The California CT Dose Law: History, Implementation, Implications, and Benefits

John M. Boone, Ph.D., FAAPM, FSBI, FACR
Professor and Vice Chair (Research) of Radiology
Professor of Biomedical Engineering
Department of Radiology
The California CT Dose Law:

- History
- Details
- Implementation
- Implications
- Benefits
- Summary
Use of CT: Locally and Nationally

Medical

~Background
The radiation from CT has caught the eye of the public.

FDA: Medical devices can shock in CT scans

Virtually all of these people are already ineligible for MRI scans - another popular imaging technology - because metal parts in their devices can't be exposed to MRI fields.

CT scans in children linked to cancer

By Steve Sternberg, USA TODAY

Each year, about 1.6 million children in the USA get CT scans to see their abdomen - and about 1,500 of those will die later in life of radiation-induced cancer, according to research out today.

What's more, CT or computed tomography scans given to kids are not calibrated for adults, so children absorb two to six times the radiation needed to produce clear images, a second study shows. These doses are much higher than the sorts of doses that people at Three Mile Island were exposed to, Brenner of Columbia University says. "Most people got a tenth the dose of a CT."

FDA Public Health Notification: Reducing Radiation Risk from Computed Tomography for Pediatric and Small Adult Patients

Hospital radiation overdoses probed

"It's pretty mystifying to me."

David Brenner, director of the Center for Radiological Research at Columbia University Medical Center, aims to how the radiation doses could have gone unnoticed for 18 months.

"There are other places where the techs might be operating more as button pushers," said Dr. Geoffrey Hubin, a professor of radiology at Stanford University. "The user becomes a little blind to these numbers."

The overdoses also could have been caught during periodic calibrations of the machines, when radiation levels are tested directly.

Najmedin Meshkati, a professor of industrial and systems engineering at the University of Southern California, said the overdoses point to a problem well-documented in medicine - the need for multiple backup systems to catch mistakes.

As a result of the radiation overdoses, the FDA issued an alert that raised the possibility that CT scanners at other hospitals could be set wrong - with deadly consequences.

Radiation-induced temporary hair loss as a radiation damage only occurring in patients who had the combination of MDCT and DSA

BEIR VII: Health Risks from Exposure to Low Levels of Ionizing Radiation

Risk of cancer from diagnostic X-rays: estimates for the UK and 14 other countries

Amy Berrington de González, Sarah Darby
Mad River Hospital

Humboldt Online
Get the News... Not the Paper

Radiation Overdoses Point Up
Dangers of CT Scans
Written by Humboldt Online Editor on 16 October 2009

New York Times
Raven
Knickerbocker, then an X-ray technologist at Mad River Community Hospital in Arcata, Calif., activated a CT scan 151 times on the same area of the head of 2 ½-year-old Jacoby Roth, investigators concluded.

California hospital fined $25,000 for pediatric CT radiation overdose
By Cynthia E. Keen
AuntMinnie.com staff writer
March 24, 2009

Parents sue California hospital over pediatric CT radiation overdose
By Cynthia E. Keen
AuntMinnie.com staff writer
November 20, 2008

A rural California hospital is being sued by parents of a child who underwent a CT exam during an emergency department visit for a neck injury. The parents allege that their 23-month-old boy received radiation burns and has permanent chromosomal damage due to excessive radiation exposure from the CT scan, which took over an hour to perform.

150 CT scans of the same area + one scout view
Equipment and/or user failure.....

- 2 ½ year old boy
- January 2008
- 150 scans to same area in ~1 hour.....
- Prompt erythema in area of scan (5-10 Gy)
Cedars-Sinai Medical Center
Cedars-Sinai Medical Center

• >150 cases: CT Overdose during Head CT perfusion
• Other cases in West Virginia and Arkansas
• Mostly on GE CT scanners
• Lawyers!
Mad River Hospital

Cedars-Sinai Medical Center
Resulting California Legislation

- Senate Bills 1237 & 38
  - Introduced by Alex Padilla

- Assembly Bill 510
  - Introduced by Bonnie Lowenthal
Senate Bill 1237

• Effective July 1, 2012
• Adds sections 115111, 115112 and 115113 to the state Health and Safety code for Public Health
• Requires those responsible for CT system operation:
  – To record the dose of radiation for every CT study produced during an exam
  – To have on an annual basis, a medical physicist verify displayed doses within 20% of the true measured dose
  – To record the CT dose metrics in the radiology report
    • Volume computed tomography dose index ($\text{CTDI}_{\text{vol}}$)
    • Dose length product (DLP)
SB1237 – Section 115112

• Requires “facilities that furnish CT X-ray services shall be accredited by an organization that is approved by the federal Centers for Medicare and Medicaid Services, and accrediting agency approved by the Medical Board of California, or the State Department of Public Health”

• Date of required compliance: July 1, 2013
• Requires a report be sent to CA Dept of Health Services:
  • Repeating a CT exam, unless ordered by a physician or radiologist or movement / interference of patient, if the following dose values are exceeded:
    • 0.05 Sv (5 rem) effective dose equivalent (50 mSv)
    • 0.5 Sv (50 rem) to an organ or tissue (500 mSv)
    • 0.5 Sv (50 rem) shallow dose equivalent to the skin (500 mSv)
  • Irradiating a body part other than the intended body part (with the same dosage requirements as above)
SB1237 – Section 115113

- Requires a report be sent to CA Dept of Health Services:
  - If an exam results in unintended patient harm (organ damage or erythema), as determined by a physician
  - Radiation exposure greater than 50 mSv (5 rem) to a fetus or embryo of a known pregnant individual unless approved by a physician
  - Irradiating the wrong person or wrong site
  - Delivered dose is >20% of the prescribed dose
AB 510

— Further clarifies SB1237
— Section 115111:

  • Nuclear Medicine PET/CT & SPECT/CT scanners* excluded
  
  • Technical factors and dose shall be electronically sent to PACS
  
  • Displayed dose verified by physicist for typical adult brain, adult abdomen, and pediatric brain protocols – within 20% of measured dose
  
  • Dose reporting is limited to systems capable of reporting dose
  
  • Dose report shall be included in “interpretive report”, not just “Radiology report”, to account for other departments using CT
The California CT Dose Law:

History

Details (behind the scene)

Implementation

Implications

Benefits

Summary
Sacramento State Capital Building

California Consumer Attorneys Association (~)
California Hospital Association
California Radiological Association (CRS)
American College of Radiology (ACR)
115111. (a) Commencing July 1, 2012, subject to subdivision (e), a person that uses a computed tomography (CT) X-ray system for human use shall record the dose of radiation on every diagnostic CT study produced during a CT examination in the patient’s record, as defined in Section 123105. CT studies used for therapeutic radiation treatment planning or delivery or for calculating attenuation coefficients for nuclear medication studies shall not be required to record the dose.

(b) The facility conducting the study may send electronically each CT study and protocol page that lists the technical factors and dose of radiation to the electronic picture archiving and communications system.

(c) (1) Until July 1, 2013, the displayed dose shall be verified.

(f) For the purposes of this section, dose of radiation shall be defined as one of the following:

(1) The computed tomography index volume (CTDI vol) and dose length product (DLP), as defined by the International Electrotechnical Commission (IEC) and recognized by the federal Food and Drug Administration (FDA).

(2) The dose unit as recommended by the American Association of Physicists in Medicine.

(e) The requirements of this section shall be limited to CT systems capable of calculating and displaying the dose.

(f) For the purposes of this section, dose of radiation shall be defined as one of the following:

(1) The computed tomography index volume (CTDI vol) and dose length product (DLP), as defined by the International Electrotechnical Commission (IEC) and recognized by the federal Food and Drug Administration (FDA).

(2) The dose unit as recommended by the American Association of Physicists in Medicine.

(g) For purposes of this section, "CT X-ray system” means the same as provided in Section 892.1750 of Title 21 of the Code of Federal Regulations.
CA Legislative Activities

- Sen. Padilla introduced SB 1237 in Feb 2010
  - Radiation Control: Health Facilities and Clinics
- Governor signed bill on September 29, 2010
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September 29, 2010

22 months

July 1, 2012
California Radiological Health Branch
Inspection Compliance and Enforcement Section (Radiation Machines)
C-CAMP
California clinical & academic medical physicists

Tony Seibert
John Boone
Linda Kroger
Mike McNitt-Gray
Chris Cagnon
Melissa Martin
Tom Nelson
UC Davis Home Grown Attempt

Ellison ACC Building

Main Hospital

PCH
UC Davis Home Grown Attempt

RADIOLOGY INTERFACE DIAGRAM

- EMR
- Invision
- PITS
- Billing
- DICOM IMAGES
- CB ORDERS
- Modalities
- ENSEMBLE
- OPENLINK
- RadWhere
- IDX
- PACS
- ConnectR
- ConnectR
- Broker & DICOM processor
- PACS/RIS Broker

- DICOM / HL7 Application connector
- CT scanner
- Dose Calculation Software
- Speech Recognition
- RIS
UC DOSE

Dose Optimization and Standardization Endeavor
University of California DOSE consortium
Dose Reporting Software Vendors

UC San Francisco
UC Davis
UC Irvine
UC Los Angeles
UC San Diego
UC San Francisco
UC Davis
UC Irvine
UC Los Angeles
UC San Diego

- CTDIvol
- DLP
- Eff Diameter
- Water-equiv Diameter
- SSDE
- Organ dose
The Structured Dose Report with Radimetrics Feed

Report: Gaga, Lady – MRN: 1234567

EXAM DATE [5/24/2012 12:35 pm]

INDICATION:
[]

DOSE:
(This was an abdomen-pelvis CT examination with two series, one with and one without contrast. Estimates of the radiation dose metrics that you received are:

- **Series 1:** (no contrast)
  - CTDIvol = 12.4 mGy
  - DLP = 496 mGy-cm

- **Series 2:** (with contrast)
  - CTDIvol = 13.2 mGy
  - DLP = 577 mGy-cm

These doses are **lower** **typical** **higher** than other patients having this same CT study)

FINDINGS:
[]

IMPRESSION:
[]
PRIMER ON CT DOSE METRICS FOR RADIOLOGISTS:
PREPARATION FOR INTERPRETING THE CT DOSE REPORT

John M. Boone, Ph.D., FAAPM, FSBI, FCR
Professor and Vice Chair of Radiology
University of California Davis Medical Center
**Report: Gaga, Lady – MRN: 1234567**

**EXAM DATE** [5/24/2012 12:35 pm]

**INDICATION:**


**DOSE:**

Dose information for this CT examination:

- **Series 1:** (no contrast)
  - CTDIvol = 12.4 mGy
  - DLP = 496 mGy-cm

- **Series 2:** (with contrast)
  - CTDIvol = 13.2 mGy
  - DLP = 577 mGy-cm

UC Davis Health System CT scanners are accredited by the American Board of Radiology, and employ modern techniques for CT dose reduction, including protocol review, automatic exposure control, and iterative reconstruction techniques. These features assure that radiation dose levels in CT are optimized and are consistent with state of the art CT practice.

**FINDINGS:**


**IMPRESSION:**


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The Structured Dose Report with Radimetrics Feed

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**text and format are up for discussion**
The Structured Dose Report with Radimetrics Feed

Report: Gaga, Lady – MRN: 1234567

EXAM DATE [5/24/2012 12:35 pm]

INDICATION:

DOSE:
[There were two exposure events in this study:
Series 1: CTDI=12.4, DLP=496, 32 cm
Series 2: CTDI=13.2, DLP=577, 32 cm
See www.ucdavis.edu/CTdose for further information.]

FINDINGS:

IMPRESSION:
Recommendations for compliance

• UCDOSE consortium of UC Medical Centers

UNIVERSITY OF CALIFORNIA

UC-DOSE
University of California Health System
Recommendations for Compliance with California Senate Bill 1237 and related pending legislation
May 10, 2012

1. EXECUTIVE SUMMARY

The UC-DOSE project (University of California Dose Optimization and Standardization Endeavor) was funded by the University of California Office of the President (UCOP) to standardize and optimize computed tomography (CT) protocols across the University of California Medical Centers, and to develop a consistent solution for responding to California Senate Bill 1237.¹ This bill takes effect on July 1, 2012, will be enforced by the California Department of Public Health Radiologic Health Branch,² and requires the reporting of CT radiation dose, and the reporting of overdoses in particular settings.
DLP value: reporting thresholds

Effective Dose = DLP × k

Effective Dose / k = DLP
March 22, 2012 | SIIM meeting in Long Beach

**SIIM Regional Meeting: Practical Imaging Informatics**

**October 24, 2011 | Hyatt Regency San Francisco**

**Program Agenda**

**GRAND BALLROOM A**

8:00 am – 9:00 am
Registration and Continental Breakfast
Grand Ballroom A Foyer

8:45 am
Welcome Remarks
Elizabeth A. Krupinski, PhD, FSII, University of Arizona
Chair, Society for Imaging Informatics in Medicine

8:55 am
Radiation Dose Monitoring in California
J. Anthony Selbert, PhD, FSII, University of California, Davis

9:00 am – 9:45 am
Radiation Dose in a Clinical Environment: Benefit and Risk – The User’s Perspective
John M. Boone, PhD, University of California, Davis
Robert G. Gould, ScD, University of California, San Francisco
Rebecca Smith-Bindman, MD, University of California, San Francisco

9:45 am – 10:30 am
Acquiring, Mining, and Reporting the Radiation Dose Data – The Vendor’s Perspective
Mike Battin, COO, PHS Technologies Group
Gregory Couch, President & CEO, Radimetrics, Inc.
Philip Zarboula, Partner, Primordial Design, Inc.

10:30 am – 11:00 am
Morning Break and Visit the Exhibits

11:00 am – 11:45 am
The California Dose Reporting Law: Implications and FAQ – The Government’s Perspective
Jerry Hensley, CHP, Chief, X-Ray Inspection, Compliance and Enforcement, California Department of Public Health
Lisa Russell, Inspector, Compliance and Enforcement, California Department of Public Health
Other states are looking at the California CT Dose law

Connecticut
Texas

........
Adoption of CA laws...

Standard PC.01.02.15
The [critical access] hospital provides for diagnostic testing.

Elements of Performance for PC.01.02.15
C 5.  For [critical access] hospitals in California that provide diagnostic computed tomography (CT) services: The [critical access] hospital documents in the patient's medical record the radiation dose \(^{\text{a}}\) (CTDivol or DLP) on every study produced during a CT examination.  

C 6.  For [critical access] hospitals in California that provide diagnostic computed tomography (CT) services: The interpretive report of a diagnostic CT study includes the volume computed tomography dose index (CTDivol) or dose-length product (DLP) radiation dose. \(^{\text{a}}\) The dose is either recorded in the patient's interpretive report or included on the protocol page, which is then attached to the interpretive report.  

Standard PC.01.03.01
The [critical access] hospital plans the patient's care.

Elements of Performance for PC.01.03.01
A 25. For [critical access] hospitals that provide diagnostic computed tomography (CT) services: The [critical access] hospital establishes imaging protocols based on current standards of practice, which address key criteria including clinical indication, contrast administration, age (to indicate whether the patient is pediatric or an adult), patient size and body habitus, and the expected radiation dose range. (See also PI.01.01.01, EP 46)  

Standard PI.02.01.01
The [critical access] hospital compiles and analyzes data.

Elements of Performance for PI.02.01.01
A 6. For [critical access] hospitals that provide diagnostic computed tomography (CT) services: The [critical access] hospital compiles and analyzes data on patient CT radiation doses and compares it with external benchmarks, when such benchmarks are available.
Solutions for Dose Reporting

Fully integrated software – reporting automatic
CTDI\textsubscript{vol} & DLP automatically are stored
Can break out each series DLP & CTDI\textsubscript{vol}
Data base of CT dose information available

Radiologist Dictation

Wastes radiologist’s time
reduces accuracy of data in report
consolidation of metrics bad practice*
no data base of CT dose is produced

*Summed DLP and maximum CTDI\textsubscript{vol}
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Software based analysis of CT doses

CT scans per day

weekends
Software based analysis of CT doses

Individual patient’s cumulative effective dose by organ
Software based analysis of CT doses
Break-down of CT procedures for different CT scanners
Software based analysis of CT doses

Dose by scanner type

ABDM/PELVIS

- GE Medical Systems: 38.126%
- Avg. Dose: 10.1 [mSv]

Siemens: 61.874%
- Avg. Dose: 16.4 [mSv]

Average Effective Dose (ICRP 103) [mSv]
Dose / Device

HEAD CT

- GE Medical Systems: 35.853%
- Avg. Dose: 1.7 [mSv]

Used this data to lobby hospital administration to purchase IR software for our Siemens’ CT scanners
Software based analysis of CT doses

CT protocol review
Software based analysis of CT doses

Protocol review: “What IF” scenarios
SSDE modification to CTDIvol

<table>
<thead>
<tr>
<th>Size-Specific Dose Estimate</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Effective Diameter [cm]</td>
<td>27.738 cm</td>
</tr>
<tr>
<td>Conversion Factor</td>
<td>1.333</td>
</tr>
<tr>
<td>CTDIvol [mGy]</td>
<td>4.36 mGy (Body 32cm)</td>
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<tr>
<td>SSDE [mGy]</td>
<td>5.812</td>
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</tbody>
</table>

Effective Diameter
27.738 cm
Conversion Factor
1.333 (relative to 32 cm)

CTDIvol: 4.36 mGy
SSDE: 5.81 mGy
Software based analysis of CT doses

Protocol review across sites (abd-pelvis)

An eXposure™ dashboard for an annual review of abdomen-pelvis protocols across multiple sites.
### Software based analysis of CT doses

Dose Alerts for patients with high doses

#### Alerts Table

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<th>Type</th>
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<th>Examination</th>
<th>Dose</th>
<th>Description</th>
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<td>001080130X CT ABDOMEN Abdomen WITH/Absent</td>
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<td>00156970X NARONI, Tyrsa X</td>
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1 to 50 of 139 alerts.
Before & After implementation of IR Software

GE CT Scanner Head CTDI\text{vol}: 2010

GE CT Scanner Head CTDI\text{vol}: 2013

with Iterative Reconstruction
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The California CT Dose Law

lessons

MP’s ↔ state legislators

MP’s ↔ state regulators

Local MP alliances can be very useful

The law was intended to solve problem X

But ended up solving problem Y

SB1237 forced us to do what we should have been doing
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