North Carolina CT Brain Perfusion Exposure Survey Summary
10/08/09
• FDA-Initial Communication

12/08/09
• FDA announces Safety Investigation of CT Brain Perfusion Scans

02/2010
• Conference of Radiation Control Program Directors forms H-39 Task Force
Excess radiation during CT brain perfusion scans, which are used to aid in the diagnosis and treatment of stroke had been reported.

• 206 patients had been exposed to excess radiation at one facility.
• Further investigation identified over 250 patients exposed to excess radiation at multiple facilities.
• Some received as much as eight times the expected level.
12/8/09 Update FDA - Safety Investigation of CT Brain Perfusion Scans

**FDA**
- Encouraged CT facilities to review their protocols.
- Assess whether any patients received excess radiation during CT perfusion scans.

**FDA**
- Review radiation dosing protocols for all CT perfusion scans to ensure that the correct dosing is planned for each study.
- If more than one study is performed on a patient during one imaging session, adjust the dose of radiation so it is appropriate for each study.

**FDA**
- Implement quality control procedures to ensure that dosing protocols are followed every time and the planned amount of radiation is administered correctly.
- Advised manufacturers to review their training for users.
Based on the FDA investigation, the CRCPD developed the H-39 Task Force on CT Brain Perfusion Exposure Survey.
Review

• Review all available FDA information regarding the CT brain perfusion investigation and all available information regarding the recent overexposures.

Develop

• Develop a survey tool for states to query CT facilities performing brain perfusion studies that reveals potential issues with past or current protocols, and helps ensure that future patients are not being overexposed.

Survey

• Oversee distribution of the survey and data collection efforts for facility procedures and technical factors used in conducting perfusion exams.
H-39 Task Force Survey Details
Three ways to Collect Data

1. Surveyors visit each facility in person, completing the survey on site and performing radiation measurements.

2. If resources prohibit making radiation measurements, the rest of the survey can be completed on site, using dose values reported by the scanner dose reports.

3. If on-site surveys are not possible, the survey may be conducted by telephone interview, acquiring as much survey information as possible.
How many CT Brain Perfusion Studies were performed in North Carolina in 2010?

588
NC Survey Process

- **October 2010**: CRCPD sends survey instructions to all State Radiation Control Directors
- **November 2010**: NC Radiation Protection Section Forms Survey Team
- **December 2010**: Begins Screening Process
- **January 2011**: NC Radiology Compliance Branch Completes Survey
Survey Team

Support

Jenny Rollins
Amy Sawyer
Kahee Kim
\textit{UNC-Chapel Hill}
Bradford Taylor
Dr. Marija Ivanovic

Surveyors

Christy Britt
Amy Harmon
Bonnie Kanoy
Laura Pring
Wynette Shumate
How many CT Scanners are Registered in North Carolina? (Non-Federal Facilities)

- 253 in Hospitals
- 258 Clinics
- 20 Research
- 3 Mobiles
- 6 Veterinarians

Total CT Scanners: 540
How Many NC Facilities Perform CT Brain Perfusion Studies?

- 11 Facilities performed CT BPS
- 352 Facilities Screened
- 540 CT Scanners
Manufacturers of CT Units

- Philips: 5
- Siemens: 7
- General Electric: 11
- Toshiba: 0
Accreditation

Stroke Center Accreditation
- 9 - Joint Commission
- 1 - American Heart Association
- 1 - No Accreditation

Scanner Accreditation
- 18 - American College of Radiology (ACR)
- 0 - Intersocietal Accreditation Commission (IAC)
- 0 - The Joint Commission
- 5 - None
CT Operators and Interpreting Staff Credentials

Technologist
- 100% (248) American Registry of Radiologic Technologist
- 94% (233)(ARRT)(CT) Advanced Certification

Interpreting Staff
- Lead physician responsible for changes to protocol
- 100% Neuroradiologist
Is dose information displayed on CT monitor?
• 100% ALL SCANNERS

Is a dose report provided to the physician?
• 82% YES
• 18% NO

If yes, does the interpreting physician review the report?
• 8-YES
• 1-NO
• 1-UNKNOWN
• 1–NO REPORT
Are the patient doses permanently recorded?

- 100% YES

Is there a procedure for reporting unusual or excessive CT DLP information?

- 45% YES
- 55% NO
Does the facility have a procedure in place for changing the protocol on the CT scanner?

- 63% Yes
- 27% No
- 0.09% Unknown

Are the protocols password protected?

- 64% YES
- 36% No
Current Protocol Vs. Past Protocol

- FDA Alerts
- Media

46% Yes
54% No

- AAPM
- Clinical Trial
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<thead>
<tr>
<th></th>
<th>CTDIvol</th>
<th>Before</th>
<th>After</th>
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<tbody>
<tr>
<td>Lowest Gy CTDIvol</td>
<td></td>
<td>0.133</td>
<td>0.100</td>
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<tr>
<td>Average Gy CTDIvol</td>
<td></td>
<td>0.649</td>
<td>0.459</td>
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<tr>
<td>Highest Gy CTDIvol</td>
<td></td>
<td>1.899</td>
<td>1.545</td>
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How do our CTDIvol numbers compare with the data currently available?

- **11/9/10**
  Update FDA-Safety Investigation of CT Brain Perfusion Scans

- **11/10/10**
  FDA Radiation Dose Quality Assurance: Questions and Answers

- **2/04/11**
  FDA Additional Clarification of 0.5 Gy CTDIvol “expected or typical level”
Summary of Problem and Scope

Follow-up Investigation

Clarification of “expected level”

Updated Recommendations for Facilities and Practitioners

Reporting Problems to the FDA

11/9/2010 FDA Update-Safety Investigation of CT Brain Perfusion Scans
At the time of the Oct. 8, 2009 Initial Communication, the FDA knew of 206 patients exposed to excess radiation at one facility, the Cedars-Sinai Medical Center. As of October 26, 2010, the agency is aware of approximately 385 patients from six hospitals who were exposed to excess radiation during CT brain perfusion scans.

Some patients reported obvious signs of excessive radiation exposure following their scans, such as hair loss or skin redness, which called attention to the problem. It is important to note that if patient doses are higher than the expected level, but not high enough to produce obvious signs of radiation injury, the problem may go undetected and unreported. Over time, excessive radiation exposure can place patients at increased risk for long-term radiation effects, such as cancer.

Patients should follow their doctors’ recommendations for receiving CT scans. A medically-needed CT scan that does not expose the patient to unnecessary radiation has benefits that far outweigh the radiation risks.
Cases of overdose involved GE Healthcare and Toshiba scanners. FDA inspected and no violations found.

The FDA evaluated the manufacturers’ specifications and found no evidence that they were involved in modifying any of the hospitals’ scanning protocols so as to cause the overexposures.

Investigation did reveal improvements that industry could make to its equipment, user information and training. In a letter dated Nov. 8, 2010, FDA communicated to industry a need for better instructions for use and more information to users about manufacturers' default protocols.
Clarification of “expected level”

Point Two: Imaging professionals responsible for conducting CT procedures must define the equipment parameters needed to provide an adequate image at the lowest dose possible. While it is inappropriate to designate a maximum dose, dose limit or universal optimal dose for brain perfusion exams or diagnostic imaging procedures in general, the FDA provides information on how to determine if the dose associated with a given protocol is reasonable.

Point One: Value referred to a measurement of peak skin dose for the unmodified Cedars Sinai brain perfusion protocol, dose value was also found to be within the range expected from literature. This value did not refer to a computed tomography dose index (CTDI) measurement.

FDA’s Initial Communication of Oct. 8, 2009 describes “expected level” for typical radiation dose of 0.5 Gy for a CT brain perfusion scan. FDA clarifies two points:
The FDA recommends that each facility set its own alert level for brain perfusion studies beyond which further review by a physicist, radiologist, and quality assurance committee may be necessary. Based on FDA’s review of the literature, a reasonable alert level could be set at 1 Gy CTDI$_{vol}$. Any alert level should not be misinterpreted as a cutoff or limit, as there may be good reasons for exceeding it.
1. If you suspect a problem with a CT device, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting Program.

2. Device manufacturers and device user facilities, which include many health care facilities, must comply with the Medical Device Reporting (MDR) Regulations of 21 CFR Part 803.¹

3. Health care personnel employed by facilities that are subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.
Do dose-index values typically fall in a range that could be inferred from the medical and scientific literature?

While a range of dose-index values is reported in the literature, a value of 0.5 Gy can serve as a useful indicator of the order of magnitude of the average CTDIvol for brain-perfusion scans.

Manufacturer-defined protocols should be used as starting points that may need revision to be appropriate for a particular patient or facility.
So, while there are not enough data yet to identify a value for CTDIvol that can be definitively labeled "typical" or "expected," the limited information publicly available and analyzed late in 2010 suggests that a CTDIvol value of 0.5 Gy is "a useful indicator of the order of magnitude of the average CTDIvol for brain-perfusion scans." In other words, it is currently reasonable to reference 0.5 Gy CTDIvol as an indicator of the magnitude of dose associated with the contrast-perfusion phase of a CT brain-perfusion study.
June 2011 CRCPD to Present a “White Paper”

- Explanation of the CT brain perfusion study
- Background information on operation of the CT

- Units by manufacturer in the initial incident
- Survey that the task force developed

- Survey results presented in detail
- Recommendations for all interested parties