TEP #5 Packet Contents

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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.

CONFLICT OF INTEREST FORM **Pg. 78-80**

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

Agenda

10:00 AM	Call meeting to order; minutes from prior meeting on website	Dr. Burstin
10:05 AM	Roll Call and Updated Conflicts	Dr. Burstin
10:15 AM	TEP Goals, Personnel Updates, CMS Updates	Dr. Smith-Bindman
10:25 AM	Discussion of Updates	Dr. Burstin
10:40 AM	Setting and Risk-Adjusting Upper Dose Thresholds	Dr. Smith-Bindman
11:00 AM	Discussion of Upper Dose Thresholds	Dr. Burstin
11:15 AM	Break	
11:25 AM	Approach to Assessing Image Quality	Dr. Smith-Bindman
11:45 PM	Discussion of Approach to Assessing Image Quality	Dr. Burstin
12:05 PM	Beta Testing Results	Dr. Smith-Bindman
12:35 PM	Discussion of Beta Testing Results	Dr. Burstin
12:55 PM	Wrap Up and Next Steps	Dr. Smith-Bindman
1:00 PM	Adjourn	

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).

We will begin the meeting shortly.

UCSF
University of California
San Francisco

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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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

Krishna Nallamshetty, 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
- Setting and risk-adjusting upper radiation dose thresholds
- Approach for setting image quality thresholds
- Review of beta testing results and challenges with missing data

Personnel Updates

- Carly Stewart - new UCSF program manager
- Andy Bindman - change in employment
- Dr. Krishna Nallamshetty - new TEP member

CMS Updates

- CMS support offered to develop corresponding hospital radiology measure

Inclusion of CT Measure in Additional CMS Programs

- TEP identified the difficulty of physician's submitting data for MIPS in hospital settings where data controlled by hospital
- Inclusion of measure in hospital reporting programs and physician program would align incentives.
- CMS is asking us to submit a CT measure for the IQR, OQR, CAH programs

CMS Updates

- CMS support for developing corresponding hospital measure
- Pivoting away from *new* QCDR measures in MIPS program

Shift in Measure Reporting to eCQM

- Redirecting the development of our CT radiation quality measure so that it can be reported as an eCQM
- eCQMs are computer automated measures derived with digitized data
- CMS supports eCQMs in MIPS and hospital based programs

Challenges in Creating an eCQM

- Radiation dose is based on *digitized and standardized data*, but these data not currently included in value sets needed for eCQMs
  - We are working with CMS, NLM to get value sets created
  - The value sets will include DICOM variables added to LOINC
- Measures of image quality are derived from *pixel data* which are significantly more complex and can't be entered into value sets
  - Threatens the potential of using image quality in measure
  - We are exploring work-arounds in order to include a quality measurement component, but an alternative is to not include measure of image quality – at least initially

Impact on Timeline

- 26 months into 36 - month project
- eCQM Accelerates timeline - we must submit the measure to the MUC list in May 2021
- MUC list is CMS's way of publicly indicating which "measures are under consideration" for potential future use
- We expect to receive an extension on submitting final testing results until September 2021
- Timeframe to submit for NQF endorsement (August) unchanged

Questions

- Do you see a benefit of having a parallel hospital measure for the proposed MIPS measure?
- Do you support our re - directing toward using an eCQM for both?
- Do you support our re - directing toward an eCQM, even if it requires that we pause on the image quality assessment?
- If we need to pause on the image quality component of the measure would that impact how low you would recommend we set the upper radiation dose threshold?

lets discuss this last question after the next section

Setting and Adjusting Upper Dose Threshold

Upper Threshold for Radiation Dose

- Measure depends on having an upper dose for each CT scan
- The thresholds will be specific for each CT - Category
  - Dose requirements vary by anatomical area
  - Upper limit for high dose abdomen > routine abdomen
- 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 dose to penetrate more tissue
  - There are no other patient characteristics or CT model factors that systematically influence radiation dose

Approach For Creating Upper Dose Threshold

- Dose thresholds were based on the physician quality study
- Set a threshold for each CT category where at least 90% of physicians assess images as excellent or adequate
- Doses above this level are unnecessary and lead to unnecessary risk.
- If at least 90% of physicians think the dose is excellent or adequate *at every* observed dose in study, the *median* for that category derived from the UC Dose registry is the upper limit

Out-of-Range By CT Category

- The proportion of exams that are out -of - range varies across CT categories
  - 5% of routine dose head CTs will be judged as too high
  - 50% of routine dose abdomen CTs will be judged as too high as the 90% threshold was met at every dose level
- More cases will be rated as out of range in those CT - categories in which radiologists were satisfied with image quality at *every* dose level

CT Scans Judged Out of Range by CT Category in UCSF Registry

- There is a strong correlation in the proportion of scans out of range across the different CT categories at the *facility level*

  If a facility has a high out-of-range value for routine abdomen they usually have high out range for other abdomen categories

- Most of the imaging facilities included in the UCSF Registry evaluated scans from across most / all CT Categories

- However, If a physician or physician group (as evaluated in MIPS) sees a limited distribution of patients, it may be easier / harder to have examinations within range depending on the category where their patients are most represented.

Adjusting for Patient Size

- Patient size assessed using the mid - scan diameter measured on axial image or scout image
- Adjustment is log-linear
- Size - adjusted dose for each CT scan will be compared with the threshold to determine if the dose is within or outside of range

How to Judge Size Adjustment

- Unless size-adjusted, the likelihood of a CT being out of range will primarily be driven by patient size
- If we are appropriately adjusting for size, we would expect similar number of out-of-range values across different size categories

Scans Judged Out of Range on Dose by Patient Size
UCSF Registry - Routine Abdomen CT

Size Decile	Decile Bounds Diameter in cm	Judged out of Range: Raw Dose	Judged out of Range: Size - Adjusted Dose
1	< 24.9 cm	21%	52%
2	24.9 - 26.6	21%	43%
3	26.6 - 27.9	26%	43%
4	27.9 - 29.0	32%	44%
5	29.0 - 30.1	40%	46%
6	30.1 - 31.3	49%	49%
7	31.3 - 32.6	62%	52%
8	32.6 - 34.1	74%	56%
9	34.1 - 36.5	85%	59%
10	> 36.5	94%	53%

Discussion Questions

- For categories where image is excellent or adequate at every dose level:

  Should we continue to use the median (50th percentile) as the upper dose threshold or

  Should we align out-of-range rates across categories by setting the dose threshold at the average out-of-range rate? (e.g.27%)

- Does the TEP endorse the risk - adjustment approach based on patient size?

Break

Approach for Assessing Image Quality

Measuring Image Quality - Image Quality Study

- Radiologists need sufficient quality images to make accurate diagnoses
- Rationale for developing the image quality component 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
- The traditional, manual approach to image quality assessment is impractical at the volume of millions of scans/year; thus an automated approach is needed.

Review of Image Quality Study

- 125 radiologists graded the image quality for 200 CT examinations from a set of 740, resulting in 25,000 interpretations.

- We identified the upper dose at which 90% of radiologists rate images as excellent or acceptable for each CT category.
  - Doses >than this are not needed and are unnecessarily high.

- We used measurements of image quality to identify the floor below which images have insufficient image quality

Identifying CT Scans with Unacceptably Low Quality

- Automated approach that best identifies poor/marginal CT cases with a low false positive rate
- Low quality threshold defined as when 25% or more physicians interpret a given case as poor or marginally acceptable
- Event is rare and therefore difficult to detect with higher threshold
- No CT category reaches a threshold where 50% of physicians rate images as poor or marginal

CT Categories Where Image Quality of Concern

- In the quality study, for a number of CT categories we observed 25% or more of physicians rating images as poor/marginal

Low Dose Head CT	(accounts for around 5% of CT scans)
Low Dose Chest CT	(accounts for around 5% of CT scans)
Routine Dose Chest CT	(accounts for around 20% of CT scans)
Low Dose Abdomen CT	(accounts for around 5% of CT scans)
Spine CT	(accounts for around 7% of CT scans)

- For the head, chest and abdomen categories where we didn't see 25% failures, we will apply the minimum quality threshold from the low dose category

Automated measures of image quality

- Four candidate measures of image quality were calculated from scan pixels: noise, noise texture, resolution, and contrast
- Machine learning algorithms were applied to these four measures to predict radiologists' scores of image quality.
- Noise alone was as good as relying on all four measures
- Using noise, the Area Under the Curve (AUC) for Head, Chest and Abdomen CT ranged from 90 – 95 percent

Understanding the Impact if Applied in Clinical Practice

- Cases labelled as inadequate image quality by the automated approach may be true positives (truly inadequate) or false positives (truly adequate).
- Positive predictive value reflects how often the automated approach correctly identifies the truly inadequate cases
- Setting the false positive rate at 5% we calculated the positive predicted values (PPVs) and the sensitivity.
- The sensitivity ranged from 28%-38% across anatomic areas
- The PPV ranged from 21% - 50%.

Testing of Automated Assessment of CT Quality
UCSF Health System

- We assessed noise in a random sample of recent cases from UCSF

  3759 cases sampled

  - 3734 (99.3%) noise measurements were successfully calculated
  - 225 (6%) were judged as having quality that was too low and out of range

- We will next evaluate thresholds and software for measuring noise / image quality at beta testing sites

Questions

- How important is it to retain image quality as a component of the radiology measure?
- Is an image quality threshold based on 25% or more radiologists rating images as poor/marginal a sensible cut - point realizing a higher threshold will be even more rare?
- Are you satisfied with using noise as the basis for judging image quality?
- Is a 5% false positive rate acceptable?

Beta Testing

Goals of Beta Testing

Beta 1

- Can we assemble the data we need for calculating the measure
- Can we determine inclusion/exclusion criteria for CTs
- Can we determine the CT category for each scan based on billing codes and diagnosis codes
- Can we assess the size - adjusted radiation dose for each scan to calculate out of range rates by physician and physician group

Beta 2

- Can we measure image quality for each scan to calculate out of range rates by physician and physician group

How Testing Data Are Being Assembled

- UCSF created software that each beta testing site has loaded onto a local server, and the required data elements are sent to the server or automatically pulled by the software.
- Data must be sent for consecutive CTs for a one-month period or until at least 5,000 CTs are assembled on the server
- Time period is Fall –Winter 2020, with timing dependent on local logistical issues
- The flow of data varies by site to fit into their work-flow- sometimes data are sent in real time, sometimes batched

Beta Testing Sites

- We are working with 6 health care systems to test our approach for assembling and analyzing data for the measure

- The data are in various stages of completeness and include

University of California, Irvine, CA	(N=5,313)
University of California, Davis, CA	(N=3,789)
University of California, San Diego, CA	(N=5,177)
Mt Sinai Health Systems, NYC, NY	(N=5,327)
Henry Ford Health Systems, Detroit, Michigan	(N=5,849)
ARA, Houston private practice affiliate of 13 imaging practices	

What We Have Asked Beta Sites to Provide

- **From Radiology PACS (DICOM Format)**

  RDSR (radiation dose standard report)

  Image pixel data :
  Additional variables on why and how CT performed

  Linkage variables to allow data sources to be merged by patient

- **From Electronic Health Record - (ICD 10 codes)**

  Diagnoses associated with visit where CT ordered

- **From Billing Claims (CPT codes)**

  Procedure codes associated with the bill

Status of Testing

- 5/6 testing sites are assembling and sharing data with UCSF
- We are mid way through B1 data collection, have *very preliminary* analyses completed; B2 testing will follow
- We will be modifying the software and algorithms in an iterative fashion as we review the initial testing results
- We plan to repeat the testing several times at each location
- We will assess physician burden of reporting on subsequent round
- The results on the following pages are based on only a portion of the data.

What We Are Learning from Beta Testing – CT Scan Data

- Federal law requires health care providers to comply with the National Electrical Manufacturers Association (NEMA) XR-29 Standard for reporting radiation dose using a structured report format in DICOM (RDSR) in order to receive full CMS reimbursement.
- We use this variable combined with additional DICOM coded variables for calculating the radiation dose for each CT scan.
- We initially found that the RDSR was not saved or stored for most CT scans: 83%-95% of CT scans were missing the RDSR

What We Are Learning from Beta Testing – CT Scan Data

- The CT manufacturers must generate the RDSR, but there is no requirement to save or store the RDSR for every CT scan
- Once we realized the problem, we asked each site to retain this information: to send this DICOM element to their PACS for storage. The storage is important for sites that batch send data.
- We have been successful at each testing site for accessing the RDSRs, but are wondering whether this could pose a problem for implementation.

What We Are Learning from Beta Testing– Claims Data

- Missing data also occurred for billing claims

  Billing Claims are missing for 2,632 (25%) of 10,351 CTs

- We have not explored the data to determine why claims missing
  - Were they inadvertently not sent to our software?
  - Did we try to assemble data too early - before bills complete
  - Could they be actually missing for some CTs ?

What We Are Learning from Beta Testing– Claims Data

- We will explore the data to determine why the billing claims are missing for some CTs.
- We believe timing of when we accessed the billing claims may have been too soon and we will repeat with a built-in delay
- If the billing claims are found to be missing, we will explore how to use the diagnostic codes (which were not missing) to determine the CT category when the the CPT codes from the bills are missing.

What We Are Learning from Beta Testing– Excluding CTs that should be Excluded from Calculations

- The beta testing sites were provided with detailed Instructions on what CT scans to include/exclude.
- We assessed our capacity to exclude CT scans that should not have been included : Across sites we identified 3% of scans for exclusion including CTs for research, biopsy, or combined with PET or SPECT imaging
- Once we have complete claims data, we will do additional data checks including review of all DICOM variables, diagnoses and claims to confirm we can identify *all* excluded scan types

How We Will Assess the Accuracy of Assigning CTs to Specific CT - Categories at Testing Sites

- We will compare the distribution of scan types (CT - Categories) at testing sites to that observed in the larger UCSF Dose Registry
  - We expect assignment of scans based *only* on body region to be accurate (e.g. extremity scans)
  - We expect head, chest and abdomen to account for most scans
  - We expect the routine dose categories to be more common than the high or low dose categories
- We will compare the sensitivity of the assignment of CTs into CT - Categories using a composite referent standard that we have shown previously to be 91% accurate

What We Are Learning from Beta Testing–
Assignment of CTs to CT - Categories

- The assignment to categories based on body region alone similar:

	Beta testing sites	UCSF Registry
Extremity CT	2.6%	2.7%

- Most CT scans were of the head, chest, and abdomen

	Beta testing sites	UCSF Registry
Head CT	24%	29%
Chest CT	19%	22%
Abdomen	41%	33%
Total	**= 84%**	**= 84%**

What We Are Learning from Beta Testing– Assignment of CTs to CT - Categories

- The routine dose categories were most common

	Beta Testing	UCSF Registry
% of Head CTs – Routine category	58%	84%
% of Chest CTs Routine category	78%	93%
% of Abdomen CTs Routine category	54%	87%
% of Cardiac CTs Routine category	72%	60%

- We did not expect the same results, but for routine to be most common

What We Are Learning from Beta Testing–
Sensitivity for Assigning CT - Categories

- The sensitivity for assigning CTs based only on body region are accurate in comparison to the gold standard composite
- The challenge is to accurately assign cases to the low, routine and high dose categories
- When creating the automated rules we tried to be most accurate for the high and low dose categories to avoid penalizing radiologists for using higher doses or for insufficient image quality
- Our results are *preliminary*

What We Are Learning from Beta Testing–
Sensitivity for Assigning CT - Categories

	Sensitivity	
	Beta Testing Sites	UCSF Registry
Head Low Dose	89%	95%
Head High Dose	70%	97%
Chest Low Dose	98%	92%
Chest - Cardiac High Dose	77%	100%
Abdomen Low Dose	94%	79%
Abdomen High Dose	88%	89%

- We will iteratively revise and retest approach to improve accuracy

Next Steps for Best Testing

- We have not yet analyzed the size - adjusted doses and assessments as out of range
- We have not yet included measurements of the image quality in the software
- We have not yet assessed the judgements by physician and TIN
- All will be assessed over the next several months and shared at the next TEP

Questions

Are there any recommendations you have as we explore the missing data?

What analyses of beta testing data would improve your confidence in our measure?

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
- As part of the next phase of work, we will develop software to comply with eCQM format
- Information about this TEP meeting and future meetings will be posted at ctqualitymeasure.ucsf.edu
- Please remember to complete honorarium request paperwork
- We will be reaching out to you to set the date for the next TEP

DEFINING AND REWARDING COMPUTED TOMOGRAPHY QUALITY AND SAFETY

TEP Meeting #5 Minutes

Meeting Date: 12/1/2020
Meeting Time: 10:00am-1:00pm PDT
Meeting Location: Virtual Conference via Zoom
Approval Date: 12/18/2020
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. The TEP will provide input and advice to UCSF to ensure that the measure 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 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 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		
Mythreyi Bhargavan Chatfield, PhD	Executive Vice President	American College of Radiology
Niall Brennan, MPP	CEO	Health Care Cost Institute
Helen Burstin, MD, MPH, FACP	Executive Vice President	Council of Medical Specialty Societies
Melissa "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
Hedvig Hricak, MD, PhD	Radiology Chair	Memorial Sloan Kettering Cancer Center

Name	Title	Organization
Attendees		
Jay Leonard "Len" Lichtenfeld, MD, MACP	Independent Consultant	Formerly Deputy Chief Medical Officer American Cancer Society, Inc.
Leelakrishna "Krishna" Nallamshetty, MD	Associate Chief Medical Officer	Radiology Partners
Matthew Nielsen, MD, MS	Professor and Chair of Urology	UNC Gillings School of Global Public Health
Debra Ritzwoller, PhD	Patient Advocate, and Health Economist	Patient Representative
James Anthony "Tony" Seibert, PhD	Professor	University of California, Davis
Arjun Venkatesh, MD, MBA, MHS	Associate Professor, Emergency Medicine	Yale School of Medicine
Todd Villines, MD, FSCCT	Professor and Director of Cardiovascular Research and Cardiac CT Programs	University of Virginia
Kenneth "Ken" Wang, MD, PhD	Adjunct Assistant Professor, Radiology	University of Maryland, Baltimore
Not in Attendance		
Lewis "Lew" Sandy, MD	Executive Vice President, Clinical Advancement	UnitedHealth Group
Mary Suzanne "Suz" Schrandt, JD	Patient Advocate	Patient Representative

Ex Officio TEP		
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
CMS & MACRA/CATA Representatives		
Marie Hall	CATA Team	Health Services Advisory Group
Minet Javellana	Measure Development Specialist	RELI Group Inc.
Janis Grady	Project Officer	Centers for Medicare & Medicaid Services
UC Team		
Rebecca Smith-Bindman, MD	Principal Investigator	University of California, San Francisco
Patrick Romano, MD, MPH	Co-Investigator	University of California, Davis
Carly Stewart	Lead Project Manager	University of California, San Francisco

Sophronia Yu	Data Analyst	University of California, San Francisco
Susanna McIntyre	Research Assistant	University of California, San Francisco
Not in Attendance		
Andrew Bindman, MD	Advisor	Kaiser Permanente, former Co-Investigator with the 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 that 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 and Zoom Video Conference.

10:00 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 3 hours and will include a discussion period after each presentation.

10:05 AM: Roll Call and Updated Conflicts Dr. Burstin

TEP members' and ex officio members' attendance is 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 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 or existing conflicts of interest.
- **Dr. Mythreyi Chatfield** stated she is Secretary Vice President for quality and safety at the American College of Radiology and had no new or existing conflicts.
- **Niall Brennan** stated he is CEO of Health Care Cost Institute and had no new or existing conflicts.
- **Dr. Krishna Nallamshetty**, a new TEP member, is replacing Dr. Jay Bronner who stepped down from the panel upon retirement. Like Dr. Bronner, Dr. Nallamshetty works at Radiology Partners where he serves as Associate Chief Medical Officer and chair of the patient safety committee. He is associate faculty at the University of South Florida in radiology and cardiology. Dr. Nallamshetty's conflicts include: he is employed by Radiology Partners, the largest radiology practice in the US; he is faculty at the University of South Florida; he is equity owner in Tower Radiology, an outpatient imaging center network in Florida; he is equity owner in Radiology Partners; and he is equity owner and on the advisory board of Hyperfine MRI.
- **Missy Danforth** stated she is Vice President for healthcare ratings at the Leapfrog Group and had no new or existing conflicts.
- **Tricia Elliot** stated her role as Director of Quality Measurement at The Joint Commission and had no new or existing conflicts.
- **Dr. Jeph Herrin** stated his affiliation with Yale University and no new or existing conflicts.
- **Dr. Leonard Lichtenfeld** stated he is an independent consultant, formerly Deputy Chief Medical Officer at the American Cancer Society. He had no new conflicts to report but noted he is no longer with the ACS.
- **Dr. Matthew Nielsen** reported he is Chief of Urology at University of North Carolina. He had no new conflicts but mentioned his existing relationship with the American Urological Association and American College of Physicians as a consultant.
- **Dr. Debra Ritzwoller** stated she is an economist with Kaiser Permanente Colorado and is serving in the capacity of a patient advocate. She restated her role as MPI on an NCI-funded lung cancer screening research center, and her involvement on other PCORI and NCI-funded lung cancer screening grants. She had no new conflicts to disclose.
- **Dr. Anthony Seibert** stated his role as a medical physicist at UC Davis Health and had no conflicts to declare.
- **Dr. Arjun Venkatesh** stated he is an emergency physician on faculty at Yale University, where he is chief for his administrative section, and a scientist at the Center for Outcomes Research and Evaluation. He disclosed he serves as a consultant for the American College of Radiology and leads quality measure development work with the American College of Emergency Physicians.
- **Dr. Todd Villines** reported he is a cardiologist in the area of multimodality imaging at the University of Virginia. He had no new conflicts but restated prior conflicts, including prior president of the Society of Cardiovascular CT, in which role he is a non-voting member of the Board of Directors. He is also current Editor-in-Chief of the Journal of Cardiovascular CT.
- **Dr. Kenneth Wang** stated he is a musculoskeletal radiologist at the University of Maryland in Baltimore. He had no new conflicts.

- **Dr. Amy Berrington** introduced herself as Branch Chief of Radiation Epidemiology at NCI and had no conflicts.
- **Dr. Mary White** stated she is Chief of the Epidemiology and Applied Research Branch in the Cancer Division at the Centers for Disease Control & Prevention and had no new conflicts.

TEP member **Dr. Hedvig Hricak** joined the call after Roll Call.

10:15 AM: TEP Goals, Personnel Updates, CMS Updates Dr. Smith-Bindman

Dr. Rebecca Smith-Bindman briefly stated the objectives of the meeting, including reviewing risk-adjusted radiation dose thresholds, image quality thresholds, and early beta testing results.

She introduced Carly Stewart, new UCSF project manager. She shared Dr. Andy Bindman – who could not be on the call – retired from UCSF and started a new position elsewhere but would continue as an advisor on this project. Lastly she shared Dr. Jay Bronner's retirement from Radiology Partners and from the TEP, and welcomed Dr. Nallamshetty in his place.

Next, she restated CMS's continued interest in developing a measure for the hospital programs (Inpatient Quality Reporting, Outpatient Quality Reporting, and Critical Access Hospital) corresponding to the MIPS measure. She reiterated the challenge, mentioned at several prior TEP meetings, of physicians using data controlled by hospitals to report in the MIPS program. She mentioned we have come up against this firsthand in our testing, where physicians sometimes were unable to access to the data where they worked as the data were owned by hospitals. Data ownership aside, practically speaking, CT scans are controlled and run jointly by the hospitals and physicians. The technologists who operate the machines are usually paid by the hospitals, so having this corresponding measure in place would align incentives between physicians and hospitals and maximize quality improvement.

The final update Dr. Smith-Bindman shared is the recent advisement from CMS that the agency is moving away from adopting new qualified clinical data registry (QCDR) measures in the MIPS program. We have thus far been developing our candidate measure as a QCDR measure and must now pivot to developing an electronic clinical quality measure (eCQM). She explained the *measurements* themselves are not so different in a QCDR vs. eCQM, but *how* data are collected and reported is very different. eCQMs are computer automated measures that use data extracted electronically from the electronic health record to measure healthcare quality. Data elements used in eCQMs must map to a value set, which is a set of allowable codes and descriptors sanctioned and maintained by the National Library of Medicine, Value Set Authority Center (VSAC). Our hope is that an eCQM measure(s) would be applied both in the MIPS and hospital-based programs.

She shared several challenges in creating an eCQM (slide 15). First, our primary measurement, radiation dose, uses data formatted in the DICOM standard; however these data elements are not currently included in existing value sets that are available for writing eCQMs. Thus, we are working with CMS and NLM to get value sets created for DICOM variables.

The second challenge to using an eCQM has to do with the image quality component, which is not derived from the same kind of digitized data. Our method is designed to assess pixel data on CT images, and there appears to be no way to add these to value sets. This issue threatens the inclusion of image quality assessment in the measure. We are exploring several workarounds that we think will be successful, but if not, an alternative is to not include the image quality part of our measure, at least in the initial rollout.

Dr. Smith-Bindman explained changes to the timeline (slide 16). We're currently 26 months into the 36-month project. Moving towards an eCQM will require UCSF to accelerate the timeline, because we would have to submit the measure to the Measures Under Consideration (MUC) List in May 2021. CMS will provide us with an extension and allow us to submit our final testing data as late as the fall of 2021. We believe we can complete most MUC list requirements by May, with final testing data submitted around September 2021, as permitted by CMS. Our timeframe for submitting the measure for NQF endorsement remains unchanged.

10:25 AM: *Discussion*: TEP Goals, Personnel Updates, CMS Updates Dr. Burstin

Dr. Burstin introduced the discussion questions:

- Do you see a benefit of having a parallel hospital measure to the proposed MIPS measure?
- Do you support our transition to an eCQM even if it requires that we pause on the image quality assessment?
- If we need to pause on the image quality assessment, would that change how low we should set the upper radiation dose threshold?

Dr. Nielsen said he thinks the pivot towards an eCQM makes sense. He's heard similar messages from colleagues about moving away from medical societies having their own niche QCDR measures, and moving towards measures in the MVP framework. He feels the hospital-based measure will be valuable for a lot of organizations, and an eCQM measure makes sense in this framework. Dr. Venkatesh seconded support for aligned MIPS and hospital-based measures, citing increased likelihood of data-sharing. As an Emergency Medicine physician (a hospital-based specialty similar to radiology), he thinks alignment between hospital measures and physician measures is desirable as there are a large number of hospital-employed radiologists in the US. "So, to me, anytime you have a chance to have a very similar measure with identical incentives living in parallel programs, that's how you make it possible for hospitals to say, 'Share data with clinicians so they can report it in MIPS,' and the hospitals get the benefit of taking on some of that burden of data collection reporting on the hospital side. To me, it seems like only a win, and I think that it'll actually help the MIPS measure to be successful by the fact that there's a concurrent hospital measure."

The panel discussed the complexity of eCQMs, particularly measuring at the individual clinician-level. Dr. Burstin suggested focusing on the hospital-based measure first, setting aside the MIPS measure. Dr. Chatfield expanded on the complexity: we can create the value sets, and build the machinery so to speak, but making sure data needed for measure calculation migrates properly will be a challenge (though further beta testing should shed light on data availability and usability). Any amount of automated data would be helpful. We must also consider

receptiveness of hospitals to ingest the software, which is sure to be impacted by the transparency and understandability of the model.

Dr. Burstin asked for clarification on whether data will come to UCSF. Dr. Smith-Bindman explained that a new eCQM would be created, and that the details are not yet final but that the registry model will be abandoned. Dr. Burstin noted that the process of vetting the measure through the MUC list and NQF process would raise issues of the appropriateness of the measure's use in different settings.

On the basis of this feedback from the TEP, UCSF plans to continue to plan, build, and test the eCQM measure for the MIPS programs. As soon as we have official notice of award from CMS, we will begin to build and test the hospital-based eCQM in parallel.

10:40 AM: Setting and Risk-Adjusting Upper Dose Thresholds Dr. Smith-Bindman

Dr. Smith-Bindman reiterated from previous presentations the goal of setting an upper radiation dose threshold as low as possible to support patient safety, but not so low it compromises image quality (slide 19). Dose thresholds are adjusted for patient size (as larger patients require higher doses), and thresholds are specific to CT category. Different anatomic regions require higher doses (e.g. brain vs. abdomen), and different clinical indications in the same region require higher doses (e.g. lung cancer screening vs. characterizing lung cancer). Patient characteristics (age and sex) and CT machine make and model contribute very little to dose variation and are not factored into the measure.

Dr. Smith-Bindman summarized the logic for setting the upper dose threshold. It is the radiation dose at which $\geq$90% of physicians in the Image Quality Study rate image quality as acceptable (slide 20). Doses above this level do not contribute to greater image quality and therefore contribute to unnecessary cancer risk from excess radiation. For categories in which $\geq$90% of physicians were satisfied with quality at every observed dose, we set the threshold at the median of the category, derived from the UCSF CT International Dose Registry (hereafter referred to as "UCSF Registry"), as previously recommended by the TEP.

Using this approach, the proportion of exams that are out-of-range will be different across categories (slide 21). For example, 5% of routine head CTs will be out-of-range, whereas 50% of routine dose abdomen CTs will be out-of-range. More cases will be rated out-of-range in the CT categories in which radiologists are satisfied with image quality at every dose, which suggests in these categories, CT operators are probably using doses that are higher than needed. The routine dose head category has the fewest number of exams judged as out-of-range, suggesting those doses are about right, currently.

The project team has only analyzed out-of-range rates in the UCSF Registry thus far, and only at the facility level (not the physician or physician group level). In the UCSF Registry, there was a strong correlation at the facility level in the proportion of scans that are out-of-range across the different CT categories (slide 22). That is to say, facilities that have out-of-range values in one category are likely to be out-of-range in other categories as well. As a caveat, the UCSF Registry does not contain any facilities that focus on a single CT category, though this could certainly

occur in actual practice. For example, a urology practice may only see high-dose abdomen CT scans. If a physician sees a limited distribution of patients, it may be easier or harder to have CT examinations within range, depending on the category.

Risk-Adjustment
A mid-scan measurement of diameter measured on either the axial or scout image is used to calculate patient size; the adjustment used for the size-adjusted dose measurement is log linear (slides 23-25). Our method compares size-adjusted dose against the threshold for that category. Without size-adjustment, the likelihood of a CT scan being out-of-range will be driven by patient size. If size is appropriately being adjusted for there would be a similar number of out-of-range values across the different size categories. Dr. Smith-Bindman showed an example of this based on about 1,000,000 routine abdomen scans from the UCSF Registry, stratified by size decile. Without adjustment, 21% of smaller patients had out-of-range doses versus 94% in the largest patients. With adjustment, approximately 50% of CT scans were out-of-range at every size.

11:00 AM: *Discussion:* Risk-Adjusting Upper Dose Thresholds Dr. Burstin

Dr. Burstin introduced the discussion questions:

- For categories in which image is excellent or adequate at every dose level:
  - Should we continue to use the median (50^{th} percentile) as the upper dose threshold, or
  - Should we align out-of-range rates across categories by setting the dose threshold at the average out-of-range rate? (e.g.27%)
- Does the TEP endorse the risk-adjustment approach based on patient size?

Dr. Venkatesh asked why the measures focus on categories where performance is already optimum (routine dose head has 5% out-of-range, for example) and suggested UCSF ought to target categories where the opportunity to reduce dose is greatest. To this, Dr. Smith-Bindman explained that there is opportunity to reduce dose in all 19 categories, and when you apply our thresholds to all categories combined, the average dose reduction is 38%. Dr. Venkatesh countered, saying including routine head in the denominator is a bit unfair; for example, a facility with a high proportion of head CTs would be at an advantage, and this impacts your ability to compare facilities against one another. Dr. Burstin summarized the point: if there is no improvement gap in head CTs, why include it in the measure?

Dr. Smith-Bindman explained that she had presented the two extreme values for how many CTs are out-of-range across the 19 categories. The doses for routine dose head demonstrate the lowest number of out-of-range values (5%) and the smallest quality gap across the 19 categories; it was selected to demonstrate the broad range. The other head categories have far greater out-of-range values. The low dose head category has 39% of CT scans judged as out-of-range, while the high dose head category has 50% out-of-range. Thus, it is important to include head CT scans in the measure. She also noted that the average does not give a complete sense of the quality gap. Many facilities are extreme outliers in dosing for head CT, including the routine dose head category, so while on average you won't make a big impact, for individual practices you could achieve a large reduction in this category.

Dr. Seibert asked to clarify if UCSF is using water-equivalent diameter. Dr. Smith-Bindman confirmed UCSF is not, because it is missing most of the time in our data. UCSF is calculating the average diameter measurements derived from patient circumference based on the CT scans. Dr. Smith-Bindman pointed out that since all CTs are compared within a single body region, adjustment for water equivalent diameter should give the same results as adjusting for diameter.

Next the panel addressed the first discussion question around setting the dose maximum at the median or the average out-of-range rate from the other categories (27%). The essential question is: do we want a more aggressive or more lenient approach to dose reduction in the categories where dose is currently adequate for image quality at all levels? Dr. Herrin wanted to know how representative the 27% mark was, and would it change if tested on a larger group of patients or hospitals? Dr. Smith-Bindman responded the 27% is based on risk-adjusted analyses from a sample of about 8 million records from the UCSF Registry, which is likely very similar to national averages of patient size and dose.

Dr. Venkatesh explained what he viewed as a tension between implementation and scientific acceptability. The 50th percentile approach would be easier to explain, easier for clinicians to understand, and potentially lead to greater improvements. On the other hand, he argued a more lenient threshold based on the 27% rate would be more acceptable to clinicians, many of whom may feel penalized for making dose decisions appropriate to the clinical indication. Dr. Wang later seconded this opinion. Dr. Venkatesh explained, in light of this tension, the historical precedent has been to choose the more modest approach that is more likely to have higher clinical face validity. He further noted that UCSF must consider, plan, and communicate how the measure benchmarks will be updated over time, referencing how this has been challenging with measure OP-9 (mammography follow-up rates) in the outpatient reporting program. Will UCSF calculate benchmarks every year? If benchmarks are based on the UCSF Registry, is that widely accepted within the radiology community? Are there resources to maintain the UCSF Registry for this purpose in the long-term, as this is not something CMS will take on?

Dr. Chatfield seconded the point of having transparency in our benchmarks, for example, publishing them each year so that clinicians know what to aim for. She offered to calculate the measure using ACR registry data to lend support and credibility to our proposed benchmarks.

Dr. Romano favored the median approach but stressed the need to reassess quality at some designated point in the future, as the median would likely move lower over time ("moving the goalposts"). NQF will require UCSF be upfront about its long-term plans to assess and maintain the thresholds. Dr. Smith-Bindman acknowledged the need to re-assess image quality over time, particularly as machines get better. Dr. Burstin agreed this could be dealt with as a three- or five-year update.

Dr. Smith-Bindman clarified that the benchmarks would be created and set, and not modified each year based on that same year's data. In other words, the thresholds would not be a moving target.

Dr. Burstin steered the discussion to the second question: does the TEP agree with the risk-adjustment approach using patient size for adjustment? Dr. Hricak strongly backed the proposed

size-adjustment approach and was particularly supportive of an approach that protects against over-dosing cachectic (smallest) patients. Dr. Chatfield agreed the size-adjusted approach makes sense, but emphasized the need for transparency in how we are using size: e.g. how is size defined; how is it calculated; how does size vary; how will size be applied for adjustment?

Dr. Villines asked about inclusion of age in risk-adjustment. Dr. Smith-Bindman explained that while age does have a small association with dose, there is no reason that it should. Dr. Romano noted that doses should not be based on age, so we have not accounted for it in the risk-adjustment model; the same goes for patient's sex. Dr. Nallamshetty suggested that age does matter to a mild degree – for example, in some preoperative planning for TAVR, you'd use a higher dose in an 80+ year old individual to get better visualization of smaller structures, though he acknowledged this is a small population of patients. Dr. Villines added that clinicians are more sensitive about dose and aggressive about dose reduction in younger people than older, and suggested perhaps dose thresholds should be lower in younger patients. Dr. Smith-Bindman responded that our CT-categories are designed to accommodate these dosing needs; for example, TAVR imaging falls into the high dose cardiac category. The adjustment is intended to equalize for factors that are important predictors of dose, not to adjust for situations where physicians may be more sensitive for the need to optimize dose. Ideally dose would be optimized for all patients.

On the basis of this feedback from the TEP, for CT categories where the image quality was rated as acceptable (excellent or adequate) for ≥90% of physicians at every observed dose, UCSF plans to set the dose maximum at the average out-of-range rate from the other categories. While this threshold is more difficult to explain, it is a more lenient threshold and would be more acceptable to clinicians. On the basis of this feedback from the TEP, UCSF will use the size-adjustment approach as described during the meeting.

11:15 AM: Break

11:25 AM: Approach to Assessing Image Quality Dr. Smith-Bindman

Dr. Smith-Bindman re-introduced the rationale for including image quality in the measure: the purpose is not to maximize image quality, but to protect against untoward effects of lowering radiation dose. It is included as a balancing measure (slide 29).

Dr. Smith-Bindman again summarized the Image Quality Study that produced 25,000 physician-graded CT studies, which were used to establish upper dose and minimum image quality thresholds (slide 30). Our automated approach to identifying exams of inadequate quality sets the threshold at the level where 25% or more physicians rate the exam as poor or marginally acceptable (slide 31). However, these poor or marginally acceptable cases are rare; in fact we observed no CT category where 50% of physicians rated images as unacceptable. Thus, while we would like to set a higher threshold (i.e. greater than 25% of physicians rating images as unacceptable), this would result in a very small number of studies failing on image quality.

Dr. Smith-Bindman then presented the categories where the project team found images of unacceptable quality using this categorized rule of ≥25% rating exams as poor or marginally acceptable: low dose head; low dose chest; routine dose chest; low dose abdomen; and spine

(slide 32). Collectively these account for approximately 40% of all CTs performed. For all head, chest, and abdomen categories where the project team did not observe unacceptable images, the plan is to apply the minimum quality threshold from their corresponding low dose categories. For example, the established minimum quality requirement for low dose abdomen CT would also be used as the minimum quality requirement for routine and high dose abdomen CT.

Dr. Smith-Bindman described how, in developing the automated approach, the project team tested four candidate measurements of image quality: noise, noise texture, resolution, and contrast (slide 33). The project team found noise alone was as good as all four of these measures in predicting image quality, not to mention simpler to describe. Thus, the project team is pursuing an approach that relies on noise, derived from image pixel data, to identify images as inadequate based on the 25% satisfaction threshold. Area under the curve (AUC) analyses for using noise to predict unacceptability ranged from 90-95%. AUC analyses show a trade-off in testing, with sensitivity on one axis and false positive rate on the other. The higher the AUC, the better the test's ability to discriminate cases from non-cases. AUC values in the range of 0.8-0.9 are considered excellent and above 0.9 are considered outstanding.

Our approach using a false positive rate of 5% (meaning, 5% of truly adequate cases are flagged as unacceptable) gives a sensitivity ranging from 28-38% across the anatomical areas.

Though the image quality assessment has not yet been tested in our beta testing sites, Dr. Smith-Bindman shared results of testing on a sample of 3,759 cases from UCSF Health System (slide 35). The project team was able to successfully run the code on 99% of images, and about 6% were judged out-of-range.

11:45 AM: *Discussion*: Approach to Assessing Image Quality Dr. Burstin

Dr. Burstin introduced the discussion questions:

- How important is it to retain image quality as a component of the radiology measure?
- Is an image quality threshold based on $\geq$25% of radiologists rating images as poor or marginally acceptable a sensible cut, considering out-of-range cases are rare with a higher threshold?
- Are you satisfied with using noise as the basis for judging image quality?
- Is a 5% false positive rate acceptable?

Missy Danforth shared her opinion that it's important to retain some assessment of image quality as a balancing measure. She said the pediatric CT dose measures on their Leapfrog surveys take a similar approach to scoring and setting performance thresholds. She feels the lack of image quality assessment has been a shortcoming of Leapfrog's work, and if available, would lend validity to dose scores. They have worked with ACR to come up with a proxy measure of quality, but having it integrated into the UCSF candidate measure would make it stronger and more successful in NQF review. Dr. Seibert seconded this opinion, noting the importance of catching unacceptable quality scans, which are a greater risk to patient safety than any dose at all. Dr. Nallamshetty was in favor of keeping the image quality assessment, suggesting many radiologists work out of multiple locations where they do not have direct control over radiation decisions. He noted radiologists tend to adapt to reading various levels of quality. He worries,

without a dose floor, we'll incentivize practitioners to focus on lowering doses and radiologists will make do with the scans, potentially risking diagnostic accuracy. Dr. Hricak stressed the importance of image quality being included in the measure in light of potential malpractice suits.

Dr. Smith-Bindman seconded this idea that radiologists adjust to image quality, citing evidence from the Image Quality Study, which found radiologists scored only 11% of images unacceptable. She noted further that we considered and tested using low radiation dose as a proxy for noise in assessing image quality, but that using the measurement of noise was twice as accurate as dose. She explained we are using a noise measurement developed by a recognized expert, Dr. Ehsan Samei at Duke University, who is allowing the measurement to be used free-of-charge for the quality measure.

Dr. Chatfield and Dr. Herrin voiced the opposite preference for eliminating the image quality assessment. They argued that since image quality was factored into the dose thresholds, it's already inherently built-in to the model. Their larger point, though, was about the complexity, practicality, and validity of folding image quality assessment into the paired measure. Dr. Chatfield cautioned that there might not be consensus around Dr. Samei's noise calculation being used as the standard as others might want their own measures of quality included.

On the question of 5% false positive rate, Dr. Hricak agreed this was acceptable. Dr. Seibert agreed.

On the question about setting the image quality threshold at ≥25% physicians dissatisfied, Dr. Romano proposed a different line of thought: if we think radiologists are too permissive with quality, perhaps we should set a lower image quality threshold (10-20% dissatisfied as opposed to 25%). Dr. Smith-Bindman emphasized the difficulty of finding the right balance: 50% seems an attractive threshold (as it would potentially identify the worst quality CT cases), but there are almost no unacceptable cases at this level. Going lower than 25% (e.g. 10%) would mean failing exams that the vast majority of physicians (90%) deemed acceptable. Dr. Romano also raised the idea of considering noise as a continuous measure, such that too much noise is considered to reflect poor quality.

Dr. Wang asked Dr. Smith-Bindman to elaborate on how image quality assessment can be incorporated into the eCQM. She said the plan is not final, but described a plan to build a free, external website or software to calculate image quality, and the eCQM would be built to receive that calculation as an input. She cited other CMS programs, such as use of decision support under PAMA, that require use of an external website and used inputs that were outside the eCQM. Additionally, there are examples of eCQMs that also use calculations too complicated to include inside the eCQM itself. Ongoing work on how to do this will be shared at a future TEP.

Dr. Burstin noted the complexity of this approach and floated the idea of pursuing image quality as a separate measure, rather than a paired measured. She proposed the idea of replacing the paired image quality assessment with an audit function, for example, doing a 5% national audit to understand if image quality is dropping. Dr. Smith-Bindman explained that CMS was insistent that image quality is a very important component of the measure.

In sum, the panel was strongly aligned in measuring image quality to protect to against lowering doses too much. Some panelists expressed concern over the complexity of including it in the eCQM and were satisfied knowing that it was factored into the dose thresholds, while other panelist felt it was essential to include in the paired model.

On the basis of this feedback from the TEP, UCSF plans to include a measure of image quality in the final measure specification but will continue to explore additional ways to identify CT examinations that are out-of-range on quality. The different approaches will be explored in beta testing and presented at the next TEP meeting.

12:05 PM: Beta Testing Results Dr. Smith-Bindman

Dr. Smith-Bindman summarized the aims of beta testing (slide 38). In beta 1, the project team is assessing whether it can: assemble the required data from testing sites; apply inclusion/exclusion criteria; determine CT category based on procedure and diagnostic codes; calculate size-adjusted dose; and determine out-of-range rates at the physician and physician group levels. In beta 2, the project team will add image quality assessment to the testing. Dr. Smith-Bindman gave an overview of how UCSF software is installed on local servers, collects data from a one-month period (around 5,000 CT studies), and exports de-identified data to UCSF for analysis (slide 39). Data is derived from three sources: PACS (RDSR, image pixel data, additional variables on why CT was performed, and linkage variables); EHR (diagnostic codes); and billing claims (procedure codes). The six testing sites use diverse EHR and PAC systems; their data is in various stages of completeness, and what is presented today is preliminary analysis of beta 1 data from five of the six sites. Dr. Smith-Bindman explained the plan to build, test, and modify the software will occur through an iterative fashion with successive testing rounds.

Dr. Smith-Bindman shared the following *preliminary* results:

One of the major lessons learned is the unavailability of RDSR data, despite federal law requiring CT manufacturers to generate this data, which UCSF uses to calculate dose (slides 43-44). The project team has found it is generated but not saved for most CT scans; 83% to 95% of CT scans were missing the RDSR across our testing sites. The UCSF team has workarounds in place to get RDSRs for the testing sites, but this is a concern affecting future implementation.

Likewise, the project team found a quarter of the sites' claims data were missing CPT codes (slides 45-46). The project team is working with sites to understand why they are missing. The following analyses and results did not include scans with missing CPT codes.

The project team was able to identify and exclude CT procedures that met exclusion criteria, for example: scans in children; scans in conjunction with radiation oncology; scans for biopsies; etc. (slide 47). The project team identified 3% of scans across the sites meeting the exclusion criteria. In the next round of testing, the project team will validate its success in identifying all such scans.

To study assignment of CT scans to CT category based on billing data, the project team compared the distribution of CTs within CT categories obtained from the beta testing sites to

what has been observed in the UCSF Registry, expecting the distribution to be similar (slides 48-52). This is indeed what was found: the categorizing of CTs based only on body region (e.g. extremity, spine) were characterized accurately and the distribution of them from the beta testing sites matched that of the Registry. Head, chest, and abdomen accounted for the bulk of scans in testing sites (84% collectively) and the Registry (84% collectively). The project team also expected routine-dose head, chest, abdomen, and cardiac scans to be more common than high- or low-dose, and this was true both at our testing sites and in the Registry. Finally, the project team measured sensitivity of the CT category assignments using a composite referent standard (based on gold standard manual chart review) that the project team has previously shown to be 91% accurate in UCSF Registry data. The goal was to maximize accuracy for high- and low-dose categories to avoid penalizing for appropriately high radiation doses and low image quality. Comparisons of the sensitivity of beta 1 data for head, chest, and abdomen high- and low-dose categories (ranging from 70-98%) with the UCSF Registry (ranging from 79-100%) were satisfactory but will be reassessed when full beta 1 data is compiled.

Dr. Smith-Bindman reviewed next steps in beta testing: analyzing size-adjusted dose and out-of-range rates; measuring image quality; and conducting analyses at the physician and physician group levels.

12:35PM: *Discussion*: Beta Testing Results Dr. Burstin

Dr. Burstin introduced the discussion questions:

- Do you have any recommendations as UCSF explores missing data?
- What analyses of beta testing data would improve your confidence in the measure?

Dr. Nallamshetty asked how difficult it will be to obtain RDSRs. Dr. Smith-Bindman explained that in general it should not be difficult. Most of the testing sites did not know they were not saving RDSRs, confusing it with the dose sheet, which was saved. The technical solution is usually a simple matter of reprogramming the machines to save the RDSR in the PACS. If sites utilize a DICOM-router, it is very easy. This could be more difficult for some sites if they need to have to make the change at each CT scan or if they need to get the machine vendors involved. Dr. Seibert shared, for example, at UCD they learned GE would have to come on site to set this up on their older machines. He cautioned that vendors may charge for this service. He agreed that the RDSR should by default be saved.

Dr. Chatfield said the ACR has grappled with this problem in their own dose index registry, and they have been working with facilities to transition to saving them. She asked when UCSF would be ready to share our measure specifications so that they can try running analyses in their registry. Dr. Smith-Bindman responded that the measure is still under development and would likely not be finalized until the MUC List submission in May.

Dr. Nallamshetty asked how we're handling mis-categorization of CT studies and how we avoid penalizing a clinician based on a misclassified scan. Dr. Smith-Bindman proposed this would likely be a manual process: ideally, physicians or physician groups would be able see their scored data and adjudicate out-of-range scans. UCSF needs to learn how to make this possible in an eCQM framework.

Niall Brennan inquired about scalability and replicability of our measure, based on the limited number of testing sites. Dr. Smith-Bindman responded that most of the testing sites are large health systems. Mt. Sinai and Henry Ford are each large systems comprised of multiple hospitals, outpatient facilities, and practice groups, including some with different EHRs. The UCs are likewise complex health systems. Despite struggles, beta testing is occurring successfully. eCQM testing will look different, and while it's hard to predict implementation while the approach is still under development, UCSF expects scalability won't be a major issue because the eCQM has stricter requirements than the previous model. Dr. Burstin added to this point that a core feature of eCQMs is availability of structured data, and encouraged UCSF work with sites as well as with ACR to ensure RDSRs are saved. She encouraged UCSF pilot the measure as much as possible. She suggested UCSF explore a regulatory solution to capturing the RDSRs.

Dr. Wang asked Dr. Smith-Bindman to describe how we are treating combined categories, for example, head, neck, chest. She responded that UCSF has created three combination categories: chest, abdomen, pelvis; head and neck; and thoracic and lumbar spine. These combinations are relatively common, while other "oddball" combinations that are extremely infrequent are excluded from evaluation. Because they are quite nuanced and not very common, thresholds for dose and image quality are generous in the combination categories. She explained, moving forward, UCSF will explore combination scans more extensively in our testing data and present more information at the next TEP meeting.

On the basis of this feedback from the TEP, UCSF plans to explore the ease with which health systems can store the RDSR, as well as any factors that might hinder their storage. Further, UCSF will reach out the FDA to understand the requirements for hospitals to generate and store the RDSR.

12:55PM: Wrap Up and Next Steps Dr. Smith-Bindman

Dr. Smith-Bindman thanked the panel for "kicking the tires" and sharing invaluable insights. The major next step for UCSF is to begin developing the eCQM software. She mentioned she would invite the panelists to participate in a TEP for the hospital-based measure when that is cleared by CMS.

Dr. Burstin wrapped up by encouraging the UCSF team to test the measure as much as possible and to get early input from stakeholders and through public commenting.

1:00PM: 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

- ☐ INDIVIDUAL/SOLE PROPRIETOR
- ☐ C CORPORATION
- ☐ S CORPORATION
- ☐ PARTNERSHIP
- ☐ TRUST/ESTATE
- ☐ LLC – Tax Classification (C=C Corporation, S=S Corporation, P=Partnership) _____
- ☐ OTHER _____

EXEMPTIONS

EXEMPT PAYEE CODE (if any) _____

EXEMPTION FROM FATCA REPORTING CODE (if any) _____

TAXPAYER IDENTIFICATION NUMBER (TIN)

SOCIAL SECURITY NUMBER ¦ ¦

OR

EMPLOYER IDENTIFICATION NUMBER ¦

DUN & BRADSTREET NUMBER

UNSPSC CODE (if applicable)

PAYMENT OPTIONS

2

Select ONE:

- ☐ Immediate with Virtual Card/Payment Plus payment *(PREFERRED)*
- ☐ 2%10,N30 with ACH payment
- ☐ N30 with ACH payment
- ☐ 1%20,N60 with check payment
- ☐ N60 with check payment

PURCHASE ORDER EMAIL

PURCHASE ORDER FAX

BUSINESS DIVERSITY

3

FEDERAL CERTIFICATIONS
(self-certify on the federal System for Award Management website)

- ☐ ANC1 (Alaska Native Corp not certified as SDB with SBA)
- ☐ ANC2 (Alaska Native Corp not a small business)
- ☐ HBCU/MI (Historically Black College or Minority Institution)
- ☐ Hub Zone (Historically Under-Utilized Small Business)
- ☐ MBE (Minority Business Enterprise)
- ☐ SBE (Small Business Enterprise)
- ☐ SDB (Small Disadvantaged Business)
- ☐ SDVOSB (Service-Disabled Veteran-Owned Small Business)
- ☐ VOSB (Veteran-Owned Small Business)
- ☐ WBE (Women Business Enterprise)
- ☐ WOSB (Women-Owned Small Business)

STATE OF CALIFORNIA CERTIFICATIONS
(self-certify on the State of CA website)

- ☐ DBE (Disadvantaged Business Enterprise)
- ☐ DVBE (Disabled Veteran Business Enterprise)
- ☐ SBE (Small Business Enterprise)
- ☐ WBE (Women Business Enterprise)

ABILITY ONE PROGRAM

- ☐ 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.

SIGNATURE

DATE

PRINT NAME

TITLE

SUBMIT COMPLETED FORM TO ONE OF THE FOLLOWING

6

EMAIL (preferred): vendors@ucsf.edu

MAIL: UCSF Supply Chain Management
1855 Folsom St Ste 304
San Francisco, CA 94143-0910

Guide for the Substitute W-9 and Supplier Information Form

1. **SUPPLIER INFORMATION** – provide information about your company.

2. **PAYMENT OPTIONS**

   PAYMENT TERMS:
   - Immediate – payment is generated 1 business day after the invoice is processed
   - 2%10,N30 – a 2% discount is taken if the invoice is paid within 10 days of the invoice received date; otherwise, invoice is paid in full 30 days from invoice date
   - N30 – payment is generated 30 days from invoice date
   - 1%20,N60 – a 1% discount is taken if the invoice is paid within 20 days of the invoice received date; otherwise, invoice is paid in full 60 days from invoice date
   - N60 – payment is generated 60 days from invoice date

   PAYMENT METHODS:
   - Virtual Card/Payment Plus – payment via a one-time use virtual credit card number issued by U.S. Bank. Merchant interchange fees apply. For more information, contact U.S. Bank's Supplier Enrollment Team at CPS.SupplierEnrollment@usbank.com or (866) 929-0054.
   - ACH – payment by electronic funds transfer. A business bank account is required.
   - Paper Check

   PURCHASE ORDERS – provide an email address and/or fax number for Purchase Order delivery.

3. **BUSINESS DIVERSITY** – select all for which your business has self-certified as defined in the Ability One Program, the System for Award Management, or on the State of California website. Refer to the links for each program and the State of California for self-certification.

4. **REQUESTER'S INFORMATION** – provide your UCSF contact's name and email address.

5. **CERTIFICATION** – sign and date the Certification.

Substitute W-9 Form Disclosures

PRIVACY ACT NOTICE:
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.

PENALTIES:
Failure to furnish TIN. If you fail to furnish your correct TIN to a requester, you are subject to a penalty of $50 for each such failure unless your failure is due to reasonable cause and not to willful neglect.
Civil penalty for false information with respect to withholding. If you make a false statement with no reasonable basis that results in no backup withholding, you are subject to a $500 penalty.
Criminal penalty for falsifying information. Willfully falsifying certifications or affirmations may subject you to criminal penalties including fines and/or imprisonment.
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.

ADDITIONAL INSTRUCTIONS: See IRS Form W-9, Request for Taxpayer Identification and Certification.

ACH Enrollment Form

Electronic Funds Transfer Authorization

☐ New Request
(Not available to individuals)

☐ Account Change

☐ Cancel

	PAYEE/COMPANY INFORMATION	
1	**NAME**	
	ADDRESS	
	CITY, STATE, and ZIP+4 CODE	
	A/R CONTACT NAME	**A/R CONTACT PHONE**
	BUSINESS EMAIL ADDRESS (for payment notification)	**EMPLOYER ID NO (EIN)**
	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 ☐ CHECKING ☐ SAVINGS	

IMPORTANT NOTE: The person signing the Authorization must be a designated officer from the Finance Department and a person other than the contact listed above.

	AUTHORIZATION	
4	I hereby authorize the University of California San Francisco (UCSF) to initiate electronic transfer of funds to the account stated above using the National Automated Clearing House (NACHA) Cash Concentration or Disbursement (CCD) for settlement of invoices. If funds to which I, or the company I represent, am not entitled are deposited in the account stated above, I authorize the University to initiate a correcting (debit) entry. This authorization will remain in effect until UCSF receives written notification of its termination. I understand payment details will be sent to the business email address provided above.	
	SIGNATURE	**DATE**
	PRINT NAME	**TITLE**

ATTACH A VOIDED CHECK OR BANK VERIFICATION LETTER TO CONFIRM ACCOUNT INFORMATION

	SUBMIT FORM AND REQUIRED DOCUMENTATION TO ONE OF THE FOLLOWING	
5	**EMAIL (preferred):** vendors@ucsf.edu	**MAIL:** 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)

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.

3.

4.

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.

3.

4.

5.

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