Peak Skin Dose Reconstruction and the Joint Commission Sentinel Event

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2010 Annual Meeting of the AAPM, Philadelphia
July 2010
What is a Joint Commission (JC) Sentinel Event?

• A sentinel event (SE) is an unexpected occurrence involving death or serious injury, or the risk thereof

• Sentinel events signal the need for immediate investigation and response

• Sentinel event and medical error are not the same; a sentinel event may not be an error and an error may not result in a sentinel event

www.jointcommission.org/SentinelEvents/PolicyandProcedures/
More About Sentinel Events

• Goals of SE response action include reducing the probability of SE in the future and developing strategies to prevent them.
• Each institution is expected to develop its own definitions of SEs, but there are 10 types of event that the Joint Commission specifically names as "Reportable"; the fluoroscopic event is one of these.
10 Defined JC Reportable Sentinel Events (Simplified)

- Suicide of patient in a staffed, around-the-clock care setting
- Unanticipated death of a full-term infant
- Abduction of a patient under care
- Discharge of an infant to the wrong family
- Rape
- Hemolytic transfusion reaction (major blood group incompatibility)
- Surgery on the wrong patient or wrong body part
- Unintended retention of a foreign object after surgery
- Severe neonatal hyperbilirubinemia
- Prolonged fluoroscopy (>1500 rads) or radiotherapy to the wrong body region or >25% above planned dose

http://www.jointcommission.org/SentinelEvents/PolicyandProcedures/
What an Institution **Must** Do in Response to a Sentinel Event

- Conduct a timely, thorough, and credible root cause analysis (RCA)
- Develop an action plan to implement improvements to reduce risk
- Implement the improvements
- Monitor the effectiveness of those improvements
Root Cause Analysis

• Focuses on systems and processes, not on individual performance (no witch hunts)
• Examines clinical and organizational processes to identify potential improvements to decrease the likelihood of such SEs in the future or determine, after analysis, that no such opportunities exist
• Patient and care-givers are anonymized in any reports to JC
More About Root Cause Analysis

• The JC encourages, but does not require, notification when a SE occurs
• Two strategies are allowed
  – Self-report (i.e. notify the JC when SE occurs)
  or
  – Do RCA and have report available on request
• The RCA must occur within 45 days of the hospital becoming aware of the event (day of procedure)
• **Failure to pursue an adequate RCA within the proper time frame and produce an action plan can result in loss of accreditation**
What Is the JC Radiologic Sentinel Event (Nov 2005)?

- **Prolonged fluoroscopy with cumulative dose >1500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose**
The JC Fleshes Out the Fluoroscopic Sentinel Event with an FAQ Page

• "Cumulative dose > 1500 rads" is the peak skin dose, taking overlap of different fields (all runs, all fluoro) into consideration

• Cumulative dose, for the JC, refers neither to a single procedure nor to a lifetime; they indicate "...monitoring cumulative dose over a period of six months to a year would be reasonable."

www.jointcommission.org/SentinelEvents, Radiation Overdose FAQ's
Problems

• Terminology
  – Cumulative Dose (CD), to the medical physicist, is the air kerma at the interventional reference point (IRP) (15 cm toward x-ray tube from isocenter or vendor specified) (ICRP, IEC)
  – Cumulative dose, in the JC definition, is essentially a cumulative Peak Skin Dose (PSD or $D_{\text{skin, max}}$), summed for a "reasonable" time

• Multiple procedures in hospital (can be hard)
• Multiple institutions (can be much harder !!!)
Strategy for Detection - I

• Monitor and record surrogates for skin dose
  – Fluoro time (possible on all machines)
  – Air Kerma (AK or $K_{a,r}$) or KERMA-Area-Product (KAP or $P_{K,A}$) readings on machines so equipped (such monitors required by FDA on new machines post-2006)
  – Skin dose software (e.g. Siemens CareGraph, PEMNET, etc.) if present
  – Number of DA or DSA runs or total # DA/DSA images
Strategy for Detection II

- Establish "threshold" values of the surrogates and a hospital notification process to trigger an investigation

- Threshold should be
  - Low enough to catch all real events
  - High enough to keep workload on physics department within realistic limits
Picking Thresholds: 2006 Thoughts


Data on 2142 interventional procedures, from RAD-IR study,
If we want to trap all events that have a CD (physics!) > 15 Gy, could investigate everything > 150 min of fluoro (<2% of events above this level)

Data on 2142 interventional procedures, from RAD-IR study, Miller et al. J Vasc Interv Radiol 2003; 14:977–990
Picking Thresholds: 2006 Thoughts

Final threshold choices:

> 150 min fluoro

> 6000 mGy on AK meter sum planes for biplanes

Data on 2142 interventional procedures, from Miller et al. J Vasc Interv Radiol 2003; 14:977–990
A Gratifying Coincidence -- What Others Are Doing

Literature specific to Fluoroscopic Sentinel Events (at least that revealed by key word search!) is limited:

Dauer et al. JVIR 20(6):782-8, 2009

Mahesh (JACR 5(4):601-3, 2008) addresses practical aspects of identifying sentinel events and suggests threshold levels for medical physics evaluation of

**Fluoro Time:** 150 minutes  
**Air Kerma:** 6000 mGy
Another Look at the RAD-IR Data

Reference Kerma vs Fluoro Time for 21 Types of Interventional Procedure

Fluoro Time [min]

Reference Point Air Kerma [Gy]

95th Percentile

Only a few procedure types generate potential cases; from this data:

- Neuroembolization
- TIPS
- Vascular embolization

(no cardiac in RAD-IR)

data from Miller et al. Radiology 2009; 253:753–764
Further Thoughts: Could we use a higher $K_{a,r}$ threshold?

This data shows that on average the PSD is 1/2 the reported cumulative (physics) dose, leading some to suggest that cases in which the CD is less than 15 Gy are very unlikely to be SEs.

709 "high-dose" cases with PSD monitoring

Further Thoughts: Can we rely on using a high AK threshold?

BUT NOTE

- Embolization cases (two circled are in that class) can have CD=PSD
- No cardiac, EP cases included in set
- Assumes good practice during procedure (not always a good assumption)

709 "high-dose" cases with PSD monitoring

Possible Monitoring Procedure

Check database for dose history of Pt.

Notify physician of cumulative dose

Procedure starts

Update physician on status during procedure

Dose-saving actions during procedure

Procedure ends

New dose data logged in DB

If investigation threshold passed, notify RSO, Event System

Physics investigation

>15 Gy

Yes

Report to RSO, Medical Director

No

Whew!
Data Sources for Dose Reconstruction

**Fluoro Unit**
- Verify # runs to PACS
- Verify fluoro times
- Verify AK, KAP

**Images from PACS**
(DICOM Header Info)
- Technique factors
- Dose (KAP or AK) info
- FOV
- Table position

**Staff Interview**
- Patient positioning
- Fluoro usage
- Procedure description

**HIS/RIS**
- Prior fluoro
- Case notes
- Fluoro time

**Database**
(may be HIS/RIS)
- Prior fluoro, equipment
Case Study 1: Cerebral Aneurysm With No AK Monitor

- Cerebral arteriogram with embolization procedure for an anterior communicating arterial aneurysm
- Fluoroscopy time exceeded the investigational limit of 150 min.
- Bi-plane c-arm fluoroscope not equipped with an air kerma monitor.
Case 1: Basic Information

- No cumulative dose (AK) data available.
- 22 frontal and lateral runs, ~20 frames each
- 1 rotational run.
- No DICOM information for fluoroscopy dose component
- 154 minutes of fluoroscopy recorded by staff (also available on unit)
Case 1: Information Collection

- DSA images obtained from modality (not all image sets sent to PACS!)
- DSA images:
  - Number, type of runs
  - Technique factors
  - Table position
  - C-arm angulation
- Staff interview:
  - Patient positioning
  - Fluoro details (fluoro FOV, etc.)
- CT images:
  - Patient size
- Note: Patient had procedures in addition to this one!

<table>
<thead>
<tr>
<th>Information</th>
<th>Fluoro Unit</th>
<th>PACS</th>
<th>HIS/RIS</th>
<th>Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoro Details</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Fluoro Time</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>DSA Runs</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positioning</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Prior Cases</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Body Habitus</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Exam Notes</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Phantom Measurements

• Phantom measurements to measure output exposure factors for:
  – Fluoroscopy
  – DSA runs
  – Rotational DSA

• Fixed SID (1 m) with phantom at isocenter

• Exposure and technique (kVp/mA or kVp/mAs per pulse) determined for each FOV

• X-ray filters appropriate for the exam
Calculations

- **Spread sheet calculation**
- **Simplify**: ignore tube angulation, divide into frontal and lateral fields
- **DSA and rotational run exposures scaled for patient position** \((1/r^2)\), and technique factors \((kVp^2, mAs)\)
- **Fluoroscopy exposure calculated for average position from run data**

<table>
<thead>
<tr>
<th>Skin Exposure Contributions (R)*</th>
<th>Frontal</th>
<th>Lateral</th>
</tr>
</thead>
<tbody>
<tr>
<td>DA Runs</td>
<td>167 (~9 R/run)</td>
<td>105 (~6 R/run)</td>
</tr>
<tr>
<td>Rotational</td>
<td>7 (7 R/rot)</td>
<td>7 (7 R/rot)</td>
</tr>
<tr>
<td>Fluoro</td>
<td>438 (7 R/min)</td>
<td>240 (4 R/min)</td>
</tr>
<tr>
<td>Total</td>
<td>612 R</td>
<td>352 R</td>
</tr>
</tbody>
</table>

*Corrected for SSD and technique

**Tissue/Air Conversion**

\[ TAR(0) \approx 1.2 \text{ Rad}_{tis}/R \]

<table>
<thead>
<tr>
<th>Patient Skin Dose (Rad(_{tis}))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frontal</td>
</tr>
<tr>
<td>Lateral</td>
</tr>
<tr>
<td>Max Overlap</td>
</tr>
</tbody>
</table>

**RESULT**: Frontal and lateral doses do not exceed 1500 Rad, even with 100% overlap
Calculations

- Spread sheet calculation
- Simplify: ignore tube angulation, divide into frontal and lateral fields
- DSA and rotational run exposures scaled for patient position \((1/r^2)\), and technique factors \((kVp^2, mAs)\)
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**Skin Exposure Contributions (R)**

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**Tissue/Air Conversion**

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\]

**Patient Skin Dose (\text{Rad}_{\text{tis}})**

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<th>Lateral</th>
<th>Max Overlap</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>735</td>
<td>423</td>
<td>1159</td>
</tr>
</tbody>
</table>

RESULT: Frontal and lateral doses do not exceed 1500 Rad, even with 100% overlap.
But Wait!

Image sets in PACS revealed 5 other fluoroscopic procedures within a period of 2-3 months.

Cumulative Peak Skin Dose for all procedures estimated to be close to 3000 rad.
Case Study 2: Dural Arteriovenous Fistulas With AK Monitor

- Transvenous embolization for dural arteriovenous fistulas
- Fluoroscopy time and air kerma exceeded the investigational limits of 150 min and 6 Gy.
- Bi-plane c-arm fluoroscope equipped with an Air Kerma Monitor
KAP Monitors

Ion chamber mounted on front of tube housing, larger than largest field size at this point

Measure KAP

Based on field size at interventional reference point, calculate AK

*Some machines may simply calculate the dose based on technique factors*
KAP Monitors: The Reference Point

IRP Position = interventional reference point (15 cm towards focal spot from isocenter or vendor specified)

MP_{FDA} = measurement point for fluoroscopic dose limit regulations (30 cm from Image Receptor faceplate)

Note: wide separation shown between MP_{FDA} and IRP can occur for rotational fluoro
Case 2: Basic Information

- Unit Equipped with a Dose Monitor
- 18 runs, ~20 frames each
- Cumulative dose (IRP) and fluoro time in Performed Procedure Step file
- Frontal $AK_{IRP}$ 10 Gy, fluoro time 182 min
- Lateral $AK_{IRP}$ 0.5 Gy, fluoro time 10 min
- DICOM tags provided run details
  - KAP per run
  - Technique factors
  - Patient (table) to source distance
  - C-arm angulation
- Fluoroscopy dose preceding DSA run included with run KAP in DICOM tag
- Air Kerma monitor calibration checked
Case 2: Calculations

- Spread sheet calculation
- Patient skin dose calculated from KAP data in DSA run DICOM tag
- For each run & associated fluoro:
  \[ AK(\text{at patient}) = \frac{KAP}{\text{Area}_{\text{FOV}}(\text{at patient})} \]
- c-arm angulation and overlap considered (minor effects)

RESULT: Maximum skin dose does not exceed 1500 Rad

### Skin Dose Contributions (Rad_{AK})*

<table>
<thead>
<tr>
<th></th>
<th>Frontal</th>
<th>Lateral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoro + DSA Runs</td>
<td>970</td>
<td>40</td>
</tr>
<tr>
<td>Rotational</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>970</td>
<td>40</td>
</tr>
</tbody>
</table>

*Corrected for SSD, angulation

### Tissue/Air Conversion

\[ TAR(0) \approx 1.3 \text{ Rad}_{\text{tis}}/\text{Rad}_{\text{air}} \]

### Patient Skin Dose (Rad_{tis})

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Frontal</td>
<td>1270</td>
</tr>
<tr>
<td>Lateral</td>
<td>60</td>
</tr>
<tr>
<td>Max Field</td>
<td>1330</td>
</tr>
</tbody>
</table>

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Case 3: Cardiac w Complications

- Middle aged male with hyperlipidemia, exertional chest pain and a positive exercise tolerance test.

- Coronary angiography and percutaneous revascularization procedure performed using single plane fluoroscopy.

- Complications of extensive catheter and subsequently intracoronary thrombosis with complete abrupt occlusion of the LAD.

16 Gy $K_{a,r}$

168 minutes fluoroscopy
Case 3: Basic Information

- Unit Equipped with a Dose Monitor
- 16 Gy cumulative $K_{a,r}$ and 168 minutes total fluoroscopy
- 53 digital runs (15 fps, ~38 frames each)
- XA image DICOM public tag information incomplete
  - Technique factors incomplete
  - Patient-to-source distance not true value
- XA image DICOM private information useful
  - Absolute table position in 3D space was given
  - Fluoroscopy and run cumulative $P_{\text{KA}}$ values for the exam
Case 3: Results

A dose map was created showing the peak skin dose vs position on the patient's back.

<table>
<thead>
<tr>
<th></th>
<th>XA</th>
<th>Fluoroscopy</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Skin Exposure</td>
<td>170 R</td>
<td>1140 R</td>
<td>1310 R</td>
</tr>
<tr>
<td>(~65 R/min)</td>
<td>(~7 R/min)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average f-Factor &amp; BSF Conversion</td>
<td>~12 mGy/R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peak Skin Dose</td>
<td>0.9 Gy</td>
<td>8.4 Gy</td>
<td>9.3 Gy</td>
</tr>
</tbody>
</table>

PSD did not exceed 15 Gy

Cumulative dose for the exam was 16 Gy, but the use of multiple oblique angles during procedure reduced the estimated PSD to about 9 Gy.
Pitfalls and Tips for Dose Detective Work

If your focus is too restricted, ...
If your focus is too restricted, you might miss something!
Practical Tidbits: AK Accuracy

- After 2006, fluoro equipment must have AKR meters; accuracy of reported air kerma at reference point must be +/- 35% (pretty loose!). Best check the calibration against a dosimeter!
  - Different field sizes
  - Different filtrations
  - Different kVp

- Pre 2006, AKR meter may be present; no FDA requirement for accuracy (you may be surprised how bad it can get)
Practical Tidbits: DICOM Data

• Wide variations over vendors -- need to check conformance statement and verify against data
• Some dose report numbers (provided for DA or DSA runs) associated with images include fluoro preceding run, some do not;
• Some dose reports are not in the DICOM image headers, but are associated with a DICOM Modality Performed Procedure Step data
• PACS may not be configured to save needed private tags
• Not all image sets may be on PACS
Practical Tidbits: DICOM Data

(1) Preceding Fluoroscopy dose included.
(2) Varies by machine.

Also note that some header information will be present, but not what you expect it to be!

<table>
<thead>
<tr>
<th>Tag</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>0018,0060x</td>
<td>ACQ KVP, 88</td>
</tr>
<tr>
<td>0018,1000x</td>
<td>ACQ Device Serial Number, 00215324</td>
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<tr>
<td>0018,1020x</td>
<td>ACQ Software Version, V3.52*R004</td>
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<td>0018,1030x</td>
<td>ACQ Protocol Name, Neuro</td>
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<td>0018,1042x</td>
<td>ACQ Contrast/Bolus Start Time, 085816.884000</td>
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<tr>
<td>0018,1110x</td>
<td>ACQ Distance Source-Detector, 103000</td>
</tr>
<tr>
<td>0018,1111x</td>
<td>ACQ Distance Source-Patient, 581.527000</td>
</tr>
<tr>
<td>0018,1114x</td>
<td>ACQ Estimated Radiographic Mag Factor (mGy/Gray)</td>
</tr>
<tr>
<td>0018,1134x</td>
<td>ACQ Table Motion (STATIC, DYNAMIC), 0</td>
</tr>
<tr>
<td>0018,1138x</td>
<td>ACQ Table Angle (relative to horizontal)</td>
</tr>
<tr>
<td>0018,1147x</td>
<td>ACQ Field of View Shape, RECTANGLE</td>
</tr>
<tr>
<td>0018,1149x</td>
<td>ACQ Field of View Dimension(s), 149.11</td>
</tr>
<tr>
<td>0018,1150x</td>
<td>ACQ Exposure Time, 890</td>
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<tr>
<td>0018,1151x</td>
<td>ACQ X-ray Tube Current, 320</td>
</tr>
<tr>
<td>0018,1154x</td>
<td>ACQ Average width of X-Ray pulse (ms)</td>
</tr>
<tr>
<td>0018,1155x</td>
<td>ACQ General level of X-Ray dose exposure</td>
</tr>
<tr>
<td>0018,115Ex</td>
<td>ACQ X-Ray dose to which patient was exposed</td>
</tr>
<tr>
<td>0018,1164x</td>
<td>ACQ Image Pixel Spacing, 0.145510.1455</td>
</tr>
<tr>
<td>0018,1190x</td>
<td>ACQ Focal Spot, 0.6</td>
</tr>
<tr>
<td>0018,1500x</td>
<td>ACQ Positioner Motion, DYNAMIC</td>
</tr>
<tr>
<td>0018,1510x</td>
<td>ACQ Positioner Primary Angle, -17</td>
</tr>
<tr>
<td>0018,1511x</td>
<td>ACQ Positioner Secondary Angle, 0</td>
</tr>
</tbody>
</table>

**VENDOR DICOM CONFORMANCE VARIES**

<table>
<thead>
<tr>
<th>Dicom Image Tag</th>
<th>Toshiba Infinix</th>
<th>Philips Allura</th>
<th>GE Innova</th>
<th>Siemens Artis</th>
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</thead>
<tbody>
<tr>
<td>Public</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Source to Patient</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>( P_{KA} )</td>
<td>( Y^{(1)} )</td>
<td>N</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Technique Factors</td>
<td>Y</td>
<td>Y</td>
<td>Y/N(^{(2)})</td>
<td>Y</td>
</tr>
<tr>
<td>C-arm Orientation</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Collimator Position</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Table Position</td>
<td>N</td>
<td>NA</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Beam Filtration</td>
<td>Y</td>
<td>NA</td>
<td>Y/N(^{(2)})</td>
<td>N</td>
</tr>
</tbody>
</table>

(1) Preceding Fluoroscopy dose included.  (2) Varies by machine.
Practical Tidbits: Miscellaneous

• Interview staff regarding operational practices and, if possible, observe a similar case

• Check assumptions regarding table positioning (patient may not be isocentric due to physician's height or preferences)

• Check assumptions regarding patient positioning on table (positioning blocks, pads may considerably elevate patient above the table)
Other Sources

• Arbique, Guild, Chason, Revell, Sorrells, Pride, and Anderson, RSNA 2009 Poster "The Fluoroscopic Sentinel Event: What to Do?" [basis for this presentation]

• Brateman and Fisher, SU-GG-I-59 poster at this meeting, "A Process to Streamline Patient Skin Dose Estimation -- What We Have and What We Do Not Yet Have"
Resources for Communication with Physicians, Administration

