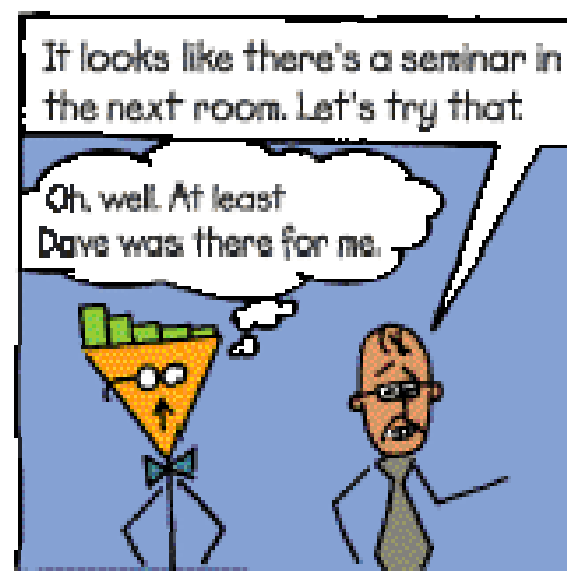
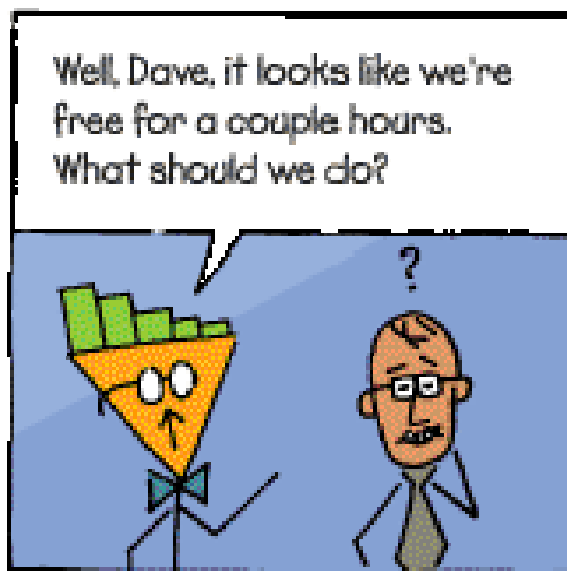


Risk Reduction in Healthcare

Healthcare System Solutions
Lean Six Sigma Black Belt





Mr. Pareto Head courtesy of [Quality Progress magazine](#)

How do you manage risks today?

- Option 1: “We don’t have any risks”
- Option 2: “Hopefully, nothing bad happens today”
(hopeful thinking, knock on wood)
- Option 3: “Everybody needs to be careful all the time!”
- Option 4: “If you make a mistake, we’ll fine/discipline/fire you!”
- Option 5: “We had a meeting and discussed the chance that <insert risk here> could happen, so go communicate to everyone”
- Option 6: “We brainstormed what could happen, and we took some actions to minimize the chance”
- Option 7: “We developed a risk assessment of our process, and have an ongoing action plan and cadence to address the highest prioritized risks”

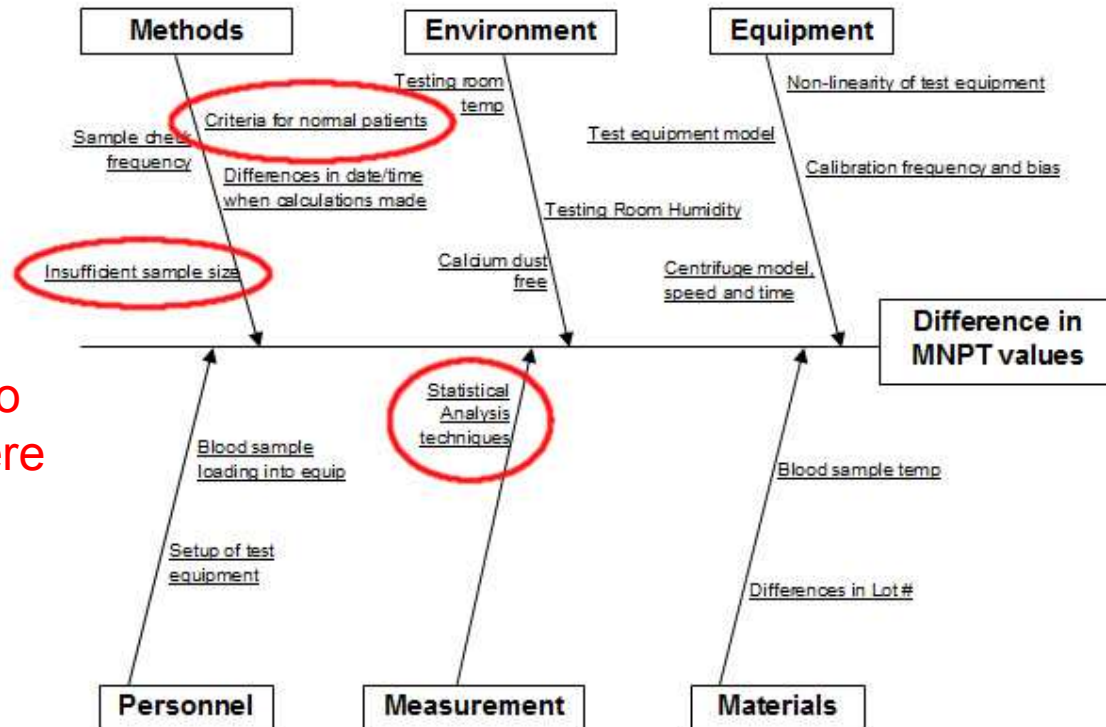


Common Risk Tools

- Here are some more formal ways of determining risk in your processes
 - Brainstorming
 - 5 Why's
 - Fault Tree Analysis
 - FMEA
 - Data Analysis

Brainstorming

- Group ideas into categories
 - Use Fishbone diagram format (Personnel, Processes, Machine, Environment, Measurement, Supplies, etc)



Gather data to determine where to start

5 Why's

- Ask why AT LEAST 5 times, keep going until root cause (process error) identified

Patient dose changes excessive **WHY?**

→ Patient INR higher at preferred lab than clinic **WHY?**

→ Lab and clinic results vary by 0.20 – 0.40 **WHY?**

→ Lab MNPT values are different **WHY?**

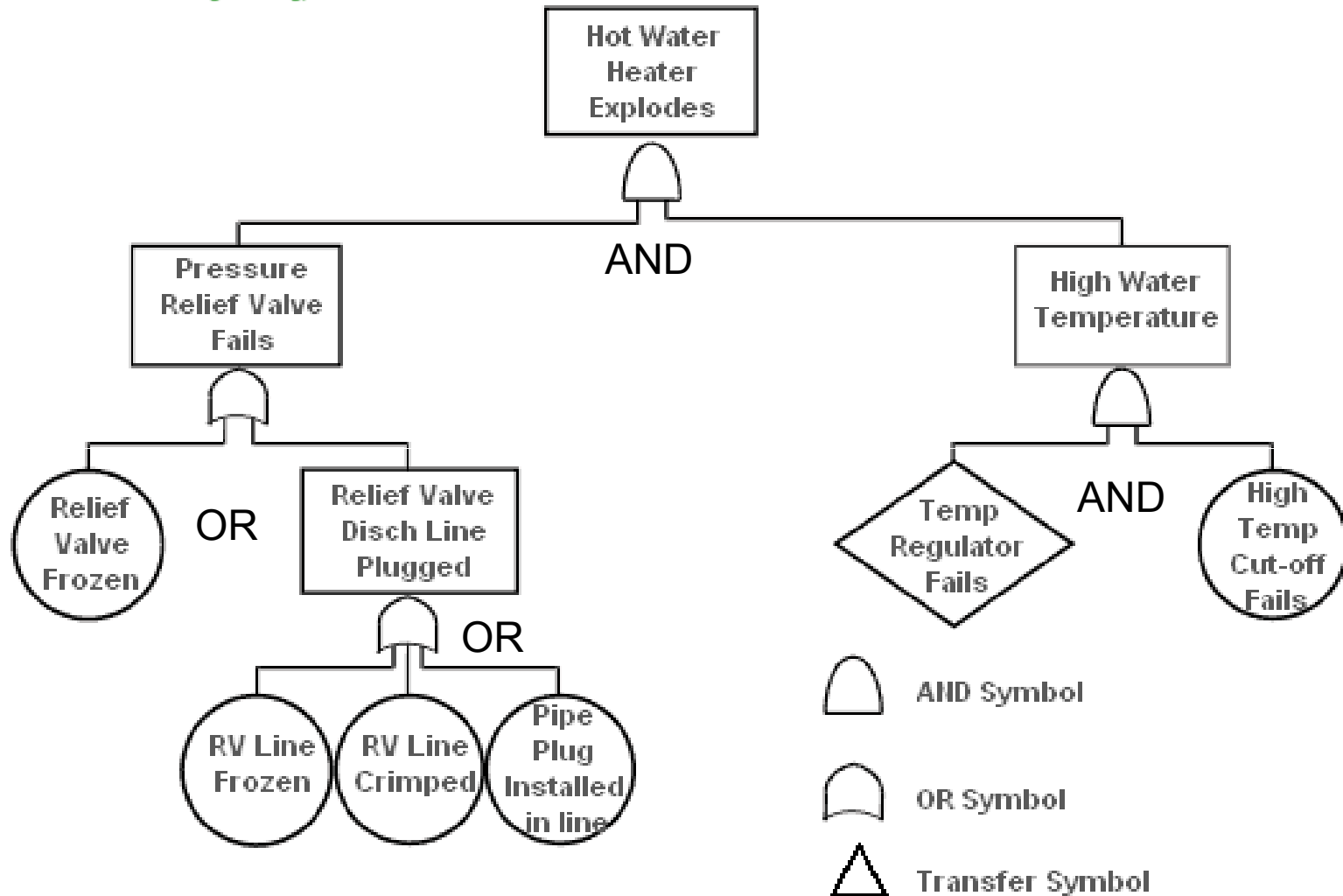
→ Labs used different normal population groups **WHY?**

→ Definition of “normal” population not well-defined (Process)

Process Change: All labs will pool data together for a community MNPT value



Fault Tree Analysis

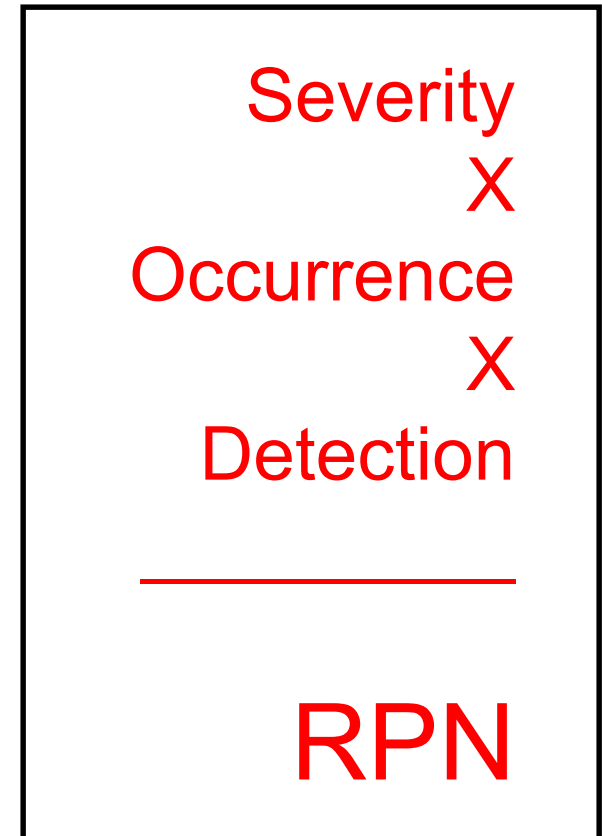


FMEA

- **Failure Mode and Effects Analysis**
 - **Failure mode** = the way in which the failure occurs
 - Implanted device runs out of batteries, wrong prescription given to patient, patient falls down, patient given wrong dose amount, illegible handwriting
 - **Effects** = potential consequence or final outcome of the failure mode
 - Adverse or sentinel event, ER visit, surgery, litigation
 - Slight pain, redness, patient would not know
- **Various names associated with it**
 - Healthcare (HFMEA), Process (PFMEA), Design (DFMEA), Safety/System (SFMEA), etc

FMEA Format

- Process Step
- Failure Mode
- Effect of Failure
- **Severity Score**
- Cause of Failure
- **Occurrence Score**
- Prevention & Detection Controls
- **Detection Score**
- **RPN**
- Actions



Example

| Process Step | Potential Failure Mode | Potential Effect(s) of Failure | S | Potential Cause(s) of Failure | Process Controls | O | Detection / Evaluation Method | D | S x O | RPN |
|--------------------|----------------------------------|--------------------------------|---|---|---|---|---|---|-------------|-----|
| Review Dose Amount | Dose change made when not needed | bleeding, clot | 7 | patient did not communicate diet to NP on day of test | standard questions to patient, training | 4 | INR test | 7 | 28 | 196 |
| | | | 7 | lab error in calibration | weekly sample checks | 2 | INR test | 7 | 14 | 98 |
| | | | 7 | patient went to a different lab than usual | training | 2 | different than listed in system, INR test | 4 | 14 | 56 |
| | Patient took wrong dose amount | bleeding, clot, adverse event | 9 | wrote down wrong dose | patient repeats dose to NP | 5 | INR test | 4 | 45 | 180 |
| | | | 9 | Selected the wrong pills | Pills are color coded | 3 | INR test | 4 | 27 | 108 |
| | | | 9 | forgot they took dose already that day | pill dispenser container by day | 2 | INR test | 4 | 18 | 72 |

Risk Priority Number

- $\text{Severity} \times \text{Occurrence} \times \text{Detection} = \text{RPN}$
- Higher the number, higher the risk to the customer (patient)
- Scoring is relative and somewhat subjective, key is consistency with team
- Difficult to compare across processes, organizations, facilities unless teams are the same

Severity Rankings

| Ranking | Effect | Process FMEA Severity |
|---------|-----------------------|--|
| 10 | Hazardous-no warning | may endanger machine or operator without warning |
| 9 | Hazardous- w/ warning | may endanger machine or operator with warning |
| 8 | Very High | major disruption in operations (100% scrap) |
| 7 | High | minor disruption in operations (may require sorting and some scrap) |
| 6 | Moderate | minor disruption in operations (no sorting but some scrap) |
| 5 | Low | minor disruption in operations (portion may require rework) |
| 4 | Very Low | minor disruption in operations (some sorting and portion may require rework) |
| 3 | Minor | minor disruption (some rework but little affect on production rate) |
| 2 | Very Minor | minor disruption (minimal affect on production rate) |
| 1 | None | No effect |

Occurrence Rankings

| Ranking | Effect | Failure Rates | Percent Defective | Cpk |
|---------|----------------|------------------|-------------------|------------|
| 10 | Extremely High | > 1 in 2 | 50% | Cpk < 0.33 |
| 9 | Very High | 1 in 3 | 33% | Cpk ~ 0.5 |
| 8 | Very High | 1 in 8 | 10-15% | Cpk ~ 0.75 |
| 7 | High | 1 in 20 | 5% | |
| 6 | Marginal | 1 in 100 | 1% | |
| 5 | Marginal | 1 in 400 | 0.25% | Cpk ~ 1 |
| 4 | Unlikely | 1 in 2000 | 0.05% | |
| 3 | Low | 1 in 15,000 | 0.007% | Cpk > 1.33 |
| 2 | Very Low | 1 in 150,000 | 0.0007% | Cpk > 1.5 |
| 1 | Remote | < 1 in 1,500,000 | 0.000007% | Cpk > 1.67 |

Detection Rankings

| Ranking | Effect | Process FMEA Detection |
|---------|----------------------|--|
| 10 | Absolute uncertainty | No known process control to detect cause mechanism and subsequent failure. |
| 9 | Very remote | |
| 8 | Remote | Remote chance that process control to detect cause mechanism and subsequent failure. |
| 7 | Very Low | |
| 6 | Low | Low chance that process control to detect cause mechanism and subsequent failure. |
| 5 | Moderate | |
| 4 | Moderately High | |
| 3 | High | High chance that process control to detect cause mechanism and subsequent failure. |
| 2 | Very High | |
| 1 | Almost Certain | Current control almost certain to detect cause mechanism and failure mode. |

Example

Provide standard questions to all nurses near phone, include in patient education material

| Process Step | Potential Failure Mode | Potential Effect(s) of Failure | S | Potential Cause(s) of Failure | Process Controls | O | Detection / Evaluation Method | D | S X O | RPN |
|--------------------|----------------------------------|--------------------------------|---|---|---|---|---|---|-------------|-----|
| Review Dose Amount | Dose change made when not needed | bleeding, clot | 7 | patient did not communicate diet to NP on day of test | standard questions to patient, training | 4 | INR test | 7 | 28 | 196 |
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process changed so copy of all dose changes should be mailed to patients as confirmation



Prioritize Actions

Choose top 2-3 items to improve

- Too many will be overwhelming and seem endless (no more than 1 action per person)
- If risk reduced, work on next highest (continuous improvement)
- List investigation plan, unless solution is obvious to all
 - More detailed data collection plan
 - Test out potential solutions (experiment)
 - Further team brainstorming and investigation

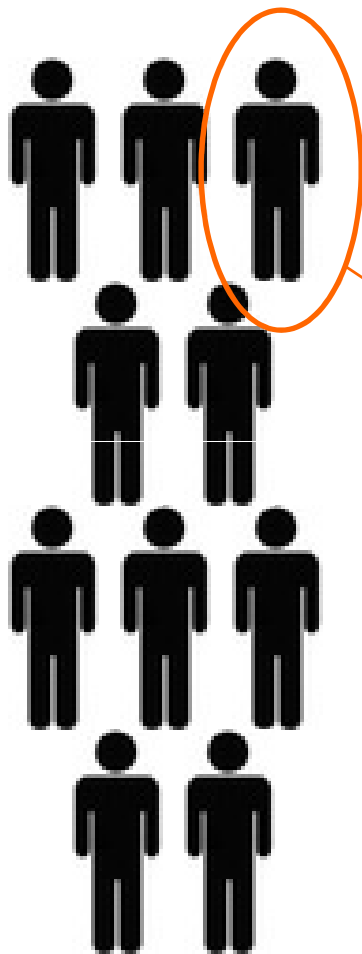


Data Analysis

- Sometimes data will tell you there is a risk, or will validate how much risk exists
- Are labs in Cedar Rapids consistent with one another when measuring INR values?
- Overall opinions said “YES” – low risk?
- Develop an experiment to prove it
 - Already exists a tool, called Gage Repeatability & Reproducibility (R&R)

Summary of Gage R&R Study

10 Patients



6 vials collected
per patient from one
blood draw

LAB A



| <u>TIME</u> | <u>INR</u> |
|-------------|------------|
| 8am | 1.9 |
| Noon | 2.0 |
| 4pm | 2.1 |

3 vials sent to each lab,
tested every 4 hours

LAB B



| <u>TIME</u> | <u>INR</u> |
|-------------|------------|
| 8am | 2.2 |
| Noon | 2.1 |
| 4pm | 2.2 |



Comparison of Labs - INR

| Patient | Average INR at Lab A | Average INR at Lab B | INR Difference |
|---------|----------------------|----------------------|----------------|
| 1 | 2.777 | 3.170 | -0.393 |
| 2 | 2.100 | 2.320 | -0.220 |
| 3 | 2.887 | 3.110 | -0.223 |
| 4 | 1.693 | 1.830 | -0.137 |
| 5 | 2.920 | 3.160 | -0.240 |
| 6 | 1.267 | 1.413 | -0.147 |
| 7 | 3.877 | 4.320 | -0.443 |
| 8 | 2.090 | 2.240 | -0.150 |
| 9 | 2.993 | 3.300 | -0.307 |
| 10 | 3.300 | 3.553 | -0.253 |
| Overall | 2.590 | 2.842 | -0.251 |

**SIGNIFICANT DIFFERENCE IN AVERAGES (p-value = 0.000)
RESULTS EXCEEDED GAGE R&R ACCEPTANCE CRITERIA**

Are you doing enough?

- JCAHO Standard LD.5.2 requires facilities to select at least one high-risk process for proactive risk assessment each year
 - such selection to be based, in part, on information published periodically by the Joint Commission that identifies the most frequently occurring types of **sentinel events** and patient safety risk factors (**adverse events**)
- New DNV ISO-9000 hospital accreditation will require prevention activity
- Never too late to start risk reduction



Final Notes

- Risk assessment has a wide spectrum of implementation
 - The more critical the problem, the more structure (tools) and detail required
 - Prevention requires formal methods and evidence of analysis and action
- Most problems are not new, they have been solved or mitigated already
 - look nationwide, and outside healthcare
- Use actual data whenever possible
 - However, not all risks can be quantified
- Start simple, then evolve to more complex methods
 - Doesn't have to be complicated, just get started...



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