The Application of Systems Engineering in Medicine

Steven W. Badelt, PhD
Managing Partner, Suttons Creek, Inc.

Industry Ambassador
The INCOSE Healthcare Working Group
sbadelt@suttonscreek.com
Steven.Badelt@incose.org
The HWG integrates SE perspectives across the Healthcare Domain.
Activity Timeline

These are just a few examples, there are many more!
Why System Engineering?

• Reduction to **cost, risk, and timelines**
• Improved **integration** across internal functions and external vendors
• Increased **reliability**
• Increased **efficiency**
SE pays significant ROI on Cost.

Source: Honor, 2009
SE pays significant ROI on Schedule.
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
Our Agenda

• SE in this Domain versus others
• Medical Devices, Medical Technology - Medtech
• Biotech - Biotechnology
• Hospitals – the next frontier
SYSTEM ENGINEERING: SUCCESS IN BIOTECH!
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
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”
SE integrates functions and sites with consistent, integrated processes.

Beasly, 2012
Systems Engineering integrates functions, teams, and design controls into the product development process.
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 …
- Tongue depressors, contact lenses
Therac-25
Malfunction 54
**Therac-25 Malfunction 54**

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>John Doe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Mode</td>
<td>Fix</td>
</tr>
<tr>
<td>Beam Type</td>
<td>X</td>
</tr>
<tr>
<td>Energy (MeV)</td>
<td>25</td>
</tr>
<tr>
<td><strong>Actual</strong></td>
<td><strong>Prescribed</strong></td>
</tr>
<tr>
<td>Unit Rate/Minute</td>
<td>0</td>
</tr>
<tr>
<td>Monitor Units</td>
<td>50</td>
</tr>
<tr>
<td>Time (Min)</td>
<td>0.27</td>
</tr>
<tr>
<td>Gantry Rotation (Deg)</td>
<td>0.0</td>
</tr>
<tr>
<td>Collimator Rotation (Deg)</td>
<td>359.2</td>
</tr>
<tr>
<td>Collimator X (CM)</td>
<td>14.2</td>
</tr>
<tr>
<td>Collimator Y (CM)</td>
<td>27.2</td>
</tr>
<tr>
<td>Wedge Number</td>
<td>1</td>
</tr>
<tr>
<td>Accessory Number</td>
<td>0</td>
</tr>
</tbody>
</table>

**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:**
What criteria would you apply to select this connector?
What criteria would you apply to select this connector?
Regulated Markets

National Regulatory Agency for Medical Devices*

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: Baseline country survey on medical devices 2019
Map Production: Public Health Information and Geographic Information Systems (GIS)
World Health Organization

© WHO 2011. All rights reserved.
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
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
    - Sphygmanometers

- **Class III**
  - Life sustaining
    - Pacemakers, heart valves

Increasing level of control and evaluation
Following design controls does not constitute good engineering practice. Design controls are a subset of systems engineering.
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
## 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

<table>
<thead>
<tr>
<th>Reference</th>
<th>Text</th>
<th>Aligned Clause for INCOSE Handbook 3.2.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>820.30a</td>
<td>(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)</td>
<td>5.5</td>
</tr>
<tr>
<td>820.30b</td>
<td>(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.</td>
<td>5.1, 5.2</td>
</tr>
<tr>
<td>820.30c</td>
<td>(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.</td>
<td>4.1, 4.2</td>
</tr>
</tbody>
</table>
# CFR 820.30 – SE Principles

<table>
<thead>
<tr>
<th>Reference</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>820.30d</strong></td>
<td>(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 output procedures 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.</td>
</tr>
<tr>
<td><strong>820.30e</strong></td>
<td>(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).</td>
</tr>
<tr>
<td><strong>820.30f</strong></td>
<td>(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.</td>
</tr>
</tbody>
</table>

Aligned Clause for INCOSE Handbook 3.2.2

4.6....

3.2.2

4.6
## 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

<table>
<thead>
<tr>
<th>Reference</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>820.30g</td>
<td>(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.</td>
</tr>
<tr>
<td></td>
<td>4.8</td>
</tr>
<tr>
<td>820.30h</td>
<td>(h)Design transfer. Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.</td>
</tr>
<tr>
<td></td>
<td>3.3.4</td>
</tr>
<tr>
<td>820.30i</td>
<td>(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.</td>
</tr>
<tr>
<td></td>
<td>5.5</td>
</tr>
<tr>
<td>820.30j</td>
<td>(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.</td>
</tr>
<tr>
<td></td>
<td>3.3.2</td>
</tr>
</tbody>
</table>

©2016 Suttons Creek, Inc
Additional references: Where is all of this?
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?
Notes on Validation - Efficacy

- Two primary sources:
  - Human Factors
    - Formative
    - Summative
  - Clinical Studies
    - IDE – Investigational Device Exemption
RISK MANAGEMENT – SAFETY, NOT TECHNICAL RISK
We’re Not So Different, You and I.
The Risk Matrix
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
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
Standards (versus Beer)

- Domestic (Domestic)
  - AAMI
  - ANSI
  - ASTM
  - IEEE
  - NEMA
  - OSHA
  - UL

- International (Imported)
  - BSI
  - CENELAC
  - CSA
  - IEC
  - ISO
  - JSA
## ISO 14971 – Risk Management

4  * Principles.................................................................................................................11
   4.1 General requirements ..........................................................................................11
       4.1.1 * USABILITY ENGINEERING PROCESS .........................................................11
       4.1.2 RESIDUAL RISK ..........................................................................................11
       4.1.3 Information for SAFETY .............................................................................12
   4.2 * USABILITY ENGINEERING FILE .....................................................................12
   4.3 Scaling of the USABILITY ENGINEERING effort ..................................................12

5  * USABILITY ENGINEERING PROCESS ..................................................................12
   5.1 * Application specification ..................................................................................12
   5.2 * Frequently used functions ...............................................................................13
   5.3 Identification of HAZARDS and HAZARDOUS SITUATIONS related to USABILITY ..............................................................................................................13
       5.3.1 Identification of characteristics related to SAFETY ......................................13
       5.3.2 * Identification of known or foreseeable HAZARDS and HAZARDOUS
              SITUATIONS ...............................................................................................14
   5.4 PRIMARY OPERATING FUNCTIONS ..................................................................14
   5.5 * USABILITY SPECIFICATION ..........................................................................15
   5.6 USABILITY VALIDATION plan ............................................................................15
   5.7 * USER INTERFACE design and implementation ..................................................16
   5.8 * USABILITY VERIFICATION ............................................................................16
   5.9 * USABILITY VALIDATION ...............................................................................17

6  * ACCOMPANYING DOCUMENT ..........................................................................17

7  * Training and materials for training .......................................................................18
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>* Accuracy of controls and instruments and protection against hazardous outputs</td>
<td>167</td>
</tr>
<tr>
<td></td>
<td>12.1 Accuracy of controls and instruments</td>
<td>167</td>
</tr>
<tr>
<td></td>
<td>12.2 USABILITY</td>
<td>167</td>
</tr>
<tr>
<td></td>
<td>12.3 Alarm systems</td>
<td>167</td>
</tr>
<tr>
<td></td>
<td>12.4 Protection against hazardous output</td>
<td>167</td>
</tr>
<tr>
<td>13</td>
<td>* HAZARDOUS SITUATIONS and fault conditions</td>
<td>169</td>
</tr>
<tr>
<td></td>
<td>13.1 Specific HAZARDOUS SITUATIONS</td>
<td>169</td>
</tr>
<tr>
<td></td>
<td>13.2 SINGLE FAULT CONDITIONS</td>
<td>170</td>
</tr>
<tr>
<td>14</td>
<td>* PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)</td>
<td>176</td>
</tr>
<tr>
<td></td>
<td>14.1 * General</td>
<td>176</td>
</tr>
<tr>
<td></td>
<td>14.2 * Documentation</td>
<td>176</td>
</tr>
<tr>
<td></td>
<td>14.3 * RISK MANAGEMENT plan</td>
<td>177</td>
</tr>
<tr>
<td></td>
<td>14.4 * PEMS DEVELOPMENT LIFE-CYCLE</td>
<td>177</td>
</tr>
<tr>
<td></td>
<td>14.5 * Problem resolution</td>
<td>177</td>
</tr>
<tr>
<td></td>
<td>14.6 RISK MANAGEMENT PROCESS</td>
<td>177</td>
</tr>
<tr>
<td></td>
<td>14.7 * Requirement specification</td>
<td>178</td>
</tr>
<tr>
<td></td>
<td>14.8 * Architecture</td>
<td>178</td>
</tr>
<tr>
<td></td>
<td>14.9 * Design and implementation</td>
<td>179</td>
</tr>
<tr>
<td></td>
<td>14.10 * VERIFICATION</td>
<td>179</td>
</tr>
<tr>
<td></td>
<td>14.11 * PEMS VALIDATION</td>
<td>179</td>
</tr>
<tr>
<td></td>
<td>14.12 * Modification</td>
<td>180</td>
</tr>
<tr>
<td></td>
<td>14.13 * Connection of PEMS by NETWORK/DATA COUPLING to other equipment</td>
<td>180</td>
</tr>
</tbody>
</table>
ISO 11608-1: Injectors

Table 2 — Dose accuracy assessment matrix

<table>
<thead>
<tr>
<th>Dose accuracy matrix</th>
<th>System designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine doses needed</td>
<td>7.3.1 7.3.2 7.3.2 7.3.1 7.3.2 7.3.2</td>
</tr>
<tr>
<td>Determine accuracy limits</td>
<td>7.4.2.1 7.4.2.2 7.4.2.1 7.4.2.1 7.4.2.2 7.4.2.1</td>
</tr>
<tr>
<td>Determine last-dose accuracy limits (variable dose only)</td>
<td>7.4.3  N/A  N/A  7.4.3  N/A  N/A</td>
</tr>
<tr>
<td>Calculate last-dose error (variable dose only)</td>
<td>10.3  N/A  N/A  10.3  N/A  N/A</td>
</tr>
<tr>
<td>Calculate dose efficiency (user-filled only)</td>
<td>N/A  7.4.4  N/A  N/A  7.4.4  N/A</td>
</tr>
<tr>
<td>Calculate tolerance intervals</td>
<td>7.4.5 7.4.5 7.4.5 7.4.5 7.4.5 7.4.5</td>
</tr>
</tbody>
</table>

7.2 Dosing regions

For multi-dose containers, the dosing regions are as defined in Figure 1.
# ISO 62366 – Human Factors

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Principles</td>
<td>11</td>
</tr>
<tr>
<td>4.1</td>
<td>General requirements</td>
<td>11</td>
</tr>
<tr>
<td>4.1.1</td>
<td>* USABILITY ENGINEERING PROCESS</td>
<td>11</td>
</tr>
<tr>
<td>4.1.2</td>
<td>RESIDUAL RISK</td>
<td>11</td>
</tr>
<tr>
<td>4.1.3</td>
<td>Information for SAFETY</td>
<td>12</td>
</tr>
<tr>
<td>4.2</td>
<td>* USABILITY ENGINEERING FILE</td>
<td>12</td>
</tr>
<tr>
<td>4.3</td>
<td>Scaling of the USABILITY ENGINEERING effort</td>
<td>12</td>
</tr>
<tr>
<td>5</td>
<td>* USABILITY ENGINEERING PROCESS</td>
<td>12</td>
</tr>
<tr>
<td>5.1</td>
<td>* Application specification</td>
<td>12</td>
</tr>
<tr>
<td>5.2</td>
<td>* Frequently used functions</td>
<td>13</td>
</tr>
<tr>
<td>5.3</td>
<td>Identification of HAZARDS and HAZARDOUS SITUATIONS related to USABILITY</td>
<td>13</td>
</tr>
<tr>
<td>5.3.1</td>
<td>Identification of characteristics related to SAFETY</td>
<td>13</td>
</tr>
<tr>
<td>5.3.2</td>
<td>* Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS</td>
<td>14</td>
</tr>
<tr>
<td>5.4</td>
<td>PRIMARY OPERATING FUNCTIONS</td>
<td>14</td>
</tr>
<tr>
<td>5.5</td>
<td>* USABILITY SPECIFICATION</td>
<td>15</td>
</tr>
<tr>
<td>5.6</td>
<td>USABILITY VALIDATION plan</td>
<td>15</td>
</tr>
<tr>
<td>5.7</td>
<td>* USER INTERFACE design and implementation</td>
<td>16</td>
</tr>
<tr>
<td>5.8</td>
<td>* USABILITY VERIFICATION</td>
<td>16</td>
</tr>
<tr>
<td>5.9</td>
<td>* USABILITY VALIDATION</td>
<td>17</td>
</tr>
<tr>
<td>6</td>
<td>* ACCOMPANYING DOCUMENT</td>
<td>17</td>
</tr>
<tr>
<td>7</td>
<td>* Training and materials for training</td>
<td>18</td>
</tr>
</tbody>
</table>
Standards Traceability

- Stakeholder Requirements Definition
- ABC123 Trace Matrix
- System Requirements
- Subsystem Requirements
- Verification Protocols
- Verification Reports

Table:

<table>
<thead>
<tr>
<th>Section/Clause ID</th>
<th>Title</th>
<th>Applies</th>
<th>Rationale</th>
<th>Evidence/Trace</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5</td>
<td>General design requirements</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.5 a)</td>
<td>Types A&amp;B</td>
<td>A</td>
<td>Required for all systems, including next generation injector.</td>
<td>DOC12345 - System Risk Analysis; DOC65432 - System Integration Verification Report; DOC76543 - Subsystem Verification Report; DOC87654 - Subsystem Verification Report</td>
</tr>
<tr>
<td>2.5 b)</td>
<td>Type A</td>
<td>A</td>
<td>Next generation system is of Type A, per section 1.0 of this standard, and must follow all clauses for Type A systems.</td>
<td>DOC12345 - System Risk Analysis; DOC65432 - System Verification Report; DOC76543 - Subsystem Verification Report; DOC87654 - Subsystem Verification Report</td>
</tr>
<tr>
<td>2.5 c)</td>
<td>Type B</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

Notes:
- "The system shall comply with ABC123:2014" Clause 1
- "The subsystem shall comply with ABC123:2014" Clause 4

©2016 Suttons Creek, Inc

Badelt and Atherton, 2014
SE APPLICATIONS IN BIOTECH
Biotech

• Pharmaceutical companies now have to follow medical technology rules.
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
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?
What happens when you place a large number of independently developed technologies in one place?

SE IN THE HOSPITAL
Healthcare Challenges

System Efficiency

The Size of Health Care Waste 2012
(in Billions of Dollars)

$662 B

$765 B

US Defense Budget
Health Care Waste

System Integration

It's quite alarming...

216 deaths
Between 2006 and 2010, alarm fatigue caused 216 hospital deaths

#1 Hazard
Worst technology hazard in 2012 by ECRI, beating est 2011's radiation exposure

942 alarms each day
942 alarms sound off each day in a typical 15-bed unit

1 alarm every 90 seconds
90% are unanswered
Alarms are reported to be unanswered 50% of the time

It's no wonder that alarm fatigue is so prevalent

Locate
Limit
Volume

How can alarm fatigue be prevented?

©2016 Suttons Creek, Inc

AND… Medical Errors…
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. 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—is limited and outdated. The report describes an incidence of 44 000-98 000 deaths annually. 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. But nowhere do 1999, Leonard Sipes
Problem Statement: Meet the requirements of the Affordable Care Act.

Solution: Application of Systems Engineering to the healthcare enterprise
# Translating SE to Healthcare

<table>
<thead>
<tr>
<th>Health system stakeholder</th>
<th>Selected challenges</th>
<th>Example systems methods and tools to address selected challenges</th>
</tr>
</thead>
</table>
| **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 |
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
e.g. - Operations Research, a.k.a. “Engineering Systems”

- 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.

e.g. – Controlling Variability

A key root cause of hospital bottlenecks and inefficiency

Daily Weekday Emergency and Elective Surgical Admissions June - August 2008

Artificial Variability

Source: Litvak, Eugene SYSTEMS APPROACHES FOR IMPROVING HEALTH INNOVATION COLLABORATIVE, December 14, 2012
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
Solving the problem of Complexity.

Operations Systems Engineering (OSE)

FIGURE 4-4 Strategy development and evaluation process. Source: Lee et al., 1987. Reprinted with permission from INFORMS.
SE in the Hospital (and Home)
Defense Acquisition Management Framework
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.
Solving the problem of Complexity.

“Prime”

Requirements

Process (Risk Management)

“Sub”
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.
“Sub”

Risk Data Go Here

Not Here

“Prime”
Integration failure: Alarm Fatigue

It's quite alarming...

Alarm fatigue occurs when hospital staff become desensitized to alarm alerts causing missed alarms or delayed response.

- 216 deaths
  - Between 2005 and 2010, alarm fatigue caused 216 hospital deaths

- #1 Hazard
  - Voted the top technology hazard of 2012 by ECRI, beating out 2011's radiation exposure

- 942 alarms each day
  - 942 alarms sound off each day in a typical 15-bed unit

- 1 alarm every 90 seconds

- 90% are unanswered
  - Alarms are reported to be unanswered 90% of the time

It's no wonder that alarm fatigue is so prevalent

Sources:
- ECRI: https://www.ecri.org/Forms/Pages/ECRI-Institute-2012-Top-10-Health-Technology-Hazards.aspx
- Macleans: http://www2.macleans.ca/2011/10/12/on-noisy-hospitals-alarm-fatigue-and-how-all-these-bells-interfere-with-sleep-and-healing/

©2016 Suttons Creek, Inc
Integration Failure: Covidien Defib Electrode Incompatibility
Integration Failure: Product Mimicry

• Your product is only one of many…
  • How is your product differentiated from others?
Integration Failure: Luer-Lock
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