Radiation exposures in medical imaging: FDA's past and present efforts

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Radiological Health Efforts: 1950’s Observations of Dade W. Moeller, Public Health Service$^{1,2,3}$

- US PHS, Wash DC- 1952
  - Task: estimation of exposure to patient and workers during DX exams
    - Medical and dental x-ray, fluoroscopy
    - Workers- initial estimate: get 0.43-2.62 mGy (50 – 300 mR ) / week
  - Initial effort focused on 20 USPHS Hospitals
- Delivery item: *Guide for the Inspection of Medical and Dental Diagnostic X-ray Installations* (Ingraham SC, Terrill JG Jr., Moeller DW. PHS, 1953)
Radiological Health Efforts: 1950’s
Observations of Dade W. Moeller, Public Health Service

• Survey meters- custom modified @ NIH to measure exposure
• Moeller volunteered to be “patient”, later used coconut
• Medical X-ray:
• Technical observations- Medical X-ray
  – X-ray tubes- really bad or missing collimation- for chest film, nearly entire patient X-ray’d
  – X-ray tubes seldom had filtration
  – Dental: intraoral exposures typically exceeded 44 mGy (5R)
Findings: Early 1950’s

- Professional Survey: Professional Bureau, American College of Radiology⁴:
  - 125,000+ x-ray units (diagnostic X-ray and therapy)
    - 55,000- medical
    - 65,000 dental
    - 11,000 osteopathic and chiropractic uses
  - 25 million x-ray exams annually by radiologists (avg 306 days/yr spent conducting exams)

- Patient Exposure: PHS survey of hospitals and other published findings²:
  - Radiographic- 24 mGy (2.7 R) (52% of exams)
  - Photofluorographic- 8.8 mGy (1.0 R) (34% of exams)
  - Fluoroscopic- cumulative- 569 mGy (65 R) (14% of exams)
  - Dental film- 44 mGy (5 R) per image
• 1957: PHS National Center for Health Statistics initiates the National Health Survey (NHS)

• Goal: To characterize State of US public health.

• Major component: Household interview

• 1960-1961: NHS collects data regarding diagnostic x-ray practice

• 38,000 households visited/125,000 respondents interviewed

• Among their findings:
  - 82 million visits to clinical sites for medical x-ray (diagnostic)
  - Most frequent exam: chest (51 million)
  - 49 million dental exams
X-ray Exposure Study- XES
PHS surveys 1964 and 1970$^{(5,6,7)}$

- 1964 Survey: Planned as extension of U.S. National Health Survey to include capture of X-ray visits:
  - Two components:
    - Household interview of U.S. population sample
    - Follow-up mail packet to clinical sites - x-ray equipment and exam data, estimation of patient exposure -> dosimetry
- Data regarding x-ray exam history was collected for 31,289 persons / 9653 households (1964)
- Survey was repeated in 1970
  - 22,500 households interviewed / 67000 persons
XES surveys: 1964 and 1970

• **Scope:** Dental & medical x-ray, fluoroscopy, and x-ray therapy

• **Film packs:** sent to clinical sites- capture beam size and dosimetry
  - Separate film packs for each modality
  - Fluoro: Two packs:
    - Large area film recorded patient exam, scanning densitometer records approximately 1386 readings from each film- 1.5 million data points
    - Folding film pack captures beam geometry to infer source-table top distance
Dosimetry

- BRH developed models to compute patient exposure based on reported x-ray technique, collimation and film packet measurement.

- Doses were computed using RANDO phantoms- exposure ratios and scatter were measured for dose calculations.

- Surveyed exams included dental, radiographic, and fluoroscopic procedures.
GONAD DOSES AND GENETICALLY SIGNIFICANT DOSE FROM DIAGNOSTIC RADIOLOGY U.S., 1964 and 1970

April 1976

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NOTE: For further information regarding this report, direct all inquiries to: Office of Information, Bureau of Radiological Health, 5600 Fishers Lane, Rockville, Maryland, 20852.

*Key personnel as of the time period during which the study was conducted.
**National Center for Health Statistics.
Mammography

Breast Exposure: Nationwide Trends- BENT\textsuperscript{8,9}

Cooperative effort: FDA’s Bureau of Radiological Health and National Cancer Institute with field support provided by state programs.

Objectives
- Characterize patient exposure
- Identify reasons for very high/very low exposures
- Reduce unnecessary exposure via improved QA practices

4 components
- Identified mammo sites completed questionnaire.
- Sites mailed dosimetry card (TLD’s) to expose.
  - NOTE: approx 10% of mammo units equipped w/ AEC
- Exposures evaluated, follow-up visits -> corrective actions
- Revisit follow-up sites after 1 year
• Pilot phase: 19 states reported data on 1567 x-ray units
• Exposures ranged from 0.25 R to 16 R!! (2.2 – 140 mGy)
• Nationwide site visits began in late 1970’s
• Participation: 42 states, P.R., DC, NYC, PHS hospitals, US Army, Navy, Air Force, 3 Canadian provinces.
• Observations:
  – Technology in use (% of all units, avg. exp @ skin entrance):
    • direct-exposure film (10%)
    • xeromammography (45%)
    • screen-film (S/F) (45%)
  – 58% of S/F systems needed follow-up- doses high (7%) / low (22%) (remaining % of follow-up revisits for other findings)\(^9\)
  – High HVL, inappropriate kVp for target (W vs Mo)\(^9\)
**Preliminary Data**

*As of 3/11/77*

**TABLE FOUR. Exposure by Type of Image Receptor in BENT Pilot States.**

<table>
<thead>
<tr>
<th></th>
<th>All Image Receptors</th>
<th>Direct Exposure Film</th>
<th>Film/Screen Combinations</th>
<th>Xerox</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of x-ray units</td>
<td>435</td>
<td>75</td>
<td>198</td>
<td>162</td>
</tr>
<tr>
<td>No. of patients examined in 1 month</td>
<td>18,759</td>
<td>1,071</td>
<td>6,201</td>
<td>11,487</td>
</tr>
<tr>
<td><strong>mean exposure (R)</strong></td>
<td><strong>1.49</strong></td>
<td><strong>3.21</strong></td>
<td><strong>0.60</strong></td>
<td><strong>1.80</strong></td>
</tr>
<tr>
<td><strong>standard deviation</strong></td>
<td><strong>2.07</strong></td>
<td><strong>3.74</strong></td>
<td><strong>0.74</strong></td>
<td><strong>1.41</strong></td>
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<tr>
<td><strong>minimum</strong></td>
<td><strong>0.00</strong></td>
<td><strong>0.18</strong></td>
<td><strong>0.00</strong></td>
<td><strong>0.18</strong></td>
</tr>
<tr>
<td><strong>1st quartile</strong></td>
<td><strong>0.32</strong></td>
<td><strong>1.10</strong></td>
<td><strong>0.13</strong></td>
<td><strong>0.89</strong></td>
</tr>
<tr>
<td><strong>median</strong></td>
<td><strong>0.91</strong></td>
<td><strong>2.00</strong></td>
<td><strong>0.33</strong></td>
<td><strong>1.40</strong></td>
</tr>
<tr>
<td><strong>3rd quartile</strong></td>
<td><strong>1.70</strong></td>
<td><strong>3.50</strong></td>
<td><strong>0.74</strong></td>
<td><strong>1.90</strong></td>
</tr>
<tr>
<td><strong>maximum</strong></td>
<td><strong>16.60</strong></td>
<td><strong>16.60</strong></td>
<td><strong>5.00</strong></td>
<td><strong>6.90</strong></td>
</tr>
<tr>
<td><strong>range (max – min)</strong></td>
<td><strong>16.60</strong></td>
<td><strong>16.42</strong></td>
<td><strong>5.00</strong></td>
<td><strong>6.78</strong></td>
</tr>
</tbody>
</table>

*Actual min value is 0.025 R, stated in FDA report to CRCPD, Seattle 1977*

**Unit of Exposure:** Roentgens free-in-air at the skin entrance site (6 cm above the tabletop or the equivalent plane) from a single craniocaudal view of a "medium-density, medium-size" breast. Backscatter is NOT included.
Dental Exposure Normalization Technique: DENT\textsuperscript{10}

- Early 1970’s: Intraoral exposures up to 44 mGy (5 R) per film;

- Bureau of Radiological Health (BRH)- studies problem, derives optimal range of exposures for radiographs

- Pilot study: 46% of surveyed sites in RI and NH have exposures exceeding recommendations

- BRH develops DENT as a QA process for identified dental offices

- State Rad Health programs conduct site visits, BRH provides equipment, planning support.
Radiation Experience Data- RED11

• 1980 Survey of U.S. hospitals
• Sample drawn from master listing of 6657 known short-stay hospitals.
• Original sample size- 126, only 81 sites participate in survey
• Fills in gaps in NEXT lineup: Captures patient volumes for imaging modalities: DX, CT, US, NM
• NO Dose data are collected/measured
• Selected findings of the study:
  – 130.2 million conventional x-ray procedures performed in short-stay hospitals- an increase of 59% over 1970 (81.7 million).
  – 52 million chest x-rays, accounting for 40% of all x-ray exams
  – 2.2 million CT exams, 73% of head.
Nationwide Evaluation of X-ray Trends - NEXT

- By 1972 NEXT begins surveying 12 commonly performed exams.
- Surveys continue through 1982.
- 1984- focus on single exam
- patient-equivalent phantoms
- Film processing quality, darkroom fog, and related aspects of diagnostic x-ray practice are characterized.
## NEXT Surveys

<table>
<thead>
<tr>
<th>Examination</th>
<th>Survey Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammography</td>
<td>1985, 1988, 1992</td>
</tr>
<tr>
<td>Computed tomography (CT)</td>
<td>1990, 2000, 2005</td>
</tr>
<tr>
<td>Pediatric Chest</td>
<td>1998</td>
</tr>
</tbody>
</table>
Teamwork
NEXT Phantoms

Adult PA Chest

Adult Abdomen and lumbosacral spine

CT Body Phantom

Image Quality Test Tools
Trends in Diagnostic X-ray Practice\textsuperscript{13}

![Bar chart showing trends in exams per 100 persons for different survey years.
- Chest
- Abdomen
- LS spine
- UGI fluoroscopy

Survey year:
- 1964
- 1970
- 2001-03

Exams per 100 persons:
- UGI fluoroscopy: 0 (1964), 0 (1970), 5 (2001-03)\]
Trends in Diagnostic X-ray Practice

Graphs showing trends in air kerma (mGy) for chest, abdomen, and LS spine over time.
Film Processing Quality\textsuperscript{14,15}

<table>
<thead>
<tr>
<th>Survey year</th>
<th>Hospitals</th>
<th>Non-hospitals</th>
<th>Mammography facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1984</td>
<td></td>
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<td></td>
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<tr>
<td>1986</td>
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<td>2002</td>
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<td>Date</td>
<td>Code</td>
<td>Total fluoro Time (m)</td>
<td>No cine runs</td>
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</tr>
<tr>
<td>01/16/2010</td>
<td>C</td>
<td>22.7</td>
<td>27</td>
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<tr>
<td>01/16/2010</td>
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<td>4.4</td>
<td>7</td>
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<tr>
<td>01/17/2010</td>
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<td>16.4</td>
<td>10</td>
</tr>
<tr>
<td>01/18/2010</td>
<td>A</td>
<td>1.2</td>
<td>11</td>
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<td>3.9</td>
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<td>01/19/2010</td>
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<tr>
<td>01/20/2010</td>
<td>D</td>
<td>10.7</td>
<td>1</td>
</tr>
<tr>
<td>01/22/2010</td>
<td>F</td>
<td>12.3</td>
<td>18</td>
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<tr>
<td>01/22/2010</td>
<td>E</td>
<td>13.8</td>
<td>21</td>
</tr>
<tr>
<td>01/25/2010</td>
<td>C</td>
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<td>41</td>
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<tr>
<td>01/25/2010</td>
<td>A</td>
<td>5.1</td>
<td>8</td>
</tr>
<tr>
<td>01/25/2010</td>
<td>F</td>
<td>3.5</td>
<td>15</td>
</tr>
</tbody>
</table>

**NEXT Procedure Codes**

(A) Cardiac catheterization diagnostic only (for example, coronary artery angiography)
(B) Coronary Intervention (for example, coronary artery angioplasty and stent-insertion)
(C) Combined diagnostic coronary angiogram and coronary artery intervention
(D) Other cardiac-intervention only procedures (for example, ASD, PFO, valvuloplasties)
(E) Other non-cardiac only procedure
(F) Combined cardiac and non-cardiac procedure
Cumulative Air Kerma

Coronary Intervention
Diagnostic Cardiac Cath

Mean Values:
0.94 Gy (Diag Cardiac Cath)
2.2 Gy (Coronary Interv)

2008-09 NEXT Survey: Cardiac Catheterization

Cumulative Air Kerma

Air Kerma (Gy)

Percent of Cases

.<.5  .5-.9  1-1.4  1.5-1.9  2-2.4  2.5-2.9  3-3.4  3.5+

Mean Values:
0.94 Gy (Diag Cardiac Cath)
2.2 Gy (Coronary Interv)
Trends in CT Procedure Volumes\textsuperscript{17,18}

![Graph showing the number of CT exams (millions) from 1980 to 2005-06.]

- **1980**: 2.2 million CT exams
- **2000**: 45 million CT exams
- **2005-06**: 77 million CT exams

Survey year

CT exams (millions)
Dose and Image Quality in Mammography

![Graph showing the change in mean glandular dose and phantom score over time. The graph indicates a decrease in dose from 1970 to 1985, followed by a steady increase until 2005. The phantom score shows a slight increase overall.]
NEXT and Public Health Activities

• Mid 1980’s: NEXT goes to Sweden\textsuperscript{20}: 
  – \textit{Survey of chest radiography using NEXT protocol and phantom}

• \textit{Inquiries regarding conducting surveys in: Canada, Malaysia, S Africa, Finland, Australia, Spain, Greece, Ireland}

• IAEA: Code of Practice adopts the NEXT chest and Abdomen/LS spine phantoms for dosimetry\textsuperscript{22}.

• Approximately twenty states have medical/dental exposure action limits- \textit{Patient Exposure and Dose Guide (2003)}\textsuperscript{21}
What’s down the road for NEXT

• Challenges:
  – Human and $$ resources limited
  – Technology changing faster than ability to develop, execute and publish surveys

• Fork in the road:
  – Compliment / coordinate with newer efforts to capture complex data via dose registries
  – Focus on surveys of exams / modalities that are presently outside the scope of current efforts to automate dose collection
Many thanks to…

• State Radiation Control offices- voluntary efforts
• ACR- supports NEXT training courses
• Equipment manufacturers- important resource regarding equipment
• Professional Societies- CRCPD, AAPM, NCRP, SCAI
• Fellow NEXT colleagues, past and present: Stanley Stern, Richard Kaczmarek, Orhan Suleiman, Mike Hilohi, Steve Balter, and many others.
References

12. For further information on the Nationwide Evaluation of X-ray Trends, visit the Conference of Radiation Control Program Directors, Inc. website at [www.crcpd.org](http://www.crcpd.org), and the Food and Drug Administration website at [www.fda.gov](http://www.fda.gov).
References


For this graphic, data were obtained from the following sources:

1995-2006 (dose and image quality): Mammography Quality Standards Act (MQSA) inspection findings. Image Quality scores are reported for following phantoms.
1985: RMI 152 phantom with 'C' insert
1988: RMI 156 phantom with 'C' insert
1992 to present: RMI 156 phantom with 'D' insert (or equivalent)