Task Group 182: Electronic Intracavitary Brachytherapy QM based on Risk Analysis

Session #3:
ZEISS INTRABEAM® System and Simple Design of Quality Management Program
presented by
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Oregon Health & Science University

Disclosures: NONE
Scope of this session:

- Model a risk based Quality Management (QM) program
- Risk analysis model: TG 100 based FMEA tool
- Intracavitary Breast IORT for early stage breast cancer
- ZEISS INTRABEAM® System
- Importance of QC & QA activities for a robust QM program

Outline

- ZEISS INTRABEAM® system
- Intracavitary Breast IORT procedure
- Design risk based QM program
ZEISS INTRABEAM® system

- X-ray probe (XRS source): 50kV, 40µA
- Electron Gun
- Accelerator Section
- Beam Deflector
- Drift tube: 10cm length, 3.2mm diameter
- Gold target: (0.5 µm)
- Internal Radiation Monitor (IRM)

4. INTRABEAM SYSTEM PRS 500 with XRS 4 software version 2.2

ZEISS INTRABEAM® system cont’d.....

- Superficial kV X-rays (HVL in mm of Al)
- Nearly spherical dose distribution
- Mean energy in water:
  - 28keV at the surface of the applicator
- Dose fall off at the rate of 1/r³ in tissue

ZEISS INTRABEAM® system (cont’d)

• Spherical Applicator set
  • Solid, hollow applicators
  • Water equivalent plastic: Polyetherimide material
  • Size: 1.5cm – 5cm in 0.5cm increments

Image courtesy Carl Zeiss Meditec.

ZEISS INTRABEAM® system cont’d....

• Surgical Arm (Floor Stand)
  • 6 degrees of motion
• Treatment Console
• QA devices
  • PAICH (Probe Adjuster & Ion Chamber Holder)
  • XRS Probe straightening tool
  • Output constancy check
• Soft x-ray ionization chamber (PTW 23342)
• PDA (Photo Diode Array)
  • Deflection/Isotropy check

courtesy Frank Wegand of Zeiss, Inc.
Intracavitary Breast IORT procedure

Consultation & Surgery schedule → Pre-Tx QA (Physicist) Pre-Tx prep (OR Staff) → Surgery & IORT Applicator selection Tx time calculation Tx delivery

QM program for Intracavitary Breast Therapy

Process Mapping → FMEA → FTA → QM

FMEA = Failure Modes

Cause

Effect

Occurrence (O)

Detectability of Failure Mode (D)

Severity (S)

RPN = O*D*S
Intracavitary Breast IORT procedure

Consultation & Surgery schedule → Pre-Tx prep (Physicist) Pre-Tx prep (OR Staff) → Surgery & IORT Applicator selection Tx time calculation Tx delivery → Process Mapping → FMEA → FTA

Process Mapping:
Consultation & Surgery Schedule
• Patient Consultation
• Schedule procedure day
• Staff schedule (Surgery & Radonc)
• System parts availability
FMEA for “Consultation & Surgery"

<table>
<thead>
<tr>
<th>Process Steps</th>
<th>Failure Modes</th>
<th>Cause</th>
<th>Effect of Failure</th>
<th>AVG (O)</th>
<th>AVG (S)</th>
<th>AVG (D)</th>
<th>RPN = O<em>S</em>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation Oncologist Schedule</td>
<td>RadOnc is not available</td>
<td>Oncologists not alerted</td>
<td>Tx delayed or aborted</td>
<td>6</td>
<td>3.5</td>
<td>1.25</td>
<td>24.75</td>
</tr>
</tbody>
</table>

Process Map:
Pre-Treatment procedure
- All applicators are available
- Surgical stand check
- Console & XRS probe check
- Isotropy check
- Source output check
FME Analysis for “Pre-Tx Procedure”

<table>
<thead>
<tr>
<th>Processes</th>
<th>Process steps</th>
<th>Failure Modes</th>
<th>Cause</th>
<th>Effects of failure</th>
<th>AVG (O)</th>
<th>AVG (S)</th>
<th>AVG (D)</th>
<th>RPN = O<em>S</em>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicator availability</td>
<td>Appl present</td>
<td>Appl not present</td>
<td>Applicator misplaced</td>
<td>Tx aborted</td>
<td>5.5</td>
<td>3.5</td>
<td>1.5</td>
<td>30.8</td>
</tr>
</tbody>
</table>

Process Map:

Surgery & IORT procedure
- Applicator selection
- Time calculation
- Treatment delivery
FMEA Analysis for “Surgery & IORT”

<table>
<thead>
<tr>
<th>Process</th>
<th>Process Steps</th>
<th>Failure Modes</th>
<th>Cause</th>
<th>Effects of failure</th>
<th>AVG (O)</th>
<th>AVG (S)</th>
<th>AVG (D)</th>
<th>RPN = O<em>S</em>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicator Selection</td>
<td>Fit lumpectomy cavity</td>
<td>Applicator too small</td>
<td>Surgeon error in fit</td>
<td>Wrong/heterogenous dose</td>
<td>5.8</td>
<td>6.8</td>
<td>5.8</td>
<td>266.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Correct size not available</td>
<td>Wrong/heterogenous dose</td>
<td>5.8</td>
<td>6.8</td>
<td>3.8</td>
<td>185</td>
</tr>
</tbody>
</table>

# of failure modes = 61
Fault Tree Analysis (FTA)

- Address the high risk (higher RPN value) failure modes
- Graphical representation to identify the cause & effect relationship
- Use logical diagram (OR gates & AND gates)
- Easy to identify the potential locations of quality measures

FTA cont’d..

- Highest RPN score: Wrong Dose
- Causes?
  - Applicator size failure
  - Tx Time calculation error
  - Delivery failure
FTA cont’d..

- Highest RPN score: Wrong Dose
  - Applicator size failure
  - Tx Time calculation error
  - Delivery failure

Fault Tree: Wrong Dose - Applicator size failure

No larger size to use

Applicator too small

Failure of Applicator Size QC

Surgeon error in fit:

Surgeon not that specified

Applicator not that specified

Wrong applicator size referenced

Supply orders not maintained
Physical not have time
Change: Backup applicators
Intermediate size applicator
Surgeon not understand fitting – Inadequate training
Surgeon handed wrong applicator
Change: Physicist hands physician applying the size
Inadequate training
Performance failure
FTA cont’d..

• Highest RPN score: Wrong Dose
  • Applicator size failure
  • Tx Time Calculation error
  • Delivery Failure

Fault Tree: Wrong Dose - Treatment Time Calculation Failure

Wrong/very wrong dose

Or

Treatment duration calculation failure

And

Failure of time calculation QA

2.4, 6, 2.6, 7

Or

Error in reading the dose

Wrong dose prescribed to the wrong depth

Or

Calculation error

Error in look-up factor

Inadequate training

Performance failure

Communication failure

Inadequate training

Performance failure

Inadequate training

Performance failure

Inadequate training

Performance failure

Incorrect reading of the factors table

Insufficient commissioning

Commissioning

Algorithm failure

Algorithm completion

Other priorities
FTA cont’d..

Highest RPN score: **Wrong Dose**
- Applicator size failure
- Tx Time Calculation error
- Delivery Failure

Fault Tree: Wrong Dose - delivery failure
Quality Management System

- Concentrate on common causes
- Inadequate training
- Performance failure
- Eliminate common causes and interrupt failure propagation
- Re-design the procedure
- Standardize procedures & checklists
- Adequate staffing & staff training
- Routine maintenance of software & hardware
- Clear line of communications

SUMMARY

- Model QM model program & Quality checklist
- FMEA sorting based on RPN vs S values
- FTA should incorporate all required QC/QA measures recommended by the vendor
- FTA helps to identify and incorporate additional QA & QC measures
SUMMARY

• Process Map: Team effort & involvement of multi-disciplinary team members
• Training, facilitator, core team members
• Risk-assessment tools: Task Group 100 & Quality & Safety resources
• Periodic review of QM program:
  • Evaluate the existing QC measures
  • Incorporate institutional ILS

Thank you!
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