Risk Management in Medical Device Design

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What this lecture is about

• Introduction to Risk Analysis of Medical Device
• Methodology to help assess the risks of Medical Device
• Examples
Risk Assessment

- A step in Risk Management
  - Analysis and Reduction of Risks
- There are many types of risk assessments used in various industries:
  - Information Security
  - Project Management
  - Supply Chain
  - Megaprojects
  - NUS Research Labs
Risk Assessment in BN3101

• Methodology
• How to apply principle to:
  – Project Management (Design Phase)
  – Design Qualification (Design Phase)
  – Design Verification (FDA Phase)
  – Design Validation (Post market)

DFMEA – Design Failure Mode and Effect Analysis
Methodology

• Quantify Severity S (alternate L=Loss)
• Quantify Probability P (alternate p=probability of a particular incidence occurring)
• For a specific incident the **Risk** is $R_i = S_i \times P_i$
• **Total Risk** $= \sum S_i P_i$
Surgifile
What we do in practice?

**Tool = DFMEA Matrix**

<table>
<thead>
<tr>
<th>Failure Mode</th>
<th>Analysis</th>
<th>Mitigation</th>
</tr>
</thead>
</table>

### Risk Analysis (DFMEA)

<table>
<thead>
<tr>
<th>RA#</th>
<th>Failure Mode</th>
<th>Failure Cause</th>
<th>Failure Consequence (Harm)</th>
<th>Severity (S)</th>
<th>Probability (P)</th>
<th>Risk (S x P)</th>
<th>Risk Control / Mitigation Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Operational Hazards (function, use of the device, use error)</td>
<td>Excessive vibrations of the reciprocating mechanism or excessive friction in the disposable tip</td>
<td>Inconvenience for the surgeon</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>Measure of acceleration by internal protocol, benchmarking of existing devices</td>
</tr>
<tr>
<td>1.1</td>
<td>Vibration of the device reduces good control of the instrument</td>
<td>Excessive noise produced by the reciprocating mechanism or the disposable tip</td>
<td>Discomfort for the surgeon</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>Benchmarking of existing devices</td>
</tr>
<tr>
<td>1.2</td>
<td>Noise of the device is uncomfortable for the operating team</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**Tool = DFMEA Matrix**
Probability of failure due to specific cause

1 *Remote*: Failure unlikely
2 *Low*: Relatively few
3 *Moderate*: Occasional
4 *High*: Repeated failures
5 *Extreme*: Almost inevitable
## Severity: Safety vs Function

<table>
<thead>
<tr>
<th>RATING</th>
<th>Patient Safety Severity Evaluation Criteria</th>
</tr>
</thead>
</table>
| 1      | No Health Hazard:  
|        | - No physical effect of the physiological complaints anticipated                                          |
| 2      | Limited Health Hazard:  
|        | - Extended Procedure Time  
|        | - Physiological complaints  
|        | - Temporary minor physical effect                                                                       |
| 3      | Moderate Health Hazard:  
|        | - Additional procedure required  
|        | - Temporary but significant physical effects  
|        | - Permanent minor physical effects                                                                      |
| 4      | Severe Health Hazard:  
|        | - Permanent significant physical effects                                                                |
| 5      | Catastrophic:  
|        | - Life Threatening                                                                                        |

<table>
<thead>
<tr>
<th>RATING</th>
<th>Device Functionality Severity Evaluation Criteria</th>
</tr>
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</table>
| 1      | Insignificant:  
|        | - Cosmetic defect  
|        | - The failure will not have any perceptible effect on the performance of the product                     |
| 2      | Low Significance:  
|        | - User nuisance  
|        | - Dissatisfaction on the part of the end user  
|        | - Product may be operable at reduced performance                                                             |
| 3      | Moderate Significance:  
|        | - Compromised function / loss of minor function  
|        | - The user may notice a negative impact on the product or system performance                              |
| 4      | High Significance:  
|        | - Compromised function / loss of major function  
|        | - Loss of system function - device completely unusable                                                      |
| 5      | Extreme Significance:  
|        | - Regulatory issue  
|        | - Involves non-compliance with government regulations                                                       |

Use This
What is acceptable Risk?  
Rule of Thumb is <8

<table>
<thead>
<tr>
<th>LIKELIHOOD</th>
<th>Minor - minor injury / adverse health outcome</th>
<th>Moderate - moderate injury / adverse health outcome</th>
<th>Serious - major injury / adverse health outcome</th>
<th>Major - death</th>
<th>Catastrophic - multiple deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rare - not expected to happen, but is possible</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Unlikely - could occur occasionally</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Likely - could occur in many circumstances</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expected - is expected to occur in most circumstances</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Certain - will occur on every occasion</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

High Risk | Medium Risk | Low Risk |
## Risk Assessment BN3101

<table>
<thead>
<tr>
<th>Failure Mode</th>
<th>Cause of Failure</th>
<th>Harm</th>
<th>Initial Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unable to come up with an acceptable concept</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unable to complete to complete design</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unable to make working prototype</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>
Risk Management is Specific to Design

St Jude Valve

Ball Cage Valve
### Risk Assessment

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</thead>
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<tr>
<td>Fracture of Cage Strut</td>
<td>Metal Fatigue</td>
<td>Initially there may be some leakage, failure of other struts may be accelerated.</td>
<td></td>
</tr>
</tbody>
</table>
| Fragmentation of Ball | Brittleness of material, fatigue | 1. Small fragmentation may cause leaks.  
2. Large fragmentation may cause immediate death |              |
Design Process

1. Understand the user need and clinical context
2. Background Information (depends on 1)
   – Industry Bench Marking, Patents, Adverse Events, Focus Group, Consultations
3. Design Specifications (User Specifications 1,2)
4. Concept Selection (Go back to 2 and 3)
5. Risk Management (2,3,4)
6. Detail Design (2,3,4,5)
7. Design Qualification (6,5,2,3)
8. Design Verification (Design output meets Design Input)
Risk Assessment for Design Verification

• Come up with the top 5 Risks
• Preferably all be less than 8
• Fully document them in terms of mitigations and verifications of mitigation
Design Rationale and Design Verification

• Continue on with your Design Rationale and Design Verification online lecture

• Take the assessment which will open from Thursday to Sunday