Radiation Safety Best Practices for the Pediatric Cath Lab
SCAI Pediatric Quality Improvement Toolkit: Radiation Safety Module

This tool kit offers the following:

- Background information on radiation physics and biology
- Strategies to:
  1. reduce radiation exposure of patient
  2. reduce radiation exposure of staff
  3. provide a follow up program for early identification of radiation injury
  4. provide a program for monitoring radiation exposure of staff & methods of improved compliance

www.SCAI.org/QIT
Introduction

• Diagnostic and interventional cardiac catheterizations utilize x-ray fluoroscopy & cineangiography, resulting in exposure of patients and staff to ionizing radiation
• Many pediatric patients undergo complex diagnostic and/or therapeutic procedures requiring greater radiation exposure
• An intensified approach to treatment of certain lesions (e.g. pulmonary atresia with ventricular septal defect) has led to increased number of catheterizations at an earlier age
• Quantifying risk of radiation exposure is difficult and not fully delineated at present
Ionizing Radiation Can be Harmful: Nothing New

PARIS, June 9.—Dr. Maxime Menard, head of the radiology department of the Cochin Hospital, smoked a cigarette while a limb was being amputated today.

The operation was necessary, as cancer had developed from the action of X-rays, which penetrated through the spleen, which was used by X-ray manipulators. The gloves were found to be insufficient.

BURNED BY THE X RAYS

Pitiable Condition of Miss Josie MacDonald After Being Photographed by Them

HAIR FELL OUT OF SCALP

Two Dentists Had the Photograph Taken to Examine Her Jaw, and She Has Required Constant Medical Attention Ever Since.

NEW TUBE ROBS X-RAY OF DANGER

Cornell Professor’s Device Eliminates Burns in Treating Patients

HIS HAND MAIMED BY RAYS

FIRST TIME 5,000 TROJAN HORSES WERE RECEIVED IN Necessity of Experimentation—Tried Successfully

X-RAY WOUND KILLS HIM

Dr. Wm. E. Spranger Bursts a Blood Vessel, Following an Old Burn

NEW HAVEN, March 13.—Dr. William E. Spranger, a former member of the faculty of the Yale Medical School and well known as an X-ray expert, is dead at the home of a daughter here. Death was due to the breaking of a blood vessel brought about by an X-ray burn several years ago.

Dr. Spranger served as a surgeon in the Franco-Prussian war, and received the decoration of the Maltese Cross from the German Government. He was 83 years old, and leaves three daughters.
Facility and Environmental Issues

Increasing awareness as the key ingredient to quality improvement efforts

Characterization of Radiation Exposure and Effect of a Radiation Monitoring Policy in a Large Volume Pediatric Cardiac Catheterization Lab

George R. Verghese,¹ MD, MBA, Doff B. McElhinney,¹ MD, Keith J. Strauss,² MSc, and Lisa Bergersen,¹ MD, MPH

Objectives: This study aimed to characterize radiation dose during cardiac catheterization in congenital heart disease and to assess changes in dose after the introduction of a radiation monitoring policy.

“… After the introduction of a radiation threshold monitoring and notification policy, there was a statistically significant decrease in radiation dose …”

examined differences in radiation dose before and after the implementation of a radiation policy. Results: Between 7/1/05 and 12/10/08, 3,386 cases were identified for inclusion. Radiation dose increased with age and procedural complexity. Patients were characterized into low, medium, and high dose categories relative to each other. “Low” dose cases included isolated pulmonary or aortic valvotomy, pre-fontan assessment, and ASD closure. “High” dose cases involved multiple procedures in pul-

Facility and Environmental Issues

PubMed:
Congenital Heart disease and Radiation

- 49 (2005-2009)
- 122 (2010-2014)

The Society for Cardiovascular Angiography and Interventions Foundation

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Radiation Biology

**Deterministic effects**
Those in which the number of cells lost in an organ or tissue is so great that there is a loss of tissue function, such as skin erythema and ulceration
- Has a threshold
- Skin changes, cataracts

**Stochastic effects**
Occur if an irradiated cell is modified rather than killed and then goes on to reproduce
- Do not appear to have a threshold and the probability of the effect occurring is related to the radiation dose
- Cancer, genetic mutations
Deterministic Effects

0-2 Gy
- < 2 Weeks: None
- 2 – 52 Weeks: None
- Permanent: None

2-5 Gy
- < 2 Weeks: Erythema
- 2 – 52 Weeks: Epilation
- Permanent: None

5-10 Gy
- < 2 Weeks: Erythema
- 2 – 52 Weeks: Prolonged/Permanent Erythema/Epilation
- Permanent: Dermal Atrophy

>10 Gy
- < 2 Weeks: Erythema/Ulceration
- 2 – 52 Weeks: Desquamation
- Permanent: Surgery

“Air kerma overestimates PSD in most instances [0.5 - 0.8]”
RAD-IR Study
Children are at potentially greater risk of stochastic effects due to:

- Greater radiation sensitivity of their tissue compared with adults
- More remaining years of life during which radiation-induced malignancies may develop
- Often multiple radiological procedures over lifetime with cumulative exposure not being tracked or monitored
## Facility and Environmental Issues

### 4 year male with PA VSD MAPCAS

- **The Pediatric Problem** -

<table>
<thead>
<tr>
<th>Date</th>
<th>Type of cath</th>
<th>Fluoro time</th>
<th>Cum air KERMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007-Dec</td>
<td>Diagnostic</td>
<td>22 min</td>
<td>229 mGy</td>
</tr>
<tr>
<td>2008-Jun</td>
<td>Diagnostic</td>
<td>35 min</td>
<td>785 mGy</td>
</tr>
<tr>
<td>2008-Jun</td>
<td>Hybrid – PA Rehab</td>
<td>13 min</td>
<td>290 mGy</td>
</tr>
<tr>
<td>2008-Aug</td>
<td>PA Rehab</td>
<td>70 min</td>
<td>2,148 mGy</td>
</tr>
<tr>
<td>2008-Dec</td>
<td>PA Rehab</td>
<td>123 min</td>
<td>2,709 mGy</td>
</tr>
<tr>
<td>2009-May</td>
<td>PA Rehab</td>
<td>102 min</td>
<td>3,788 mGy</td>
</tr>
<tr>
<td>2009-Dec</td>
<td>PA Rehab</td>
<td>77 min</td>
<td>1,012 mGy</td>
</tr>
<tr>
<td>2011-Mar</td>
<td>PA Rehab</td>
<td>129 min</td>
<td>1,965 mGy</td>
</tr>
<tr>
<td>2011-Nov</td>
<td>Exit Angio</td>
<td>3 min</td>
<td>148 mGy</td>
</tr>
</tbody>
</table>

Additional X-ray exposure: 84 x CXR, 16 x AXR, 4 x CT chest, 4 x CT brain, 2 x NJ tube placement, 1 x cystourethrogram

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Quantifying the Stochastic Risk

- Cancer after exposure to low level radiation < 100 mSv (BEIR VII report 2006)
  - Excess cancer cases ~1%
  - Excess cancer related death ~0.5%

  - Estimate by linear no-threshold model: 1 in 1,000
  - Estimate using biological data ($\gamma$-H2AX foci): 4 in 1,000
Defining Radiation Exposure
Terminology can be confusing:

- (m) Sievert
- Roentgen
- Air Kerma
- Dose Area (m) Gray
- Product
- Effective Dose
- Peak Skin Dose

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Facility and Environmental Issues

The “Education” Problem

“Our patient has radiation illness!!”
Google: “symptoms of radiation illness”
→ Fatigue, fever, nausea, vomiting, weakness, bruising
Google: “Dose for radiation illness”
→ 1 sievert
Google: “conversion gray to sievert”
→ 1 gray = 1 sievert
Patient received 5,400 mGy (5.5Gy) cumulative air kerma and has nausea and vomiting
→ “Our patient has radiation illness”
Radiation - Terms

Exposure / energy produced
- The amount of ionizing radiation a person is exposed to
- Measured in coulomb/kg (C/kg) or roentgens (R)

Absorbed dose
- The amount of energy deposited in any material, or the amount of radiation needed to transfer a certain amount of energy (1 joule/kg).
- Measured in gray (Gy) or rad (1 Gy = 100 rad)

Dose equivalent
- The absorbed dose multiplied by a quality factor allowing for different tissue sensitivities, or the equivalent dose of radiation having the same damaging effect as an equal dose of gamma rays (accounting for different biological effects of radiation).
- Measured in sievert (Sv) or rem (1 Sv = 100 rem)
Fluoroscopy time (minutes):
- Quantifies length of the procedure; does not provide an estimate of radiation exposure
- Does not take account frame rate variations
- Does not include cine/digital acquisition
- Does not account for higher dose settings that are required for larger patients
- Does not account for collimation and use of protective filters
Radiation Exposure: Units of Measurement

**Total Air Kerma (mGy):**
- Procedural cumulative dose at the interventional reference point (dose delivered to air)
- Reference point: usually along central ray of x-ray beam 15cm back from isocenter
- Measured and displayed on all fluoroscopic equipment sold in USA after 2006
- Can be used to monitor thresholds for deterministic effects of radiation exposure

**Peak Skin Dose (mGy):**
- Maximum dose received by any local area of the skin
- Not measured directly
- Derived from total air kerma using a variety of calculations, taking into account angles & projections of x-Ray beams (will require a physicist to get involved to calculate the accurate dose)
- Less than total air kerma for most (but not all) procedures
- Determines deterministic effects of radiation exposure
  - The Joint Commission identifies a cumulative peak skin dose > 15 Gy as a sentinel event (cumulative peak skin dose over 6-12 months)
Radiation Exposure: Units of Measurement

Dose Area Product (mGy cm²):
• Cumulative sum of product of instantaneous air kerma and x-Ray field area
• Good measure for total energy delivered to patient
• Provided by most modern fluoroscopic equipment
• Important as a marker of stochastic risk; not a marker for deterministic risk

Effective Dose (mSv):
• Used to express detriment to whole body if only part of the body is exposed
• Important as a marker of stochastic risk; not a marker for deterministic risk
Effective Dose Examples

Low levels of radiation (<100 mSv):
- Annual background radiation: 3 mSv
- Chest X-Ray: 0.1 mSv
- Whole body CT Scan: 10 mSv
- Pediatric cardiac catheterization:
  - Most procedures: <20 mSv
  - Diagnostic /simple interventions: <5 mSv
How to set up a local QI project in the cath lab centered on radiation exposure and related injuries?
Facility and Environmental Issues

Strategies and steps: Reduction in patient dose

- Collect Your Data -

- Collect important radiation-related data for every procedure such as:
  - Dose (Total Air Kerma and DAP)
  - Fluoroscopy time
  - Age, weight, BSA
  - Procedure type

- Have a named member of staff responsible for radiation safety and all radiation-related QI efforts
- Collected data need to be readily accessible (either spreadsheet or database management system)
Facility and Environmental Issues

Strategies and steps: Reduction in patient dose
- Analyze Your Data -

• Plot the median dose (total air kerma) per observation period
• Observation period should be long enough to contain a sufficient number of patients but short enough to allow monitoring of QI efforts (e.g. 3 month intervals)
• Depending on case volumes, analyze data not only for all procedures, but also differentiate by age groups and procedure types (especially if larger variations exist between observation periods)
• Identify outliers that exceed the 95th percentile for exposure
Facility and Environmental Issues

Radiation Safety Aim No 1: Reduction in patient dose
- Compare Your Data -

- Compare median radiation dose (by procedure type and age) to data recently reported in the literature (Verghese et al. Catheter Cardiovasc Interv. 2012. 79(2):294-301)
- Metrics established by the QMWG (Quality Metrics Working Group) can be used to compare your data to that of other centers
- Where/when available use data from registries such as IMPACT to compare performance to other centers
Radiation Safety Best Practices for the Pediatric Cath Lab
Radiation Metrics by the QMWG

- Developed by the Quality Metric working group of the ACC
- **Title:** High Radiation Exposure During Transcatheter Atrial Septal Defect (ASD) Closure
- **Metric description:** Proportion of isolated transcatheter ASD closure procedures that exceed the 95th percentile for radiation exposure stratified by age
- **Numerator:** Proportion of isolated transcatheter ASD closure procedures that exceed the 95th percentile for radiation exposure stratified by age
- **Denominator:** Number of isolated transcatheter closure ASD procedures
- **Related Metrics:** Developed for the following procedures ➔ Transcatheter Pulmonary Valvuloplasty, Transcatheter Aortic Valvuloplasty, Transcatheter Coarctation Intervention, Transcatheter Pulmonary Artery Stent, Transcatheter Patent Ductus Occlusion
### Facility and Environmental Issues

#### TABLE IV. Radiation Dose by Case Type in Age Strata

<table>
<thead>
<tr>
<th>Age groups</th>
<th>Procedure type</th>
<th>n</th>
<th>Weight (kg) mean</th>
<th>Fluoroscopy time (min) median</th>
<th>Air KERMA (mGy) median [IQR]</th>
<th>DAP (mGy m²) median [IQR]</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1</td>
<td>Pulmonary valvotomy (isolated)</td>
<td>86</td>
<td>4.3</td>
<td>28</td>
<td>233 [129, 388]</td>
<td>797 [459, 1,355]</td>
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<tr>
<td></td>
<td>Aortic valvotomy</td>
<td>43</td>
<td>4.4</td>
<td>30</td>
<td>307 [200, 447]</td>
<td>957 [629, 1,524]</td>
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<tr>
<td></td>
<td>Pre-Glen Evaluation</td>
<td>128</td>
<td>5.2</td>
<td>41</td>
<td>412 [266, 686]</td>
<td>1378 [954, 2,040]</td>
</tr>
<tr>
<td></td>
<td>Aorta dilation and or stent</td>
<td>42</td>
<td>5.3</td>
<td>34</td>
<td>452 [252, 766]</td>
<td>1298 [827, 2,592]</td>
</tr>
<tr>
<td></td>
<td>Prox R or L angioplasty and or stent only</td>
<td>43</td>
<td>4.7</td>
<td>53</td>
<td>571 [396, 913]</td>
<td>1852 [1,415, 2,824]</td>
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<tr>
<td>≥2 prox or distal R or L angioplasty or stent</td>
<td>75</td>
<td>5.5</td>
<td>73</td>
<td>892 [491, 1,265]</td>
<td>2744 [1,868, 4,154]</td>
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<tr>
<td></td>
<td>Pulmonary vein dilation</td>
<td>52</td>
<td>5.5</td>
<td>90</td>
<td>968 [597, 1,920]</td>
<td>3501 [2,333, 5,039]</td>
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<tr>
<td>1–4</td>
<td>PDA device or coil closure</td>
<td>61</td>
<td>13.0</td>
<td>17</td>
<td>240 [139, 321]</td>
<td>800 [558, 1,430]</td>
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<tr>
<td></td>
<td>Pre-Fontan Assessment</td>
<td>128</td>
<td>12.6</td>
<td>45</td>
<td>464 [286, 734]</td>
<td>2,395 [1,413, 3,880]</td>
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<tr>
<td></td>
<td>ASD or PFO closure (isolated)</td>
<td>29</td>
<td>14.7</td>
<td>30</td>
<td>540 [361, 753]</td>
<td>2,197 [1,614, 3,048]</td>
</tr>
<tr>
<td></td>
<td>RVOT dilation and or stent only</td>
<td>27</td>
<td>11.5</td>
<td>42</td>
<td>788 [318, 1,418]</td>
<td>3,007 [1,457, 4,486]</td>
</tr>
<tr>
<td></td>
<td>Prox R or L angioplasty and or stent only</td>
<td>44</td>
<td>11.9</td>
<td>53</td>
<td>827 [551, 1,313]</td>
<td>3,513 [2,717, 4,706]</td>
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<tr>
<td></td>
<td>Pulmonary vein dilation</td>
<td>34</td>
<td>10.1</td>
<td>86</td>
<td>973 [620, 1,504]</td>
<td>4,769 [3,012, 6,499]</td>
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<tr>
<td>5–9</td>
<td>≥2 prox or distal R or L angioplasty or stent</td>
<td>100</td>
<td>11.4</td>
<td>74</td>
<td>1,156 [579, 1,445]</td>
<td>4,295 [2,824, 6,695]</td>
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<tr>
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<td>ASD or PFO closure (isolated)</td>
<td>40</td>
<td>22.0</td>
<td>31</td>
<td>522 [331, 862]</td>
<td>2,816 [1,431, 3,978]</td>
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<tr>
<td></td>
<td>RVOT dilation and or stent only</td>
<td>23</td>
<td>25.9</td>
<td>36</td>
<td>852 [434, 1,360]</td>
<td>4,348 [2,548, 6,211]</td>
</tr>
<tr>
<td></td>
<td>Prox R or L angioplasty and or stent only</td>
<td>22</td>
<td>22.0</td>
<td>52</td>
<td>931 [668, 1,733]</td>
<td>5,303 [4,396, 6,615]</td>
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<tr>
<td></td>
<td>Fenestration device and other intervention</td>
<td>78</td>
<td>70.4</td>
<td>66</td>
<td>1,074 [795, 1,466]</td>
<td>5,130 [3,033, 7,608]</td>
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<tr>
<td>10–15</td>
<td>≥2 prox or distal R or L angioplasty or stent</td>
<td>51</td>
<td>20.6</td>
<td>73</td>
<td>1,776 [1,088, 2,793]</td>
<td>6,420 [3,882, 10,930]</td>
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<tr>
<td></td>
<td>ASD or PFO closure (isolated)</td>
<td>27</td>
<td>49.7</td>
<td>34</td>
<td>1,459 [814, 2,324]</td>
<td>7,492 [4,419, 10,582]</td>
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<tr>
<td></td>
<td>RVOT dilation and or stent only</td>
<td>25</td>
<td>45.7</td>
<td>52</td>
<td>2,019 [977, 3,065]</td>
<td>9,449 [5,917, 18,958]</td>
</tr>
<tr>
<td>≥16</td>
<td>≥2 prox or distal R or L angioplasty or stent</td>
<td>37</td>
<td>44.2</td>
<td>78</td>
<td>3,612 [2,211, 6,206]</td>
<td>18,497 [11,440, 24,072]</td>
</tr>
<tr>
<td></td>
<td>ASD or PFO closure (isolated)</td>
<td>99</td>
<td>73.3</td>
<td>28</td>
<td>1,403 [983, 2,225]</td>
<td>9,871 [6,097, 15,341]</td>
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<tr>
<td></td>
<td>PDA device or coil closure</td>
<td>20</td>
<td>73.3</td>
<td>34</td>
<td>2,163 [1,226, 4,161]</td>
<td>11,018 [5,651, 27,145]</td>
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<tr>
<td></td>
<td>Aorta dilation and or stent</td>
<td>54</td>
<td>68.4</td>
<td>36</td>
<td>2,404 [1,547, 4,547]</td>
<td>12,302 [7,854, 25,875]</td>
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<tr>
<td>≥2 prox or distal R or L angioplasty or stent</td>
<td>66.9</td>
<td>77</td>
<td>77</td>
<td>4,519 [2,943, 6,478]</td>
<td>18,947 [11,402, 33,107]</td>
<td></td>
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<tr>
<td></td>
<td>RVOT dilation and or stent only</td>
<td>37</td>
<td>70.7</td>
<td>59</td>
<td>4,545 [1,960, 5,536]</td>
<td>22,148 [12,025, 39,371]</td>
</tr>
<tr>
<td></td>
<td>Prox R or L angioplasty and or stent only</td>
<td>21</td>
<td>66.8</td>
<td>54</td>
<td>4,842 [3,080, 5,508]</td>
<td>30,067 [18,801, 39,794]</td>
</tr>
</tbody>
</table>
## Patient Radiation Exposure in a Modern, Large-Volume, Pediatric Cardiac Catheterization Laboratory

Andrew C. Glatz · Akash Patel · Xiaowei Zhu · Yoav Dori · Brian D. Hanna · Matthew J. Gillespie · Jonathan J. Rome

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Time (min)</th>
<th>Age (yrs)</th>
<th>BMI (kg/m²)</th>
<th>Area (cm²)</th>
<th>Dose (mGy)</th>
<th>Dose Area (mGy·cm²)</th>
<th>Dose Area Rate (mGy·cm²·min⁻¹)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-year-old</td>
<td>30 (20-45)</td>
<td>30 (20-45)</td>
<td>16 (12-20)</td>
<td>23 (18-32)</td>
<td>5 (4-6)</td>
<td>11 (9-13)</td>
<td>1 (0.5-1.5)</td>
</tr>
<tr>
<td>8-year-old</td>
<td>25 (20-30)</td>
<td>25 (20-30)</td>
<td>15 (10-20)</td>
<td>20 (16-24)</td>
<td>4 (3-5)</td>
<td>8 (6-10)</td>
<td>0.5 (0.3-0.7)</td>
</tr>
<tr>
<td>7-year-old</td>
<td>20 (15-25)</td>
<td>20 (15-25)</td>
<td>14 (10-16)</td>
<td>18 (14-22)</td>
<td>3 (2-4)</td>
<td>6 (4-8)</td>
<td>0.3 (0.2-0.5)</td>
</tr>
<tr>
<td>6-year-old</td>
<td>15 (10-20)</td>
<td>15 (10-20)</td>
<td>13 (9-15)</td>
<td>16 (12-20)</td>
<td>2 (1-3)</td>
<td>4 (3-6)</td>
<td>0.2 (0.1-0.3)</td>
</tr>
</tbody>
</table>

### Table 2: Radiation exposure measures by type of interventional case, stratified by patient weight category when 37% observations available.

<table>
<thead>
<tr>
<th>Interval</th>
<th>Person</th>
<th>Age (yrs)</th>
<th>BMI (kg/m²)</th>
<th>Area (cm²)</th>
<th>Dose (mGy)</th>
<th>Dose Area (mGy·cm²)</th>
<th>Dose Area Rate (mGy·cm²·min⁻¹)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-year-old</td>
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<td>11 (9-13)</td>
<td>1 (0.5-1.5)</td>
</tr>
<tr>
<td>8-year-old</td>
<td>25 (20-30)</td>
<td>25 (20-30)</td>
<td>15 (10-20)</td>
<td>20 (16-24)</td>
<td>4 (3-5)</td>
<td>8 (6-10)</td>
<td>0.5 (0.3-0.7)</td>
</tr>
<tr>
<td>7-year-old</td>
<td>20 (15-25)</td>
<td>20 (15-25)</td>
<td>14 (10-16)</td>
<td>18 (14-22)</td>
<td>3 (2-4)</td>
<td>6 (4-8)</td>
<td>0.3 (0.2-0.5)</td>
</tr>
<tr>
<td>6-year-old</td>
<td>15 (10-20)</td>
<td>15 (10-20)</td>
<td>13 (9-15)</td>
<td>16 (12-20)</td>
<td>2 (1-3)</td>
<td>4 (3-6)</td>
<td>0.2 (0.1-0.3)</td>
</tr>
</tbody>
</table>

### Table 3: Radiation exposure measures by type of interventional case, stratified by patient weight category when 37% observations available.

<table>
<thead>
<tr>
<th>Interval</th>
<th>Person</th>
<th>Age (yrs)</th>
<th>BMI (kg/m²)</th>
<th>Area (cm²)</th>
<th>Dose (mGy)</th>
<th>Dose Area (mGy·cm²)</th>
<th>Dose Area Rate (mGy·cm²·min⁻¹)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-year-old</td>
<td>30 (20-45)</td>
<td>30 (20-45)</td>
<td>16 (12-20)</td>
<td>23 (18-32)</td>
<td>5 (4-6)</td>
<td>11 (9-13)</td>
<td>1 (0.5-1.5)</td>
</tr>
<tr>
<td>8-year-old</td>
<td>25 (20-30)</td>
<td>25 (20-30)</td>
<td>15 (10-20)</td>
<td>20 (16-24)</td>
<td>4 (3-5)</td>
<td>8 (6-10)</td>
<td>0.5 (0.3-0.7)</td>
</tr>
<tr>
<td>7-year-old</td>
<td>20 (15-25)</td>
<td>20 (15-25)</td>
<td>14 (10-16)</td>
<td>18 (14-22)</td>
<td>3 (2-4)</td>
<td>6 (4-8)</td>
<td>0.3 (0.2-0.5)</td>
</tr>
<tr>
<td>6-year-old</td>
<td>15 (10-20)</td>
<td>15 (10-20)</td>
<td>13 (9-15)</td>
<td>16 (12-20)</td>
<td>2 (1-3)</td>
<td>4 (3-6)</td>
<td>0.2 (0.1-0.3)</td>
</tr>
</tbody>
</table>

### Table 4: Radiation exposure measures by type of interventional case, stratified by patient weight category when 37% observations available.

<table>
<thead>
<tr>
<th>Interval</th>
<th>Person</th>
<th>Age (yrs)</th>
<th>BMI (kg/m²)</th>
<th>Area (cm²)</th>
<th>Dose (mGy)</th>
<th>Dose Area (mGy·cm²)</th>
<th>Dose Area Rate (mGy·cm²·min⁻¹)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-year-old</td>
<td>30 (20-45)</td>
<td>30 (20-45)</td>
<td>16 (12-20)</td>
<td>23 (18-32)</td>
<td>5 (4-6)</td>
<td>11 (9-13)</td>
<td>1 (0.5-1.5)</td>
</tr>
<tr>
<td>8-year-old</td>
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<td>25 (20-30)</td>
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<td>2 (1-3)</td>
<td>4 (3-6)</td>
<td>0.2 (0.1-0.3)</td>
</tr>
</tbody>
</table>

### Table 5: Radiation exposure measures by type of interventional case, stratified by patient weight category when 37% observations available.

<table>
<thead>
<tr>
<th>Interval</th>
<th>Person</th>
<th>Age (yrs)</th>
<th>BMI (kg/m²)</th>
<th>Area (cm²)</th>
<th>Dose (mGy)</th>
<th>Dose Area (mGy·cm²)</th>
<th>Dose Area Rate (mGy·cm²·min⁻¹)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-year-old</td>
<td>30 (20-45)</td>
<td>30 (20-45)</td>
<td>16 (12-20)</td>
<td>23 (18-32)</td>
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<td>0.3 (0.2-0.5)</td>
</tr>
<tr>
<td>6-year-old</td>
<td>15 (10-20)</td>
<td>15 (10-20)</td>
<td>13 (9-15)</td>
<td>16 (12-20)</td>
<td>2 (1-3)</td>
<td>4 (3-6)</td>
<td>0.2 (0.1-0.3)</td>
</tr>
</tbody>
</table>
C3PO-QI: Radiation Dose Benchmarks

Abstract

OBJECTIVES: The aim of this study was to define age-stratified, procedure-specific benchmark radiation dose levels during interventional catheterization for congenital heart disease.

BACKGROUND: There is a paucity of published literature with regard to radiation dose levels during catheterization for congenital heart disease. Obtaining benchmark radiation data is essential for assessing the impact of quality improvement initiatives for radiation safety.

METHODS: Data were obtained retrospectively from 7 laboratories participating in the Congenital Cardiac Catheterization Project on Outcomes collaborative. Total air kerma, dose area product, and total fluoroscopy time were obtained for the following procedures: 1) patent ductus arteriosus closure; 2) arterial septal defect closure; 3) pulmonary valvuoplasty; 4) aortic valvuoplasty; 5) treatment of coarctation of aorta; and 6) transcatheter pulmonary valve placement.

RESULTS: Between January, 2009 and July, 2013, 2,713 cases were identified. Radiation doses are presented including median, 75th percentile, and 95th percentile. Radiation doses varied widely between age groups and procedure types. Radiation exposure was lowest in patent ductus arteriosus closure and highest in transcatheter pulmonary valve placement. Total fluoroscopy time was a poor marker of radiation exposure and did not correlate well with total air kerma and dose area product.

CONCLUSIONS: This study presents age-stratified radiation dose values for 6 common congenital heart interventional catheterization procedures. Fluoroscopy time alone is not an adequate measure for monitoring radiation exposure. These values will be used as baseline for measuring the effectiveness of future quality improvement activities by the Congenital Cardiac Catheterization Project on Outcomes collaborative.
Radiation Safety Best Practices for the Pediatric Cath Lab

**Facility and Environmental Issues**

**Radiation Safety Aim No 1: Reduction in patient dose**

- Setting Goals for QI -

- Set realistic goals for your institution
- **Examples of possible aims:**
  - Reduction in median dose by 5% over a 12 month period
  - Reduction in the number of cases that exceed the 95th percentile (for previous year) for specific age and procedure types by 50%
  - Aim to be within one IQR of the median compared to other centers when using radiation specific metrics (QMWG) and national registries (IMPACT)
Strategies and steps: Reduction in patient dose

- What do I need to do? (specific actions!)

- Engage and consult with the institutional radiation physicist
- Understand the options available on your equipment that facilitate radiation reduction without compromising image quality
- Use available online resources
  - **Step Lightly (Image Gently)**
    - Introduced by the Alliance for Radiation Safety in Pediatric Imaging
    - Downloadable checklist for dose reduction
    - Downloadable outline of dose reduction and quality maintenance steps to take in the department
    - [http://imagegently.dnnstaging.com/Education.aspx#1989769-protocol-recommendations](http://imagegently.dnnstaging.com/Education.aspx#1989769-protocol-recommendations)
Facility and Environmental Issues

Strategies and steps: Reduction in patient dose
- What do I need to do? (specific actions!)

• Follow general radiation dose reduction principles
  o ALARA - As Low As Reasonably Achievable
    - Refers to all aspects of radiation safety
    - Using the lowest possible dose while completing procedure safely
  o Recognize the importance of time, shielding, and distance

• Follow general published dose reduction guidelines
    - Page 551 refers to specific procedural techniques that can be used to reduce radiation exposure
Facility and Environmental Issues

Radiation Safety Aim 1: Reduction in patient dose
- What do I need to do? (specific actions!)

• Utilize other published data and documents to aid with other specific measures that can reduce radiation exposure and improve radiation safety. Examples are listed below:
  o Use of radiation protection drapes
  o Adjustment of flat-panel fluoroscopic equipment variables utilizing close cooperation with physicist
  o Use of modern / updated fluoroscopic imaging equipment
Facility and Environmental Issues

Radiation Safety Aim 1: Reduction in patient dose
- What do I need to do? (specific actions!)

- Some measures have the ability to yield large dose reductions. Possible examples (among many) that could be implemented:
  - Reduce the standard frame rate for fluoroscopy and digital acquisition
  - Basic frame rate settings should be sufficiently low so that operators have to “opt out” if higher frame rates are required for specific cases, rather than “opting in” to reduce the frame rates
  - Use fluoro record whenever possible (new imaging equipment often provides excellent quality)
  - Encourage use of equipment (shields) and radiation drapes (to reduce effect of radiation scatter)
  - Regularly review and adjust individual settings for different patient sizes (together with physicist)
Median cath lab exposure per case will be ≤ 95% of the median dose achieved during the preceding year.

**Key Drivers**

- **Equipment, Process & Operator**
  - Increased use of collimation when appropriate
  - Reduce magnification unless absolutely needed
  - Decrease to lowest acceptable frame rate (e.g. 7.5 or 10 fps)
  - Increase use of fluoroscopy recording instead of digital acquisition
  - Use of Live Zoom (replay zoom?) rather than electronic or geometric magnification

- **Physician**
  - Decrease to lowest acceptable frame rate (e.g. 7.5 or 10 fps)

- **Staff**
  - Enable system alerts for staff and physicians

**Interventions**

**Specific Aim**
Facility and Environmental Issues

Strategies and steps: reduction in patient dose
- Follow your results (QI Example) -

Increased use of Fluoro Record

Fluoro frame rates from 30 to 15 fps
Acquisition frame rates from 30 to 15 fps

Median Cath Lab Exposure Per Case

- Monthly Median
- Annual Median

---

Radiation Safety Best Practices for the Pediatric Cath Lab

SCAI
April 7, 2015
### Radiation Safety Best Practices for the Pediatric Cath Lab

#### Strategies and steps: reduction in patient dose

- **Follow your results (QI Example)**

<table>
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<tr>
<th>Procedure</th>
<th>Phase I (n=413)</th>
<th>Phase II (n=459)</th>
<th>Phase III (n=350)</th>
<th>Phase IV (n=89)</th>
<th>Cum. Air Kerma (mGy)</th>
<th>Fluoroscopy time (min)</th>
</tr>
</thead>
<tbody>
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<td>All procedures</td>
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<tr>
<td></td>
<td>(n=413)</td>
<td>(n=459)</td>
<td>(n=350)</td>
<td>(n=89)</td>
<td>710</td>
<td>25 - 204</td>
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<tr>
<td>Cum. Air Kerma (mGy)</td>
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<td>Range</td>
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<td>11 - 17,540</td>
<td>1 - 204</td>
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<td>452</td>
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<td>Fluoroscopy time (min)</td>
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<td>Range</td>
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<td>6 - 114</td>
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<td>(n=32)</td>
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<td>(n=8)</td>
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<td>126</td>
<td>88 - 1,930</td>
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<td>Fluoroscopy time (min)</td>
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<td>Range</td>
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<td>17</td>
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<td></td>
<td>16</td>
<td>8 - 44</td>
<td>15</td>
<td>10</td>
<td>5 - 12</td>
<td></td>
</tr>
</tbody>
</table>


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Staff exposure is just as important as patient exposure!!
Radiation Safety Best Practices for the Pediatric Cath Lab

Facility and Environmental Issues

Radiation Safety Aim 1B: Reduction in staff dose

-What do I need to do?-  

- Any measure aimed at reducing patient dose usually also results in a reduction of staff dose
- Alternatively, one can set individual QI aims (e.g. reducing median monthly deep dose equivalent by 10%)
- Emphasize the importance of distance, shielding, and protective eye wear (for other specific measure follow general published documents and guidelines such as Chambers et al, CCI 2011)
- Need to wear dosimeters consistently (see aim 2)
- Utilize modern staff monitoring systems
Facility and Environmental Issues

Radiation Safety Aim 1B: Reduction in staff dose
- Look back and follow your results -

Physician Deep Dose Equivalent (mrem/month)

Is your staff compliant and are YOU compliant (and setting an example for your staff)?
Radiation Safety Aim 2: Compliance in staff monitoring
- The Problem -

• Staff and physician attitude towards capturing and recording data related to radiation exposure not always perfect

  o 10 pediatric interventional cardiac centers from 9 countries (Latin America)
  o Only 64% of cardiologists used dosimeters regularly
  o Only 36% of cardiologists were aware of personal values
Facility and Environmental Issues

Radiation Safety Aim No 2: Compliance in staff monitoring

- What to measure (examples) -

• Compliance with wearing of dosimeters
  • Unannounced internal on-the spot surveys once a month (confirming correct badges are worn)
• Identify outliers
  • Physician / staff dose <5th or >95th percentile
• Identify the number of occurrences where a member of staff has exceeded the level II warning threshold of 625 mrem/month
  • Frequently due to inappropriate wearing of dosimeters
• Use modern staff monitoring systems
**Facility and Environmental Issues**

**Monitoring radiation exposure of staff**
- What to aim for (examples) -

**Measurable aims:**
- > 90% compliance with wearing of dosimeters
- 50% Reduction in number of outliers
- 25% Reduction in the frequency with which a staff member exceeds level II warning threshold (625 mrem/month)
How good are you detecting and following radiation injury in your patients?
Radiation Safety Aim 3: Identify patients with radiation related skin injuries

Radiation Safety Aim 3:
Identify patients with radiation related skin injuries

Background
- Deterministic effects usually have a threshold
- Radiation related skin injury unlikely for peak skin dose < 2Gy (air kerma usually being higher than this)
- The Joint Commission has identified a peak skin dose > 15Gy as a sentinel event (The Joint Commission. Radiation overdose as a reviewable sentinel event.
  http://www.jointcommission.org/assets/1/18/Radiation_Overdose.pdf
  Accessed September 2013)
- Radiation related skin injuries are more common in larger patients due to higher dosage required
- Skin injuries such as erythema can be easily overlooked
- Patient and staff education as well as careful physical examination are required to detect radiation-related skin injuries
# Radiation Exposure of Skin

## Facility and Environmental Issues

### Radiation Safety Best Practices for the Pediatric Cath Lab

Chambers C et al. Radiation Safety Program for the Cardiac Catheterization Laboratory.

---

**TABLE II. Chronology and Severity of Tissue Reactions From Single-Delivery Radiation Dose**

<table>
<thead>
<tr>
<th>Single site (Gy) acute skin dose</th>
<th>Prompt (&lt;2 weeks)</th>
<th>Early (2–8 weeks)</th>
<th>Mid term (6–52 weeks)</th>
<th>Long term (&lt;40 weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–2</td>
<td>No observable effects expected</td>
<td>Epilation</td>
<td>Recovery from hair loss</td>
<td>None expected</td>
</tr>
<tr>
<td>2–5</td>
<td>Transient erythema</td>
<td>Erythema, epilation</td>
<td>Recovery; high doses cause permanent partial epilation</td>
<td>Recovery; higher dose cause dermal atrophy/induration</td>
</tr>
<tr>
<td>5–10</td>
<td>Transient erythema</td>
<td>Erythema, epilation; dry/moist desquamation</td>
<td>Prolonged erythema permanent epilation</td>
<td>Telangiectasia; dermal atrophy/induration</td>
</tr>
<tr>
<td>10–15</td>
<td>Transient erythema</td>
<td>Erythema, epilation</td>
<td>Dermal atrophy with secondary ulceration; atrophy/induration</td>
<td>Telangiectasia; dermal</td>
</tr>
<tr>
<td>&gt;15</td>
<td>Transient erythema; Very high dose causes moist desquamation edema/ulceration</td>
<td>Erythema, epilation</td>
<td>High dose dermal necrosis surgical repair likely</td>
<td>Late skin breakdown</td>
</tr>
</tbody>
</table>

Deterministic Effects

0-2 Gy
- < 2 Weeks: None
- 2 – 52 Weeks: None
- Permanent: None

2-5 Gy
- < 2 Weeks: Erythema
- 2 – 52 Weeks: Epilation
- Permanent: None

5-10 Gy
- < 2 Weeks: Erythema
- 2 – 52 Weeks: Prolonged/Permanent Erythema/Epilation
- Permanent: Dermal Atrophy

>10 Gy
- < 2 Weeks: Erythema/Ulceration
- 2 – 52 Weeks: Desquamation
- Permanent: Surgery

“Air kerma overestimates PSD in most instances [0.5 - 0.8]”
RAD-IR Study
Radiation Safety Aim 3: Identify patients with radiation related skin injuries

Follow-up protocol

- Essential to identify patients with deterministic skin effects
- Dose-dependent follow-up of higher risk patients (do not use fluoroscopy time to guide need for follow-up, but use total air kerma instead)
- Combination of patient information sheets, staff education, follow-up phone calls (including standardized questions), and clinic visits
Radiation skin injury surveillance protocol based on total air kerma

- All patients receive a follow-up phone call within 1 week
- Dose ≥ 3000mGy
  - Patient receives radiation letter day of procedure
  - Radiation burn questions included in 1 week follow-up call
- Dose ≥ 6000mGy and Dose < 9000mGy
  - Patient receives radiation letter day of procedure
  - Radiation burn questions included in 1 week follow-up call
  - Follow-up for in-patients during routine assessment
- Dose > 9000mGy
  - Patient receives radiation letter day of procedure
  - Radiation burn questions included in 1 week follow-up call
  - 3 week radiation follow-up phone call
  - 4-6 week follow-up phone call
  - 4-6 week follow-up visit by cath lab APN/MD with continued monitoring

APN: Advanced Practice Nurse
Examples of measurable goals:

- Patients with exposure $\geq 3000$ mGy receive follow-up phone call ($\geq 90\%$)
- Patients with exposure $\geq 9000$ mGy have follow-up cardiology clinic visit within 4-6 weeks ($\geq 95\%$)
- 95% of patients that are seen in follow-up visit should have a documented complete skin examination
Facility and Environmental Issues

Radiation skin injury surveillance protocol (QI Example)

Specific Aim

Patients with exposure ≥ 3000 mGy receive follow-up phone call ≥ 90%

Patients with exposure ≥ 9000 mGy have follow-up clinic visit within 4-6 weeks ≥ 95%

Key Drivers

Patient Education

Phone Calls

Documentation

Continuous Improvement

Clinic Follow-Up

Interventions

Provide patient education day of procedure regarding exposure

Standardized list of questions for follow up calls

Conduct 1-week, 3-week, follow up call, as defined by protocol

Document skin assessment at 4-6 week clinic visit.

Review and analyze follow-up process routinely

Continued monitoring of patients exposed to ≥ 9000 mGy.

Last revised: 9/28/11

www.SCAI.org/QIT
Specific Aim

Achieve 95% compliance in conducting radiation injury assessments on patients at 4-6 week follow-up clinic visits.

Key Drivers

- Patient Education
- Physical Assessment
- Documentation
- Continuous Improvement

Interventions

- Radiation exposure education and letter to patient/family
- Complete skin assessment of trunk (front, back, axillae)
- Document patient follow-up (e.g. phone calls, clinic visit & skin assessment for dermal injury, referral to burn clinic)
- Document, review and analyze follow-up process routinely
Radiation skin injury surveillance protocol
- Looking at your results: Radiation burns reported -

Unpublished data from a local QI initiative
Radiation skin injury surveillance protocol
- Looking at your results: Patients in Follow-Up Protocol –

Unpublished data from a local QI initiative
Radiation Safety Best Practices for the Pediatric Cath Lab

Facility and Environmental Issues

Where do we go from here?

www.SCAI.org/QIT

The Society for Cardiovascular Angiography and Interventions Foundation

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Patients Typically Receive Radiation Exposure from Multiple Exams and Modalities Over the Course of Treatment

A Centralized Solution is a Better Solution

Radiation Safety Best Practices for the Pediatric Cath Lab

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Real-time Staff Dose
Easy to Interpret
Empowers User to Adjust Working Behavior
"We are heading towards era of significant public reporting... and increased regulation"
Bibliography

Bibliography

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