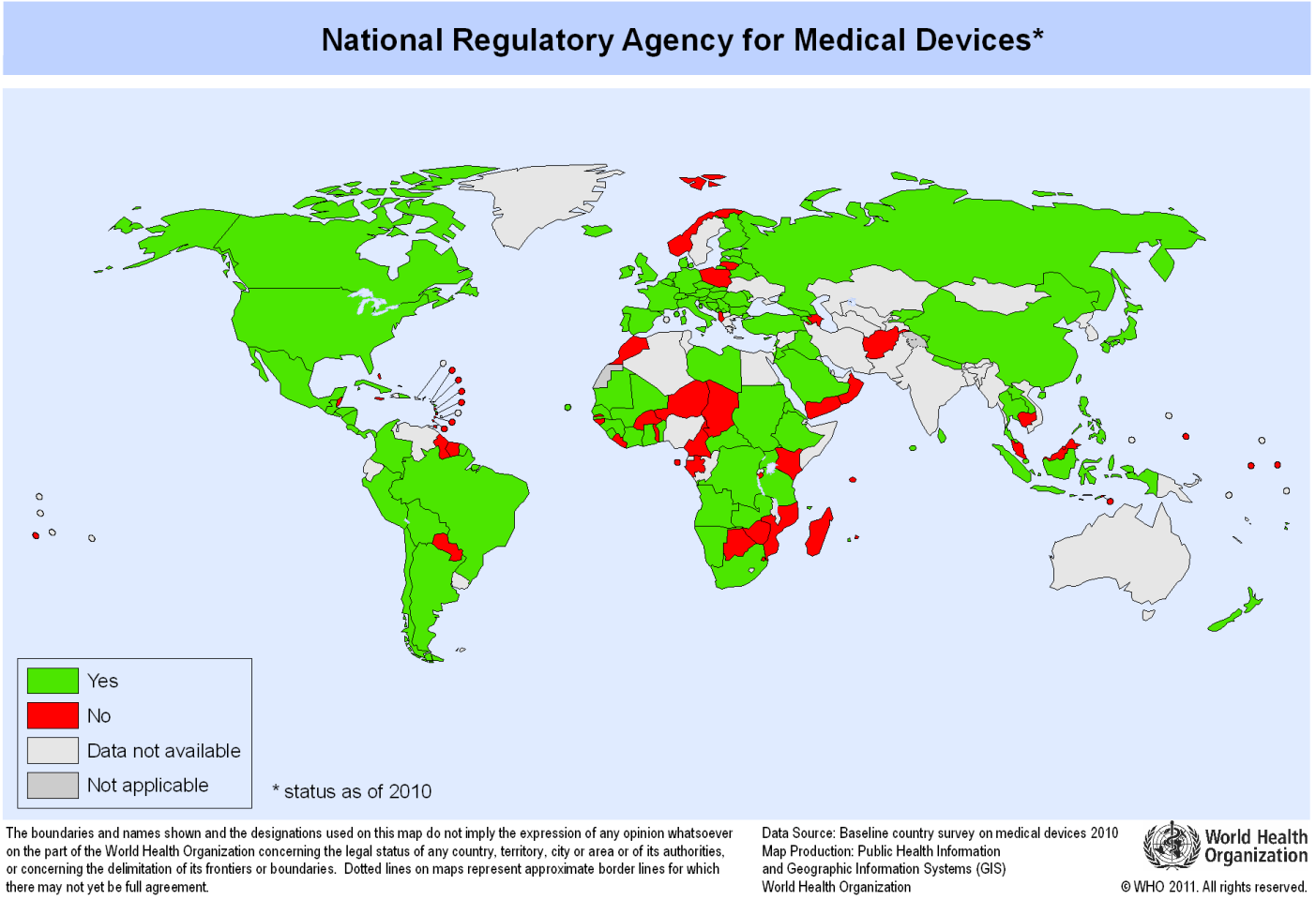
Regulated Markets



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Regulated Markets

- These are just a few examples:
  - In the US, the Food and Drug Administration (FDA), Center for Devices and Radiological Health
  - In the EU, CE marking
  - In Japan, very similar to EU, but the standards typically have a few additional requirements
  - In China, typically need to submit similar documentation as is required in the country of origin
- Keywords: Safety and Efficacy

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Device Classification in the US

Depending on the classification, marketing a device requires pre-market notification, device listing, good manufacturing practices (GMP), record keeping, controls, performance standards, investigational device exemption use under approved for use with institutional review boards.

- Class I
  - Failure poses no risk to life
    - Tongue Depressors
    - Stethoscopes
- Class II
  - Non life sustaining, but must meet specific controls and performance standards
    - Sphygmomanometers
- Class III
  - Life sustaining
    - Pacemakers, heart valves

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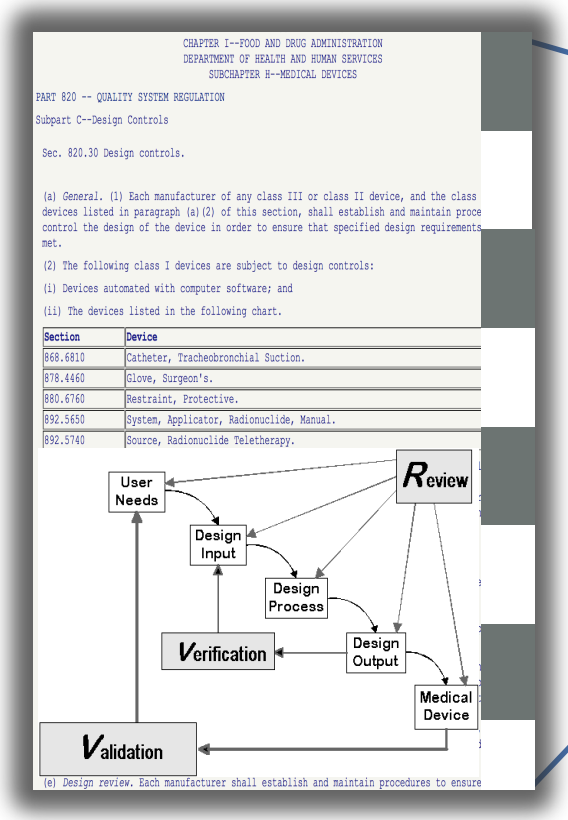
The WHAT: Medical Device Regulations



CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 820 -- QUALITY SYSTEM REGULATION

Subpart C--Design Controls

Sec. 820.30 Design controls.

(a) *General.* (1) Each manufacturer of any class III or class II device, and the class devices listed in paragraph (a)(2) of this section, shall establish and maintain proce control the design of the device in order to ensure that specified design requirements met.

(2) The following class I devices are subject to design controls:

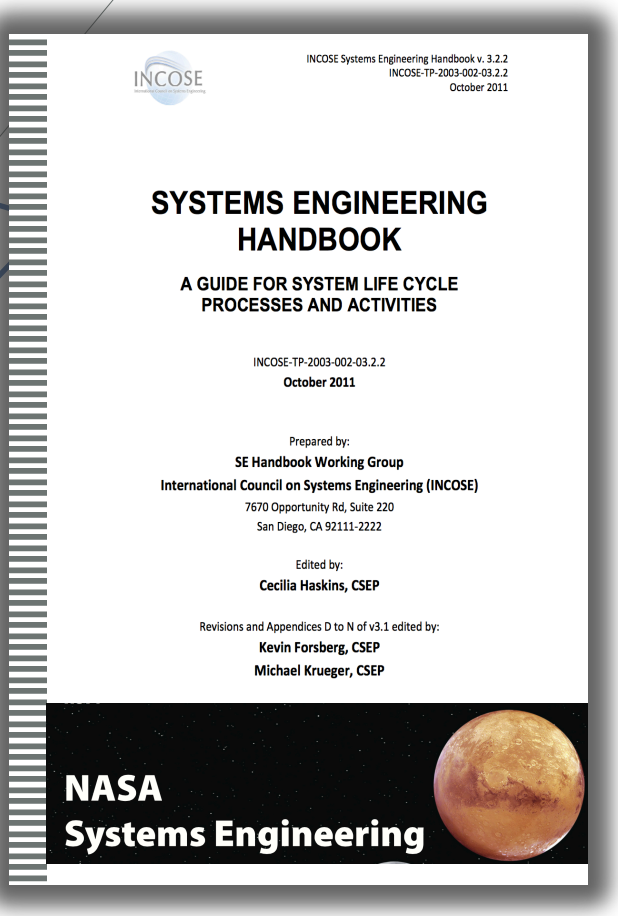
(i) Devices automated with computer software; and

(ii) The devices listed in the following chart.

Section	Device
868.6810	Catheter, Tracheobronchial Suction.
878.4460	Glove, Surgeon's.
880.6760	Restraint, Protective.
892.5650	System, Applicator, Radionuclide, Manual.
892.5740	Source, Radionuclide Teletherapy.

(e) *Design review.* Each manufacturer shall establish and maintain procedures to ensure

The HOW: Systems Engineering



INCOSE

INCOSE Systems Engineering Handbook v. 3.2.2
INCOSE-TP-2003-002-03.2.2
October 2011

SYSTEMS ENGINEERING HANDBOOK

A GUIDE FOR SYSTEM LIFE CYCLE PROCESSES AND ACTIVITIES

INCOSE-TP-2003-002-03.2.2
October 2011

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Revisions and Appendices D to N of v3.1 edited by:
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NASA Systems Engineering

Following design controls does not constitute good engineering practice. Design controls are a subset of systems engineering.

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Primary Research: Suttons Creek, Inc., 2013

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A Summary of 21CFR820.30

- (b) Design and Development Planning
- (c) Design Input
- (d) Design Output
- (e) Design Review
- (f) Design Verification
- (g) Design Validation
- (h) Design Transfer
- (i) Design Changes
- (j) Design History File
- + Risk Management

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CFR 820.30 – SE Principles

Code of Federal Regulations, Title 21, Volume 8, Part 820, Subpart C, Section 820.30 "Design Controls" … aka… 21CFR820.30		
Reference	Text	Aligned Clause for INCOSE Handbook 3.2.2
820.30a	(a)General. (1) Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. (2) The following class I devices are subject to design controls: (i) Devices automated with computer software; and (ii) The devices listed in the following chart. (OMITTED)	5.5
820.30b	(b)Design and development planning. Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.	5.1, 5.2
820.30c	(c)Design input. Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.	4.1, 4.2

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CFR 820.30 – SE Principles

Code of Federal Regulations, Title 21, Volume 8, Part 820, Subpart C, Section 820.30 "Design Controls" … aka… 21CFR820.30		
Reference	Text	Aligned Clause for INCOSE Handbook 3.2.2
820.30d	(d)Design output. Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.	4.6…..
820.30e	(e)Design review. Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. The results of a design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the design history file (the DHF).	3.2.2
820.30f	(f)Design verification. Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.	4.6

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CFR 820.30 – SE Principles

Code of Federal Regulations, Title 21, Volume 8, Part 820, Subpart C, Section 820.30 "Design Controls" … aka… 21CFR820.30		
Reference	Text	Aligned Clause for INCOSE Handbook 3.2.2
820.30g	(g)Design validation. Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.	4.8
820.30h	(h)Design transfer. Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.	3.3.4
820.30i	(i)Design changes. Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.	5.5
820.30j	(j)Design history file. Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.	3.3.2

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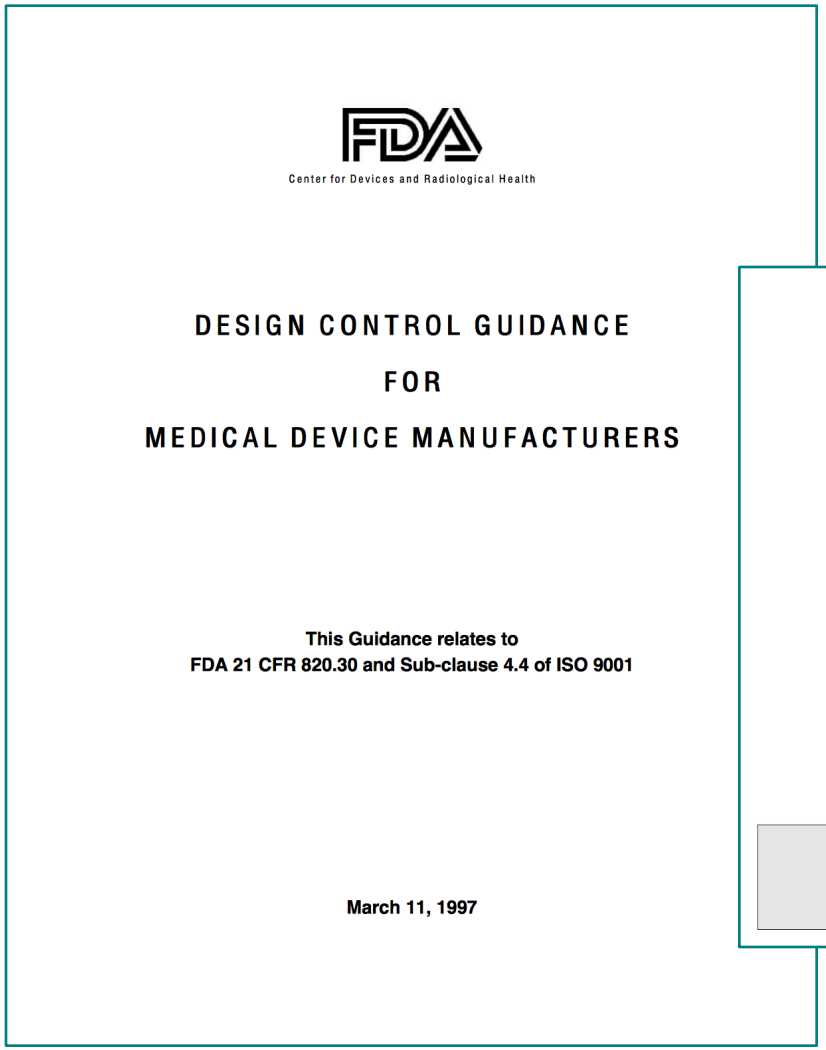
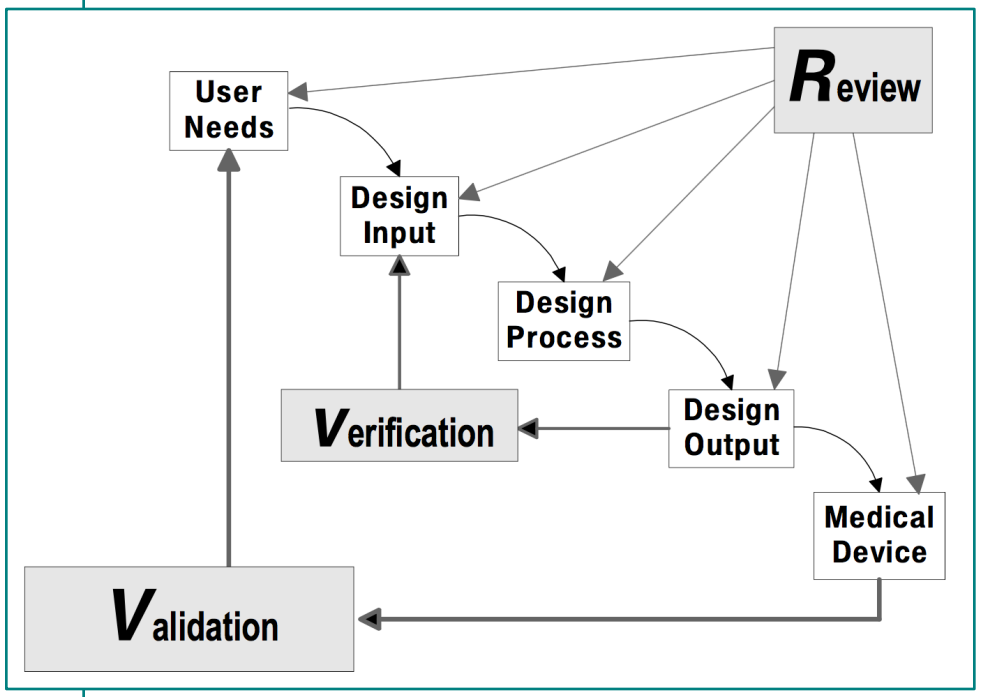
Additional references: Where is all of this?





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Design Inputs

- Medical device technologies do not follow the standard defense acquisition models…
- Definition of the product and “intended use” are provided and validated by each medical device company…
- So how do you know if you have the correct starting point?

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Notes on Validation - Efficacy

- Two primary sources:
  - Human Factors
    - Formative
    - Summative
  - Clinical Studies
    - IDE – Investigational Device Exemption

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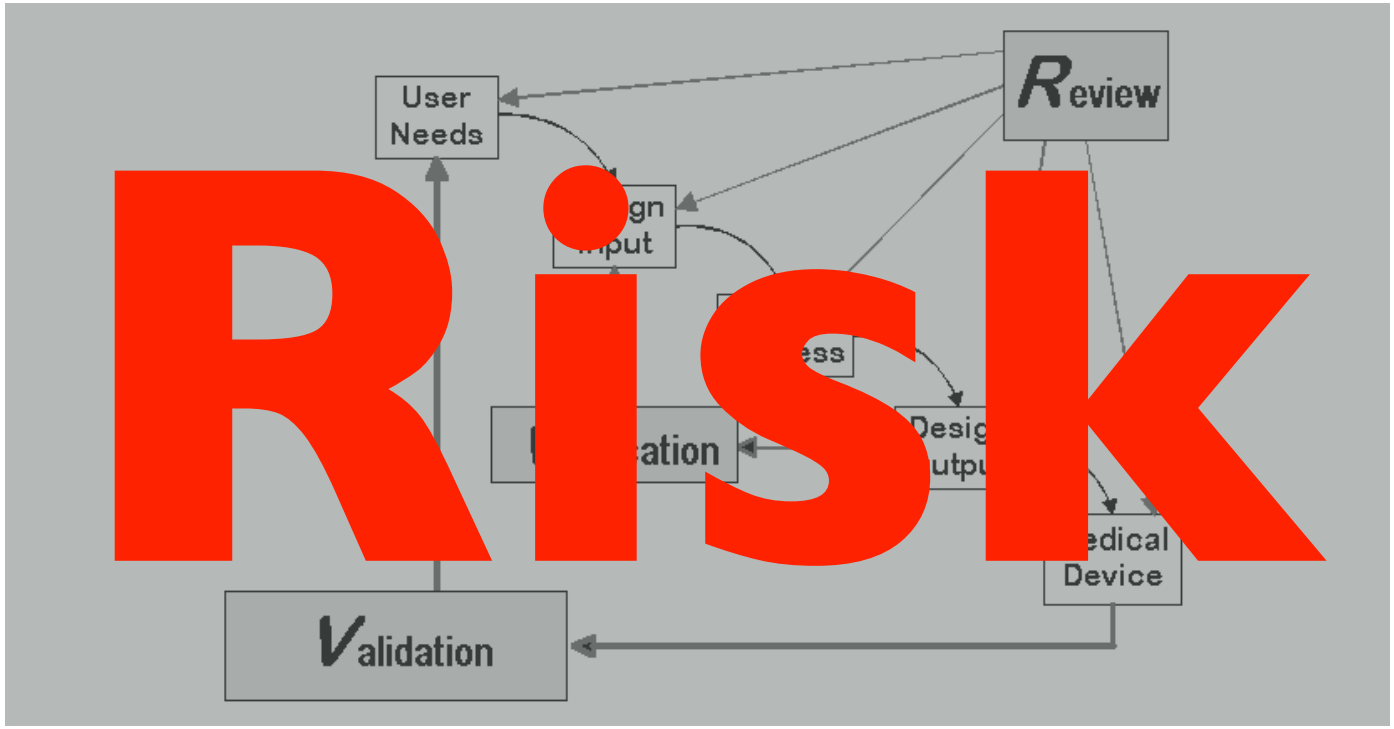

RISK MANAGEMENT – SAFETY, NOT TECHNICAL RISK

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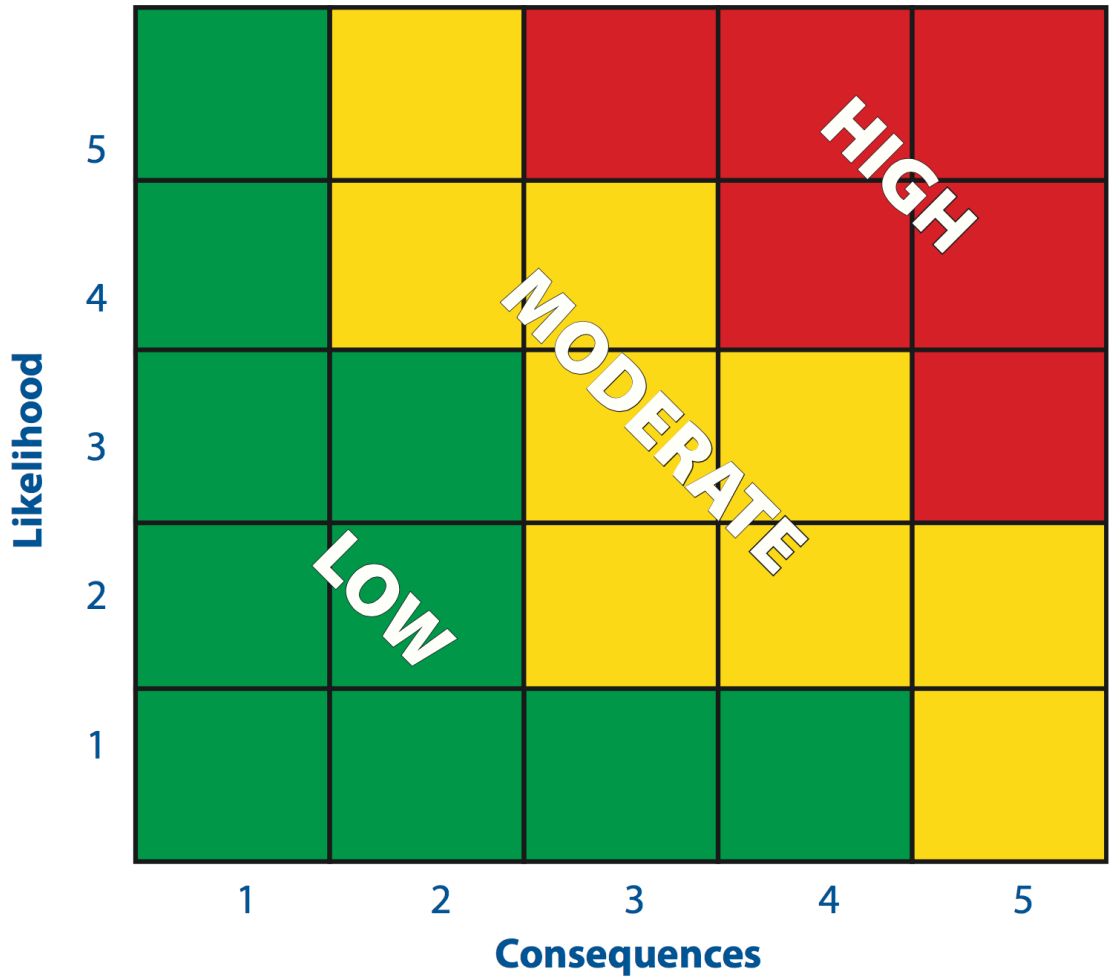
We're Not So Different, You and I.
The Risk Matrix



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Aerospace: Technical Risk Management

- Risk is defined as the combination of (1) the probability that a program or project will experience an undesired event and (2) the consequences, impact, or severity of the undesired event, were it to occur.
- The undesired event might come from technical or programmatic sources (e.g., a cost overrun, schedule slippage, safety mishap, health problem, malicious activities, environmental impact, or failure to achieve a needed scientific or technological objective or success criterion).
- The concept of "value of information" is central to making the determination of what analysis is appropriate and to what extent uncertainty needs to be quantified.
- Medtech…. Just Safety and Efficacy...

Source: NASA

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Case Study: Risk Identification

- Risk analysis (per ISO 14971) is required for medical device development
- It is common for teams to identify risks by brainstorming at the beginning of a risk analysis. There is an over-reliance on tools and a lack of confidence in making decisions (regulatory fear)
- Brainstorming fails because teams suffer from absence blindness
- Successful *risk analysis* begins first with a rigorous, structured process for *risk identification*
- The application of this process has improved risk identification rates by a factor of 10

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STANDARDS IN MEDTECH

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Standards (versus Beer)

- Domestic (Domestic)
  - AAMI
  - ANSI
  - ASTM
  - IEEE
  - NEMA
  - OSHA
  - UL
- International (Imported)
  - BSI
  - CENELAC
  - CSA
  - IEC
  - ISO
  - JSA

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ISO 14971 – Risk Management

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IEC 60601-1:2009 – 3rd Edition

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IEC 62304 - Software

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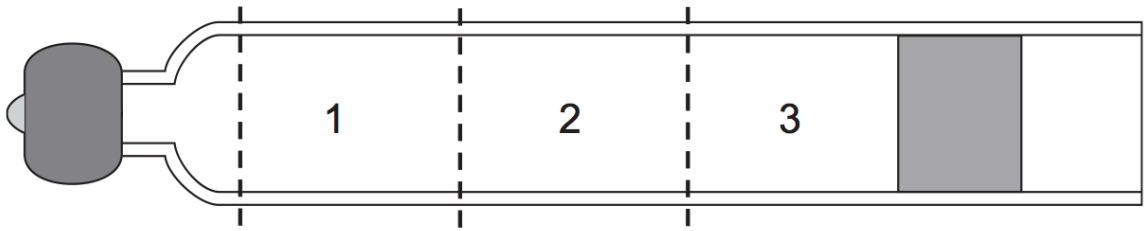
ISO 11608-1: Injectors

Table 2 — Dose accuracy assessment matrix

Dose accuracy matrix	System designation					
	A	B1	B2	C	D1	D2
Determine doses needed	7.3.1	7.3.2	7.3.2	7.3.1	7.3.2	7.3.2
Determine accuracy limits	7.4.2.1	7.4.2.2	7.4.2.1	7.4.2.1	7.4.2.2	7.4.2.1
Determine last-dose accuracy limits (variable dose only)	7.4.3	N/A	N/A	7.4.3	N/A	N/A
Calculate last-dose error (variable dose only)	10.3	N/A	N/A	10.3	N/A	N/A
Calculate dose efficiency (user-filled only)	N/A	7.4.4	N/A	N/A	7.4.4	N/A
Calculate tolerance intervals	7.4.5	7.4.5	7.4.5	7.4.5	7.4.5	7.4.5

7.2 Dosing regions

For multi-dose containers, the dosing regions are as defined in Figure 1.



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ISO 62366 – Human Factors

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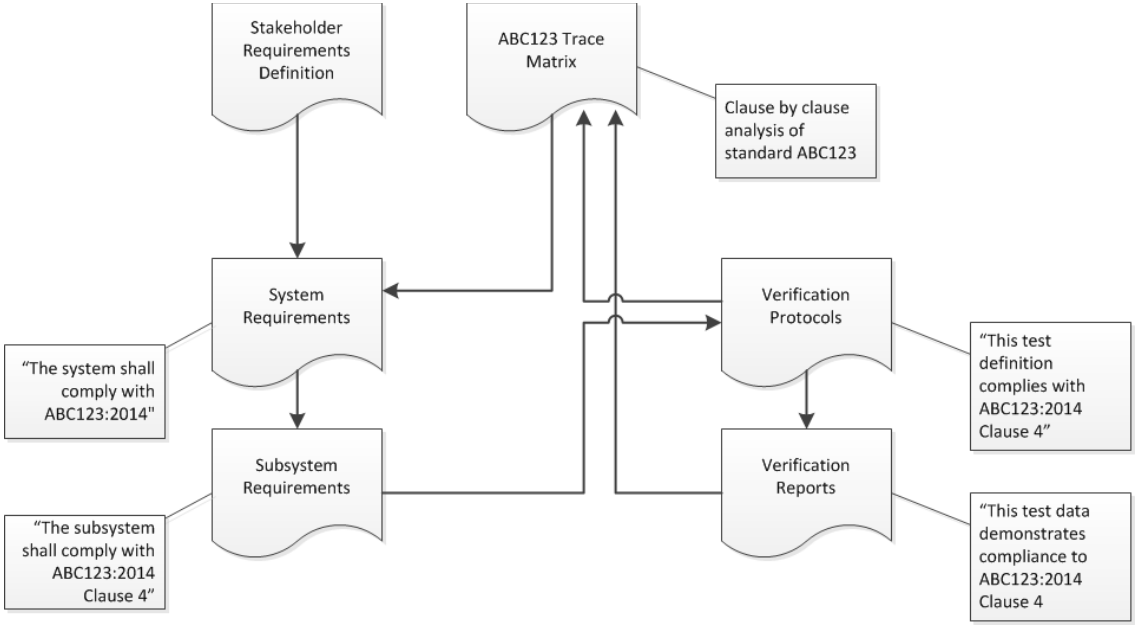
Standards Traceability



Section/ Clause ID	Title	Applies	Rationale	Evidence/Trace
2.5	General design requirements	-		
2.5 a)	Types A&B	A	Required for all systems, including next generation injector.	DOC12345 - System Risk Analysis; DOC65432 - System Integration Verification Report DOC33223 – Technical Analysis DOC76543 - Subsystem Verification Report DOC55544 - Receiving Inspection Report
2.5 b)	Type A	A	Next generation system is of Type A, per section 1.0 of this standard, and must follow all clauses for Type A systems.	DOC12345 - System Risk Analysis; DOC65432 - System Verification Report DOC76543 - Subsystem Verification Report DOC87654 - Subsystem Verification Report
2.5 c)	Type B	N/A	Next generation system is of Type A, per section 1.0 of this standard, and is not required to follow clauses for Type B systems.	

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Badelt and Atherton, 2014

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SE APPLICATIONS IN BIOTECH

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Biotech

- Pharmaceutical companies now have to follow medical technology rules.

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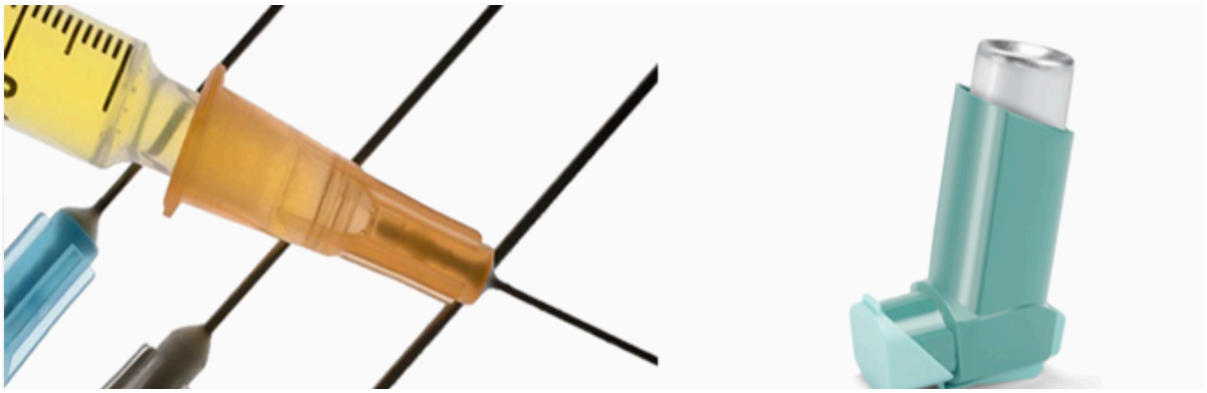
Combination Products



- The FDA and other regulatory bodies have decided that the market has been insufficiently regulated with regards to the drug – device combination.
  - Drug-device interactions
  - Use models

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Consumer health

- When is something a medical device?
  - Diagnosis
  - Treatment
- What happens when you report to your physician using information from your bathroom scale?
- When is a phone app, fitbit,
- How does this scale with all of our connected technologies?

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What happens when you place a large number of independently developed technologies in one place?

SE IN THE HOSPITAL

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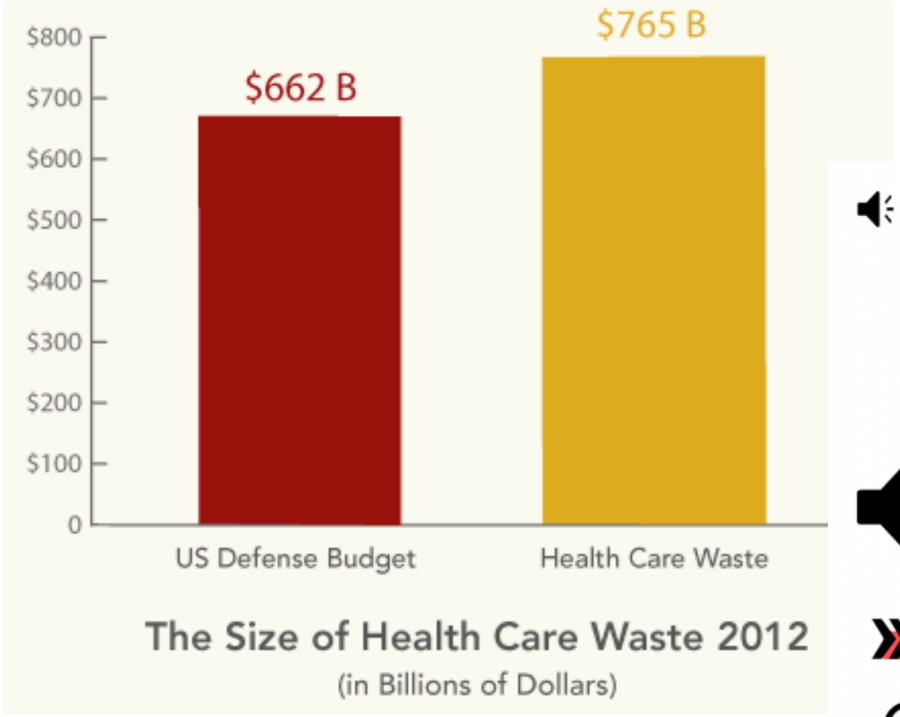
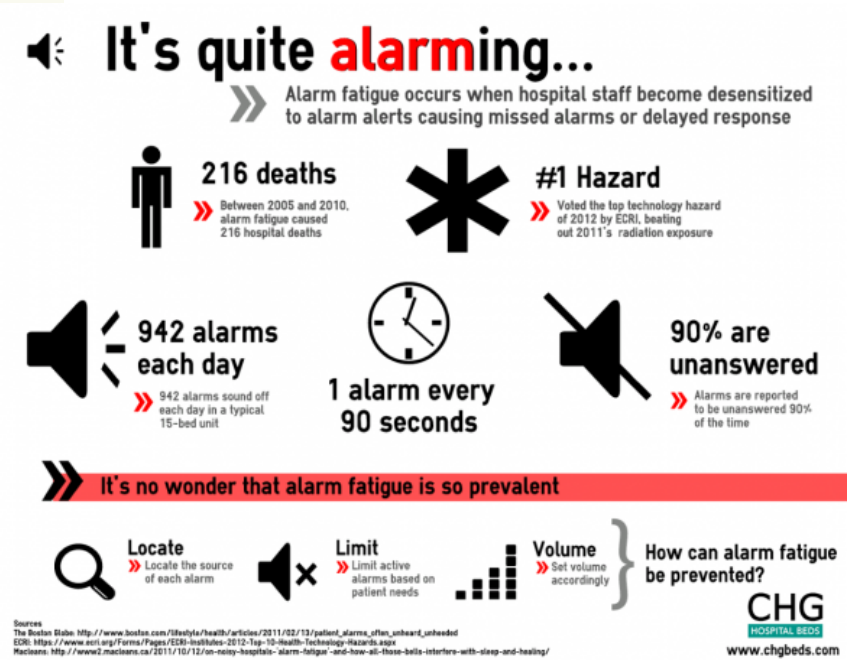
Healthcare Challenges

System Efficiency



System Integration



AND… Medical Errors…

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BMJ 2016;353:i2139 doi: 10.1136/bmj.i2139 (Published 3 May 2016)

ANALYSIS

Medical error—the third leading cause of death in the US

Medical error is not included on death certificates or in rankings of cause of death. **Martin Makary** and **Michael Daniel** assess its contribution to mortality and call for better reporting

Martin A Makary *professor*, Michael Daniel *research fellow*

Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, MD 21287, USA

The annual list of the most common causes of death in the United States, compiled by the Centers for Disease Control and Prevention (CDC), informs public awareness and national research priorities each year. The list is created using death certificates filled out by physicians, funeral directors, medical examiners, and coroners. However, a major limitation of the death certificate is that it relies on assigning an International Classification of Disease (ICD) code to the cause of death.[1] As a result, causes of death not associated with an ICD code, such

How big is the problem?

The most commonly cited estimate of annual deaths from medical error in the US—a 1999 Institute of Medicine (IOM) report[7]—is limited and outdated. The report describes an incidence of 44 000-98 000 deaths annually.[7] This conclusion was not based on primary research conducted by the institute but on the 1984 Harvard Medical Practice Study and the 1992 Utah and Colorado Study.[8,9] But as early as 1993, Lucian, a chief

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"BETTER HEALTH CARE AND LOWER COSTS: ACCELERATING IMPROVEMENT THROUGH SYSTEMS ENGINEERING"
PCAST
- Problem Statement:
Meet the requirements of the Affordable Care Act.
- Solution:
Application of Systems Engineering to the healthcare enterprise

Translating SE to Healthcare

Health system stakeholder	Selected challenges	Example systems methods and tools to address selected challenges
Patients	- Uncoordinated care - Inefficient use of their time and effort - Care not centered on their needs, goals, and circumstances	- Operations management to ensure resources are available when needed - Checklists or dashboards to ensure reliable care delivery - Reengineering processes to incorporate patient input
Small clinical practices	- Clinician stress and burnout - Inefficient workflows for delivering care - Inconsistent usability of different health-information tools - Uneven delivery of evidence-based prevention and treatment	- Lean techniques for eliminating waste in workflows and clinical processes - Human-factors engineering techniques to ensure health-information tools are easily usable
Large health-care organizations	- Managing new payment models that reward outcomes vs. process - Errors and gaps in care - Wasted resources from inefficient workflows - Wasted resources from unnecessary administrative processes	- Standardized protocols that incorporate new evidence and can be tailored to individual patients - Predictive analytics to identify potential risks before problems occur - Supply-chain management to minimize waste in supplies and pharmaceuticals
Communities	- Little coordination among community organizations, local governments, and health-care organizations - Partnering to address the many factors that affect people's health	- Modeling how policies can build on community resources - Operations research to identify at-risk community members and efficiently deliver preventive health services - Big-data methods for identifying patients who need more intensive coordination of their health care

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Systems Approach to Health: A Working Definition

A systems approach to health is one that applies scientific insights to understand the elements that influence health outcomes; models the relationships between those elements; and alters design, processes, or policies based on the resultant knowledge in order to produce better health at lower cost.

Examples of Systems Approaches to Health

Multiple systems approaches have the potential to improve health and health care, including:

- Human factors engineering
- Industrial and systems engineering
- Production system methods
- Modeling and simulation
- Predictive analytics
- Supply chain management
- Operations management and queuing theory

Source: Bringing a Systems Approach to Health Kaplan, et Al., 2013

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e.g. - Operations Research, a.k.a. “Engineering Systems”

- Edelman Prize in 1992 for the New Haven Health Department Study on clean-needle exchange (Kaplan and Heimer, 1992).
- Applied probabilistic modeling techniques, “the lateral thinking was very impressive.”
- Predicted a substantial reduction in the HIV/AIDS progression that occurred through the use of dirty needles if the government sponsored clean-needle exchanges.
- Studies suggest that the program reduced HIV/ AIDS incidence by 33 percent.

Source: Building a Better Delivery System: A New Engineering/Health Care Partnership, Grossman, et Al., 2011

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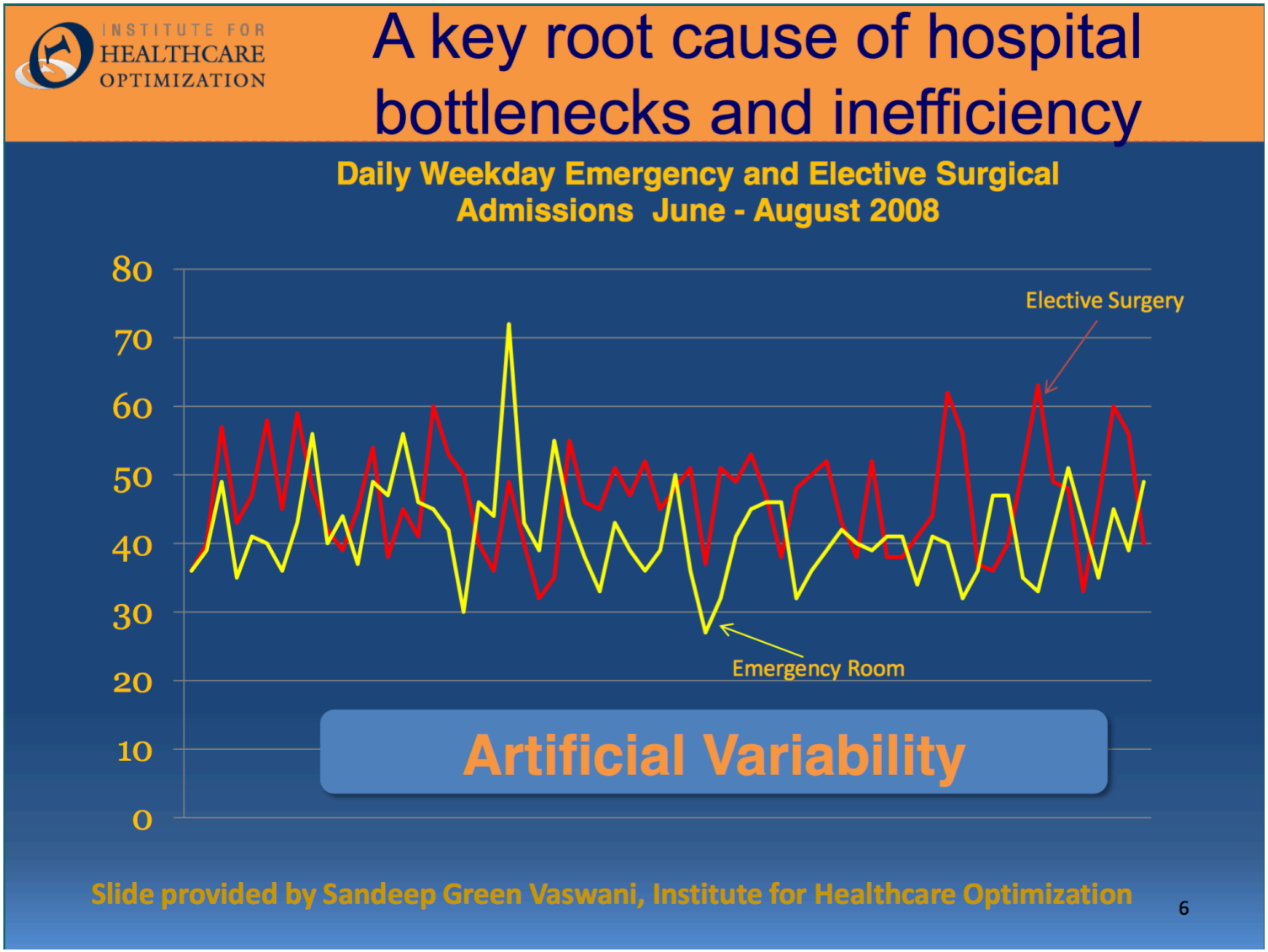
e.g. – Controlling Variability



Source: Litvak, Eugene SYSTEMS APPROACHES FOR IMPROVING HEALTH INNOVATION COLLABORATIVE, December 14, 2012

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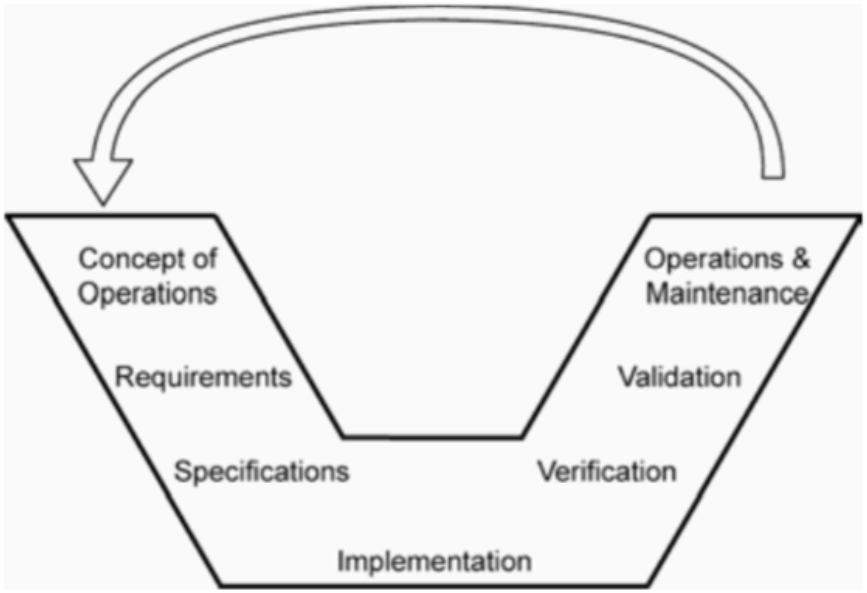
John's Hopkins - Patient Care Program Acute Care Initiative – Early Example

- Early Example Program: Checklists could reduce the incidence of catheter-related bloodstream infections
- 80 percent decrease in infections per catheter-day when implemented across ICUs throughout an entire state
- Nationally, could save
  - 30,000 lives per year
  - $2 billion in health care costs



Source: Bringing a Systems Approach to Health Kaplan, et Al., 2013

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Operations Systems Engineering (OSE)

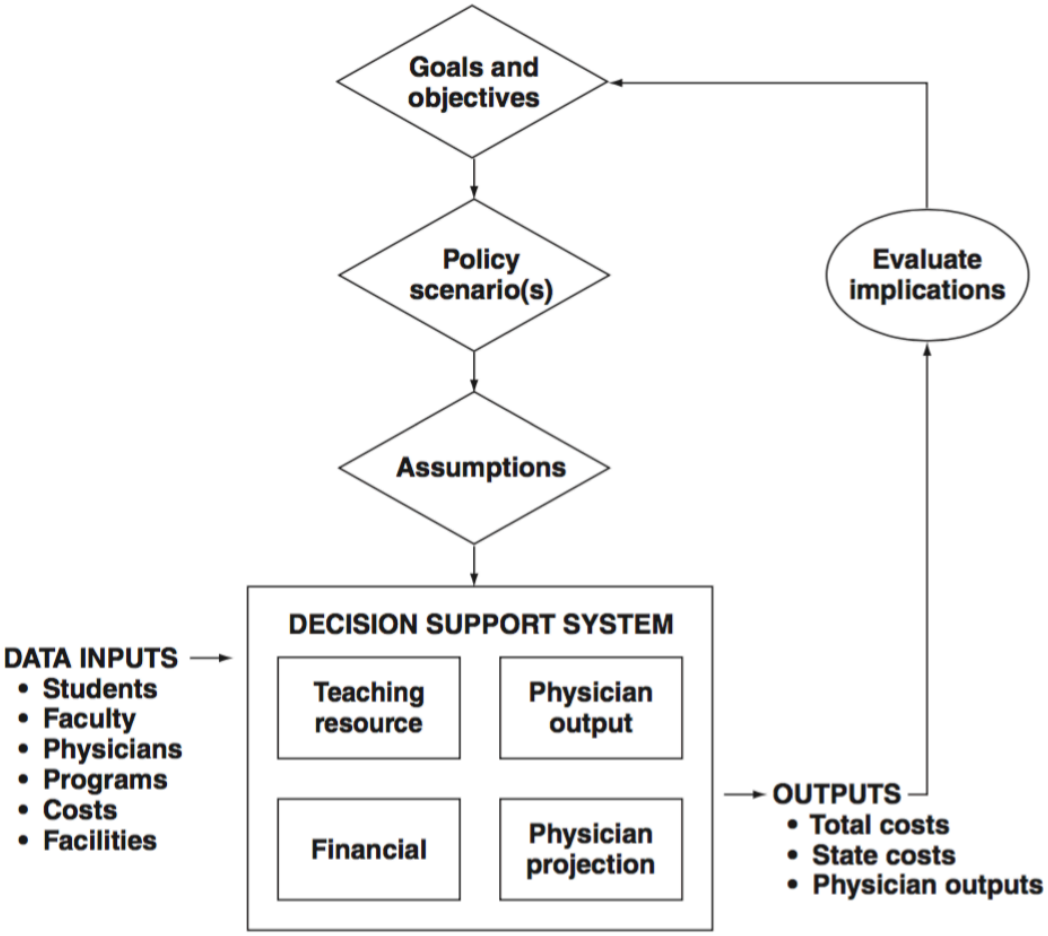

FIGURE 4-4 Strategy development and evaluation process. Source: Lee et al., 1987. Reprinted with permission from INFORMS.

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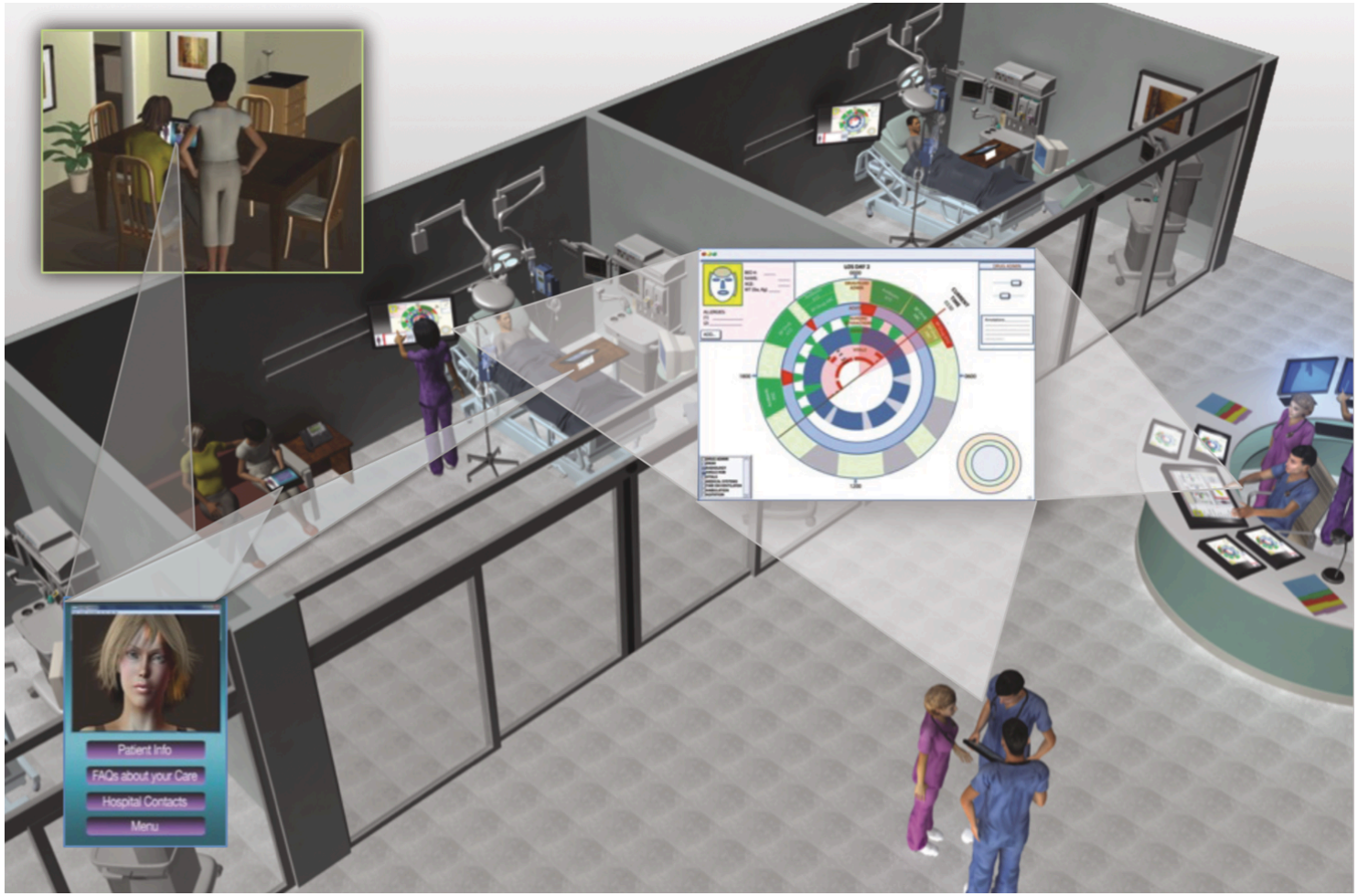
SE in the Hospital (and Home)



A. D. RAVITZ ET AL., 2013

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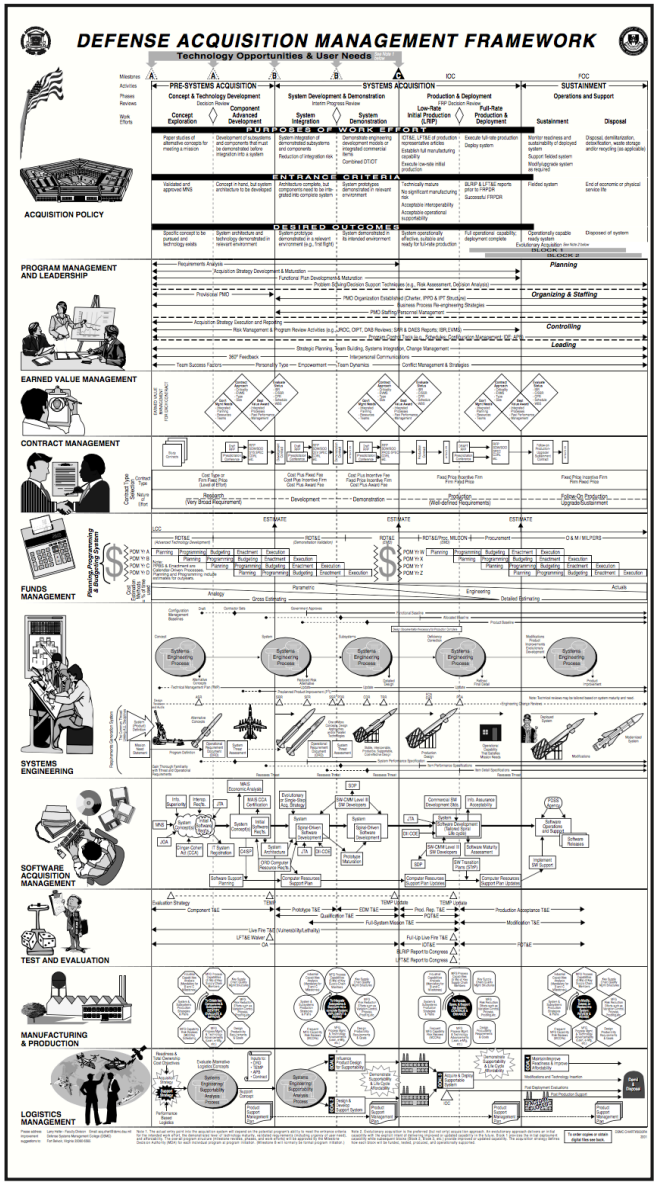
Defense Acquisition Management Framework



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Defense Buys Top-Down

- The “Prime” is driving requirements, specifying what they will buy. Top-Down
- The “Prime” is specifying how technical program processes, including risk, are driven. Top-down.

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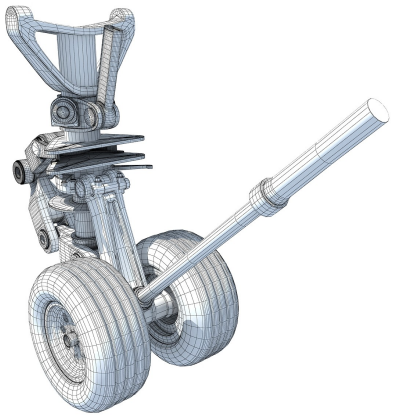
“Prime”

LOCKHEED MARTIN

Requirements

Process
(Risk Management)

“Sub”



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Healthcare Does Not Buy Top-Down

- The Vendor (medtech) is driving requirements, specifying what they will build. Bottom-Up.
- The Vendor (medtech) is specifying how technical program process, which is only communicated to regulator agencies.

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"Sub"

Risk Data Go Here

FDA

Not Here

"Prime"

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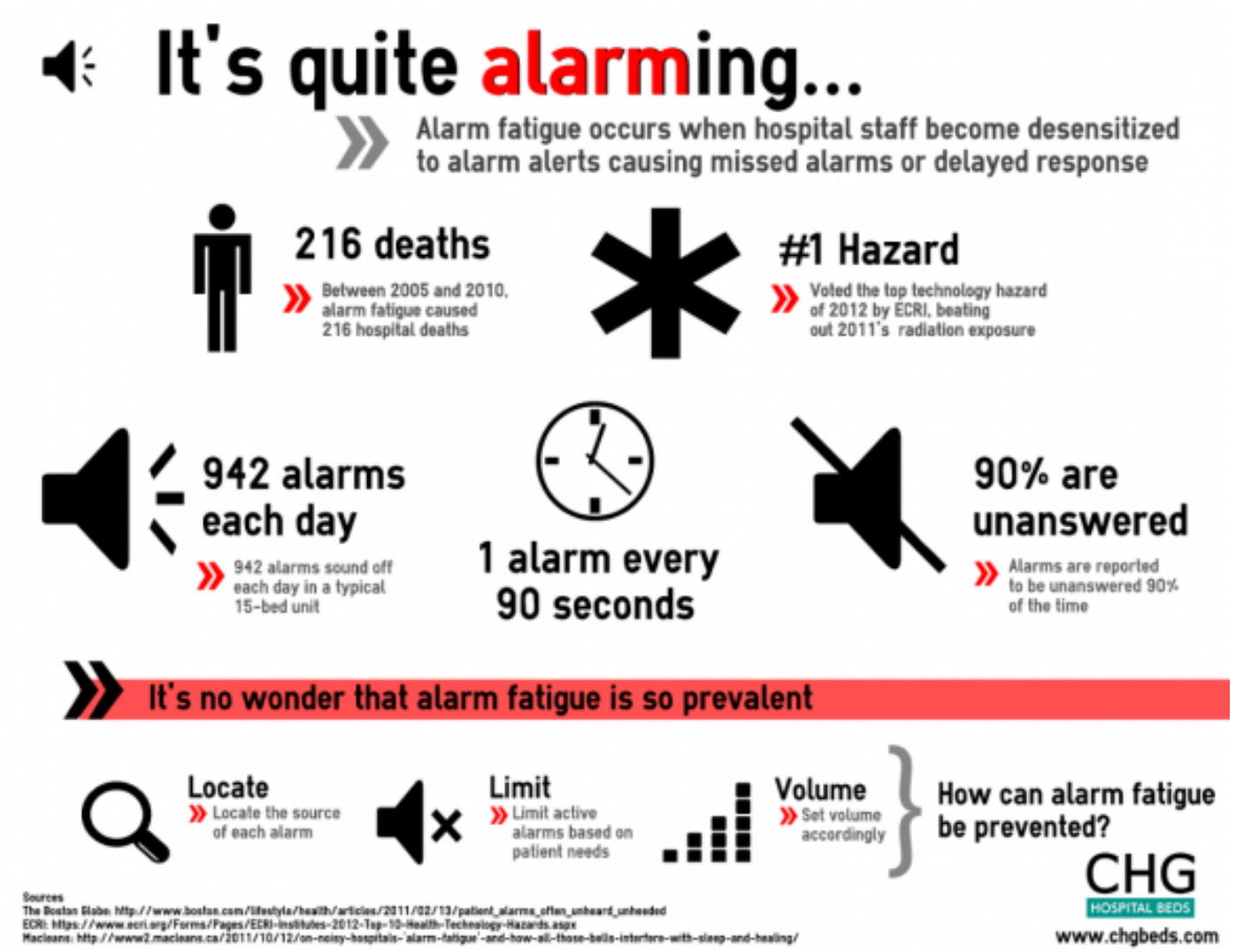
Integration failure: Alarm Fatigue



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Integration Failure: Covidien Defib Electrode Incompatibility

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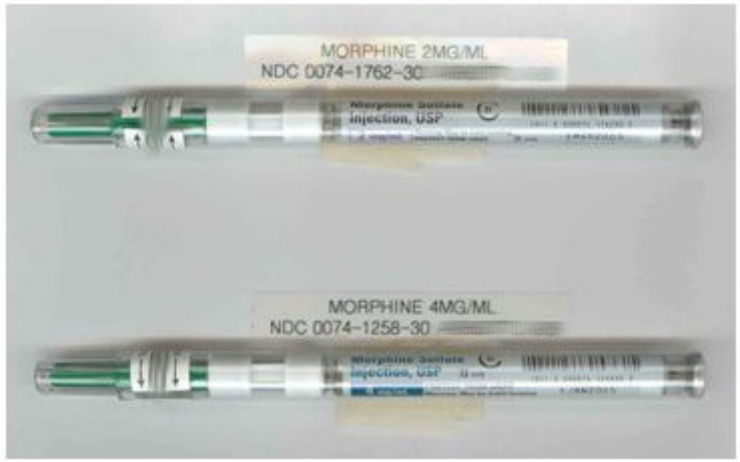
Integration Failure: Product Mimicry

- Your product is only one of many…
  - How is your product differentiated from others?



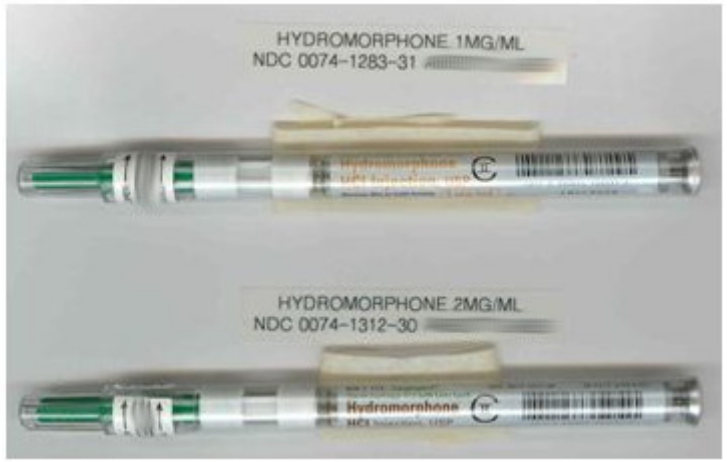


Photo: Patient Safety Authority, 2007

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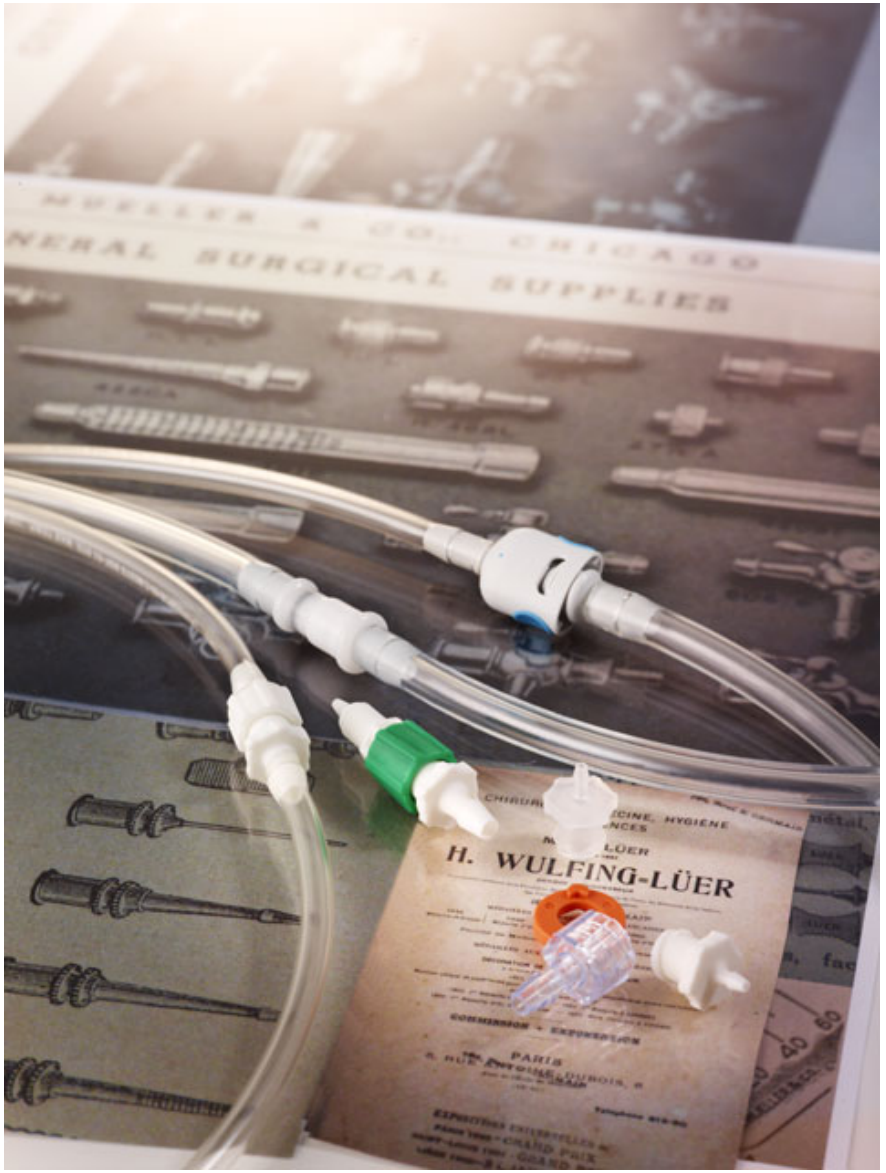
Integration Failure: Luer-Lock



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The Future of SE in Healthcare

- SE applied to, and by, the Hospital
  - Improving existing practice
  - Advancing future practice as technology advances
  - Integrated patient medical records
- Case study – Kaiser Permanente, Mayo Clinic, Johns Hopkins
- New standards emerging
  - AAMI 80001- Medical IT
  - IEEE 11073

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