Evidence-Based Maintenance (EBM)

Binseng Wang, ScD, CCE, fAIMBE, fACCE
Director, Quality & Regulatory Affairs,
WRP32 Management, Inc.

Opinions provided here are solely of the author and does not represent those of his employer or any entity with which he is associated.

Speaker Biography

- Binseng Wang is Director, Quality & Regulatory Affairs for WRP32 Management LLC, a medical device management and manufacturing company located in White Plains NY – USA
- Previously, he worked as
  - VP, Quality & Regulatory Affairs for Sundance Enterprises Inc. (a manufacturer of devices for pressure ulcer prevention and treatment)
  - Adjunct Professor with the Biomedical Eng. Program - Dept. Electrical Eng. & Computer Science, Milwaukee School of Engineering (MSOE)
  - VP, Quality & Regulatory Compliance for Aramark Healthcare Technologies (the largest independent service organization in the US)
  - VP, Quality Assurance &Regulatory Affairs for MEDIQ/PRN Life Support Services, Inc. (the largest medical equipment company in the US)
  - Visiting scientist with the National Institutes of Health, and
  - Special Advisor on Medical Equipment to the Secretary of Health's in Sao Paulo state, Brazil
- Earned a Doctor of Science degree from the Massachusetts Institute of Technology (MIT) and is certified as a Clinical Engineer and ISO 9001 Auditor.
- Fellow of the American College of Clinical Engineering (ACCE) and American Institute of Medical & Biological Engineering (AIMBE).
- Received the 2010 Association for the Advancement of Medical Instrumentation (AAMI) Clinical/Biomedical Engineering Achievement Award and the ACCE Lifetime Achievement award in 2015. Inducted into CE Hall of Fame in 2017.

ABSTRACT

After dispelling the initial false alarm of electric shocks, the clinical engineering (CE) community spent decades attempting to develop rational methods to improve medical equipment maintenance at lower costs. Analyses of data collected in the USA and UK have proven that the amount of patient incidents caused by maintenance errors is much lower than the Six Sigma quality level sought by world-class manufacturing companies. Nevertheless, many government agencies and manufacturers are still skeptical that it is possible to maintain equipment safely and effectively without following strictly manufacturers' recommendations. Several methods of planning and evaluating maintenance strategies have been proposed and tested with limited success, such as "Risk-Based Criteria" and "Reliability-Centered Maintenance" (RCM). A new one is Evidence-Based Maintenance (EBM), which has been defined as "A continual improvement process that analyzes the effectiveness of maintenance resources deployed in comparison to outcomes achieved previously or elsewhere, and makes necessary adjustments to maintenance planning and implementation." EBM treats each piece of medical equipment as a "black box" and uses the scientific method of detecting different outcomes caused by varying inputs to choose the most appropriate maintenance strategy. By comparing the failures causes found during repairs and scheduled maintenance (outcomes) after the adoption of different maintenance strategies (inputs), CE professionals can determine the least resource intensive maintenance strategy without sacrificing equipment safety and reliability. Results of initial EBM studies have confirmed that most manufacturers' recommendations are excessive and unnecessary and, thus it is possible to obtain appreciable reductions in labor and parts costs.

CAUTION!

- I am here not to teach you but to share my experience. I know the Arabian reality and environment are often different from what we have in USA, so it would presumptuous for me to tell you to follow our American methods.
- Galileo Galilei said: “You cannot teach a man anything, you can only help him find it within himself.”
- Also some of my American colleagues may have different opinions from what I am presenting here. This will help you gain different perspectives.
- You should understand why we Americans do what we do and, then, take the applicable portions and adapt them to your own reality. Above all, try to avoid the mistakes we made.
- Imitating Alexander Pope who said “to err is human; to forgive, divine.” I would say “to learn from one’s own mistakes is smart; to learn from those made by others, sublime.”

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- Prior Maintenance Strategies
  - Risk-Based Criteria
  - Reliability-Centered Maintenance
- Evidence-Based Maintenance
  - Scheduled Maintenance
  - Corrective Maintenance
  - Maintenance Evaluation
- Discussion & Conclusions

Risk-Based Criteria (Fennigkoh & Smith model - 1989)

- "Sanctioned" by The Joint Commission (TJC) and, thus, widely adopted
- Each piece of equipment is given a value, Equipment Management (EM) number:

EM = Function + Physical Risk + Maintenance Requirements

- If EM $\geq$ 12, the equipment is included in the equipment management program. Otherwise, it is excluded.
- Maintenance strategy
  - Excluded equipment: repaired as needed
  - Included equipment: "preventive" (scheduled) maintenance, monthly, quarterly, semi-annually or annually, according to the EM value

Fennigkoh L & Smith B (1989), Clinical equipment management JCAHO PTSM Series, 2:5-14

Fennigkoh & Smith's Approach

CRITERIA	CATEGORY	SUBGROUP	NUMERICAL VALUE
Function	Therapeutic	Life support	10
		Surgical and intensive care	9
		Physical therapy and treatment	8
	Diagnostic	Surgical and intensive care monitoring	7
		Additional Physiological monitoring and diagnostic	6
	Analytical	Analytical laboratory	5
		Laboratory accessories	4
		Computer and related	3
	Miscellaneous	Patient related and other	2
Physical Risk		Patient death	5
		Patient or operator injury	4
		Inappropriate therapy or misdiagnosis	3
		No significant risks	1
Maintenance Requirements		Extensive	5
		Average	3
		Minimal	1

Challenges of Risk-Based Criteria

- Both "Function" and "Physical Risk" are estimates of "risk severity" without considering "risk probability"
- ISO 14971 defines risk as

Risk := Probability & Severity [of harm]

- Even ISO 14971 is incomplete because it ignores
  - "Scope" of harm, i.e., the number of patients potentially affected
  - The "probability" must consider all the stakeholders who has a role in the deployment and use of technology, i.e., the Swiss-cheese model of failure (J. Reason, 1997)

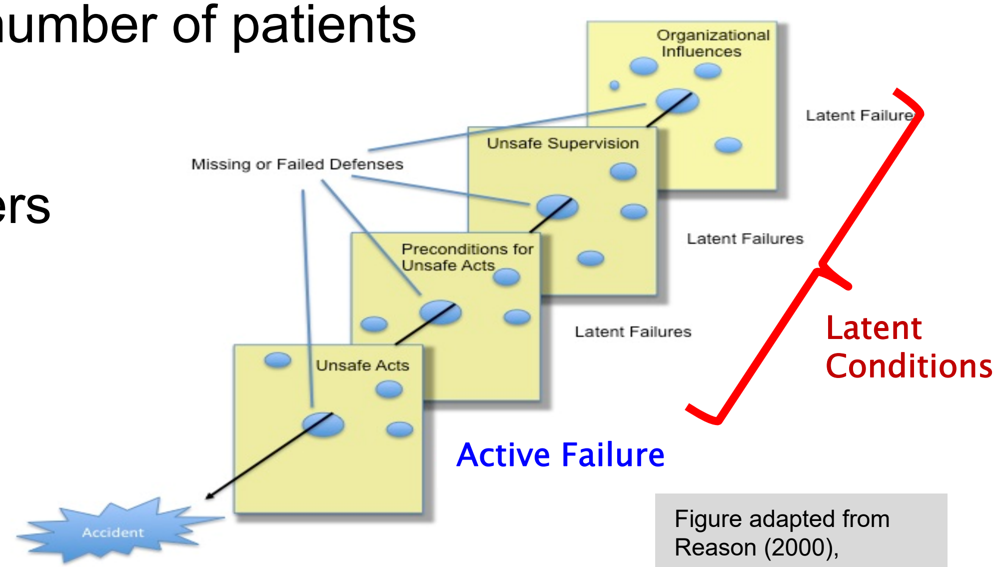


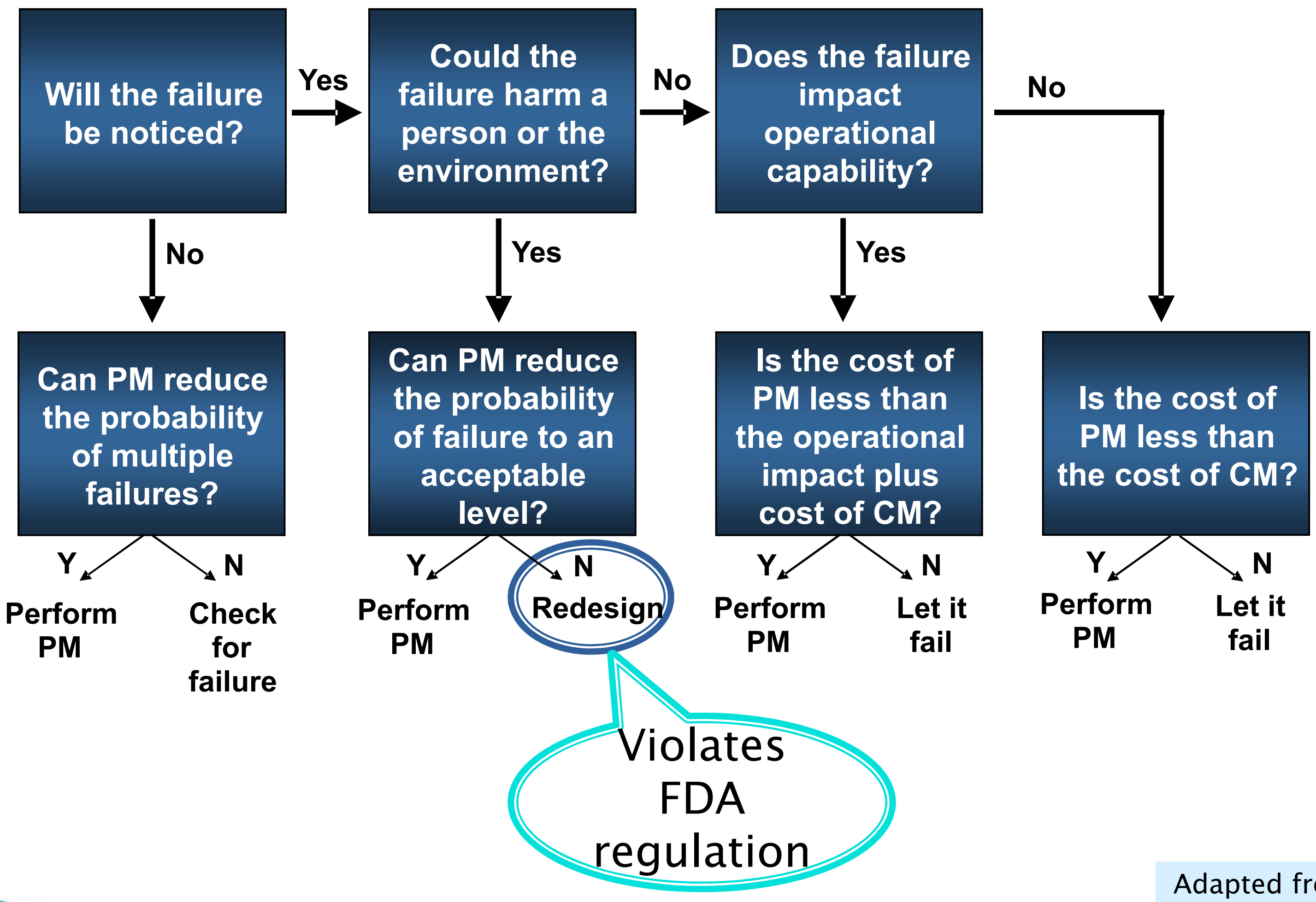
Figure adapted from Reason (2000),

Reliability-Centered Maintenance (RCM)

- RCM is "*a process used to determine what must be done to ensure that any physical asset continues to do what its users want it do to in its present operating context*."
- RCM allows one to improve asset performance and, at the same time, contain and even reduce the cost of maintenance.

Ref.: Reliability-Centered Maintenance Moubray, 1997

RCM Decision Process



Adapted from Moubray, 1997

RCM Process & Challenges

- Planning
  - Asset selection
  - Characterization of function & failure patterns
  - Failure mode and effect analysis (FMEA)
  - Decision process
  - Develop performance measures
  - Define maintenance schedules & work instructions
  - Staff training
- Implementation
  - Implement adopted strategies
  - Maintenance data collection
- Evaluation
  - Evaluate maintenance performance
  - Use evaluation results to revise & update strategies

FM&E unknown due to closed software

Difficult without OEM assistance

Do OEMs readily provide service manuals in Arab countries?

Contents

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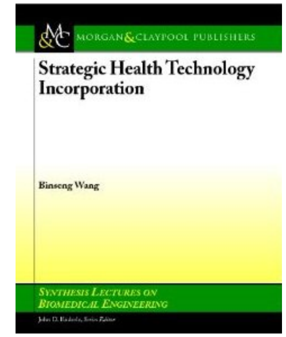

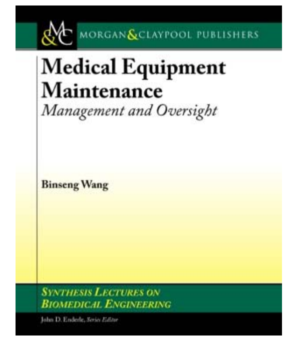

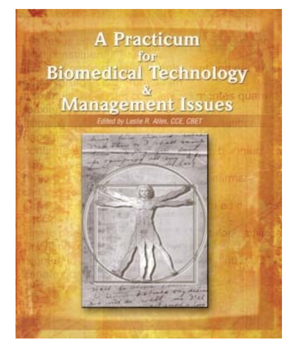

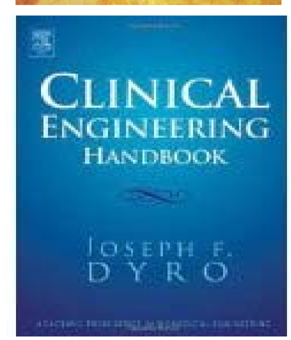

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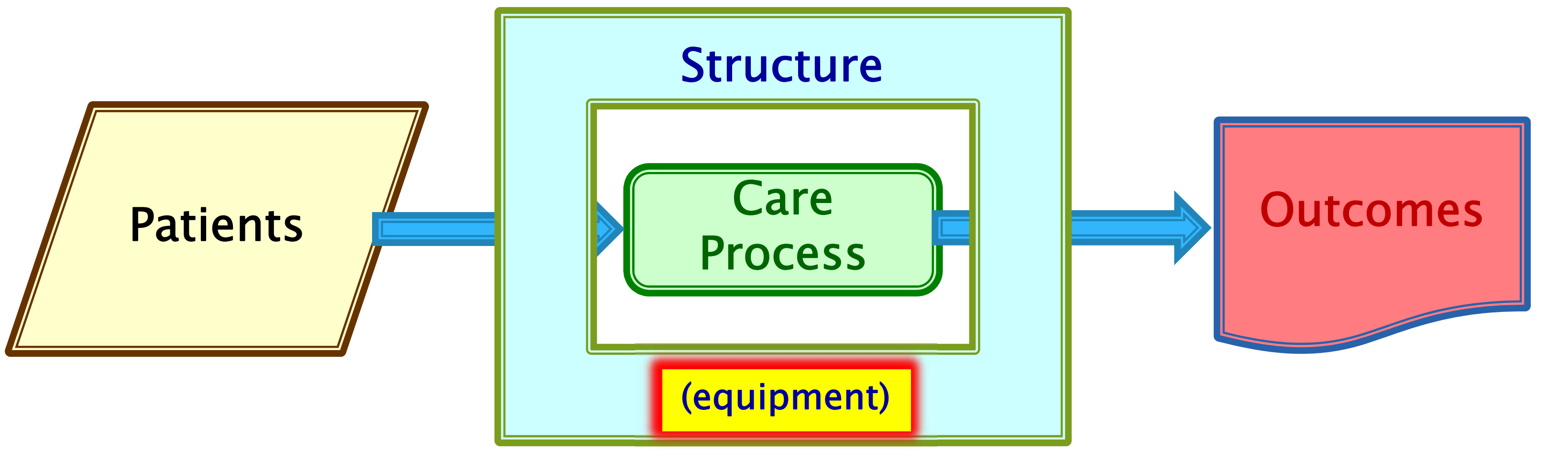
The Scientific Method

- First formally proposed by someone who said "Eppur si muove" (and yet it does move) and followed by others
  - Galileo Galilei (1564-1642)
  - Francis Bacon (1561-1626)
  - René Descartes (1596-1650)
- But it is probably much older
  - Some claim it actually goes back to Hippocrates (460-370 bce)
  - Carl Sagan said it is actually in our genes after >tens of thousand years of evolution

Donabedian’s Care Quality Model



STRUCTURE	CARE PROCESS	OUTCOME

• Material Resources (building, equipment, etc.)
• Human Resources (personnel # & qualification)
• Organizational Structure
	• Patients & care takers: seeking or carrying out care
	• Providers:
	  • Diagnosis
	  • Therapy
	  • Other services
		• Improvement in patient’s knowledge and behavior
		• Patient satisfaction with care

Source: Donabedian A. Evaluating the quality of medical care. *Milbank Quart.,* 44:186-203,1966.

Evidence-Based Maintenance – EBM

PROPOSED DEFINITION

A continual improvement process that analyzes the effectiveness of maintenance resources deployed in comparison to outcomes achieved previously or elsewhere, and makes necessary adjustments to maintenance planning and implementation.

Tackle = Structure

Fishing = Process

Catching = Outcome

Scheduled Maintenance (SM)

- Also known as
  - Planned maintenance
  - Preventive or preventative maintenance
  - Pro-active maintenance
  - Inspection and preventive maintenance (IPM)
- Goal
  - **Enhance reliability of equipment** => increase availability of equipment ("reliability") => improve patient safety & care
- Objectives
  - Reduce preventable failures => Preventive maintenance (PM)
  - Detect failures in progress => Inspection (for potential failures)
  - Detect hidden failures => Inspection (for hidden failures)

Corrective Maintenance (CM)

- Also known as
  - Unscheduled maintenance
  - Repairs
  - Reactive maintenance
- Goal
  - Restore equipment safety and/or functionality as soon as possible => increase availability of equipment ("reliability")
- Objectives
  - Reduce "down time"
  - Detect failure causes and determine future possible preventive actions => Preventive maintenance (PM) enhancement
  - Detect failures in progress => Inspection (for potential failures)
  - Detect hidden failures => Inspection (for hidden failures)
- Thus a full scale inspection (not PM) is required after each (functional) repair to ensure that equipment is safe and performing according to its original specifications.

SM Accreditation Requirements

- All devices included in inventory
- All devices maintained per manufacturers' recommendations unless placed under Alternative Equipment Management (AEM) program, with exception of imaging, lasers, and "new" equipment
- SM completion rate of 100% for both critical/high risk and non-critical/non-high-risk (**2017 CMS/TJC requirement**)
- Only equipment under AEM is required to be evaluated for
  - Safety
  - Effectiveness

NOTE: AEM is a concession granted by US government (CMS) for hospitals that do not want to follow manufacturers' recommendations.

Maintenance Evaluation

- Primary goals of equipment maintenance (including SM)
  - Safety: equipment is safe for patients and clinical users
  - Reliability: equipment is available for use whenever needed
- Therefore:
  - **Safety Evaluation**: determine if the maintenance strategy is enhancing the safety of patients and clinical users (i.e., reduce equipment malfunctions that negatively affect patients and clinical users)
  - **Reliability Evaluation**: determine if the maintenance strategy is enhancing the reliability of equipment and, thus, the care of patients (i.e., making equipment more available for use when needed)

Safety

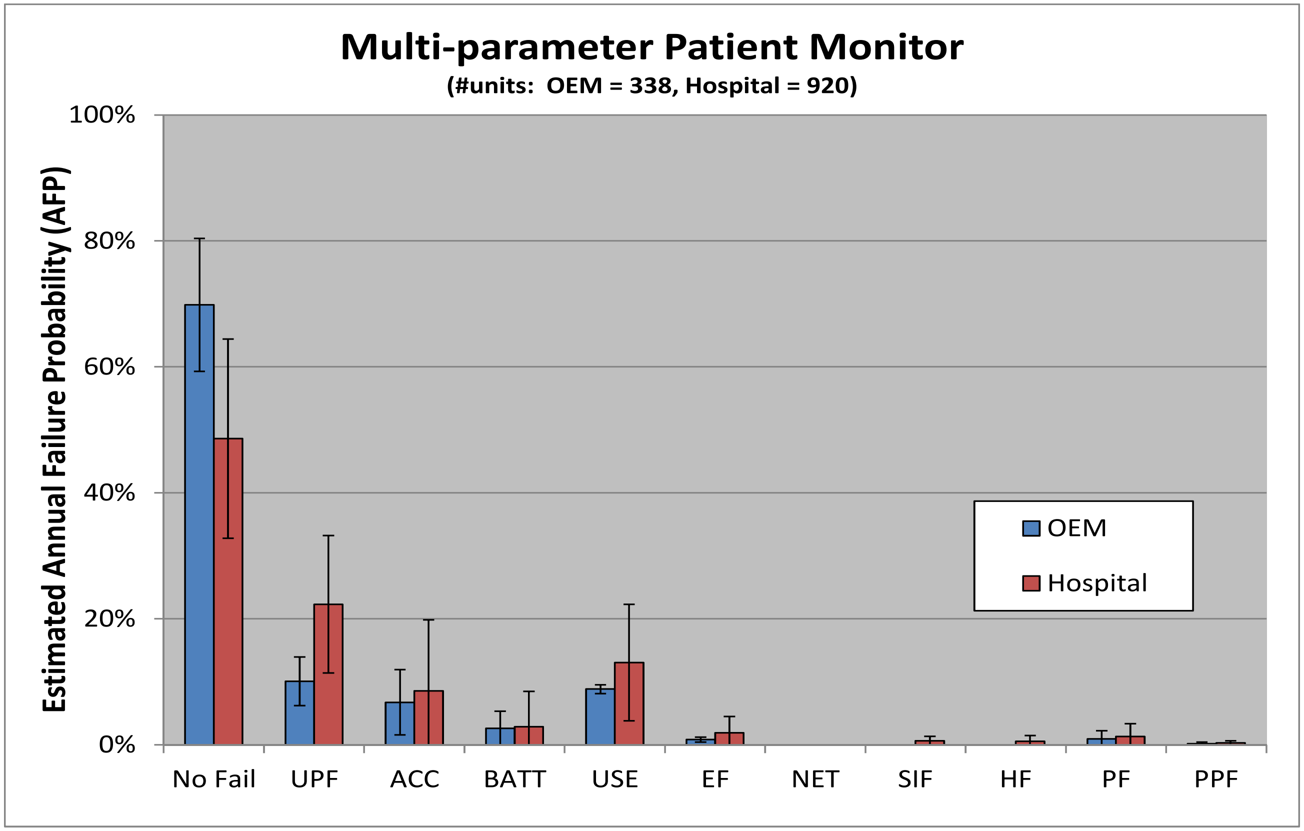
Effectiveness = Reliability

Failure Cause Codes (FCC)

Code	Failure Cause Description	SM/CM
NPF	No problem found (or the reported problem was not duplicated).	both
UPF	Unpreventable failure, typically caused by normal wear and tear but is unpredictable.	CM
ACC	Accessory failure, excluding batteries, typically caused by normal wear and tear.	both
BATT	Battery failure, i.e., battery(ies) failed before the scheduled replacement time. Does not include scheduled replacement of batteries.	both
NET	Failure in or caused by network, while the equipment itself is working without problems. Applicable only to networked equipment.	both
USE	Failures induced by use, e.g., abuse, abnormal wear & tear, accident, or environment issues.	CM
EF	Evident failure, i.e., a problem that can be detected, but was not reported by the user, without running any special tests or using specialized tester.	SM
SIF	Service-induced failure, i.e., caused by CM or SM that was not properly completed or a part that was replaced and failed prematurely ("infant mortality").	CM
HF	Hidden failure, i.e., a problem that could not be detected by the user under normal circumstances, unless running a special test or using specialized tester.	SM
PF	Potential failure, i.e., failure is either about to occur or in the process of occurring but has not yet caused equipment to stop working or problems to patients or users.	SM
PPF	Preventable and predictable failure, typically caused by wear and tear that can be predicted or detected.	CM

Maintenance Effectiveness Evaluation with EBM

- Alternative Equipment Management (AEM) compared to manufacturers' recommendations (OEM)



Safety Evaluation with EBM

- Record all patient incidents (including "close calls" or "near misses"), including those involving lasers, imaging/radiologic, and laboratory equipment
- Investigate all incidents and perform root-cause analysis (RCA)
- Classify RCA conclusion with a "**failure cause code**" (FCC)
- For incidents assigned with codes SIF, HF, PF or PPF (potential maintenance omissions), determine the underlying cause
  - "unsafe acts" (or "active failures") committed by individual staff (employed by hospital, OEM, or third party), e.g., lapses or slips
  - "latent conditions" created by the organization due to oversight or deliberate violation of regulations, codes or standards.

Accident and Operational Safety Analysis – US DOE Handbook, 2012
https://energy.gov/sites/prod/files/2013/09/f2/DOE-HDBK-1208-2012_VOL1_update_1.pdf

James Reason's Swiss Cheese Model

A way to visualize the redundancy approach to reduce probability of harm has been proposed by Prof. James Reason using slices of Swiss cheese to represent individual protective mechanisms.

$$\textbf{risk = probability * severity}$$

The introduction of individual protective mechanisms changes the equation above to:

$$\text{risk}=\left(\prod_i P_i\right)*\text{severity}$$

where Pi denotes the "cheese slice" #i's probability of harm (failure)

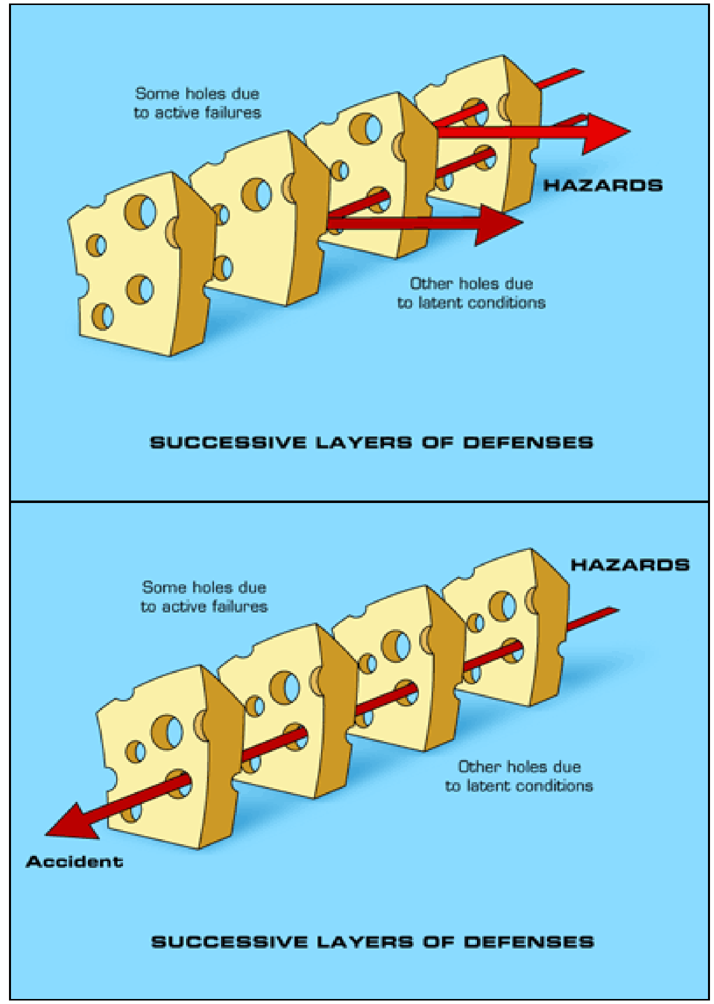


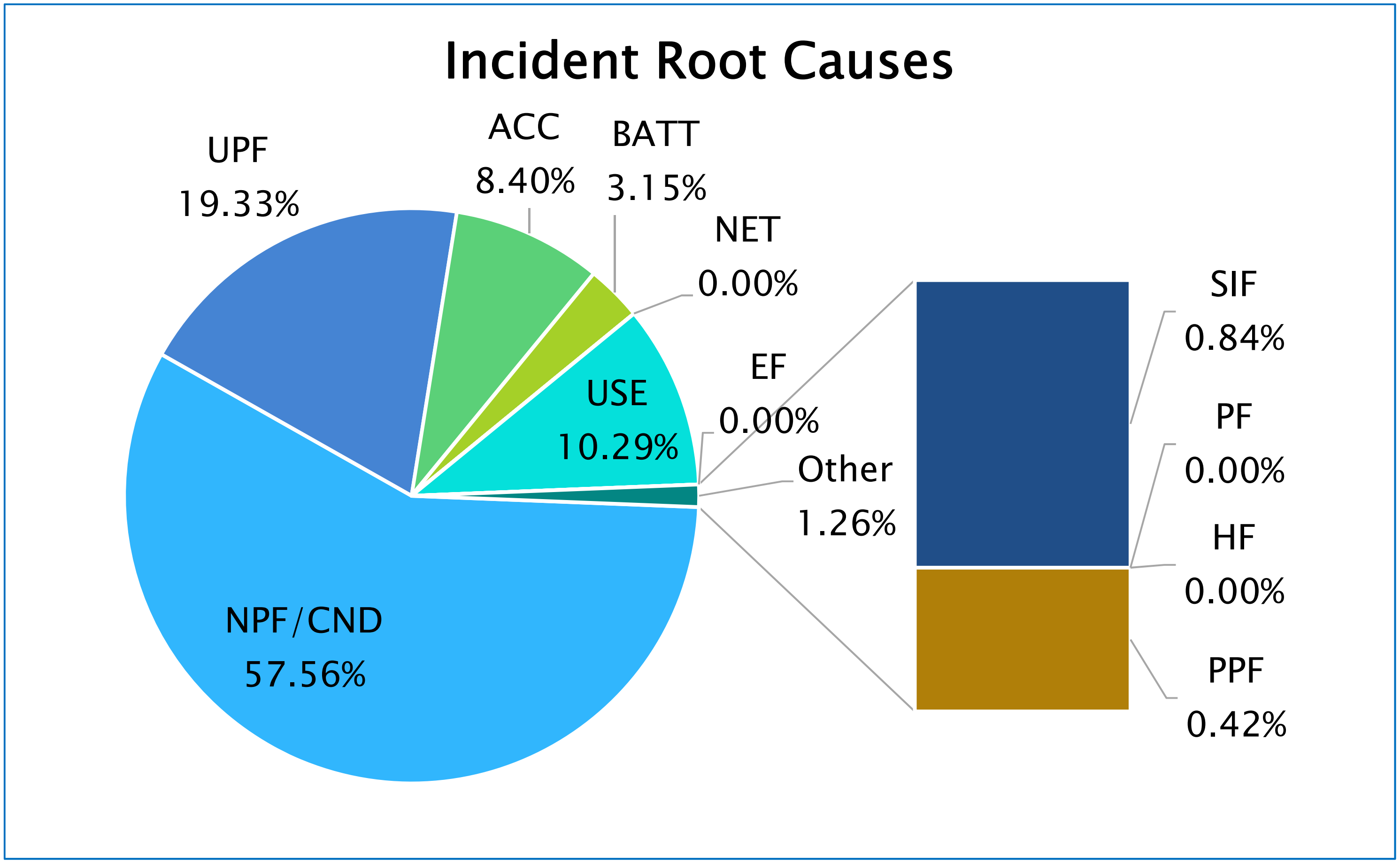
Figure adapted from Reason (2000), Duke Univ. MC patientsafetyed.duhs.duke.edu/module_e/swiss_cheese.html

An Example of Safety Evaluation

Data Type	YEAR 2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Decade Total	%
# incidents reports received	31	28	47	46	48	49	62	88	58	61	**518**	NA
# incidents investigated	28	26	39	36	41	48	61	84	53	60	**476**	**91.9%**
# investigated incidents with harm, including deaths (to patient or user)	12	11	16	21	11	21	23	38	17	27	**197**	**41.4%**
# investigated incidents with deaths	6	5	4	8	7	9	9	12	7	7	**74**	**15.5%**
# investigated incidents with deaths but no equipment or accessory failures	5	4	2	4	4	7	9	8	3	5	**51**	**10.7%**
# investigated incidents traced to equipment or accessory failures	14	8	14	19	19	24	22	31	21	30	**202**	**42.4%**
# investigated incidents potentially related to maintenance omission	1	0	0	1	0	2	0	0	1	1	**6**	**1.3%**
# equipment managed	694,148	827,503	944,449	942,006	920,109	895,064	905,747	1,195,054	1,176,401	1,182,936	9,683,417	
# SM performed	555,318	662,002	755,559	753,605	744,209	726,933	768,669	935,020	885,629	905,955	7,692,900	
# repairs performed	277,659	331,001	377,780	376,802	358,546	359,177	364,629	455,046	474,211	473,016	3,847,868	

Data collected by Aramark Healthcare Technologies and presented at MD-Expo Oct. 2014

An Example of AEM Safety Evaluation



Code
NPF
UPF
ACC
BATT
NET
USE
EF
SIF
HF
PF
PPF

Data collected by Aramark Healthcare Technologies and presented at MD-Expo Oct. 2014

An Example of Safety Evaluation

- Safety Results Compared with Other Data Sources
  - TJC Sentinel Event RCA: 0.024-0.286 DPMO or 6.5-6.96 sigma level (Wang et al., BIT, 2013*)
  - World-class manufacturing companies goal: 3.4 DPMO or 6 sigma
  - Flight Safety Foundation's "risks to passengers" on commercial aviation in 2015: 2.8 DPMO or 6.04 sigma (world)**
- Safety Evaluation – Conclusion
  - One decade performance of 0.26-0.35 DPMO or 6.46-6.52 sigma[§] is substantially better than the six-sigma level sought by world-class manufacturing organizations, and **comparable to the safety record attained by the best commercial aviation carriers around the world**[§]

* Wang B, Rui T & Balar S. An estimate of patient incidents caused by medical equipment maintenance omissions, Biomed Instrum & Techn., 47:84-91, 2013
§ Data collected by Aramark Healthcare Technologies and presented at MD-Expo Oct. 2014
** https://flightsafety.org/asw-article/accidents-fatalities-down-in-2015/

Reliability Evaluation with EBM

- Assign a "failure cause code" (FCC) for all scheduled maintenance (SM) and repair workorders
- Determine the amount of SIF, HF, PF and PPF found
- Determine within each of these 4 FCCs the number of equipment groups (i.e., same brand and model, and similar ages, utilization location and intensity, and users)
- Look for the equipment groups with "unusually" high #FCCs per group, especially PPFs
- For these groups, determine the underlying cause
  - "unsafe acts" (or "active failures") committed by individual staff (employed by hospital, OEM, or third party), e.g., lapses or slips
  - "latent conditions" created by the organization due to oversight or deliberate violation of regulations, codes or standards.
- If >50% of the FCCs analyzed is due to "latent conditions," then determine whether it is caused by the adoption of AEM strategy, i.e., a maintenance frequency and/or procedure different than those recommended by the respective manufacturer. If so, revise it.

An Example of Reliability Evaluation

- Data Analyzed
  - Single hospital group (3 sites)
  - 3 years: 2012-2014
  - Inventory: ~7,900 units

	total	per year	CM/PM rate
CMs	5381	1794	23%
PMs	11012	3671	46%

- FCC Analysis
  - Few SIF, HF, PF and PPF
  - However, one equipment group had several HF (9 out of 65 units) => further review needed
    - Most due to premature component wear out not subject to OEM-recommended SM
- Conclusion: Revise SM strategy by increasing frequency higher than the recommended by OEM

Code	#WO	Equip Groups
SIF	6	6
HF	16	7
PF	4	4
PPF	7	5

Use of EBM Evaluations

- Results of Maintenance Strategy, Safety and Reliability Evaluations should be used to revise and refine SM and CM strategies, i.e., to determine corrective & preventive actions (CAPA)
  - CAPA for “unsafe acts” (or “active failures”) committed by individual staff:
    - Training
    - Revision of work instructions
    - Disciplinary actions
  - CAPA for “latent conditions” created by the organization
    - **Revision of SM/CM strategies** (procedures, frequencies, work instructions, etc.)
    - Supervision of in-house and external service staff

Plan=>Do=>Check=>Act

Contents

- Prior Maintenance Strategies
  - Risk-Based Criteria
  - Reliability-Centered Maintenance
- Evidence-Based Maintenance
  - Scheduled Maintenance
  - Corrective Maintenance
  - Maintenance Evaluation
- Discussion & Conclusions

Discussion & Conclusions

- Data analysis (Wang et al., BIT 2013) show SIF is very rare
- Most maintenance errors are caused by active failures (human) instead of latent conditions (maintenance strategy) => no reason to revert to OEM recommendations
- True PM is becoming obsolete with technology advance and will NOT provide job security
- The EBM methodology can be applied to all modalities (biomed, imaging, lab) of equipment => no reason to follow OEM recommendations for imaging & laser equipment
- University Hospital of Careggi in Florence, Italy, in collaboration with the University of Firenzi, has reproduced our results using EBM and found opportunities to improve maintenance (of defibrillators)

Discussion & Conclusions (cont.)

- Accurate and reliable EBM data needed to prove that we are keeping equipment SAFE and RELIABLE are difficult to collect.
- Should we give up simply because it is difficult?!
- President Kennedy said : "We choose to go to the moon in this decade and do the other things, not because they are easy, but because they are hard, because that goal will serve to organize and measure the best of our energies and skills…"

- Data analyzed shows that **it is possible to do the RIGHT maintenance RIGHT and at the lowest possible costs!**

President JF Kennedy's Address at Rice University on the Nation's Space Effort, September 12, 1962

Acknowledgements

- Hundreds of my former colleagues at Aramark Healthcare Technologies provided the data presented here. Dr. Malcolm Ridgway, Jared Koslosky, Jim Fedele, Salil Balar and many others contributed to the concepts presented here. Torgeir Rui was responsible for most of the data analyses.
- Several other healthcare organizations and independent service organizations have started also to implement EBM.
- However, I am solely responsible for all the mistakes and confusion in this presentation.
- Bassam Tabshouri (AUB) helped to review and improve this presentation.

Thank you! شكرا!

- Thank you again for inviting me and hope you will learn from the mistakes that my American colleagues and I have made and take clinical engineering to the next level!
- Please contact me if you have any questions, comments or suggestions
  - Binseng Wang
  - binseng@alum.mit.edu