

# **TEP Packet Contents**

<b>AGENDA</b>	<b>Pg. 2</b>
<b>PRESENTATION SLIDES</b>	<b>Pg. 3-48</b>
<b>TEP MEETING 4 Part 2 MINUTES</b>	<b>Pg. 49-60</b>
<b>HONORARIUM DOCUMENTATION</b>	<b>Pg. 61-63</b>
<b>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.</b>	
<b>CONFLICT OF INTEREST FORM</b>	<b>Pg. 64-66</b>

**YOU WILL ONLY NEED TO RE-SUBMIT THIS FORM TO OUR TEAM IF THERE HAVE BEEN ANY CHANGES SINCE OUR PREVIOUS MEETING IN APRIL 2020, 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.**

# Technical Expert Panel Meeting Agenda

*Wednesday, August 5th, 2020*

*11:00am-2:00pm Pacific Time*

*Call in number: +1 669 900 6833*

*Zoom Meeting ID: 979 3558 4581*

<https://ucsf.zoom.us/j/97935584581?pwd=ZWVvQ0RBc29JSWZ3R1V4S3F1SnpMdz09>

***Password: 916446***

11:00 AM Call meeting to order. Minutes from prior meeting on website. Dr. Helen Burstin

11:05 AM Roll Call and Updated Conflicts Dr. Burstin

11:15 AM Updates Dr. Bindman

11:35 AM Approach to Setting Upper Dose Thresholds Dr. Bindman

12:00 PM Discussion of Approach to Setting Upper Dose Thresholds Dr. Burstin

12:15 PM Approach to Assessing Image Quality Dr. Smith-Bindman

1:00 PM Discussion of Approach to Assessing Image Quality Dr. Burstin

1:25 PM Wrap Up and Next Steps Dr. Bindman

1:30 PM Adjourn

*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](http://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 Susanna McIntyre (Host).*



University of California  
San Francisco

*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 Susanna McIntyre (Host)**



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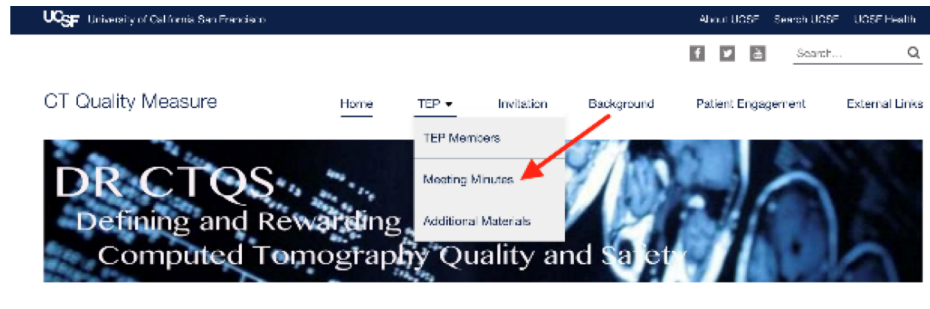
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ctqualitymeasure.ucsf.edu

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 Burstyn, 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

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

# TEP Goals

- Communicate updates: Timeline and Progress
- Guidance on revised approach to setting upper radiation dose thresholds
- Guidance on approach for setting image quality threshold

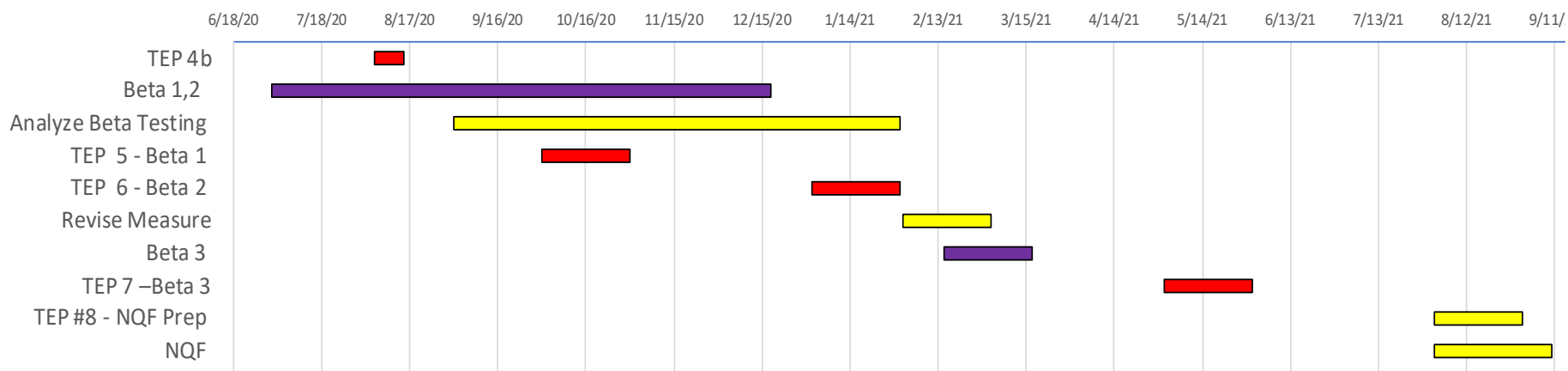


# Where Are We In Our Journey

- 22 months into 36 month project
- Anticipating confirmation from CMS of funding for year 3
- Research team minimally impacted by COVID-19
- Some COVID-19 related delays in working with external testing sites
- Have adjusted testing plan to accommodate



# MIPS Project Timeline



TEP Meetings



Testing



Measure Development



# Inclusion of CT Measure in Additional CMS Programs

- TEP identified the difficulty of physician's submitting data for MIPS in hospital settings where data are controlled by hospital
- Inclusion of measure in hospital reporting programs and physician program would align incentives.
- We were encouraged by CMS to submit a CT measure to the MUC list (measure under consideration) for the IQR, OQR, CAH
- The eCQM measure only includes an assessment of dose (not image quality)
- Inclusion of image quality assessment in MIPS ensures most CTs (performed in the ED and IP and CAH) will have quality assessment

# Questions

- Would the adoption of the measure described ease concerns about physicians being able to report in the MIPS program?



## Upper Threshold for Radiation Dose

- Measure requires that we establish a dose for each CT scan above which it will be rated as too high
- Threshold will be specific for each CT-Category
  - 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 Category



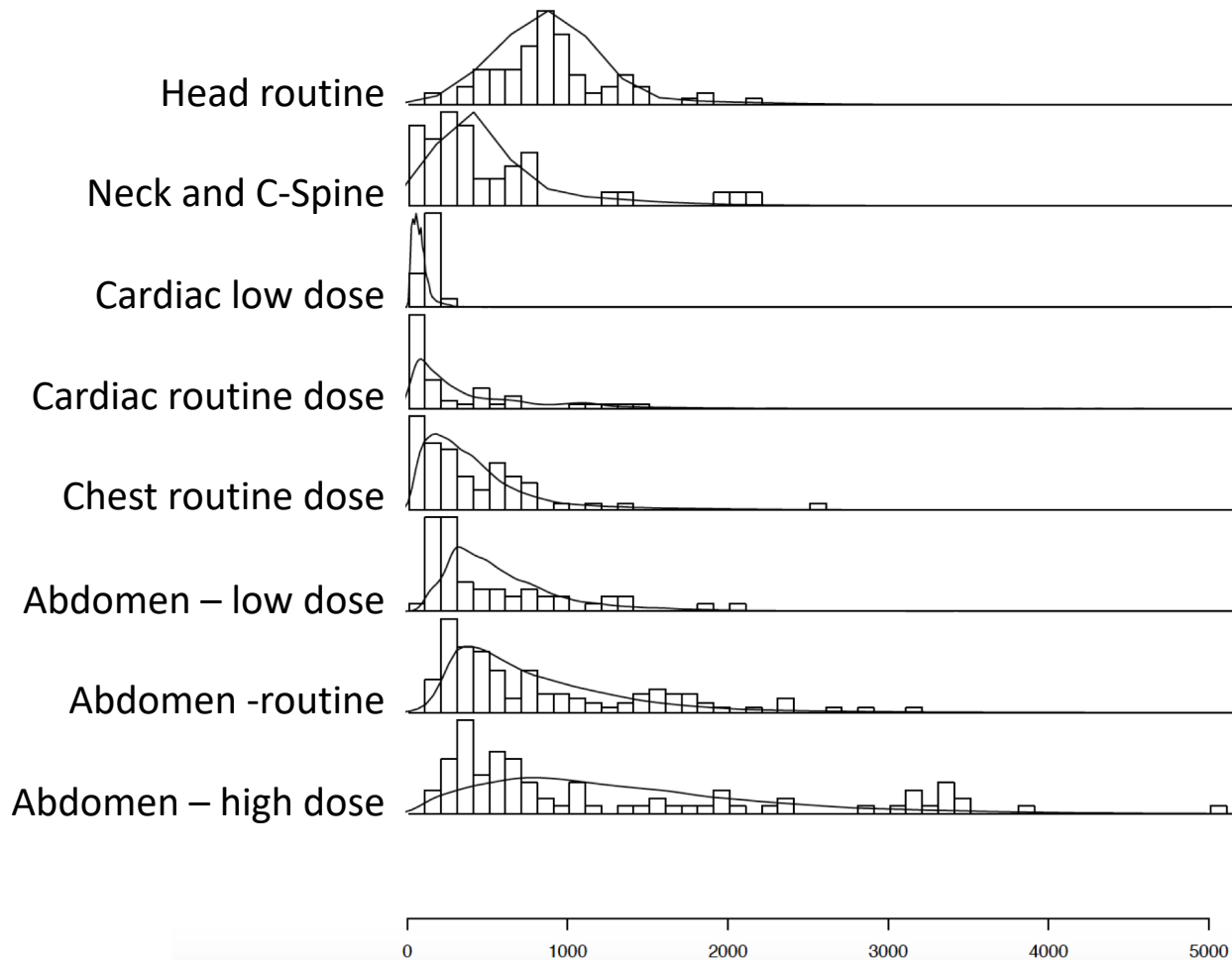
Distribution in Dose Length Product

0 1000 2000 3000 4000 5000

## Radiologists' Assessments Across Dose Range

- 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 with an average of 35 interpretations per case

# Distribution of Sampled Cases Parallels Distribution in Registry Doses



Smoothed solid line =  
dose distribution in  
registry

Histogram = dose  
distribution in  
sampled cases

# Categories for Physician Assessment of Image Quality

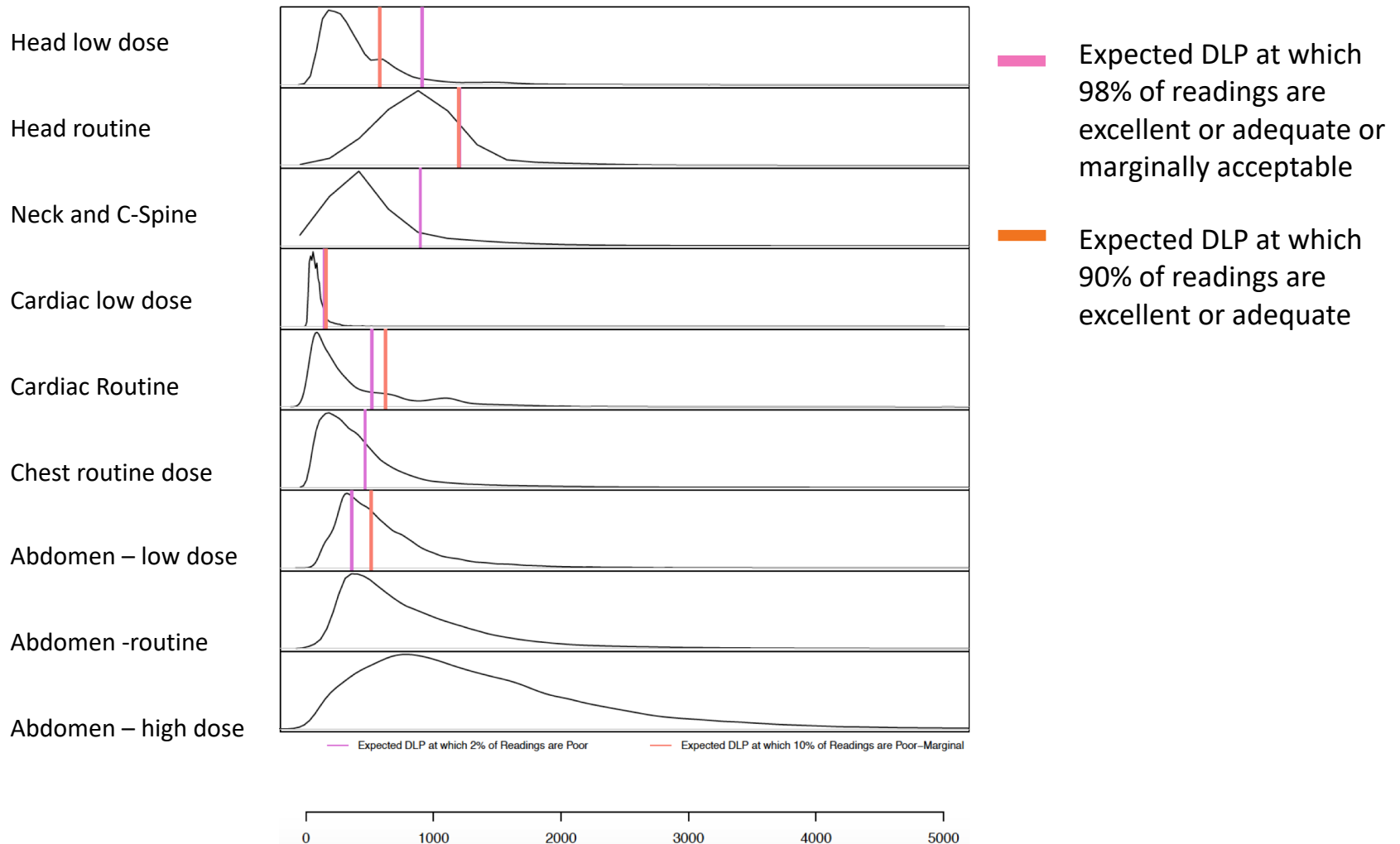
<b>Quality</b>	<b>What it Means</b>
Excellent	Images provide the needed information.
Adequate	Image quality is acceptable but not excellent. You would re-scan and change the parameters for a higher quality image if it is easy to repeat, but if not, this is good enough for what you need.
Marginally acceptable	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.



# Prior Proposal on Upper Radiation Dose Threshold

- Set dose above where at least 98% of physicians assess images as being excellent or adequate or marginally acceptable
- At least 90% of physicians think dose is excellent or adequate
- Thresholds adjusted for patient size
- For CT categories in which even the lowest observed dose meets criteria, set upper threshold based on average reduction from other categories

# Locations of these Dose Thresholds Across CT-Category



## Feedback From The TEP

- TEP members expressed that they believed our proposal on the upper dose threshold was overly conservative
- TEP recommended we incorporate median doses into our decision rules for categories in which even the lowest observed dose satisfied criteria.
- TEP recommended we avoid labelling scans with radiation doses above the threshold as “failures”

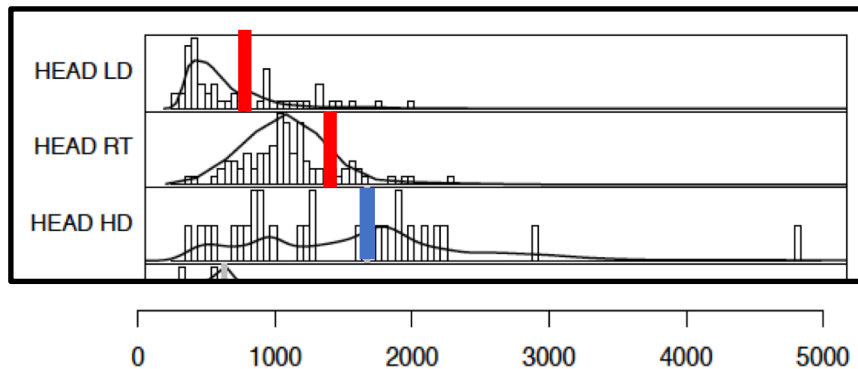
## Revised Rule For Creating Upper Dose Threshold

- Set a threshold for each CT category where at least 90% of physicians assess images as being excellent or adequate
- If at least 90% of physicians think dose is excellent or adequate at every observed dose in study, use the median as upper limit
- This rule would result in 38% of cases in the UCSF registry as “out of range”

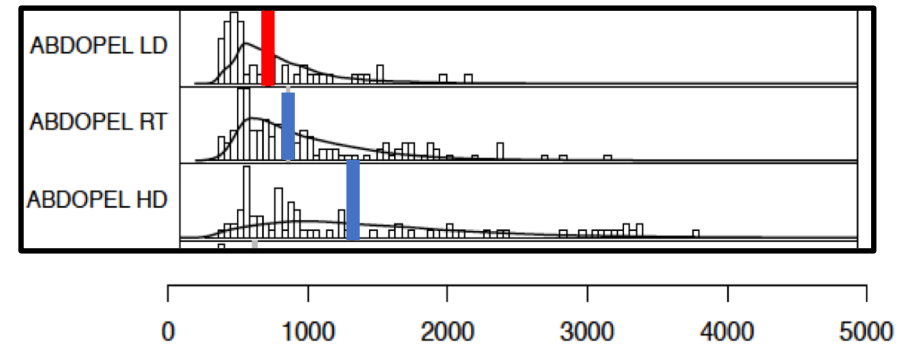


# Radiation Dose Thresholds

## Three Head Categories



## Three Abdomen Categories



**Red Line:** Threshold based on dose level where 90% of physicians rate image quality as excellent or acceptable

**Blue Line:** Threshold based on median dose

# Discussion Questions

- Do you endorse the revised approach for setting the upper dose threshold?



# Measuring Image Quality

- Radiologists need sufficient quality images to make accurate diagnoses
- Rationale for developing the image quality measure is to protect against untoward effect of incentivizing lower radiation dose
- Balancing measure to ensure doses are not too low– not to maximize image quality
- Standard approach to assessing image quality : sample cases submitted and judged by radiologists
- This is Impractical as a way to process millions of scans

# 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-Categories, the percentage of ratings as adequate or excellent increased with dose, but the change was small
- In some CT-Categories there was no association between the rating of image quality and radiation dose

# The Concept Behind Measuring Image Quality

- The test cases provide a way to create a gold-standard measure of image quality
- Goal is to find an automated approach that identifies cases that have inadequate (marginal or poor) image quality



# Automated measures of image quality

- Several measures of quality were calculated using data stored in the CT data
- Radiomics: noise, noise texture, resolution, contrast
- Machine learning algorithm that learns from the data how those quantities, collectively, relate to radiologists' scores of image quality.
- These two approaches were combined

# Radiomics

- Noise: Average level of non-anatomical fluctuations in images
- Noise texture: Average visual texture of fluctuations in images
- Resolution: The sharpness of the images
- Contrast: The average level of signal differentiation represented by images

# Machine Learning of Image Quality

- Computer first “trained” on a subset of images which includes radiologists’ gold-standard assessment of image quality
- Training not dictated by giving computer rules but allowing computer to use artificial intelligence to “learn” from radiologists’ assessment
- Computer then asked to assess image quality of other images blinded to the radiologists’ interpretation



## Defining an Inadequate CT Image

- The cases were labelled as inadequate based on a predetermined threshold (25%) of radiologists rating the scan as “marginal” or “poor”

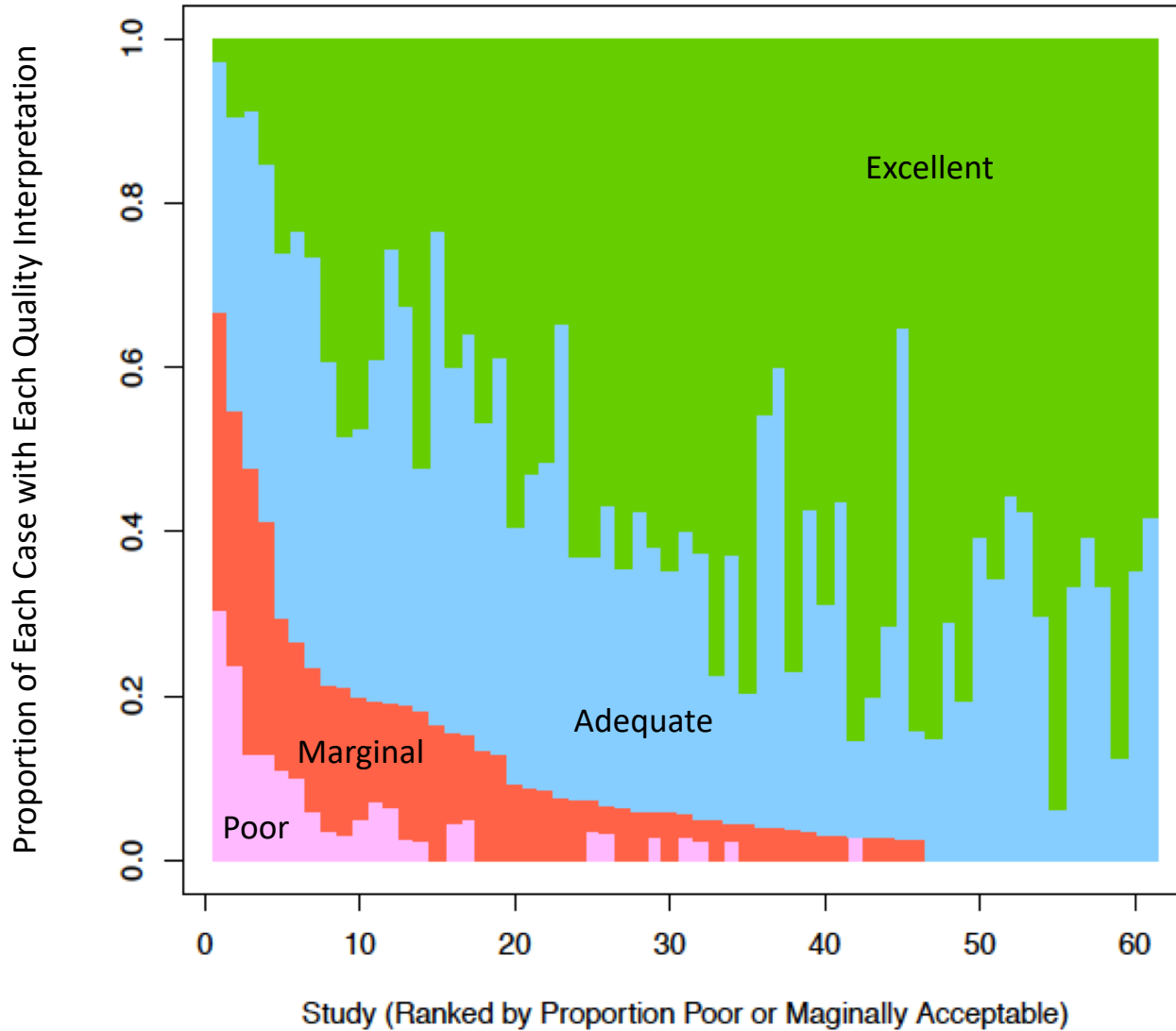
*Setting the proportion lower will result in lots of failed scans*

*Setting the proportion higher becomes extremely rare event*

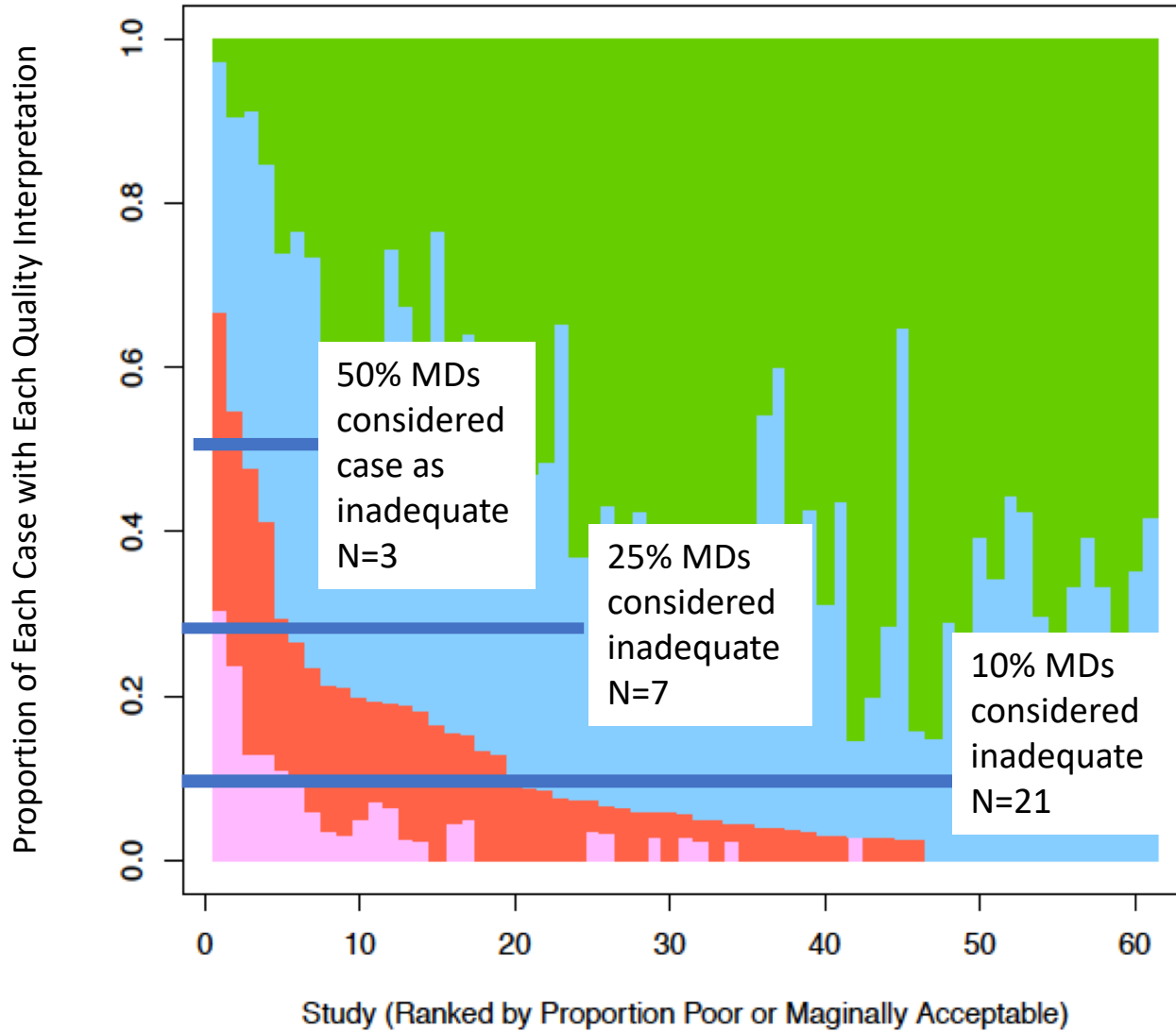


# Gold Standard Assessment

CT Category=Routine Chest ; N=61 Cases



# CT Category: Routine Chest, N=61 Cases



## Observed Inadequate Image Quality Rate

- The percent of the 740 cases we considered Inadequate varies by the threshold

### Definition of Inadequate Threshold

Head CT

Abdomen CT

Chest CT

10%

41%

28%

38%

25%

12%

8%

12%

50%

1%

2%

3%

# Statistical Evaluation of the Success of the Automated Measures of Image Quality

- Area Under Curve
  - What is it
  - What does it tell us
  - What value is indicative of a successful automated approach

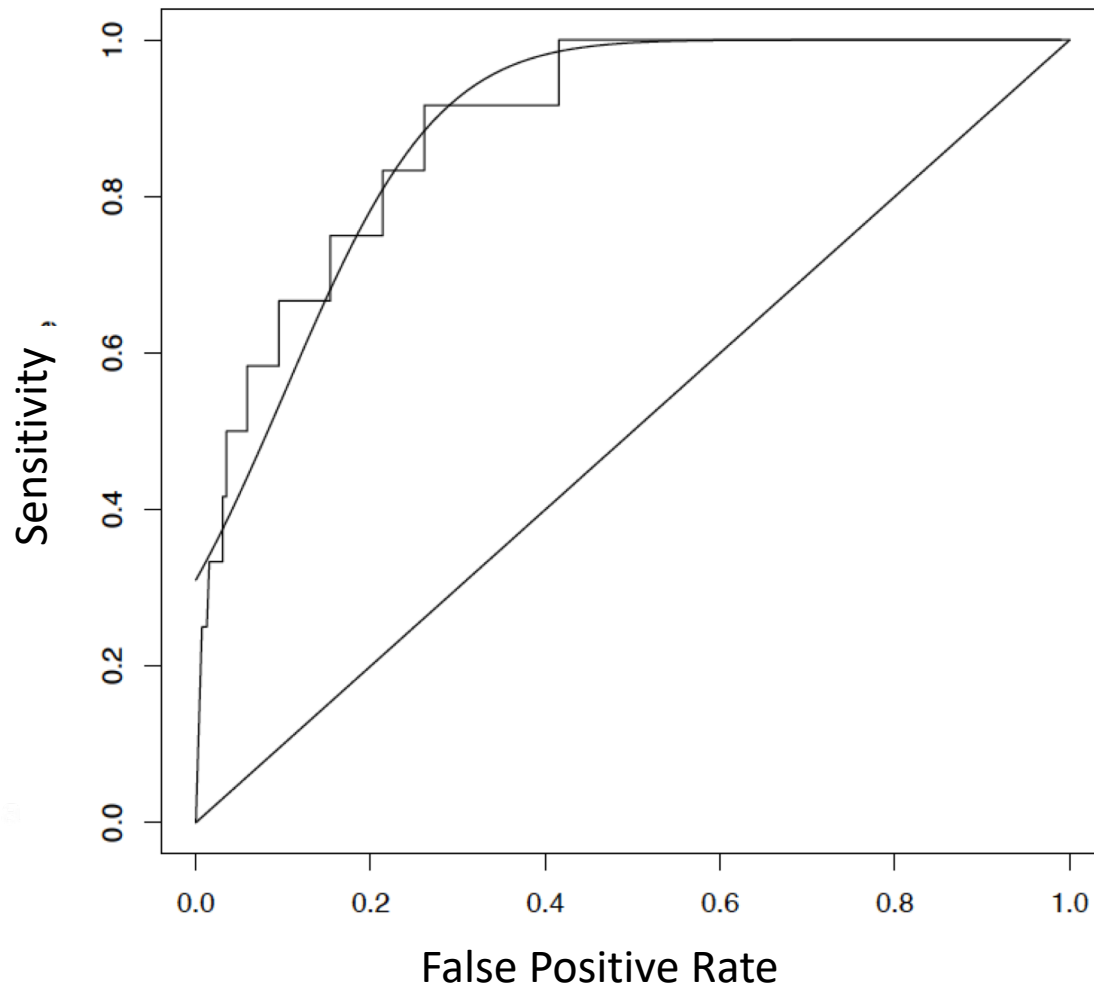


## Generating AUC Curves

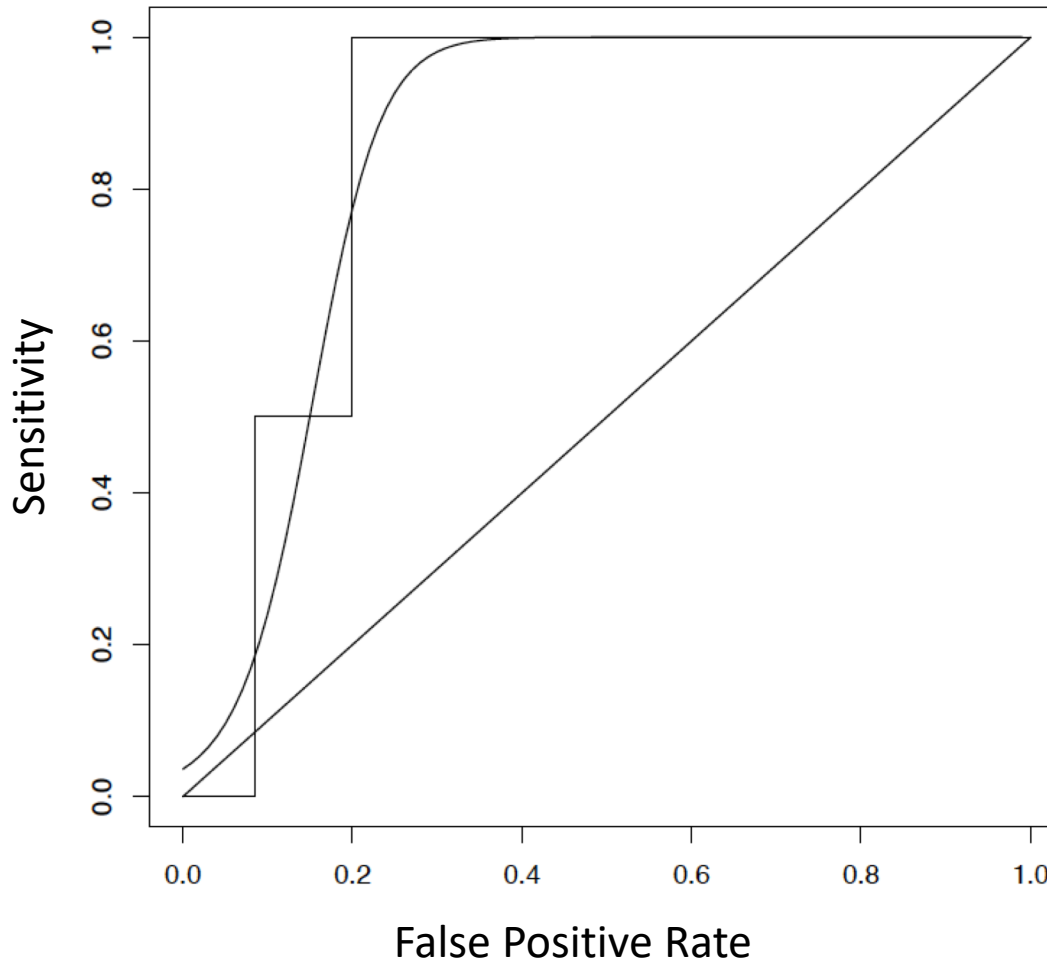
- For each CT category, we generated an ROC curve by plotting sensitivity by false positive rate
- Calculated the AUC of the ROC curves



# All CT Categories Combined - AUC 89%



# Abdomen and Pelvis- AUC 86%





# Results - AUC

## Area Under the Curve

### Derived Quantitative Measurements

Head

92%

Chest

85%

Abdomen

86%



# Is It Time for Champagne?



imgflip.com

## Understanding the Impact if Applied in Clinical Practice

- Cases labelled as inadequate by the automated approach may be true positives (truly inadequate) or false positives (truly adequate).
- Positive predictive value reflects how often automated approach correctly identifies the truly inadequate cases
- Positive predictive value influenced by prevalence
- Setting the false positive rate at 5% and 10% we calculated the positive predicted value that is associated with these false positive rates

# Results - PPV

## Probability that an identified case is Inadequate

	<b>5% False Positive</b>	<b>10% False Positive</b>
<b>Head</b>	0%	59%
<b>Chest</b>	45%	40%
<b>Abdomen</b>	15%	33%

# How Does Automated Image Quality Compare

- Screening Mammogram      PPV 5%      FP 10%
- Diagnostic Mammography      PPV 31%      FP 8%



# Impact of Patient Size

	<b>Smallest</b>	<b>Small</b>	<b>Average</b>	<b>Large</b>	<b>Largest</b>
	n = 102	n = 102	n = 102	n = 102	n = 102
Excellent	0.57	0.55	0.54	0.61	0.59
Adequate	0.31	0.32	0.34	0.31	0.31
Marginally Acceptable	0.09	0.09	0.10	0.06	0.07
Poor	0.03	0.03	0.03	0.02	0.03

- We are exploring contribution of patient size to assessment of the image quality to see if it needs to be incorporated into assessments.

# Questions

- Is 25% threshold to consider exam inadequate a reasonable threshold
- Is a 10% false positive rate acceptable



## Next Steps in Testing

- Can we calculate radiation doses, image quality in the real world to formulate judgments of practice?
- Beta testing at 6 sites
- Early results at next TEP







# DEFINING AND REWARDING COMPUTED TOMOGRAPHY QUALITY AND SAFETY

## **TEP Meeting #4 Part 2 Minutes**

Meeting Date: 8/5/2020

Meeting Time: 11:00am-1:30pm PDT

Meeting Location: Virtual Conference via Zoom

Approval Date: 8/27/2020

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
<b>Attendees</b>		
Mythreyi Bhargavan Chatfield, PhD	Executive Vice President	American College of Radiology
Niall Brennan, MPP	CEO	Health Care Cost Institute
Jay Bronner, MD	President and Chief Medical Officer	Radiology Partners
Helen Burstin, MD, MPH, FACP	Executive Vice President	Council of Medical Specialty Societies
Tricia Elliot, MBA, CPHQ	Director, Quality Measurement	Joint Commission
Jeph Herrin, PhD	Adjunct Assistant Professor	Yale University
Hedvig Hricak, MD, PhD	Radiology Chair	Memorial Sloan Kettering Cancer Center

Name	Title	Organization
<b>Attendees</b>		
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
Kenneth Wang, MD, PhD	Adjunct Assistant Professor	University of Maryland, Baltimore
<b>Not in Attendance</b>		
Missy Danforth	Vice President of Health Care Ratings	The Leapfrog Group
Arjun Venkatesh, MD, MBA, MHS	Assistant Professor	Yale School of Medicine
Todd Villines, MD, FSCCT	Professor and Director of Cardiovascular Research and Cardiac CT Programs	University of Virginia

<b>Ex Officio TEP</b>		
Amy Berrington de Gonzalez, DPhil	Branch Chief & Senior Investigator	National Cancer Institute; Division of Cancer Epidemiology & Genetics, Radiation Epidemiology Branch
Mary White, ScD	Chief, Epidemiology and Applied Research Branch	Centers for Disease Control and Prevention
<b>CMS &amp; CATA Representatives</b>		
Janis Grady	Project Officer	Centers for Medicare & Medicaid Services
<b>Not in Attendance</b>		
Marie Hall	CATA Team	Health Services Advisory Group
<b>UC Team</b>		
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
Susanna McIntyre	Research Assistant	University of California, San Francisco

**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.

**11:00 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 2.5 hours and will include a discussion period after each presentation.

**11:05 AM: Roll Call and Updated Conflicts** \_\_\_\_\_ **Dr. 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 had no new conflicts of interest. Dr. Mythreyi Chatfield stated her affiliation with the American College of Radiology (ACR), and had no new conflicts of interest to disclose. 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. Jay Bronner stated his relationship with Radiology Partners, and had no conflicts of interest. Tricia Elliot restated her role as the Director of Quality Measurement at The Joint Commission, and no new conflicts of interest. Dr. Jeph Herrin stated his affiliation with Yale University, 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. Matthew Nielsen reported his affiliation with

the University of North Carolina. Dr. Debra Ritzwoller stated her affiliation with Kaiser Permanente Colorado and as a patient/guardian stakeholder, and had no new conflicts. 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 and not representing government, and stated no new conflicts. Dr. Mary White reported her affiliation with the Centers for Disease Control & Prevention, and had no new conflicts of interest. 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. 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, and reported no new conflicts. Dr. Anthony Seibert stated his role as a medical physicist at UC Davis Health, and had no conflicts of interest to declare.

**11:15 AM: Updates****Dr. Andrew Bindman**

Dr. Bindman provided the TEP with updates related to; (1) progress on the timeline, and (2) the potential for having the developed measure adopted in other CMS programs in addition to MIPS.

Dr. Bindman informed the TEP that UCSF is 22 months into a 36-month long project. UCSF has provided CMS with an update on progress to date as a part of a process to request the third year of funding. UCSF is hopeful that CMS will agree that the project is on track and merits the on-going support.

Dr. Bindman updated the TEP about the impact of COVID-19 on the project. He reported that the core research team at UCSF, UC Davis and associated collaborators at Duke University and the University of Maryland have been able continue to work together online without a major interruption. The major way in which COVID-19 has impacted the project is in working with external testing sites. While those sites, for the most part, have remained very committed to the idea of working with us on the project, the IT partners at these sites have faced competing demands, such as; getting telehealth operating to enable their health care system to remain functional. This has created some delays in terms of when data will be collected from those testing sites. Recognizing this, adjustments to the testing plan have been made to ensure that all the necessary results will be collected in order to complete the project on time. Dr. Smith-Bindman then provided a description of a schematic showing how testing will be conducted at six different healthcare systems. There are three different parts of testing. Beta one focuses on the Computed Tomography (CT) categories and our assessment of the upper dose threshold. Beta two focuses on the quality measure that is the primary focus of today's TEP meeting. Beta three will include an assessment of the burden of data collection on providers. While the original plan was to move all testing sites together through these different phases, UCSF now plans to move sites through the different beta testing phases on a rolling basis. UCSF believes that learning from the process of onboarding the first sites can be used to accelerate the testing process with the sites that are delayed.

Dr. Bindman thanked the TEP for the prior feedback that identified that a challenge related to using the measure in the Merit-based Incentive Payment System (MIPS) Program is that

physicians who perform these tests in the context of a hospital setting may have difficulty gaining access to the data that are needed to submit to the MIPS Program. This is because hospitals typically own and operate the IT system. If the hospital was not part of any incentive structure related to the reporting, hospital leaders may not prioritize making the data available to the radiologist. With the help of our CMS project officer, Janis Grady, Dr. Bindman and Dr. Smith-Bindman have had several conversations with leaders within the CMS quality programs. In response, CMS encouraged UCSF to submit the CT measure to the Measures Under Consideration (MUC) list for the Inpatient Quality Reporting Program (IQR) program as well as the Outpatient Quality Reporting Program (OQR) and the Critical Access Hospital (CAH) programs. While it may prove difficult to complete testing in time for the measure to be adopted by CMS for 2021, and there are some important differences in the reporting of how these programs work, UCSF regards the potential widespread adoption of the measure across different CMS quality programs as a positive development. The IQR, OQR and CAH programs do not use a registry-based way of reporting, the same way that there is available for physicians. UCSF is exploring the possibility of developing an Electronic Clinical Quality Measure (eCQM), which is a digital way of reporting information from electronic record reporting systems. While there are many hurdles to overcome, UCSF is committed to working with CMS to make this happen, due to the team's belief that having the measure implemented in hospital and physician-based quality programs would help to align incentives for improving quality of care.

Dr. Bindman solicited feedback from the TEP on the project updates. UCSF received a positive response to the possibility of having the measure adopted in hospital as well as physician-based quality programs. A question was raised about the timing of the measure moving forward on the MUC list, Dr. Bindman replied that this was still being discussed with CMS. Another question was asked as to whether UCSF still planned to rely on a QCDR for the MIPS measure, and Dr. Bindman confirmed that was still the plan. While the hospital programs do not make use of QCDRs, Dr. Bindman said that UCSF would try to make the data collection process of hospitals via an eCQM similar to what the QCDR would do in the MIPS program. Another question was asked about whether the data fields for making the measure an eCQM existed. Dr. Bindman said that while the digital data necessary for the measure existed in DICOM standardized data fields within electronic health records, it had not yet been mapped for the purposes of quality measure development, but that CMS was in conversations with the National Library of Medicine on UCSF's behalf to make this possible. The TEP representative from the Joint Commission not only endorsed the idea of a hospital based measure, but expressed interest in working with UCSF to help make sure that any problems in the data fields could be addressed to help get the measure implemented. Dr. Smith-Bindman acknowledged that some data fields in the Digital Imaging and Communications in Medicine (DICOM) may not be reliable but that she believes that the ones needed for the measure, such as the reporting of radiation dose, are done in a valid and standardized way across hospitals. The representative from the ACR raised a question about whether data from DICOM are accurately stored in electronic health records. Dr. Smith-Bindman stated that as a part of Beta testing, UCSF is testing whether it can extract data directly from the DICOM and combine that with other data in the electronic record, such as that on the clinical indication for the CT exam, as well as the billing type, as a way to accurately categorize CT scans and assess the radiation dose. The TEP will have an opportunity to review these testing data at upcoming TEP meetings.

**11:35 AM: Approach to Setting Upper Dose Thresholds Dr. Bindman**

Dr. Bindman reviewed the strategy discussed at the prior TEP meeting (TEP #4 Part I) for setting the upper radiation dose threshold. The plan is to place CT scans into dose range categories based on anatomical area and clinical indications. Then, using the ratings 125 physicians made in assessing 740 test cases in these categories with varying levels of radiation, the following rule was proposed: the upper dose threshold should be no lower than where at least 98% of the physicians assess the images as being excellent or adequate or marginally acceptable, which is the same as saying fewer than 2% rate the images as poor, and that at least 90% of the physicians are saying that the dose is excellent or adequate, which is the same as saying 10% rating the images as poor or marginally acceptable. The dose would be adjusted for patient size. The challenge of this definition was that in some categories there was no dose in the range tested that did not meet the criteria, meaning every observed dose would be considered acceptable. UCSF did not believe setting the lowest possible dose in those categories as the upper dose threshold was reasonable, and had proposed therefore to lower the upper dose by the percentage change in the categories where an upper threshold using the defined criteria was acceptable. However, the feedback of the TEP was that this approach was too conservative. The recommendation was to incorporate median doses into our decision rules for categories in which even the lowest observed dose satisfied the criteria. UCSF created a modified rule with the following criteria: at least 90% of the physicians believe the dose is excellent or adequate, and for categories where even the lowest observed dose met this criteria, that the median dose would be considered the upper dose threshold. UCSF modelled this in the UCSF Dose Registry and found that applying this modification to the rule would result in 38% of the cases in being categorized as out of range. The UCSF team requested TEP input on this modification. At the prior TEP meeting, some members also objected to the use of the term “failure” when applied to scans that exceed the dose threshold. UCSF has proposed to define these exams as “out of range”.

**12:00PM: Discussion; Approach to Setting Upper Dose Thresholds Dr. Burstin**

A couple of the TEP members raised the concern that using the median could be problematic because over time the median would change as doses come down. UCSF clarified that the median would only be used for determining the dose for setting a threshold at the outset and that the median would not be re-calculated each year. It would simply be the way of determining the upper threshold for those categories in which even the lowest observed doses among the test cases fulfilled the criteria. A question was asked by Dr. Siebert as to whether, in addition to patient size, the assessment should be assessed for type of CT machine and their varying capabilities. Dr. Smith-Bindman answered by saying that UCSF has found when they have studied it in data from the UCSF Dose Registry, that actually the imaging machine used, the manufacturer, and the model, are relatively small predictors of dose. They do matter, but they don't matter very much, and that the much more important predictor is how the scanner is being used. These findings were published in the British Medical Journal (BMJ) last year. Furthermore, Dr. Smith-Bindman stated that in discussing this with four leading manufacturers at the Radiological Society of North America (RSNA) annual convention, they all confirmed from their own analysis that almost every scanner out there, the brand new ones or the old ones have the ability to use lower doses. The manufacturers acknowledged that they have struggled with how to get their physicians who buy their equipment to use it most effectively. Dr. Siebert stated



after Dr. Smith-Bindman's answer that he fully agreed with her. Dr. Bindman then read from the chat that Dr. Sandy and Dr. Bronner both wrote that they thought the revised threshold relying on the median looked about right. Dr. Burstin raised that she wondered if 38% of cases being out of range is too high and in particular wondered if it was falling disproportionately on some categories. The representative from the ACR also raised concerns about the percentage of scans that might be rated as out of range. Dr. Bindman reminded the TEP that even if that many scans were rated as out of range that the assessment of an individual clinician or medical group would still be done along a curve based on the percentage of scans that are out of range. A patient representative asked if there were clinical indications that might be a reason for higher doses. Dr. Bindman reminded the TEP that clinical indications are included in setting dose ranges within anatomical areas. Dr. Smith-Bindman elaborated on that by pointing out that bias in setting up these categories was to allow clinicians to have certain scans that ordinarily could be done with lower doses to be placed in the higher dose categories if there was anything in the clinical indications that might suggest a need for it. Another question was asked as to whether the UC Dose Registry was sufficiently representative for setting the thresholds. Dr. Smith-Bindman said that the UCSF Dose Registry has scans from more than 150 imaging facilities and that comparisons with ACR's registry has revealed very similar dose ranges by anatomical areas. For example, the distribution in dose for kidney stones studies in the UCSF Dose Registry is identical to the dose in the ACR registry. The dose in the UCSF Dose Registry for patients who undergo non-contrast abdomen or multi-phase contrast are the same as in the ACR registry. In addition, as a part of this project, UCSF will be building a QCDR which would ultimately be used for reporting to CMS. This QCDR would provide another means of assessing dose ranges used in practice and provide a point of comparison with the UCSF Dose Registry.

While there was no formal vote on adopting the term "out of range" instead of failure or the application of the median dose as the upper dose threshold for those CT categories in which there is no dose at which at least 90% of radiologists rate the images as excellent or adequate, the TEP members acknowledged that UCSF had been responsive to the earlier feedback and had proposed a viable plan to proceed.

**12:15PM: Approach to Assessing Image Quality Dr. Rebecca Smith-Bindman**

Dr. Smith-Bindman provided a presentation on how the project team is approaching the assessment of image quality. The point of this work is not to identify distinctions at the high end of quality, but to protect against the risk that as payment is used to incentivize the use of lower radiation doses, that the doses that are used are not too low and thereby undermine sufficient image quality to make accurate diagnoses. The purpose of this quality component is not to maximize image quality, it is to ensure there is adequate image quality to make diagnosis. UCSF does not enter into this work with the belief that image quality is currently a significant issue, and this is supported by the results of the image quality study that UCSF conducted. In rating the test case images from across a wide range of CT categories and doses, 49% of all radiologists' ratings were excellent, 40% were adequate, 8% were marginally acceptable and only 3% were rated as poor. For most CT categories, the percentage of ratings as adequate or excellent increase with dose. For most categories, as there is more dose use, there were a higher percentage of

excellent and adequate examinations, although the changes were relatively small. There were some categories where there was no association between the rating of image quality and radiation dose.

The concept behind the image quality study is to develop a radiologist consensus of a gold standard of inadequate image quality. Inadequate image quality was defined as those scans rated by a significant number of radiologists as marginally acceptable or poor. Using that gold-standard, UCSF undertook a process to automate the way in which CT scans with inadequate image quality could be identified using radiomics and machine learning. Radiomics describes measurements from radiology images that are stored data as part of the image. The four assessed measures are noise, noise texture, resolution, and contrast. Noise measures level of fluctuation in the images that's not due to the anatomical changes, these anatomical changes between lung and liver, but these are the fluctuations that don't depend on change in the tissue composition. Noise texture has to do with the average visual texture of those fluctuations through how radiologists will see those differences. Resolution reflects how sharp the images are, and a radiologist's capacity to see differences between smaller and smaller lesions. Contrast reflects the average level of signal differentiation represented on images. The project team used machine-learning algorithms that learn from the data to figure out how these radiomic measures collectively relate to our radiologists' gold standard scores of image quality. For machine learning of image quality, the algorithm is trained on a subset of the 740 cases that include the radiologist's gold standard assessment of image quality for each case, and the algorithm used artificial intelligence (AI) to learn from the radiologist's assessments, and then the algorithm is tested on a separate subset of these examinations blinded to the radiologists' interpretation.

The cases were labeled as inadequate based on a predetermined threshold where 25% of radiologists interpreted the scan as marginal or poor quality. This meant at this threshold that 25% of radiologists thought the images were marginal or poor, which UCSF interpreted as meaning that the quality of the exam was not good enough. If the proportion were set lower, that would result in a large number of out-of-range scans. If the proportion were set higher, to identify scans that are an even worse quality, then it becomes an extremely rare event and almost impossible to find. For most of the categories, there would not be a sufficient number of cases that would be characterized as out of range when there is a requirement for a substantially higher number of radiologists rating these cases as marginal or poor quality.

To test how well the automated AI approach works to identify inadequate images the UCSF project team calculated the area under an Receiver Operating Characteristic (ROC) curve plotting the sensitivity by the false-positive rate using the radiologists' reading as the gold standard. The higher the area under the curve the better the automated approach is working. An area under the curve of 0.7 to 0.8 is considered acceptable, 0.8 to 0.9 is considered excellent and greater than 0.9 is considered outstanding. Combining all of the categories, the generated Area Under Curve (AUC), using the automated approach is 89%. Similarly, the AUC values for the head categories, for the chest categories, and the abdomen categories, were all in a range considered excellent or outstanding.

While the ROC curve analysis can provide an estimate of overall performance it does not address the sensitivity and specificity at single point along the ROC curve. To understand the

performance of the automated approach when applied in clinical practice, UCSF evaluated the positive predictive value. This describes how many cases identified as inadequate are truly inadequate. The positive predictive value is influenced by the prevalence. UCSF modelled a false-positive rate at 5%, and then at 10%. UCSF thought that a 10% false positive rate would be as high as the practicing community would tolerate.

For example, for head CT, if UCSF set the false-positive rate as being 5%, 23% of truly inadequate cases would be identified. If the false-positive rate is 10%, then the sensitivity for finding inadequate cases increases to 40%. The corresponding positive predictive value with a 5% false-positive rate is 46%, while for a 10% false-positive rate, the positive predictive value is 36%. The positive predictive value is better at a 5% false-positive rate, but the sensitivity is better with the 10% false-positive rate.

With a false-positive rate of 5%, the positive predictive values for different anatomical areas range from 31% to 54%. These results are preliminary and UCSF is in the process of replicating them with an independent team. To put these results in context, the overall positive predictive value of screening mammography nationally is only 4% with a false positive rate of 11%. The proposed image quality measure will perform better than this, but there will still be some images falsely labelled as inadequate. This is likely to be random in which case it will create some background noise in the assessment of radiologists, but should not skew their performance relative to one another. UCSF will be exploring potential confounders to try to ensure that the false positives are random and not systematically associated with certain practitioners. For example, in preliminary analysis UCSF did not find that patient size was associated with false positives.

**1:00PM:** *Discussion: Approach to Assessing Image Quality* **Dr. Burstin**

For the discussion, TEP members were asked to comment on whether a 25% threshold of physician ratings of a scan as inadequate seemed appropriate, and whether they believed a 5% or 10% false-positive rate was an acceptable rate when trying to identify the truly abnormal quality exams. Dr. Siebert asked a clarifying question as to whether images rated as inadequate quality could be due to things such as patient movement or other artifacts rather than radiation dose. UCSF team explained that the test cases were curated to eliminate those that would be rated as inadequate because of patient movement or other artifacts, so as to isolate the impact of the radiation dose in the assessment. Dr. Siebert went on to comment that while he would prefer a 5% rather than a 10% false positive rate he recognized the impact on the positive predictive value and could see if needed the application of a 10% false positive rate. A patient representative acknowledged that this was a rather technical question, but that she hopes to get input of a larger cross-section of the patient community to weigh in on this in the future. In considering the sensitivity of finding poor quality images, Dr. Bindman made the point that it may be less critical to find all of them, and more critical to have a reliable way of finding at least some of them so that there is a signal back to radiologists that going too low with doses does carry some risk of being penalized. Dr. Bindman said this was akin to knowing that audits occur on some tax returns, and that this acts as a deterrent for more than just those who receive the audit. Dr. Wang endorsed this way of thinking and suggested this might allow for a lower false positive rate. He also raised a question about whether the 25% threshold was high enough

because still 75% of radiologists were saying image was adequate or excellent. Other TEP members thought this had merit. Dr. Smith-Bindman said she would look into a higher threshold, but raised the concern that such rare cases might be even harder to identify using an automated approach. TEP members appreciated the care the UCSF team has taken to identify poor quality images, but also suggested that simplifying the approach would make it easier for the community to accept it. The ACR representative suggested that, like the proposed hospital measures, perhaps the image quality component should be dropped and only focus on the radiation dose. Others suggest that low radiation dose might be used to define an inadequate scan. Dr. Smith-Bindman agreed to look into that further, but suggested that she did not think it would work as well as the radiomics used in making the assessment. A question was asked if the images would still be needed if the image quality assessment were dropped. Dr. Smith-Bindman suggested they would still be needed to assess patient size. Dr. Burstin also raised whether changing from a balancing measure to a paired set of measures might be a better approach. Dr. Smith-Bindman said that this was the original idea, but that CMS had pushed for the balancing measure.

Following the discussion, UCSF indicated it would explore how well the automated approach for assessing image quality would work if the threshold for characterizing a scan as inadequate depended on more than 25% of radiologists rating a scan as marginal or poor.

UCSF also indicated that it would continue to work to simplify the measure by exploring whether low radiation dose can be a surrogate for inadequate image quality.

**1:25PM:      Wrap Up and Next Steps      **Dr. Bindman****

Dr. Bindman summarized the feedback from the TEP that members concur with notion of using a measure of image quality as a backstop. The goal is not to necessarily identify each scan with questionably inadequate image quality but to create a deterrent as a check against radiologists being too aggressive in lowering dose. To the degree possible, UCSF should try to simplify the approach for measuring image quality and consider how well low radiation dose can be an effective surrogate for inadequate image quality by, for example, looking at how well low radiation dose predicts inadequate exams. UCSF will also explore a higher threshold than 25% of what is considered an inadequate image. At the next TEP meeting, UCSF will provide updates on these analyses as well as results from beta testing in settings independent of the UC Dose Registry. Two of the testing sites will be providing UCSF, not just with electronic data, but their entire CT scans. UCSF is building in a phase in which it will look at any of the scans that are judged to be out of range, and then independently go through those scans and make sure whether to see if those are true positives or false positives, and so forth. This will enhance what has been done with the test sample and the UC Dose Registry.

**1:30PM:      Adjourn      **Dr. Burstin****

Dr. Burstin closed the meeting by congratulating the UCSF team for its impressive work and thanked the TEP for its rich discussion of the results.



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	CITY, STATE, and ZIP+4 CODE		CITY, STATE, and ZIP+4 CODE
	PHONE	FAX	EMAIL
	<b>TAX CLASSIFICATION</b> <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 _____		<b>EXEMPTIONS</b> EXEMPT PAYEE CODE (if any) _____ EXEMPTION FROM FATCA REPORTING CODE (if any) _____
	<b>TAXPAYER IDENTIFICATION NUMBER (TIN)</b> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; padding: 5px;">SOCIAL SECURITY NUMBER   :       :       :</div> <div style="font-size: 24pt; margin: 0 10px;"><b>OR</b></div> <div style="border: 1px solid black; padding: 5px;">EMPLOYER IDENTIFICATION NUMBER           :</div> </div>		<b>DUN &amp; BRADSTREET NUMBER</b>  <b>UNSPSC CODE (if applicable)</b>
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REQUESTER'S INFORMATION			
<b>4</b>	UCSF CONTACT NAME		UCSF CONTACT EMAIL
	CERTIFICATION		
<b>5</b>	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.		
	SIGNATURE		DATE
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SUBMIT COMPLETED FORM TO ONE OF THE FOLLOWING			
<b>6</b>	EMAIL (preferred): <a href="mailto:vendors@ucsf.edu">vendors@ucsf.edu</a>		MAIL: UCSF Supply Chain Management 1855 Folsom St Ste 304 San Francisco, CA 94143-0910

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	<b>BUSINESS EMAIL ADDRESS</b> (for payment notification)	<b>EMPLOYER ID NO (EIN)</b>
PREVIOUS BANKING INFORMATION (REQUIRED IF REQUESTING AN ACCOUNT CHANGE)		
<b>2</b>	<b>DEPOSITORY INSTITUTION NAME</b>	
	<b>TRANSIT ROUTING NUMBER</b>	<b>ACCOUNT NUMBER</b>
NEW BANKING INFORMATION		
<b>3</b>	<b>DEPOSITORY INSTITUTION NAME</b>	
	<b>TRANSIT ROUTING NUMBER</b>	<b>ACCOUNT NUMBER</b>
	<b>ACCOUNT TYPE</b> <input type="checkbox"/> CHECKING <input type="checkbox"/> SAVINGS	

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<b>5</b>	<table> <tr> <td><b>EMAIL (preferred):</b> <a href="mailto:vendors@ucsf.edu">vendors@ucsf.edu</a></td> <td><b>MAIL:</b> UCSF Supply Chain Management C/O Supplier Registration 1855 Folsom St Ste 304 San Francisco, CA 94143-0910</td> </tr> </table>	<b>EMAIL (preferred):</b> <a href="mailto:vendors@ucsf.edu">vendors@ucsf.edu</a>	<b>MAIL:</b> UCSF Supply Chain Management C/O Supplier Registration 1855 Folsom St Ste 304 San Francisco, CA 94143-0910
<b>EMAIL (preferred):</b> <a href="mailto:vendors@ucsf.edu">vendors@ucsf.edu</a>	<b>MAIL:</b> UCSF Supply Chain Management C/O Supplier Registration 1855 Folsom St Ste 304 San Francisco, CA 94143-0910		

## 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)

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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.

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**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)

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**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)

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**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)

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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)

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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)

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5.

Printed Name \_\_\_\_\_

Signature \_\_\_\_\_

Date Signed \_\_\_\_\_

Email completed form to [Naomi.Lopez-Solano@ucsf.edu](mailto:Naomi.Lopez-Solano@ucsf.edu)