

To The Patient Safety Steering Committee

Thank you for the opportunity to present additional information of why I believe you should endorse the proposed measure of CT Radiation Dose, Measure PSM-044-10.

As a reminder, the measure calls for a) the collection of facility level measures of CT radiation dose – typical doses used at each facility b) the documentation of radiation dose in the medical record – i.e. more recording of dose information is better and c) participation in a radiation dose audit program that would permit comparison of a facilities performance to other facilities.

I have provided further information / comments on the following

**1. Background on the metrics chosen for this measure and how these dose metrics closely reflect the doses to which patients are exposed.** I highlight some of our work collecting these proposed dose indices across 12 large institutions reflecting dozens of machines and thousands of patients, thereby demonstrating the feasibility for collecting these dose measures. [Pages 2 – 7]

*In summary: The proposed dose parameters reflect the radiation dose that a patient is exposed to and dictate the absorbed organ doses to the patient. These are precisely those measures crucial to measure in order to understand the safety of imaging, and these measures can be easily and reliably collected.*

**2. Descriptions of current programs that collect these dose indices [Page 8].**

*These measures have been widely used for over a decade in several other countries, are called for in a bill that has passed the California State legislature to be collected beginning in 2012,*

**3. Response to the AAPM comment [Page 9]**

*The comment highlighting the importance of patient weight is relevant to understanding the appropriateness of dose used for an individual patient. This is not relevant towards consideration of a measure which is to be evaluated at the facility level. While patient size may influence dose by 2-3 fold (between the smallest and largest patients) other factors, such as choice of specific protocol, can influence the dose by up to 100 fold, and these factors, rather than individual patient weight, will drive the facility level dose indices measures. Lastly the measure calls for collecting dose information by age group, and thus there is no risk of mixing up doses for child and adult patients.*

**4. Excerpts from letters of support from two leading physicists** who are actively involved in this area who strongly support the measure as written, including a past president of the American Association of Physicists in Medicine and the leader of the National Council on Radiation Protection (NCRP) efforts in this area. [Page 10]

**5. A context for understanding how an audit program** could lead to immediate and practical improvement in dose by collecting/ assembling dose data across sites, and creation of reference levels. I provide a few tables/graphs showing distribution of dose indices from our data and from the ACR dose registry. [Pages 11-12]

Thank you for your ongoing consideration of this measure. I believe this could have an immediate impact on quality and very much appreciate your willingness to discuss it again..

Rebecca Smith-Bindman, MD  
Measure Developer  
Professor  
University of California San Francisco  
Radiology and Biomedical Imaging,  
Epidemiology and Biostatistics,  
Obstetrics Gynecology and Reproductive Sciences

## **1. BACKGROUND ON THE METRICS CALLED FOR IN THIS MEASURE, THEIR VALIDITY AND EASE OF COLLECTION.**

The Proposed CT Dose measure calls for the collection of several metrics reflecting CT dose indices including DLP, CTDI and Effective Dose. CTDI and DLP are calculated and displayed by all current CT scanners, and Effective dose reflects a combination of the dose measure the CT machine generates and a measure of how harmful that dose may be to the patient based on the site of the body that is radiated and the age of the patient.

Each metric reflects slightly different aspects of dose, and each was included because it provides a unique reflection of dose and can be used to improve quality and safety.

These dose parameters all reflect the dose that the patient is exposed to and *dictate the absorbed organ doses to the patient*. Absorbed doses will vary by sex and weight, but are *primarily* determined by the doses that come out of the machine. These measures are highly correlated with the doses patients receive; higher DLPs, CTDIs and Effective doses are associated with higher absorbed dose to the patient's organs and higher patient detriment (harm). If these doses were lowered patients would be exposed to lower doses of radiation, have correspondingly lower absorbed organ doses and would be expected to have less detriment from these exposures to radiation. I am surprised there were concern from the comments and committee members regarding the importance of these measures are reflecting what happens to the patients.

The dose parameters themselves are vitally important as they 1) closely reflect organ doses and details are provided below to help you see this relationship and 2) are precisely those measurements that the technologist and physician can influence to lower doses. That is why these measures were chosen for this metric. Estimating absorbed organ doses would be a more precise way to compare doses between two examinations, however, this is simply not practical. It is much more complicated to estimate these parameters, there are over 30 different organs where these doses can be compared (making it computationally impossible to compare facilities and quality) and it does not make sense to measure because the technologist cannot directly influence these. Thus while using organ dose might add a very small amount to precision, its not clear that its relevant feasible and thus organ dose was not proposed as a practical or useful metric for patient safety assessment. In contrast, the output of radiation from the machine is far simpler to measure and in fact is the important variable, as this is what the radiologist and the technologist can influence. As pointed out by Dr Brink, Chair of Radiology at Yale who wrote a comment, the measures are primarily proposed to reflect the average CT dosing at the institutional level and small variations in patient size will average out across institutions. The further measure of effective dose reflects the age of the patient, the most important second variable after dose from the machine in predicting future cancer risk

I have collected the proposed measures across 12 institutions. My work describing DLP and Effective Dose across four Bay Area institutions were published last year in the Archives of Internal Medicine. An ongoing NIH study is being conducted across 8 HMOs (including small and large facilities) where data collection is complete. We successfully collected CTDI, effective dose and several other dose metrics with relative ease and I am sharing some of those results in this summary below. Please do not circulate – as they are not yet published. These results reflect the collection of dose indices across thousands of patients, ranging in age and size from newborn through adults age 30 years. These results show 1) the feasibility of collecting the proposed dose information 2) the need for a quality metric as the doses are much higher and more variable than they need to be and 3) demonstrate that the dose metrics are highly correlated with organ doses.

The organ doses were calculated by Dr. Choonsik Lee, PhD an Investigator in the Radiation Epidemiology Branch, in the Division of the Cancer Epidemiology and Genetics at the National Cancer Institute. His research includes the development of dosimetry databases and Monte Carlo dose calculations using human models that permit estimating absorbed radiation dose that takes into account patient weight. His method for estimating organ doses has been validated against direct measurement. (Organ doses for reference adult male and female undergoing computed tomography estimated by Monte Carlo simulations. Choonsik Lee, Kwang Pyo Kim, Daniel Long, Ryan Fisher, Chris Tien, Steven Simon, Andre Bouville, and Wesley Bolch. In Press Medical

Physics) These data were generated quickly to demonstrate the strong relationship between the dose measures and organ doses, but the data are not final (there are outliers that have not yet been explored.) Several graphs were generated to demonstrate the association between the CTDIvol (abbreviated as CTDI) and Effective Dose measurements and absorbed organ specific doses to relevant organs based on abdominal, chest and head CT.

The data shown in the Tables that follow reflect doses recorded from several thousand CT examinations and corresponding calculations of patient absorbed doses. There is no other publication that demonstrates these relationships.

## **TABLES**

### **1. Abdominal CT (the most common CT performed in the US accounting for 25% of all CT exams in US)**

1a CTDI vs. Absorbed Dose to the Colon (the results for other abdominal organs nearly identical)

1b CTDI vs. Absorbed Dose to the Colon *showing ACR* Accreditation program threshold of 20-25 CTDI

1c Effective Dose versus Absorbed Dose to the Colon

### **2. Chest CT**

2a. CTDI vs. Absorbed Dose to the Breast

2b. CTDI vs. Absorbed Dose to the Breast showing UK QC threshold

2c. Effective Dose vs. Absorbed Dose to the Breast

### **3. Head CT**

3a. CTDI vs. Absorbed Dose to the Brain

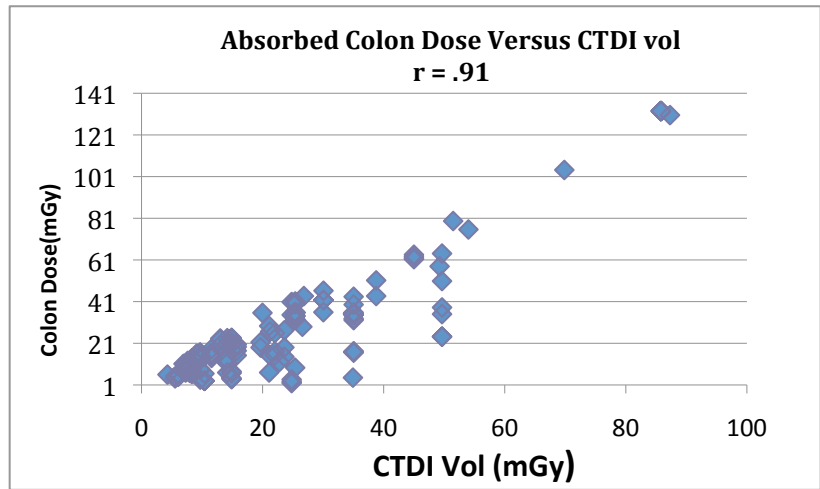
3b. CTDI vs. Absorbed Dose to the Brain, *showing ACR threshold*

3c. Effective Dose vs. Absorbed Dose to the Brain

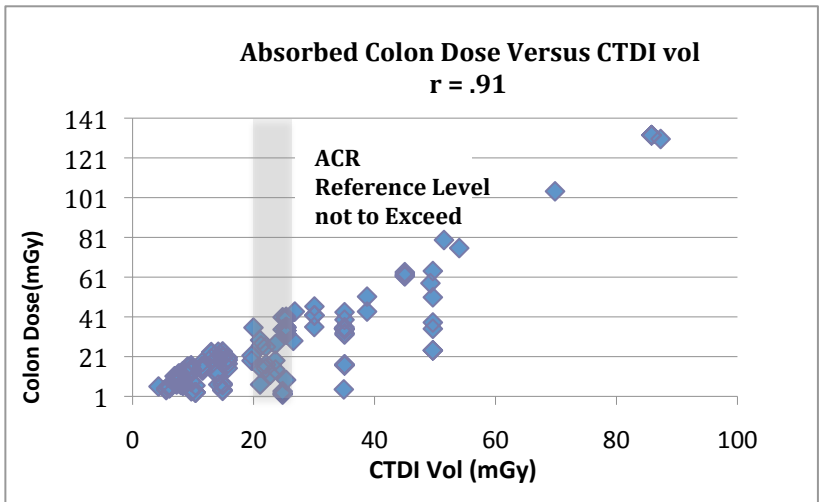
### **4. Comparison of Organ specific absorbed doses by age (a proxy for size) adjusted to CTDI. Demonstrates the modest importance of size, and the variation in the predictive value of CTDI for various organ doses.**

**Table 1. Abdominal CT**

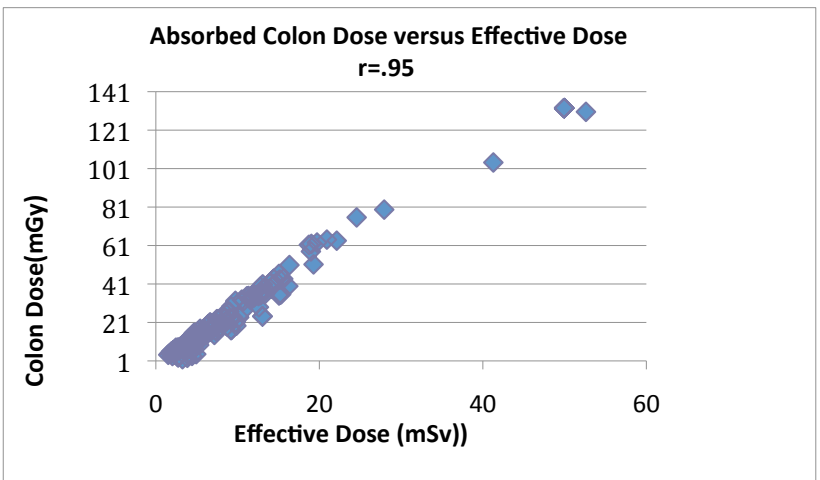
**1 a. CTDI vs. Colon Dose.**



**1b. CTDI vs. Colon Dose showing the ACR Accreditation program threshold of 20-25 CTDI**

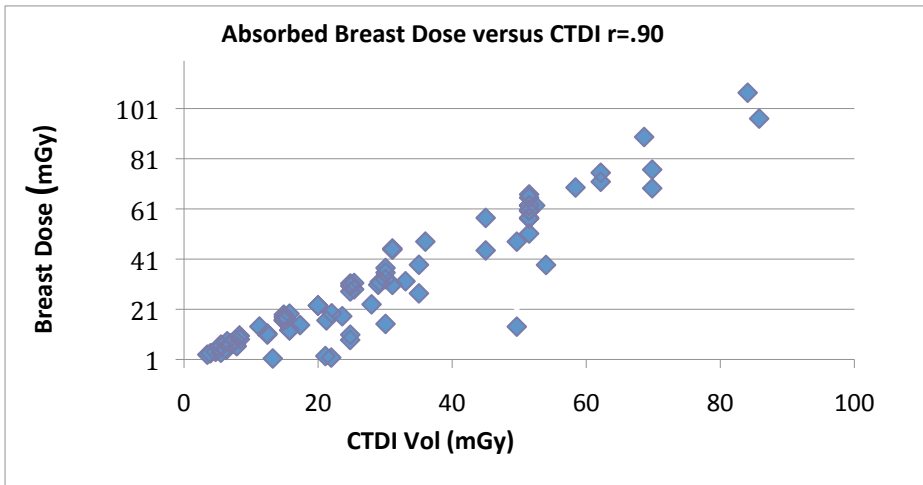


**1c. Effective Dose vs. Colon Dose**

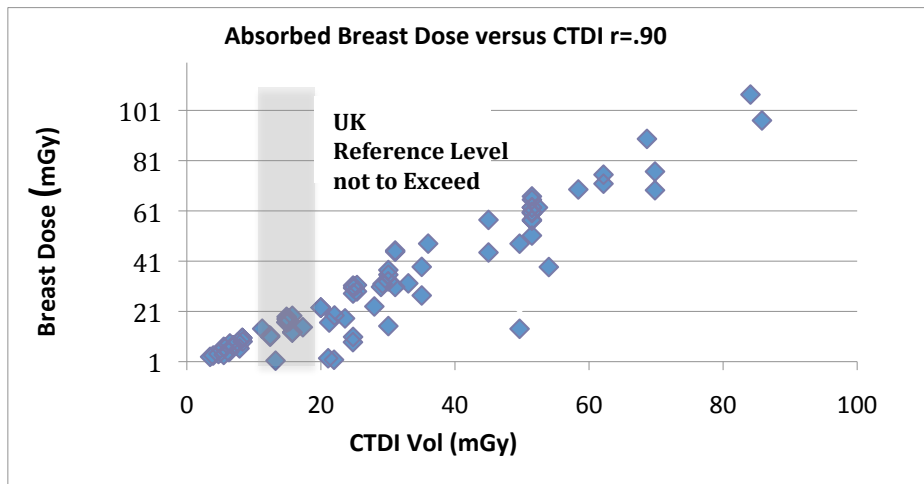


## 2 Chest CT

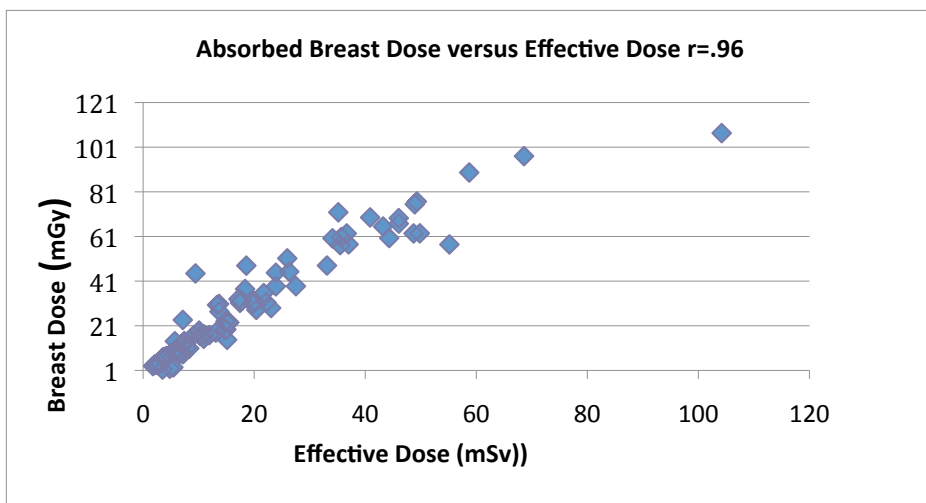
### 2a. CTDI vs. Absorbed Dose to the Breast



### 2b. CTDI vs. Absorbed Dose to the Breast showing UK QC threshold

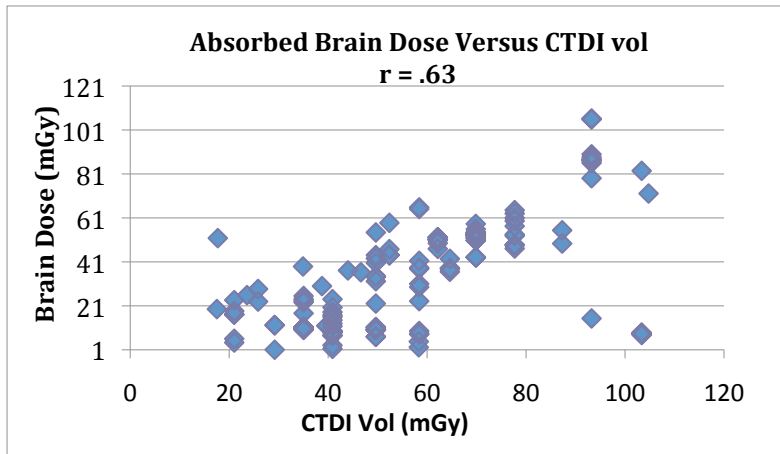


### 2c. Effective Dose vs. Absorbed Dose to the Breast

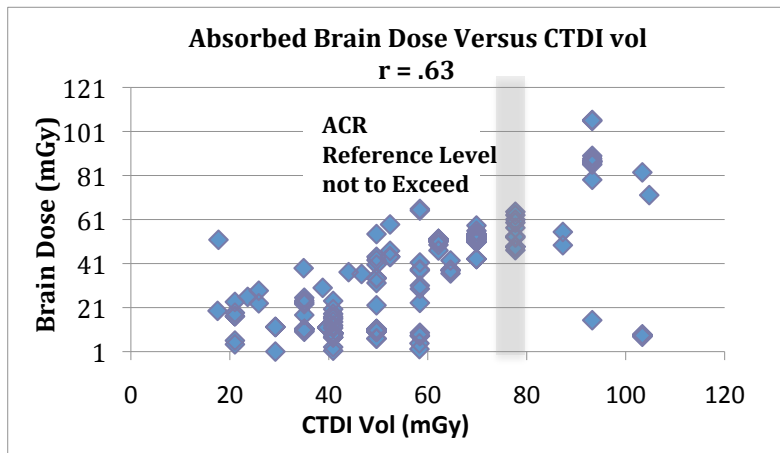


### 3. Brain CT

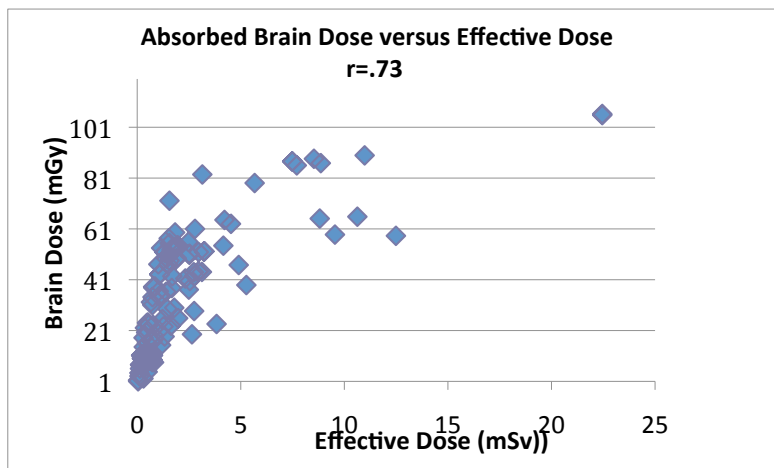
#### 3a. CTDI vs. Absorbed Dose to the Brain



#### 3b. CTDI vs. Absorbed Dose to the Brain, showing ACR Accreditation program threshold



#### 3c. Effective Dose vs. Absorbed Dose to the Brain

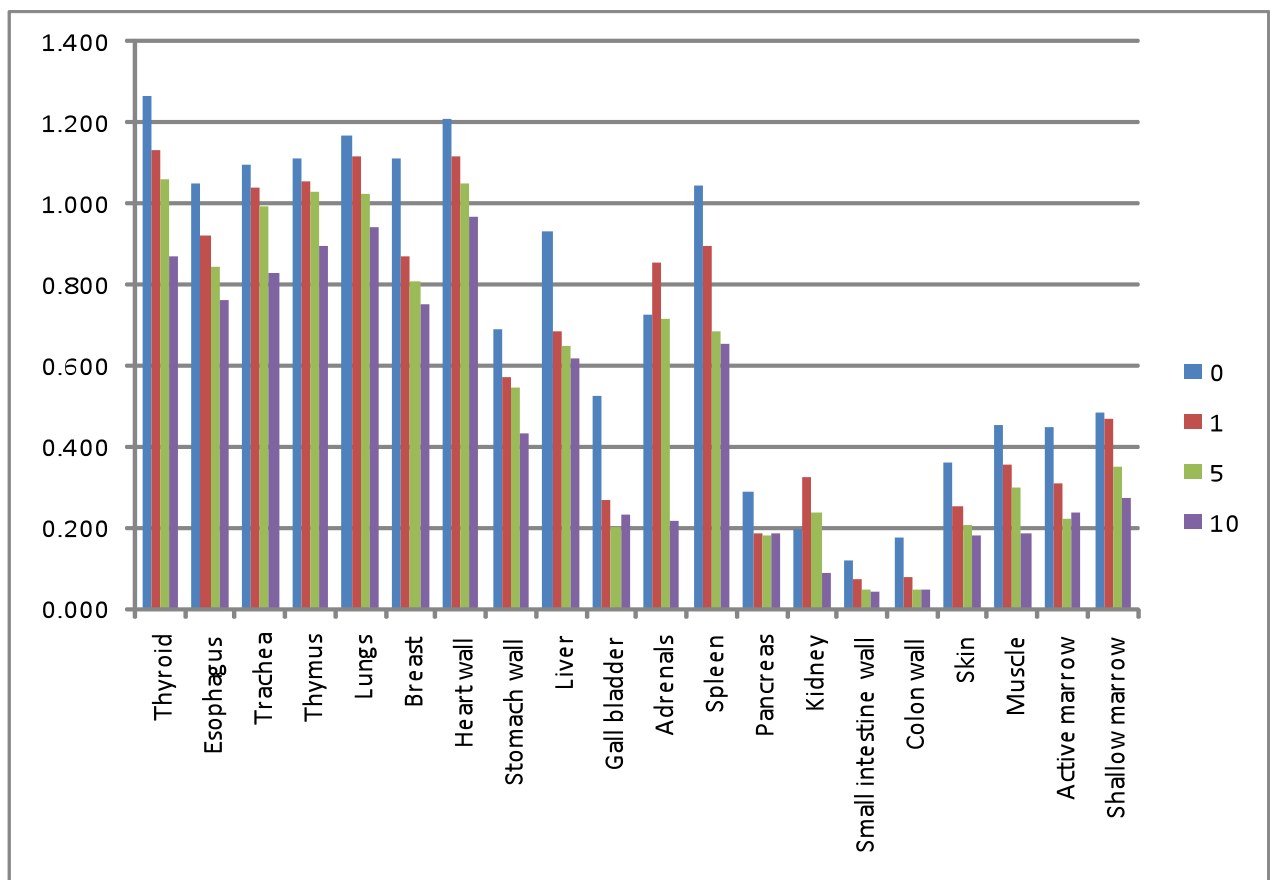


**Table 4. Comparison of CTDI and organ specific absorbed doses by age (a proxy for size.)**

The Y axis is organ doses (mGy) normalized to CTDIvol (mGy) and this graph is for a Chest CT. For each cluster of 4 lines, you can see the difference in absorbed dose by patient size – the smaller patient will have the higher dose – blue line- compared with the larger patient, purple line.

The closer the lines to a CTDI of 1, the closer the CTDI will reflect organ doses. The organs to the right tend not to be within the radiation area of a chest CT and thus the dose to these organs is not reflected in the CTDI

Of note – The average weight of a newborn is 8 pounds and the average weight of a 10 year old is 80-100 pounds (thus a huge 10 fold difference in weight). This demonstrates the importance of size (note the difference in organ doses between the smallest patient, blue line, and the largest patient, purple line) within each organ, can be 50% or so higher although this is relatively modest considering that the weight difference is 10 fold different between these extremes. The variation in the CTDI settings can be 10 or 100 fold difference between sites.



## **2. FEASIBILITY OF COLLECTING THESE DOSE MEASURES**

Each of the proposed measures were developed for the purpose of understanding the dose used in CT, have been discussed and agreed upon by the large community of physicists who work in this area. These are broadly considered the best (and only measures available) to quantify doses used in CT in a reliable, valid and meaningful way.

Large quality assessment and improvements programs have collected all of these measures successfully.

The **US FDA** has collected and quantified CTDI by anatomic areas for many years through collaboration with State radiological protection programs. The most recent data describing CTDI<sub>vol</sub> were collected in 2005, including a national survey of CTDI from a random cross sectional of facilities that conduct CT across all US states. Over 95% of scanners at that time provided CTDI measurements and the number has improved substantially. Jeffrey E. Shuren is the director of the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA) and wrote a letter of support for this measure that was submitted with the measure, highlighting the importance of these dose indices.

**From:** "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>  
**Date:** March 26, 2010 8:31:04 AM EDT  
**To:** "Rebecca Smith-Bindman" <rebecca.smith-bindman@radiology.ucsf.edu>  
**Subject:** National Quality Forum

Rebecca,

National Quality Forum adoption of a metric of CT radiation dose for purposes of quality assurance is a good idea. I believe your proposal is a reasonable starting point for improving quality, as long as it is part of a more comprehensive program. In addition, the Food and Drug Administration (FDA) is on the record as favoring facility monitoring of CTDI<sub>vol</sub> and DLP. The idea of facility monitoring of CTDI<sub>vol</sub> and DLP was the core recommendation of the FDA's initial public communication following the disclosure of over-exposures associated with CT brain perfusion scans at Cedars-Sinai Medical Center, and the concept of facility development and compliance with locally established diagnostic reference levels (DRLs) is discussed in the FDA white paper on dose reduction.

Jeff Jeffrey Shuren, M.D., J.D.  
Director, Center for Devices and Radiological Health  
Food and Drug Administration

Further, all of the proposed measures have been collected and monitored at the facility level for over a decade in the UK and other European Countries, and thus what I am proposing is in no way novel, or controversial. Please see enclosed publications of dose data from the UK dose quality assurance programs (NRPB-SR250: Normalized Organ Doses for X-Ray Computed Tomography Calculated Using Monte Carlo Techniques) and from the Spanish quality assurance program (Automated Effective Dose Estimation in CT, Gracoa et al. Radiation Protection Dosimetry (2010), Vol. 138, No. 1, pp. 71–77). I had several correspondences with Dr. Shrimpton who has run the UK program since its inception who provided comments as well as support of the measure.



### 3. Response to the AAPM comment

#### Comment

*While this measure is well intended, we believe there are problems with this approach that will not allow it to be used as intended, primarily because size of the patient is NOT taken into account. That is, as described below, it is entirely appropriate for dose indices to vary with patient size; however if one only looks at the dose index value - without any information about patient size - it is impossible to determine whether variations in the dose indices between patients for a given exam type are due to appropriate adaptations of system output to differences in patient size or inappropriate variation in protocols. This has tremendous implications for making appropriate adjustments for patient size, such as reducing tube output for pediatric patients. If a site is looking to reduce the variation in a dose index value, without any information about patient size, then this could lead to a lack of adjustment for patient size or diagnostic task. This would result in a one size fits all approach to adjusting scanner output - which may lead to the same technical factors being used for both pediatric and adult patients - and which goes against what we know is appropriate clinical practice. Therefore, we recommend that this proposal either be modified or delayed until it can be implemented with appropriate information recorded (i.e., some index of patient size); otherwise, variations in dose indices that are entirely appropriate may be (and already have been) interpreted as being inappropriate variations within a clinical practice.*

#### Response

The measure calls for collection of patient dose indices within very clear size strata, including infant (<1 years); small child (1-5 years); medium child (>5 – 10 years); large child (>10-15 years) and adult (>15 years). These patient age groups were chosen based on the variation of CT settings and resulting radiation dose based on patient size and these size categories are used by The ICRU (International Commission on Radiation Units and Measurements) . Thus there is no risk of this CT dose measure mixing together child and adult protocols as suggested by the authors of this comment. All facility level assessment will be done within the size strata. Facilities will therefore try to minimize the doses they use within each strata, not across strata. If facilities do not perform CT in children, they will not collect or report this measurement. There is no way to imagine this measure will lead to the use of a one-size fits all approach.

As demonstrated in the proceeding sections, the dose indices will strongly predict absorbed doses. There will be some variation in those absorbed doses by patient size (see Tables 3 and 4 above) but these will be relatively small compared to the differences *between the* types of protocols that are used. The difference in protocols can lead to profound differences in doses (see Tables 5 below and our prior report in the Archives of Internal Medicine.) This while differences in protocols can lead to 10 fold, or 100-fold difference in the doses, patient size may account for a 1-3 fold difference, even when weight varies profoundly as shown between an 8 pound and 80 pound child in Table 4. To forgo assessing the big picture (current practice where dose varies 10 or 100 fold for the same type of study) because of potential uncertainty due to weight (and whether a 1-3 fold variation may have been necessary because of extreme obesity) makes no sense to me.

Further, and most importantly, this measure is specified at the facility level and thus differences in patient weight should average out across patients within a facility. This is highlighted by Dr. Brink, Chair of Radiology at Yale in his positive comment on the measure, and discussed within the measure as a possible limitation. If a facility sees all obese patients, their doses should be higher (but perhaps 2 fold higher) than a facility that sees all very thin patients. However, the measure seeks to help identify facilities with doses that are 10 fold higher than they need to be AND there are not many facilities that only assess obese patients. If they is a gastric bypass hospital, there doses should appropriately be slightly higher than average.

The data that is recorded in the patients medical record – part b of the measure – will need to be understood in the context of several factors: why the study was done, how large the patient etc.

#### **4 EXCERPTS FROM TWO LETTER OF SUPPORT SUBMITTED WITH THIS MEASURE:**

##### **FULL LETTERS AVAILABLE ON NQF WEBSITE**

**Richard Morin, former President and Chairman of the Board of the American Association of Physicists in Medicine; Chair of the American College of Radiology (ACR) Commission on Medical Physics; Chair of the ACR Safety Subcommittee; a member of the Board of Chancellors of the American College of Radiology, former chair the ACR Commission on Medical Physics, and Current Chair of the American College of Radiology Dose Index Registry wrote a strong letter of support:**

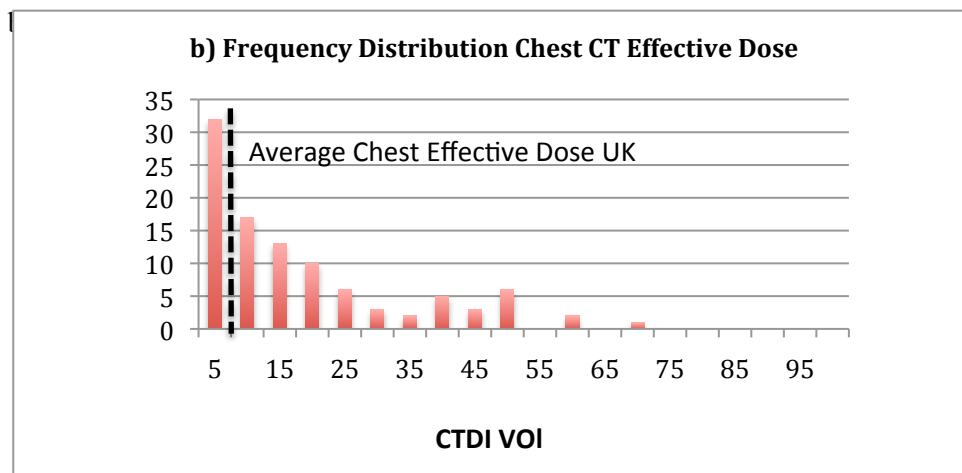
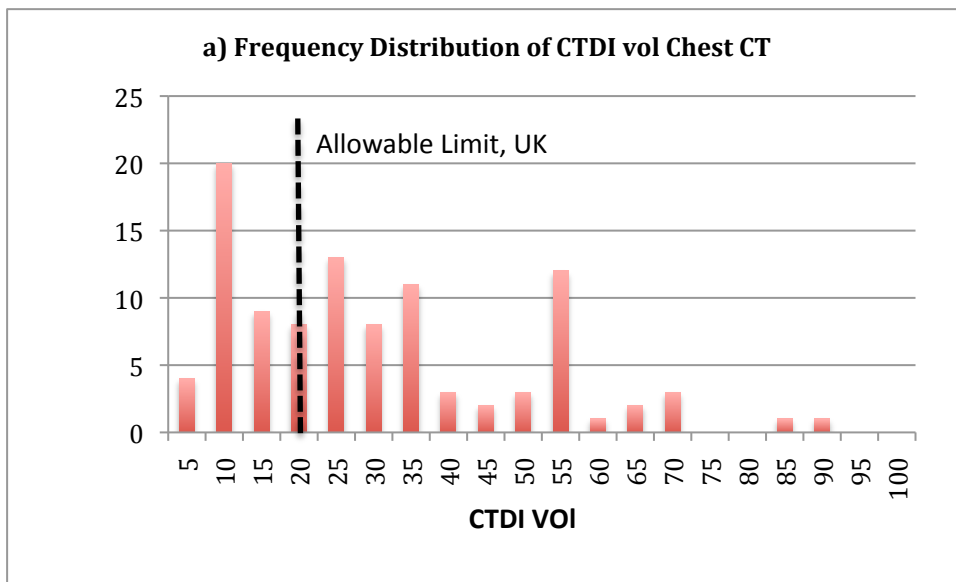
*I am strongly supportive of the quality metric you are submitting to the National Quality Forum focused on quantifying the radiation associated with Computed Tomography. This is an extremely important topic, which addresses a real safety concern, given the large number of patients who undergo CT every year. There is much higher than acceptable variation in the dose indices associated with CT, and there is currently no program where data are collected from actual CT scans conducted across the country, and no simple metrics for facilities to know how they are doing with respect to other facilities. Measuring and reporting a dose index in a simple and consistent fashion are extremely important first steps toward reducing variation, and thereby improving the safety and quality of CT imaging...**I believe the rapid adoption of the metric you have proposed would immediately provide guidance for radiology facilities to collect dose index information to understand how their dose indices compare with optimal performance standards. These data would be extremely easy for facilities to collect, and could immediate lead to local quality improvement efforts where problems are identified. It would also encourage facilities to compare dose indices, and thus encourage them to wisely optimize doses. Please let me know if I can provide you or the NQF any other information for consideration of this metric.***

**Jerry Bushberg director of Health Physics Programs at UC Davis, School of Medicine, Scientific Vice-President and member of board of directors of the National Council on Radiation Protection and Measurement's (NCRP) and chair the NCRP scientific advisory committee on Radiation Protection in Medicine.**

*I strongly support the quality metric you are submitting to the National Quality Forum focused on quantifying the radiation associated with Computed Tomography. Measuring and reporting dose information in a simple and consistent fashion would be an extremely important first step toward reducing variation, and thereby improving the safety and quality of CT imaging. Currently, many imaging facilities are not aware of the doses they are using, and this metric would increase awareness among facilities about the importance of assessing radiation doses, and would provide a way for them to do so in a simple and straight forward fashion. I believe the adoption of the metric you have proposed would guide radiology facilities that want to collect dose index information, and would help them to understand how their dose indices compare with optimal performance standards. ...*

5. Distribution of Dose Metrics and possible ways to provide feedback to facilities if these data were collected and submitted to an audit program. This program can be UCSF (I will create an audit program over the next 6 months) or any other institution that wants to do so. This proposed part C of the measure is fulfilled if a facility participates in an Audit program

5a) Distribution of Dose for CTDI and effective dose for Chest CT for one facility participating in our 8 center HMO study. Note that the median/median dose is substantially above the maximum suggested value in the UK, the standard deviation is twice as high as the UK, and the proportion above a CTDI vol of 50 is substantial. Similarly, using the metric of Effective dose, most patients fall above the average value in the UK – and this is despite most patients in this survey being children



5b) Distribution in CTDIvol and DLP for abdominal CT collected as part of the ACR Dose Registry. There were 8 institutions that provided data for this collection. These data were shared by Dr. Morin – Please do not circulate.

The ACR accreditation program sets an upper threshold for CTDI vol for Abdominal CT of 20-25. Note the Average CTDI for 6/7 of the facilities are above the top recommended threshold of the ACR Certification level and the max is ten fold higher. These numbers are shockingly high and variable and if facilities began collecting these data, they would soon enact changes to their dose protocols

## CT of the Abdomen

Abdomen		CTDIvol Sum per Exam				DLP Sum per Exam			
Institution	N	Avg CTDI vol	Std Dev	Min	Max	Avg DLP	Std Dev	Min	Max
Total	1829	26	22	1	293	1079	643	45	7433
A	938	28	20	5	293	1196	636	227	5159
B	505	16	11	1	189	787	368	45	2866
C	85	33	31	8	200	982	675	263	5512
D	119	40	26	8	179	1605	1060	232	7433
E	164	32	35	7	245	989	508	252	2851
F	18	29	22	8	87	948	459	345	2159

### An Audit Program and Incentivizing Participation

If provided with “credit” for reporting the dose information they collect with this measure, facilities are more likely to participate in an audit program. This part C of the measure was added after speaking with CMS who felt participating in an audit program would potentially be something that facilities could and should be rewarded for. Facilities could provide their entire dose distribution for each anatomic area and age group as specified in the measure. If these data were shared with a group that provides audit services and this could be used to generate the populations distribution in dose and to compare the particular facilities dose.

Further these data could be used to compare each facilities mean/median/standard deviation and the proportion above specific cutoffs: such as 20, 40 and 70 for CTDI or 10, 20 or 50 mSv for Effective Dose

Alternatively the facility could assess important thresholds and provide just the specific requirements of an audit program such as the mean, the proportion above specific cutoffs: such as 20 mSv, 40 mSv and 70 mSv for CTDI or 10, 20 or 50 mSv for effective Dose