Postmarket Surveillance of Medical X-ray Imaging

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Medical X-ray Imaging Studies

- Most studies are done to support premarket review
- Few studies are performed in support of postmarket surveillance activities
  - No FDA mandated post-approval studies
  - Studies not required as a condition of approval
Premarket Studies

- Medical x-ray imaging premarket submissions
  - Physical laboratory testing
  - Clinical image evaluation
- Examples of Premarket Guidance for Industry and FDA Staff
  - Full field digital mammography
  - Display accessories for full field digital mammography
  - Medical image management devices (PACS)
  - Solid state x-ray imaging devices
Premarket Studies

- CDRH research to support premarket review
  - Bench testing methods for the premarket evaluation of image quality and imaging system QA/QC
  - Classifier development and testing strategies for high-dimensional datasets (imaging and -omics devices)
  - Premarket clinical study designs and endpoints for imaging and computer-assist devices

"From medical images to multiple-biomarker microarrays,"

Postmarket Programs

- Mammography Quality Standards Act (MQSA)
- Nationwide Evaluation of X-ray Trends (NEXT)
- Medical Imaging Initiative
MQSA

- Requires accreditation and certification of equipment, facilities
- Establishes personnel qualifications, quality control practices, equipment standards
- Monitors compliance of over 8000 facilities through annual inspections in partnership with states
- Ensures quality of over 30M exams performed annually
Between 10/1/94 and 5/31/96, 76.4% of facilities passed accreditation on first attempt (99% today).
MQSA Dose vs. Phantom Score

Phantom scores increase while dose decreases
Collaborative survey conducted with the Conference of Radiation Control Program Directors (CRCPD) and participating state radiation control programs

Assesses x-ray exposure and utilization for commonly performed diagnostic exams

Surveys periodically repeated to observe trends

- FDA develops survey procedures, designs and builds x-ray phantom as needed, trains state surveyors
- Surveyors conduct site visits — population representative sample (N ~ 350)
- FDA analyzes data, publishes findings
<table>
<thead>
<tr>
<th>Examination</th>
<th>NEXT Survey Years</th>
<th>Mean Dose Indicator for most recent survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest Radiography</td>
<td>1984, 1986, 1994, 2001</td>
<td>0.12 mGy (entrance skin air kerma)</td>
</tr>
<tr>
<td>Mammography</td>
<td>1985, 1988, 1992</td>
<td>MQSA 2008: 1.6 mGy (digital) 1.8 mGy (SF) (mean glandular dose to std breast)</td>
</tr>
<tr>
<td>Abdomen and Lumbosacral Spine</td>
<td>1987, 1989, 1995, 2002</td>
<td>2.7 mGy (Abdm) / 3.4 mGy (LS) (entrance skin air kerma)</td>
</tr>
<tr>
<td>Computed Tomography (CT)</td>
<td>1990, 2000, 2005-06</td>
<td>Adult abdomen-pelvis: effective dose (mSv) 23.0 (axial) / 13.8 (helical)</td>
</tr>
<tr>
<td>Dental Radiography (bitewing)</td>
<td>1993, 1999</td>
<td>1.6 mGy (entrance skin air kerma)</td>
</tr>
<tr>
<td>Pediatric Chest</td>
<td>1998</td>
<td>0.05 mGy (entrance skin air kerma)</td>
</tr>
<tr>
<td>Cardiac Catheterization</td>
<td>2008-09</td>
<td>4.8 million cardiac invasive fluoroscopic cases in U.S.</td>
</tr>
</tbody>
</table>
### Adult & Pediatric Annual US CT Exam Rate (millions) by Facility Type (2005-06 NEXT)

<table>
<thead>
<tr>
<th>Facility Type</th>
<th>Adult CT exams</th>
<th>Pediatric CT exams</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals</td>
<td>63.2</td>
<td>4.1</td>
</tr>
<tr>
<td>Non-Hospitals</td>
<td>10.1</td>
<td>0.6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>73.3 (SE = 5.7)</strong></td>
<td><strong>4.7 (SE=0.3)</strong></td>
</tr>
</tbody>
</table>

**2000 NEXT CT survey**

45.1 (all adult and pediatric)

*84% of surveyed hospitals indicated they perform CT exams on pediatric patients
60% of surveyed non-hospital sites indicated they perform CT exams on pediatric patients
ACR Accreditation for CT
responses from 222 surveyed facilities- 2005-06 NEXT

- Not planning to apply: 66%
- Plan to apply within year: 26%
- Currently in application: 3%
- Are currently Accredited: 5%
Patient Caseloads are Increasing

<table>
<thead>
<tr>
<th>Year</th>
<th>Cardiac Cath Labs*</th>
<th>Interventional Angiography*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1998</td>
<td>3.3M</td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>3.4M</td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td>4.2M</td>
<td>4.2M</td>
</tr>
<tr>
<td>2006</td>
<td>4.2M</td>
<td></td>
</tr>
</tbody>
</table>

*Source: IMV Benchmark reports 2004/05 Interventional Angiography, 2006 Cardiac Cath Labs; Data represent total department caseloads and likely include diagnostic/therapeutic mix.
### Dose Display: Features and Recording

Does the Fluoro unit have Dose-Area Product (DAP) or Air Kerma display at operator’s working location?

<table>
<thead>
<tr>
<th>Fluoro equipment assembled before June 06</th>
<th>DAP</th>
<th>Air kerma</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>63%</td>
<td>56%</td>
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<td></td>
<td>87%</td>
<td>89%</td>
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</table>

Percent of surveyed facilities that record cumulative values of displayed dose indicators following clinical cases:

<table>
<thead>
<tr>
<th>DAP:</th>
<th>45%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air kerma:</td>
<td>34%</td>
</tr>
<tr>
<td>Fluoro Time</td>
<td>99%</td>
</tr>
</tbody>
</table>
Medical Radiation Initiative

- **Goal to reduce unnecessary exposure to medical radiation**
  - Focus on equipment safety, operator qualification and facility quality practices

- **Monitoring key quality indicators**
  - Dose – establish local, national registries
  - Imaging protocols – standardize imaging parameter sets
  - Image quality – accredit facilities and regular physics evaluation of equipment
  - Adverse events – ensure early reporting, analysis and action
How do we get there?

- Awareness
- Decision Support
- Facility Accreditation
- Equipment Safety
- Information Systems
Questions

More information at: