Implementation of TG-100 in a small community clinic

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OCHSNER HEALTH SYSTEM
NEW ORLEANS, LOUISIANA
Congratulations to New NWAAPM Board Rep
Outline

- TG-100 Risk Analysis Methodology
  - Process Mapping
  - Failure Mode and Effects Analysis (FMEA)
  - Fault Tree Analysis (FTA)
- Summary Recommendations
- Post TG-100 Report Efforts
- QM/FMEA Development at Ochsner
AAPM TG-100: APPLICATION OF RISK ANALYSIS METHODS TO RADIATION THERAPY QUALITY MANAGEMENT

- Saiful Huq, chair
- Benedick Fraass
- Peter Dunscombe
- John Gibbons
- Geoffrey Ibbott
- Amo Mundt
- Sasa Mutic
- Jatinder Palta
- Frank Rath
- Bruce Thomsen
- Jeffrey Williamson
- Ellen Yorke
TG-100 Report

TG-100 Report is contained in Two Parts:

- **Part I**
  - Theory and Justification
  - Implementation Guidelines
  - Recommendations for users, vendors, AAPM, regulators
  - Examples and exercises

- **Part II**
  - Example QM Program development for IMRT
TG-100 Definitions

- **Quality:**
  - Features which meet the needs of the patient (medical, psychological, and economic)
  - Process which delivers treatment in accordance with accepted standards
  - Free from errors or mistakes

- **Failure:** Not meeting a desired level of quality.
Quality Management (QM): All activities designed to achieve quality

Quality Control (QC): Procedures that verify the status of a specific Tx parameter

Quality Assurance (QA): Procedures that verify quality goals are met
QC/QA in a Quality Management Program

Bruce Thomadsen, Quality Management in Radiation Therapy-General Concepts, AAPM 2004 Refresher Course
Problems with traditional Quality Management (QM) approaches:

- Excessive demand on physics resources
- Delay in QM protocols for new technologies
- No QM protocol covers all permutations of practice
- Emphasis on device-specific QA
- QA traditionally done retrospectively (e.g., Root Cause Analysis (RCA))
Prospective Approach to QM

Emphasis on Team Approach (i.e., all staff involved in procedures participate)

Three QM Tools Used:

- Process Mapping
- Failure Mode and Event Analysis (FMEA)
- Fault Tree Analysis (FTA)
Process Map

Definition: An illustration of the temporal relationships between different steps in a process

May be displayed graphically in a tree or flow-chart diagram
TG-100 Process Map

6 Initial treatment planning directive

- Specify images for target/structure delineation 11
- Specify protocol for delineating target and structures 17
- Specify registration goals 23, 38
- Indicate motion/uncertainty Management 13, 14
- Suggest initial guidelines for treatment parameters
  - Special Instructions (pacemakers, allergies, preps, etc.) 9
- Specify dose limits and goals 26
- Account for previous treatments or chemotherapy 4
Failure Modes and Effects Analysis (FMEA)

For each step in the process map:
1. Identify all potential failure modes
2. Identify the root causes of each failure mode
3. Numerically rank each failure mode using a Risk Priority Number (RPN):

\[ RPN = O \cdot S \cdot D \]

- O (Occurrence) – Likelihood of failure mode
- S (Severity) – Severity of failure mode
- D (lack of Detectability) – Likelihood failure mode remains undetected
# TG-100 O, S and D Values

<table>
<thead>
<tr>
<th>Qualitative Frequency in %</th>
<th>Qualitative Categorization</th>
<th>Categorization</th>
<th>Estimated Probability of failure going undetected in %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure unlikely</td>
<td>0.01</td>
<td>No effect</td>
<td>Inconvenience</td>
</tr>
<tr>
<td></td>
<td>0.02</td>
<td>Inconvenience</td>
<td>Inconvenience</td>
</tr>
<tr>
<td>Relatively few failures</td>
<td>0.05</td>
<td>Minor dosimetric error</td>
<td>Suboptimal plan or treatment</td>
</tr>
<tr>
<td></td>
<td>0.1</td>
<td>Limited toxicity or tumor underdose</td>
<td>Wrong dose, dose distribution, location or volume</td>
</tr>
<tr>
<td>Occasional failures</td>
<td>&lt;0.2</td>
<td>Potentially serious toxicity or tumor underdose</td>
<td>Very wrong dose, dose distribution, location or volume</td>
</tr>
<tr>
<td></td>
<td>&lt;=2</td>
<td>Possible very serious toxicity or tumor underdose</td>
<td>Very wrong dose, dose distribution, location or volume</td>
</tr>
<tr>
<td></td>
<td>&lt;=5</td>
<td>Catastrophic</td>
<td></td>
</tr>
<tr>
<td>Failures inevitable</td>
<td>&gt;5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Sample Risk Combinations

RPN vs. S

Percent Error

Quantity Value
**FMEA Example: IMRT**

<table>
<thead>
<tr>
<th>Major Processes</th>
<th>Step</th>
<th>Failure Modes</th>
<th>Causes of Failure</th>
<th>Effects of Failure</th>
<th>AVG O</th>
<th>AVG S</th>
<th>AVG D</th>
<th>AVG RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1- Patient Database Information</strong></td>
<td>Entry of patient data in electronic database or written chart</td>
<td>1. Incorrect Patient ID</td>
<td>Errors in manual entry</td>
<td>Very wrong dose</td>
<td>3.78</td>
<td>7.89</td>
<td>3.89</td>
<td>106.78</td>
</tr>
</tbody>
</table>
Fault Tree Analysis (FTA)

Graphical display of the sequence of a failure mode

- Begins on the left with a failure mode
- Possible errors/mistakes which result in the failure are connected by nodes.
- Nodes may be logical OR or AND gates depending on whether one or all of the errors are required for the failure
Fault Tree - Pre-QM Program

Wrong or very wrong dose, dose distribution, location or volume due to RTP Anatomy failure

Error in delineating GTV/CTV (MD) and other structures for planning and optimization

Or

>3*sigma error contouring errors: wrong organ, wrong site, wrong expansions (1)

Excessive delineation errors resulting in <3* sigma segmentation Errors (2)

Other potential failures

Or

Lack of standardized procedures

Hardware failure (Defective materials/tools/equipment)

Inadequate design specification

Inadequate programming

Human failure (Inadequate assessment of operational capabilities)

Human failure (Inattention)

Human failure (Failure to review work)

Lack of staff (Rushed process, lack of time, fatigue)
Fault Tree Example – Adding QC/QA
TG-100: How to Perform a Risk Analysis

1. Define the Process
   1. Assemble a multi-disciplinary team
   2. Develop a process map

2. Perform an FMEA risk assessment
   1. List each process step
   2. Identify failure modes for each step
   3. Identify potential causes of each failure mode
   4. Identify potential effects of each failure mode
TG-100: How to Perform a Risk Analysis

2. Perform an FMEA risk assessment
5. Identify current process controls
6. Determine failure likelihood
7. Calculate the Risk Priority Number (RPN)
8. Identify Failure Modes with highest RPNs
9. Develop new process controls
TG-100 Recommendations

- Individual Clinics
  - Every clinic should develop a risk-analysis QM program
  - Key personnel should attend training as required
  - Begin with high-risk procedures (e.g., SBRT)
  - FMEA should be done on ongoing basis
TG-100 Recommendations

- AAPM
  - Future QA Task Groups should use FMEA
  - Assist users with implementation:
    - Establish a WG to provide user guidance
    - Sponsor educational talks at AAPM, Chapter Meetings, CRCPD, etc.
    - Establish a repository website with example FMEAs
  - Work with other societies to promote risk-based QM Programs
TG-100 Recommendations

- Regulators
  - TG-100 Report is not intended for regulatory purposes
  - Should be familiar with TG-100 methodology
  - AAPM and CRCPD should
    - Provide a guidance document for regulators
    - Provide in-depth educational presentations
    - Create a repository of sample QM programs for review
Post TG-100 Efforts
TreatSafely
IMPROVING QUALITY AND SAFETY IN RADIATION MEDICINE

TreatSafely is dedicated to the development of novel teaching and mentoring programs that improve quality and safety in radiation medicine.

INTRODUCING I.TREATSAFELY.ORG

We've just put the finishing touches on our newest offering - i.treatsafely.org.

This video-based peer-to-peer training site has been developed to provide practical guidance on enhancing the quality and safety of radiation therapy. The content is provided by users like you and can be used for educational and training purposes as well as to standardize practice within and across clinics.

Once you have had a look we'd love to hear your comments, suggestions, and ideas for improving the site.

MINIMIZING ERROR, MAXIMIZING QUALITY - GLOBALLY

www.treatsafely.org
TreatSafely Workshop
Mary Bird Perkins Cancer Center
August 18-19, 2012
AAPM Working Group on Implementation of TG-100

AAPM COMMITTEE TREE

Work Group on the Implementation of TG-100 (WG100)

- bookmark this page (bookmarks show under “My AAPM” in the menu to left)

Committee Website | Directory: Committee | Membership

Email: You may send email to this group now using gmail or outlook.
- or -
You may save the address 2018.WG100@aapm.org
to your local address book. This alias updates hourly from the AAPM Directory.

Charge: To promote and facilitate the implementation of TG 100 methodology in a multidisciplinary radiotherapy environment. Charge:

1. To develop core educational/training materials for use in the promotion of TG 100 methodology.
2. To develop a step-by-step implementation guide for use by multidisciplinary radiotherapy teams.
3. To liaise effectively with professional organizations representing the members of the multidisciplinary radiotherapy care team.


Approved Date(s): 1/4/2016

Committee Keywords:

Board of Directors
- Administrative Council [Status]
- Work Group on the Implementation of TG-100 [Status]
  - Unit No. 37 - Developing Repository Proposal (UN37) [Status]
  - Unit No. 38 - Review of WG100 Workshops (UN38) [Status]

Status Reports from AAPM Groups

Chair

Per Helvorsen
Workgroup Chair
AAPM Working Group on Implementation of TG 100

- Workshops
  - 450 participants total, including international participants.

- Implementation Guide
- Repository
WG 100: Implementation Guide

QUALITY & SAFETY RESOURCES

Quality & Safety Resources: This site highlights quality and safety tools developed by AAPM committees for use by our members.

- Tutorials on Integrating Formal Risk Management (TG-100) into your practice
  These short videos have been created by the Work Group on the Implementation of TG-100 to help AAPM members understand and participate in implementing formal risk management concepts in their clinics. Members are encouraged to discuss them with their teams.

- Radiation Oncology - Incident Learning System (RO-ILS)
  ASTRO and AAPM sponsor the national RO-ILS system. All members of the public are welcome to access guides, quarterly, and annual reports. These reports can be helpful in identifying opportunities for improvement in individual clinics. (WGRIDILS, WGIP)

- Safety Profile Assessment (SPA)
  This survey can be used by clinics to assess the safety profile of the department. Groups can use it to identify opportunities for improvement and can take it again to assess changes over time.

- Links to Medical Radiation Incident References
  The following links are to documents and educational material in the area of error management and patient safety in radiotherapy. Suggestions for additional links to other relevant information should be made to the Chair of Working Group on the Prevention of Errors in Radiation Oncology.

- Responding to Public Radiation Incidents
  This site provides links for AAPM members to connect to information from different organizations related to responding to radiation incidents.

- IRDC Houston QA Center
  This site connects you to the Imaging and Radiation Oncology Core formerly known as the Radiological Physics Center. The organization supports quality for clinical trials.

- Analysis of Normal Tissue Effects in the Clinic
  This site connects to published information from the collaborative quantitative analysis of normal tissue effects in the clinic (QUANTEC), the pediatric effort known as PENTEC, and the hypofractionated effort known as HYTLC.
Ochsner Health System

• Started 1942 by Alton Ochsner, MD
• Currently own/partner with 14 hospitals in Gulf Coast
• Radiation Oncology Department treats at 3 sites
  • Treat ~1000 new patients/year
  • 4 MDs, 4 Physicists, ...
  • 4 Varian linacs
Select Process to Evaluate (SBRT for Lung)

Multidisciplinary team (1 MD, 3 physicists, 3 dosimetrists, 2 therapists, 1 nurse, 1 manager)

Develop Process Map (2 meetings)

Identify potential failure modes (FM) (2 meetings)

Estimate Risk Priority Numbers (individually)

Rank FMs by RPN (physics)

Determine modifications to QM program for highest risk FMs (1 meeting)
Ochsner FMEA Results

- Process Map
  - 15 Major Steps. 84 Sub-processes
- Failure Modes
  - 8 members ranked
  - 71 Failure Modes Identified
- Risk Priority Numbers
  - Wide range among members
  - 6 processes with $\text{<RPN>} > 100$
Ochsner SBRT Process Map

1. Imaging and Diagnosis
2. Entry into ARIA
3. Immobilization and Positioning
4. Conventional CT Simulation
5. 4D CT Simulation
   1. Patient coached to breathe normally
   2. Reflective Marker block placed on patient abdomen
   3. IR camera aligned with block
6. Other Imaging
7. Transfer Images
8. Initial Treatment Plan Directive
9. RTP Anatomy Contouring
10. Treatment Planning
11. Plan Approval
12. Plan Preparation
13. Initial Treatment
14. Subsequent Treatments
15. Final Treatment
# Ochsner SBRT Failure Modes

<table>
<thead>
<tr>
<th>Major Process</th>
<th>Step</th>
<th>Failure Mode</th>
<th>Cause of Failure</th>
<th>Effects of Failure</th>
<th>Occurrence</th>
<th>Severity</th>
<th>Detect</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immobilization and Positioning</td>
<td>Patient check in for sim</td>
<td>Not checked into Aria or EPIC</td>
<td></td>
<td>1. Patient delay 2. Billing problems</td>
<td>2.50</td>
<td>2.00</td>
<td>3.00</td>
<td>15.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wrong patient</td>
<td></td>
<td>1. Patient delay 2. Unnecessary CT radiation</td>
<td>1.75</td>
<td>9.00</td>
<td>2.75</td>
<td>43.31</td>
</tr>
<tr>
<td>CT Sim Immobilization</td>
<td></td>
<td>Equipment not available</td>
<td>Out of bags; Pump on machine; etc</td>
<td>1. Patient delay</td>
<td>5.75</td>
<td>2.50</td>
<td>5.00</td>
<td>71.88</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SBRT Black Board shifts</td>
<td>Indexing only at top of board</td>
<td>1. Patient set up incorrectly</td>
<td>4.00</td>
<td>3.33</td>
<td>4.67</td>
<td>62.22</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bag or plastic sheet loose</td>
<td>Hole in bag or sheet. 2. Pump not working</td>
<td>1. Immobilization compromised;</td>
<td>5.00</td>
<td>4.33</td>
<td>2.33</td>
<td>50.56</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Indexer not used correctly</td>
<td>Setup incorrect</td>
<td></td>
<td>2.33</td>
<td>3.33</td>
<td>3.67</td>
<td>28.52</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Incorrect bag type used</td>
<td>Patient delay</td>
<td></td>
<td>3.00</td>
<td>4.00</td>
<td>4.67</td>
<td>56.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Laser positions</td>
<td>Lasers incorrect</td>
<td>Patient setup incorrect</td>
<td>3.40</td>
<td>6.20</td>
<td>3.80</td>
<td>80.10</td>
</tr>
</tbody>
</table>
QM Program Evaluation

- Step 3: Patient Immobilization and Positioning
  - Step 3.6: Mark laser positions on patient

**Failure Mode:** Patient moves after marks placed (RPN Value: 141)

The time required for CT-simulation of an SBRT lung patient can be long. After an initial set of scout images and helical scan, the region of interest must be determined and scanned for the 4D acquisition. These scans must then be sent to the GE Advantage Windows workstation to be evaluated. If there is too much error in the breathing trace, they must be repeated. Even with the Medical Intelligence bag, this protracted simulation time increases the probability of patient movement.

Pre-treatment image guidance should resolve any shifts in patient position, but if the area to be treated is difficult to visualize, they may go undetected.

**Solution:** Recheck the marks after CT is complete

By rechecking the position of the lasers on the patient after the CT is completed, errors in patient setup can be determined and a re-scan performed if necessary.
QM Program Evaluation

- Step 14: First and Subsequent Treatments
  - Step 14.6: Cone beam CT performed
- Failure Mode: Patient moves after CBCT (RPN Value: 108)

The correct shifts based on IGRT assumes that the patient remains fixed from the time of CBCT until treatment is complete. Patient movement during this time will result in a geometric miss which may result in the wrong area treated. The probability of post imaging movement is proportional to the time delay between the CBCT imaging and treatment.

Solution: Minimize time between CBCT and initial treatment

First, a maximum time should be established between a CBCT and a treatment. The group has suggested five minutes, but this may be reevaluated. If the delay in obtaining physician and physics approval exceeds this maximum time, another CBCT should be performed.

In the current process, physicians are often delayed in coming to the linac to evaluate a CBCT alignment. The therapists should be encouraged to try and get the MD present earlier for the CBCT.
QM Program Evaluation

- **Step 7:** Radiation Treatment Planning Anatomy Contouring
  - **Step 7.2:** MD contours the PTV
- **Failure Mode:** MD contours wrong area (RPN Value: 105)

The physician often relies on outside data to determine the location and size of the lesion. If these data are incorrect or are not available, the wrong area could be targeted. Additionally, there are often multiple lesions in the same area, some of which may have already received treatment. These may be contoured inadvertently.

- **Solution:** Review of target volumes by other staff

During the planning process, physics and/or dosimetry can verify that there is documentation of target volumes on two different imaging modalities. Additionally, SBRT volumes can be reviewed by MD during the Tuesday treatment planning conference. The group recommends that initial treatments begin on Wednesday or Thursday only, allowing adequate time to review contours during planning conference.
Conclusions

- TG-100 differs from traditional methods in its recommendations of a prospective approach to QM.
- TG-100 defines three tools for developing QM program:
  - Process Mapping
  - Failure Modes and Effects Analysis
  - Fault Tree Analysis
- There are a number of TG-100 resources available for free on the AAPM website.
Conclusions

- FMEA can be performed easily in a small clinic.
- Changes in procedures or the QM program need not be substantial to reduce risk.
- A multi-disciplinary approach improves understanding of aspects of patient care unique to some specialties.