

Risk Management In Healthcare





Improve Patient Safety in Healthcare by Applying Proven Methods From Other Industries That Were Designed Specifically to Identify and Reduce Risk.



Aerospace

- Military Standards
- Federal Specifications
- Aerospace Specifications



Automotive

- Automotive Industry Action Group (AIAG)
- Society of Automotive Engineers (SAE)
- International Organization of Standards (ISO)



Healthcare

- Joint Commission on the Accreditation of Health Organizations (JCAHO)
- Medicare - Hospital Acquired Conditions (HAC) October 1, 2008.





To Meet These Standards We Have Various Quality Tools:

- Failure Mode & Effects Analysis (FMEA)
- Root Cause Analysis (RCA)
- Value Analysis / Value Engineering (VA / VE)
- Fault Tree Analysis (FTA)
- Total Quality Management (TQM)
- Standardized Work
- Six Sigma

Let's Look At FMEA...





...Failure Mode and Effects Analysis (FMEA)

What Is FMEA?

- A Tool To Manage Risk
- Recognizing And Evaluating Potential Failures Of A Design, Process, Or Application And Their Effects
- Identifying Actions That Can Eliminate The Failures Or Reduce The Rate Of Occurrence
- Documenting The Process

FMEA Is A Proactive - Not A Reactive Quality Tool

Why Do FMEAs?.



Because...

The “Easy Stuff” is Already
Being Done!

What Do We Get With FMEAs?.





In Aerospace:

- Safer Missions

FMEA Analysis:

- Redundant Design Features
- Failsafe Back-up Systems
- Applying Design Margins And Safety Factors.





In Automotive:

- Improved Quality
- Improved Safety
- Lower Warranty Costs
- Improved Customer Satisfaction
- Increased Market Share



FMEA Analysis by PlanTech:

- Moving From Physical Testing To Making Design Improvements
- Moving From Inspection To Error Proofing And Ultimately Making Design And Process Improvements
- Design Review Based On Failure Modes – Managing Change.



In Healthcare:

- Improved Safety
- Improved Quality
- Reduced Costs
- Reduced Expenses
 - Hospital Acquired Conditions (HAC)
 - Unreimbursed

FMEA Analysis Can Help:

- Identify and Apply Best Practices
- Capture Lessons Learned
- Manage Knowledge
- Meet Medicare HAC Requirement.





The FMEA Process



Function / Perf Req	Potential Failure Mode	Potential Effect of Failure	S E V	Potential Cause / Mech of Failure	O C C	Current Controls (P) & (D)	D E T	R P N	Rec Action
<p>What is the process supposed to do?</p> <p>• What requirements must the process meet?</p> <p>• What makes a good process?</p>	<p>How we fail to meet the process intent.</p> <p>• What went wrong</p> <p>• Must relate to the process step / performance requirement</p> <p>• Consider Multiple Failure Modes</p>	<p>The effect of the failure on the patients</p> <p>• Describe as a symptom</p> <p>• Include effect on safety and government regulation</p>	<p>How Serious the Effect of Failure is</p> <p>• Scale of 1 - 10</p> <p>1 not serious 10 very serious</p> <p>• Best to use a standard scale tailored to your requirements</p>	<p>An indication of misuse; results in the Failure Mode</p> <p>• Be specific No "medical error" or "Equipment Malfunction"</p> <p>• Must be correctable and controllable</p> <p>• Do not group causes</p> <p>• Always look for multiple Causes</p>	<p>The probability that the Cause will occur</p> <p>• Scale of 1 - 10</p> <p>1 hardly occurs 10 Occurs frequently</p> <p>• Best to use a standard scale tailored to your requirements</p>	<p>Controls that are currently in place</p> <p>• D = Things that detect Causes & / or Failure Modes</p> <p>• P = Things that prevent Causes & / or Failure Modes</p>	<p>Ranking for the most capable Detection control</p> <p>• Scale of 1 - 10</p> <p>1 very good detection 10 no detection</p> <p>• Best to use a standard scale tailored to your requirements</p>	<p>S x O x D</p> <p>Risk Priority Number</p> <p>• Measure of risk</p> <p>Will be between 1 and 1000</p> <p>• The higher the RPN the higher the risk</p>	<p>Actions to decrease the risk</p> <p>• Over what is normally done</p> <p>• Must be Actionable and Executable</p>



Function Perf Req	Potential Failure Mode	Potential Effect of Failure	S E V	Potential Cause / Mech of Failure	O C C	Current Controls (P) & (D)	D E T	R P N	Rec Action
Reduce the risk of retained foreign objects	Not separating sponges, sutures when counting	Wrong count, last count should be wrong if not counted at first, retained foreign object	9	Not visualizing each individual piece by both circulating RN & CST, Being in a hurry, not knowing the policy	3		8	216	Train new staff & students on correct method of surgical counts Educate staff in department mtgs / skills lab

Better

All foreign objects Removed after Surgery No foreign object left	Retained foreign Object - Sponge	HAC—lost revenue due to non-reimbursed expense (8) Infection (9) Worse (10)	10	Failure to reconcile all foreign objects post surgery	2	Post surgical physical counts (8) Training (P) SOP / WI (P)	8	160	Implement post-surgical scan
All foreign objects Removed after Surgery No foreign object left	Retained foreign Object - Sponge	HAC—lost revenue due to non-reimbursed expense (8) Infection (9) Worse (10)	10	Foreign objects miscounted	3	Post surgical physical counts (8) Training (P) SOP / WI (P)	8	240	Add redundant object counts (numbered) Add post-surgical Checklist Implement post-surgical scan
All foreign objects Removed after Surgery No foreign object left	Retained foreign Object - Sponge	HAC—lost revenue due to non-reimbursed expense (8) Infection (9) Worse (10)	10	Surgery running late counter hurrying	1	Post surgical physical counts (8) Training (P) SOP / WI (P)	8	80	Implement post-surgical scan



Function Perf Req	Potential Failure Mode	Potential Effect of Failure	S E V	Potential Cause / Mech of Failure	O C C	Current Controls (P) & (D)	D E T	R P N	Rec Action
Reduce Medication Errors	Administered to wrong patient	Serious ADR or death	8	Nurse failed to verify drug to be administered	2		1	16	Training for all nurses on 5 rights for med. admin. Ensure implementation of patient I.D. prior to admin. meds.

Better

Administer medication Correct medication Correct dose Correct patient Admin on time	Medication administered to wrong patient	Minor Discomfort (6) Patient becomes Sick (7) HAC – lost revenue due to non-reimbursed expense (8) Serious ADR or death (10)	10	Nurse failed to verify patient to be administered	2	None (10)	10	200	Implement Patient monitoring. i.e. blood pressure Implement patient bar coding
Administer medication Correct medication Correct dose Correct patient Admin on time	Medication administered to wrong patient	Minor Discomfort (6) Patient becomes Sick (7) HAC – lost revenue due to non-reimbursed expense (8) Serious ADR or death (10)	10	No cross- check of patient identification	2	Visual (8)	8	100	Implement Patient monitoring. i.e. blood pressure Implement patient bar coding



Function Perf Req	Potential Failure Mode	Potential Effect of Failure	SEV	Potential Cause / Mech of Failure	OCC	Current Controls (P) & (D)	DET	RPN	Rec Action
Infection control sheet filled out.	Unnecessary Inappropriate Precaution	Risk spread of Infection in the dept. Becomes overwhelmed with unnecessary precautions, tend to be ignored, necessary ones too.	2	Inadequate assessment info and time to decide.	8		8	128	Ask questions in step 1 to protect Triage nurse but complete infection control form in step 4

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Infection control sheet filled out. Filled out Correct info Correct spelling On time Legible	Infection Control Sheet not filled out	Risk of infection (7) Infection spreading to other areas of hospital (7) Visitors become infected (8) HAC – lost revenue due to non-reimbursed expense (8)	8	Nurse fails to fill out sheet	8	Visual (8)	8	512	Add redundant check with checklist
Infection control sheet filled out. Filled out Correct info Correct spelling On time Legible	Infection Control Sheet has Incorrect information	Risk of infection (7) Infection spreading to other areas of hospital (7) Visitors become infected (8) HAC – lost revenue due to non-reimbursed expense (8)	8	The patient's chart is mis-read	4	Visual (8)	8	256	Add redundant check with checklist



- Medicare no-pay rule for 10 non-reimbursable conditions becomes effective October 1, 2008
- New policies including wrong surgery, wrong patient, wrong body part to be added in April 2009
- Evidence-based prevention standards required for each no-pay condition
- Data required to show compliance
- Third party review of events
- Plans to expand HAC outside the inpatient setting
- ISO - *“Say What You Do, Do What You Say, Prove It”*.



Our Organization

- Tom Prose, MD, MPH, MBA – Chief Healthcare Expert – 20 Years Experience
- Jim Bongiorno – PMP, BSEE - Project Manager, Engineer, Business Owner – 35 Years Experience
- Bob Myers – BS, Managing FMEA Consultant – 30 Years Experience.
- Our FMEA Consultant Facilitators Are Certified.



Over 30 Years Industry Experience

- Automotive OEM's and Supply Chain
- Medical Device Manufacturers
- Aerospace And Defense
- Electronics
- Retail

Over 10 Years of FMEA Experience

- Design, Process, Machinery, Logistics and Safety.



Proven Methodology:

- Obtain Management Sponsorship
- Define Project And Scope
- Identify The Team
- Review Functions And Requirements
- Conduct Kick-off Meeting
- Standardize Rankings Scales
- Initiate Meeting & Conduct JIT Training
- Facilitate The FMEA And Summarize Meeting
- Reviews With Sponsor
- Archive The Results
- Risk Reduction / Continuous Improvement.



Our Enablers for Success

- The Right People
 - Certified Consultant Facilitators
 - Knowledge / Skills / Attitude
- Doing The Right Things
 - Standard Methods
 - Proper Focus
- Doing Things Right
 - Focus On Quality And Metrics
 - Quality / Cost / Throughput.



Typical FMEA Approach

- Projects Pushed Haphazardly
- High Cost To Complete
- Poor Quality Due to a Lack of Standards
- No Common Methodologies
- Wasted Management Effort
- Weak Recommended Actions and /or Not Implemented
- Metrics Not Established

**RESULTING
IN LITTLE
OR NO
VALUE.**



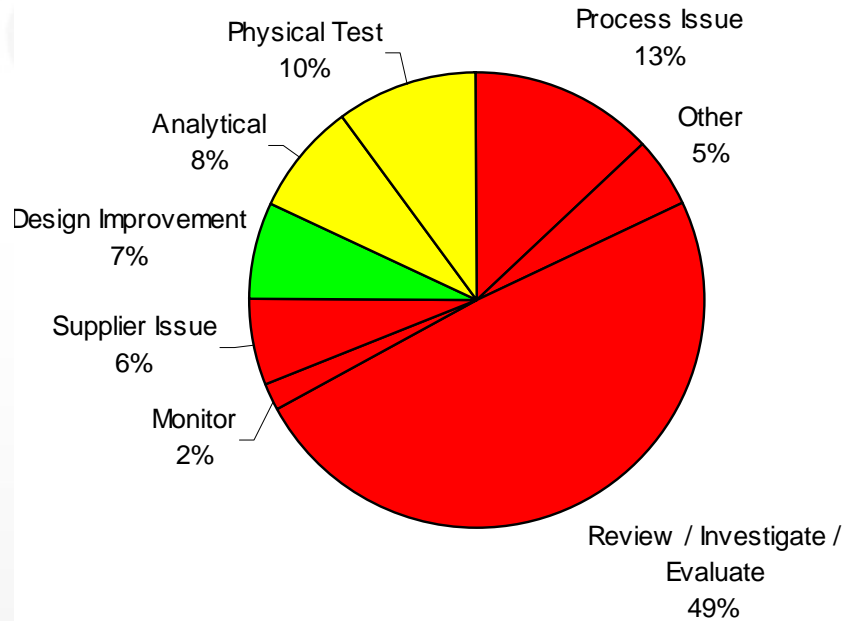
PlanTech's FMEA Service

- Planned Continuous Flow of Work
 - Increased Throughput By 50%
- Reduced Cost - 30% Reduction
- Improved Quality due to Standardization
- Prescribed Methodology
- Management Becomes Sponsors
- Effective Recommended Actions Implemented
- Metrics Instituted
 - Quality
 - Throughput
 - Planned vs Actual

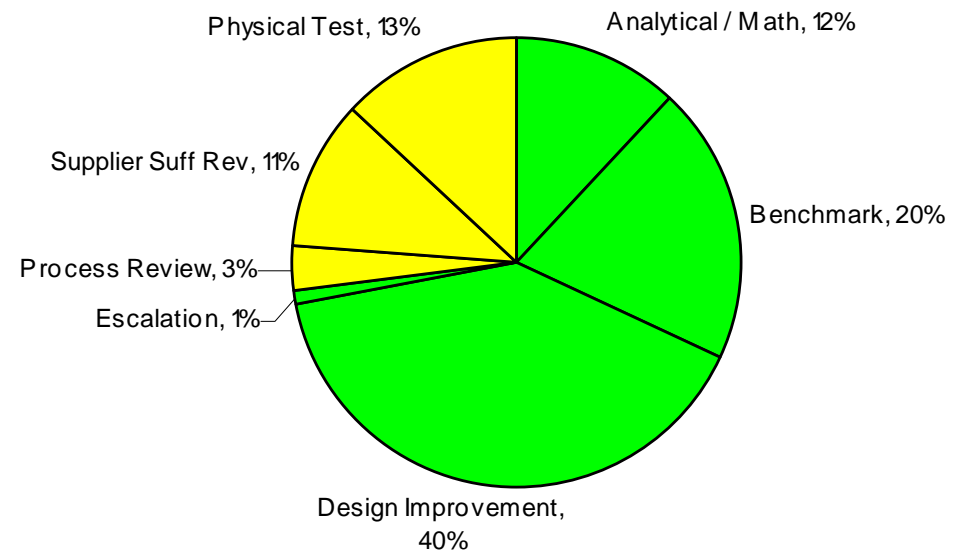
**RESULTING
IN
HIGH VALUE.**



Waste – Before



Value - After





- Impartiality To Technical Content And Historical Biases
- Structure
 - Common FMEA Methodology and Standards
 - Focused Meeting Time
- Robust Team Participation
- Effective use of Healthcare Expertise
- Certified FMEA Consultant Facilitators.



FMEA Drives Organizational Change

- Reduced Calibration (Algorithm) Failures Through FMEA Application
 - Engine Control Modules
 - Transmission
 - Body Controls
 - Electric Vehicles
- Biased (SOD) Ranking Scale Standards
 - Encourage Design Improvements
 - Reduce Physical Testing
 - Increased Error Proofing and Improved Controls
- Improved Product Reliability And Durability
 - Effective Recommended Actions
 - Design Review by Failure Mode.



- Select Project and Scope (HAC?)
- Assign and Train Team Members
- Identify Process Steps And Functions
- Customize Risk Rankings (SOD)
- Analysis:
 - Risk Event (Failure Mode)
 - Consequence (Effect)
 - Contributory Factor (Cause)
 - Mitigation (Controls / Recommended Actions)
- Archive (Best Practices)
- Continuous Improvement.



- Consulting / Training
- Facilitation
- Staff Augmentation
 - Healthcare Technical
 - FMEA Professionals
- Software
 - FMEA
 - FMECA
 - HFMEA
 - 10 X 10 Risk Matrix and Analysis
- Managed Services
 - Outsourcing.



Contact PlanTech

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