Application of SHERPA to Predict and Prevent use error in medical devices

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What is SHERPA?

• Systematic Human Error Reduction & Prediction Analysis

• A software supported tool to document and analyse safety critical tasks in healthcare, medical device design and other industries

• Combines FMEA, HAZOP, root cause analysis and procedures development in a single package
Proactive use error analysis using SHERPA

Select safety critical tasks

Find out how people really perform the task (Task Analysis)

Identify Use Errors & outcomes

Evaluate alternative risk reduction strategies

Evaluate existing risk control measures

Evaluate Performance influencing factors
SHERPA Design objectives

• Extend the capabilities of conventional FMEA
• Address retrospective incident causal analysis (inputs to CAPA)
• Support task analysis via an intuitive graphical interface
• Support identification of failure modes using an activities classification with associated library of failure modes
• Support numerical assessment of factors influencing use error (Performance Influencing Factors)
• Automatically generate IFUs from the task and risk analyses
• Speed up the risk analysis process
Feedback on effectiveness

• ‘One of the best techniques for human error analysis prediction & reduction’ (Rail Safety & Standards Board HF Good Practice Guide, 2012)

• Most highly rated by expert users of human error identification techniques (Kirwan, 1992)

• Validation studies
  – Concurrent validity 0.8, Reliability 0.9 (Stanton & Stevenage 1998)
Stage 1 - Carry out Hierarchical Task Analysis

Preconditions
The correct model of syringe driver is in use
The driver has been thoroughly cleaned using alcohol wipes and is serviceable
An appropriate amount of the correct drug is available

Goal
Administer a subcutaneous medication using a syringe driver

Plan 0
Do 1-4 in order

1. Prepare the syringe driver
   Nurse 1
2. Prepare patient
   Nurse 1
3. Prepare insertion site
   Nurse 1
4. Insert the needle
   Nurse 1

nurse 1
Second level of Task Analysis
Stage 2: Classify the activity types & consider credible Failure Modes

<table>
<thead>
<tr>
<th>Action</th>
<th>Checking</th>
<th>Information Entry</th>
<th>Information communication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action omitted</td>
<td>Check omitted</td>
<td>Information not entered</td>
<td>Information not communicated</td>
</tr>
<tr>
<td>Right action, wrong object checked</td>
<td>Wrong object checked</td>
<td>Information entered into wrong place</td>
<td>Wrong information communicated</td>
</tr>
<tr>
<td>Action incomplete</td>
<td>Check incomplete</td>
<td>Wrong information entered</td>
<td>Information communication incomplete</td>
</tr>
<tr>
<td>Action too late/early</td>
<td>Check incomplete</td>
<td>Information entry not verified</td>
<td>Information communication unclear</td>
</tr>
</tbody>
</table>
Stage 3 - Assign failure modes to task steps

Plan 1.1
Do 1 and 2 in order

1.1.1
Calculate the rate
Nurse 1

1.1.2
Set the rate on the driver
Nurse 1

OR

AND

Fm 1.1.1.1
CALC2 Wrong input values used for calculation

Fm 1.1.1.2
CALC3 Calculation performed incorrectly

Fm 1.1.2.1
INFE2 Wrong information entered

Fm 1.1.2.2
INFE4 Information entry not checked/verified
<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
<th>Agent/Person</th>
<th>Activity Type</th>
<th>Failure Mode</th>
<th>Error Description</th>
<th>Consequences</th>
<th>Existing Risk Control Measures / Recovery</th>
<th>New RCM</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1.1</td>
<td>Calculate the rate</td>
<td>Nurse 1</td>
<td>Calculation</td>
<td></td>
<td></td>
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<td></td>
<td>Fm 1.1.1.1</td>
<td></td>
<td>Calculation</td>
<td></td>
<td>CALC2 Wrong input values used for calculation</td>
<td>Rate incorrect</td>
<td>Wrong amount of drug is given</td>
<td>Self monitoring</td>
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<tr>
<td></td>
<td>Fm 1.1.1.2</td>
<td></td>
<td>Calculation</td>
<td></td>
<td>CALC3 Calculation performed incorrectly</td>
<td>Rate incorrect</td>
<td>Wrong amount of drug is given</td>
<td>Self monitoring</td>
</tr>
<tr>
<td>1.1.2</td>
<td>Set the rate on the driver</td>
<td>Nurse 1</td>
<td>Information Entry</td>
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<tr>
<td></td>
<td>Fm 1.1.2.1</td>
<td></td>
<td>Information Entry</td>
<td></td>
<td>INFE2 Wrong information entered</td>
<td>Rate is entered incorrectly</td>
<td>Drug is infused at wrong rate</td>
<td>Self monitoring</td>
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<td></td>
<td>Fm 1.1.2.2</td>
<td></td>
<td>Information Entry</td>
<td></td>
<td>INFE4 Information entry not checked/verified</td>
<td>Rate is entered incorrectly</td>
<td>Drug is infused at wrong rate</td>
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<tr>
<td>Step</td>
<td>Description</td>
<td>Role</td>
<td>Comments</td>
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<tr>
<td>1</td>
<td>Prepare the syringe driver</td>
<td>Nurse 1</td>
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<tr>
<td>Plan 1</td>
<td>Do in Sequence</td>
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<tr>
<td>1.1</td>
<td>Set the administration rate</td>
<td>Nurse 1</td>
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<tr>
<td>Plan 1.1</td>
<td>Do 1 and 2 in order</td>
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<tr>
<td>1.1.1</td>
<td><strong>WARNING: Make sure that a second person verifies the calculation results</strong></td>
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<tr>
<td></td>
<td>Calculate the rate</td>
<td>Nurse 1</td>
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<tr>
<td>1.1.2</td>
<td><strong>WARNING: Get a second person to check that the rate has been inserted correctly</strong></td>
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<td></td>
<td>Set the rate on the driver</td>
<td>Nurse 1</td>
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<tr>
<td>1.2</td>
<td>Prepare the drug</td>
<td>Nurse 1</td>
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<tr>
<td>Plan 1.2</td>
<td>Do in any order 1.2.1 and 1.2.2.</td>
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<td>Do in order 1.2.3 to 1.2.5</td>
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<tr>
<td>1.2.1</td>
<td>Clean hands</td>
<td>Nurse 1</td>
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<tr>
<td>1.2.2</td>
<td>Confirm the drug and dosage</td>
<td>Nurse 1</td>
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</tbody>
</table>
How Performance Influencing Factors (PIFs) affect failure types

- Action errors
- Checking errors
- Communication errors (person to person)
- Info retrieval errors
- Selection errors

Device design:
- Controls
- Displays
- Labelling
- Access
- Anthropometrics

Task features:
- Frequency of change
- Similarity to other tasks
- Isolated actions
- Complexity
- Frequency

Context:
- Distractions
- Roles & responsibilities
- Perceived risks
- Fatigue
- Morale
SLI = Success Likelihood Index
Measures of the quality of the factors that influence use error probability

1.00 = Performance Influencing Factors (PIFs) are best case-error is unlikely

0.00 = Performance Influencing Factors (PIFs) are worst case-error is very likely
Using SHERPA for causal analysis of incidents and close calls (CAPA)
Improvements in use error probability following redesign

- Success Likelihood Index (SLI) = 0.75
- Failure Probability = 0.0047

7.1 The need to enter the information was not obvious
7.2 The interface (e.g. screen, form) did not support error free information entry
Applications: Design of new devices

• User interaction with the device can be modelled at a functional level during initial design development

• High consequence use errors can be identified and appropriate Risk Control Measures implemented in the design

• Error inducing factors in the context of use can be taken into account in the design

• Predictive human error assessment can be used to evaluate cost effectiveness of alternative design options
Applications: Evaluation of existing devices

• Use experienced users (Consensus groups) to analyse how devices are used in the wild (often differ from documented IFUs)

• Evaluate impact of actual use patterns by applying SHERPA error identification process

• Evaluate cost effectiveness of interventions

• Redesign if appropriate
Applications: retrospective causal analysis of incidents and close calls (CAPA)

- Use task analyses to document the actual pattern of device use when the error occurred
- The Swimlane analyser provides timeline analysis of incident scenario
- PIF models allow device and context specific causal factors to be assessed to identify problem areas
- The software evaluates the relative contribution of device design and context of use factors to observed errors
- This allows the expected cost effectiveness of alternative use error reduction strategies to be evaluated
Conclusions

• SHERPA has been applied in many safety critical industries over the past 30 years
• It provides much more comprehensive analyses than conventional FMEAs
• SHERPA software (Human Factors Risk Manager) provides support for early design studies and as an input for user trials
• SHERPA provides support for meeting regulatory standards such as IEC 60601-1-6 for Usability Engineering and ISO 14971:2007 for Risk Assessment

Demonstration copies of the SHERPA software are available