Patient Safety Concerns in Diagnostic Radiology?

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Department of Medical Physics
RAMPS/GNYCHPS Spring Symposium – April 30, 2010
Projected Cancer Risks From Computed Tomographic Scans Performed in the United States in 2007

Arch Intern Med. 2009;169(22):2071-2077

Amy Berrington de González, DPhil; Mahadevappa Mahesh, MS, PhD; Kwang-Pyo Kim, PhD; Mythreyi Bhargavan, PhD; Rebecca Lewis, MPH; Fred Mettler, MD; Charles Land, PhD

msnbc.com

15,000 will die from CT scans done in 1 year

Scans have higher levels of radiation than thought, researchers say
Benefits?
Background Radiation in U.S.

~6.3 mSv/yr
~0.02 mSv/day
(~2 mrem/day)

NCRP
Absorbed Dose

\[ D = \frac{d\bar{\varepsilon}}{dm} \]

Equivalent Dose

\[ H_T = \sum_R w_R D_{T,R} \]

<table>
<thead>
<tr>
<th>Radiation type</th>
<th>Radiation weighting factor, ( w_R )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Photons</td>
<td>1</td>
</tr>
<tr>
<td>Electrons and muons</td>
<td>1</td>
</tr>
<tr>
<td>Protons and charged pions</td>
<td>2</td>
</tr>
<tr>
<td>Alpha particles, fission frag-</td>
<td>20</td>
</tr>
<tr>
<td>ments, heavy ions</td>
<td>Neutrons</td>
</tr>
</tbody>
</table>
Risk Evaluations

- Monte-Carlo transport and energy deposition
- Equivalent Dose
- Age-Adjusted
- Gender-Adjusted
- Organ risk factors
Effective Dose

\[
E = \sum_{T} w_T H_T = \sum_{T} w_T \sum_{R} w_R D_{T,R}
\]

<table>
<thead>
<tr>
<th>Tissue</th>
<th>(w_T)</th>
<th>(\sum w_T)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone-marrow (red), Colon, Lung, Stomach, Breast, Remainder tissues*</td>
<td>0.12</td>
<td>0.72</td>
</tr>
<tr>
<td>Gonads</td>
<td>0.08</td>
<td>0.08</td>
</tr>
<tr>
<td>Bladder, Oesophagus, Liver, Thyroid</td>
<td>0.04</td>
<td>0.16</td>
</tr>
<tr>
<td>Bone surface, Brain, Salivary glands, Skin</td>
<td>0.01</td>
<td>0.04</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>1.00</td>
</tr>
</tbody>
</table>

* Remainder tissues: Adrenals, Extrathoracic (ET) region, Gall bladder, Heart, Kidneys, Lymphatic nodes, Muscle, Oral mucosa, Pancreas, Prostate (♂), Small intestine, Spleen, Thymus, Uterus/cervix (♀).
Absorbed fractions and S factors from reference anatomic phantoms

**MIRD Formalism**

*Medical Internal Radionuclide Dosimetry*

**Equation:**

\[
D_{(r_k \leftarrow r_h)} = \frac{\sum_i \Delta_i \phi_i(r_k \leftarrow r_h)}{M_k}
\]

- **Energy Emited per Decay**
- **Equilibrium Dose Constant**
- **Fraction of energy emitted in Source Region \( r_h \) absorbed in Target Region \( r_k \)**
- **Absorbed Fraction**

**Absorbed Dose from Source Region \( r_h \) to Target Region \( r_k \)**

**Number of decays in Source Region \( r_h \)**

**Cumulated Activity**

**\( \hat{A}_h \)**
Doses in CT

- ESD
- CTDI
- DLP = CTDI x L
- E/DLP for adults:
  - Head 0.0023
  - Neck 0.0054
  - Chest 0.017
  - Abd 0.015
  - Pelv 0.019

Verdun, 2008

ACR, 2004
Diagnostic CT Scans:
Assessment of Patient, Physician, and Radiologist
Awareness of Radiation Dose and Possible Risks

TABLE 3
Dose Estimates for One CT Scan versus One Chest Radiograph

<table>
<thead>
<tr>
<th>Respondent Group</th>
<th>CT &lt; CR</th>
<th>CT &gt; CR</th>
<th>CT &gt; 10 × CR</th>
<th>CT &gt; 100 × CR</th>
<th>CT = 100–250 × CR</th>
<th>CT ≥ 500 × CR</th>
</tr>
</thead>
</table>

Published online before print
10.1148/radiol.2312030767
Radiology 2004; 231:393–398
Radiation Passport 1.0

iPhone application

**Exposure**
- **Common** - 99.187 mSv
- **Background** - 99.187 mSv
- **Exams** - 128.417 mSv (12)
  - **Interventional**
    - Abdominal Angio - 12 mSv
      - October 11, 2009
  - **X-Ray**
    - Elbow (Unilateral) - 0.001 mSv
      - April 3, 2009
  - **Dental**
    - CT Scan - 0.2 mSv
      - August 13, 2006
  - **CT Scan**
    - Pulmonary Embolism - 15 mSv

**Total Exposure** - 227.604 mSv
## Typical Radiation Doses - General Radiology

<table>
<thead>
<tr>
<th>Examination</th>
<th>Effective Dose mSv</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental</td>
<td>0.05 (0.02-0.09)</td>
</tr>
<tr>
<td>Chest</td>
<td>0.1 (0.02-0.81)</td>
</tr>
<tr>
<td>Head</td>
<td>0.1 (0.1-0.22)</td>
</tr>
<tr>
<td>Mammography</td>
<td>0.7 (1-3 gland)</td>
</tr>
<tr>
<td>Abdomen/Pelvis</td>
<td>1.2 (0.7-1.2)</td>
</tr>
</tbody>
</table>

## Typical Radiation Doses - Computed Tomography

<table>
<thead>
<tr>
<th>Examination</th>
<th>Effective Dose mSv</th>
</tr>
</thead>
<tbody>
<tr>
<td>PET Attenuation (CT Only)</td>
<td>0.72</td>
</tr>
<tr>
<td>Head</td>
<td>2 (0.8-5)</td>
</tr>
<tr>
<td>Chest</td>
<td>7 (4.6-20.5)</td>
</tr>
<tr>
<td>Abdomen or Pelvis</td>
<td>10 (6-27.4)</td>
</tr>
<tr>
<td>CT Angiography</td>
<td>13 (4.6-15.8)</td>
</tr>
</tbody>
</table>
Typical Radiation Doses - Nuclear Medicine

<table>
<thead>
<tr>
<th>Examination</th>
<th>Effective Dose mSv</th>
</tr>
</thead>
<tbody>
<tr>
<td>F-18 FDG 15mCi</td>
<td>9</td>
</tr>
<tr>
<td>(Nuclear Med only)</td>
<td></td>
</tr>
<tr>
<td>I-131 MIBG 1mCi</td>
<td>7.5</td>
</tr>
<tr>
<td>Tc-99m pertechnet.</td>
<td>5</td>
</tr>
<tr>
<td>Tc-99m stress</td>
<td>6</td>
</tr>
<tr>
<td>I-131 therapy</td>
<td>270</td>
</tr>
</tbody>
</table>
# Typical Radiation Doses

**Fluoroscopy Entrance Skin Dose**

<table>
<thead>
<tr>
<th>Examination</th>
<th>Skin Dose mGy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatic Embolization</td>
<td>2000 (1251-9500)</td>
</tr>
<tr>
<td>Arterial Embolization</td>
<td>3000 (1761-8073)</td>
</tr>
<tr>
<td>Biliary Drainage</td>
<td>660 (401-3569)</td>
</tr>
<tr>
<td>IVC Filter</td>
<td>260 (162-2686)</td>
</tr>
<tr>
<td>Mediport – Chest</td>
<td>12 (8-620)</td>
</tr>
</tbody>
</table>

*Dauer, Thornton... JVIR 2009*
*Adapted from Brenner et al. 2001*
One size does not fit all...

There’s no question — CT helps us save kids’ lives!
But... When we image, radiation matters!
Children are more sensitive to radiation.
What we do now lasts their lifetime.
So, when we image, let’s image gently.
More is often not better.
When CT is the right thing to do:
• Child size the kVp and mA
• One scan (single phase) is often enough
• Scan only the indicated area

A timely message from the Alliance for Radiation Safety in Pediatric Imaging.

Visit www.imagengently.org;
Make pediatric x-ray examinations gentler than they used to be.
Auto Exposure control

Classification: Unclassified
How do we assure quality control on an ongoing basis?

- Medical Physicist verifies CT dose on new equipment prior to 1st patient use, at least 1x per year and at x-ray tube changes.
- CT dose measurements meet American College of Radiology, State, and Local guidelines for dose.
- CT machine settings are developed by Radiologists and Radiology specialists.
- Technique Charts showing machine settings and standard delivered doses are posted at each CT.
Variability in CT doses for real individuals

Mean 13-fold variation
Between highest to lowest dose
For each study type
Machine Model & Type = 2.5 to 5-fold variation

MSKCC - Prins, et al, 2010
Ongoing Evaluations
Principles of Radiation Safety in Radiology

- **Justification**
  - Benefit greater than risk

- **Optimization**
  - Benefit AHARA
  - Risk ALARA

- **Limitation**
  - Occupational doses based on risk of safe industries
Control: 70 colonies     8 Gy: 32 colonies
Can We Predict Effects at Low Doses?

While moderate/high doses cause well-documented effects, we cannot measure significant effects at the doses where typical diagnostic or regulated doses occur.
Classic Risk Paradigm

- Energy deposited in the nucleus
- Ionizations produced
- DNA broken
- Mutations
- Chromosomal Aberrations
- Cell Death
- Cell Transformation

CANCER
Expanded Risk Paradigm

Energy deposited in the nucleus OR cytoplasm

GENETIC SENSITIVITY

DNA may be broken, or other molecules may be

Epigenetic factors

DNA Damage

Oxidative Status

Up regulation of antioxidant enzymes

Inhibition of superoxide anions

Cancer

Other Proteins

PCNA, RPA, and APE

Tissue Response

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Need an Expanded Paradigm for Low-Dose Response

Production of damage
- Linear processes
  - Deposition of energy
  - DNA damage

Responses to damage
- Non-linear processes
  - Induction of Apoptosis
  - Gene & Protein expression
Evaluation Conclusions Vary

- **BEIR VII - NAS**
  - Available biological and biophysical data supports a linear-no-threshold (LNT) risk model.

- **ICRP 99/103**
  - While existence of a low dose threshold may be likely for radiation related cancers in some tissues, the evidence does not support a universal threshold. **DDREF-modified LNT** suggested as prudent.

- **French Academy**
  - New radiobiology focus. Biological differences at high vs. low doses. **LNT overestimates risk at low doses.**
Low Dose - Linear Risk Model

(\sim 5\% \text{ per } \text{Sv})

ICRP-103 for cancer and heredity effects

<table>
<thead>
<tr>
<th>Exposed Population</th>
<th>Cancer</th>
<th>Heredity Effects</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole</td>
<td>5.5</td>
<td>0.2</td>
<td>5.7</td>
</tr>
<tr>
<td>Adult</td>
<td>4.1</td>
<td>0.1</td>
<td>4.2</td>
</tr>
</tbody>
</table>

A statistically significant increase in cancer has not been detected in populations exposed as adults to doses of less than 50 mSv.

No hereditary effects in atomic bomb survivor offspring.
## Patient Risks

<table>
<thead>
<tr>
<th>Risk</th>
<th>Radiation Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of contracting cancer increased by less than ½%</td>
<td>50 mSv</td>
</tr>
<tr>
<td>Temporary Sterilization (Men)</td>
<td>150 mGy</td>
</tr>
<tr>
<td>Temporary blood count change</td>
<td>250 mSv</td>
</tr>
<tr>
<td>Cataract</td>
<td>&lt;1000 mGy</td>
</tr>
<tr>
<td>Permanent Sterilization (Women)</td>
<td>2500 mGy</td>
</tr>
<tr>
<td>Skin Erythema (reddening)</td>
<td>3000 mGy</td>
</tr>
</tbody>
</table>
Fetal Radiation Risk

- **Most Risk - 1\textsuperscript{st} Trimester**
- **No Malformations <100mGy**
- **No Malformations 100-1000mGy 3\textsuperscript{rd} Trimester**
- **Termination of pregnancy at <50 mGy is NOT justified based upon radiation risk**
- **Take care - especially during multiple pelvic CTs, long fluoro, or radiotherapy**

Wagner, ICRP, IAEA, ACOG
ICRP-103 on Individual Risks

“it remains the policy of the Commission that its recommended nominal risk coefficients should be applied to whole populations and not to individuals...[and] believes that this policy provides for a general system of protection that is simple and sufficiently robust” (p.55)
Radiogenic Health Effects Have Not Been Consistently Demonstrated Below 10 Rem

Radiogenic health effects (primarily cancer) have been demonstrated in humans through epidemiological studies only at doses exceeding 5–10 rem delivered at high dose rates. Below this dose, estimation of adverse health effect remains speculative. Risk estimates that are used to predict health effects in exposed individuals or populations are based on epidemiological studies of well-defined populations (for example, the Japanese survivors of the atomic bombings in 1945 and medical patients) exposed to relatively high doses delivered at high dose rates. Epidemiological studies have not demonstrated adverse health effects in individuals exposed to small doses (less than 10 rem) delivered in a period of many years.

Limit Quantitative Risk Assessment to Doses at or Above 5 Rem per Year or 10 Rem Lifetime

In view of the above, the Society has concluded that estimates of risk should be limited to individuals receiving a dose of 5 rem in one year or a lifetime dose of 10 rem in addition to natural background. In making risk estimates, specific organ doses and age-adjusted and gender-adjusted organ risk factors should be used. Below these doses, risk estimates should not be used. Expressions of risk should only be qualitative, that is, a range based on the uncertainties in estimating risk (NCRP 1997) emphasizing the inability to detect any increased health detriment (that is, zero health effects is a probable outcome).
Have we evaluated total imaging doses for our patients?

<table>
<thead>
<tr>
<th></th>
<th>All patients N=68</th>
<th>1997 cohort N=43</th>
<th>2002 cohort N=25</th>
<th>1997 vs. 2002 p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>5y Cumulative ED, mSv</td>
<td>4.56 (3.3-54.4)</td>
<td>4.65 (3.5-62.3)</td>
<td>4.55 (3.3-50.2)</td>
<td>0.56</td>
</tr>
<tr>
<td>Annual ED, mSv</td>
<td>0.92 (0.7-11.0)</td>
<td>0.97 (0.7-12.5)</td>
<td>0.91 (0.7-10.9)</td>
<td>0.85</td>
</tr>
</tbody>
</table>

Cumulative Imaging Radiation Exposure Following Breast-Conservation Therapy

Jennifer L. Marti, MD¹, Lawrence T. Dauer, PhD², Michelle Stempel, MPH¹, Sujata Patil, PhD³, Jennifer B. Kaplan, MD⁴, Leslie L. Montgomery, MD, FACS⁵

Annals of Surgical Oncology - pending
Are Diagnostic Doses Really a Concern for Our Patients?

- Risks models based on dose averages and large populations.
- Risk vs. Benefit to Individual.
- Benefit must always be considered.
- Justification and Optimization are paramount.
In most symptomatic adults, radiation doses for diagnostic radiology procedures, including CT scans, result in extremely small risk, **typically well-justified** by the medical need. 

Risks are ~ 2-3 x larger for children.
Suggestions

- NO radiation when you don’t do the exam! Ensure each exam is justified.
- Carefully scrutinize screening protocols for ‘healthy’ subjects and post-therapy screening protocols for pediatric patients and patients with long-term survival expectation.
- Communicate dose and risk with staff (especially referring physicians) and patients.
- Medical Physics review/testing of final machine std protocols!!
Research Challenges – Some Questions Still Need Answers…

- Molecular markers of DNA damage at low doses?
- DNA repair fidelity and capacity for double and multiple strand breaks at low doses?
- Adaptation, hypersensitivity, bystander effects, hormesis, and genomic instability for radiation carcinogenesis?
- How to best communicate risk with patients?
- Benefits?
## Radiation Hazard Index (RHI)

<table>
<thead>
<tr>
<th>RHI</th>
<th>ED Range</th>
<th>Background Equivalent</th>
<th>Typical Examples</th>
<th>Risk Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>10,000Sv</td>
<td>-</td>
<td>Industrial Uses</td>
<td>$10^{+2}$ Greater</td>
</tr>
<tr>
<td>9</td>
<td>1000Sv</td>
<td>-</td>
<td>Food Irradiation</td>
<td>$10^{+1}$ Great</td>
</tr>
<tr>
<td>8</td>
<td>100Sv</td>
<td>Centuries</td>
<td>Radiotherapy: dose to tumor</td>
<td>$10^{0}$ Major</td>
</tr>
<tr>
<td>7</td>
<td>10Sv</td>
<td>Century</td>
<td>Acute Total Body Gi / Bone Marrow</td>
<td>$10^{-1}$ Major</td>
</tr>
<tr>
<td>6</td>
<td>1Sv</td>
<td>Decades</td>
<td>Increased Ca Risk</td>
<td>$10^{-2}$ Strong</td>
</tr>
<tr>
<td>5</td>
<td>100mSv</td>
<td>Decade</td>
<td>Dose Limits</td>
<td>$10^{-3}$ Moderate</td>
</tr>
<tr>
<td>4</td>
<td>10mSv</td>
<td>Years</td>
<td>CT Nuclear Med Diag</td>
<td>$10^{-4}$ Low</td>
</tr>
<tr>
<td>3</td>
<td>1mSv</td>
<td>Months</td>
<td>Abdominal x-ray</td>
<td>$10^{-5}$ Very Low</td>
</tr>
<tr>
<td>2</td>
<td>0.1mSv</td>
<td>Weeks</td>
<td>Chest x-ray, Mammography</td>
<td>$10^{-6}$ Minimal</td>
</tr>
<tr>
<td>1</td>
<td>0.01mSv</td>
<td>Days</td>
<td>Bone Density, Skull</td>
<td>~0 Negligible</td>
</tr>
</tbody>
</table>

Dauer, 2008
Research Challenges – What Data are still Needed?

- Prospective cohort and nested case-control studies of moderate-dose medical exposures.
- Epidemiological study consortia for medically exposed populations (CTs, Pediatrics, IR).
- Occupational low-dose studies.
- Exposed Population studies.
- Current Policies justified and optimized themselves?