Quality Audits and Accreditation

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Landauer Medical Physics
Disclosures

I do not have any conflicts of interest to disclose.

(apart from how my interest in design conflicts with this slide template)
Learning Objectives

• To understand the role of audit as integral to a well-crafted QM program
• To differentiate between different types of audit, and to appreciate their role (if any) in the QM program
• To clarify the relationship between external accreditation and the management of a QM program
Designing a Process QM Program

1. Understand the process
2. Identify hazards
3. Mitigate risk
4. Develop controls
5. Implement
6. Audit
Audit:

Someone checks your work
Audit – A Useful Taxonomy

- Internal vs. external
- Integral vs. stochastic
- Engaged vs. perfunctory
- “Friendly” vs. “hostile”
- Evaluative vs. authoritarian
Internal Integral Engaged “Friendly” Evaluative Audit

- **Compliance audit**
  - Are the Procedures being adhered to?

- **Effectiveness audit**
  - Are the Policies appropriate?
  - Are controls appropriate and effective?
  - Are the Procedures adequate?

- **Variance tracking**
  - Reporting database, including near-misses
  - Reviewed regularly by management
Audit: Assessment vs. Control
The Toilet Seat Problem: A Hazard Analysis
Hazards to be considered

• Physical - Sitting on the cold, hard bowl rim
• Sanitary - Sitting on a pre-moistened seat
• Emotional - Domestic strife
System state has three components:
Down/Up | Clean/Soiled | Available/Occupied
Mitigation 1 - Hardwire

- Policy
  - Users will sit.

- Procedure
  - Sit.

- Controls
  - Bolt seat down
  - Lower ceiling
Mitigation 1 - Hardwire

• Audit
  – Controls make this system “foolproof.” No need for audit?

• System considerations
  – A broader scope audit will reveal folks working around the system, using unauthorized mechanisms to accomplish the task.
Mitigation 2 – No-standing policy

• Policy
  – Users shall sit.
  – The seat shall be down at all times.

• Procedure
  – Always sit.
  – Don’t put the seat up.
Mitigation 2 – No-standing policy

• Audit
  – Need to find a way to audit “always sit.”
  – Need to find a way to audit “never lift seat.”
  – Audit may be limited to accident reporting.

• System considerations
  – Heavily compliance-dependent, naïve users likely to do the wrong thing.
  – Documentation, training, credentialing are only hazard mitigation.
Mitigation 3 – Special procedure approach

• Policy
  – The seat shall always be left down after use.
  – The seat shall always be left clean after use.
• Procedure
  – If you plan to sit, proceed.
  – If you plan to not sit:
    • Raise the seat.
    • Do your business.
    • Lower the seat.
Mitigation 3 – Special procedure approach

• Audit
  – No need to audit “always sit” – not in play.
  – Can audit compliance by sampling.
  – Audit through event reporting can capture both non-compliance and accidents.

• System considerations
  – Burden of compliance is asymmetric.
  – There’s the risk of dividing users into antagonistic camps.
Mitigation 4 – Fair use

- **Policy**
  - The seat shall always be left clean after use.
  - Each user shall assure seat position is appropriate prior to intended use.

- **Procedure**
  - Assure appropriate seat position for your intended use.
  - Do your business.
Mitigation 4 – Fair use

• Audit
  – No need to audit “always sit” or seat position – not in play.
  – Event reporting can capture both non-compliance and accidents.

• System considerations
  – Accidents of one type are likely to be underreported since they are directly caused by non-compliance, without witnesses.
  – Naïve users likely to do the right thing.
Congratulations, job well done.
External Auditor: The Mother-in-Law
External Audit: The Mother-in-law Visit

- Compliance audit
  - “Are you doing it my way?”
- Effectiveness audit
  - “My way has worked for me and your father for 53 years, that’s not good enough for you?”
- Variance tracking
  - Swift and sure
External “Hostile” Audits

• Regulatory
  – State Rad Health
  – NRC
• Billing
  – “Compliance”
  – Mandatory practice accreditation
• Clinical trials
  – Quality audit
  – Credentialing
• Practice accreditation
  – The Joint Commission
  – ACR, ACRO, ASTRO
Regulatory / Billing

Your carefully designed QM program

Compliance
Philadelphia VAMC
(A cautionary tale)

- The University of Pennsylvania contracted with the VAMC to provide a prostate seed service.
- In a February 2003 case 40 of 74 seeds (40!!) were retrieved from the bladder intra-operatively by the urologist. Not a Medical Event.
- In an October 2005 case 45 of 90 seeds (45!!!!) were retrieved from the bladder intra-operatively by the urologist and 2 more in the patient room. Not a Medical Event.
Philadelphia VAMC (cont.)

• In one 2008 case seeds of the wrong strength (20% low) were ordered and implanted. This was determined to be a Medical Event.

• Subsequent NRC audit identified 92 of 116 implants (79%) performed over 6+ years as Medical Events.
Philadelphia VAMC (cont.)

![Diagram showing bladder, prostate, and rectum with prescribed dose of 180 Gray and administered dose of 24 Gray.]

2013 Summer School, Colorado Springs, CO
Philadelphia VAMC (cont.)

- NRC noted the lack of a “safety culture.”
- External reviews in the same timeframe by ACRO, Joint Commission and others revealed no problems.
Clinical Trials Credentialing

Your carefully designed QM program

RPC QARC ITC
## RPC Audits

### On-Site Dosimetry Review Audit

Discrepancies Discovered (Jan. ’05 – Mar. ’11)

<table>
<thead>
<tr>
<th>Discrepancies Regarding</th>
<th>Number of Institutions Receiving rec. (n = 156)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review QA Program</td>
<td>115 (74%)</td>
</tr>
<tr>
<td>Photon Field Size Dependence (small FSD)</td>
<td>62 (40%)</td>
</tr>
<tr>
<td>Wedge Factor (WF)</td>
<td>50 (32%)</td>
</tr>
<tr>
<td>Off-axis Factors (OAF)/Beam symmetry</td>
<td>46 (29%)</td>
</tr>
<tr>
<td>Electron Calibration</td>
<td>27 (17%)</td>
</tr>
<tr>
<td>Photon Depth Dose</td>
<td>25 (16%)</td>
</tr>
<tr>
<td>Electron Depth Dose</td>
<td>18 (12%)</td>
</tr>
<tr>
<td>Photon Calibration</td>
<td>13 (8%)</td>
</tr>
</tbody>
</table>

\[
\text{Monitor Units} = \frac{\text{Prescription Dose}}{(\text{calibration}) \cdot (\text{FSD}) \cdot (\text{WF}) \cdot (\text{depth dose}) \cdot (\text{OAF})}
\]
External Auditor Approval Rates

- Mother-in-law: 0%
- RPC: 20%
- Goldilocks: 30%
### Phantom Results

Comparison between institution’s plan and delivered dose.

<table>
<thead>
<tr>
<th></th>
<th>H&amp;N</th>
<th>Prostate</th>
<th>Spine</th>
<th>Lung</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irradiations (all years)</td>
<td>1139</td>
<td>313</td>
<td>120</td>
<td>458</td>
</tr>
<tr>
<td>Pass (all years)</td>
<td>928 (81%)</td>
<td>265 (85%)</td>
<td>78 (65%)</td>
<td>361 (79%)</td>
</tr>
<tr>
<td>Fail (all years)</td>
<td>211</td>
<td>48</td>
<td>42</td>
<td>97</td>
</tr>
<tr>
<td>Irradiations (2011)</td>
<td>109</td>
<td>56</td>
<td>40</td>
<td>80</td>
</tr>
<tr>
<td>Pass (2011)</td>
<td>101 (93%)</td>
<td>45 (80%)</td>
<td>31 (78%)</td>
<td>68 (85%)</td>
</tr>
<tr>
<td>Fail (2011)</td>
<td>8</td>
<td>11</td>
<td>9</td>
<td>12</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Criteria</th>
<th>7%/4mm</th>
<th>7%/4mm</th>
<th>5%/3mm</th>
<th>5%/5mm</th>
</tr>
</thead>
</table>

Failure rate doubles going to ±5%/3mm criteria
Practice Accreditation

Your carefully designed QM program

Accreditation review

2013 Summer School, Colorado Springs, CO
MIPPA
(Another cautionary tale)

- Medicare Improvements for Patients and Providers Act of 2008 required accreditation by CMS-approved entity in order to bill Medicare for “advanced imaging.”
- ACR was obvious choice, followed by IAC.
- 2/4/2010 Inside CMS published an article entitled “Joint Commission's Entry As Imaging Accreditsor Surprises Other Winners”
MIPPA (cont.)

“Asked about the Joint Commission’s qualifications, a CMS spokesman told *Inside CMS* that the agency’s internal professional panel required the Joint Commission to ‘expand its radiology staff and their own review criteria’ before being recommended for approval. That staff expansion was the addition of one radiologist.”
MIPPA (cont.)

United States Government Accountability Office
Report to Congressional Committees

May 2013

MEDICARE IMAGING ACCREDITATION

Establishing Minimum National Standards and an Oversight Framework Would Help Ensure Quality and Safety of Advanced Diagnostic Imaging Services

GAO-13-246
MIPPA (cont.)

• 2013 GAO review: “... there are significant differences among the accrediting organizations, which arise from CMS’s lack of minimum national standards.”
• “... TJC stated that the [GAO] report places inordinate value on image accuracy and professional credentials.”
• “... TJC stated that [GAO reviewers] provided no data to show that phantom testing results in better image quality in practice.”
# The RadOnc accreditation business

<table>
<thead>
<tr>
<th>Organization</th>
<th>Accredited organizations</th>
<th>Reviewed by</th>
<th>Length</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACR (RadOnc) formerly ACR/ASTRO</td>
<td>493 current, 99 under review</td>
<td>On-site surveyors, MD and physicist $1000/day honorarium</td>
<td>3 years</td>
<td>$9,500</td>
</tr>
<tr>
<td>ACRO</td>
<td>170± current</td>
<td>Off-site MD review on 100 point scale, paid $75/chart; Physicist and administrator site visit, honorarium</td>
<td>3 years</td>
<td>$8,500</td>
</tr>
<tr>
<td>ASTRO</td>
<td>0</td>
<td>TBD, largely on-line?</td>
<td>TBD</td>
<td>TBD</td>
</tr>
</tbody>
</table>
RadOnc Accreditation – Why?

• Competitive advantage
• Positioning for possible future requirement
• Need to be seen to do something about “Safety is No Accident”
• Lever with MDs to comply with Practice Standards
• Lever for practice standardization across systems.
• (implicit) A commercial product that can substitute for managing a difficult and expense local QM program
Summary - Audits that you will know...

• Internal audit designed as part of the QM program and fully supported financially and culturally by the organization.
• Third party audits that are not well integrated with the QM program but may provide value as independent assay.
• Third party audits that provide no value to the QM program.