National Patient Radiation Dose Registry

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• Diagnostic Reference Levels
• U.S. approaches to DRLs
• Radiation dose registries
• Existing registries
• FDA’s role and goals
Diagnostic Reference Levels
Principles of Radiation Protection

- Justification
- Optimization of protection
- Dose limits

http://www.icrp.org/docs/DRL_for_web.pdf
Diagnostic Reference Levels (DRLs)

• A form of investigation level for medical imaging
• Objective: to help avoid radiation dose to the patient that does not contribute to the clinical purpose of a medical imaging task

http://www.icrp.org/docs/DRL_for_web.pdf
DRL Values

- Tied to defined clinical and technical requirements for the medical imaging task
- Usually derived from distributions of dosimetric quantities *observed in practice* in the relevant region or country
- Benchmark—indicator of radiation dose for an average–sized patient; what is achievable with good practice
- Applicable to *groups* of patients
Diagnostic reference levels (DRLs) should be used by regional, national and local authorized bodies. The numerical values of DRLs are advisory, however, implementation of the DRL concept may be required by an authorized body.


http://www.icrp.org/docs/DRL_for_web.pdf
DRL Values

- *Not* applicable to individual patients
- *Not* dose constraints or dose limits
- *Not* regulatory
- *Not* sufficient by themselves
- Optimizing radiation dose includes maintaining adequate image quality!
Diagnostic Reference Level

• 75th percentile of the dose data collected from a number of facilities for a specific examination

• Individual facilities review their mean dose
  – If > DRL, investigate equipment, protocols, operators
  – If < DRL, practice acceptable, not necessarily optimized
  – If <<DRL, check image quality
Local Data

Local Facility

Central Facility

Local data/Comparison to DRL
Facility submits radiation dose data

Facility receives periodic benchmarking reports

Develops and implements improvement plan

Cyclic, Data Driven Improvement Process

Analyzes results

Courtesy Richard Morin, Ph.D., Mayo Clinic Jacksonville
DRLs Work!

• UK: Recalculated every 5 years based on the results of national surveys
• 2000 DRLs
  – 20% lower than 1995 DRLs
  – ≈ half of mid-1980’s DRLs
• Use of DRLs is *mandatory* in the EU
Figure 4. Third quartiles for dose–area product (DAP) per examination. IVU, intravenous urography.

Federal Guidance Report 14

• Recommendations for Agency actions:
  – For each type of examination, Federal facilities and agencies should promote the development of national reference levels for use as quality assurance and quality improvement tools.
U.S. Approaches to DRLs
NEXT

• Nationwide Evaluation of X-Ray Trends
• Since 1973; FDA/CRC PD collaboration
• National surveys of representative samples of U.S. clinical facilities
• Comprehensive data on radiation exposure, image quality and QA practices for selected imaging examinations
• Increasingly infrequent
NEXT Data in Action

- NCRP Report No. 172 on reference levels (2012)
- Possible initial DRLs for interventional cardiology (2012)
Published 2012

Much of the data from NEXT surveys

All NEXT data are pre-2005
Patient radiation doses in interventional cardiology in the U.S.: Advisory data sets and possible initial values for U.S. reference levels

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Purpose: To determine patient radiation doses from interventional cardiology procedures in the U.S and to suggest possible initial values for U.S. benchmarks for patient radiation dose from selected interventional cardiology procedures [fluoroscopically guided diagnostic cardiac catheterization and percutaneous coronary intervention (PCI)].

• Published 2012
• Data from 2008-2009 NEXT survey

Where are we going to get new data?
Radiation Dose Registries
What is a Dose Registry?

• Information system
  – Collect and compare patient radiation dose data across facilities
• Standard methods of data collection
  – DICOM RDSR, IHE REM profile
• May or may not collect protected health information (PHI)
Imaging Modalities

- CT
- Nuclear medicine
- Fluoroscopy
- Radiography
Uses

• Justification
  – Has the proposed study already been done?

• Optimization of protection
  – Establishment of diagnostic reference levels

• Individual risk assessment
  – Communication of an estimate of stochastic risk for an individual patient

• Research
  – Utilization, collective population dose, epidemiologic studies, etc.
<table>
<thead>
<tr>
<th>Purpose</th>
<th>PHI?</th>
<th>Facility data?</th>
<th>Dose data?</th>
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<tr>
<td>Justification</td>
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<td>Risk Assessment</td>
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Recording Patient Radiation Dose

- National Quality Forum Measure #0510—Exposure Time Reporting for Procedures Using Fluoroscopy (AMA Physician Consortium for Performance Improvement)

- National Quality Forum Measure #0739—Radiation Dose of Computed Tomography (CT) (UCSF)

- CMS Physician Quality Reporting System #145—Exposure Time Reporting for Procedures Using Fluoroscopy
Radiation Dose Registry

- National Quality Forum Measure #0470—Participation in a systematic national dose index registry (American College of Radiology)

- CMS Physician Quality Reporting System (for 2014)—Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry (for CT)
Federal Guidance Report 14

• Summary and recommendations for facility action:
  – Facilities should use reference levels as a quality improvement tool by collecting and assessing radiation dose data. Each facility should also submit its radiation dose data to a national registry, if and when such a registry is available.
Why a National Dose Registry?

- Accurate and objective data on patient radiation dose on a national basis
- Determine and disseminate national benchmarks (DRLs) for patient radiation dose
- Help individual facilities:
  - Compare to similar facilities across the U.S.
  - Target specific areas for improvement
A national patient radiation dose registry is an *infrastructure prerequisite* for National diagnostic reference levels.
Reference Level Recommendation 2:

- National reference levels that are specific for the U.S. population should continue to be developed.
Existing Registries
Examples

• National Cardiovascular Data Registry (NCDR)
  IMPACT Registry
  – American College of Cardiology
  – Fluoroscopy time for certain cardiac interventional fluoroscopy procedures (other dose metrics and IF cardiology procedures to be added)

• Dose Index Registry (DIR)
  – American College of Radiology
  – Radiation dose data for CT (other imaging modalities to be added)
DIR Status

- Launched in May 2011
- 544 facilities registered across the US; 272 contributing data
- Over 1.7 million exams
- Over 3 million scans

Source: American College of Radiology
Courtesy Richard Morin, Ph.D., Mayo Clinic Jacksonville
Summary Stats for Facility Median Value

<table>
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<th>Metropolitan Location</th>
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<tr>
<td>Median (mGy)</td>
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<td>Max (mGy)</td>
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# Mapping to RadLex Playbook

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<td>CT ABD+PELVIS WO/CST</td>
<td>CT ABDOMEN &amp; PELVIS WO IVC</td>
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FDA’s Role and Goals
21 USC 360ii

FDA has authority to:
Plan, conduct, coordinate, and support research, development, training and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation
Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

- Education and Communication
- Appropriate Use
- Facility Guidelines and Personnel Qualifications
- Equipment Safety
- Tracking Radiation Safety Metrics

Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

February 2010

Center for Devices and Radiological Health

U.S. Food and Drug Administration
Initiative Goal 2.1

• Goal: Requirements for CT and fluoroscopic device capability to record radiation dose information for use in patient medical records or a radiation dose registry.

• Radiation Dose Structured Report (RDSR)
  – Joint effort of industry, FDA, professional organizations
  – DICOM object that provides a format for automatic transmission of radiation-related data from the device
  – Implemented for CT, fluoroscopy, radiography

Initiative Goal 1.3

• Goal: The healthcare professional community, in collaboration with FDA, should continue efforts to develop DRLs for CT, fluoroscopy, and nuclear medicine procedures locally and also through a national radiation dose registry.

• National radiation dose registry
• National diagnostic reference levels

Guiding Principles

• Registry participants should include all facilities where medical imaging using ionizing radiation is performed (e.g., medical offices, dental offices, chiropractors)

• Facilities should be able to participate at minimal or no cost
Guiding Principles

- Aggregated data should be publicly and freely available
- Raw data should be accessible to researchers (with appropriate safeguards)
Summary
Summary

• A national radiation dose registry
  – Supports optimization of protection
  – Is a prerequisite for national DRLs

• Regulators, accreditation organizations and professional organizations cannot require either participation in dose registries or use of DRLs unless they exist

• Professional societies have demonstrated that dose registries are feasible
Summary

• FGR 14 recommends use of national DRLs and submission of data to a national radiation dose registry
• Support for a national dose registry is consistent with the Federal public health mission
• Goals include universal participation and maximum possible dissemination of data
• Adequate image quality must be maintained
Thank You!

Questions?

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