Establishing a patient safety program in Interventional Radiology

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Or...Complying with JC standards

• JC Sentinel Event
  – Defined as:

  “Prolonged fluoroscopy with cumulative dose >1500 rads [15 Gy] to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose”

• “Sentinel event” and “medical error” are not synonymous
Definitions

- Interventional reference point (IRP)
- FDA reference point
- Cumulative dose
  - $K_{a,r}$
  - Reference point dose
- Kerma area product
  - Dose area product
- Peak skin dose
- 95% area load
- Dose index
Relative merits of each

Radiation injuries

- Radiation-induced skin injuries are particularly troublesome for several reasons
  - Patient does not experience any sensations
  - Latent period means that cause and effect may not be connected by patient or physician

<table>
<thead>
<tr>
<th>Effect</th>
<th>Single-dose threshold (Gy)</th>
<th>Onset</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early transient erythema</td>
<td>2</td>
<td>~2 – 24 h</td>
</tr>
<tr>
<td>Malignant erythema</td>
<td>6</td>
<td>~10 d</td>
</tr>
<tr>
<td>Temporary epilation</td>
<td>3</td>
<td>~3 wk</td>
</tr>
<tr>
<td>Permanent epilation</td>
<td>7</td>
<td>~3 wk</td>
</tr>
<tr>
<td>Dry desquamation</td>
<td>14</td>
<td>~4 wk</td>
</tr>
<tr>
<td>Moist desquamation</td>
<td>18</td>
<td>~4 wk</td>
</tr>
<tr>
<td>Secondary ulceration</td>
<td>24</td>
<td>&gt;6 wk</td>
</tr>
<tr>
<td>Late erythema</td>
<td>15</td>
<td>8 – 10 wk</td>
</tr>
<tr>
<td>Ischemic dermal necrosis</td>
<td>18</td>
<td>&gt;10 wk</td>
</tr>
<tr>
<td>Dermal atrophy (1st phase)</td>
<td>10</td>
<td>&gt;12 wk</td>
</tr>
<tr>
<td>Dermal atrophy (2nd phase)</td>
<td>10</td>
<td>&gt;1 y</td>
</tr>
<tr>
<td>Induration (invasive fibrosis)</td>
<td>10</td>
<td>&gt;1 y</td>
</tr>
<tr>
<td>Telangiectasia</td>
<td>10</td>
<td>&gt;1 y</td>
</tr>
<tr>
<td>Dermal necrosis (late phase)</td>
<td>&gt; 12?</td>
<td>&gt;1 y</td>
</tr>
<tr>
<td>Skin cancer</td>
<td>None Known</td>
<td>&gt;5 y</td>
</tr>
</tbody>
</table>

Radiation injuries

- Also, radiation injuries can be particularly gruesome and, depending on severity, may never completely heal.

http://www.uth.tmc.edu/radiology/exhibits/koenig_wagner/index.html, 10/08

Wagner LK, Archer BR. Minimizing Risks from Fluoroscopic X Rays: Bioeffects, Instrumentation, and Examination, 3rd edition; Houston, TX; R. M. Partnership, 2000

Radiation injuries

- In some cases, deterministic effects are not the only concern
- Stochastic effects, most notably cancer, can also be induced (but not linked) by prolonged fluoroscopic procedures


http://www.uth.tmc.edu/radiology/exhibits/koenig_wagner/index.html, 10/08
Three-pronged approach

- Pre-procedure actions
- Intra-procedure actions
- Post-procedure actions

Pre-Procedure

- Consent ing process
  - Medico-legal aspects
  - Dr. Wagner’s “advice”
- Patient education
  - Requires staff education
  - Easy-to-understand pamphlets
- Identification of at-risk patients
  - Certain conditions may pre-dispose patient to injury
    - Diabetes mellitus, connective tissue disorders
    - Prior high-CD procedures (JC aspects)
    - RIS
- Credentialing of users of fluoroscopic equipment
  - AAPM TG124
- Procedure planning
Intra-Procedure

• Cumulative dose (CD) thresholds
• Ongoing faculty and staff education
  – Removal of grid
    • Fellow credentialing
  – Store loop/store monitor, not acquisition
    • Dr. Tam
  – Be in the room
    • YDNKWIHUYKWIH
• Reduced-dose protocols
  – Patients identified during pre-procedure process
• Situational awareness
  – Prior high-CD procedure – projection considerations
    • Irradiate different skin site, prevent sentinel event(?)

10/9/2009 A. Kyle Jones, Ph.D. SWAAPM Fall 2009
Post-Procedure

• Follow-up protocol
• Record dose descriptors *somewhere*
  – CD/DAP/#of DynaCT/# of exposures/time
    • RIS
    • Medical record
    • PACS
    • Structured dose reporting (DICOM dose) is coming

• Flag high-CD cases
  – 3 Gy (SIR)
  – Procedure-dependent?
PRE-PROCEDURE ELEMENTS
Informed consent

“Informed consent is a patient's right to be presented with sufficient information, by either the physician or their representative, to allow the patient to make an informed decision regarding whether or not to consent to a treatment or procedure.”

http://www.med-ed.virginia.edu/courses/rad/consent/
Informed consent

- Lack of informed consent is grounds for malpractice lawsuit
- Ethical considerations

I (we) also realize that the following risks and hazards may occur in connection with this particular procedure: **Specific Information Here**

- ARTERIOGRAPHY/VENOGRAPHY
  1. Injury to artery or vein.
  2. Loss of function or damage to parts of the body supplied by the artery or vein.
  3. Swelling, pain, tenderness, or bleeding at site of blood vessel perforation.
  4. Aggravation of the condition that necessitated the procedure.
  5. Allergic reaction to injected contrast media.
  6. Possible kidney damage from injected contrast media.

- INTERVENTIONAL
  - Pain
  - Bleeding
  - Infection
  - Damage to Surrounding Structures
  - Pneumothorax (Collapsed Lung)
  - Hemothysis (Coughing Up Blood)
  - Risk of radiation-induced skin injury; In rare cases of lengthy or complex procedures utilizing x-ray, radiation-induced skin injuries have been reported (<1% of cases)

- Off-Label Use
I (we) also realize that the following risks and hazards may occur in connection with this particular procedure: *Specific Information Here*

- Arteriography
- Venography

1. Injury to artery or vein
2. Loss of function or damage to parts of the body supplied by the artery or vein
3. Swelling, pain, tenderness or bleeding at site of blood vessel perforation
4. Aggravation of the condition that necessitated the procedure
5. Allergic reaction to injected contrast media
6. Possible kidney damage from injected contrast media
7. ____________________________

- Interventional
  - Pain
  - Bleeding
  - Infection
  - Damage to surrounding structures
  - Pneumothorax
  - Hemoptyis (coughing up blood)
  - Headache
  - Nausea/Vomiting
  - Nerve damage
  - Paralysis
  - Side effects of intrathecal chemo therapy
  - Stroke
  - ____________________________

*Just as there may be risk and hazards in continuing my present condition without treatment, there are also risks and hazards related to the performance of the surgical, medical, and/or diagnostic procedures planned for me.*

*I (we) realize that common to surgical, medical, and/or diagnostic procedures, is the potential for infection, blood clots in veins and lungs, hemorrhage, pain, emergent coronary bypass surgery, myocardial infarction, arrhythmia’s, renal failure, stroke, allergic reactions, and even death.*
Patient education

• PA/physician must have the tools and knowledge to simply explain the risks to the patient without inducing panic

• One approach to this is a pamphlet/handout
  – Mechanism of injury
  – How we prevent injuries
  – Decisions made during the case
Identify “high-risk” patients

• Certain conditions are suspected to pre-dispose patients to radiation-induced skin injuries
  – Diabetes mellitus (microvascular disease)
  – Connective tissue disorders
    • Marfan syndrome
  – Ataxia telangiectasia
  – Drug interactions
• Also, a recent high-CD procedure can result in the induction of injuries at lower CD levels


Identify “high-risk” patients

• Most easily done during the consenting process
• The RIS can be a valuable tool for automatically identifying and flagging these patients
• “High-risk” patients can perhaps be routed to a dose-sparing protocol, physician can be advised
  – Fewer acquisition runs, more storing/saving
  – Alternate CD thresholds
  – Delay procedure?
Physician/staff credentialing

• Physicians performing complex procedures should be credentialed in the safe use of fluoroscopic equipment
  – TG 124 – M. Martin talk at ACMP 09
  – Credentialing course (Wagner, Archer)

• Continuing education

• Understand dose-saving features of each type of equipment on which they work
INTRA-PROCEDURE ELEMENTS
Cumulative dose (CD) thresholds

- All equipment manufactured after June 2006 is required by law to display cumulative air kerma.
- Alerting the physician at certain CD thresholds guarantees there are no surprises at the end of a case.
- Decisions can be made based on medical management at each threshold:
  - Pace of procedure
  - Good practice – YDNKWIHUYKWIH
  - Continuation of procedure at a later time (how long?)
Establishing CD thresholds

- Considering our practice, we have opted for certain CD thresholds
- When our Cath Lab opens, tailored CD levels will be implemented
  - Patient position
  - Higher CD levels
<table>
<thead>
<tr>
<th>Threshold</th>
<th>Actions Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000 mGy</td>
<td>Technologist will notify radiologist that a CD of <strong>2000 mGy</strong> has been reached. Radiologist will ensure that radiation is being used appropriately and sparingly. Procedure continues normally.</td>
</tr>
<tr>
<td>3000 mGy</td>
<td>Technologist will notify radiologist that a CD of <strong>3000 mGy</strong> has been reached. Radiologist will ensure that radiation is being used appropriately and sparingly. <strong>Case should be flagged upon completion.</strong></td>
</tr>
<tr>
<td>+1000 mGy</td>
<td>Technologist will notify radiologist that a CD of <strong>6000 mGy</strong> has been reached. Threshold for erythema may have been reached, depending on the position of the patient relative to the IRP and orientation of the C-arm during the procedure. Radiologist will assess risk/benefit pace of procedure. Radiologist will ensure that radiation is being used appropriately and sparingly. <strong>Technologist considers paging on-duty medical physicist.</strong></td>
</tr>
<tr>
<td>6000 mGy</td>
<td>Technologist will notify radiologist that a CD of <strong>7000 mGy</strong> has been reached. Radiologist will ensure that radiation is being used appropriately and sparingly.</td>
</tr>
<tr>
<td>7000 mGy</td>
<td>Technologist will notify radiologist that a CD of <strong>8000 mGy</strong> has been reached. <strong>Threshold for severe skin effects may have been reached.</strong> Radiologist will assess risk/benefit pace of procedure and consider continuing the procedure at a later time, depending on patient’s condition. If procedure continues, radiologist will ensure that radiation is being used appropriately and sparingly. Extreme caution should be exercised past this point, and all possible dose reduction methods used, including restricting use of acquisition mode and DSA.</td>
</tr>
<tr>
<td>8000 mGy</td>
<td>Technologist will notify radiologist that a CD of <strong>x000 mGy</strong> has been reached. Radiologist will ensure that radiation is being used appropriately and sparingly.</td>
</tr>
<tr>
<td>+1000 mGy</td>
<td>Technologist will notify radiologist that a CD of <strong>x000 mGy</strong> has been reached. Radiologist will ensure that radiation is being used appropriately and sparingly.</td>
</tr>
</tbody>
</table>

*DynaCT runs do not contribute significantly to peak skin dose (PSD). This should be considered in cases that utilize DynaCT heavily. An average DynaCT run contributes approximately 200 mGy to the displayed CD.*
Other recommendations

<table>
<thead>
<tr>
<th>Parameter</th>
<th>First Notification</th>
<th>Subsequent Notifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak skin dose (PSD)</td>
<td>2,000 mGy</td>
<td>500 mGy</td>
</tr>
<tr>
<td>Reference point air kerma (K_{a,r})</td>
<td>3,000 mGy</td>
<td>1,000 mGy</td>
</tr>
<tr>
<td>Kerma-area-product (P_{KA})</td>
<td>300 Gy \cdot cm^2*</td>
<td>100 Gy \cdot cm^2*</td>
</tr>
<tr>
<td>Fluoroscopy time (FT)</td>
<td>30 min</td>
<td>15 min</td>
</tr>
</tbody>
</table>

* Assuming a 100-cm$^2$ field at the patient’s skin. The value should be adjusted to the actual procedural field size.


<table>
<thead>
<tr>
<th>Air kerma at the IRP (Gy$_a$)</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Advise physician that IRP air kerma is 2 Gy$_a$ so that he/she can assess the benefit-risk pace of the procedure.</td>
</tr>
<tr>
<td>4</td>
<td>Advise physician that IRP air kerma is 4 Gy$_a$ and that the threshold for erythema might have been reached, depending on how the beam is oriented and how often it has been rotated. Consider moving the projected view to a different skin site.</td>
</tr>
<tr>
<td>6</td>
<td>Advise physician that IRP air kerma is 6 Gy$_a$ and that the threshold for moderate to severe skin effects might have been reached, depending on how the beam is oriented and how often it has been rotated. Consider moving the projected view to a different skin site.</td>
</tr>
<tr>
<td>8</td>
<td>Advise physician that IRP air kerma is 8 Gy$_a$ and that beyond this point there is a potential for severe skin effects, depending on how the beam is oriented and how often it has been rotated. Benefit-risk depends on how critical the patient’s condition is.</td>
</tr>
</tbody>
</table>

Reduced-dose protocols

• Many elements of a protocol can be adjusted to reduce radiation dose to the patient
  – Reduce IAKRD for fluoroscopy
  – Reduce IAKRD for acquisition
  – Reduce frame rate for acquisition*
  – Reduce pulse rate for fluoroscopy*
  – Use lower-dose ADRC curve (have to know them)
  – Use additional filtration*
Situational awareness

• For patients who have undergone a recent high-CD procedure, use a different projection to reduce cumulative skin dose
  – Reduce 95% area load
  – May not reduce PSD
• May not be able to completely eliminate overlap, but for angled projections can have large benefit
  – Importance of tight collimation
• Work of Alex Pasciak, Ph.D.
POST-PROCEDURE ELEMENTS
Record dose descriptors

- Medical record has been suggested
  - Perhaps difficult
  - May not be searchable
    - Dictated
    - Scanned
- DICOM Structured Dose Reporting is coming soon
  - S. Balter talk at AAPM 09
  - First upgrade to our new Siemens zee software
  - Current generation of objects not supported by many PACS
- DICOM headers contain some information
### Interventional Radiology

<table>
<thead>
<tr>
<th>Patient</th>
<th>Position</th>
<th>DR</th>
<th>KVP</th>
<th>mAs</th>
<th>0.0CL</th>
<th>0.0Cu</th>
<th>0.1Cu</th>
<th>Total</th>
<th>Exposure</th>
<th>Time</th>
<th>Report Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>HFS</td>
<td>DR</td>
<td>66kV</td>
<td>475mA</td>
<td>115.0ms</td>
<td>0.0CL small</td>
<td>0.2Cu</td>
<td>48.0cm</td>
<td>45.4µGy²</td>
<td>16-Apr-09 14:26:13</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>HFS</td>
<td>DR</td>
<td>66kV</td>
<td>486mA</td>
<td>118.1ms</td>
<td>0.0CL small</td>
<td>0.2Cu</td>
<td>48.0cm</td>
<td>47.7µGy²</td>
<td>16-Apr-09 14:27:13</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>HFS</td>
<td>DR</td>
<td>68kV</td>
<td>436mA</td>
<td>105.6ms</td>
<td>100CL small</td>
<td>0.1Cu</td>
<td>48.0cm</td>
<td>69.1µGy²</td>
<td>16-Apr-09 14:32:10</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>HFS</td>
<td>DR</td>
<td>68kV</td>
<td>437mA</td>
<td>105.8ms</td>
<td>100CL small</td>
<td>0.1Cu</td>
<td>48.0cm</td>
<td>69.4µGy²</td>
<td>16-Apr-09 14:33:19</td>
<td></td>
</tr>
</tbody>
</table>

***Accumulated exposure data***

- Phys: Exposures: 4  Fluoro: 2.0min Total: 769.4µGy²  22.2mGy

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**File Under:** Diagnostic Imaging / Nuclear Medicine

**DIC55077 (4/21/09)**
Record dose descriptors

• Other possibilities include RIS or logbooks
  – Would like it to be searchable
    • Tracking
    • Practice improvement
    • Identify/prevent sentinel events

• We went with the RIS
  – Manual entry into designated fields (not intended)
  – Reports can be generated, already linked with procedure (accession number)
  – Automatic analysis of data/entry into database
Record dose descriptors

• What we record:
  – CD
  – DAP
  – Number of acquisition runs
  – Number of Dyna CT
  – Fluoroscopy time

• Any additional dose delivered within 60 days should be considered additive
Flagging and follow-up of high CD cases

• A high CD case is flagged by the technologist, triggering a follow-up protocol:
  – Patient informed that high CD (>= 3 Gy) was reached
  – Instructed on what to be aware of (pamphlet?)
    • Signs/symptoms (red area the size of your hand)
    • Instructions (do not scratch or itch)
    • Actions (call us)
  – Telephone or in-person f/u scheduled for 2-3 weeks
  – Print protocol, scan into EMR

• Flag = 3 Gy
  – SIR Safety and Health Committee
Peak skin dose (PSD) reconstruction

- Ideally you have some summary report of the dose descriptors
  - On the monitor
  - Exam protocol

- Otherwise, information from the DICOM header(s) will be needed, along with fluoroscopy time

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PSD reconstruction

• The aforementioned information is used along with information from the DICOM header
  – Magnification factor (patient position)
  – Images (position of radiation field)
  – Need collimator positions in absence of CD data
• All of these data can be used in conjunction with
  – Backscatter factor
  – f-factor

to estimate PSD
Measuring PSD

• GAFCHROMIC® film can be used to measure PSD

• Dose information can be assessed in two ways:
  – A calibrated strip can be used to estimate PSD
  – The film can be scanned and decalibrated to determine PSD

http://online1.ispcorp.com/_layouts/Gafchromic/content/products/xrr/pdf/doseverstripguide.pdf, 10/08
http://online1.ispcorp.com/_layouts/Gafchromic/content/products/xrr/pdf/doseverstripguide.pdf,10/08
Know your allies

• We as diagnostic folks (thank God) rarely see these doses
  – Folks = physicians and physicists
• Thus we need some help when we encounter them
• Dermatologists may not have a good handle either
• Radiation oncologists seem to be the best to discuss these matters with
Other areas for concern

- Effective doses
- Marrow doses (organ dose)
  - Older patients
  - Solid tumor induction not typically a concern, but leukemia latent period ~ 2 yr

**Table 3**

<table>
<thead>
<tr>
<th>Examination</th>
<th>Average Effective Dose (mSv)*</th>
<th>Values Reported in Literature (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head and/or neck angiography</td>
<td>5</td>
<td>0.8–19.6</td>
</tr>
<tr>
<td>Coronary angiography (diagnostic)</td>
<td>7</td>
<td>2.0–15.8</td>
</tr>
<tr>
<td>Coronary percutaneous transluminal angioplasty, stent placement, or radiofrequency ablation</td>
<td>15</td>
<td>6.9–57</td>
</tr>
<tr>
<td>Thoracic angiography of pulmonary artery or aorta</td>
<td>5</td>
<td>4.1–9.0</td>
</tr>
<tr>
<td>Abdominal angiography or aortography</td>
<td>12</td>
<td>4.0–48.0</td>
</tr>
<tr>
<td>Transjugular intrahepatic portosystemic shunt placement</td>
<td>70</td>
<td>20–180</td>
</tr>
<tr>
<td>Pelvic vein embolization</td>
<td>60</td>
<td>44–78</td>
</tr>
</tbody>
</table>

* Values can vary markedly on the basis of the skill of the operator and the difficulty of the procedure.

Other areas for concern

• Wound healing
  – Pre-surgery spinal embolization
  – 8, 10, 12 Gy cases
  – How do wounds heal after these doses are delivered < 24 hr prior to surgery?
    • Damage to fibroblasts
    • Literature – only a few papers about mouse experiments

Further reading

  — SIR Standards of Practice Committee
  — SIR Safety and Health Committee
  — Discharge/consenting examples
Acknowledgements

• Louis K Wagner, Ph.D.
• Joseph Steele, M.D.