TEP Meeting 2 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 NAOMI KNOW.

CONFLICT OF INTEREST FORM **Pg. 50-52**

YOU WILL ONLY NEED TO RE-SUBMIT THIS FORM TO OUR TEAM IF THERE HAVE BEEN ANY CHANGES SINCE OUR PREVIOUS MEETING IN FEBRUARY 2019, IN AFFILIATION FOR YOURSELF, YOUR PARTNER, OR ANY DEPENDENTS. PLEASE REVIEW ANY PREVIOUS DECLARATION OF CONFLICT FORMS TO ENSURE THAT WE HAVE THE MOST RECENT LISTING OF CONFLICTS, AND GUARANTEE FULL TRANSPARENCY AMONGST ALL TEP MEMBERS.

Technical Expert Panel Meeting Agenda

Tuesday, July 2, 2019
Zoom Meeting ID: 437 542 801
https://ucsf.zoom.us/j/437542801

9:00 AM	Call meeting to order	Dr. Helen Burstin
9:02 AM	Roll Call and Updated Conflicts	Dr. Burstin
9:15 AM	Defining the Proposed Measure	Dr. Patrick Romano
9:30 AM	Discussion of Measure Definition	led by Dr. Burstin
9:45 AM	Determining Radiation Dose Thresholds	Dr. Smith-Bindman
10:05 AM	Discussion of Radiation Dose Thresholds	led by Dr. Burstin
10:30 AM	Quick Recess	
10:40 AM	Study to Automate Assessment of CT Image Quality	Dr. Andy Bindman
10:50 AM	Discussion of Study to Automate Assessment of CT Image Quality	led by Dr. Burstin
11:10 AM	Alpha Testing of Proposed Measure	Dr. Rebecca Smith-Bindman
11:30 AM	Discussion of Alpha Testing	led by Dr. Burstin
11:50 AM	Wrap up and Next Steps	Dr. Bindman
12:00 PM	Adjourn	Dr. Burstin

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

Welcome to the
DR CTQS
Technical Expert Panel Meeting

Thank you for joining.
Everyone will be muted upon entry, if you have questions or comments, please use the hand raising option or send a chat message to Susanna.

We will begin the meeting shortly.

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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 use the hand raising option or send a chat message to Susanna 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.

If you need technical assistance during the meeting,
please email or call Naomi;
Naomi.Lopez-Solano@ucsf.edu
415.502.1370

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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?

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What Constitutes a Conflict?

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

Conflict of Interest Statements

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

Roll Call

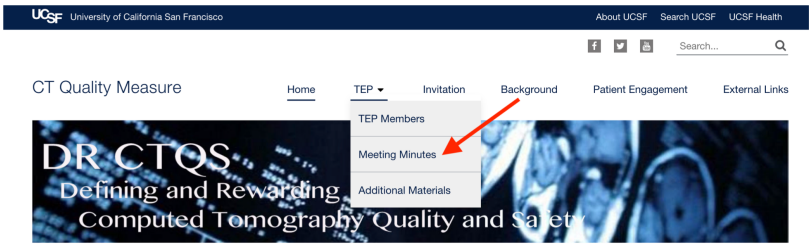
TEP Chair
Helen Burstin, MD, MPH, FACP

Members
Mythreyi Bhargavan Chatfield, PhD
Niall Brennan, MPP
Jay Bronner, MD
Missy Danforth,
Tricia Elliott, MBA, CPHQ
Jeph Herrin, PhD
Hedvig Hricak, MD, PhD
J. Leonard Lichtenfeld, MD, MACP
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

ctqualitymeasure.ucsf.edu

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



DR CTQS - TEP Website

Minutes Posted

TEP Goals

- Agreement on measure construct
- Make progress on measure specification
- Agreement on stratification approach
- Agreement on approach to setting thresholds for image quality and radiation dose thresholds

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Defining the Proposed Measure

Dr. Patrick Romano

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What Problem Are We Solving?

- Radiation doses for computed tomography (CT) vary widely across patients and providers, even within the USA
- Ionizing radiation is a known carcinogen, and CT radiation exposure has been associated with increased cancer incidence
- CT doses can be substantially reduced (on average) without compromising diagnostic accuracy
- We are partnering with CMS, other payers, professional organizations, and other stakeholders to make radiologic care safer for all Americans by reducing the harm caused by excess radiation exposure

Measure Concept

- To identify diagnostic CT scans that are performed in an unsafe manner, either because they utilize excessive radiation doses (given the clinical indications for imaging) or because they have low image quality, undermining their diagnostic value

- Balancing measure:
  - Indiscriminate efforts to reduce radiation dose may compromise image quality
  - Indiscriminate efforts to improve image quality may lead to excess radiation

Measure Concept

- Unit of analysis: individual CT scan
- Level of analysis: provider or provider group
- Each CT scan will be put into a category for the anatomic area and indication, based on information on why the study was done
- Numerator: Each CT scan will then be assessed for "failure" on either of two criteria:
  - Is the radiation dose too high for that category?
  - Is the image quality too low?
- Failure rate interpretation similar to a mortality rate – higher is worse
- Phrasing as "either" avoids additional NQF burden of an "all or none" composite measure

Inclusion and Exclusion Criteria

- Inclusion (Denominator)
  - All diagnostic CT scans performed on adult (ages 18 and older) by a clinician or group of clinicians during a reporting year.
- Exclusion
  - CT scans done for research, for surgical or interventional procedures including diagnostic biopsies, for guidance in radiation oncology treatment, or in association with nuclear medicine tests including positron emission tomography (PET) and single photon emission tomography (SPECT).
  - CT scans missing key data on patient age, radiation dose, image quality, or patient size (technical exclusions)
  - Whole body scans
  - Multiple areas scanned at the same time (treat as separate scans if possible)

Challenges

- Need to account for differences in what constitutes an appropriate radiation dose based on:
  - Anatomic region
  - Clinical indication for scan
  - Size of patient
- Need to automate the process for determining the radiation dose and image quality for each scan in a valid and reliable way that does not cause undue burden on clinicians
- Need to address data quality and outlier issues

Stratifying by anatomy and indication

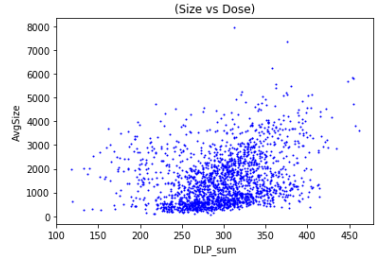
- Anatomical areas
  - Head, neck, chest, cardiac, abdomen, spine, extremity
- Clinical indications
  - We have created a list of approximately 50 clinical indications
  - e.g. Chest CT: lung cancer screening, pulmonary embolism, interstitial lung disease
- Dose/ Quality Strata
  - Combine anatomic areas and clinical indications into strata with similar dose/quality needs
  - Low dose: cardiac calcification, lung cancer screening, rule out pulmonary embolus
  - Routine dose: most scans within an anatomical area
  - High dose: liver (e.g., hepatocellular carcinoma), pancreas, urogram

Risk adjustment

- Indirectly standardize radiation dose (within strata) based on factors that are known to increase the dose needed to maintain image quality
- The only identified factor that is outside the control of the provider and facility is body size
- Body size is estimated as the average of the water equivalent diameter over the entire imaging range
- Estimate "expected dose" for each patient based on body size and assigned stratum, using national reference data (from UCSF registry)
- Standardized dose (for scan *i* in stratum *k*) =

$$[Dose_{ik} \,/\, E\wedge(Dose_{ik})] \times [\sum_{i=1}^{n}(Doseik)/n_k]$$

LOWESS plots



ABDOPEL HD SCANS
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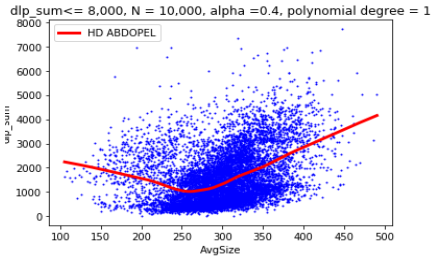

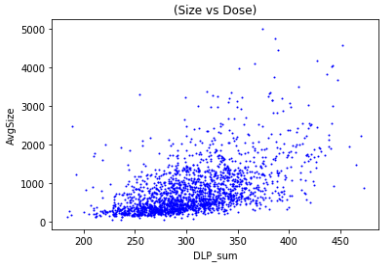

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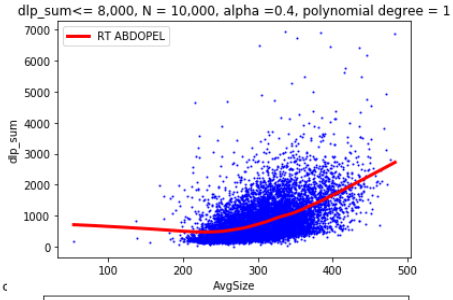

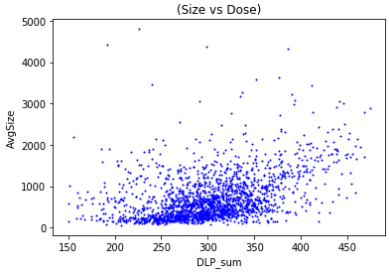

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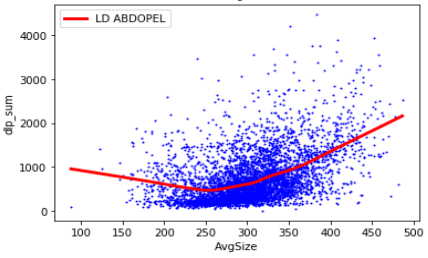
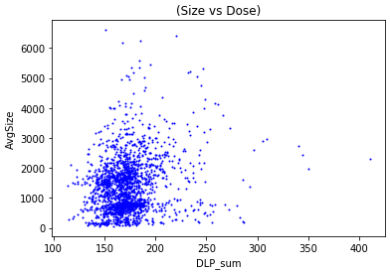


LOWESS plots



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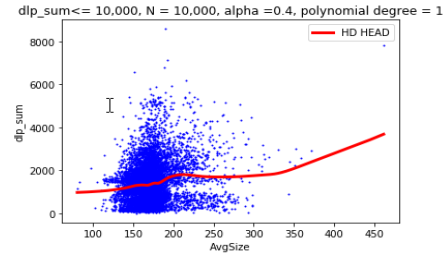

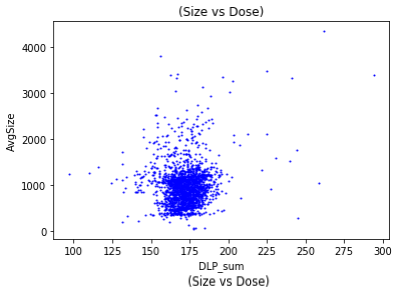

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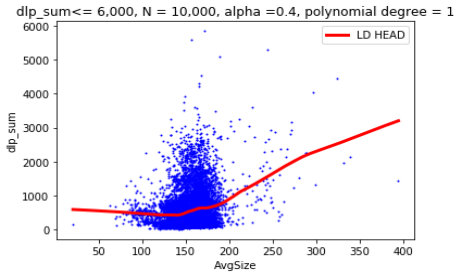

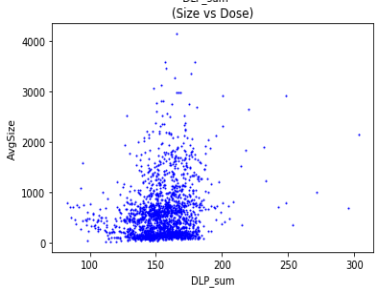

HEAD LD SCANS
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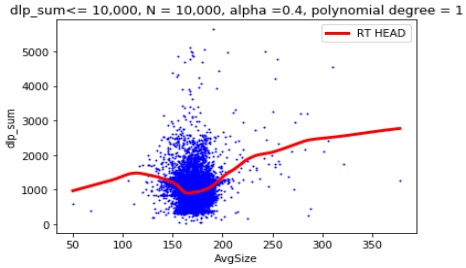

Discussion of Measure Definition

Questions:

- Do you agree with conceptualization of measure as a failure rate?
- Do you agree with proposed inclusion and exclusion criteria?
- Do you agree with adjusting radiation dose for size?
- Do you agree with deletion of multiple areas scanned at same size (other than for chest, abdomen, pelvis)?

Determining Radiation Dose Thresholds

Dr. Rebecca Smith-Bindman

UCSF
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Determining Radiation Dose Thresholds Within Anatomy/Indication Strata

- Evidence/Guidelines
- Empirical evidence from registry data
- Empirical evidence from planned study

Radiation Dose – Evidence and Guidelines

- Few evidenced based standards on what is the “right” dose or needed image quality
- Publications for specific indications (e.g. stones, PE) generally observe that doses can be reduced but few prospective studies showing impact of protocol choices and accuracy
- There is large variation even within well defined categories
- The EU is developing guidelines on target doses (by anatomic area/ clinical indication) informed by observed dose and expert opinion

  Stroke, sinusitis, cervical spine, PE, calcium scoring, coronary angiography, lung cancer evaluation, hepatocellular carcinoma, abdominal pain,

Radiation Dose- Registry – Observed Doses

- **American College of Radiology CT dose registry**
  - > 600 imaging centers, > 6 million CTs (in 2015)
  - Observed doses for anatomic areas have been published
  - These are based on what the radiologist chose to do (e.g. single, double phase) rather than indication (pain, cancer)
- **UCSF International CT dose registry**
  - 161 imaging centers in the US and UK, Europe, Asia, > 7 million CTs
  - CT exams collected on consecutive scans; 5,000 CTs daily
  - Information on study indication, study description, protocol used to identify clinical indication
  - Observed variation in doses by clinical indication can support establishing dose thresholds

UCSF Radiation Dose- Registry: Strata

Abdominal scans by clinical indication groups

Indication	DLP 50th	(25th 75th)
COLONOGRAPHY	438	(316 ,533)
PELVIS	494	(326 ,788)
CANCER	495	(248 ,984)
STONES	520	(338 ,773)
ENTEROGRAPHY	616	(420 ,923)
ABDOMEN AND PELVIS NOS	666	(430 ,1062)
LIVER	772	(395 ,1472)
TRAUMA	832	(466 ,1694)
ANGIOGRAPHY	1099	(675 ,1714)
METS	1121	(862 ,1437)
UROGRAM	1186	(641 ,1871)
PANCREAS	1369	(954 ,1915)
HCC	1376	(861 ,2185)
BLEEDING	1478	(939 ,2285)
RENAL MASS	1615	(1063 ,2261)

Radiation Dose and Quality Needs - Collapsing Categories?

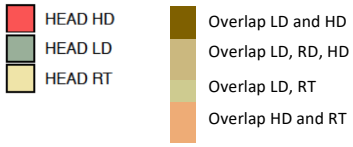
DOSE	REGION		
	HEAD	CHEST/CARDIAC	ABDOMEN/PELVIS
LOW DOSE	CRANIAL FLOOR FACIAL SKELETON SINUS TEMPORAL BONE	CALCIUM SCORING LUNG CANCER SCREENING	COLONOGRAPHY STONES
ROUTINE DOSE	HEAD STROKE TRAUMA	ANGIOGRAPHY CANCER CARDIAC - CORONARY CARDIAC, NOS CHEST, NOS INTERSTITIAL LUNG DISEASE PULMONARY EMBOLISM TRAUMA	ABDOMEN NOS CANCER ENTEROGRAPHY LIVER PELVIS TRAUMA
HIGH DOSE	ANGIOGRAPHY	DISSECTION METASTASIS TAVR	ANGIOGRAPHY BLEEDING HEPATOCELLULAR CA METASTASIS PANCREAS RENAL MASS UROGRAM

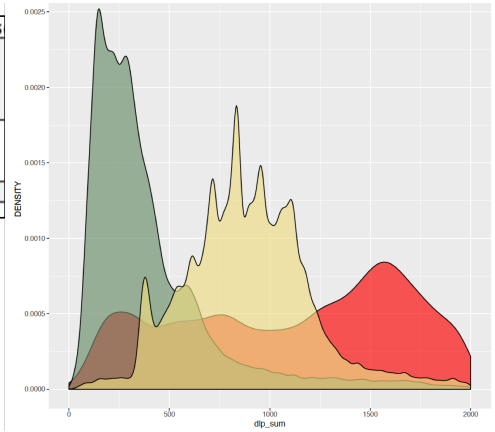
NECK
CSPINE
TSPINE
LSPINE
EXTREMITY UPPER
EXTREMITY LOWER

CAP/CAP Angio

Radiation Dose- Head Indication Categories

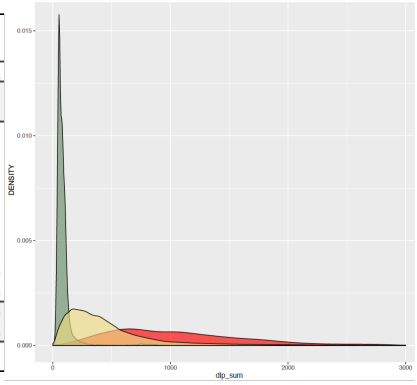
		n	(percent)	50th	25th	75th	5
LOW	Cranial floor	2,243	(0.3)	313	(215 , 427)		
LOW	Facial bones	22,544	(2.6)	411	(239 , 716)		
LOW	Sinuses	58,024	(6.6)	262	(163 , 399)		
LOW	Temporal bone	9,947	(1.1)	419	(281 , 652)		
ROUTINE	Routine Head	695,238	(79.0)	855	(692 , 1056)		
ROUTINE	Stroke	21,595	(2.5)	950	(774 , 1422)		
ROUTINE	Trauma	45,635	(5.2)	1160	(835 , 1509)		
HIGH	Angiography	25,129	(2.9)	1464	(771 , 1955)		





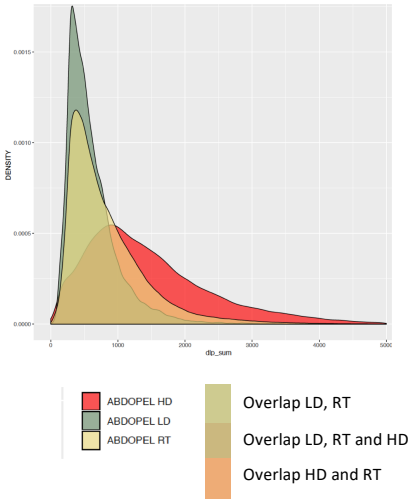
Radiation Dose Chest

				DLP (mGy-cm)		
		n		50th	25th	75th
LOW	Calcium score	21,403	(3.1)	65	(40 , 100)	
LOW	Lung Cancer Screening	18,073	(2.6)	72	(53 , 97)	
ROUTINE	Cardiac	22,407	(3.3)	208	(95 , 541)	
ROUTINE	Chest	437,155	(63.6)	316	(175 , 526)	
ROUTINE	Pulmonary Emoblism	105,118	(15.3)	382	(249 , 575)	
ROUTINE	Angiography	48,515	(7.1)	438	(305 , 730)	
ROUTINE	Coronary arteris	3,575	(0.5)	479	(271 , 898)	
ROUTINE	Cancer	7,308	(1.1)	555	(279 , 860)	
ROUTINE	Interstitial Lung Disease	2,594	(0.4)	595	(374 , 812)	
ROUTINE	Trauma	11,967	(1.7)	918	(563 , 1656)	
ROUTINE	Angiography + Calcium Score	2,028	(0.3)	935	(573 , 1060)	
HIGH	Dissection, Chest	4,702	(0.7)	853	(553 , 1349)	
HIGH	Metastasis	2,601	(0.4)	1215	(950 , 1539)	

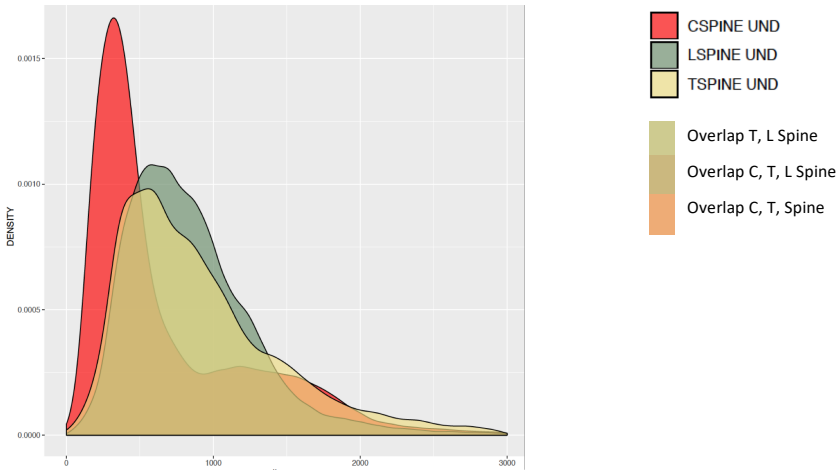


Radiation Dose Categories: Abdomen

				DLP (mGy-cm)	
LOW	Colonography	8,003	(0.9)	438	(316 , 533)
LOW	Stones	64,674	(7.0)	520	(338 , 773)
ROUTINE	Pelvis	31,351	(3.4)	494	(326 , 788)
ROUTINE	Cancer	8,507	(0.9)	495	(248 , 984)
ROUTINE	Enterography	7,439	(0.8)	616	(420 , 922)
ROUTINE	Abdomen and Pelvis	704,959	(76.1)	666	(430 , 1063)
ROUTINE	Liver	3,164	(0.3)	772	(395 , 1472)
ROUTINE	Trauma	15,035	(1.6)	832	(466 , 1694)
HIGH	Bleeding	3,756	(0.4)	1478	(939 , 2285)
HIGH	Hepatocellular CA	5,473	(0.6)	1097	(718 , 1817)
HIGH	Metastasis	3,059	(0.3)	1121	(862 , 1437)
HIGH	Renal Mass	8,645	(0.9)	1615	(1063 , 2261)
HIGH	Pancrease	4,702	(0.5)	1369	(954 , 1915)
HIGH	Urogram	33,700	(3.6)	1186	(641 , 1871)
HIGH	CT Angiography	23,973	(2.6)	1116	(681 , 1744)



Radiation Dose Categories: Spine



Calibrating Dose With Quality Assessment

- Will have opportunity to examine how dose is related to quality in our prospective study of radiologists Andy will describe later in this meeting
- The study will ask radiologists to rate the quality of a diverse cases
- Our plan is to determine what quality radiologists believe is required for each of the anatomic area and high/routine/low categories identified

Discussion of Radiation Dose Thresholds

- Do you agree with broad empirical approach of assessing doses within categories and determining thresholds within each category
- When practice does not follow the best evidence (e.g. kidney stones) should targets reflect practice (which may not be appropriate), or highest quality care
- Are the categories good enough (will rare categories that require high dose introduce rounding error and don't need to be called out)

10 minute Break

We will resume at ____

University of California
San Francisco

Study to Automate Assessment of
CT Image Quality

Dr. Andy Bindman

University of California
San Francisco

Image Quality (Balancing Component)

- Radiologists need sufficient quality images to make accurate diagnoses
- Adequate radiation doses needed to produce sufficient image quality
- While incentivizing lower radiation doses we don't want to encourage sub-optimal image quality

Assessing Image Quality

- Radiologists' assessments of image quality in free text reports- not easily accessed
- Can derive "image noise" measure from CT report but not clear how it relates to radiologists' judgment of quality
- Potential to use machine learning (artificial intelligence) to read images to judge image quality but again not clear how that relates to radiologists' assessment of image quality

Image Noise

- As radiation dose decreases, image noise increases creating “quantum mottle” – less contrast and resolution between structures
- Within a single CT there is variation in measured noise according to anatomic area and due to transition areas from one anatomic structure to another
- Global image noise* provides a means to sample across parts of image and across images of a single CT scan.

*Christianson et al. Automated Technique to Measure Noise in Clinical CT Examinations. AJR 2015.

Machine Learning of Image Quality

- Computer first ”trained” on a subset of images within each of the strata (anatomy and indication) 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

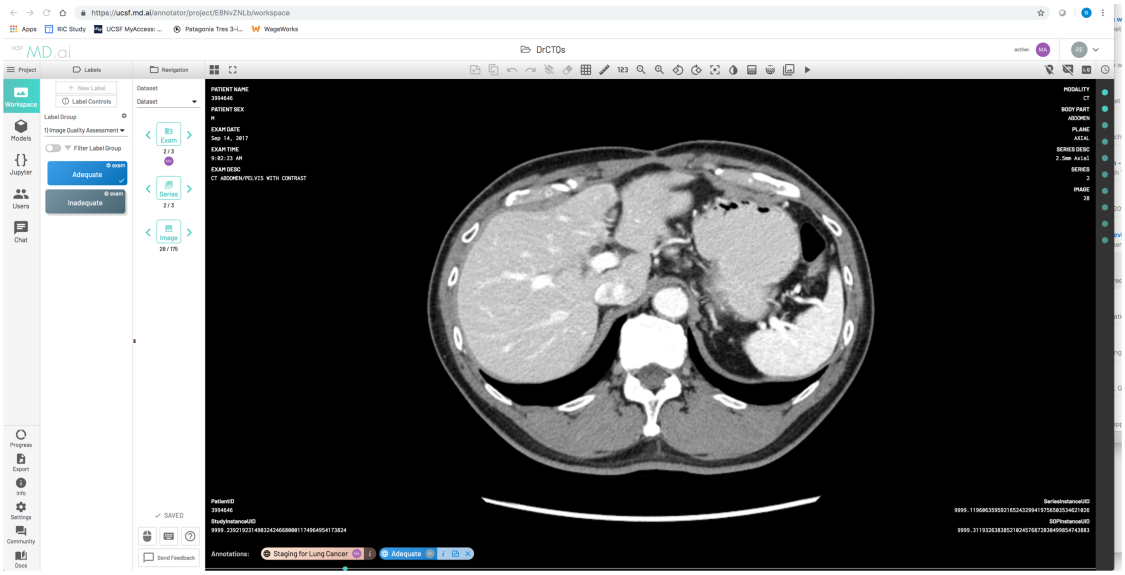
Planned Study

- Compare radiologists' assessment of image quality as gold-standard against:
  - Global noise derived from CT scan
  - Computer reading of image quality (artificial intelligence)
- Test cases to vary in dose within strata by anatomy and indication
- Study to be powered to not only judge validity of automated assessments (noise or AI) but to inform radiation dose threshold within each strata

Study Design

- Number of radiologists: 100 · Each clinical Indication: > 10
- Number of different cases: 700 · Each case seen by > 10 radiologists
- Source of radiologists: private practice, academic, urban, rural, small groups and large. All U.S., all actively practicing and reading CT
- Number of cases per radiologist: 200 (across dose ranges, anatomic area)
- Radiologists to judge whether CT scan is adequate or not for specified clinical indications (chosen to reflect variable radiation needs)
- Cases chosen randomly across dose thresholds, but cases with very large dramatic findings are deleted so as not to be distracting of primary goal

Radiologists will review cases on-line using MD.Ai



Planned Study Analysis

- Agreement in rating of adequacy of image by radiologists (referent standard) with (1) global noise thresholds and (2) AI assessment

- Will determine a dose and image quality floor threshold for each strata above which most (95% of radiologists) think doses are adequate

- Will determine a dose and image quality ceiling whereby increasing dose does not increase the number of radiologists who rate images as adequate (ie ceiling where everyone is satisfied so that going higher in dose does not improve adequacy

How We Will Use Results

- Based on agreement with radiologists' interpretation may select either global noise or AI as means to automate assessment of image quality
- Will use radiation doses from images radiologists' determine to be adequate in conjunction with guidelines and registry information to help set measure thresholds within strata

Timing of Study and Sharing Results with TEP

- Conducting study in fall of 2019
- Analyzing results in the winter of 2019
- Spring of 2020 will share with TEP

Discussion of Study to Automate Assessment of CT Image Quality

- What are your thoughts about our proposed methods (global noise calculation or AI) for automating the assessment of image quality?
- What level of agreement between global noise or AI with radiologists' assessments would make you comfortable deploying it in payment decisions?
- What thoughts do you have on how we can use the assessments of a radiation dose floor (when image quality erodes) and ceiling (when image adequacy no longer improves) in combination with the registry and evidence based guidelines to set thresholds?

Alpha Testing of Proposed Measure

Dr. Rebecca Smith-Bindman

UCSF
University of California
San Francisco

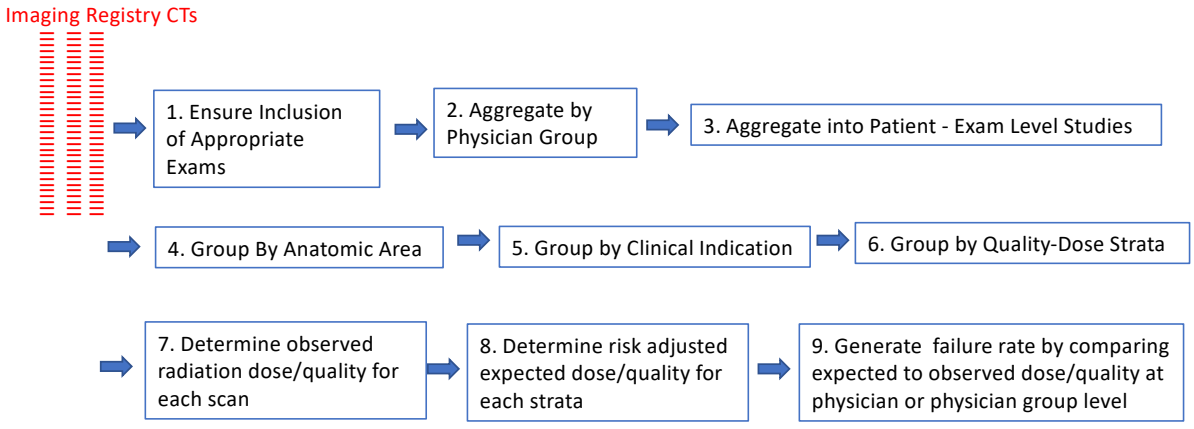
Alpha Testing : Assessing Measure at UCSF

- Key inputs of the measure (dose and quality thresholds) and capacity to assess at level of individual physician are not yet available (using surrogates)

- The goal of alpha testing – is to demonstrate that we can aggregate the data to clinician groups, exclude examination types that are not included, categorize by anatomic area/clinical indication strata, compare doses to risk-adjusted expected dose, and assess failure rate by clinician group that accounts for underlying patient variables

- Study sample – 161 physician groups (facilities), 7million CTs, 3 yrs

Alpha Testing Steps



Inclusion of appropriate exams (1)

- The UCSF Dose registry was created to assemble consecutive CT scans from diverse organizations, imaging facilities, and physicians

- Excluded

Non-CT or CT combined with PET, SPECT	9%
CTs where measure does not apply radiation oncology, RFA ablation, research	9%
CT biopsy, measure does not apply	3.7%

Aggregate by physician / physician group and patient (2 and 3)

- In the alpha testing we aggregated CTs by physician group as working within a single imaging facility. Anticipate using individual MD and TIN in next round of testing

- Some exams missing information on the facility, physician group, or CT scanner (2% excluded) If CT scanner available, it was mapped to the physician group associated with the scanner

- CT scans identified by patient ID, date, time, for each radiating event (with/without contrast separate) and needed to be regrouped by exam. A patient could have two exams in a day, but at different times.

Aggregate by anatomic area, indication, quality/dose strata (4,5,6)

- CTs grouped by anatomic area (0.35% of exams unclassifiable)
  - CTs grouped by indication (7% of exams unclassifiable)
    - Indications grouped into dose/quality strata

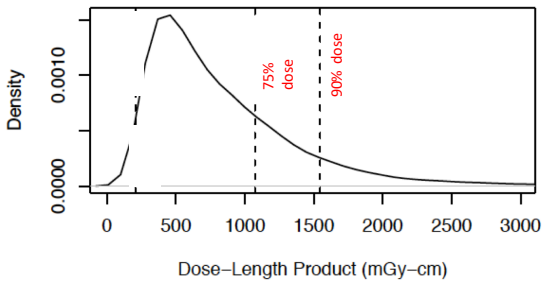
Validation of assignment to categories done as part of quality study

- A clinical history will be assigned to each of the 700 cases that physicians will review. Two radiologists will confirm the characterization of the indication is correct.
- Its only assignment of cases to broad combination of anatomic area and indication that matter

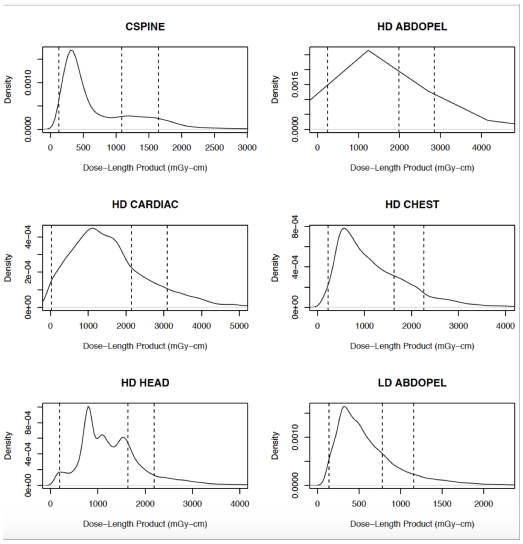
DOSE	REGION		
	HEAD	CHEST/CARDIAC	ABDOMEN/PELVIS
LOW DOSE	CRANIAL FLOOR FACIAL SKELETON SINUS TEMPORAL BONE	CALCIUM SCORING LUNG CANCER SCREENING	COLONOGRAPHY STONES
ROUTINE DOSE	HEAD STROKE TRAUMA	ANGIOGRAPHY CANCER CARDIAC - CORONARY CARDIAC, NOS CHEST, NOS INTERSTITIAL LUNG DISEASE PULMONARY EMBOLISM TRAUMA	ABDOMEN NOS CANCER ENTEROGRAPHY LIVER PELVIS TRAUMA
HIGH DOSE	ANGIOGRAPHY	DISSECTION METASTASIS TAVR	ANGIOGRAPHY BLEEDING HEPATOCELLULAR CA METASTASIS PANCREAS RENAL MASS UROGRAM

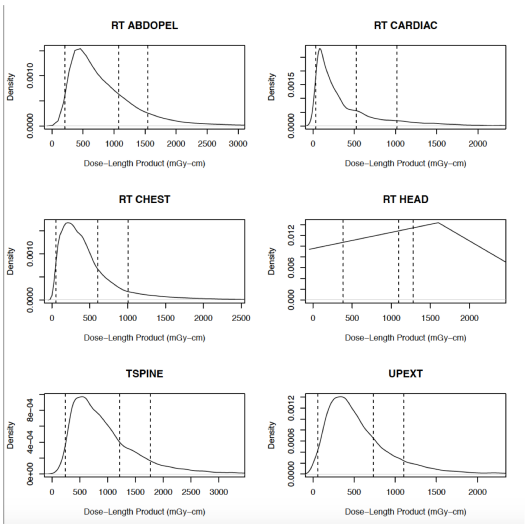
Determined expected dose for each dose strata

Distribution in Dose Routine Abdomen CT



We replicated determining risk adjusted cutoffs or all categories



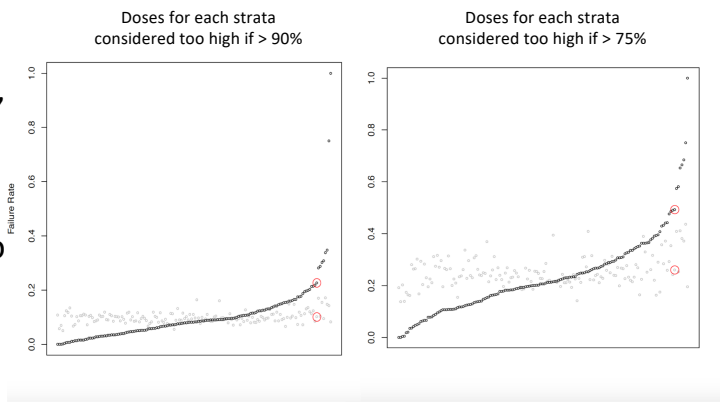


Determined observed, risk adjusted expected dose (7,8)

- We determined the observed radiation dose for each scan
- We characterized the expected dose for each anatomic area/indication/ dose quality strata
- We assessed the distribution in dose, and modelled (a) doses top 10%, and (b) top 25% as abnormal

Determining (a part of) the failure rate (9)

- We don't have image quality component in registry
- Within each group of CT scans (by physician cluster), we calculated the proportion of exams that failed, compared to the expected failure rate at two different high dose thresholds
- Overall not a lot of difference in expected failure rates across (light grey) with greater difference in observed failure rates



What was learned from alpha testing

- We can successfully categorize the vast majority of eligible CT exams within the dose/quality strata
  - Fewer than 10% of CT exams are excluded for technical reasons (missing information on physician, anatomy or indication)
- We can compare observed and expected doses
- Planned beta testing will allow us to (a) replicate in a diverse sample,(b) test capacity to aggregate physicians based on TINs, (c) incorporate image quality into calculation of failure rate, and (d)evaluate burden of reporting on clinicians

Discussion

- Do you agree with stratification by anatomic area and clinical indication, followed by aggregation across strata?
- Suggestions for how to handle “technical” exclusions related to missing data
- Any other suggestions for what we should test as we plan for beta testing?

Wrap Up & Next Steps

- Thank you for your attention and input
- The University of California team will reflect on advice and develop a plan in cooperation with CMS on next steps
- Information about this TEP meeting and future meetings will be posted at ctqualitymeasure.ucsf.edu
- We will be reaching out to you soon to set the date for the next TEP meeting (September) which will focus on the planned beta testing and will be done as a webinar.
- Honorarium request reminder

We are adjourned!

DR CTQS – TEP Meeting #2
Virtual Conference via Zoom
07/02/2019 – 09:00am-12:00pm Pacific

Meeting Minutes

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 1V1CMS331638-01-00. 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 electronic data 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.

Several TEP members were unable to attend the TEP meeting on July 2. To benefit from their input, an abbreviated alternative TEP meeting was held on July 30, which followed the same format as the July 2, but was compressed in time. Attendees of this session were given all of the slides that were presented at the July 2nd TEP session and listened to a presentation that used a subset of these.

Table 1. TEP Member Name, Title, and Affiliation

Name	Title	Organization
Attendees July 2, 2019		
Niall Brennan, MPP	CEO	Health Care Cost Institute
Helen Burstin, MD, MPH, FACP	CEO	Council of Medical Specialty Societies
Jay Bronner, MD	President and Chief Medical Officer	Radiology Partners
Jeph Herrin, PhD	Adjunct Assistant Professor	Yale University
Matthew Nielsen, MD, MS	Professor	University of North Carolina
Debra Ritzwoller, PhD	Patient	Patient Representative
J. Anthony Seibert, PhD	Professor	University of California, Davis
Arjun Venkatesh, MD, MBA, MHS	Assistant Professor	Yale School of Medicine
Todd Villines, MD, FSCCT	Professor	University of Virginia

Kenneth Wang, MD, PhD	Adjunct Assistant Professor	University of Maryland, Baltimore
Attendees July 30, 2019		
Mythreyi Bhargavan Chatfield, PhD	Executive Vice President	American College of Radiology
Tricia Elliot, MBA, CPHQ	Director, Quality Measurement	Joint Commission
Hedvig Hricak, MD, PhD	Radiology Chair	Memorial Sloan Kettering Cancer Center
Leonard Lichtenfeld, MD, MACP	Interim Chief Medical Officer	American Cancer Society, Inc.
Lewis Sandy, MD	Executive Vice President, Clinical Advancement	UnitedHealth Group
Not In Attendance		
Missy Danforth	Vice President of Health Care Ratings	The Leapfrog Group
Suzanne Schrandt, JD	Patient	Patient Representative

Ex Officio TEP		
Attendees July 2, 2019:		
Mary White, ScD	Chief, Epidemiology and Applied Research Branch	Centers for Disease Control
Attendees July 30, 2019		
Amy Berrington, DPhil	Branch Chief & Senior Investigator Radiation Epidemiology Branch	National Cancer Institute
CMS & CATA representatives		
Janis Grady	Project Officer	CMS

UCSF team		
Attendees		
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
Monika Ray, PhD	Statistician	University of California, Davis
Naomi López-Solano, CCRP	Project Manager, Logistics	University of California, San Francisco
Diana Ly, MPH	Project Manager, Strategy	University of California, San Francisco
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, the minutes from the first TEP meeting, honorarium documentation, and a conflict of interest form. All documents can be found on pgs. 2-45 of the TEP Meeting Packet. The meeting was conducted with the use of PowerPoint slides all of which are referenced with page numbers of where they can be found in the TEP Meeting Packet.

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

Helen Burstin called the meeting to order. She noted that the meeting will last for three hours with a break at the halfway point, and will include a discussion period after each presentation.

9:02 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 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 sake 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. She is now on the board of the Society to Improve Diagnosis in Medicine, although this is not a conflict of interest. Dr. Jay Bronner stated no new conflicts of interest. Dr. Jeph Herrin stated his affiliation

with Yale University, and no new conflicts of interest. Dr. Matt Nielsen reported his affiliation with the University of North Carolina. He noted he is now the Quality Improvement Chair at AUA, however this association is not directly related to imaging. Dr. Debra Ritzwoller stated her affiliation with KP Colorado and as a patient/guardian stakeholder. Dr. Tony Seibert is a faculty member at UC Davis. His current conflicts include being a member of the Bayer Radimetrics Advisory Board, and Governor of the American Board of Radiology. Dr. Todd Villines noted a change in affiliation: previously he was at Walter Reed in Bethesda; he is now a professor at the University of Virginia. Dr. Villines reported no change in conflicts. Dr. Ken Wang noted his affiliation with the VA in Baltimore and University of Maryland. Of note, he is participating on his personal time not representing government. His conflicts include a small start-up and occasional reimbursements from Radiology Society of North America. Dr. Mary White reported her affiliation with the CDC and no conflicts of interest. Dr. Arjun Venkatesh reported no updates to conflicts of interest, but reminded the group that he works under contract with CMS for the development of hospital quality measures and quality rating systems, and also leads quality measure development for the American College of Emergency Physicians. Niall Brennan also joined the call later and stated that he had no conflicts and that he is currently the President and CEO of the Health Care Cost Institute.

July 30 Make-Up TEP

TEP members were asked to disclose any COIs when introducing themselves for the sake of group transparency. TEP members re-stated their affiliations and any existing conflicts. Dr. Hedvig Hricak is currently the Chair of the Memorial Sloan Kettering Cancer Center Department of Radiology. She disclosed her current conflict as a board member of IBA. Dr. Mythreyi Chatfield stated her affiliation with the American College of Radiology, as the Executive Vice President of Quality and Safety, and had no conflicts of interest to disclose. Tricia Elliot restated her role as the Director of Quality Measurement at The Joint Commission, and no new conflicts of interest. Dr. Leonard Lichtenfeld reminded the panel of his role as the Interim Chief Medical Scientific Officer of the American Cancer Society. He did not have any conflicts but mentioned his stock ownership in Google and noted that they have some interest in using augmented intelligence in radiology analytics. Dr. Lewis Sandy stated his affiliation with UnitedHealth Group as the Executive Vice President of Clinical Advancement, and had no conflicts of interest to disclose. Dr. Amy Berrington restated her role as the Branch Chief and Senior Investigator in the Radiation Epidemiology Branch at the National Cancer Institute, and had no conflicts of interest to disclose.

Review of goals for TEP #2 meeting:

1. Agreement on measure construct
2. Make progress on measure specification
3. Agreement on stratification approach

4. Agreement on approach to setting thresholds for image quality and radiation dose thresholds

9:15 AM Defining the Proposed Measure Dr. Patrick Romano

Presentation focused on elucidating the construction of the proposed measure. Description of the measure concept, including: balancing aspects, the numerator and denominator, inclusion and exclusion criteria, stratification and risk adjustment strategies, and possible challenges were presented to the TEP.

Dr. Romano noted that CT radiation doses vary widely and exposure to CT radiation has been associated with increased cancer incidence. The idea of this measure is to identify diagnostic CT scans that are performed unsafely either through the (1) utilization of excessive radiation doses or (2) having poor image quality undermining their diagnostic value. The numerator is the number of scans that "fail" on either of those two criteria. The denominator is defined as the number of diagnostic CT scans performed on adults by a clinician or group of clinicians during a reporting year. This failure rate interpretation is similar to a mortality rate where a higher proportion is worse.

Dr. Romano listed proposed exclusions, which include: CT scans done for research, for surgical or interventional procedures including diagnostic biopsies, for guidance in radiation oncology treatment, or in association with nuclear medicine tests including positron emission tomography (PET) and single photon emission tomography (SPECT); CT scans missing key data on patient age, radiation dose, image quality, or patient size (technical exclusions); whole body scans; and additionally, multiple areas scanned at the same time (but these would be treated as separate scans if possible).

It will be important to track patterns and frequency of missingness. In some cases, it may be possible to impute missing variables from available data elements.

This measure concept gives rise to several challenges: identifying the appropriate radiation dose based on anatomic region, clinical indication, and patient size; creating an automated process to determine radiation dose and image quality in a valid and reliable way; and how to address data quality issues.

To address appropriate differences in the amount of radiation used by anatomic area and clinical indication, the UC team is proposing to stratify these characteristics. The anatomic areas and clinical indications will be combined into strata with similar dose and quality needs. Risk adjustment will focus on body size derived from the CT scan. An "expected dose" will be estimated for each patient based on body size and assigned stratum.

Dr. Romano presented lowess plots revealing a relationship between patient size and radiation dose for some body regions. In general, the larger the patient size, the higher the radiation doses, however there are extreme outliers on both ends of this distribution including implausibly high doses. For head scans specifically, there is no clear relationship between size and dose.

This material was presented by Dr. Smith-Bindman at the July 30 make-up TEP using a subset of the slides presented on July 2.

9:30 AM *Discussion*: **Measure Definition** **Dr. Burstin**

Discussion of conceptualization of measure as a failure rate. There was concern that if patients are very large, they might require very high doses and that the images might still be of poor quality. This could result in a clinician failing the measure based on patient characteristics rather than provider performance. It was explained that the measure will be adjusted for patient size and that the TEP would be given additional opportunity at a later time to assess the adequacy of the adjustment.

Dr. Burstin suggested that the overall failure rate would be more useful for clinicians if it also included the component failure rates related to radiation dose and image quality.

There was a concern for using missing key data as part of the exclusion criteria as this could provide an avenue for gaming. It was noted that the degree to which this exclusion arose would be assessed at the provider level and that future consideration would be given to how to incorporate it into an assessment of the failure rate.

This portion of the meeting concluded with the TEP endorsing the proposed approach for specifying the measure as a failure rate derived in strata defined by anatomic area and clinical indication and risk adjusted for patient size.

July 30th 2019: The discussion of the measure composition was led by Dr. Andrew Bindman. One TEP member suggested that scans on the same patient for the same indication be considered a measure of poor quality. Dr. Bindman discussed that this was outside the current scope of the measure, but could contribute to a future radiology quality measure. TEP members endorsed the measure construct, and the stratification and risk-adjustment approach, but raised questions regarding the details of how the clinical indication categories and image quality thresholds would be defined. These questions were discussed later in the meeting.

9:45 AM **Determining Radiation Dose Thresholds** **Dr. Smith-Bindman**

Dr. Smith-Bindman presented work on establishing radiation dose thresholds that will serve as the standard that radiologists will be tested against. It was shared that there are few evidence-based standards on proper radiation dose or needed image quality. A large number of publications have looked at dose specific indications, and those studies have found that doses can be reduced.

Dr. Smith-Bindman shared information about the size of the CT dose registries at UCSF and the American College of Radiology. She pointed out that there is demonstrated empirical evidence from these registries about how dose ranges vary by anatomic area. She indicated that the empirical data from these registries can inform the dose thresholds which will become the basis of the failure rate. She showed how the mean doses varied across anatomical areas but that wide within-area variation persisted. She indicated that she thought it was likely that it would be possible to collapse categories of indications within anatomical areas based on their requiring somewhat similar doses. Dr. Smith-Bindman presented figures demonstrating the distribution of low, medium, and high doses within several anatomical areas including head, chest, and abdomen, further exhibiting the large variation of dose.

She noted that information from the planned image quality sub-study will help to further refine the dose thresholds within anatomic areas and by indication. In brief, it is anticipated that when radiologists rate the image quality of CT scans that vary in dose that at some dose threshold virtually all radiologists will rate image quality as adequate so that doses above this threshold are likely to be excessive.

This material was presented by Dr. Smith-Bindman at the July 30 make-up TEP using a subset of the slides presented on July 2.

10:05 AM *Discussion*: **Radiation Dose Thresholds** **Dr. Burstin**

Issue was brought up of incomplete scans and how they fit into these thresholds. Dr. Smith-Bindman explained that incomplete scans are excluded from measure, although the relevance of repeated scans due to incomplete scanning was noted.

TEP expressed strong support for empirical approach based on the registry data and the anticipated results from the image quality study to set radiation dose standards for anatomic areas and clinical indications collapsed into categories along the lines that were proposed (low, routine, and high).

A question was raised about physicians who have specialty practices focused on patients with a narrower range of indications, and whether this will result in a lower failure rate than radiologists with a broader practice. Dr. Smith-Bindman explained that in general, every CT scan performed will be assessed and

compared with the specific anatomical area and indication category, and will contribute to the overall failure rate. Having fewer indications represented in a practice should not bias the measure as the comparison is within a stratum. She also noted that there are a few indications with very clear guidelines for imaging and that specialists that focus on these areas may have lower failure rates because they are meeting those standards. She noted that lung cancer screening for example, has clearly defined radiation dose targets because CMS requires reporting to the ACR dose registry for this specific category, and the systems for standardizing radiation dose and meeting these thresholds are already in place for this indication. A radiologist working exclusively within the narrow category of lung cancer screening may be better able to manage the less complex task than those who need to manage CT scans for multiple indications. However, she added that while this might be true in theory it may not be the case in practice. For kidney stones, there are also guidelines recommending the use of low doses, yet the UCSF data registry suggests that most physicians still use doses for this category that are not following the guidelines. Thus specialty physicians who do a lot of renal stone CT may not in the end have a lower failure rate.

Action: TEP members had been surveyed prior to the meeting about their opinions as to which CT scans within specified anatomic areas had clinical indications that required doses that were higher or lower than routine. The TEP requested that the survey results be shared with all TEP members so as to develop a shared understanding of any changes that were made based on their input.

July 30th 2019: The discussion of Radiation Dose Thresholds was led by Dr. Bindman. A question was brought up by the TEP regarding as to whether dose thresholds would be determined on the basis of dose per protocol chosen for a diagnosis or dose per indication for the CT scan. Dr. Bindman clarified that this measure is examining dose per indication because the choice of which protocol to use is a discretionary decision made by the clinician performing the test which has implications for the safety and quality of the test. Adjusting for the choice of protocol would be an over-adjustment given the goal is to minimize dose but preserve image quality for a clinical indication for a CT scan.

There was discussion of the possibility of gaming the indications to provide clinicians performing CT scans to have higher thresholds of acceptable dosing or more latitude in the image quality. Dr. Bindman acknowledged that some clinicians might try to find a way to game how they are evaluated but said that the use of information on clinical indications coded at the time of test ordering in combination with information on what test was billed for after performing the test should minimize the opportunity for gaming. He reminded TEP members that CMS applies high penalty for fraud related to false billing.

One TEP member questioned whether the use of broad categories to assess dose and quality would be too broad to allow physicians to understand the areas they need to improve. Dr. Smith-Bindman discussed the potential to incorporate granular feedback of performance within the different anatomical area/clinical indication stratum so that clinicians could learn from their assessments and have information to allow them to improve over time.

10:30 AM Quick Recess

10:40 AM Study to Automate Assessment of CT Image Quality Dr. Andy Bindman

Presentation began with Dr. Bindman's explanation that image quality is a balancing measure to radiation dose. He introduced challenges in establishing an assessment of image quality, namely, radiologists' assessments of image quality are in free text reports and not easily accessed. Potential surrogates include (1) image noise measures or (2) machine learning, but it is not currently known how either relate to radiologist judgement of quality.

For the image noise approach, Dr. Bindman explained that as radiation dose decreases, image noise increases creating a "quantum mottle" similar to when a television picture becomes blurry. Global image noise is a single measure of noise that summarizes the image quality of a single CT scan. The second approach the UC team is exploring relies on artificial intelligence (AI) to automate the assessment of image quality. A computer would first be trained on images and provided with information on the radiologists' assessment of image quality. In this way, the computer would "learn" how radiologists arrived at that assessment.

Dr. Bindman introduced the planned quality sub-study to compare radiologists' assessment of image quality as gold-standard against global noise derived from CT scan and AI reading of image quality. In judging whether the images are adequate, the radiologists will be provided with information on the clinical indication for the CT scan. He introduced study design alongside how participants will review cases online using MD.Ai. He explained that the analysis of the study will compare the agreement in the radiologists' rating of image with (1) global noise, and (2) a computer assessment done using AI. Depending on the results of the study, the UC team may recommend that either global noise or AI be used to automate assessment of image quality when calculating the failure rate. In addition, the sub-study will be used as previously described by Dr. Smith-Bindman to identify a radiation dose threshold above which radiologists are virtually unanimous (e.g. >95%) in rating image quality as adequate for the anatomical area and clinical indication. Dr. Bindman noted that the study will be conducted in fall 2019. The next planned TEP meeting in September will provide members with additional details on the planned study and the TEP meeting anticipated for late winter/early spring 2020 will be used to share results of the image quality sub-study.

This material was presented by Dr. Bindman at the July 30 TEP using a subset of the slides presented on July 2.

10:50 AM *Discussion*: **Study to Automate Assessment of CT Image Quality Dr. Burstin**

Concerns were raised about validity of using radiologists' ratings of image quality as gold standard, when the reliability of reviewers is unknown. Many radiologists read for multiple facilities at one time, so they are accustomed to reading images of varying quality. Radiologists' view of what is an acceptable image has changed over time, particularly as software has emerged to improve the adequacy of what may have previously been considered an inadequate image. Dr. Smith-Bindman explained that reliability will be assessed as a component of the image quality sub-study. It is anticipated that there will be 20-30 readings per test case which should provide an ability to develop a clear sense of how reproducible radiologists' opinions of quality are. The UC team expects that by including radiologists from a wide variety of settings that the study will provide an empirically derived reference standard.

Question was brought up about whether signal will be reviewed, and how patient motion will affect measure. Dr. Smith-Bindman explained that patient motion is outside the scope of this project, but that such events would presumably be random across providers so that it should not have a disproportionate effect on any particular clinician or clinician group being evaluated. The UC sub-study will explore the value of including information on signal.

Construct of gold standard received approval from TEP but concerns were raised about the durability of the measure and the "moving target" nature of what is viewed as adequate image quality. What is set as the gold standard today may not be the gold standard later. Dr. Burstin noted that this could be a concern due to the measure being used for payment. However, the TEP members acknowledged that this concern may be premature without yet knowing results of the study.

July 30th 2019: The discussion of the Study to Automate Assessment of CT Image Quality was led by Dr. Bindman. Concerns were expressed by the TEP about the resources needed to implement the automated assessment mechanisms, and the potential for added burden on physician groups. Dr. Bindman acknowledged the potential complexity which along with physician burden would be tested as a part of this project. Results would be shared with TEP so that they could provide additional input. Dr. Bindman also mentioned that some of the logistics for executing the work would fall to whoever takes on the role of measure steward and that this role would be discussed with TEP members at upcoming meetings as well.

11:10 AM Alpha Testing of Proposed Measure Dr. Smith-Bindman

Dr. Smith-Bindman reported on initial findings from alpha testing which uses surrogate thresholds for dose assessments. The goal of alpha testing is to demonstrate the degree to which the measure can be calculated from data that providers submit regarding their CT scans. Dr. Smith-Bindman pointed out that the UC CT International Dose Registry was not created with this purpose in mind but that it provides a good testing ground for evaluating the plausibility of the proposed approach. As a first test (alpha), the UC team has used the UC Dose Registry to execute a series of steps that will be needed to do measure reporting. This includes aggregating the data into clinician groups, excluding examination types that are not included in calculating the measure, categorizing CT scans into anatomic area/clinical indication strata, comparing observed doses to risk-adjusted doses, and assessing failure rate by clinician group.

The UC team determined the observed radiation dose for each eligible scan within anatomically defined strata, calculated the patient size associated with each CT and modeling a failure rate based on either the top 10% or the top 25% as a failure.

The UC team learned from alpha testing that a little more than 20% of CT scans in the registry would be excluded because they were done for research, in conjunction with nuclear scans, in association with radiation oncology treatments or in support of procedures. Another 10% were excluded due to missing information. For the remainder, the UC team was able to derive observed radiation doses and to calculate expected radiation doses based on anatomic area and patient size. The UC team also demonstrated how an assessment of performance could be done with these data.

Future alpha testing will incorporate clinical indication into the assessment of radiation thresholds. Subsequent beta testing will allow the UC team to: (a) replicate this testing in a diverse sample, (b) test our capacity to aggregate physicians based on TINs, (c) incorporate image quality into calculation of failure rate, and (d) evaluate the burden of reporting on clinicians.

11:30 AM *Discussion*: **Alpha Testing** **Dr. Burstin**

Question was raised about how the UC team proposes to determine the clinical indication for the CT scan. TEP members were informed that the UC team plans to use type of CT scan and billing codes for this and that TEP members will be given more detail about this about an upcoming TEP meeting.

Questions were raised about how UC team will use body circumference to risk adjust. Concern raised about how we will do this with scans where it is hard to see body circumference or outline, such as cardiac scans. TEP members were

informed that UC team has experience in calculating patient size from CT scans within the UC CT International Dose Registry. Some of these preliminary results were shown in Dr. Romano's presentation at this meeting and more detail will be presented on this at a subsequent TEP meeting. A suggestion was made to include size as a predictor in the image quality sub-study. The UC team agreed that this was a good idea and would be done.

11:50 AM **Wrap up and Next Steps** **Dr. Bindman**

Dr. Bindman thanked TEP members for their time and contributions, expressed the UC team's intention to reflect on feedback with its CMS partners and develop a plan to address advice from the panel. Dr. Bindman indicated that plans were underway to hold the next TEP meeting in September or October of this year. That meeting is expected to be a webinar and the topics will include more detail on the image quality sub-study as well as plans for the beta testing component of the project. A UC team member will be following up with TEP members for their availability. Finally, TEP members were reminded of optional honorarium and how to submit paperwork to receive the funds.

12:00 PM **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)

PURCHASE ORDERS

2

PO FAX

PO EMAIL

Select **ONE** option below:

PAYMENT TERMS		DISCOUNT PAYMENT TERMS	REQUIREMENTS
☐ N30	**OR**	☐ 2%10,N30	Payment by ACH **AND** electronic invoicing
☐ N45	**OR**	☐ 1%20,N45	Payment by ACH **OR** electronic invoicing
☐ N60	**OR**	☐ 1%20,N60	None
☐ IMMEDIATE			Payment by Virtual Card/Payment Plus

Refer to the Guide on page 2 for electronic invoicing registration

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

UCSF CONTACT PHONE

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. **PURCHASE ORDERS** – provide a fax number and/or email address for Purchase Order delivery and select only ONE of the seven payment terms options.

   PAYMENT TERMS:
   - N30 – payment is generated 30 days from invoice date
   - N45 – payment is generated 45 days from invoice date
   - N60 – payment is generated 60 days from invoice date
   - Immediate – payment is generated 1 business day after the invoice is processed and approved
   - 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
   - 1%20,N45 – a 1% discount is taken if the invoice is paid within 20 days of the invoice received date; otherwise, invoice is paid in full 45 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

   PAYMENT METHODS:
   - ACH – payment by electronic funds transfer. A business bank account is required.
   - Virtual Card/Payment Plus – payment via a one-time use virtual credit card number issued by US Bank. Once an invoice is processed, US Bank will provide the credit card information necessary to access and process the payment. Merchant interchange fees apply. Supplier information will be forwarded to US Bank to facilitate registration and payment notification.
   - Paper Check

   ELECTRONIC INVOICE SUBMISSION METHODS:
   - Transcepta – a third party service provider that handles supplier electronic invoice submissions for UCSF. Register at: http://connect.transcepta.com/ucsf
   - UCSF BearBuy Supplier Portal – an alternate method to submit invoices electronically. Register at: https://solutions.sciquest.com/apps/Router/SupplierLogin?CustOrg=UCSF

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, email address, and phone number.

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