CARS’s Knowledge Based Learning System for Radiation Oncology (RO)

- Patient safety
- Mistake and error reduction
- Coordinated user interface and human factors
- Optimizing treatment
- Accommodating patient variability
Disclosure

• I am an engineer

• Founding member of CARS (Rock Mackie, Bruce Thomadsen, Jatinder Palta and myself)
  • 501C3 and PSO
  • None of us receive any financial compensation
Do we need it?

- What does the evidence show?
- Are mistakes made or are there errors in RO?
- Are treatments always optimal?
- Are devices highly reliable and easy to use?
- Are “work arounds” required?
Functional Requirements

• Provide value to all stakeholders in RT
• Easy and intuitive to use
• Reduce errors, incidents and near misses
• Speed the seamless deployment of new technologies
• Proactive approach using clinic’s process analytic results to improve quality and prevent incidents
• Provide information to device designers to improve equipment use, treatment quality, reliability and safety
• Assist in the deployment and use of TG 100 risk based analytical tools
How Does the CARS’s System Work?

- Individual clinics provide the results from TG 100 risk assessment based, process analyses
  - Process maps or trees
  - Failure Mode and Effects Analysis (FMEA)
  - Fault Tree Analysis (FTA)
  - Systemic development of Quality Management strategies and practices in RO
- Individual clinics report errors, mistakes, near misses, problems and ideas to improve a process or devices/equipment/software (and complaints)
- The CARS’s system will use several algorithms to identify trends, high risk areas of processes, problems with emerging technologies and device/equipment/software problems or issues
Process Analytics

Process maps or trees will define the process in appropriate detail
And when linked to the FMEA will identify highest risk and poorly controlled areas of the process.

<table>
<thead>
<tr>
<th>Step #</th>
<th>Step Description</th>
<th>Step Function</th>
<th>Failure Mode</th>
<th>Causes of Failure Mode</th>
<th>Effects of Failure Mode</th>
<th>O</th>
<th>S</th>
<th>D</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>12—Day N treatment</td>
<td>Treatment delivered</td>
<td>LINAC hardware failures/wrong dose per MU; MLC leaf motions inaccurate, flatness/symmetry, energy—all the things that standard physical QA is meant to prevent</td>
<td>Poor design (hardware), inadequate maintenance, software failure, lack of standardized procedures (weak physics QA process), human failure (incorrectly used procedure/practice), standard Linac performance QM failure (not further considered here), inadequate training</td>
<td>Wrong dose, wrong dose distribution, wrong location, wrong volume</td>
<td>5.4</td>
<td>8.2</td>
<td>7.2</td>
<td>354</td>
</tr>
</tbody>
</table>
A fault tree is created in conjunction with the FMEA
• Highest frequency root causes
• Management deficiencies in quality management
TG 100 Tool Templates

• Used as starting points for clinics to analyze their own processes

• Making the use of TG 100 tools easier to use

• Standard use of TG 100 tools
Occurrence Reporting System – incidents, mistakes, errors, problems encountered, opportunities for improvement and device complaints

- Mechanism for clinics to report incidents, near misses, problems with existing or new technologies or new applications of existing technologies, ideas for process or equipment improvements and device complaints
- Hierarchical reporting structure allows varying levels of clinical staff interaction
  - Software Issue
  - User interface
    - Screen complexity
    - Inadequate on screen instructions
- Use bar coding technology, smart phone/tablet devices in treatment room with pull down menus and Voice Activated Input – make it easier to report issues
  - Directly input to CARS KBLS, interpreted and analyzed
  - Allows for further details to be added later but not required
• Algorithms will continually analyze all inputs – patterns, high risk/poorly controlled processes, emergency situations, device compliant patterns, etc.
• CARS experts provide expert advice and analysis
  • RCA
  • Incident report information
  • Advice on process analytics tools
  • Vet all clinic process analytics results
• Data base is searchable allowing users to look for
  • Information on new software or devices
  • Reports and early warnings will also be issued
Outputs/Reports

• High risk (safety and quality) areas of processes
• Potential issues – process analytic results
• Quality management deficiencies (scheduling models, lack of time and formal procedures and processes, etc.)
• Device and software companies - problematic areas of their current designs, insight to clinic processes including user interfaces
• Regulators – real time issue and problems
Next Steps

• Collaborate with RO-ILS

• Expand to include imaging

• Expand platform to include oncology, radiation oncology and medical physicists
  • Personal experience – using Tykerb and Xeloda to treat breast cancer that has spread to the brain

• Next generation
  • Learn from patient and/or process variability, embrace it and accommodate it
  • Develop patient specific protocols, procedures, methods and practices
Questions