Session: How to set up a QA programme

Current trends in QA for radiotherapy

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Introduction

- The medical physics/radiation oncology world are full of
  - Tolerance levels
  - Action levels
  - Time intervals
- For testing a huge amount of parameters
  - Treatment units
  - CT scanners
  - Treatment planning systems
- Especially, technical and physical ones
This is mainly Quality Control!

• Quality Control
  – Activities that force a particular aspect of a system to conform to expected standards
  – Daily, weekly… measurements seems to be good examples of this

• Quality assurance have long been recognized as important and have been widely applied, but until recently been limited in concept to quality control of physical and technical aspects. (ESTRO booklet no 4)¹

• According to the “American Society for Quality - ASQ”²
  – Control
    • An evaluation to indicate needed corrective responses; the act of guiding a process in which variability is attributable to a constant system of chance causes
  – Quality control:
    • The observation techniques and activities used to fulfil requirements for quality

¹) http://www.estro-education.org/publications/Pages/ESTROPhysicsBooklets.aspx
²) http://www.asq.org/learn-about-quality/quality-assurance-quality-control/overview/overview.html
What we should concentrate on!

- **Assurance**
  - The act of giving confidence, the state of being certain or the act of making certain

- **Quality assurance**
  - The planned and systematic activities implemented in a quality system so that quality requirements for a product or service will be fulfilled

http://www.asq.org/learn-about-quality/quality-assurance-quality-control/overview/overview.html
Let’s introduce:
Quality management tools

• Process mapping
  - Processes and their sub processes

• Identify the processes which are more error prone
  - FMEA (Failure Mode and Error Analysis)
  - RCA (Root Cause Analysis)

• Identify measures for control
  - SPC (Statistical Process Control)

• Measure the quality of the measures/control points/barriers/filters
  - Score actual and potential deviations (e.g. ROSIS)

• Taxonomy
Process maps

- Process map is a visual demonstration of work processes
- The map shows how inputs, outputs, and tasks are linked together
  - Identifies the major steps in the process
  - Who performs the steps
- Identifies and understand process flow, deviations, breakdowns, mistakes, delays - detects where improvements may be made
- Numerous formats or approaches exist - *As-is* and/or *To-be*
Tools for process mapping – some examples

- **IDEF (Integration Definition Function Modeling)**
  - A group of modelling methods that can be used to describe operations in an enterprise
  - IDEF was created by the United States Air Force

- **Business Process Modelling Notation BPMN**

**Work plan**

1. Establish process boundaries
2. Develop the data gathering plan
3. Interview the process participants
4. Generate the process map
5. Analyze and use the map

Federal Information Processing Standards Publications (FIPS PUBS) are issued by the National Institute of Standards and Technology
IDEF0 – eye-def zero

- The method is designed to model the decisions, actions, and activities of an organization or system
- A method to describe functions and their relationships
- Inputs (left) are transformed or consumed by the function to produce outputs (right)
- Controls specify the conditions required for the function to produce correct outputs (top)
- Mechanisms (bottom)
  - Upward pointing arrows identify some of the means that support the execution of the function
  - Arrows that point downward are call arrows

Additional IDEF1-14 for various purposes
Several levels of details
Business Process Modelling Notation BPMN

- Example based on swimlanes
  - Flowchart superimposed on a grid
  - Grid rows are organizations, departments, functions, or individuals
  - Grid columns are chronological
  - Team or joint activities indicated by boxes
BPMN Swimlanes: Breast cancer patient

Based on http://csob.berry.edu/faculty/jgrout/processmapping/Swim_Lane/swim_lane.html

 Courtesy of John Grout
Brownboard example

BROWNBOARD – A tool to facilitate improved supply chain traceability
Helena Lindh et al, Presented at NOFOMA 2008
Fishbone or Ishakawa diagram
HDR Tx - example

From Thomadsen et al 2003
Use process maps to identify critical steps in the process and/or when investigating incidents and accidents

- **FMEA – Failure Mode and Error Analysis**
- During the FMEA, which is a proactive method, the following questions have to be answered for each step in each sub-process;
  - a) *what* could possibly go wrong (potential failure mode),
  - b) *how* could that happen (i.e., what are the causes that result in a failure mode) and finally
  - c) what *effects* would this failure mode produce (potential effects of failure)

- **HAZard and OPerability study (HAZOP)**
  - Widely used in industrial hazard analysis
  - Define: Intention, Deviations, Causes and Consequences

- **Analytical Trees**
  - Fault Tree Analysis (FTA)
FMEA – close up

- For each failure mode, estimate:
  - The severity of its effects ("S")
  - The probability the failure occurs ("O")
  - The probability that the failure will be undetected ("D")
- Form the “Risk Priority Number” RPN:
  - RPN = O*S*D
- O, S, D range [1, 10]
- Concentrate on the highest RPN
  - Used by AAPM Tg 100 for IMRT (chaired by S Huq) and by Risk management course run by the ROSIS group

http://en.wikipedia.org/wiki/Failure_mode_and_effects_analysis
### Example of a FMEA analysis – Setting up a patient and deliver a treatment at an incorrect position

<table>
<thead>
<tr>
<th>Potential failure mode</th>
<th>Potential cause(s) of failure</th>
<th>Potential effect(s) of failure</th>
<th>O</th>
<th>S</th>
<th>D</th>
<th>RPN</th>
<th>Proposed action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect isocentre</td>
<td>Shift between reference point and isocentre <em>not present</em> in R/V system</td>
<td>Dose delivered to wrong volume, PTV under-dosed and/or OAR overdosed during <em>all</em> fractions</td>
<td>4[1]</td>
<td>10[2]</td>
<td>3[3]</td>
<td>120</td>
<td>Second check of all parameters, isocentre check at 1st setup, review methods</td>
</tr>
<tr>
<td></td>
<td>See above</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6[4]</td>
<td>Isocentre check at 1st setup</td>
</tr>
<tr>
<td></td>
<td>Shift specified incorrectly in set-up instructions (R/V)</td>
<td></td>
<td>4</td>
<td>6[5]</td>
<td>3</td>
<td>72</td>
<td>Training, Isocentre check at 1st setup</td>
</tr>
<tr>
<td></td>
<td>Shift specified correctly but made incorrectly</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Staff omitted to make shift</td>
<td></td>
<td>2</td>
<td>6</td>
<td>10</td>
<td>120</td>
<td>Training, review methods</td>
</tr>
</tbody>
</table>

---

[1] The value was chosen based on that this do not happens to often. Suggestion is that the data is missing once per 1000 cases. In Lund we have about 2600 patients annually and it seems to be an accurate number that this data is missing not more than 2-3 times a year. 4=1:2000

[2] If this will be undetected though out the full treatment the ranking of 10 maybe be adequate.

[3] This number is incredible hard to set since it depends very much on the clinical environment. If for example it is possible to acquire the patient position (treatment position) by a simple action by the therapist this can be added to the setup and the patient will be treated “correctly” at each fraction. On the other hand since the data is missing one may step back in the process to get the correct data. Based on the latter process a low number is assigned.

[4] This probably occurs much more often than the above case.

[5] The delectability is definitely lower in this case compared to the first failure situation.

[6] Having a lower severity for this failure mode seems appropriate since there are chances to detect this at the following treatment sessions.
Retrospective techniques of risk identification

- Fault Tree Analysis (as for prospective) or Root Cause Analysis (RCA)
- Events and Causal Factors Analysis (ECFA)
- Sequential Timed Events Plotting (STEP)
- Man Technology Organisation (MTO)
ECFA - Events and Conditional Factors Analysis

Systemic factors
- National regulation
  Not sufficient

Systemic conditions
- Responsibilities
  Not defined
- Hospital budget
  Too low

 Contributing factors
- Wrong repair procedure
- No control measurements
- Wrong decision authority
- Lack of equipment
- Med physics not informed
- No frequent clinical examinations

Primary events
- No output
- Have a look
- "Repair"
- Needle stuck
- No dosimetry
- 27 patients treated
- 8 patients died

This method is trained during the annual Risk Management course given by the ROSIS group.
Statistical Process Control - SPC

- An effective method of monitoring a process through the use of control charts
- Control charts distinguish background variation from events of significance based on statistical techniques
  - Random variation in the data is de-emphasized by the way the process behaviour limits are constructed
- Using process behaviour charts is an interactive procedure that requires process knowledge and interpretation by the user
Example: Control charts

Based on the principles outlined by Todd Pawlicki et al.

**Quality assurance**

*Moving from IMRT QA measurements toward independent computer calculations using control charts*

ROSIS – Radiation Oncology Safety Information System

- To establish an international reporting system in radiation oncology
- To use this system to reduce the occurrence of incidents in RO
  - By enabling RO departments to share and view reports on incidents
  - By collecting and analysing information on the occurrence, detection, severity and correction of RO incidents
  - By disseminating these results and generally promoting awareness of incidents and a safety culture in RO
Taxonomy

- Classification system
- Classify failures according to some aspect of their characteristics e.g.
  - Provide insights into what kept the persons involved from performing their intended actions
  - Provide guidance for changing the situation to prevent failure in the future
- Taxonomies can provide guidance in selecting between possible corrective actions
### Table 2

Frequency distribution of incident types, from the different databases and reports, in each domain of the radiation treatment process.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Type</th>
<th>Number of Incidents</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>NRC</td>
</tr>
<tr>
<td>Systematic and sporadic incidents</td>
<td>Systematic</td>
<td>0</td>
</tr>
<tr>
<td>Prescription</td>
<td>Sporadic</td>
<td>3</td>
</tr>
<tr>
<td>Preparation</td>
<td>Systematic</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Sporadic</td>
<td>29</td>
</tr>
<tr>
<td>Treatment</td>
<td>Systematic</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Sporadic</td>
<td>30</td>
</tr>
<tr>
<td>Total number of incidents</td>
<td></td>
<td>67</td>
</tr>
<tr>
<td>Systematic incidents: process and infrastructure incidents</td>
<td>Process</td>
<td>0</td>
</tr>
<tr>
<td>Prescription</td>
<td>Infrastructure</td>
<td>0</td>
</tr>
<tr>
<td>Preparation</td>
<td>Process</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Infrastructure</td>
<td>12</td>
</tr>
<tr>
<td>Treatment</td>
<td>Process</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Infrastructure</td>
<td>0</td>
</tr>
<tr>
<td>Total number of systematic incidents</td>
<td></td>
<td>62</td>
</tr>
<tr>
<td>Sporadic incidents: process and infrastructure incidents</td>
<td>Process</td>
<td>0</td>
</tr>
<tr>
<td>Prescription</td>
<td>Infrastructure</td>
<td>0</td>
</tr>
<tr>
<td>Preparation</td>
<td>Process</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>Infrastructure</td>
<td>0</td>
</tr>
<tr>
<td>Treatment</td>
<td>Process</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>Infrastructure</td>
<td>3</td>
</tr>
<tr>
<td>Total number of sporadic incidents</td>
<td></td>
<td>62</td>
</tr>
<tr>
<td>Incidents with errors in prescription elements</td>
<td>Dose</td>
<td>3</td>
</tr>
<tr>
<td>Prescription</td>
<td>Volume</td>
<td>0</td>
</tr>
<tr>
<td>Preparation</td>
<td>Dose</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>Volume</td>
<td>9</td>
</tr>
<tr>
<td>Treatment</td>
<td>Dose</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Volume</td>
<td>20</td>
</tr>
</tbody>
</table>

NRC — United States Nuclear Regulatory Commission.
IAEA — International Atomic Energy Agency.
ROSIS — Radiation Oncology Safety Information System, a part of the European Society for Therapeutic Radiology and Oncology (ESTRO).

**Risk analysis in radiation treatment:**

Application of a new taxonomic structure

Edidiong U. Ekaette\(^a\,^1\), Robert C. Lee\(^a\,^{b,c,e}\), David L. Cooke\(^a\,^{d,2}\), Karie-Lynn Kelly\(^a\,^{e,3}\), Peter B. Dunscombe\(^b\,^{e,4}\)
Summary

1. Define the different steps within the radiotherapy process.
   A. Process tree.
   B. Define sub processes.

2. Identify which of the processes are more error prone, and the consequence of the error on the final outcome.
   A. FMEA
   B. Assign responsibilities. Avoid grey zones.

3. Look for control variables for each of the (sub) processes. Study its variability. (SPC-control charts).

4. Study error propagation across processes and subprocesses including QA/QC tests
   A. Fault tree analysis)/Root cause analysis

5. Sensitivity analysis (outcome error v.s. Parameter error). This should be used to set up tolerances to our control variables.

Thanks to Nuria Jornet for the inspiration to this slide but also to the presentation.
Thank You!

Risk management course in Dublin 2006

Mary Coffey
Ola Holmberg
Joanne Cunningham
Chiara Leva
Pierre Scalliet
Nuria Jornet
Peter Dunscombe
...
And A lot of other nice people
QC in relation to QA

From B Thomadsen, IJROBP Suppl 1 2008.
Applied to the sub process: Treatment planning

- Import images
- Contouring of volume
- Prescription
  - QC: Correct patient
  - QC: Appropriate VOI
  - QC: Correct prescription
  
- Subprocess: Treatment Planning
  - QA: Plan review
  - Product: Validated plan
Reason's Model

Latent Failures

Management Decision
Organisational Process

Conditions of Work (current)

Background conditions:
- Workload
- Supervision
- Communication
- Training/knowledge/ability
- Equipment
- QA

Active Failures

Unsafe Acts:
- Omissions
- Action slips / failures
- Cognitive failures (mistakes and memory lapses)
- Violations

Multilayered Defences