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UNIVERSITY OF CALGARY

Fault Tree Analysis

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Disclosure

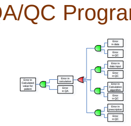
Peter Dunscombe is a Member of TreatSafely, LLC

treatsafely.org

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,

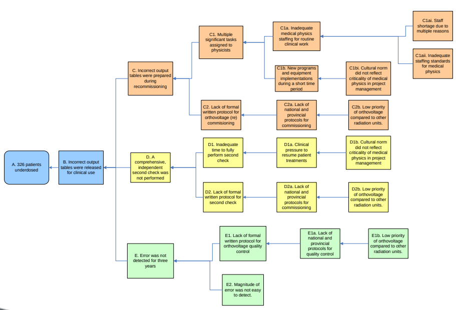
- Identifying key core structural safety features
- Designing the QA/QC Program.



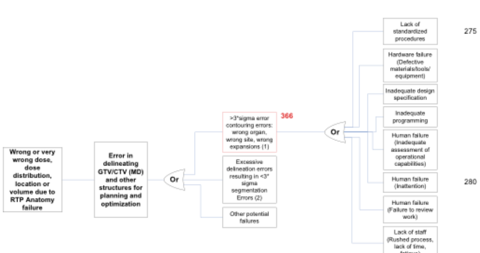
Learning Objectives

- 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)

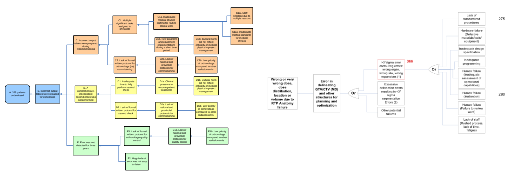


Fault Tree Analysis (FTA)



RCA and FTA

Look similar?



RCA and 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.

Fault Tree 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

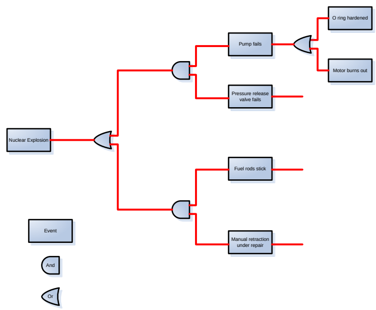
A Fault Tree Analysis is normally carried out by a small team:

- 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.

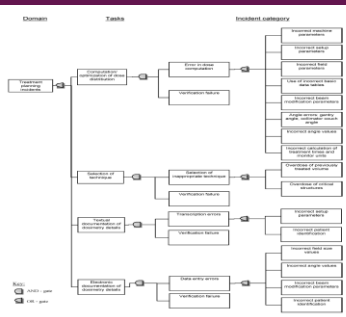
Varieties of Fault Trees

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

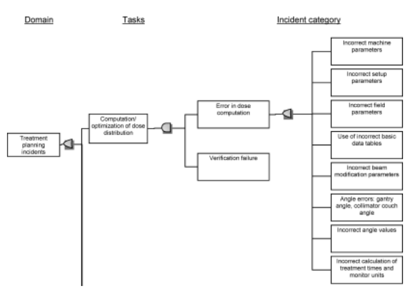


Ekaette's Fault Tree



Ekaette et al. Risk Analysis. 2007 (27) 1397

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.

Classification of Basic Cause

Facility Management/Planning

1 **Inadequate Human Resources**
- 1.1 Inconsistent with prof. recommendations
- 1.2 Inconsistent with vendor specs
- 1.3 Inconsistent with regulations
- 1.4 No provision for increase in activities
- 1.5 Personnel availability

2 **Inadequate Capital Resources**
- 2.1. Inadequate budget for equipment
- 2.2. Inadequate support/service contracts
- 2.3. Inadequate training support
- 2.4. Insufficient IT infrastructure
- 2.5. Inappropriate or inadequate equipment

3 **Policies, Procedures, Regulations**
- 3.1. Relevant policy nonexistent
- 3.2. Policy not implemented
- 3.3. Policy inadequate
- 3.4. Policy not followed
- 3.5. External regulation not followed
- 3.6. Conflicting policies

4 **Training**
- 4.1. Facility training inadequate
- 4.2. Vendor training inadequate
- 4.3. Training needs not identified
- 4.4. Inadequate assessment of staff competencies
- 4.5. Lack of continuing education

5 **Communication**
- 5.1. Poor/incomplete/unclear/missing documentation
- 5.2. Inadequate communication patterns designed
- 5.3. Inappropriate or misdirected communication
- 5.4. Failure to request needed information
- 5.5. Medical records incorrect/incomplete/absent
- 5.6. Lack of timeliness
- 5.7. Verbal instruction inconsistent w documentation

6 **Physical Environment**
- 6.1. Physical environment inadequate
- 6.2. Distracting environment
- 6.3. Interruptions
- 6.4. Conflicting demands/priorities

7 **Leadership and External Issues**
- 7.1. Inadequate safety culture
- 7.2. Failure to remedy past known shortcomings
- 7.3. Environment not conducive to safety
- 7.4. Hostile work environment
- 7.5. Inadequate supervision
- 7.6. Lack of peer review
- 7.7. Leaders not fluent in the discipline
- 7.8. Outdated practices

Clinical Infrastructure

8 **Materials/Tools/Equipment**
- 8.1. Availability
- 8.2. Defective
- 8.3. Used incorrectly
- 8.4. Inadequate assessment of material/tool/equipment for the task

9 **Acceptance Testing & Commissioning**
- 9.1. Not following best-practice documents
- 9.2. Lack of independent review
- 9.3. Lack of review of pre-existing reports
- 9.4. Lack of effective documentation

10 **Equipment Design and Construction**
- 10.1. Inadequate P&Ps for QA and QC
- 10.2. Inadequate hazard assessment
- 10.3. Inadequate design specification
- 10.4. Inadequate assessment of operational capabilities
- 10.5. Poor human factors engineering
- 10.6. Interoperability problems
- 10.7. Networking problems (IT)
- 10.8. Software operation failure
- 10.9. Poor construction (physical)

11 **Equipment Maintenance**
- 11.1. Failure to report problems to vendor
- 11.2. Failure to follow vendor field change orders
- 11.3. Failure to provide adequate preventive maintenance
- 11.4. Failure by vendor to share failure/safety issues
- 11.5. Unavailability of local and field support

12 **Environment (within the facility)**
- 12.1. Ergonomics (room layout, equipment setup)
- 12.2. Machine collision issues (room specific)
- 12.3. Environment (water, HVAC, electrical, gas)
- 12.4. IT infrastructure and networking issues
- 12.5. Delay in corrective actions for facility problems

13 **External Factors (beyond Facility Control)**
- 13.1. Natural environment
- 13.2. Hazards

Clinical Process

14 **Failure to detect a developing problem**
- 14.1. Environmental masking
- 14.2. Distraction
- 14.3. Loss of attention
- 14.4. Lack of information

15 **Failure to interpret a developing problem**
- 15.1. Inadequate search
- 15.2. Missing information
- 15.3. Incorrect information
- 15.4. Expectation Bias

16 **Failure to select the correct rule**
- 16.1. Incomplete or faulty rule
- 16.2. Old or invalid rule
- 16.3. Misapplication of a rule

17 **Failure to develop an effective plan**
- 17.1. Information not seen or sought
- 17.2. Inappropriate assumptions
- 17.3. Failure to recognize a hazard
- 17.4. Information misinterpreted
- 17.5. Inadequate management of change
- 17.6. Inadequate assessment of needs & risks
- 17.7. Side effects not adequately considered
- 17.8. Mistaken options

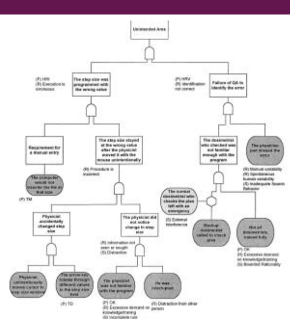
18 **Failure to execute the planned action**
- 18.1. Stereotype take-over/faulty triggering
- 18.2. Plan forgotten in progress
- 18.3. Plan misinterpreted
- 18.4. Plan too complicated (bounded reality)

19 **Patient-Related Circumstances**
- 19.1. Misleading representation
- 19.2. Cognitive performance issues
- 19.3. Non-compliance
- 19.4. Language issues and comprehension
- 19.5. Patient condition, eg. physical capabilities, inability to remain still

20 **Human Behavior Involving Staff**
- 20.1. Unclear roles, responsibilities & accountabilities
- 20.2. Acting outside one's scope of practice
- 20.3. Slip causing physical error
- 20.4. Poor judgment
- 20.5. Language and comprehension issues
- 20.6. Intentional rules violation
- 20.7. Negligence

21 **Other**

Root Cause Tree



Thomadsen et al. IJROBP 2003 (57) 1496

Varieties of Fault Trees

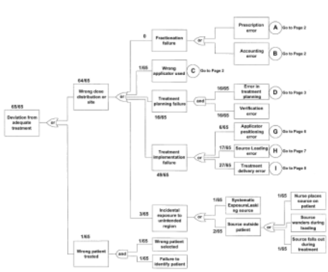
1. Standard Fault Tree
2. Root Cause Tree
3. **Probabilistic Fault Tree (data based)**
4. Probabilistic Fault Tree (elicitation based)
5. TG 100's FTA

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

Probabilistic Fault Tree (Thomadsen)



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Probabilistic Fault Tree (Thomadsen)

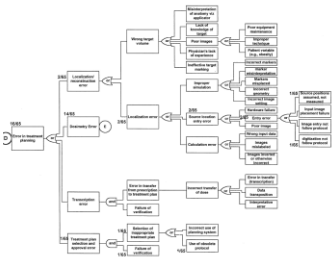

Fig. 5. Continuation of a branch of the LDR fault tree. The numbers follow the same rules as in Fig. 4

Thomadsen et al. IJROBP 2003 (57) 1496

Interesting quote from Thomadsen's paper

"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"

Thomadsen et al. IJROBP 2003 (57) 1496

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."

Thomadsen et al. IJROBP 2003 (57) 1496

Prescient observation by Thomadsen

2003

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2006

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH

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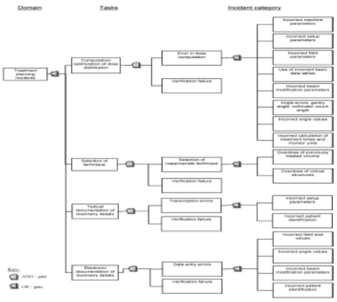
Probabilistic Fault Tree Analysis (Ekaette)

- Focused on Treatment Preparation for External Beam Radiotherapy.
- Expert team of 3 medical physicists, 1 oncologist, 7 therapists/dosimetrists.
- 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

Probabilistic Fault Tree Analysis (Ekaette)



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Probabilistic Fault Tree Analysis (Ekaette)

Table IV. Incident Probability Distribution Per Task in *Preparation* and *Treatment* Domains

	Incident Reports (Probability with 95% Confidence Intervals)					Expert Elicitation Exercise (Based on an Estimated Average of 2,894 Patients per Year)			
	2002 (Total of 2,831 Patients)	2003 (Total of 2,914 Patients)	2004 (Total of 2,886 Patients)	2005 (Total of 2,945 Patients)	2006 (From March to October – Total of 1,523 Patients)	Min	Mean	Max	Standard Deviation
Prescription	<1E−05	<1E−05	<1E−05	0.0003 ± 0.0007	0.0020 ± 0.0022	0.00020	0.00060	0.00200	0.00021
Simulation and cast and mould	0.0014 ± 0.0014	0.0010 ± 0.0012	0.0003 ± 0.0007	0.0024 ± 0.0018	0.0204 ± 0.0071	0.00010	0.00240	0.01030	0.00213
Treatment planning	0.0004 ± 0.0007	0.0003 ± 0.0007	0.0007 ± 0.0010	0.0014 ± 0.0013	0.0092 ± 0.0048	0.00001	0.00010	0.00050	0.00005
Data entry	0.0018 ± 0.0015	<1E−05	0.0003 ± 0.0007	0.0027 ± 0.0019	0.0079 ± 0.0044	0.00002	0.00063	0.00723	0.00070
Preparation domain	0.0035 ± 0.0022	0.0014 ± 0.0013	0.0014 ± 0.0014	0.0068 ± 0.0030	0.0394 ± 0.0098	0.00033	0.00373	0.02003	0.00226
Treatment domain	0.0106 ± 0.0038	0.0110 ± 0.0038	0.0097 ± 0.0036	0.0105 ± 0.0037	0.0190 ± 0.0069	-	-	-	-
Total probability of error	0.0141 ± 0.0043	0.0124 ± 0.0040	0.0110 ± 0.0038	0.0173 ± 0.0047	0.0584 ± 0.0118				

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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TG 100’s Fault Tree Analysis

Failure Modes and Effects Analysis helps to prioritize failure modes for further analysis.

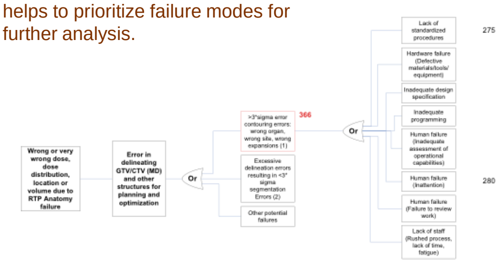
Fault Tree Analysis helps to identify:

•possible systemic program weaknesses

•where to put barriers and checks.

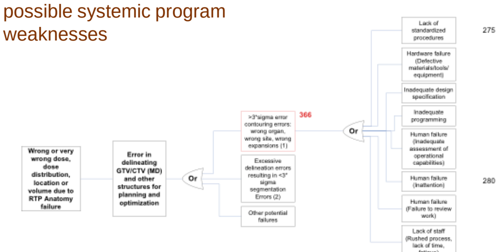
TG 100’s Fault Tree – FMEA input

Failure Modes and Effects Analysis helps to prioritize failure modes for further analysis.



TG 100’s Fault Tree – systemic program issues

Fault Tree Analysis helps to identify possible systemic program weaknesses



TG 100's Progenitor Causes

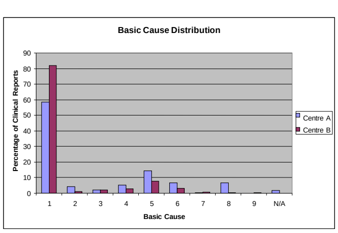
Category	Occasions
Human Failures	230
Lack of Standardized Procedures	99
Inadequate Training	97
Inadequate Communication	67
Hardware/Software Failure	58
Hardware	9
Software	44
Hardware or software	5
Lack of staff	37
Inadequate design specifications	32
Inadequate Commissioning	18
Use of defective materials/tool/equipment	12

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



1 Standards/Procedures Practices
2 Materials/Tools/Equipment
3 Design
4 Planning
5 Communication
6 Knowledge/Skill
7 Capabilities
8 Judgment
9 Natural Factors

From a literature review

frontiers in ONCOLOGY
REVIEW ARTICLE
published: 28 September 2012
doi: 10.3389/fonc.2012.00129

Recommendations for safer radiotherapy: what's the message?

*Peter Dunscombe**
Department of Oncology, University of Calgary, Calgary, AB, Canada

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)

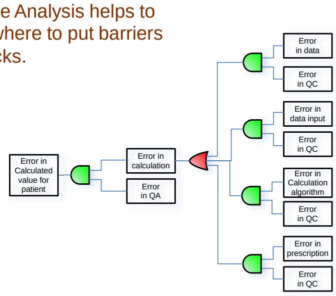
TG 100's Key Core Requirements

TG 100	Incident Learning	Literature
Standardized procedures	✔	✔
Adequate staff, physical and IT resources	✔	✔
Adequate training of staff	✔	✔
Maintenance of hardware and software resources	✔	✔
Clear lines of communication among staff	✔	✔

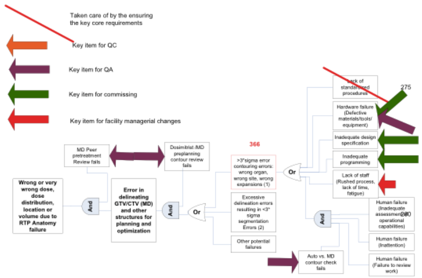
TG 100's Key Core Requirements are endorsed by Incident Learning experience and consensus recommendations in the literature.

Safety Barriers

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



TG 100 – putting it all together



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.