AAPM TG 251
Survey of Pediatric Fluoroscopic Air Kerma Rate Values
Recommended Application of Results

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Disclosures
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  Andrew Kuhls-Gilchrist, an employee of Canon Medical, played no role in the design, sponsorship, data analysis, or preparation of the report.

Survey of Pediatric Fluoroscopic Air Kerma Rate Values
Recommended Application of Results

• Survey: measured data will be analyzed
• Pediatric: focus is on children 0 – 21 years of age
• Fluoroscopic: also includes fluorographic
• Air Kerma: patient doses are not calculated
• Rate: cumulative Air Kerma is not the focus
• Recommended Application: How can the analyzed results be used to positively impact patient care?

TG 251 Charge
• Collect fluoroscopic and fluorographic Air Kerma Rates (AKR)
• Use variable thickness phantoms to simulate infants to adults
• Survey state-of-the-practice
• Use a standardized protocol
• Disseminate results so QMPs can evaluate fluoroscopic equipment performance over a wide range of patient thicknesses
• Compliance testing of 10 R/min fluoro seldom impacts patient care
• On a unit < 10 years of age, when was the last time maximum measured exposure rate exceeded 10 R/min?
TG 251 Charge

QMPs evaluate fluoroscopic output parameters vs patient thickness

- Does unit properly manage exposure rate for smallest patients?
  - Historically, tube current and Voltage increased in tandem as patient thickness increased; pulse width and filter thickness did not exist.
  - Today four parameters managed by automatic brightness control: example of popular unit
    - Control parameters to the right are reasonable for a husky adult patient, but not a small child!
    - How would you change these? More later!

Why Measure RAK vs Patient Thickness?

- Example of a Medical Physics 3.0 Application
  - Is the exposure rate during fluoroscopy and fluorography appropriate for the size (thickness) of the patient?
  - Adult facilities purchase vast majority of fluoroscopes
    - Majority of pediatric fluoroscopy occurs in adult facilities,
      - Imaging equipment is quite well designed and Configured for imaging adult patients "out of the box",
    - BUT, some necessary configurations for pediatric imaging may not exist!

  Insuring the use of design strengths while compensating for design weaknesses for a specific size patient and imaging task.

THE QUESTION!

- Why should your Son or Daughter, Niece or Nephew, Grandson or Granddaughter receive less care during imaging than that received by their parents, uncle or aunt, or grandparents???

  Properly managed radiation dose and image quality as a function of patient size.

- Pediatric Risks
  - Deterministic skin injury from single examinations unlikely
  - Peak skin dose Threshold > 2000 mGy
  - AKR is reduced due to limited patient thickness
  - ALARM levels used for adults are typically not applicable
  - Stochastic risks are the greater concern
    - Longer expected survival than adults
    - Effective doses per examination > 100 mSv may be a concern
    - Children may be more radiosensitive than adults for:
      - Leukemia, thyroid, skin, breast or brain cancers
Why Measure RAK vs Patient Thickness?

- Children’s bodies are smaller
- For a fixed AKR, dose to any organ in the child will be greater than the organ dose to the adult
- Fluoroscopy time may increase
  - Imaging smaller body parts is more demanding
  - Gaining access into smaller regions of anatomy
- Configuration of fluoroscope
  - Majority of manufacturers have had more opportunity to fine tune their products to the requirements of the limited range of adult sized patients.

Limitations of TG 251

- Steps must be taken when adjusting AKRs to ensure that diagnostic image quality is maintained.
- AAPM charge did not include image quality evaluation.
  - Best performed by clinicians, application specialists and QMP working together as a TEAM.
  - Initial non-diagnostic image quality should trigger clinician response, but
  - Clinicians will not flag examinations performed by excessive doses.
- Data from AAPM charge cannot be used to develop Diagnostic Reference Levels (DRLs).

Standardized Survey Protocol

Reproducible and practical
- Six classifications of fluoroscopes
- Mobile fluoroscopes
- General fluoroscope
- Interventional fluoroscopes

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mini C-arm</th>
<th>Mobile C-arm</th>
<th>C-arm Flex</th>
<th>IRB</th>
<th>IRC</th>
<th>EPH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exam Level</td>
<td>Normal</td>
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<td>Flip Mode</td>
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<td>Right</td>
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<td>Tube Voltage</td>
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<td>70</td>
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<td>144</td>
<td>150</td>
<td>149</td>
<td>150</td>
<td>150</td>
<td>150</td>
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</tbody>
</table>

Reproducible and practical
- Type of examination
### Standardized Survey Protocol

**Reproducible and practical**
- Type of examination
- Multiple phantom thicknesses
- Surveyed Fluoroscopic mode(s)
- Standard detector dose

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<th>Position</th>
<th>Model C-arm</th>
<th>SSD (cm)</th>
<th>Source to C-arm</th>
<th>PDD (Gy)</th>
<th>BP</th>
<th>IRC</th>
<th>BEP</th>
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### Standardized Survey Protocol

**Reproducible and practical**
- Type of examination
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- Added filter

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Standardized Survey Protocol
Reproducible and practical
• Type of examination
• Multiple phantom thicknesses
• Surveyed Fluoroscopic mode(s)
• Standard detector dose
• Added Filter
• Common Field of View (FOV)

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<th>Mobile C-arms</th>
<th>Source to Tabletop Distance (cm)</th>
</tr>
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<tr>
<td>Phan thickness</td>
<td>5</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Source to Chamber Distance</td>
<td>38</td>
<td>73</td>
<td>Var</td>
</tr>
<tr>
<td>Source to Image Receptor Distance</td>
<td>44</td>
<td>100</td>
<td>~ 80</td>
</tr>
</tbody>
</table>

Source to Chamber Distance: Typically 30 cm from Image Receptor Face

Variable Entrance Plane

Standardized Survey Protocol
Reproducible and practical
• Type of examination
• Multiple phantom thicknesses
• Surveyed Fluoroscopic mode(s)
• Standard detector dose
• Common Field of View (FOV)
• Source to Chamber Distance:
  • Typically, 30 cm from Image Receptor Face
  • Typically, 100 cm for C-arms; 30 cm above GF tabletop; 45 cm for Mini C-arm

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Source to Chamber Distance: Typically 30 cm from Image Receptor Face
Reproducible and practical

- Fluoroscopy Pulse Rate
- Measure two modes for mobile C-arm
- Pulse rates continue to decline with time
- Fluorographic and Fluoroscopic Pulse Rates
  - 30 pulses/sec for IRC disappearing: 15 and 7.5 pulses/sec
Standardized Survey Protocol

Reproducible and practical

- Fluoroscopy Pulse Rate
- Measure two modes for mobile C-arm
- Pulse rates continue to decline with time
- Fluorographic Pulse Rates
- 30 pulses/sec for IRC falling out of favor
- Fluorographic Presentation
- Expect DSA acquisitions 5 – 10 times greater per pulse than DA acquisitions
- Grids should be removed if possible for patient thicknesses ≤ 10 cm


Standardized PMMA Phantom

Reproducible and practical

- Cross sectional area: 10 x 10 inches
- 5 pieces: 2 inches thick
- 1 piece: 1 inch thick
- 1 piece: 0.5 inch thick
- 7 thicknesses in the table can be constructed
- Additional pieces allow construction of phantom thicknesses from 1.5 – 300 mm thick in 1.5 mm increments.
- 1/16, 1/8, and 1/4 inches thick
- Non polished saw cut edges and thicknesses reduce costs

1Kleinman PL, et al. Patient size measured on CT images as a function of age... AJR 194(6), 389-400.

Radiation Detector

Solid State vs Ionization Chamber

- Ionization Chamber
  - Response should be ‘constant’ relative to effective energy of x-ray beam
  - Records backscatter from PMMA phantom in the beam
  - Depending on construction, may not affect Automatic Brightness Control (ABC) response of fluoroscope when shadowing ABC sensor
- Solid State Detector
  - Should not record backscatter from PMMA phantom
  - If shadows ABC sensor, radiation output is elevated
  - Error in response may increase when using small detector on a cable
  - Backscatter factor of 1.35 applied to solid state detector readings.

Results

Distribution and Number of Units Evaluated

- Vendor distribution
  - Seven vendor’s units evaluated
  - Smaller vendors present only for mobile C-arms
  - Interventional fluoroscopy provided only by larger manufactures
- Clinical Setting
  - Pediatric Hospitals 60%
  - Adult Hospitals 40%

<table>
<thead>
<tr>
<th>Clinical Setting</th>
<th>Number of units evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult hospital</td>
<td>1 20 9 5 10 7 52</td>
</tr>
<tr>
<td>Pediatric hospital</td>
<td>11 20 20 13 10 5 79</td>
</tr>
</tbody>
</table>
Results
AKR vs Fluoroscope Type
• 10, 15, 20, and 25 cm
  • Median AKR similar for a given thickness for all but continuous mode mobile C-arms
  • AKR scales unique for each thickness plot

AKR vs Type of Fluoroscope vs size

Results
AKR vs Fluoroscope Type
• 10, 15, 20, and 25 cm
  • Median AKR similar for a given thickness for all but continuous mode mobile C-arms
  • AKR scales unique for each thickness plot
  • Continuous mode delivers 3 times the AKR in the continuous vs pulsed mode at 8 p/sec
  • Occurs due to configuration choices of vendor with majority market share of mobile C-arms
  • Example of single vendor with majority market share skewing results.

Results
AKR vs Fluoroscopic Mode vs Patient Size
• 5, 10, 15, 20, and 25 cm
  • 25th, 50th, and 75th percentile listed in table
  • Pediatric AKR approximately 10% less than adult facilities for given thickness

AKR for Fluoroscopic Mode vs Size

Results
AKR vs Fluoroscopic Mode vs Patient Size
• 5, 10, 15, 20, and 25 cm
  • 25th, 50th, and 75th percentile listed in table
  • Pediatric AKR approximately 10% less than adult facilities for given thickness
  • Pulsed AKR for GF and mobile C-arms at 7.5 p/s and IRR and IRC at 15 p/s is similar
  • Additional filtration for IRR and IRC
Results

AKR vs Fluoroscopic Mode vs Patient Size [violin plots]

• 15 cm
  • AKR in Pediatric facilities is 89% of adult facilities for IRR

Results

AKR vs Fluoroscopic Mode vs Patient Size [violin plots]

• 15 cm
  • AKR in Pediatric facilities is 89% of adult facilities for IRR
  • 15 cm
  • AKR in Pediatric facilities is 41% of adult facilities for IRC
  • Results occur because configurations of 40% of surveyed IRC units in study were substantially altered by QMP working with vendor and cardiologists at facility.

Results

AKR/pulse (mGy/pulse) vs Fluorographic Mode vs Patient Size

• AKR/pulse is smaller in pediatric vs adult facilities (white vs gray lines)
  • As expected, results for IRR 
    Digital Subtraction Radiography are substantially more than IRC which performs non subtracted Radiography
  • IRR
  • IRC

Results

Mini C-arm vs standard mobile C-arm

• 5 cm PMMA phantom

<table>
<thead>
<tr>
<th>Mini C-arm Con</th>
<th>C-arm pulsed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoroscopy</td>
<td>1.5 mGy/min</td>
</tr>
<tr>
<td>Fluorographic</td>
<td>0.049 mGy/pulse</td>
</tr>
</tbody>
</table>

Mini Fluoroscopy delivers 1.2 times dose of C-arm continuous
3.8 times dose of C-arm pulsed

Mini Fluorographic delivers 2 times dose of C-arm single shot

Mini C-arms do not deliver substantially higher AKR values than a properly pulsed standard mobile C-arm!!
Results

Reduction in AKR relative to largest (25 cm) phantom thickness

• "MONEY SHOT"
  • First approximation
    • AKR triples for 5 cm increased thickness for thicknesses < 15 cm
    • AKR doubles for 5 cm increased thickness for thicknesses > 15 cm

<table>
<thead>
<tr>
<th>Phantom Thickness (cm)</th>
<th>IRC 7.5 p/s</th>
<th>IRC 15 p/s</th>
<th>EP 7.5 p/s</th>
<th>EP 15 p/s</th>
<th>IR 7.5 p/s</th>
<th>IR 15 p/s</th>
<th>GF 7.5 p/s</th>
<th>GF 15 p/s</th>
<th>m(p) 7.5 p/s</th>
<th>m(p) 15 p/s</th>
<th>Total Average Across Rows %</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>58.5%</td>
<td>56.4%</td>
<td>54.7%</td>
<td>51.0%</td>
<td>45.8%</td>
<td>48.1%</td>
<td>52.4%</td>
<td>54.4%</td>
<td>70.5%</td>
<td>71.6%</td>
<td>68.9%</td>
</tr>
<tr>
<td>15</td>
<td>85.1%</td>
<td>83.5%</td>
<td>81.2%</td>
<td>78.9%</td>
<td>73.7%</td>
<td>74.6%</td>
<td>79.5%</td>
<td>80.5%</td>
<td>87.0%</td>
<td>87.6%</td>
<td>83.2%</td>
</tr>
<tr>
<td>10</td>
<td>95.9%</td>
<td>94.6%</td>
<td>94.6%</td>
<td>93.8%</td>
<td>87.9%</td>
<td>87.7%</td>
<td>92.3%</td>
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<td>99.9%</td>
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</tr>
<tr>
<td>5</td>
<td>98.1%</td>
<td>98.1%</td>
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(PEDiatric Reconfiguration Choices)

Voltage

• Phantom thicknesses 5 – 25 cm: Constant 70 kV
  • Increase filter thickness and decrease mAs for pediatric patients
  • Decrease focal spot for smaller patients
  • Image MTF improves

• Do the opposite for large patients
  • Interventional unit’s large kW x-ray tubes desirable

Pulse Width determines degree of motion blur in image

• Cardiac Studies with IRC unit
  • Max of 5 msec pulse width for pediatrics
    • Pulse width as high as 8 msec occur
  • Max of 10 msec pulse width for adults
  • Unit does better job of meeting this requirement

• Non-Cardiac Studies for mobile C-arms
  • Max of 15 msec pulse width for large adults
    • Must be larger than desired 10 msec because of limited tube current of fixed anode x-ray tubes!
**Pediatric Reconfiguration Choices**

Pulse Width determines degree of motion blur in image:
- Cardiac Studies
  - Max of 5 msec pulse width for pediatrics
  - Max of 10 msec pulse width for adults
- Non-Cardiac (IRR) Studies
  - Max of 15 msec pulse width for adults
  - GF units are well configured
  - Mobile C-arms are a disaster
- 26 – 29 msec pulse width is too large
- Tube current much more limited

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**Pediatric Reconfiguration Choices**

2015 Collaboration Between Medical Imaging and Technology Alliance (MITA) and Image Gently Alliance (IGA)

“Essential Questions for Consideration in the Design of Interventional X-ray Equipment Intended for Pediatric Use”

A resource that QMPs can use to guide reconfiguration of imaging equipment within their facilities.

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**Pediatric Reconfiguration Choices**

You will likely receive ‘push back’ from your equipment vendor if you request reconfigurations to improve pediatric imaging.
- Vendor false claim: Your request is not possible because it was not part of our 510(k) approval received from the FDA.
- Vendor false claim: Equipment warranty will be voided.

In response, FDA issued a statement in 2017:
“For previously 510(k) cleared x-ray imaging devices, optimization of imaging parameters and provision of pediatric specific protocols by manufacturers solely at the request of end users generally does not by itself necessitate submission of a new 510(k).”

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**Summary**

Annual compliance testing of fluoroscopes must do more than measure the maximum AKR of a fluoroscope to verify the fluoroscope’s capability of reasonably managing the AKR during fluoroscopy of all sized patients, which may include small pediatric patients.

TG-251 describes a pathway for QMPs, radiologists, cardiologists, and the manufacturers of fluoroscopy equipment to work together towards practical QA methods that use phantom-based measurements to improve clinical practice.

An example of Medical Physics 3.0 effectively improving patient care.
Thank you

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