Using FMEAs to Improve Healthcare Study Design

Pat Baird, Baxter Healthcare

pat_baird@baxter.com

Presentation for the INCOSE Symposium 2011 Denver, CO USA

Agenda

| Hospitals as Systems of Systems |
| Healthcare and Aviation |
| Examples of Healthcare Challenges |
| Applying SE to Healthcare: FMEA |
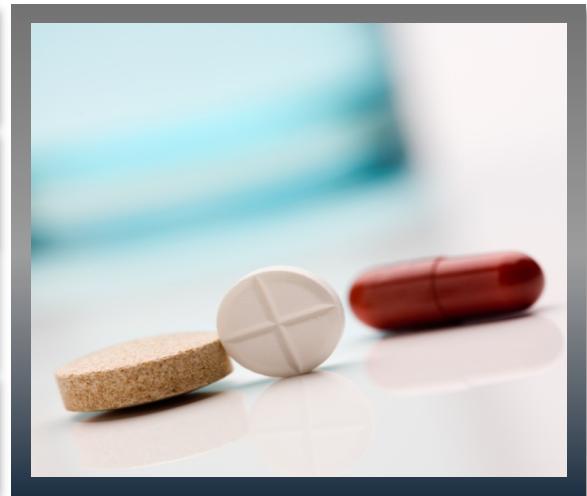
Healthcare needs Systems Engineers

Hospitals are a System of Systems

The Path for Just One Device's Patient Context-MD Data

Credit: Luis Melendez

Surely there is a precedent for dealing with complex safety situations…

can't we just look to another industry ??
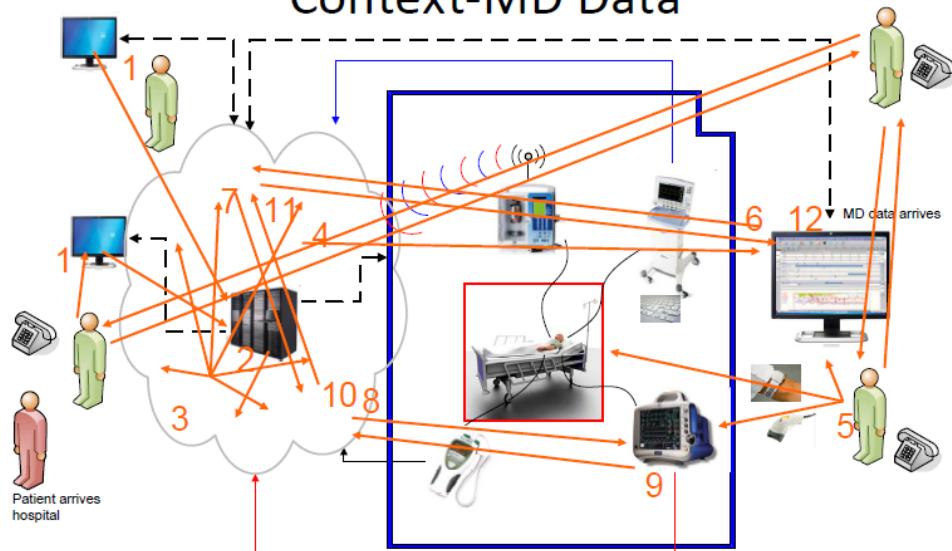
Source: Julian Goldman, MD, Partners HealthCare, "Medical Device Data Systems (MDDS) a hospital's perspective"

Inevitable Comparisons to Aviation

Naval Aviation Safety and Its Application to Medicine

What Pilots Can Teach Hospitals Ab... Safety

By KATE MURPHY
Published: October 31, 2006

What can medicine learn from aviation?
...physicians and hospitals are implementing
... and achieving mixed results.
...2010.

AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

Medication administration process assessment: applying lessons learned from commercial aviation.

Donahue M, Brown JP, Fitzpatrick JJ. J Nurs Adm. 2009;39:77-83.

U.S. Navy photo by
Photographer's Mate Third Class (AW/SW) Joshua Karsten.

By Kirk T. Harmon, MD, FACOEM

Healthcare is not Aviation

Entirely different usage model

Who pays ?

Who regulates manufacturers ?

Who regulates facilities ?

Who licenses primary operators (pilots vs. MD) ?

What is the reporting structure (MD vs. Nurse vs. Pilot) ?

What freedom is there to chose an alternate ?

Who sets the flight path ?

Healthcare needs Systems Engineers
at many levels

Research

Process Improvement

Incident Investigation

Example Process: Adverse Drug Events

Did the drug cause an injury?

Study by Brigham and Women's Hospital

6 Sites

75% of ADEs were were preventable

ADEs cost **$3.8B** per year

All Preventable Events cost **$16B**

Example Process: IV Admin. Errors

Did the IV administration execute per policy?

Study by Northwestern Memorial Hospital

Observational study for medication administration errors using infusion pumps (n = 426)

67% of deliveries had an error

 4% had potential of harm

48 events self-reported in 2 years

55 events independ. observed in **1 shift on 1 day**

Research: MDs vs. Statistics

Do MDs understand the statistics they are given?

Tested medical residents (n=277, 11 different residency programs) understanding of statistics typically used in medical journals

Only 41% passed the test

Source: Medicine Residents' Understanding of the Biostatistics and Results in the Medical Literature
Windish, Huot, Green, *JAMA* 2007

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Healthcare needs Systems Engineers

Clinicians Think Differently than SE
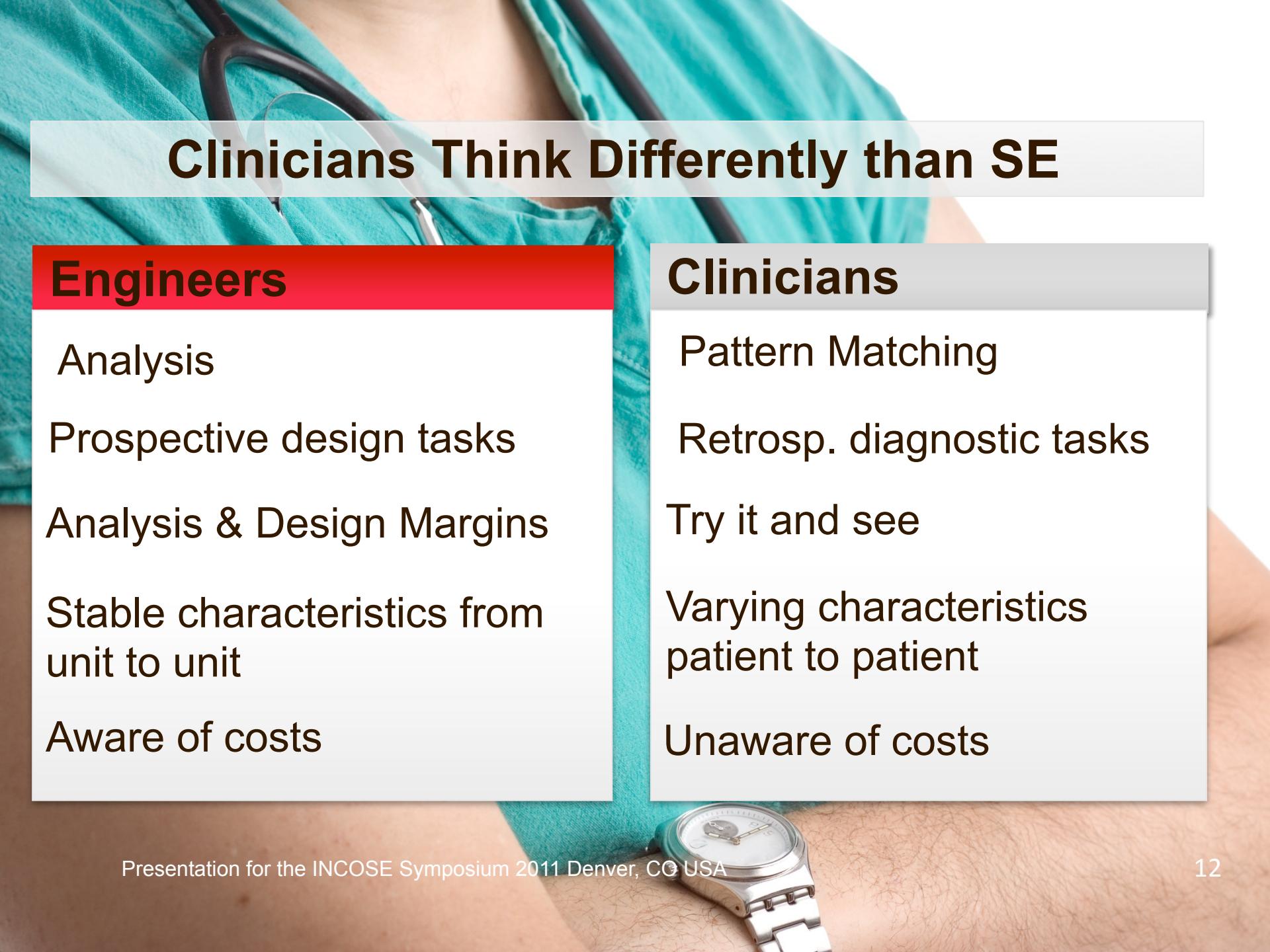
| Engineers	Clinicians
Analysis	Pattern Matching
Prospective design tasks	Retrosp. diagnostic tasks
Analysis & Design Margins	Try it and see
Stable characteristics from unit to unit	Varying characteristics patient to patient
Aware of costs	Unaware of costs

Medical Study Design -
"Association of Door-to-Balloon Time and Mortality…"

Rathore Saif S, Curtis Jeptha P, Chen Jersety, et al.
Association of door-to-ballon time and mortality in patients
admitted to hospital with ST elevation myocardial infarction:
national cohort study. BMJ 2009;338:b1807.

- A STEMI is a type of heart attack due to a blocked blood supply. A PCI procedure involves inserting a deflated balloon into the artery, positioning the balloon near the obstruction, inflating the balloon to crush the obstruction, then deflating and removing the balloon. Afterward PCI, other treatments such as implanting stents are typically performed.

- This particular study wanted to examine the correlation between the "door-to-balloon time" and patient mortality.

Medical Study – Process Flow

Identify candidate patients	Search medical records for patients with this condition
Determine STEMI time	Extract diagnosis time from records
Determine balloon time	Extract balloon time from records
Calculate door-to-balloon time	= Balloon time – STEMI time
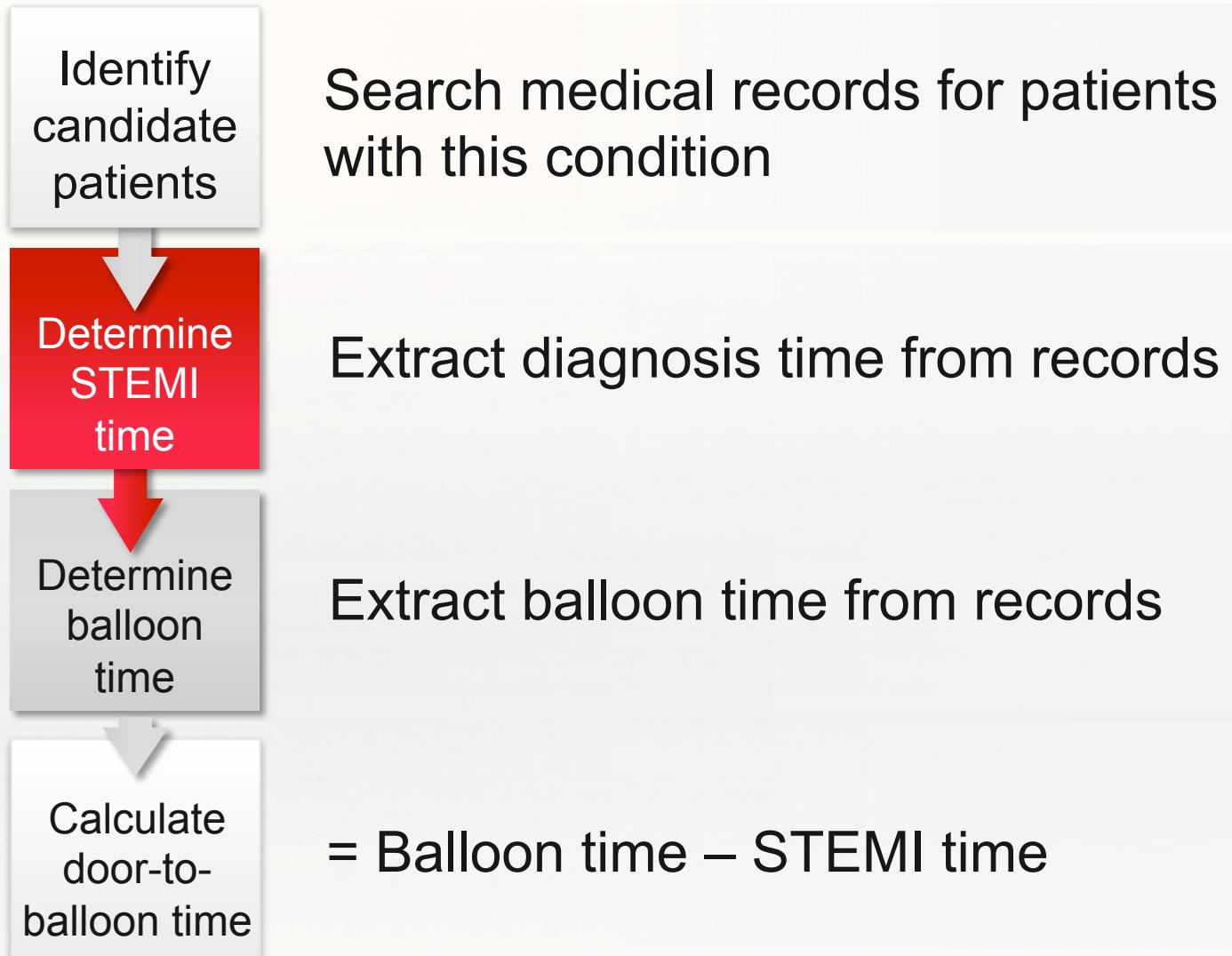
Medical Study – Risk Table

	Severity			
		Catastrophic	Major	Moderate	Minor
Likelihood	Frequent	UNACCEPT (16)	UNACCEPT (12)	UNDESIRE (8)	ACCEPT (4)
	Occasional	UNACCEPT (12)	UNDESIRE (9)	UNDESIRE (6)	ACCEPT (3)
	Uncommon	UNDESIRE (8)	UNDESIRE (6)	ACCEPT (4)	ACCEPT (2)
	Remote	ACCEPT (4)	ACCEPT (3)	ACCEPT (2)	ACCEPT (1)

Severity Rankings
Catastrophic – Study leads to incorrect conclusion (e.g. more than 30% incorrect)
Major – study conclusion is questionable (e.g. correct within 30% to 15%)
Moderate – study conclusion is substantially correct (e.g. correct within 15% to 5%)
Minor - study conclusion is materially correct (e.g. correct within 5%)

Occurrence Rankings
Frequent – will happen several times over the course of the study
Occasional – likely to happen at least once during the study
Uncommon – unlikely but possible to happen. If the study were repeated 3 – 5 times, this error would likely occur.
Remote – unlikely to happen even with repeated studies; may occur with 5+ repeats.

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Medical Study – FMEA

Step #	Description	Failure Mode	Cause	Lik.	Sev.	RPN	Score	Mitigation
1	Identify candidate patients (confirmed STEMI)	Too many patients counted	Duplicate records	3	2	6	UNDESIRE	Exclude duplicate records
		Too few patients	Missing STEMI in record	2	3	6	UNDESIRE	No action possible
			Incomplete record because transferred patient	3	4	12	UNACCEPT	Exclude transfers

Medical Study – FMEA contd.

Step #	Description	Failure Mode	Cause	Lik.	Sev.	RPN	Score	Mitigation
2	Note time STEMI identified	Recorded time nominally incorrect (1-5 min difference)	Difference in clocks between units	4	1	4	ACCEPT	N/A
		Recorded time significantly incorrect (5 - 30 min difference)	Medical record filled out at end of shift.	2	3	6	UNDESIRE	No action possible
		Recorded time grossly incorrect (30+ min)	Value mis-keyed into medical record	2	4	8	UNDESIRE	Exclude door-to-balloon times of < 30 min and > 180 min
		Time not recorded	Value not entered into medical record	2	4	8	UNDESIRE	No action possible

Medical Study – FMEA contd.

Step #	Description	Failure Mode	Cause	Lik.	Sev.	RPN	Score	Mitigation
3	Note time balloon inflated	Recorded time nominally incorrect (1-5 min difference)	Difference in clocks between units	4	1	4	ACCEPT	N/A
		Recorded time significantly incorrect (5 - 30 min difference)	Medical record filled out at end of shift.	2	3	6	UNDESIRE	No action possible
		Recorded time grossly incorrect (30+ min)	Value mis-keyed into medical record	2	4	8	UNDESIRE	Exclude door-to-balloon times of < 30 min and > 180 min
		Time not recorded	Value not entered into medical record	2	4	8	UNDESIRE	No action possible
			Patient expired before balloon	2	4	8	UNDESIRE	Exclude

Medical Study – FMEA contd.

Step #	Description	Failure Mode	Cause	Lik.	Sev.	RPN	Score	Mitigation
4	Calculate door-to-balloon time	Mathematical error	Did not account for midnight rollover in timestamp	2	4	8	UNDESIRE	Make sure formula accounts for rollover

Results:
1. Consider validation patient records for duplicates & transfers
2. Need to determine appropriate timing resolution

Side discussions yield interesting questions…
What really is the shortest door-to-balloon time seen in practice?
What is the longest waiting time in which the patient survived?
Include or exclude events where patient expires before the balloon?
If we were to gather those additional data points, are they consistent with the study conclusions?
All of these discussions explore additional information sources that the study authors might not have considered.

Other Uses for FMEA

After we taught a Clinician how to use FMEAs, she created a one for her daughter's wedding…

TAKEAWAY: If Murphy's Law applies, there's an FMEA.