Fault Tree Analysis

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Disclosure

Peter Dunscombe is a Member of TreatSafely, LLC

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Purpose of a Fault Tree Analysis

To make the (radiotherapy) system safer through using postulated failure modes, tracing the failure pathways back and, on the basis of the FTA,

• Identifying key core structural safety features
• Designing the QA/QC Program.
Learning Objectives

- Identify several varieties of Fault Trees
- Point out the disastrous consequences of failing to learn from a Fault Tree Analysis
- Use Fault Trees to help identify key core components of a safe radiation treatment program
- Position QA/QC activities in the Fault Tree

Root Cause Analysis (RCA)

Fault Tree Analysis (FTA)
A Fault Tree Analysis can be regarded as a hypothetical Root Cause Analysis.
• An actual event starts an RCA
• Postulated failure modes are used to start and FTA.
• However, in both, the failure pathway is traced back.
• Postulated failure modes can be imported from a Failure Modes and Effects Analysis.

FTAs are extensively used in high risk, high reliability industries such as the chemical, nuclear and aviation industries.
Varieties of Fault Trees

• A Fault Tree can be descriptive or quantitative.
• A quantitative Fault Tree can be developed from reported data (Thomadsen) or expert elicitation (Ekaette).
• A Fault Tree can be extended to a Root Cause Tree by including Basic or Root Causes.

Thomadsen et al. IJROBP 2003 (57) 1496
Ekaette et al. Risk Analysis. 2007 (27) 1397

Performing a Fault Tree Analysis

A Fault Tree Analysis is normally carried out by a small team:
• Leader – knowledge of FTA and subject area of review
• Facilitator – expertise in FTA
• Content experts – knowledge of subject area of review and preferably multidisciplinary in our environment.

Varieties of Fault Trees

1. Standard (Engineering) Fault Tree
2. Root Cause Tree
3. Probabilistic Fault Tree (data based)
4. Probabilistic Fault Tree (elicitation based)
5. TG 100’s FTA
Engineering Fault Tree

Ekaette’s Fault Tree

Ekaette et al. Risk Analysis. 2007 (27) 1397
Varieties of Fault Trees

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Root Cause Tree

- A Root Cause Tree proceeds to the right beyond just events to the Basic or Root Causes.
- Either free text Root Causes could be used or a more structured assignment, for example from a Basic Causes Table.

Root Cause Tree
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Probabilistic Fault Tree (Thomadsen)

- Focused on HDR and LDR Brachytherapy.
- Based on 134 reports (1980-2001) in the NRC and IAEA databases.
- Produced a conventional FTA, a process map and an example of a root cause analysis tree.
- Classified failures according to three taxonomies.

Thomadsen et al. IJROBP 2003 (57) 1496
“In industries such as nuclear power, where probabilistic risk assessment originated, most failures occur only when several systems fail concurrently, and the combination of probabilities becomes important. Most medical events, although they have several root causes and concurrent unusual situations, fail along a single branch of the fault tree.”

Prescient observation by Thomadsen et al.

“Errors often follow violations in protocols, particularly failures to perform verification procedures, and indicators that things are not correct are often present yet ignored during events.”
Prescient observation by Thomadsen

2003

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Probabilistic Fault Tree Analysis (Ekaette)

• Focused on Treatment Preparation for External Beam Radiotherapy.
• Expert team of 3 medical physicists, 1 oncologist, 7 therapists/dosimetrist.
• Examined NRC, ROSIS and IAEA reports to identify what could go wrong.
• Expert elicitation required some training in understanding probabilities.

Ekaette et al. Risk Analysis. 2007 (27) 1397
Overall, however, the expert probability estimates used in conjunction with the fault tree method produced an overall incident probability result for the Preparation domain of 0.37%, which is comparable to the 0.14–0.68% incident probability range experienced in 2002–2005.

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Fault Tree Analysis helps to identify:

- possible systemic program weaknesses
- where to put barriers and checks.
TG 100’s Progenitor Causes

<table>
<thead>
<tr>
<th>Category</th>
<th>Occasions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Failure</td>
<td>294</td>
</tr>
<tr>
<td>Lack of Standardized Procedures</td>
<td>99</td>
</tr>
<tr>
<td>Inadequate Training</td>
<td>87</td>
</tr>
<tr>
<td>Inadequate Communication</td>
<td>87</td>
</tr>
<tr>
<td>Hardware/Software Failure</td>
<td>58</td>
</tr>
<tr>
<td>Faults</td>
<td>9</td>
</tr>
<tr>
<td>Software</td>
<td>44</td>
</tr>
<tr>
<td>Hardware or software</td>
<td>5</td>
</tr>
<tr>
<td>Lack of staff</td>
<td>17</td>
</tr>
<tr>
<td>Inadequate design specifications</td>
<td>12</td>
</tr>
<tr>
<td>Inadequate Knowledge/Training</td>
<td>18</td>
</tr>
<tr>
<td>Use of defective materials/equip</td>
<td>12</td>
</tr>
</tbody>
</table>

TG 100’s Key Core Requirements

To prevent failures in radiation therapy in general (and IMRT in particular), a QM program should have elements that TG 100 terms key core requirements for quality. These core requirements are:

- Standardized procedures
- Adequate staff, physical and IT resources
- Adequate training of staff
- Maintenance of hardware and software resources
- Clear lines of communication among staff

From Incident Learning Systems
From a literature review

**Recommendations for safer radiotherapy:**
what’s the message?

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- Training (7)
- Staffing/skills mix (6)
- Documentation/SOP (5)
- Incident Learning System (5)
- Communication/questioning (4)
- Check lists (4)
- QC and PM (4)
- Dosimetric Audit (4)
- Accreditation (4)
- Minimizing interruptions (3)
- Prospective risk assessment (3)
- Safety Culture (3)

TG 100’s Key Core Requirements

<table>
<thead>
<tr>
<th>TG 100</th>
<th>Incident Learning</th>
<th>Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standardized procedures</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Adequate staff, physical and IT resources</td>
<td>✔</td>
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<td>Adequate training of staff</td>
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<td>Maintenance of hardware and software resources</td>
<td>✔</td>
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</tr>
<tr>
<td>Clear lines of communication among staff</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

TG 100’s Key Core Requirements are endorsed by Incident Learning experience and consensus recommendations in the literature.

Safety Barriers

Fault Tree Analysis helps to identify where to put barriers and checks.
Varieties of Fault Trees

1. Standard (Engineering) Fault Tree
   Descriptive tree ending on an event, e.g. mechanical failure

2. Root Cause Tree
   Descriptive tree ending on progenitor cause or latent condition, e.g. inadequate training

3. Probabilistic Fault Tree (data based)
   Quantitative tree with probabilities from error database(s)

4. Probabilistic Fault Tree (elicitation based)
   Quantitative tree with consensus probabilities based on experience and available literature

5. TG 100’s FTA
   Descriptive consensus based "Root Cause" Tree

Summary

- Several varieties of Fault Trees exist
- The New York incident was predicted years before it happened
- TG 100 has used Fault Trees to help identify key core components of a safe radiation treatment program
- QA/QC can be placed in the context of an FTA.