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IF YOU WISH TO RECEIVE AN HONORARIUM FOR YOUR PARTICIPATION IN THIS MEETING, PLEASE COMPLETE THE ATTACHED W9 FORM (IF YOU HAVEN'T ALREADY) AND LET SUSANNA KNOW.	
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YOU WILL ONLY NEED TO RE-SUBMIT THIS FORM TO OUR TEAM IF THERE HAVE BEEN ANY CHANGES SINCE OUR PREVIOUS MEETING IN OCTOBER 2019, IN AFFILIATION FOR YOURSELF, YOUR PARTNER, OR ANY DEPENDENTS. PLEASE REVIEW ANY PREVIOUS DECLARATION OF CONFLICT FORMS TO ENSURE THAT WE HAVE THE MOST RECENT LISTING OF CONFLICTS, AND GUARANTEE FULL TRANSPARENCY AMONGST ALL TEP MEMBERS.

DR CTQS

Defining and Rewarding

Computerized Tomography Quality and Safety

Technical Expert Panel Meeting Agenda

Monday, April 20, 2020

9:00am-10:30am Pacific Time

Call in number: +1 669 900 6833

Zoom Meeting ID: 432-672-687

<https://ucsf.zoom.us/j/432672687?pwd=bHpzUmRGdm5MbjFDTWV6dWJrMEpQdz09>

Password: 050119

9:00 AM	Call meeting to order. Minutes from prior meeting on website.	Dr. Helen Burstin
9:05 AM	Roll Call and Updated Conflicts	Dr. Burstin
9:15 AM	Method for Automating the Categorization of CT Scans	Dr. Rebecca Smith-Bindman
9:35 AM	Discussion of Method for Automating the Categorization of CT Scans	Dr. Burstin
9:50 AM	Method for Setting the Upper Radiation Dose Threshold	Dr. Andy Bindman
10:10 AM	Discussion of Method for Setting the Upper Radiation Dose Threshold	Dr. Burstin
10:25 AM	Wrap Up and Next Steps	Dr. Bindman
10:30 AM	Adjourn	Dr. Burstin

Thank you for attending the DR CTQS TEP meeting - we look forward to your continued collaboration. Visit our website for more information, ctqualitymeasure.ucsf.edu

Welcome to the DR CTQS Technical Expert Panel Meeting

Thank you for joining.

Everyone will be muted upon entry, if you have questions or comments, please send a chat message to everyone. If you have technical issues, please send a chat message to Diana Ly (Host).

We will begin the meeting shortly.

We will unmute lines during roll call and during discussion segments of meeting. If you have questions or comments during other times, please send a chat message to everyone within Zoom.

Please make sure you are signed in to only ONE audio connection (either computer OR phone, not both) – to avoid issues with sound/echoes. Just muting your sound on the computer, while being connected by phone will not work.

If you need technical assistance during the meeting,
please send a chat message to Diana Ly (Host)

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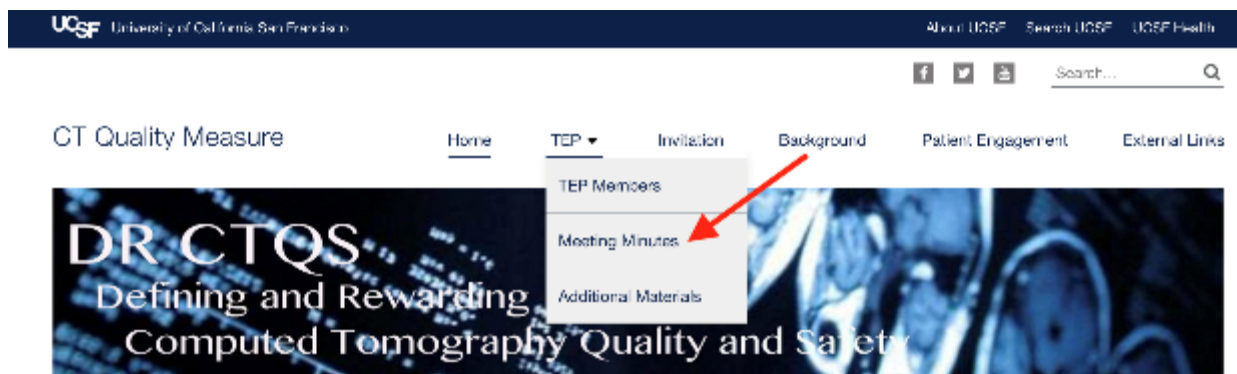
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ctqualitymeasure.ucsf.edu

Hover over TEP (on the top menu), then select Meeting Minutes



DR CTQS - TEP Website

Minutes Posted



What Constitutes a Conflict?

- You, your spouse, your registered domestic partner, and/or your dependent children
 - 1. Received income or payment as an employee, consultant or in some other role for services or activities related to diagnostic imaging?
 - 2. Currently own, or have held in the past 12 months, an equity interest in any health care related company which includes diagnostic imaging as a part of its business?
 - 3. Hold a patent, copyright, license or other intellectual property interest related to diagnostic imaging?



What Constitutes a Conflict?

- You, your spouse, your registered domestic partner, and/or your dependent children
 - 4. Hold a management or leadership position (i.e., Board of Directors, Scientific Advisory Board, officer, partner, trustee, etc.) in an entity with an interest in diagnostic imaging?
 - 5. Received and cash or non-cash gifts from organizations or entities with an interest in diagnostic imaging?
 - 6. Received any loans from organizations or entities with an interest in diagnostic imaging?
 - 7. Received any paid or reimbursed travel from organizations or entities with an interest in diagnostic imaging?

Conflict of Interest Statements

- Each of you has submitted information to UCSF on your conflicts
- Following order on next slide please state your name, affiliation, and any conflicts you recorded on those forms
- Please state any updates in conflicts since completing the form



Roll Call

TEP Chair

Helen Burstin, MD, MPH, FACP

Members

Mythreyi Bhargavan Chatfield, PhD

Niall Brennan, MPP

Jay Bronner, MD

Missy Danforth,

Tricia Elliott, MBA, CPHQ

Jeph Herrin, PhD

Hedvig Hricak, MD, PhD

J. Leonard Lichtenfeld, MD, MACP

University of California
San Francisco

Matthew Nielsen, MD, MS

Debra P. Ritzwoller, PhD

Lewis G. Sandy, MD, FACP

M. Suzanne Schrandt, JD

J. Anthony Seibert, PhD

Arjun Venkatesh, MD, MBA, MHS

Todd Villines, MD, FSCCT

Kenneth Wang, MD, PhD

Ex officio (non-voting) Members

Amy Berrington de Gonzalez, DPhil

Mary White, ScD

Determining Indication for CT Categories (CT-Cat)



University of California
San Francisco



Review Measure Concept

- To identify diagnostic CT scans that are performed in an unsafe manner, either because they utilize excessive radiation doses (given the clinical indications for imaging) or because they have low image quality, undermining their diagnostic value
- Balancing measure:
 - Indiscriminate efforts to reduce radiation dose may compromise image quality



Measure Concept

- Unit of analysis: individual CT scan
- Level of analysis: practitioner or practitioner group
- Each CT scan will be put into a category for the anatomic area and indication (CT-Cat) based on why the CT obtained.
- Each CT scan will then be assessed for “failure” on 2 criteria

Is the radiation dose too high for that category?

Is the image quality too low? (*next TEP*)



CT Categories

- CT-Cat established through a combination of literature review, empirical data from UCSF International CT Dose Registry, and input of TEP members
- For some anatomical areas there are low and high dose exceptions to the routine category based on clinical indications
- For some anatomical areas, CT scans are done within only a routine dose range

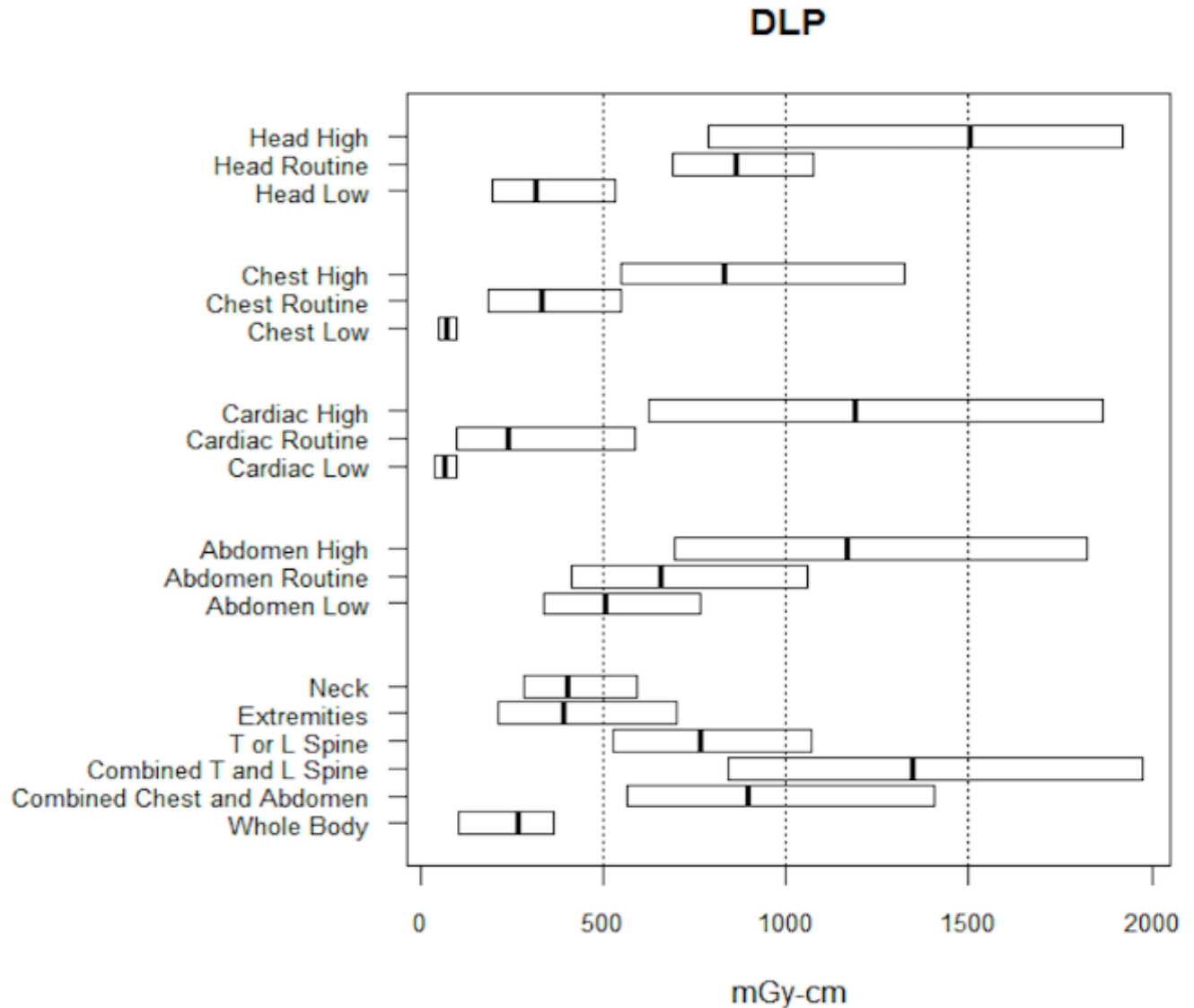


Dose by CT-Cat

Boxes show the 25th, 50th, 75th Percentile of Dose



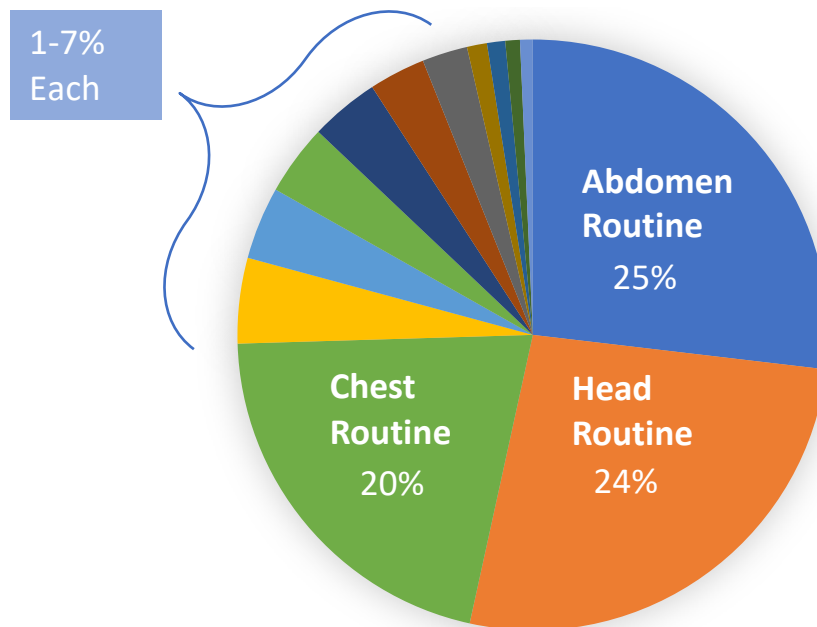
University of California San Francisco



Anatomic Areas with High/Low Dose Exceptions

Category	Percent
1. Head - Low	3%
2. Head - Routine	24%
3. Head - High	1%
4. Chest - low	0%
5. Chest - Routine	20%
6. Chest High	0%
7. Cardiac - low	1%
8. Cardiac - Routine	1%
9. Cardiac High	0%
10. Abdomen - Low	2%
11. Abdomen-Routine	25%
12. Abdomen- High	3%

CT Categories



Anatomic Areas without High/Low Dose Exceptions

13. Extremity	1%
14. C-spine / Neck	7%
15. L-Spine or T-Spine	4%
16. Full Body	<1%

Combined Anatomic Areas

17. Combined Chest / Abdomen	4%
18. Combined T / L Spine	1%
19. Combined Head / Neck	2%

Alpha-2 Testing

- The purpose was to determine and validate the accuracy of determining the indications for CT exams (CT-Cat)
- Two approaches for automated assignment of CT-Cat :
 - EHR data (diagnostic codes associated with test order and bill)
 - DICOM structured data stored with CTs within radiology records
- There are tradeoffs for both approaches
 - EHR data more difficult to obtain and may be incomplete
 - DICOM data not fully standardized and potentially gameable



Alpha-2 Testing

- Performed on 4153 UCSF patients who received CT scan
- Gold Standard= CT-Cat based on detailed chart review compared to:
 - EHR data: algorithms based on combinations of diagnostic codes from the physician visit where test ordered and billing code used that identifies anatomic area, contrast, and some indications.
 - DICOM data: NLP approaches applied to reason for scan, protocol name, and study description
- Calculated the sensitivity, specificity, and overall accuracy for categorizing each CT scan into a CT-Cat

Identifying CT-Cat Using Claims Data

- Using defined indication(s) and anatomic area(s) for each CT-Cat an expert coder mapped to specific diagnoses and billing codes
- Categorization required inclusion/exclusion of specific procedure codes (CPT/HCPCS) and diagnostic codes (ICD10CM)
- Experimented with mapping to CT-Cat using different combinations of procedure and diagnostic codes
- For example to identify a CT as a low dose abdomen scan, we used information on whether
 - The CT was billed specifically for colon cancer screening
 - Whether the CT used/didn't use intravenous contrast
 - Whether the CT was associated with specific diagnostic codes that might reflect renal stones or urinary bladder assessment

Approach for Iteratively Revising Algorithm

- When creating automated rules in DICOM and EHR data for assigning a CT scan to a particular CT-category, we tried to minimize cases in which we might mistakenly penalize radiologists for using higher doses
 - For high dose categories we maximized the sensitivity for detecting a high dose scan
 - For low dose categories we maximized specificity for a low dose scan (meaning we wouldn't assign a case to a low dose category unless we were sure it was a low dose indication.)

For CT scans where there was more than 1 indication identified, we defaulted to the higher dose category

Summary of Results Alpha Testing (UCSF)

- DICOM derived categorization combined with billing codes accurately categorized 92% of CT scans
- EHR derived algorithm using diagnostic and billing codes accurately categorized 80 % of scans



Accuracy of DICOM Data for CT-Cat

	Sensitivity	Specificity	Likelihood Ratio	
			<u>Positive</u>	<u>Negative</u>
Abdomen-Routine	0.84	0.92	11	0.17
Head - Routine	0.96	1	389	0.04
Chest - Routine	0.96	1	195	0.04
Neck or C-spine	1.00	1	near perfect	0.00
T or L Spine	0.88	1	near perfect	0.12
Head - Low	0.95	1	near perfect	0.05
Abdomen- High	0.89	0.96	22	0.12
Abdomen - Low	0.79	0.99	65	0.21
Head - High	0.97	1	779	0.03
Cardiac - Routine	1.00	1	828	0.00
Cardiac - low	0.95	1	near perfect	0.05
Extremity	1.00	1	near perfect	0.00
Chest - low	0.92	1	near perfect	0.08
Chest High	1.00	1	832	0.00
Cardiac High	1.00	1	209	0.00

Next Steps For Validating CT Cat

- Our plan is to go forward with testing the two approaches for determining CT-Cat, but leaning towards DICOM because of greater accuracy
- Validate among different groups of physicians
 - University of California - Davis, San Diego, Irvine
 - Private practice: Houston affiliation of 13 imaging centers
 - Large academic hospital-based practices: Mt Sinai, Henry Ford
- Compare distribution of scan types (CT-Cat) to that in UC Dose Registry
- Compare dose distribution in each CT-Cat to those in UC Dose Registry
- Compare characterization of CTs into different CT-Cat based on EHR vs Radiology DICOM codes

Questions

1. Does the CT-Cat system of categorizing CT scans for the purposes of judging CT scan quality make sense?
2. Are you satisfied that we can accurately automate the assignment of CT scans into CT-Cat?
3. What suggestions do you have for us as we plan for beta testing at outside sets that will help us to choose between the two (EHR vs DICOM) automated approaches?

Establishing Radiation Dose Upper Threshold

Andrew Bindman



University of California
San Francisco



Upper Threshold for Radiation Dose

- Measure requires that we establish a dose for each CT scan above which it will be rated as failed if too high
- Threshold will be specific for each CT-Cat
 - The upper limit for high dose abdomen > limit for routine abdomen scans
- Goal is to set an upper threshold as low as possible to support safety but not so low that it risks image quality
- This measure will be adjusted for patient size
 - larger patients require higher doses

Approach for Choosing Thresholds

- UC Dose registry to see range used in practice within each CT CAT

CT-CAT = Chest Routine Dose

Distribution in Dose Length Product



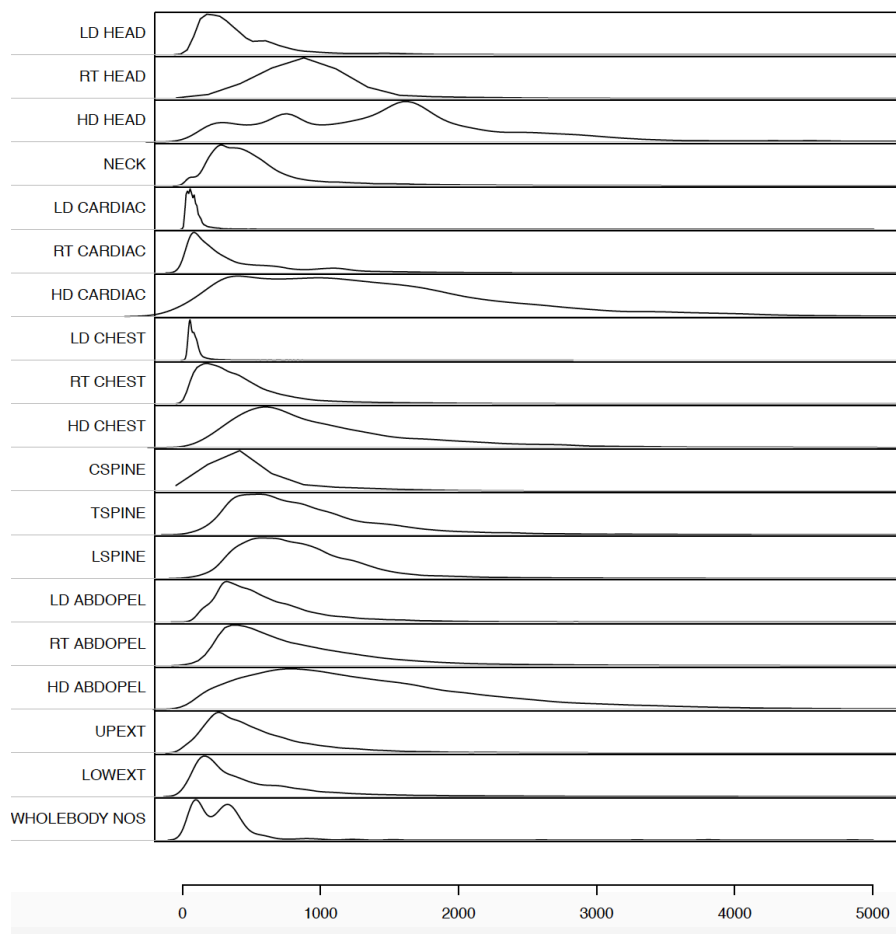
0 1000 2000 3000 4000 5000

DLP mGy-Cm



Distribution in Dose by CT-Cat

UC International CT Dose Registry



Approach for Choosing Thresholds

- Threshold based on radiologist assessment of when a higher dose does not contribute to improvements in image quality
- To ascertain radiologist assessment of image quality related to dose we conducted a study with 125 radiologists from across the country who each read 200 scans from a sample of 740 test cases of varying doses within each CT-

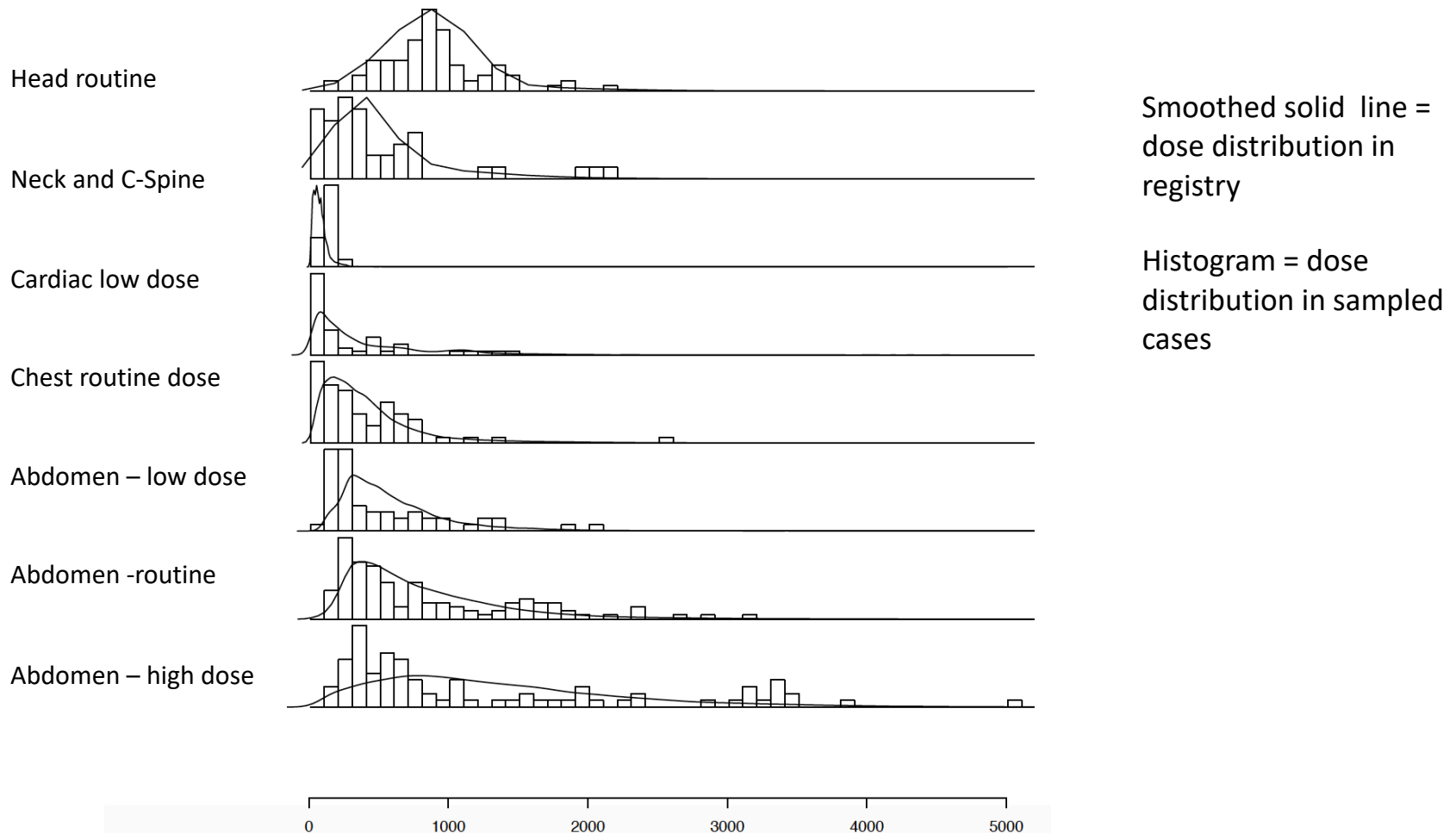
■ A total of 25,000 interpretations of CT scans, average 35 interpretations per case

Sampled Test Cases in Quality Study

- The test cases (N=740) were sampled from actual cases from UC Dose registry
- Cases were selected to represent 4 largest CT manufacturers
- Test cases were slightly oversampled at the low end of dose where we assumed most image quality issues would arise.



Distribution of Sampled Cases Parallels Distribution in Registry Doses



Categories for Physician Assessment of Image Quality

Quality	What it Means
Excellent	Images provide the needed information.
Adequate	Image quality is acceptable but not excellent. You would re-scan and change the parameters for a higher quality image if it is easy to repeat, but if not, this is good enough for what you need.
Marginally acceptable	Image quality is less than ideal and may compromise diagnostic quality. If the patient cannot easily be re-scanned you will interpret this but would change parameters for future scans of this type.
Poor	Image quality is not adequate for diagnosis and should be repeated.



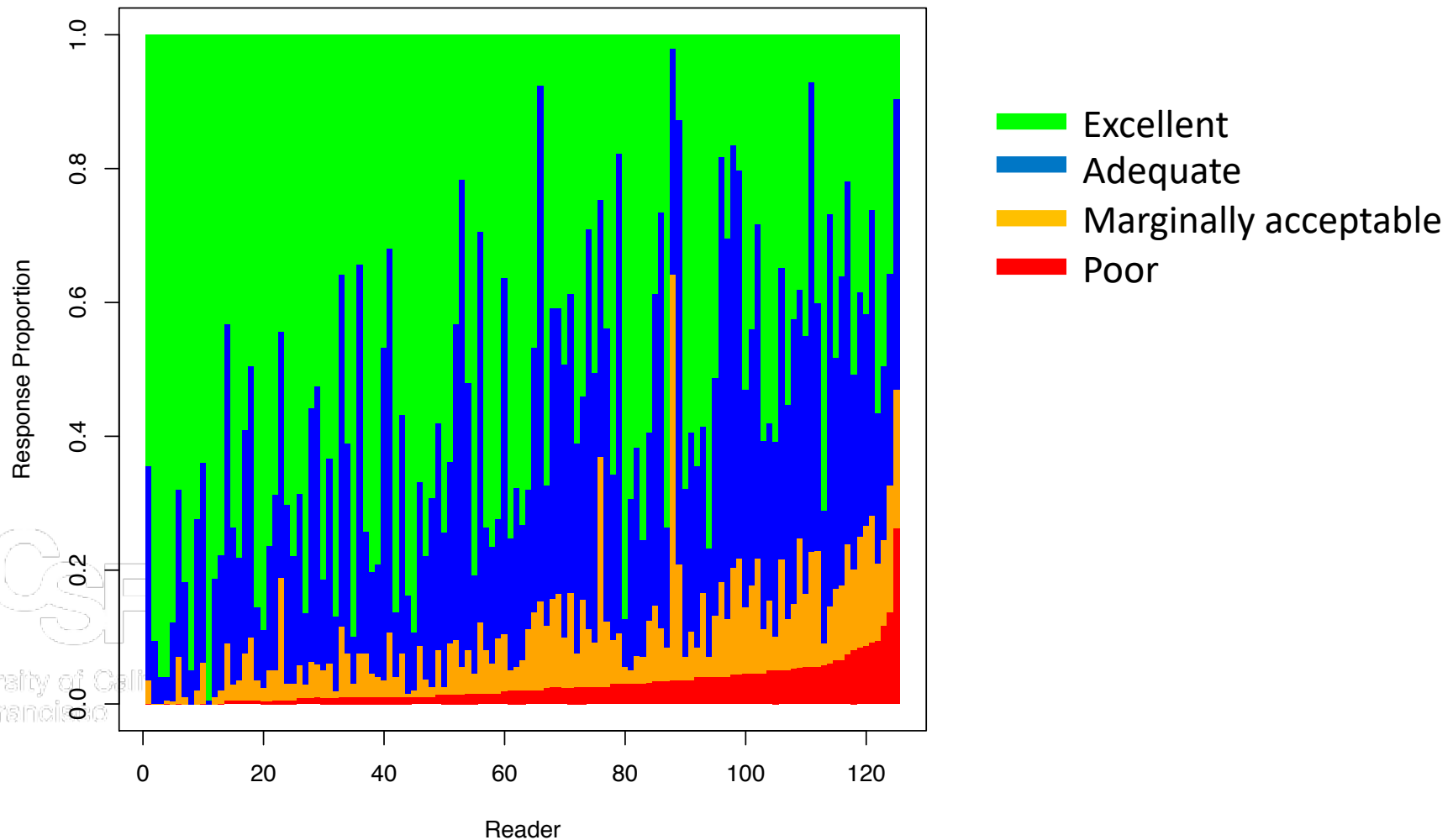
Interpretations of Test Cases in Quality Study

- Most images were rated as having sufficient image quality
 - Excellent 49%
 - Adequate 40%
 - Marginally acceptable 8%
 - Poor = not acceptable 3%
- For most CT-Cats, the percentage of ratings of image quality increased with dose, but the change across the dose distribution was small

■ In some CT-Cats there was no association between quality and dose

- The percentage of cases considered poor or marginal varied among radiologists (can adjust for how hard of a grader)

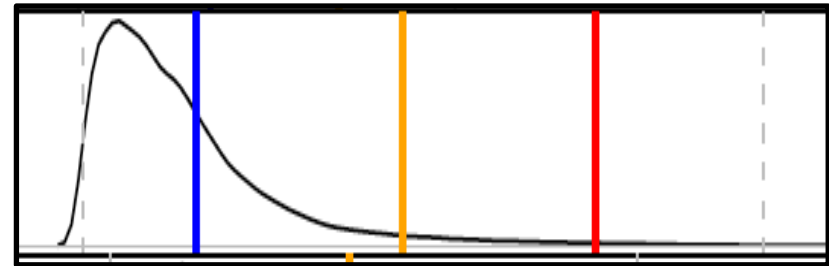
Proportion of Interpretations Into Each of the 4 categories by Reader



Percent of Physicians who rated exams as Excellent or Adequate [vs Poor or Marginal] by Dose

- The percent of physicians who rated cases as excellent or adequate plateaus at doses below where many scans are done

CT-Cat = Chest - Routine



Percent of Physicians who grade as Excellent or Adequate	98%	99%	99.5%
Percent of Physicians who graded as Marginal or Poor	2%	1%	0.5%

CT Scan Image Quality By Observed Doses

	% of CT Scans	Proportion of Exams considered Excellent, Adequate or Marginally Acceptable			Proportion of Exams considered Excellent or Adequate		
		Proportion at Minimum Observed DLP	Proportion at Maximum Observed DLP	Difference	Proportion at Minimum Observed DLP	Proportion at Maximum Observed DLP	Difference
Abdomen-Routine	25%	98%	100%	(1%)	92%	97%	(5%)
Head - Routine	24%	95%	99%	(4%)	85%	93%	(9%)
Chest - Routine	20%	97%	100%	(3%)	90%	94%	(4%)



Setting Upper Radiation Dose Threshold

- Set dose above where at least 98% of physicians assess images as being excellent or adequate or marginally acceptable

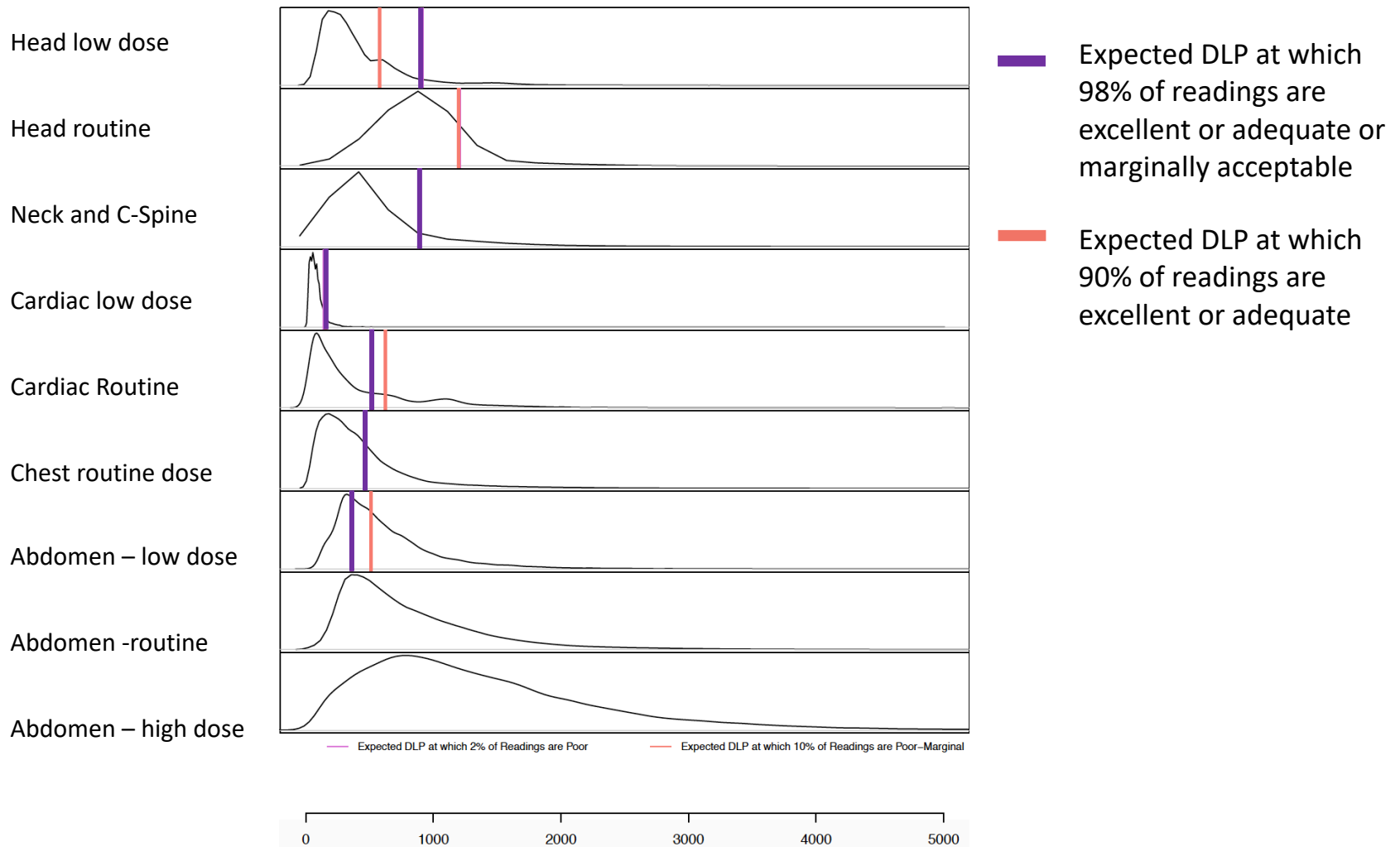
AND

- At least 90% of physicians think dose is excellent or adequate
- Thresholds adjusted for patient size and differences in rating

distributions across radiologists



Locations of these Dose Thresholds Across CT-Cat



Rules Based On Dose

- On average, approximately 20% of CT scans would be considered above thresholds in 13 CT-Cat
- For 2 categories where even the lowest observed dose satisfies criteria propose that we set upper threshold at the average reduction of the 13 CT-Cat
- For 4 categories where there is no relationship between quality and dose propose that we set upper threshold at the average reduction of the 13 CT-Cat



Questions

1. Do you support our method for establishing dose upper threshold based on epidemiology and radiologists' ratings of quality?
2. Does our approach of incorporating ratings of poor as well as poor and marginal in setting the upper limit seem balanced?
3. Are we being too lenient, too aggressive, or just right in setting upper dose threshold?

Next TEP

Method for automating evaluation of image quality to ensure that doses below upper threshold are not reduced so much as to undermine image quality

Aiming to re-group with a webinar in late May or early June



Wrap Up & Next Steps

- Thank you for your attention and input
- The University of California team will reflect on advice and develop a plan in cooperation with CMS on next steps
- Information about this TEP meeting and future meetings will be posted at ctqualitymeasure.ucsf.edu
- We will be reaching out to you soon to set the date for the next TEP meeting



■ Honorarium request reminder

We are adjourned!



University of California
San Francisco



DEFINING AND REWARDING COMPUTED TOMOGRAPHY QUALITY AND SAFETY

TEP Meeting #4 Part 1 Minutes

Meeting Date: 4/20/2020

Meeting Time: 9:00am-10:30am Pacific

Meeting Location: Virtual Conference via Zoom

Approval Date: May 11th, 2020

Recorded by: UCSF Team

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has granted an award to the University of California San Francisco (UCSF) to develop a measure of computed tomography (CT) image quality and radiation safety. The project is a part of CMS's Medicare Access & CHIP Reauthorization Act (MACRA)/Measure Development for the Quality Payment Program. The project title is "DR CTQS: Defining and Rewarding Computed Tomography Quality and Safety". The Cooperative Agreement number is 1V1CMS331638-02-00. As part of its measure development process, UCSF convened groups of stakeholders and experts who contributed direction and thoughtful input to the measure developer during measure development and maintenance.

Project Objectives:

The goal of the project is to create a quality measure for CT to ensure image quality standards are preserved and harmful effects of radiation used to perform the tests are minimized. Radiation doses delivered by CT are far higher than conventional radiographs (x-rays), the doses are in the range known to be carcinogenic, and there is a significant performance gap across health care organizations and clinicians which has consequences for patients. The goal of the measure is to provide a framework where health care organizations and clinicians can assess their doses, compare them to benchmarks, and take corrective action to lower them while preserving the quality of images so that they are useful to support clinical practice. The measure will be electronically specified using procedural and diagnostic codes in billing data as well as image and electronic data stored with CT scans, typically stored within the Picture Archiving and Communication Systems (PACS) - the computerized systems for reviewing and storing imaging data or Radiology Information Systems (RIS).

TEP Objectives:

In its role as a measure developer, the University of California San Francisco is obtaining input from a broad group of stakeholders to develop a set of recommendations to develop a radiology quality and safety measure. The proposed measure will be developed with the close collaboration of the leadership from diverse medical societies as well as payers, health care organizations, experts in safety and accreditation, and patient advocates. A well-balanced representation of stakeholders on the TEP is intended to ensure the consideration of key perspectives and obtain balanced input.

Scope of Responsibilities:

The TEP's role is to provide input and advice to the measure developer (University of California San Francisco) related to a series of planned steps throughout the 3-year project. The specific steps will include developing and testing a risk-adjusted measure which can be used to monitor CT image quality in the context of minimizing radiation doses while maintaining acceptable image quality. The TEP will assist UCSF in conceptualizing the measure and any appropriate risk adjustment of it. The TEP will assist UCSF with identifying barriers to implementing the proposed measure and test sites in which the developer can assess the feasibility and

performance of its use. The TEP will assist UCSF with interpreting results obtained from the test sites and in suggesting modifications of the measure prior to it being incorporated into a software tool which will be made available to providers to enable them to report and monitor their performance. The TEP will provide input and advice to UCSF regarding the software tool to ensure that it is valuable for a wide range of stakeholders and CMS.

Guiding Principles:

Participation on the TEP is voluntary. Individuals participating on the TEP understand that their input will be recorded in the meeting minutes. Proceedings of the TEP will be summarized in a report that may be disclosed to the general public. If a participant has disclosed private, personal data by his or her own choice, then that material and those communications are not deemed to be covered by patient-provider confidentiality. Questions about confidentiality will be answered by the TEP organizers.

All potential TEP members must disclose any significant financial interest or other relationships that may influence their perceptions or judgment. It is unethical to conceal (or fail to disclose) conflicts of interest. However, the disclosure requirement is not intended to prevent individuals with particular perspectives or strong points of view from serving on the TEP. The intent of full disclosure is to inform the TEP organizers, other TEP members and CMS about the source of TEP members' perspectives and how that might affect discussions or recommendations.

All potential TEP members should be able to commit to the anticipated time frame needed to perform the functions of the TEP.

Estimated Number and Frequency of Meetings:

TEP is expected to meet three times per year, either in-person or via a webinar. This meeting was originally set to occur in-person, but was changed to a virtual meeting as mandated by federal social distancing measures and state-wide Shelter-in-Place orders.

Table 1. TEP Member Name, Title, and Affiliation

Name	Title	Organization
Attendees		
Niall Brennan, MPP	CEO	Health Care Cost Institute
Helen Burstin, MD, MPH, FACP	Executive Vice President	Council of Medical Specialty Societies
Mythreyi Bhargavan Chatfield, PhD	Executive Vice President	American College of Radiology
Jay Bronner, MD	President and Chief Medical Officer	Radiology Partners
Missy Danforth	Vice President of Health Care Ratings	The Leapfrog Group
Tricia Elliot, MBA, CPHQ	Director, Quality Measurement	Joint Commission
Jeph Herrin, PhD	Adjunct Assistant Professor	Yale University

Name	Title	Organization
Attendees		
Hedvig Hricak, MD, PhD	Radiology Chair	Memorial Sloan Kettering Cancer Center
Leonard Lichtenfeld, MD, MACP	Interim Chief Medical Officer	American Cancer Society, Inc.
Matthew Nielsen, MD, MS	Professor	UNC Gillings School of Global Public Health
Debra Ritzwoller, PhD	Patient	Patient Representative
Lewis Sandy, MD	Executive Vice President, Clinical Advancement	UnitedHealth Group
Mary Suzanne Schrandt, JD	Patient	Patient Representative
Anthony "Tony" Seibert, PhD	Professor	University of California, Davis
Todd Villines, MD, FSCCT	Professor and Director of Cardiovascular Research and Cardiac CT Programs	University of Virginia
Kenneth Wang, MD, PhD	Adjunct Assistant Professor	University of Maryland, Baltimore
Not in Attendance		
Arjun Venkatesh, MD, MBA, MHS	Assistant Professor	Yale School of Medicine

Ex Officio TEP		
Mary White, ScD	Chief, Epidemiology and Applied Research Branch	Centers for Disease Control and Prevention
Not in Attendance		
Amy Berrington de Gonzalez, DPhil	Branch Chief & Senior Investigator	National Cancer Institute; Division of Cancer Epidemiology & Genetics, Radiation Epidemiology Branch
CMS & CATA Representatives		
Janis Grady	Project Officer	Centers for Medicare & Medicaid Services
Marie Hall	CATA Team	Health Services Advisory Group
UC Team		
Rebecca Smith-Bindman, MD	Principal Investigator	University of California, San Francisco
Andrew Bindman, MD	Principal Investigator	University of California, San Francisco
Patrick Romano, MD, MPH	Co-Investigator	University of California, Davis
Naomi López-Solano, CCRP	Project Manager	University of California, San Francisco
Diana Ly, MPH	Project Manager	University of California, San Francisco

Susanna McIntyre	Research Assistant	University of California, San Francisco
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Technical Expert Panel Meeting

Prior to the meeting, TEP members received a copy of the agenda, presentation slides, link to DR-CTQS study website which contains minutes from the prior TEP meetings, honorarium documentation, and a conflict of interest form. The meeting was conducted with the use of PowerPoint slides.

9:00 AM **Call meeting to order by TEP Chair** **Dr. Helen Burstin**

Dr. Helen Burstin called the meeting to order. She noted that the meeting will last for 1.5 hours and will include a discussion period after each presentation. Part 2 of TEP #4 will be conducted at a later date, as response to the COVID-19 pandemic allows.

9:05 AM **Roll Call and Updated Conflicts** **Dr. Helen Burstin**

TEP members and Ex Officio members attendance listed above.

Conflict of interest defined as you, your spouse, your registered domestic partner, and/or your dependent children:

1. received income or payment as an employee, consultant or in some other role for services or activities related to diagnostic imaging
2. currently own, or have held in the past 12 months, an equity interest in any health care related company which includes diagnostic imaging as a part of its business
3. hold a patent, copyright, license or other intellectual property interest related to diagnostic imaging
4. hold a management or leadership position (i.e., Board of Directors, Scientific Advisory Board, officer, partner, trustee, etc.) in an entity with an interest in diagnostic imaging
5. received and cash or non-cash gifts from organizations or entities with an interest in diagnostic imaging
6. received any loans from organizations or entities with an interest in diagnostic imaging
7. received any paid or reimbursed travel from organizations or entities with an interest in diagnostic imaging

COIs were disclosed to UCSF prior to this TEP meeting via paperwork. No members had new financial conflicts that precluded their participation. TEP members were also asked to verbally disclose any COIs when introducing themselves for the purpose of group transparency. TEP members re-stated their affiliations and any existing conflicts. Dr. Helen Burstin stated her affiliation as the CEO of the Council of Medical Specialty Societies, and her status as a faculty member at the George Washington University Medical School. She is now on the

board of the Society to Improve Diagnosis in Medicine, although this is not a conflict of interest. Dr. Jay Bronner stated his relationship with Radiology Partners, and had no conflicts of interest. Dr. Jeph Herrin stated his affiliation with Yale University, and no new conflicts of interest. Dr. Matthew Nielsen reported his affiliation with the University of North Carolina. He noted he is the Quality Improvement Chair at the American Urological Association, however this association is not directly related to imaging. Dr. Debra Ritzwoller stated her affiliation with Kaiser Permanente Colorado and as a patient/guardian stakeholder. Dr. Kenneth Wang noted his affiliation with the Veterans Administration in Baltimore and University of Maryland. Of note, he is participating on his personal time not representing government. His conflicts include a small start-up and occasional reimbursements from Radiology Society of North America. He also has a patent pending in the area of ultrasound imaging. Niall Brennan stated that he had no new conflicts and that he is currently the President and CEO of the Health Care Cost Institute. Dr. Hedvig Hricak is currently the Chair of the Memorial Sloan Kettering Cancer Center Department of Radiology. She disclosed her current conflict as a board member of IBA. Dr. Mythreyi Chatfield stated her affiliation with the American College of Radiology, as the Executive Vice President of Quality and Safety, and had no new conflicts of interest to disclose. Tricia Elliot restated her role as the Director of Quality Measurement at The Joint Commission, and no new conflicts of interest. Dr. Leonard Lichtenfeld reminded the panel of his role as the Interim Chief Medical Scientific Officer of the American Cancer Society. He did not have any conflicts but mentioned his stock ownership in Google and noted that they have some interest in using augmented intelligence in radiology analytics. Dr. Lewis Sandy stated his affiliation with UnitedHealth Group as the Executive Vice President of Clinical Advancement and had no new conflicts of interest to disclose. Suzanne Schrandt restated her role as the Director of Patient Engagement at the Arthritis Foundation. She also disclosed her new relationship as the Senior Patient Engagement Advisor for the Society to Improve Diagnosis in Medicine. Dr. Anthony Seibert stated his role as a medical physicist at UC Davis Health, and had no conflicts of interest to declare. Dr. Todd Villines stated his role as a cardiologist at the University of Virginia, he disclosed his changes in conflicts of interest to the TEP; he no longer has any relationships with industry stakeholders, and he is the editor in chief of the Journal of Cardiovascular CT, and he is a non-voting board member of the Society of Cardiovascular CT. Finally, Missy Danforth restated her role as the Vice President of Health Care Ratings at the Leapfrog Group, and had no new conflicts to declare. Dr. Mary White reported her affiliation with the Centers for Disease Control & Prevention, and had no new conflicts of interest.

9:15 AM: Method for Automating the Categorization of CT Scans, Dr. Rebecca Smith-Bindman

Dr. Smith-Bindman began with a review of measure concept, which is to identify diagnostic CT scans that are performed in an unsafe manner, either because they utilize

excessive radiation doses (given the clinical indications for imaging) or because they have low image quality, undermining their diagnostic value. This also includes a balancing measure to ensure that indiscriminate efforts to reduce radiation dose do not compromise image quality. She reminded the TEP that the measure will evaluate at the level of each individual CT scan, and the level of analysis will be the practitioner or practitioner group. Each CT will be put into a category for the anatomic area and indication (CT-Cat) based on why the CT was obtained. Within each CT-Cat, a CT scan will then be assessed for “failure” on two criteria: 1) is the radiation dose too high for that category? and 2) is the image quality too low for that category? The second criterion will not be discussed as a part of the meeting today but will be the focus of discussion during the second part of the fourth TEP meeting (TEP#4, part 2).

The categories of the CT-Cat were established through a combination of literature review, empirical data from the UCSF International CT Dose Registry, and input from TEP members. Dr. Smith-Bindman displayed a graph (slide #14 of presentation) which illustrated the percentage of CT scans that fall within the 19 proposed CT categories of the CT-Cat. The categories that contained the highest proportion of scans were: Abdomen Routine (25%), Head Routine (24%), and Chest Routine (20%). The remaining 16 categories each accounted for 1-7% of CT scans.

One of challenges in implementing the measure will be to put the CT scans into the CT-Cat categories in an automated fashion. The UC project team has been using data from the UCSF health system to test (Alpha 2) the accuracy of the automated approach to determine and validate the accuracy of determining the indications for CT exams. The project team has developed two approaches for automated assignment of CT-Cat. The first approach uses electronic health record (EHR) data (i.e. the diagnostic codes associated with a test order) in combination with electronic billing codes. An expert coder mapped specific procedure codes (Current Procedural Terminology/Healthcare Common Procedure Coding System (CPT/HCPCS)) and diagnostic codes (International Classification of Diseases, Tenth revision, Clinical Modification (ICD-10CM)) to each CT-Cat.

The second method uses the DICOM data stored with each CT radiology record in combination with billing codes. Some of the DICOM fields are standardized but the reason for the scan, protocol name, and study description are free text. The UC team has applied natural language processing (NLP) to these fields.

Dr. Smith-Bindman discussed the tradeoffs of both approaches, mainly; EHR data is more difficult to obtain and may be incomplete, and DICOM data is not fully standardized and potentially gameable. The Alpha-2 Testing was performed on 4,153 UCSF patients who received a CT scan. The UC project team developed a “gold-standard approach” wherein the CT-Category was determined via a detailed chart review, and then compared to the assignment to a CT-Cat based on the EHR and DICOM approaches. An assessment was made of the sensitivity, specificity, and overall accuracy of each of the two automated approaches.

When creating automated rules with the EHR and DICOM data for assigning a CT scan to a particular CT-category, the UC project team aimed to minimize cases in which radiologists might mistakenly be penalized for using higher doses. This was operationalized by maximizing the sensitivity for high dose categories and maximizing the specificity low dose categories. Also for CT scans where there was more than one indication, the CT scan was defaulted to the higher radiation dose category.

Based on the alpha testing, the DICOM approach accurately categorized 92% of CT scans. The EHR derived algorithm, accurately categorized 80% of scans.

Dr. Smith-Bindman displayed a table (slide #20 of presentation) that showed the sensitivity, specificity, and likelihood ratio of the accuracy of the DICOM data approach for each category of the CT-cat. Sensitivity ranged from 0.79 to 1.0, across categories, and specificity ranged from 0.92 to 1.0 across categories. The positive and negative likelihood ratios were indicative of a high level of accuracy, especially for the the DICOM data approach.

The next steps for validating CT Categories were then discussed. Thus far, the plan is to go forward with testing the two approaches for determining CT-Cat, but the UC project team is currently leaning towards the DICOM method because of the greater accuracy in this approach. The team plans to validate this approach among different groups of physicians such as: University of California health systems at Davis, San Diego, and Irvine, a private practice with imaging centers in Austin, Texas, and large academic hospital-based practices at Mt Sinai Hospital in New York, New York, and Henry Ford Hospital in Detroit, Michigan. These locations reflect diversity in practice, EHR, types of CT scanners, and geographic location.

9:35 AM Discussion: Method for Automating the Categorization of CT Scans, Dr. Burstin

Dr. Burstin opened up the meeting to discussion of these topics. (Dr. Wang) began with a clarifying question regarding use of the claims data. Dr. Smith-Bindman clarified that the billing codes contribute to both approaches for determining CT-cat (EHR and DICOM.)

(Dr. Chatfield) The ACR representative suggested that the American College of Radiology (ACR), Dose-Index Registry data might provide another place in which to test the accuracy of CT-Cat. .

(Dr. Sandy) suggested that there may need to be a process to enable a practitioner or medical group the opportunity to review the automated assignment as a way to re-assure that assessments of the radiation dose and image quality are being done on the proper CT-Cat. (Dr. Burstin) backed this suggestion, as such processes can help build the reliability of the measure over time.

(Dr. Villines) indicated that he was positively impressed by the sensitivity and specificity numbers that were shared in this portion of the presentation. He asked whether the project team anticipated any issues with applying the automation rules to different EHRs across or different PACS Systems?

Dr. Smith-Bindman explained that the team has chosen sites that vary in the types of CT scanners, EHRs and PACS systems. The project team also plans to collect data using different approaches aside from the UCSF developed software tool. This would include data reporting from dose-management software companies and by the CT manufacturers. The different data collection methods will be compared.

(Dr. Burstin) expressed confusion about DICOM not being reliable, as it was her understanding that this is an international standard. She also expressed that she felt that “game-ability” of the measure is more likely to occur via the billing claims data.

Dr. Smith-Bindman clarified that while some DICOM fields are standardized the ones used for CT-Cat are not. The NLP approach to these data developed at UCSF will be tested at the other sites. Furthermore there are shifts underway which will likely make the “reason for study” field in the DICOM data more consistent across sites. ACR has developed decision support software that is likely to be widely adopted, and that standardizes the indication for imaging. This field will be used to populate this ‘reason for study’ field. Because radiologists influence the recording of the reason for scan in the DICOM data there is the potential that they could alter

what is recored in anticipation of how they might be judged on a quality measure. The UC team believes that this is unlikely to be a problem prior to the implementation of the measure and that systems could be put in place to monitor this over time.

Dr. Bindman pointed out that one potential benefit of the EHR data approach is that the information is entered by the practitioner who orders the test not the practioner that performs the test. This makes it less gameable.

(Dr. Burstin) suggested that there may be a difference in the accuracy of CT-Cat between large health care system versus single radiologist practices. It may be difficult to get a reasonable reliability estimate for an individual doctor with much smaller sample sizes. Dr. Burstin requested that future meetings provide information to help form a judgment of whether it will be practical and valid to have this measure apply to inividual practitioners. Dr. Smith-Bindman agreed to provide such data at future TEP meetings.

(Dr. Siebert) asked a clarifying question about, in terms of the CT Categories what is considered abdomen and what is considered pelvis; i.e. where does one end and another begin? Dr. Smith-Bindman responded that for the purposes of this work, the abdomen category is defined as including any abdomen and any pelvis. They are combined together. This is based on her previously published research that the two categories are almost indistinguishable when looking at a CT scan.

In response to this, (Dr. Hricak) mentioned that there is an opportunity to evaluate when CT scans inappropriately include certain anatomical areas that are not clinically indicated. Dr. Smith-Bindman acknowledged the value of such a measure but that it was beyond the scope of the current work measuring CT radiation doses for the scans as performed.

9:50 AM: Method for Setting the Upper Radiation Dose Threshold, Dr. Andrew Bindman

Dr. Bindman began with review of the purpose of an upper radiation dose threshold. This measure requires that a radiation dose threshold be established for each CT scan, above which a scan will be rated as failed. The threshold will be specific for each CT-Cat. For example, the upper limit for high dose abdomen will be greater than the upper limit for routine abdominal scans. The goal is to set an upper threshold as low as possible to support safety, but not so low that it risks the quality of the image. Because larger patients require greater dose, the measure will be adjusted within each CT-Cat for patient size.

To set the upper radiation dose threshold the UC project team combined information from the UC International CT Dose Registry (UC Dose Registry) with data collected in a study of radiologists who rated the image quality of a test set CT scans. The UC Dose Registry provided empirical data on the distribution of radiation doses used within each CT-Cat from the 151 participating institutions. These data were combined with the assessments from the 125 radiologists who each rated the image quality of 200 of the test cases. These test cases (N=740) were sampled from actual cases from UC Dose Registry and were selected to represent the four largest CT manufacturers. These test cases were sampled across the range of radiation doses within a CT-Cat and were intentionally slightly oversampled at the low end of dose where it was assumed that most of the image quality issues would arise. The radiologists were asked to rate the images on a 4-point scale defined as follows: **Excellent** (“images provide the needed information”), **Adequate** (“image quality is acceptable but not excellent. You would re-scan and change the parameters for a higher quality image if it is easy to repeat, but if not, this is good enough for what you need.”), **Marginally Acceptable** (“image quality is less than ideal and may

compromise diagnostic quality. If the patient cannot easily be re-scanned you will interpret this but would change parameters for future scans of this type.”), and **Poor** (“image quality is not adequate for diagnosis and should be repeated.”).

The majority of cases were rated as having sufficient image quality (Excellent= 49%, Adequate= 40%, Marginally Acceptable= 8%, Poor= 3%). For most CT-Cats, the percentage of readings in which the ratings were adequate or excellent increased with dose, but the percentage change relative to the dose distribution was small. For a few CT-Cats there was no association between radiologists’ assessment of quality and dose. The number of cases rated as poor or marginal varied among radiologists. Recognizing these differences, the data were adjusted for how hard of a grader a radiologist was. A graph was displayed of the proportion of interpretations into each of the 4 categories by radiologist reader (slide #32).

The UC project team used the radiation doses on the test cases within a CT-Cat superimposed on the distribution of doses within that CT-Cat from the UC Dose Registry. This allowed the UC project team to identify when increases in radiation doses did not meaningfully contribute to a higher proportion of radiologists rating the image quality as excellent, adequate or marginally acceptable. The table demonstrating the CT Scan image quality rating by observed dose can be found on slide #33.

Dr. Bindman then proposed a rule for setting the upper radiation dose threshold. The rule would set the upper limit of acceptable (non failing) where at least 98% of radiologists assess images as being excellent or adequate or marginally acceptable AND at least 90% of physicians rate the dose as excellent or adequate. He then demonstrated how this rule would play out in the UCSF data across a range of CT-Cats (figure found on slide #36).

If these proposed rules were applied, on average, approximately 20% of CT scans would be considered above threshold in 13 CT-Cats. For two categories, where even the lowest observed dose satisfies the criteria and for the four categories in which there is no association between radiation dose and image quality, the UC project team proposes that the upper threshold is set at the average reduction of the 13 CT-Cats.

10:10 AM Discussion: Method for Setting the Upper Radiation Dose Threshold, Dr. Burstin

(Dr. Villines) expressed his approval for the approach that has been developed thus far. In terms of the categories of physician assessment of image quality, he noted that in his clinical practice, “Excellent” is usually defined as textbook quality, if not too much radiation dose, while “Adequate” is usually defined as typical diagnostic quality. He also brought up if the complicating factor of image noise will be brought into the analysis and shared with the TEP in this presentation. Dr. Bindman replied that the question of image noise will be one topic of discussion during Part 2 of TEP #4.

(Dr. Bronner) asked if the clinical history associated with the CT exams used in the Image Quality Sub-Study was known to the radiologist readers. Dr. Bindman replied that a simplified history was provided to the participants that would have been sufficient for them to be oriented to the proper CT-Cat..

(Dr. Sandy) had a question about where to set the threshold. He posited a simpler rule: setting the threshold at the modal point of every scan that is studied. He felt that the UC project team approach was too lenient. (Dr. Chatfield) from the ACR said that she agreed that we were being too lenient and pointed out the ACR’s convention is to set the 75th percentile as the upper limit.

Dr. Bindman asked the TEP if anyone thought that the current construction of the thresholds was too aggressive. The TEP responded no, although some members thought that there is a level of complexity that may make it difficult for radiologists to interpret their results.

10:25 AM Wrap Up and Next Steps _____ **Dr. Bindman**

Dr. Bindman thanked the TEP for their advice and noted that the UC project team would reflect on the input and incorporate it into discussions with CMS. He stated that the agenda for Part 2 of TEP #4 would include presentations on the proposed method for automating evaluation of image quality to ensure that doses below upper threshold are not reduced so much as to undermine image quality.

He reminded the TEP that information about this meeting and future meetings will be posted at ctqualitymeasure.ucsf.edu, as well as reminded the members of the possibility to receive an honorarium for their participation.

This meeting will occur via webinar in late May or early June. Members of the UCSF team will reach out to TEP members to begin scheduling this follow-up meeting.

10:30 AM Adjourn _____ **Dr. Burstin**



Substitute W-9 & Supplier Information Form

SUPPLIER INFORMATION			
1	NAME (as registered with the IRS)		
	TRADE NAME/DBA		
	PRIMARY ADDRESS (number, street, and apt or suite no)		REMITTANCE ADDRESS (if different from primary)
	CITY, STATE, and ZIP+4 CODE		CITY, STATE, and ZIP+4 CODE
	PHONE	FAX	EMAIL
	TAX CLASSIFICATION <input type="checkbox"/> INDIVIDUAL/SOLE PROPRIETOR <input type="checkbox"/> C CORPORATION <input type="checkbox"/> S CORPORATION <input type="checkbox"/> PARTNERSHIP <input type="checkbox"/> TRUST/ESTATE <input type="checkbox"/> LLC – Tax Classification (C=C Corporation, S=S Corporation, P=Partnership) _____ <input type="checkbox"/> OTHER _____		EXEMPTIONS EXEMPT PAYEE CODE (if any) _____ EXEMPTION FROM FATCA REPORTING CODE (if any) _____
	TAXPAYER IDENTIFICATION NUMBER (TIN) <div style="display: flex; align-items: center; justify-content: space-around;"> <div style="border: 1px solid black; padding: 5px; text-align: center;">SOCIAL SECURITY NUMBER : : : :</div> <div style="font-size: 1.5em; font-weight: bold;">OR</div> <div style="border: 1px solid black; padding: 5px; text-align: center;">EMPLOYER IDENTIFICATION NUMBER : :</div> </div>		DUN & BRADSTREET NUMBER UNSPSC CODE (if applicable)
PAYMENT OPTIONS			
2	Select ONE: <input type="checkbox"/> Immediate with Virtual Card/Payment Plus payment (<i>PREFERRED</i>) <input type="checkbox"/> 2%10,N30 with ACH payment <input type="checkbox"/> N30 with ACH payment <input type="checkbox"/> 1%20,N60 with check payment <input type="checkbox"/> N60 with check payment		PURCHASE ORDER EMAIL
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	<input type="checkbox"/> SBE (Small Business Enterprise) <input type="checkbox"/> SDB (Small Disadvantaged Business) <input type="checkbox"/> SDVOSB (Service-Disabled Veteran-Owned Small Business) <input type="checkbox"/> VOSB (Veteran-Owned Small Business) <input type="checkbox"/> WBE (Women Business Enterprise) <input type="checkbox"/> WOSB (Women-Owned Small Business)		<input type="checkbox"/> ABILITY ONE PROGRAM <input type="checkbox"/> ABILITY ONE
REQUESTER'S INFORMATION			
4	UCSF CONTACT NAME		UCSF CONTACT EMAIL
CERTIFICATION			
5	Under penalties of perjury, I certify that: 1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and 2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and 3. I am a U.S. citizen or other U.S. person (defined in the instructions); and 4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because of underreporting interest or dividends on your tax return. The Internal Revenue Service does not require your consent to any provision on this document other than the certifications required to avoid backup withholding.		
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- ACH – payment by electronic funds transfer. A business bank account is required.
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Section 6109 of the Internal Revenue Code requires you to provide your correct TIN to persons who are required to file information returns with the IRS to report interest, dividends, and certain other income paid to you; mortgage interest you paid, the acquisition or abandonment of secured property; the cancellation of debt; or contributions you made to an IRA, or Archer MSA or HSA. The person collecting this form uses the information on the form to file information returns with the IRS, reporting the above information. Routine uses of this information include giving it to the Department of Justice for civil and criminal litigation, and to cities, states, the District of Columbia, and U.S. possessions for use in administering their laws. The information also may be disclosed to other countries under a treaty, to federal and state agencies to enforce civil and criminal laws, or to federal law enforcement and intelligence agencies to combat terrorism. You must provide your TIN whether or not you are required to file a tax return. Under section 3406, payers must generally withhold a percentage of taxable interest, dividend, and certain other payments to a payee who does not give a TIN to a payer. Certain penalties may also apply for providing false or fraudulent information.

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Misuse of TINs. If the requester discloses or uses TINs in violation of federal law, the requester may be subject to civil and criminal penalties.

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PREVIOUS BANKING INFORMATION (REQUIRED IF REQUESTING AN ACCOUNT CHANGE)		
2	DEPOSITORY INSTITUTION NAME	
	TRANSIT ROUTING NUMBER	ACCOUNT NUMBER
NEW BANKING INFORMATION		
3	DEPOSITORY INSTITUTION NAME	
	TRANSIT ROUTING NUMBER	ACCOUNT NUMBER
	ACCOUNT TYPE <input type="checkbox"/> CHECKING <input type="checkbox"/> SAVINGS	

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Conflict of Interest Declaration for Technical Expert Panel (TEP) to Develop a Radiation Quality and Safety Measure

Please answer each of the questions below and submit the completed form to the University of California San Francisco (UCSF). UCSF will confirm prior to each TEP meeting that the information you have submitted is up to date and if you indicate that it is not, we will ask you to provide an update as a part of your participation in the TEP.

1. Have you, your spouse, your registered domestic partner, and/or your dependent children received income or payment as an employee, consultant or in some other role for services or activities related to diagnostic imaging?

No

Yes (please describe each person as well as all roles with specified organizations)

1.

2.

3.

4.

5.

2. Do you, your spouse, your registered domestic partner, and/or your dependent children currently own, or have held in the past 12 months, an equity interest in any health care related company which includes diagnostic imaging as a part of its business?

DO NOT REPORT Mutual Funds or Index Funds.

No

Yes (please describe each person and the equity interests)

1.

2.

3.

4.

5.

3. Do you, your spouse, your registered domestic partner, and/or your dependent children hold a patent, copyright, license or other intellectual property interest related to diagnostic imaging?

No

Yes (please describe each person and nature of the patent, copyright, license, or other intellectual property)

1.

2.

3.

4.

5.

4. Do you, your spouse, your registered domestic partner, and/or your dependent children hold a management or leadership position (i.e., Board of Directors, Scientific Advisory Board, officer, partner, trustee, etc.) in an entity with an interest in diagnostic imaging?

No

Yes (please describe each person and nature of the patent, copyright, license, or other intellectual property)

1.

2.

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5.

5. Have you, your spouse, your registered domestic partner, and/or dependent children received and cash or non-cash gifts from organizations or entities with an interest in diagnostic imaging?

No

Yes (please describe each person, whether the gift was cash or non-cash, and the organization which provided the gift)

1.

2.

3.

4.

5.

6. Have you, your spouse, your registered domestic partner, and/or dependent children received any loans from organizations or entities with an interest in diagnostic imaging?

No

Yes (please describe each person who received any loans and the organization which provided it)

1.

2.

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7. Have you, your spouse, your registered domestic partner, and/or dependent children received any paid or reimbursed travel from organizations or entities with an interest in diagnostic imaging? Do not include travel paid/reimbursed by (a) local, state or federal governments; (b) US institutions of higher learning; (c) academic teaching hospitals or medical centers; or (d) research institutions affiliated with US institutions of higher education.

No

Yes (please describe each person who received paid or reimbursed travel as well as the organization which provided it)

1.

2.

3.

4.

5.

Printed Name _____

Signature _____

Date Signed _____

Email completed form to Naomi.Lopez-Solano@ucsf.edu