Quality in Radiation Therapy: what is it and how do you achieve it?

1. Overview of definitions and approaches to Quality
   Pawlicki

2. ROSIS
   Knöös

3. Peer Review Quality Audits
   Halvorsen

4. The Regulator’s Viewpoint
   Zelac

5. QA in IGRT
   Bissonnette

6. Evidence Based QA
   Dunscombe

Radiation Oncology Safety Information System – ROSIS

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Representing the ROSIS group
Introduction

With hindsight, it is easy to see a disaster waiting to happen. We need to develop the capability to achieve the much more difficult - to spot one coming.

When addressing this - we need to know:

- **What** can go wrong in the process? (Hazard identification)
  - Systematic review of inherent hazards in system
  - Many methods can be used, e.g. foresight and review of retrospective data (reported incidents)
- **How likely** is this to happen? (Frequency analysis)
  - Determination of frequency of these events
  - Retrospective data (reported incidents) – "near misses" have special role since data is more often captured at this stage
- **What are the consequences?** (Consequence analysis)
  - Estimation of impact if the event occurs
  - Consequence models are required – in radiotherapy e.g. undesired outcome of treatment
- The combination of frequency and consequence tells us the **risk**
What we need?

• What errors and/or
• What incidents
• The frequency
• One have to remember – low probability
• Learn from each other!!!

Collect, compile, classify, conclude
Different reporting/recording systems

• Mandatory reporting systems:
  – Reporting of certain events is required (e.g. reporting to regulatory authorities of events above certain magnitude)

• Voluntary reporting systems:
  – Reporting is encouraged (e.g. reporting to professional body)

• Internal reporting systems:
  – Reporting inside organisation (e.g. local incident reports)

• External reporting systems:
  – Reporting outside organisation (e.g. web-based systems)
From the initial report to ESTRO/ESQUIRE

- A risk management project was proposed to ESTRO in early 2001 by M. Coffey and O. Holmberg, Dublin
- The project aims to establish a common database for the exchange of information on radiotherapy incidents and corrective actions, both in relation to processes and to equipment.
- The system will emphasize safety reporting rather than error reporting
- Risk management strategies from areas outside radiotherapy will be considered
- It is envisioned that the database will enable knowledge to be shared and continuously updated as an aid to clinical centres, in a confidential way.
Aims of ROSIS

- 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

Development of ROSIS

- Data Collection
- Reporting System & Database
- Website & Online database
- Course, Logo, Revision of website
- Classification, Revision of reporting system & database, Newsletters, Collaboration, Local ROSIS system

- 2001 2002 2003 2004 2005 2006 2007

1st meeting - 10th – 11th August 2001
OH, MC and TK
Report process

- Users have to register to submit reports
  - Manually taken care of and Clinical ID number given to the contact person
- All reports are filled in on-line and automatically emailed to the ROSIS group
- The reports are manually transferred to an Access database
  - Security and filtering garbage
- Once in a while the on-line database is updated manually (821) about 1100 in the off-line version

Collecting

- Web based forms
- Clinic has to register to get a unique ID number
  - ID number is only parameter entered during anonymous reporting of incidents
- Incident reports
  - Web forms emailed but will in future be transferred into the live database SECURITY ISSUES
  - The reports are manually transferred to an Access database
    - Security and filtering garbage
Classification

• Purpose
  – Organise reports
  – Facilitate analysis
  – Improve safety
• Scope
  – All incidents and near-incidents relevant to an RO dept
  – Preventative & corrective factors
• Intent
  – Maximise learning - Collect detailed information
• Feasibility
  – Incorporated into online Reporting System (WIP)
• To be evaluated
  – Sensitivity
  – Reliability and Validity

Participants

• 66 departments representing 16 countries in Europe
• 8 in Asia
• 11 in North America
  – 8 USA and 3 Canada
• 3 in South America
• 1 in Australia
Share and view

Website with on-line database

www.rosis.info

Screen shots

www.rosis.info
Who detect incidents?

<table>
<thead>
<tr>
<th>Category of staff</th>
<th>Percent</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosimetrist</td>
<td>5%</td>
<td>43</td>
</tr>
<tr>
<td>Oncologist</td>
<td>8%</td>
<td>70</td>
</tr>
<tr>
<td>Other</td>
<td>3%</td>
<td>22</td>
</tr>
<tr>
<td>Physicist</td>
<td>11%</td>
<td>92</td>
</tr>
<tr>
<td>Technical maintenance</td>
<td>0%</td>
<td>1</td>
</tr>
<tr>
<td>Therapist (sim/CT)</td>
<td>4%</td>
<td>37</td>
</tr>
<tr>
<td>Therapist (trt unit)</td>
<td>69%</td>
<td>591</td>
</tr>
</tbody>
</table>

Example of on-line analysis tool

What QC process or defence layer catch incidents?

www.rosis.info
**Promoting awareness**

- **Analysis**
  - Hazard identification, taxonomy
- **Reports**
  - Compiled reports based on data in the ROSIS database
- **Awareness and learning tool**
  - Risk management course in Dublin (next year probably North America)

**Process Classification**

- Where in process did it originate?
- What element was affected?
- 4 “levels”
  - Level 1 – 7 items
  - Level 2 – 20 items
  - Level 3 – 58 items
  - Level 4 – 18 items
Level 2 and 3 for “Treatment Delivery”

Reports

Radiation Oncology Safety Information System
http://www.rosis.info

Feedback letter March 2006
SPOTLIGHT ON DENTAL RADIOGRAPHY

Radiation Oncology Safety Information System
http://www.rosis.info

Feedback letter August 2006
SPOTLIGHT ON PATIENT IDENTIFICATION

Radiation Oncology Safety Information System
http://www.rosis.info

Feedback letter January 2007
SPOTLIGHT ON DATA TRANSFER

- [Item 1]
- [Item 2]
Problems encountered

• Not real on-line
  – Reports submitted via email
  – Takes too long time to enter the reports and updating the on-line database
  – Requires staff and time resources
• Web site basically constructed by non-professional
  – Spare-time and leisure

WiP

• Discussions with AAPM working group on “Prevention of Errors in Radiation Oncology”
• and with ASTRO (E Klein, St Louis, USA)
• A common classification system
• New website and extended database
• Fund raising – application for a EU project
• Trinity College Dublin
• IAEA
• Lund University Hospital, Sweden

• UCL St Luc University Hospital, Belgium
• Politecnico di Milano; Italy
• Clinical Institute Humanitas, Spain
• Institute Curie, France
• ESTRO, Europe
• ASTRO, US
• AAPM, US
• IT/Law company support
• RT Manufacturers
• ROSIS
• UK, Switzerland and other national work groups?
Parallel development

• Creating and setting up a similar system together with IAEA for interventional radiology

Late 2007

• Ola Holmberg, IAEA, Vienna
• Mary Coffey, Dublin, Ireland
• Tommy Knöös, Lund, Sweden
• Joanne Cunningham, Dublin, Ireland
• Peter Dunscombe, Calgary, Canada
• Eric Klein, St Louis, USA