EXPERIENCE WITH CALIFORNIA LAW ON REPORTING CT DOSE

Management and Reporting of Imaging Procedure Dose Education Symposium: AAPM 2013 Indianapolis, Indiana

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DISCLOSURES

- Co-investigator, University of California Dose Optimization and Standardization Endeavor (UC DOSE)
- User, Radimetrics eXposure software (as part of the UC DOSE consortium)

HISTORICAL PERSPECTIVES

- Rapid increase in the availability, capability, and use of CT over the last decade
- Contribution of dose burden by CT for medical imaging of ~50% for 15% of performed exams
- Radiation overdose incidents with CT brain perfusion exams, chiefly in California, resulting in 200+ overexposures in 18 months

Cedars-Sinai, L.A.
EQUIPMENT AND/OR USER FAILURE.....

- 2 ½ year old boy
- 150 scans to same area over a period of 1 hour.....
- Acute erythema in area of scan (5-10 Gy)
- Cataracts, cancer, cognitive impairment are possible outcomes

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

SB1237 – SECTION 115111

- Requires those responsible for CT system operation:
  - To record the dose of radiation for every CT study produced during an exam
  - To electronically send the study and technical factors to the picture archive and communication system (PACS)
  - 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 (CTDIvol)
    - 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

SB1237 – **SECTION 115113**

- 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
    - 0.5 Sv (50 rem) to an organ or tissue
    - 0.5 Sv (50 rem) shallow dose equivalent to the skin
  - Irradiating a body part other than the intended body part (with the same dosage requirements as above)

AB510

- Further clarifies SB1237
  - Section 115111:
    - Nuclear Medicine 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
**AB510**

- **Section 115112**
  - Accreditation not required if:
    - Radiation treatment planning or delivery
    - Attenuation coefficients for Nuc Med studies
    - Image guidance for IR procedures

- **Section 115113**
  - Establishes dose levels for “any individual for whom a physician did not provide approval for the exam” (same dose levels as SB1237)
  - Establishes dose levels for “a CT x-ray for an examination that does not include the area of the body that was intended to be imaged by the ordering physician or radiologist”

**ISSUES**

- Law does not indicate specifics of reporting CTDI$_{vol}$ and DLP…. Summed? By Series?

- Interpretation as to what “reporting” means
  - Access to PACS dose image adequate?
  - What about reconstruction/reformatting procedures that do not deliver dose?

- Failure to comply with law?

**UC DAVIS PERSPECTIVE ON THE LAW**

- Automate transfer of dose metrics to report
- Provide mechanism to report CTDI$_{vol}$ and DLP
- ...... not as straightforward as initially thought
- RIS as repository of data?
- Alternate methods researched .....
- Final solution uses speech dictation system

**UC DAVIS DOSE REPORTING AUTOMATION**
**AUTOMATED POPULATION OF CTDI & DLP**

- 2 values only; multiple exams summed
- No explanatory information / text

**RECOMMENDATIONS FOR COMPLIANCE**

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. This bill takes effect on July 1, 2012, will be enforced by the California Department of Public Health Radiologic Health Branch, and requires the reporting of CT radiation dose, and the reporting of overdoses in particular settings.

**UC DOSE GUIDELINES**

2. **DOSE REPORTING (115111) effective July 1, 2012**

B. Guidelines on How to Comply with this Section of the Law

1. Electronically send ("Push") the scanner's "Dose Report" or "Protocol Page" to your electronic archive (e.g. PACS).

   AND one of the following (2 or 3):

2. Report CTDIvol and DLP for each series in the Radiology Report (see Appendix A).
   a. Include the anatomic area imaged (head, neck, chest, abdomen/pelvis, spine, extremity)
   b. Include the phantom size reference (32cm or 16cm).

   OR

3. Attach the protocol page / dose sheet that includes the radiation dose for each series, to the radiology report.

4. Do not add the CTDIvol and DLP values from different series. Adding them is misleading, inappropriate and may be inconsistent with the meaning of the law; reporting values separately for each series is unambiguous and recommended.

5. In the Radiology Report itself, the UC DOSE consortium recommends explanatory text accompany the reporting of the CTDIvol and DLP numbers. Sample text might include:

   The dose indicators for CT are the Volume Computed Dose Index (CTDIvol) and the Dose Length Product (DLP), and are measured in units of mGy and mGy-cm, respectively. These indicators are not patient dose, but values generated from the CT scanner acquisition factors and may substantially underestimate or overestimate the absorbed dose based on patient size and other factors. A medical physicist or other qualified health professional should be consulted for specific questions regarding the radiation dose for this exam.
REPORTING CTDI & DLP IN REPORT.....

- UC Davis: following UC DOSE recommendations
- Automated solution to include values in report
  + Implementation of dose calculation engine
  + Extraction of series by series CT dose metrics
  + Provision of web-services calls and HL7 messaging
  + Inclusion of user defined message in speech engine
  + Creation of final report in RIS with dose metrics

SYSTEMS INTEGRATION - DOSE REPORTING

- Radiology Interface Diagram
- PACS
- Dose Calculation Software
- Speech Recognition
- RIS
- CT scanner
- DICOM / HL7 Application connector
- PACS/RIS Broker
- Broker & DICOM processor

IMPLEMENTATION CONSIDERATIONS

- Modifying radiologist templates to accept data
- Delays to extract dose data prior to dictation
- Exam splitting requiring assignment of accession numbers with same dose metrics
- Tabular data not handled by HL7 (formatting)
- Radiologists requesting minimal content

SINGLE ACQUISITION EXAM

CT DOSE:

This patient [MRN 2085681] received a total dose of [1] exposure event(s) during this CT examination. The CTDI\textsubscript{vol} and DLP radiation dose values for each series are:

<table>
<thead>
<tr>
<th>Exposure Event</th>
<th>Scan/Series</th>
<th>Anatomic Area</th>
<th>Phantom</th>
<th>CTDI\textsubscript{vol} (mGy)</th>
<th>DLP (mGy-cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>Scout</td>
<td>32 cm</td>
<td>13</td>
<td>402</td>
</tr>
</tbody>
</table>

The dose indicators for CT are the Volume Computed Tomography (CT) Dose Index (CTDI\textsubscript{vol}) and the Dose Length Product (DLP), and are measured in units of mGy and mGy-cm, respectively. These indicators are not patient dose, but values generated from the CT scanner acquisition factors and may substantially underestimate or overestimate the absorbed dose based on patient size and other factors. A medical physicist or other qualified health professional should be consulted for specific questions regarding the radiation dose for this exam.

*** This dose report template is for demonstration purposes only. The dose report template can be configured on a site-by-site basis. ***
**MULTIPLE ACQUISITION EXAM**

Our radiologists want short reports
No more “consult with Medical Physicist”

<table>
<thead>
<tr>
<th>Exposure Event</th>
<th>ScanSeries</th>
<th>Anatomic Area</th>
<th>Phantom</th>
<th>CTDvol (mGy)</th>
<th>DLP (mGy-cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>Scout</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>Abdomen</td>
<td>32 cm</td>
<td>18</td>
<td>343</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>Abdomen</td>
<td>32 cm</td>
<td>21</td>
<td>1136</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>Abdomen</td>
<td>32 cm</td>
<td>10</td>
<td>250</td>
</tr>
<tr>
<td>5</td>
<td>200</td>
<td>Abdomen</td>
<td>32 cm</td>
<td>18</td>
<td>0</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>Abdomen</td>
<td>32 cm</td>
<td>18</td>
<td>346</td>
</tr>
</tbody>
</table>

The dose indicators for CT are the volume Computed Tomography (CT) Dose Index (CTDvol) and the Dose Length Product (DLP), and are measured in units of mGy and mGy-cm, respectively. These indicators are not patient dose, but values generated from the CT scanner’s acquisition factors and may substantially underestimate or overestimate the absorbed dose based on patient size and other factors. A medical physicist or other qualified health professionals should be consulted for specific questions regarding the radiation dose for this exam. *This dose report template is for demonstration purposes only. The dose report template can be configured on a site-by-site basis.*

**TRAUMA CT DOSE REPORTING**

Sometimes the dose report is missing or late
Either gets populated with single DLP value or nothing
Problem is sorting scans after acquisition

**EXAMPLE REPORTS WITH DOSE DATA**

Radiation dose:

- Total DLP for CT brain and C-spine is 1178
- No P.O. contrast was administered

**EXAMPLE REPORTS**

Our radiologists want short reports
No more “consult with Medical Physicist”

DOSE REPORT: This study involved (1) CT acquisition(s). The CTDvol and DLP values are included below as required by state law:

1. Series: 3; Abdomen; 32 cm; CTDvol=17.7 mGy; DLP=856.7 mGy-cm

For further information on CT radiation dose, see [http://www.ucdmc.ucdavis.edu/radiology/RadiationDose.html](http://www.ucdmc.ucdavis.edu/radiology/RadiationDose.html)

RADIATION DOSE:

This study involved (3) CT acquisition(s). The CTDvol and DLP values are included below as required by state law:

1. Series: 3; Chest; 32 cm; CTDvol=2.9 mGy; DLP=3 mGy-cm
2. Series: 3; Chest; 32 cm; CTDvol=26.4 mGy; DLP=26 mGy-cm
3. Series: 2; Chest; 32 cm; CTDvol=13.5 mGy; DLP=632 mGy-cm

For further information on CT radiation dose, see [http://www.ucdmc.ucdavis.edu/radiology/RadiationDose.html](http://www.ucdmc.ucdavis.edu/radiology/RadiationDose.html)

**EXAMPLE REPORTS WITH DOSE DATA**

Linked studies often have same dose data; others have different accession numbers

**Exam: CT ABDOMEN + CT PELVIS WITH CONTRAST**

**DATE OF STUDY:** 10/9/2012 2:41 AM

**CLINICAL INFORMATION:** Signs/Symptoms or Diagnosis: Pelvic CT Scan

**TECHNIQUE:** Helically acquired contrast enhanced multidetector CT of the abdomen and pelvis acquired in the portal venous phase, extending from the lung bases through the kidneys. Unfractioned administration of 125 ml of Omnipaque 350 injected at a rate of 2.5 ml/sec. Images are reconstructed in the axial plane with subsequent reformatting in coronal and sagittal planes.

**DOSE REPORT:**

**COMPARISON:** None

**FINDINGS:**

There is no acute fracture of the pelvic bones.

There is moderate collapse of the disk with diffuse similar bulging with kyphosis at C4-5 with partial uncovering of the left C4-5 facet.

The following accession numbers are related to this dose report:

3563977

3563978
WEBSITE FOR INFORMATION

- Reduce verbiage in report
- Currently “too technical”

AUDIT OF DOSE REPORT COMPLIANCE

September 15-25 (random audit)
83.4% compliance

October 9 (all scans audited)
91.5% compliance

November 29 (all scans audited)
95.4% compliance

Findings:
- Speech templates improperly set up
- Reports are sometimes not generated, and radiologists fail to populate dose
- Many studies do not result in patient dose (e.g. reconstructions)

UC DOSE GUIDELINES....

3. FACILITY ACCREDITATION (115112) Effective July 1, 2013

3B. Guidelines on How to Comply with this section of the Law

Get all equipment (inpatient, outpatient) accredited by one of the organizations approved by CMS/CDPH.
The three approved accreditation bodies are:

1. The American College of Radiology CT accreditation program
   http://www.acr.org/accreditation/computed.aspx
2. The Joint Commission
   http://www.jointcommission.org/accreditation/diagnostic_imaging_centers.aspx
3. Intersocietal Commission for Accreditation of CT Laboratories (ICACTL)
   http://www.acactl.org/acactl/index.htm

DETERMINATION OF REPORTABLE DOSE

- Section 3 (115113)
- An Effective Dose (E.D.) that exceeds 0.05 Sv (5 rem)
- A dose in excess of 0.5 Sv (50 rem) to any organ or tissue
- Shallow dose to the skin of 0.5 Sv (50 rem) to the skin
- Dose to fetus that is greater than 50 mSv (5 rem)

- Reporting dose with the current limits is unlikely except for dose to the fetus in certain circumstances

- A medical physicist should be involved in any formal dose estimation
RECOMMENDATIONS:

4. MEDICAL EVENT REPORTING (115113) Effective July 1, 2013

- California Clinical and Academic Medical Physicists (C-CAMP)
  - [Link to SB-1237Section3_v7.pdf]
  - John M. Boone: University of California Davis
  - Christopher Cagnon: University of California, Los Angeles
  - Melissa Martin: Therapy Physics, Inc. Gardena, CA
  - Michael McNitt-Gray: University of California, Los Angeles
  - Thomas R. Nelson: University of California, San Diego
  - J. Anthony Seibert: University of California Davis

PATIENT EFFECTIVE DOSE ≥ 50 mSv

- Determine DLP with appropriate k-factor that would result in effective dose ≥ 50 mSv
- Two tables required
  - CTDIvol and DLP determined with 16 cm diameter phantom for pediatric body exams
  - CTDIvol and DLP determined with 32 cm diameter phantom for pediatric body exams

DLP VALUE: REPORTING THRESHOLDS

- CTDIvol and DLP with 16 cm phantom for pediatric body exam

<table>
<thead>
<tr>
<th></th>
<th>0 year old</th>
<th>1 year old</th>
<th>5 year old</th>
<th>10 year old</th>
<th>adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>head &amp; neck</td>
<td>3840</td>
<td>5800</td>
<td>8770</td>
<td>11900</td>
<td>16120</td>
</tr>
<tr>
<td>head</td>
<td>4540</td>
<td>7460</td>
<td>12500</td>
<td>15620</td>
<td>23800</td>
</tr>
<tr>
<td>neck</td>
<td>2540</td>
<td>4160</td>
<td>4540</td>
<td>6320</td>
<td>8470</td>
</tr>
<tr>
<td>chest</td>
<td>1280</td>
<td>1920</td>
<td>2770</td>
<td>3840</td>
<td>3570</td>
</tr>
<tr>
<td>abd/pelvis</td>
<td>1020</td>
<td>1660</td>
<td>2500</td>
<td>3330</td>
<td>3330</td>
</tr>
<tr>
<td>trunk (C/A/P)</td>
<td>1130</td>
<td>1780</td>
<td>2630</td>
<td>3570</td>
<td>3330</td>
</tr>
</tbody>
</table>

- CTDIvol and DLP with 32 cm phantom for pediatric body exam

<table>
<thead>
<tr>
<th></th>
<th>0 year old</th>
<th>1 year old</th>
<th>5 year old</th>
<th>10 year old</th>
<th>adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>head &amp; neck</td>
<td>3840</td>
<td>5800</td>
<td>8770</td>
<td>11900</td>
<td>16120</td>
</tr>
<tr>
<td>head</td>
<td>4540</td>
<td>7460</td>
<td>12500</td>
<td>15620</td>
<td>23800</td>
</tr>
<tr>
<td>neck</td>
<td>2940</td>
<td>4160</td>
<td>4540</td>
<td>6320</td>
<td>8470</td>
</tr>
<tr>
<td>chest</td>
<td>550</td>
<td>830</td>
<td>1200</td>
<td>3840</td>
<td>3570</td>
</tr>
<tr>
<td>abd/pelvis</td>
<td>440</td>
<td>720</td>
<td>1080</td>
<td>3330</td>
<td>3330</td>
</tr>
<tr>
<td>trunk (C/A/P)</td>
<td>490</td>
<td>770</td>
<td>1140</td>
<td>3570</td>
<td>3330</td>
</tr>
</tbody>
</table>

ORGAN DOSE THRESHOLD: 500 mSv

- “Cumulative CTDIvol” if same anatomic region scanned multiple times (and organ included)
  - Scans with table movement
    - Pediatric: cumulative CTDIvol ≥ 200 mGy
    - Adult: cumulative CTDIvol ≥ 250 mGy
  - Scans with no table movement (e.g., neuroperfusion)
    - Pediatric: cumulative CTDIvol ≥ 650 mGy
    - Adult: cumulative CTDIvol ≥ 650 mGy
SKIN DOSE THRESHOLD: 500 mSv

- Want to identify scans resulting in a peak skin dose that exceeds 500 mGy (multiple scans with no table motion)
  + DLP tends to underestimate
  + CTDI\text{vol} tends to overestimate (30 to 100%)

- Use recommendations for organ dose threshold

FETAL DOSE THRESHOLD: 50 mSv

- This event may occur in certain clinical scenarios
  + Scans with table movement
    - Cumulative CTDI\text{vol} of abd/pelvis $\geq 25$ mGy
  + Scans with NO table movement (abd/pelvis perfusion)
    - Cumulative CTDI\text{vol} of abd/pelvis $\geq 65$ mGy

CURRENT SITUATION – DOSE REPORTING

- Since July 1, 2012, there have been no (0) reported CT overdose events to California DPH
  + Likely due to very high dose reporting requirements
  + Lower threshold dose limits needed?

- In the last month, 3 reportable therapy events
  + Wrong patient or wrong treatment site

- No cases referred for escalated enforcement action
  + Prior compliance history to be taken into account

- The state has not yet evaluated compliance to section 115111 and reporting CTDI & DLP .....
**SUMMARY**

- California dose reporting law – national attention
- Resultant emphasis on CT dose and safety
- Compliance & oversight by state is imminent
- Non-compliance? Notice of Violation (NOV)
- Multiple NOV’s: financial $$ penalties

**WHERE TO GET INFORMATION.....**

- UC DOSE (rorl.radiology.ucsf.edu)
- AAPM (aapm.org)