Applying Failure Modes and Effects Analysis (FMEA) in Healthcare

Preventing Infant Abduction, A Case Study

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Objectives of this document:

- Describe the WakeMed Healthcare System
- Define FMEA
- Explain the use of this tool in healthcare
- Describe the FMEA project selection process
- Explain the application of the FMEA process to “Preventing Infant Abduction at WakeMed”
- Report on the results achieved by the project team

Background of WakeMed

WakeMed is a multi-facility health care system consisting of 629 acute care beds, 515 at New Bern Avenue and 114 at Western Wake Medical Center. WakeMed employs 5800 employees and is affiliated with UNC Healthcare through its residency programs.

What is an FMEA?

FMEA (Failure Modes and Effects Analysis) as its applied in Healthcare is a proactive team-oriented approach to risk reduction that seeks to improve patient safety by minimizing risk potential in high-risk processes.

Rather than focus on a problem - after its occurrence, FMEA looks at what “could” go wrong at each process step, the so-called “Failure Modes,” assigns a risk score to each of these possibilities, and provides for a team-oriented approach to focus resources on priority issues. Since the 1960’s they’ve been used in the nuclear, military, aviation, food, and automotive industries, now they’re being used in Healthcare and other service industries.
Why Use FMEAs in Healthcare?

Recently, JCAHO (Joint Commission on the Accreditation of Healthcare Organizations) added a new requirement for the use of FMEA to reduce risks, improve patient safety, and enhance patient satisfaction in high-risk processes.

“JCAHO Standard LD.5.2 requires facilities to select at least one high-risk process for proactive risk assessment each year. This selection is to be based, in part, on information published periodically by the JCAHO that identifies the most frequently occurring types of sentinel events. The National Center for Patient Safety will also identify patient safety events and high risk processes that may be selected for this annual risk assessment.”

Furthermore, the 1999 Institute of Medicine (IOM) report, “To Err is Human: Building a Safer Health System,” urged health organization to reduce medical errors by 50% over the following 5 years through changes to healthcare systems. The report stated that most medical errors do not result from “individual recklessness,” but instead from “basic flaws” in the way the healthcare system is organized.

Choosing a Process for an FMEA Project

Many different processes occur within a hospital setting, each with varying degrees of risk. So how do you choose a process to work on? The possibilities include considering the following:

- Sentinel Event Alerts (Past alerts have covered medication abbreviations, wrong-site surgery, delay in treatment, etc.)
- JCAHO’s Patient Safety Goals
- Other identified high-risk processes within the hospital
Choosing Infant Abduction as an FMEA Project at WakeMed

According to FBI statistics, 145 cases of infant abductions have been documented since 1983 (<1 year old, taken by a non-family member), an average of 14 infant abductions per year since 1987.¹

83 infants were taken from hospitals and 62 were taken from other locations, such as residences, day-care centers, and shopping centers.²

While arguably “statistically insignificant,” given that there are 4.2 million births per year in 3500 birthing centers throughout the country², this crime transcends statistics due to its highly-charged nature. There are approximately 7,800 births/year in the WakeMed system.

Furthermore, when these situations occur, infant abductions affect the local community and beyond. National news coverage can be expected and these incidents can adversely affect hospitals via the publicity generated and liability concerns. In one case, an Oklahoma City couple filed a $56 million suit against their city hospital.¹

What Motivates the Perpetrator?

The need to present their partners with a baby often drives the female offender (141 of the 145 cases). Several motivating factors have been cited in FBI statistics, including the following:

- Preventing the partner from deserting her
- Salvaging the relationship
- Miscarriage
- Inability to conceive²

¹ T. Farley, “Parents Sue City Hospital for $56 Million,” The Daily Oklahoman, March 8, 1991
Conducting the FMEA

In the pages that follow the FMEA process will be applied to minimizing the potential for Infant Abduction at WakeMed:

FMEA Project Methodology:

Step 1: Define the FMEA Topic
Step 2: Assemble the Team
Step 3: Review the Process / Create a Process Flowchart
Step 4: Brainstorm Potential Failure Modes, Causes, and Effects
Step 5: Evaluate the Risk of Failure, or Hazard Score
Step 6: Calculate the Total Risk Priority Number Score
Step 7: Create an Action Plan
Step 8: Determine FMEA Project Success

Step 1: Define the FMEA Topic

The first step is to clearly define the FMEA topic:

“Minimize the potential for Infant Abduction at WakeMed’s Western Wake Campus”
Step 2: Assemble the Team

Next, assemble a team of process experts and those that would be involved in any expected changes to policies, procedures, equipment, or personnel. In our case, we chose representatives from the Women’s Pavilion and Birthplace, Public Safety, Engineering, and Performance Improvement.

FMEA Team Members:

- Todd Reichert  FMEA Team Leader, Performance Improvement
- Monica Blochowiak  Nurse Manager, WW Women’s Pavilion
- Blair Creekmore  Staff Nurse, WW Post Partum
- Michael Prince  Supervisor, WW Public Safety
- Barbara Werner  Supervisor, WW Women’s Pavilion
- Cheryl Baker  Supervisor, WW NICU
- Sara Owens  Staff Nurse, WW Special Care Nursery
- Michael Baker  Supervisor, Engineering, WW

WW = Western Wake Campus (WakeMed)
Step 3: Review the Process

Develop a flowchart of the existing process, listing all process steps. This will assist in the next step of the FMEA process, when “Failure Modes” will be identified.

Western Wake Process Flow Diagram
WPBP - Maintaining Infant Security

1. Mother Admitted into Labor and Delivery Unit
2. Baby Born (ID Band Only)
3. Special Care Needs?
   - Yes: Move to Special Care Nursery (SCN)
   - No: 13
4. F
5. Computer Info Deleted & HUGS Band Removed
6. (Locked Unit)
Infant Security Precautions Discussed with Mom, Family, Visitors

Wash Baby?

Baby Washed

B

Baby Leaves Special Care Nursery (SCN)

Discharge?

C

No, Newborn Nursery or Post-Partum

End

3

Yes

No

4
Apply HUGS Band
Enter Info into Computer System

Space Available in Post Partum?

Delay, until space is available

Yes

Move to Post Partum

Problem: Sometimes HUGS bands aren't applied until reaching Post Partum

D
7. Security Precautions Reviewed w/ Mom + Visual Check of Bands - Mom & Baby

8. Bands Checked and Tightened as Necessary Each Shift

9. Charge Nurse Checks Computer Records (against census?) Each Shift Corrections made, Bands Located as necessary

Baby Removed From Room?  
No  
Yes  

E
ID Band Checked and Verified, HUGS Tag Presence Checked

Special Care Needs?

Yes → F

No → 10

To Be Discharged?

Yes → Begin Discharge Process

No → Move to Circ., Nursery, etc.

10

End

Check Band

Remove Info from Computer System

Remove HUGS Band

End
Step 4: Brainstorm Potential Failure Modes, Causes, and Effects

At this step, we want to identify what “could” go wrong at each of the process steps, these are referred to as “Failure Modes,” “why it might happen,” the causes of those failures, and the effects of those failures. (Refer to the attached FMEA worksheet.)

Step 5  Evaluate the Risk of Failure, or Hazard Score

The relative risk of a failure and its effects are composed of three factors in an FMEA: Severity, Probability of Occurrence, and Detection Capability.

- The “severity” is the consequence of the failure should it occur
- The “probability of occurrence” is the likelihood of a failure mode occurring
- The “detection rating” is our ability to catch the error before causing patient harm

Various scoring guidelines exist, below is a scoring guideline from the “The Basics of FMEA” by S.L. Goodman. You may wish to adapt the scoring guidelines to suit the process under study. Scores for this case study can be found on the attached FMEA worksheet.
**SEVERITY RATING SCALE**

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Extremely dangerous</td>
<td>Failure could cause death of a customer (patient, visitor, employee, staff member, business partner) and/or total system breakdown, without any prior warning.</td>
</tr>
<tr>
<td>9</td>
<td>Very dangerous</td>
<td>Failure could cause major or permanent injury and/or serious system disruption with interruption in service, with prior warning.</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Dangerous</td>
<td>Failure causes minor to moderate injury with a high degree of customer dissatisfaction and/or major system problems requiring major repairs or significant re-work.</td>
</tr>
<tr>
<td>6</td>
<td>Moderate danger</td>
<td>Failure causes minor injury with some customer dissatisfaction and/or major system problems.</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Low to Moderate danger</td>
<td>Failure causes very minor or no injury but annoys customers and/or results in minor system problems that can be overcome with minor modifications to system or process.</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Slight danger</td>
<td>Failure causes no injury and customer is unaware of problem however the potential for minor injury exists; little or no effect on system.</td>
</tr>
<tr>
<td>1</td>
<td>No danger</td>
<td>Failure causes no injury and has no impact on system.</td>
</tr>
</tbody>
</table>

## OCCURRENCE RATING SCALE

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
<th>Potential Failure Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Certain probability of occurrence</td>
<td>Failure occurs at least once a day; or, failure occurs almost every time.</td>
</tr>
<tr>
<td>9</td>
<td>Failure is almost inevitable</td>
<td>Failure occurs predictably; or, failure occurs every 3 or 4 days.</td>
</tr>
<tr>
<td>8/7</td>
<td>Very high probability of occurrence</td>
<td>Failure occurs frequently; or failure occurs about once per week.</td>
</tr>
<tr>
<td>6/5</td>
<td>Moderately high probability of occurrence</td>
<td>Failure occurs about once per month.</td>
</tr>
<tr>
<td>4/3</td>
<td>Moderate probability of occurrence</td>
<td>Failure occurs occasionally; or, failure once every 3 months.</td>
</tr>
<tr>
<td>2</td>
<td>Low probability of occurrence</td>
<td>Failure occurs rarely; or, failure occurs about once per year.</td>
</tr>
<tr>
<td>1</td>
<td>Remote probability of occurrence</td>
<td>Failure almost never occurs; no one remembers last failure.</td>
</tr>
</tbody>
</table>

## DETECTION RATING SCALE

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>No chance of detection</td>
<td>There is no known mechanism for detecting the failure.</td>
</tr>
<tr>
<td>9</td>
<td>Very Remote/Unreliable</td>
<td>The failure can be detected only with thorough inspection and this is not feasible or cannot be readily done.</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Remote</td>
<td>The error can be detected with manual inspection but no process is in place so that detection left to chance.</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Moderate chance of detection</td>
<td>There is a process for double-checks or inspection but it not automated and/or is applied only to a sample and/or relies on vigilance.</td>
</tr>
<tr>
<td>4</td>
<td>High</td>
<td>There is 100% inspection or review of the process but it is not automated.</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Very High</td>
<td>There is 100% inspection of the process and it is automated.</td>
</tr>
<tr>
<td>1</td>
<td>Almost certain</td>
<td>There are automatic “shut-offs” or constraints that prevent failure.</td>
</tr>
</tbody>
</table>

Calculating the RPN

**Risk Priority Number =**

\[ \text{Severity} \times \text{Occurrence} \times \text{Detectability} \]

Since scores are 1-10, the resultant Risk Priority Number will be from 1-1000. Failure Modes with RPN scores \( \leq 100 \) are generally considered minor scores and might not be considered further by the team when an action plan is created in step 7.

- **In our example, “Child not banded (in L&D)”**:  
  Severity of the potential effects was rated a “10” (Highest Severity relative to providing infant security – no HUGS protection at this time)  
  Probability was rated a “7” (High)  
  Detection was rated a “5” (Moderate)

  Therefore, the RPN for this failure mode is \( 10 \times 7 \times 5 = 350 \) (High)

**Step 6  Calculate the Total RPN Score**

Next, add the totals of all RPN scores for all failure modes to get a grand total. This creates a baseline for future comparison. In our process, our score was 4,164 (See the attached FMEA worksheet.)

**Note:** process scores can only be compared to themselves, not against other processes, since they may have more or less process steps.
Step 7  Create an Action Plan

- Identify the failure modes that have an RPN Score of 100 or higher. These are the items that require the greatest attention. (In our example, we decided to address all failure modes, regardless of score.)

- Develop an action plan to address each of these high-hazard score failure modes. The action plan should include who?, what?, when?, why?, etc.

Items Included in the Action Plan:

- Policy Update: All normal newborns will be banded ASAP, do not wait for bathing to be completed

- Policy Update: L&D Nurse will obtain the HUGS Band and Patient ID Bands simultaneously

- Policy Update: Transferring & Receiving Nurse will confirm patient ID & HUGS bands, documenting on the Post Partum flow sheet

- Policy Update: L&D Nurse will be responsible for activating the HUGS tag and ensuring that the info is entered correctly into the computer system (personally inputting or contacting the Clinical Secretary.)

- Training: HUGS computer system entry training will be provided to the Clinical Secretaries

- Checklists: Create infant security & safety sheet to be shared with mom in L&D, and signed by mom (in Spanish also? Include pictures for universal understanding?) Obtain approval by Forms Committee and Risk Management

- Checklists: Create checklist/script for education of patient & SO (significant other) by staff re: doors, sensors, band tightness, band tampering, etc.

- Alarms: Isolate Women's Pavilion from "testing alarms" in other areas, "Strobes only," Install badge reader & Mag Lock on back stairwell and exterior exit door. Remove auto sensor from WP -> Telemetry door, and install badge reader, "Authorized Personnel Only" sign. Add badge & mag lock at stairwell.

- Policy Update: Update Code Pink Policy (Infant Abduction). Require monitoring of all egress points during Code Pink by hospital personnel & provide staff education
- Policy Update: Create/Review roles & responsibilities in Code Pink policy
- Alarms: Conduct Quarterly Code Pink Drills (per policy)
- HUGS System: Ask HUGS representative about other band options to deal with ankle swelling reduction & chafing concerns
- HUGS System: Ask HUGS rep. if pre-printed instructions are available
- Checklists: Add “HUGS band check/tightening” to the Nurse assessment flowsheet & educate staff
- Checklists: Add “HUGS check against census” to the L&D Charge Nurse checklist
- Checklists: Add “HUGS check against census” to the Post Partum Charge Nurse checklist
- Policy Update: Post Partum Nurse to check HUGS band presence before accepting infant, otherwise infant is to be returned for tagging
- Policy Update: All infants leaving the Special Care Nursery (except for direct discharge) must be immediately HUGS banded. Update questionnaire / audit form.
- Training: Conduct HUGS system refresher for Special Care Nursery Nurses
- Security: Have the supplier check/repair Physician & Employee entrance to ensure proper reactivation after the door closes
- Security: Budget for, and provide additional security cameras and other security features around area perimeters

Step 8 Determine FMEA Project Success

Recalculate the RPN scores after implementation of the action plan, and compare with the first FMEA analysis. Address any items with a recalculated RPN Score of 100 or higher. See the attached worksheet for our scoring after implementation of the action plan. In our case, our score was reduced from 4,164 to 1,372 – a 67% improvement!
Lessons Learned

Although conducting an FMEA can be a time consuming process, the results can be very worthwhile. However, be sure to obtain management support for the project, and a team leader’s skills in keeping a team motivated and progressing through the project is essential to ensure the completion of a successful project.

In Conclusion

FMEA is a tool for proactive risk assessment that is now being used in healthcare. Infant Security was chosen as the 2003 FMEA project at WakeMed because of the high volume of births in the WakeMed system and the significance of this concern to the hospital and the community that we serve. Through the use of FMEA, significant reductions in scored risk have been realized.

References:

ISMP Website, Example of a Health Care Failure Mode and Effects Analysis for IV Patient Controlled Analgesia (PCA), ISMP.Com


Understanding the Failure Modes and Effects Analysis, an on-line course, HCPProfessor.com, 2002. Phone #: 800-650-6787.

Applying Failure Modes and Effects Analysis (FMEA) in Healthcare

Preventing Infant Abduction, a Case Study

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Objectives of this Presentation

- Define FMEA
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- Describe the project selection process
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- Report on results achieved by the project team
WakeMed: A multi-facility health care system

- 629 acute care beds: 515 at New Bern Avenue and 114 at Western Wake Medical Center
- 68 rehabilitation beds
- 55 skilled nursing beds
- A home health agency
WakeMed: A multi-facility health care system

- WakeMed Faculty Physicians Practice
- 5800 employees; 779 medical staff at New Bern Avenue, 506 at Western Wake (of the 506, 411 are also on staff at NBA)
- UNC affiliation - residency programs
What is an FMEA?

- FMEA – Failure Modes and Effects Analysis is a proactive team-oriented approach to risk reduction
  - ID what “could” go wrong at each process step?
  - Assign “risk” scores
  - Team-oriented approach to focus resources on priority issues
What is an FMEA?

- Since the 1960’s they’ve been used in the nuclear, military, aviation, food, and automotive industries.

- They’re now being used in Healthcare and other service industries.
Why Use FMEAs in Healthcare?

- 1999 Institute of Medicine (IOM) report, “To Err is Human: Building a Safer Health System.”

- The report urged health organization to reduce medical errors by 50% over the following 5 years through changes to healthcare systems.

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Choosing a Process for an FMEA Project

- Sentinel Event Alerts (Published by JCAHO)
  - Issue 9 – April 9, 1999, Infant Abductions: Preventing Future Occurrences
  - Past alerts have covered medication abbreviations, wrong-site surgery, delay in treatment, etc.

- JCAHO’s Patient Safety Goals

- Other identified high-risk processes within the hospital
Choosing Infant Abduction as a Process for an FMEA Project

- According to FBI statistics, 145 cases of infant abductions have been documented since 1983 (<1 year old, taken by a non-family member), an average of 14 infant abductions per year since 1987.¹

- 83 infants were taken from hospitals, and 62 were taken from other locations, such as residences, day-care centers, and shopping centers.¹

¹ FBI’s National Center for Violent Crime (NCAVC) and the National Center for Missing and Exploited Children (NCMEC)
Choosing Infant Abduction as a Process for an FMEA Project

While arguably “statistically insignificant,” given that there are 4.2 million births per year in 3500 birthing centers throughout the country\(^1\), this crime transcends statistics due to its highly-charged nature\(^2\)

\(^1\) 7800 births annually at WakeMed (average)

\(^2\) T. Farley, “Parents Sue City Hospital for $56 Million,” The Daily Oklahoman, March 8, 1991
Choosing Infant Abduction as a Process for an FMEA Project

- Infant abductions affect the local community and beyond:
  - National news coverage
  - Adversely affect hospitals via the publicity generated and liability concerns. In one case, an Oklahoma City couple filed a $56 million suit against their city hospital.

² T. Farley, “Parents Sue City Hospital for $56 Million,” The Daily Oklahoman, March 8, 1991
What Motivates the Perpetrator?

- The need to present their partners with a baby often drives the female offender (141 of the 145 cases)
  - Preventing the partner from deserting her
  - Salvaging the relationship
  - Miscarriage
  - Inability to conceive

FMEA Project Methodology:

- **Step 1:** Define the FMEA Topic
- **Step 2:** Assemble the Team
- **Step 3:** Review the Process / Create a Process Flowchart
- **Step 4:** Brainstorm Potential Failure Modes, Causes, and Effects
FMEA Project Methodology:

- **Step 5:** Evaluate the Risk of Failure, or Hazard Score
- **Step 6:** Calculate the Total Risk Priority Number Score
- **Step 7:** Create an Action Plan
- **Step 8:** Determine FMEA Project Success
Step 1: Define the FMEA Topic

“Minimize the potential for Infant Abduction at WakeMed’s Western Wake Campus”
Step 2: Assemble the Team

FMEA Team Members:

- Todd Reichert, FMEA Team Leader, Performance Improvement
- Monica Blochowiak, Nurse Manager, WW Women’s Pavilion
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- Michael Prince, Supervisor, WW Public Safety
- Barbara Werner, Supervisor, WW Women’s Pavilion
- Cheryl Baker, Supervisor, WW NICU
- Sara Owens, Staff Nurse, WW Special Care Nursery
- Michael Baker, Supervisor, Engineering, WW

WW = Western Wake Campus (WakeMed)
Step 3: Review the Process

Develop a flowchart of the existing process, listing all process steps
Start

Mother Admitted into Labor and Delivery Unit

Baby Born (ID Band Only)

Special Care Needs?

Yes → Move to Special Care Nursery (SCN) (Locked Unit)

No → A

F

Computer Info Deleted & HUGS Band Removed

B
Infant Security Precautions Discussed with Mom, Family, Visitors

- A
  - Infant Security Precautions Discussed with Mom, Family, Visitors
    - 3
      - Wash Baby?
        - Yes
          - Baby Washed
        - No
          - C

- B
  - Baby Leaves Special Care Nursery (SCN)
    - 14
      - Discharge?
        - Yes
          - End
        - No
          - No, Newborn Nursery or Post-Partum

- C
  - C
Apply HUGS Band
Enter Info into Computer System

Space Available in Post Partum?

Delay, until space is available

Move to Post Partum

Problem: Sometimes HUGS bands aren't applied until reaching Post Partum
Security Precautions Reviewed w/ Mom + Visual Check of Bands - Mom & Baby

Bands Checked and Tightened as Necessary Each Shift

Charge Nurse Checks Computer Records (against census?) Each Shift Corrections made, Bands Located as necessary

Baby Removed From Room?

Yes

E

No
Infant Security Process Flowchart

Special Care Needs?

No

ID Band Checked and Verified, HUGS Tag Presence Checked

Yes

To Be Discharged?

No

Move to Circ., Nursery, etc.

Yes

Begin Discharge Process

Check Band

Remove Info from Computer System

Remove HUGS Band

End

Return to Postpartum

Check ID Band, Return baby to Mom
Step 4: Brainstorm Potential Failure Modes, Causes, and Effects

At this step, we want to identify what “could”¹ go wrong at each of the process steps, “why it might happen,” the causes of those failures, and the effects of those failures.

¹ These are referred to as “Failure Modes”
### Step 4: Brainstorm Potential Failure Modes, Causes, and Effects

<table>
<thead>
<tr>
<th>Step</th>
<th>Failure Mode</th>
<th>Cause of Failure</th>
<th>Effect of Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>N/A</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td>2</td>
<td>Child not banded</td>
<td>Not in Policies &amp; Procedures, Not in Standard of Care, Not Emphasized, Not Understood</td>
<td>No HUGS Protection</td>
</tr>
<tr>
<td>3</td>
<td>Insufficient IS info provided to mom</td>
<td>Forgetfulness, Training Issues, Not Assuming Responsibility</td>
<td>Mom Doesn’t know Infant Security Precautions</td>
</tr>
<tr>
<td>3</td>
<td>Mom not paying attention</td>
<td>Not the Best Time for Mom</td>
<td>Mom Doesn’t know Infant Security Precautions</td>
</tr>
<tr>
<td>3</td>
<td>Info not understood</td>
<td>Cultural/Language Barriers</td>
<td>Mom Doesn’t know Infant Security Precautions</td>
</tr>
<tr>
<td>4</td>
<td>Baby may not be HUGS banded prior to washing</td>
<td>Caregiver Knowledge Deficit about New System</td>
<td>Baby may be Moved w/o HUGS Protection</td>
</tr>
</tbody>
</table>
## Step 4: Brainstorm Potential Failure Modes, Causes, and Effects

<table>
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<tr>
<th>Step</th>
<th>Failure Mode</th>
<th>Cause of Failure</th>
<th>Effect of Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Info not entered into computer system, including name/room#</td>
<td>Room # Changed, ?</td>
<td>Delayed Response to HUGS Alarm</td>
</tr>
<tr>
<td>5</td>
<td>Delay in entering info into computer system</td>
<td>Workload issues</td>
<td>Delayed Response to HUGS Alarm</td>
</tr>
<tr>
<td>5</td>
<td>&quot;Unfounded&quot; Alarms</td>
<td>Too Close to Sensor(s), Baby Kicking, Family Tampering w/ HUGS Tag</td>
<td>Staff Desensitization</td>
</tr>
<tr>
<td>5</td>
<td>Alarm ringing - doors not locking</td>
<td>Mechanical Failure, Fire Alarm, Door Open During Alarm</td>
<td>Compromised IS Protection</td>
</tr>
</tbody>
</table>
### Step 4: Brainstorm Potential Failure Modes, Causes, and Effects

<table>
<thead>
<tr>
<th>Step</th>
<th>Failure Mode</th>
<th>Cause of Failure</th>
<th>Effect of Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td><strong>HUGS band not applied until reaching post partum (sometimes)</strong></td>
<td>SCN Transfer,</td>
<td>No HUGS Protection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not in &quot;Standard of Care,&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(See FM #2)</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td><strong>Bands loosening</strong></td>
<td>Diminished Swelling of Infant's Limb</td>
<td>HUGS Band may Fall Off</td>
</tr>
<tr>
<td>8</td>
<td><strong>Bands not checked and/or tightened properly</strong></td>
<td>Not Emphasized, Workload Issues</td>
<td>HUGS Band may Fall Off, or may already have fallen off</td>
</tr>
<tr>
<td>9</td>
<td><strong>Not checked against census</strong></td>
<td>Not on Charge Nurse Flow Sheet, Knowledge Issue, Workload Issue</td>
<td>Erroneous Computer Records, Delayed Response to HUGS Alarm</td>
</tr>
<tr>
<td>9</td>
<td><strong>Transferred rooms, not updated</strong></td>
<td>Line of Responsibility Unclear</td>
<td>Erroneous Computer Records, Delayed Response to HUGS Alarm</td>
</tr>
</tbody>
</table>
## Step 4: Brainstorm Potential Failure Modes, Causes, and Effects

<table>
<thead>
<tr>
<th>Step</th>
<th>Failure Mode</th>
<th>Cause of Failure</th>
<th>Effect of Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>HUGS band may not be checked when moving to nursery, other, for blood draws,</td>
<td>Not Emphasized, Workload Issues, Training Issues, Nurse may perform ID Check Only</td>
<td>Possible Lack of HUGS Protection</td>
</tr>
<tr>
<td></td>
<td>circ., etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11, 12, 13</td>
<td>N/A</td>
<td>&quot;Not Part of Routine,&quot; Limited Staff to Cover SCN - &quot;Can't leave,&quot; No Computer/No HUGS Bands/Supplies</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Leaving SCN other than for discharge w/o HUGS band (may include family room</td>
<td>&quot;Not Part of Routine,&quot; Limited Staff to Cover SCN - &quot;Can't leave,&quot; No Computer/No HUGS Bands/Supplies</td>
<td>Lack of HUGS Protection</td>
</tr>
<tr>
<td></td>
<td>visiting)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>misc.</td>
<td>Side door not reactivating properly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>misc.</td>
<td>Other entrance issues related to cameras and other security features</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Step 5  Evaluate the Risk of Failure, or Hazard Score

- The relative risk of a failure and its effects is composed of three factors in an FMEA: Severity, Probability of Occurrence, and Detection Capability

- The “severity” is the consequence of the failure should it occur

- The “probability of occurrence” is the likelihood of a failure mode occurring

- The “detection rating” is our ability to catch the error before causing patient harm
## Severity Rating Scale

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Extremely dangerous</td>
<td>Failure could cause death of a customer (patient, visitor, employee, staff member, business partner) and/or total system breakdown, without any prior warning.</td>
</tr>
<tr>
<td>9</td>
<td>Very dangerous</td>
<td>Failure could cause major or permanent injury and/or serious system disruption with interruption in service, with prior warning.</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td>Failure causes minor to moderate injury with a high degree of customer dissatisfaction and/or major system problems requiring major repairs or significant re-work.</td>
</tr>
<tr>
<td>7</td>
<td>Dangerous</td>
<td>Failure causes minor injury with some customer dissatisfaction and/or major system problems.</td>
</tr>
<tr>
<td>6</td>
<td>Moderate danger</td>
<td>Failure causes minor injury with some customer dissatisfaction and/or major system problems.</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>Failure causes very minor or no injury but annoys customers and/or results in minor system problems that can be overcome with minor modifications to system or process.</td>
</tr>
<tr>
<td>4</td>
<td>Low to Moderate danger</td>
<td>Failure causes no injury and customer is unaware of problem however the potential for minor injury exists; little or no effect on system.</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>Failure causes no injury and has no impact on system.</td>
</tr>
</tbody>
</table>

## Occurrence Rating Scale

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
<th>Potential Failure Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Certain probability of occurrence</td>
<td>Failure occurs at least once a day; or, failure occurs almost every time.</td>
</tr>
<tr>
<td>9</td>
<td>Failure is almost inevitable</td>
<td>Failure occurs predictably; or, failure occurs every 3 or 4 days.</td>
</tr>
<tr>
<td>8 7</td>
<td>Very high probability of occurrence</td>
<td>Failure occurs frequently; or failure occurs about once per week.</td>
</tr>
<tr>
<td>6 5</td>
<td>Moderately high probability of occurrence</td>
<td>Failure occurs about once per month.</td>
</tr>
<tr>
<td>4 3</td>
<td>Moderate probability of occurrence</td>
<td>Failure occurs occasionally; or, failure once every 3 months.</td>
</tr>
<tr>
<td>2</td>
<td>Low probability of occurrence</td>
<td>Failure occurs rarely; or, failure occurs about once per year.</td>
</tr>
<tr>
<td>1</td>
<td>Remote probability of occurrence</td>
<td>Failure almost never occurs; no one remembers last failure.</td>
</tr>
</tbody>
</table>

## DETECTION RATING SCALE

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>No chance of detection</td>
<td>There is no known mechanism for detecting the failure.</td>
</tr>
<tr>
<td>9</td>
<td>Very Remote/Unreliable</td>
<td>The failure can be detected only with thorough inspection and this is not feasible or cannot be readily done.</td>
</tr>
<tr>
<td>8</td>
<td>Remote</td>
<td>The error can be detected with manual inspection but no process is in place so that detection left to chance.</td>
</tr>
<tr>
<td>7</td>
<td>Moderate chance of detection</td>
<td>There is a process for double-checks or inspection but it not automated and/or is applied only to a sample and/or relies on vigilance.</td>
</tr>
<tr>
<td>6</td>
<td>High</td>
<td>There is 100% inspection or review of the process but it is not automated.</td>
</tr>
<tr>
<td>5</td>
<td>Very High</td>
<td>There is 100% inspection of the process and it is automated.</td>
</tr>
<tr>
<td>4</td>
<td>Almost certain</td>
<td>There are automatic “shut-offs” or constraints that prevent failure.</td>
</tr>
</tbody>
</table>

Calculating the RPN

**Risk Priority Number** =

Severity x Occurrence x Detectability

Scores are 1-10;
The resulting number is 1-1000

*(Minor problem: RPN ≤ 100)*
## Step 5  Evaluate the Risk of Failure, or Hazard Score

<table>
<thead>
<tr>
<th>Step</th>
<th>Failure Mode</th>
<th>Frequency of Failure</th>
<th>Degree of Severity</th>
<th>Chance of Detection</th>
<th>Risk Priority #</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>N/A</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td>2</td>
<td>Child not banded</td>
<td>7</td>
<td>10</td>
<td>5</td>
<td>350</td>
</tr>
<tr>
<td>3</td>
<td>Insufficient IS info provided to mom</td>
<td>4</td>
<td>5</td>
<td>8</td>
<td>160</td>
</tr>
<tr>
<td>3</td>
<td>Mom not paying attention</td>
<td>8</td>
<td>5</td>
<td>8</td>
<td>320</td>
</tr>
<tr>
<td>3</td>
<td>Info not understood</td>
<td>2</td>
<td>5</td>
<td>8</td>
<td>80</td>
</tr>
<tr>
<td>4</td>
<td>Baby may not be HUGS banded prior to washing</td>
<td>9</td>
<td>10</td>
<td>3</td>
<td>270</td>
</tr>
</tbody>
</table>
## Step 5  Evaluate the Risk of Failure, or Hazard Score

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<tr>
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<th>Degree of Severity</th>
<th>Chance of Detection</th>
<th>Risk Priority #</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Info not entered into computer system, including name/room#</td>
<td>8</td>
<td>10</td>
<td>5</td>
<td>400</td>
</tr>
<tr>
<td>5</td>
<td>Delay in entering info into computer system</td>
<td>4</td>
<td>10</td>
<td>5</td>
<td>200</td>
</tr>
<tr>
<td>5</td>
<td>&quot;Unfounded&quot; Alarms</td>
<td>3</td>
<td>10</td>
<td>10</td>
<td>300</td>
</tr>
<tr>
<td>5</td>
<td>Alarm ringing - doors not locking</td>
<td>2</td>
<td>10</td>
<td>10</td>
<td>200</td>
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Step 5  Evaluate the Risk of Failure, or Hazard Score

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</thead>
<tbody>
<tr>
<td>6</td>
<td>HUGS band not applied until reaching post partum (sometimes)</td>
<td>5</td>
<td>10</td>
<td>2</td>
<td>100</td>
</tr>
<tr>
<td>7</td>
<td>Bands loosening</td>
<td>9</td>
<td>8</td>
<td>6</td>
<td>432</td>
</tr>
<tr>
<td>8</td>
<td>Bands not checked and/or tightened properly</td>
<td>3</td>
<td>8</td>
<td>8</td>
<td>192</td>
</tr>
<tr>
<td>9</td>
<td>Not checked against census</td>
<td>8</td>
<td>7</td>
<td>7</td>
<td>392</td>
</tr>
<tr>
<td>9</td>
<td>Transferred rooms, not updated</td>
<td>7</td>
<td>7</td>
<td>7</td>
<td>343</td>
</tr>
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</table>
### Step 5  Evaluate the Risk of Failure, or Hazard Score

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<td>HUGS band may not be checked when moving to nursery, other, for blood draws, circ., etc.</td>
<td>7</td>
<td>5</td>
<td>3</td>
<td>105</td>
</tr>
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<td>11, 12, 13</td>
<td>N/A</td>
<td>uria)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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</tbody>
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**Total RPN (Baseline)**: 4164
Calculating the RPN

- In our example, “Child not banded (in L&D)”:  
  
  Severity of the potential effects was rated a “10” (Highest Severity) 
  
  Probability was rated a “7” (High)  
  
  Detection was rated a “5” (Moderate)  
  
  RPN for this failure mode: 10x7x5 = 350 (High)
### Prioritized Failure Mode RPN Scores

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<tr>
<th>Step</th>
<th>Failure Mode</th>
<th>Risk Priority # (Before)</th>
</tr>
</thead>
<tbody>
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<td>7</td>
<td>Bands loosening</td>
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<td>3</td>
<td>Info not understood</td>
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</tr>
<tr>
<td></td>
<td>Misc. Side door not reactivating properly</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Misc. Other entrance issues related to cameras and other security features</td>
<td></td>
</tr>
</tbody>
</table>
Step 6  Calculate the Total RPN Score

Add the totals of all RPN scores to get a grand total

4,164 in this example
Step 7  Determine an Action Plan

- Identify the failure modes that have an RPN Score of 100 or higher. These are the items requiring the greatest attention.

- Develop an action plan to address each of these high-hazard score failure modes. The action plan should include who, what, when, why, etc.
Items Included in the Action Plan:

- **Policy Update**: All normal newborns will be banded ASAP, do not wait for bathing to be completed.

- **Policy Update**: L&D Nurse will obtain the HUGS Band and Patient ID Bands simultaneously.

- **Policy Update**: Transferring & Receiving Nurse will confirm patient ID & HUGS band, documenting this info on the Post Partum flow sheet.
Items Included in the Action Plan:

- **Policy Update**: L&D Nurse will be responsible for activating the HUGS tag and ensuring that the info is entered correctly into the computer system (personally inputting or contacting the Clinical Secretary.)

- **Training**: HUGS computer system entry training will be provided to the Clinical Secretaries.
Items Included in the Action Plan:

- **Checklists:** Create infant security & safety sheet to be shared with mom in L&D, and signed by mom (in Spanish also? Include pictures for universal understanding?) Obtain approval by Forms Committee and Risk Management.

- **Checklists:** Create checklist/script for education of patient & SO (significant other) by staff re: doors, sensors, band tightness, band tampering, etc.
Items Included in the Action Plan:

- **Alarms**: Conduct Quarterly Code Pink Drills (as per policy.)

- **HUGS System**: Ask HUGS representative about other band options to deal with ankle swelling reduction & chafing concerns.
Items Included in the Action Plan:

- **HUGS System**: Ask HUGS rep. if pre-printed instructions are available.

- **Checklists**: Add “HUGS band check/tightening” to the Nurse Assessment flowsheet & educate staff.
Items Included in the Action Plan:

- **Policy Update**: Post Partum Nurse to check HUGS band presence before accepting infant, otherwise infant is to be returned for tagging.

- **Policy Update**: All infants leaving the SCN (except for direct discharge) must be immediately HUGS banded. Update questionnaire / audit form.

- **Training**: Conduct HUGS system refresher for SCN Nurses.
Items Included in the Action Plan:

- **Security**: Have supplier check/repair Physician & Employee entrance to ensure proper reactivation after door closes.

- **Security**: Budget for, and provide additional security cameras and other security features around area perimeters.
Step 8  Determine FMEA Project Success

- Recalculate the RPN scores after implementing the action plan
- Compare with the first FMEA analysis
- Address any items with a recalculated RPN Score of 100 or higher
## Step 8  Determine FMEA Project Success

<table>
<thead>
<tr>
<th>Step</th>
<th>Failure Mode</th>
<th>Before Implementing Action Plan</th>
<th>After Implementing Action Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency of Failure</td>
<td>Degree of Severity</td>
<td>Chance of Detection</td>
</tr>
</tbody>
</table>
| 1    | N/A                                       | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | 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----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- |-----
### Step 8  Determine FMEA Project Success

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<td>Degree of Severity</td>
<td>Chance of Detection</td>
</tr>
<tr>
<td>5</td>
<td>Info not entered into computer system, including name/room#</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>Delay in entering info into computer system</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>&quot;Unfounded&quot; Alarms</td>
<td>3</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>Alarm ringing - doors not locking</td>
<td>2</td>
<td>10</td>
</tr>
</tbody>
</table>
## Step 8  Determine FMEA Project Success

### Before Implementing Action Plan

<table>
<thead>
<tr>
<th>Step</th>
<th>Failure Mode</th>
<th>Frequency of Failure</th>
<th>Degree of Severity</th>
<th>Chance of Detection</th>
<th>Risk Priority #</th>
<th>Frequency of Failure</th>
<th>Degree of Severity</th>
<th>Chance of Detection</th>
<th>Risk Priority #</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>HUGS band not applied until reaching post partum (sometimes)</td>
<td>5</td>
<td>10</td>
<td>2</td>
<td>100</td>
<td>1</td>
<td>10</td>
<td>2</td>
<td>20</td>
</tr>
<tr>
<td>7</td>
<td>Bands loosening</td>
<td>9</td>
<td>8</td>
<td>6</td>
<td>432</td>
<td>5</td>
<td>8</td>
<td>3</td>
<td>120</td>
</tr>
<tr>
<td>8</td>
<td>Bands not checked and/or tightened properly</td>
<td>3</td>
<td>8</td>
<td>8</td>
<td>192</td>
<td>2</td>
<td>8</td>
<td>3</td>
<td>48</td>
</tr>
<tr>
<td>9</td>
<td>Not checked against census</td>
<td>8</td>
<td>7</td>
<td>7</td>
<td>392</td>
<td>4</td>
<td>7</td>
<td>4</td>
<td>112</td>
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<tr>
<td>9</td>
<td>Transferred rooms, not updated</td>
<td>7</td>
<td>7</td>
<td>7</td>
<td>343</td>
<td>2</td>
<td>7</td>
<td>2</td>
<td>28</td>
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</table>
### Step 8  Determine FMEA Project Success

<table>
<thead>
<tr>
<th>Step</th>
<th>Failure Mode</th>
<th>Frequency of Failure</th>
<th>Degree of Severity</th>
<th>Chance of Detection</th>
<th>Risk Priority #</th>
<th>Frequency of Failure</th>
<th>Degree of Severity</th>
<th>Chance of Detection</th>
<th>Risk Priority #</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>HUGS band may not be checked when moving to nursery, other, for blood draw s, circ., etc.</td>
<td>7</td>
<td>5</td>
<td>3</td>
<td>105</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>11, 12, 13</td>
<td>N/A</td>
<td>----</td>
<td>----</td>
<td>----</td>
<td>----</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Leaving SCN other than for discharge w/o HUGS band (may include family room visiting)</td>
<td>5</td>
<td>8</td>
<td>8</td>
<td>320</td>
<td>1</td>
<td>8</td>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>misc.</td>
<td>Side door not reactivating properly</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>misc.</td>
<td>Other entrance issues related to cameras and other security features</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total RPN (Baseline)** 4164  
**Total RPN (After)** 1372  
**Percent Improvement** 67.05%
Lessons Learned

- FMEA can be a time consuming process
- Be sure to obtain management support
- Keep the team motivated
- The results are worthwhile
In Conclusion

- FMEA is a tool for proactive risk assessment now used in healthcare

- Infant Security was chosen as the 2003 FMEA project because of the high volume of births in the WakeMed system (approx. 7800 births/year) and the significance of this issue.

- Significant reductions in scored risk have been realized through the use of this tool.
Questions?
References:

ISMP Website, *Example of a Health Care Failure Mode and Effects Analysis for IV Patient Controlled Analgesia (PCA)*, ISMP.Com


References:


Understanding the Failure Modes and Effects Analysis, an on-line course, HCProfessor.com, 2002. Phone #: 800-650-6787.