

Why and How to Track Radiation Exposure

Beebe Symposium

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Nothing to Disclose



Uses For a Registry

- Justification
- Optimization
- Individual Risk Assessment
- Research

Justification

- Use: Is the proposed study necessary?
 - Are there previous imaging studies that will answer the clinical question?
 - What were the findings? Where are the images?
- Information needed:
 - Previous examinations (type, date, findings, location)
- PHI needed? Yes
- Facility identifiers needed? Yes
- Dose data needed? No (not really a dose registry!)
- Example: EHR

Optimization

- Use: To establish reference levels
- Information needed:
 - Data for examinations from a number of patients at each facility
- PHI needed? No
- Facility identifiers needed? Yes
- Dose data needed? Yes
- Examples: NEXT, EU model, ACR

Individual Risk Assessment

- Use: Communication of an estimate of stochastic risk for an individual patient
- Information needed:
 - All previous examinations for that patient
- PHI needed? Yes
- Facility identifiers needed? No
- Dose data needed? Yes
- Example: web risk “calculators”

Research

- Use: Utilization, population dose, epidemiologic studies, etc.
- Information needed:
 - All available data
- PHI needed? Ideally, Yes
- Facility identifiers needed? Yes
- Dose data needed? Yes
- Example: NEXT (utilization, dose/exposure, practice patterns)

Purpose	PHI?	Facility data?	Dose data?
Justification	Yes	Yes	No
Optimization	No	Yes	Yes
Risk Assessment	Yes	No	Yes
Research	Yes	Yes	Yes

Imaging Modalities

- CT
- Fluoroscopy
- Radiography
- Nuclear medicine

FDA's Role

- Provide expertise in
 - Development of diagnostic reference levels
 - Radiation dose reporting
- Work with manufacturers and end-users to standardize dose reporting
- Work with Federal agencies and NGOs to support registry development efforts
- Help develop educational material on use of DRLs



Proposed Guiding Principles

- Aggregated data should be publicly and freely available
- Raw data should be accessible to researchers
- Registry participants should include all facilities where medical imaging using ionizing radiation is performed (e.g., medical offices, dental offices, chiropractors)

Proposed Guiding Principles

- Facilities should be able to participate at no or minimal cost
- Reference levels are a QA/QI tool
 - Not dose limits
 - Not a regulatory or enforcement tool

Issues

- Who will host the registry?
 - Design, setup, storage
- Who will operate the registry?
 - Storage, analysis, data dissemination
- Who will fund the registry?

Thank you

Questions?

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