Population Doses from Medical Imaging: Should we be Concerned?

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Population Doses from Medical Imaging: Should we be Concerned?

... and if so, what can be done?

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There is no question that CT has revolutionized medical practice.

Bronchial obstruction not seen on plain film, but visible on CT

*Heitzman 1986*
Why are we particularly concerned about CT?

1. CT usage has increased rapidly in the past decade
2. Compared to most radiological examinations, CT produces a larger radiation dose...
3. CT doses are typically large enough that there is direct epidemiological evidence for an increase in cancer risk.
4. Pediatric CT
5. CT-based screening
Why are we particularly interested in CT?

Frequency of CT scans per year

**USA**

- CT scans per year in the US (millions)
- Number of CT scans per person / year

**UK**

- CT scans per year in the UK (millions)
- Number of CT scans per person / year

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Year:
- 1980
- 1985
- 1990
- 1995
- 2000
- 2005

CT scans per year in the UK (millions):
- 1980: 0.0
- 1985: 0.01
- 1990: 0.02
- 1995: 0.03
- 2000: 0.04
- 2005: 0.05

CT scans per year in the US (millions):
- 1980: 0
- 1985: 0.05
- 1990: 0.1
- 1995: 0.15
- 2000: 0.2
- 2005: 0.25

Number of CT scans per person / year:
- 1980: 0
- 1985: 0.01
- 1990: 0.02
- 1995: 0.03
- 2000: 0.04
- 2005: 0.05
Mean individual total radiation dose in the US: 1980 vs. 2007

1980: 3.6 mSv

2007: 6.3 mSv

1990 data: NCRP Report 93
2007 data: Mettler et al. 2008, IMV 2008
CT scanners / million population (2005)

From OECD Health Data, 2007
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Typical organ doses from single diagnostic x-ray examinations

<table>
<thead>
<tr>
<th>Examination</th>
<th>Relevant organ</th>
<th>Relevant organ dose (mGy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental x-ray</td>
<td>Brain</td>
<td>0.005</td>
</tr>
<tr>
<td>PA Chest x-ray</td>
<td>Lung</td>
<td>0.01</td>
</tr>
<tr>
<td>Lateral chest x-ray</td>
<td>Lung</td>
<td>0.15</td>
</tr>
<tr>
<td>Screening mammogram</td>
<td>Breast</td>
<td>3</td>
</tr>
<tr>
<td>Adult abdominal CT (200 mAs)</td>
<td>Stomach</td>
<td>11</td>
</tr>
<tr>
<td>Adult head CT (200 mAs)</td>
<td>Brain</td>
<td>13</td>
</tr>
<tr>
<td>Child abdominal CT (50 / 200 mAs)</td>
<td>Stomach</td>
<td>8 / 30</td>
</tr>
<tr>
<td>Child head CT (100 / 200 mAs)</td>
<td>Brain</td>
<td>18 / 35</td>
</tr>
</tbody>
</table>
There is a considerable variation in CT doses from institution to institution

From the 2000-01 FDA NEXT CT survey
Multiple CT examinations

- 30% of patients who have CT scans have at least 3 scans
- 7% of patients who have CT scans have at least 5 scans
- 4% of patients who have CT scans have at least 9 scans

(Mettler et al 2000)

• Mean number of CT scans delivered to trauma patients in their initial evaluation: 3

(Winslow et al 2008)
Multiple CT examinations (lifetime)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Cumulative CT Examination Count</th>
<th>Cumulative Effective Dose (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median</td>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>Mean</td>
<td>6.1</td>
<td>54.3</td>
</tr>
<tr>
<td>99th Percentile</td>
<td>38</td>
<td>399</td>
</tr>
<tr>
<td>Maximum</td>
<td>132</td>
<td>1375</td>
</tr>
</tbody>
</table>

Among patients who had a CT scan in 2007:

- 33% had more than 5 CT scans in the previous 20 yrs
- 5% had more than 22 CT scans in the previous 20 yrs
- 1% had more than 38 CT scans in the previous 20 yrs

(Sodickson et al 2009)
The most likely organ dose range for CT

Taking onto account

* Machine variability,
* Usage variability,
* Age variability,
* Multiple scans (mean 2)

the relevant organ dose range for CT is

5 - 100 mSv
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3. CT doses are typically large enough that there is direct epidemiological evidence for an increase in cancer risk
4. Pediatric CT
5. CT-based screening
Low dose radiation risks
Hiroshima and Nagasaki

5-100 mSv
Number of solid cancers in A-bomb survivors exposed to doses from 5-100 mSv

<table>
<thead>
<tr>
<th>Study population (5-100 mSv)</th>
<th>Cancer incidence (1958-98)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total solid cancers observed</td>
<td>27,789</td>
</tr>
<tr>
<td>Solid cancers expected (controls)</td>
<td>4,406</td>
</tr>
<tr>
<td>Radiation-related excess solid cancers</td>
<td>4,325</td>
</tr>
<tr>
<td></td>
<td>81</td>
</tr>
</tbody>
</table>

Small but statistically significant increase in risk

Preston et al 2007
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Pediatric CT Scans in the USA

1989: ~½ million

2007: ~3½ to 7 million

(of these, ~¾ to 1.5 million are on children under 5)
For a given machine mAs setting, CT doses are larger for children than for adults. But there is the potential to reduce the mAs for children, by factors of 2-4, without losing diagnostic information.
Estimated radiation-induced lifetime cancer risks as a function of age at exposure

From BEIR-VII (2006)
Why are we particularly concerned about CT?

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Screening with CT

- Lung
- Heart
- Colon
- Whole Body
Estimating the radiation-induced cancer risks from CT exams

- Direct epidemiology on people who received CT scans
- Risk estimation based on organ doses
Epidemiological studies of cohorts of patients who had pediatric CT

- UK ~200,000 children
- Ontario: ~275,000 children
- Israel: ~80,000 children
- Australia ~150,000 children
- France ~25,000 children
- Sweden ~35,000 individuals

CHILD-MED-RAD
Dose-based approach to estimating the radiation-induced cancer risk for a CT exam,

1. Estimate the dose to each organ, as a function of age, gender, and type of CT exam

2. Apply estimates of age-, gender-, and organ-specific risks-per-unit dose
   (low-dose risks from A-bomb survivors, “transferred” to a Western population)

3. Sum the estimated risks for all organs
Estimated % lifetime attributable cancer mortality risk, as a function of age at exam, for a single CT exam.
What are the uncertainties associated with these risk estimates?

About a factor of 3 in either direction
Individual risks vs population risks

- The individual risks from CT are small, so the benefit / risk ratio for any individual will typically be large.

- But the exposed population is large (5 million children, ~65 million adults / yr in the US).

- Even a very small individual radiation risk, when multiplied by a large (and increasing) number of individuals, has the potential to produce a significant long-term public health concern.
What can be done to reduce the population risk, without compromising patient care?

- Reduce the dose per scan
- Minimize unnecessary imaging
- Use other imaging modalities where possible
Reducing the dose per scan

1. Patient-size adapted mA

2. z-axis modulation

3. angular modulation
"Image Gently"
FDA has good intentions, also

Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

Like all medical procedures, computed tomography (CT), fluoroscopy, and nuclear medicine imaging exams present both benefits and risks. These types of imaging procedures have led to improvements in the diagnosis and treatment of numerous medical conditions. At the same time, these types of exams expose patients to ionizing radiation, which may elevate a person’s lifetime risk of developing cancer. As part of a balanced public health approach, the U.S. Food and Drug Administration (FDA) seeks to support the benefits of these medical imaging exams while minimizing the risks.

Through the Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging, FDA is advocating the universal adoption of two principles of radiation protection: appropriate justification for ordering each procedure, and careful optimization of the radiation dose used during each procedure. Each patient should get the right imaging exam, at the right time, with the right radiation dose.

In support of this goal, FDA will use our regulatory authority and also collaborate with others in the Federal government and the healthcare professional community to:

1. Promote safe use of medical imaging devices;
2. Support informed clinical decision making; and
3. Increase patient awareness.

By coordinating these efforts, we can optimize patient exposure to radiation from certain types of medical imaging exams, and thereby reduce related risks while maximizing the benefits of these studies.
Can CT usage be reduced? (or the rate of increase slowed?) without compromising patient care....

Some common potential CT scenarios where there is evidence that CT usage could potentially be reduced:

- CT for renal colic
- CT for minor head trauma
- CT for abdominal pain
- CT for abdominal and chest trauma
- CT angiography for pulmonary embolus
Can CT usage be reduced? (or the rate of increase slowed?) without compromising patient care....

• A significant fraction of CT scans (⅓ ??) could practically be replaced by alternate approaches, or need not be performed at all

• Targeting this “one third” is more than half the battle

• Physicians are subject to significant pressure:
  - Throughput
  - Legal
  - Economic

Clinical Decision Rules

- Economic
- From patients
What proportion of CT scans could potentially be avoided?

Many retrospective studies of the proportion of CT scans that could have been avoided if high-sensitivity CT decision rules had been applied.

<table>
<thead>
<tr>
<th>Decision Rule for mild traumatic brain injury</th>
<th>Sensitivity</th>
<th>Percent of CT scans that would be avoided</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canadian</td>
<td>0.99</td>
<td>44</td>
</tr>
<tr>
<td>NCWFNS</td>
<td>0.96</td>
<td>44</td>
</tr>
<tr>
<td>New Orleans</td>
<td>0.99</td>
<td>31</td>
</tr>
<tr>
<td>Nexus-II</td>
<td>0.97</td>
<td>44</td>
</tr>
<tr>
<td>NICE</td>
<td>0.99</td>
<td>39</td>
</tr>
<tr>
<td>Scandinavian</td>
<td>0.96</td>
<td>50</td>
</tr>
</tbody>
</table>

Stein et al 2009
Decision rules for diagnosing pediatric appendicitis

- **Equivocal symptoms**
  - **CT**
    - +
    - Appendectomy

- **Low Risk**
  - In patient observation

- **Medium risk**
  - **Ultrasound**
    - +
    - Appendectomy
  - **CT**
    - +
    - Appendectomy

- **High Risk** (e.g. Alvarado scoring system)
  - **CT**
    - +
    - Appendectomy

Based on Garcia Pena 2004
200 trauma patients studied, who had some radiation imaging

• 169 had CT scans
• Total number of CTs: 660
• Cost $837,000

Had ACR Appropriateness Criteria been applied.....

• 44% of CTs would not have been carried out
• None of the major injuries would have been excluded from CT imaging
• 11 minor injuries, none of which required follow up, would have been excluded from CT imaging
• 39% decrease in cost
Clinical Decisions Rules: Awareness and Use

The Canadian CT Head Decision Rule, among US ER physicians (n=239)

Aware of the decision rule: 31%
Use the decision rule: 12%

Most significant factor for usage was “teaching vs non-teaching hospital”

Canadian CT Head Rule

CT head is only required for minor head injury patients with any one of the following findings. Minor head injury patients present with a GCS score of 13-15 after witnessed loss of consciousness, amnesia, or confusion.

High-Risk (for Neurosurgical Intervention)
1. GCS score < 15 at 2 hours after injury
2. Suspected open or depressed skull fracture
3. Any sign of basal skull fracture*
4. Vomiting ≥ 2 episodes
5. Age ≥ 65 years

Medium-Risk (for Brain Injury on CT)
6. Amnesia before impact ≥ 30 minutes
7. Dangerous mechanism**

*Signs of Basal Skull Fracture:
- hemotympanum, ‘raccoon’ eyes, CSF otorrhea/rhinorrhea, Battle’s sign

**Dangerous Mechanism:
- pedestrian struck by motor vehicle
- occupant ejected from motor vehicle
- fall from elevation ≥ 3 feet or 5 stairs

Rule not applicable if:
- Nontrauma case
- GCS < 13
- Age < 16 years
- Warfarin or bleeding disorder
- Obvious open skull fracture

Eagles et al 2008
Three potential approaches towards increased utilization of CT decision rules

1) Promote increased awareness of radiation issues

2) Incorporate decision rules into a computerized radiology order entry system

3) Build decision rules into a managed care preauthorization program
Radiation and Pediatric Computed Tomography: A Guide for Health Care Providers

Radiation Risks and Pediatric Computed Tomography (CT): A Guide for Health Care Providers

CT is an extremely valuable tool for diagnosing illness and injury in children. For an individual child, the risks of CT are small and the individual risk-benefit balance almost always favors the benefit. Approximately 2.3 million CT examinations are performed annually on children in the U.S. The use of CT in adults and children has increased about 7-fold in the past 10 years. Much of this increase is due to increased availability, technical improvements, and other factors.

Unique Considerations for Radiation Exposure in Children

Radiation exposure is a concern in both adults and children. However, there are two unique considerations in children:

- Children are considerably more sensitive to radiation than adults, as demonstrated in epidemiologic studies of exposed populations.
- Children also have a longer life expectancy, resulting in a larger window of opportunity for expressing radiation damage.

As an example, compared with a 40-year-old, the same radiation dose given to a neonate is several times more likely to produce a cancer over the child’s lifetime.

NATIONAL CANCER INSTITUTE
THE SOCIETY FOR PEDIATRIC RADIOLOGY

Radiation Risks and Pediatric Computed Tomography (CT)

The use of pediatric CT, a valuable imaging tool, has been increasing rapidly. Because of the growing use of CT and the potential for increased radiation exposure to children undergoing these scans, pediatric CT has become a public health concern. This brochure discusses the value of CT and the importance of minimizing the radiation dose, especially in children. It will address the following issues:

- CT as a diagnostic tool
- Unique considerations for radiation exposure in children
- Radiation risks from CT in children: a public health issue
- Immediate strategies to minimize CT radiation exposure to children

CT as a Diagnostic Tool

CT is an extremely valuable tool for many conditions in children. As with many medical imaging procedures, the overall benefits of pediatric CT far outweigh the potential risks. However, some precautions should be taken to minimize radiation exposure to children. The use of CT in children should be limited to cases where there is an increased likelihood of benefit.

Unique Considerations for Radiation Exposure in Children

Radiation exposure is a concern in both adults and children. However, there are two unique considerations in children:

- Children are considerably more sensitive to radiation than adults, as demonstrated in epidemiologic studies of exposed populations.
- Children also have a longer life expectancy, resulting in a larger window of opportunity for expressing radiation damage.

As an example, compared with a 40-year-old, the same radiation dose given to a neonate is several times more likely to produce a cancer over the child’s lifetime.

Moreover, the same exposure parameters used for a child and an adult will result in larger doses to the child. There is no need for these larger doses to children, and CT settings can be reduced significantly while maintaining diagnostic image quality. Therefore, children should not be scanned using adult CT exposure parameters. Currently, adjustments are not frequently made in the exposure parameters that determine the amount of radiation children receive from CT, resulting in a greater...
Three potential approaches towards increased utilization of CT decision rules

1) Promote increased awareness of radiation issues

2) Incorporate decision rules into a computerized radiology order entry system

3) Build decision rules into a managed care preauthorization program
MGH Radiology Order-Entry and Decision-Support System

Head CT has low utility for the clinical indications provided

Indicated 7-9  Marginal 4-6  Low Utility 1-3

Alternate procedures to consider:

MR  PET  CTA  MRA

Options:
- Proceed with exam
- Cancel or select new exam
- Change indications and resubmit

At least one box MUST be selected from either of the following groups

SIGNS / SYMPTOMS

- Acromegaly
- Speech changes (or Aphasia), new or progressive
- Concussion mild or moderate acute, no neurological deficit
- Coordination changes, new or progressive
- Dementia
- Head injury mild or moderate acute, no neurological deficit
- Headache
- Hyperprolactinemia
- Pain in face
- Weakness- right side / left side / both
- Acute visual deficit (other than photophobia and aura)
- Syncope/fainting
- Signs of meningeal irritation (such as stiff neck)
- Amenorrhea
- Abnormal gait (Ataxia)
- Seizures new or progressive
- Cranial nerve palsy (specify):
- Dizziness
- Head injury moderate or severe acute, stable
- Hearing changes
- Mental Status change (after trauma)
- Sensation loss
- TIA with transient neurological disturbance
- Mass or lump
- Vision changes
- Signs of increased intracranial pressure (such as funduscopic exam)
MGH Radiology Order-Entry and Decision-Support System: Effect on Outpatient CT Volume

Three potential approaches towards increased utilization of CT decision rules

1) Promote increased awareness of radiation issues

2) Incorporate decision rules into a computerized radiology order entry system

3) **Build decision rules into a managed care preauthorization program**
At the Beth Israel Deaconess ER, a CT preauthorization program did not change CT usage patterns.

Smulowitz et al. 2009
Conclusions

I: Are CT risks real?

- The suggestion is that CT doses will produce a small increase in individual cancer risk..... Is this
  a) Based fairly directly on epidemiological evidence?
  b) “Extrapolated from high radiation dose exposures studied in the Atomic Bomb experience”?

- The typical organ dose range for CT (5 to 100 mSv) is the same dose range for which there is a statistically significant increase in risk in A-bomb survivors

- That being said, we await the results of the epidemiological studies over the next few years....
Conclusions

II. Even if the risks from CT are real, the individual risks are small

• The concern is really about the population exposure from 70 million CT scans per year
Conclusions

III. The CT-related population exposure can be reduced

- Reduce the dose per scan (not so hard)
- Reduce the number of clinically unwarranted CT scans (hard)