

## **CT Dose Collaboratory**

### **Study Protocol**

A Randomized Trial to Evaluate a Simple Audit and a Multicomponent Intervention to  
Standardize Radiation Doses for CT

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#### **Study PI**

Rebecca Smith-Bindman, MD

Professor of Radiology, Epidemiology & Biostatistics

Health Policy, Obstetrics, Gynecology, and Reproductive Medicine

University of California, San Francisco

350 Parnassus Avenue Suite 307C

San Francisco, CA 94122

Phone: (415) 353-4946

Fax: (415) 353-2790

[Rebecca.Smith-Bindman@ucsf.edu](mailto:Rebecca.Smith-Bindman@ucsf.edu)

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## **A. Protocol Abstract**

The proposed project is a multi-site collaboration focused on implementing improved standards for conducting computed tomography (CT) with respect to the doses used to obtain these examinations; studying strategies to implement these standards across diverse healthcare facilities using a cluster randomized, stepped-wedge design; and then more broadly disseminating the strategies based on what was learned in the implementation trial; and conducting an observational study of dissemination during years 4-5. The broad goal of this work is to improve the safety of CT by lowering the doses to which patients are exposed and thus reduce the number of cancers that result from these exposures. This project is focused on determining the best approaches to accomplish this. We will study the change process itself as it varies across different types of healthcare facilities with varying organizational structures to understand the best strategies to adapt our interventions based on context and other factors to improve its chances of success. This project will be conducted in partnership with diverse healthcare delivery institutions in the U.S., Asia, and Europe. All participating institutions have: Radimetrics installed, a Bayer Health software product for radiation dose monitoring; identified a site leader who is an institutional champion for change; and demonstrated an organizational commitment to dose optimization.

## **B. Background and Significance**

Despite how frequently CT is used (75 million CT examinations are conducted annually in the U.S.) and the high doses of radiation it delivers (up to 500 times higher than a chest x-ray), there are few standards for the conduct of CT examinations. This has resulted in excessive variation in the doses that patients receive when they undergo CT, and the routine use of doses higher than needed for medical diagnoses – doses associated with an increased risk of cancer. Several recent studies have confirmed an elevated risk of cancer associated with exposure to CT.<sup>1,2</sup> Although there has been increasing attention paid to CT use from consumer advocates, medical groups, quality organizations, and state and national legislators around improving the safety of medical imaging, little progress has been made: our recent research documents that radiation

doses remain higher than needed for diagnosis.<sup>3,4</sup> The manufacturers are developing lower dose devices, but these will not replace existing machines for decades or longer as over 10,000 machines are currently in operation. Thus, current machines need to be made safer.

No U.S. professional or governmental organization is responsible for collecting, monitoring, or reporting patient dose information for CT, and no comprehensive standards or guidelines cover conduct of CT studies. The general principle is that doses should be "as low as reasonably achievable,"<sup>43</sup> but no guidelines define reasonable or achievable. In the absence of explicit guidelines, practice variation potentially introduces unnecessary harm from excessive radiation and a practice climate in which almost any dose is acceptable. The FDA issued a national advisory for hospitals to carefully check their CT protocols<sup>40</sup> after patients received brain radiation doses approximately 1000-times higher than the average dose for brain CT. One hospital reported "intentionally" using high doses to get clearer images,<sup>41</sup> highlighting the lack of standards. The absence of guidelines on radiation dosing in the U.S. contrasts with quality assurance programs in Europe that have been in place for more than a decade.<sup>44</sup> European programs use diagnostic reference levels<sup>45-48</sup> that help facilities identify when their average doses are too high. These programs define upper limits for radiation dose that should be exceeded only for justified reasons documented in medical records. The UK has had CT mandates for more than 15 years, with extensive radiation dose monitoring at institutional, local, and national levels. However, concrete benchmarks have been created even in the UK for only a few routine imaging protocols and have not been updated since 2003, generating interest in standardizing and optimizing CT radiation doses across a range of indications and protocols. This study will draw on the UK experience and collect data on a large number of CT indications with a goal of creating benchmarks covering a larger proportion of protocols and practices.

Diverse organizations agree that patients must receive the lowest radiation dose possible to achieve the necessary medical benefit from CT.<sup>42</sup> Organizations such as the American College of Radiology,<sup>49</sup> the Institute of Medicine (IOM),<sup>20,50</sup> the Center for Medicare and Medicaid Services,<sup>51, 39,40</sup> the Joint Commission on Health Care Accreditation,<sup>52</sup> U.S. Congress,<sup>53,54</sup> and the Image Gently social marketing campaign for children<sup>55</sup> all stress safer CT practices. Recognizing

the potential risks of dose variation and radiation overdosing, the FDA plans to increase oversight of CT<sup>39,40</sup> and called for institutions and professional societies to create diagnostic reference levels that, if exceeded, would trigger investigative action and dose-reduction strategies.<sup>39</sup> Achieving safer CT also requires more quality information on current radiation exposures—data that we collect in a related, PCORI sponsored project. The next step is generating, applying, and evaluating validated dose-lowering and optimizing strategies across diverse healthcare institutions—the goal of this proposal.

Concrete data are needed on successful strategies to lower and optimize CT radiation doses. This will require balancing the importance of CT to clinical care with the risk of radiation injury from medical errors and the potential of elevated cancer risk even when protocols are followed. The first step is lowering CT doses when feasible. Evidence suggests average CT doses could be reduced by 50% or more without reducing diagnostic accuracy.<sup>56</sup> In this project, we will leverage the expertise of nationally respected scientists and radiation physicists to assess and reduce CT doses at facilities and standardize and optimize protocols across participating organizations. We will compare different strategies in a clustered randomized controlled trial (RCT) of implementation using a stepped-wedge design and work closely with our partner organizations to study and implement lasting and sustainable changes to improve CT safety.

## **C. Study Objectives**

### **C.1 Primary Objective:**

- Using a stepped-wedge cluster randomized controlled trial (RCT), evaluate the effects of a simple audit and of a tailored multicomponent intervention on lowering facility-level radiation doses from diagnostic CT imaging, relative to baseline, for head, chest, and abdomen/pelvis CT. We will randomize facilities based on time zone and independence of facilities within their associated healthcare organizations.
  - Primary outcome: Effective dose

## **C.2 Secondary Objectives:**

- (1) Evaluate the effects of a simple audit and a multicomponent intervention on lowering facility-level radiation doses using additional dose metrics, including CTDIvol (Computed Tomography Volumetric Dose Index) and DLP (Dose Length Product).
  - Outcomes: CTDIvol, DLP
- (2) Evaluate the delayed and/or longer-term effects of the two interventions on effective dose, CTDIvol and DLP.
- (3) Identify facilitators and barriers (assessed through surveys of participating facilities) associated with successful and failed implementation of dose optimization (i.e., improvements in doses after each intervention). This will be assessed following completion of the simple audit, multicomponent intervention, and one year following the multicomponent intervention.
  - Outcomes: Effective dose

## **D. Research Design and Methods**

### **D.1 Study Design**

We will conduct a pragmatic stratified randomized controlled trial (RCT) of two interventions using a two-phase stepped-wedge design. We will first evaluate the effect of a single-component intervention (simple audit). Second, we will evaluate the effect of a multicomponent intervention (audit + tailored recommendations + quality improvement collaborative calls combined with Change/Implementation Team support) with considerable external support and a close relationship with the University of California leadership team, but local flexibility. We will also assess whether participation in an in-person meeting (where education in quality improvement is emphasized) enhances the impact of the audit and/or the multicomponent intervention. We will determine if the simple, inexpensive audit and feedback approach is as effective as the intensive, multicomponent intervention at reducing facility-level mean radiation dose or the percentage of examinations with doses above the benchmark compared to baseline. Since audit with feedback is expected to be only weakly effective, we will implement it first. The

second intervention will give tailored feedback on needed changes plus guidance using quality improvement methods that facilitate organizational change.

A total of 116 facilities from one of 20 parent institutions will participate in the trial. The individual facilities will be the unit of comparison in the trial. However, in order to ensure that facilities that are highly integrated with each other (for example, share staff and management) do not get randomized to separate groups (which would be impractical to implement and lead to complete cross over) we assessed the relative independence of each facility so that we can keep interdependent facilities in the same randomized units (which in some cases will include more than one facility). Thus, the unit of comparison is the individual facility, whereas the unit of randomization is the facility cluster (see G below). This resulted in 84 units (facility clusters) to be randomized.

The 84 facility clusters will be randomly divided into three tracks, which will undergo the audit and multicomponent intervention in a staggered fashion. In addition to this, one of the three randomization tracks will be invited to participate in the in-person meeting (where focused education on quality improvement and strategies for dose optimization will be provided) to coincide with provision of the simple audit, and one randomization track will be invited to the in-person meeting to coincide with the multicomponent intervention. By offering participation in the in-person meeting at different times in relation to the audit and multicomponent intervention, we will assess whether the in-person meeting enhances the impact of each intervention on outcomes.

For our secondary outcomes focused on assessing factors associated with optimization in dose, a mixed-methods approach with interviews and surveys will determine factors and strategies associated with successful implementation. Surveys will combine material from existing validated surveys (such as the Change Process Capability Questionnaire (CPCQ)) adapted to radiology-specific quality improvement to measure organizational priority and readiness for change, and from the Physician Practice Connections–Readiness Survey (PPC-RS) to measure implementation changes over time.

## **E. Setting and Participating Institutions**

The study will be conducted with healthcare institutions that already utilize Radimetrics software, and that contribute data to the UCSF Radiation Dose Registry (UCSF-RDR, see F below). Purchase of Radimetrics demonstrates our collaborators' commitment to assessing and optimizing CT doses, and facilitates the standardized collection of radiation dose data across diverse institutions. Any healthcare institution that uses Radimetrics, and is able to electronically transfer data to the UCSF-RDR using this software (some institutional firewalls preclude doing this), is eligible for inclusion in the study. All Radimetrics customers were invited to participate in the project through an email invitation that was sent broadly to each customer. All customers interested in participating and who could complete the logistical requirements (establish data connections, complete data use agreements, complete institutional review board approvals, create a local quality improvement team and agree to complete the study aims) were invited to participate in the trial.

The healthcare institutions included below are participating in the study. Some of the institutions listed below include a single physical facility, whereas others have many associated facilities. While we encouraged all facilities associated within each healthcare institution that contribute a minimum number of examinations (120 scans within a three month period) to participate, a healthcare institution could participate even if only some of its facilities wanted or were qualified to participate. The included institutions provide geographic, socioeconomic, age, and racial/ethnic diversity of patients; contain representation from the major manufacturers and types of equipment used and diversity in delivery models. Healthcare institutions outside the U.S. are included, as CT efforts around dose optimization have been going on for far longer in Europe, and doses may be different from those in the U.S. The institutions noted with an asterisk are located outside the U.S.



	<b>Institution</b>	<b>Abbreviation</b>	<b>Number of Facilities</b>
(*)	University Hospital of Basel	BAS	2
	Center for Diagnostic Imaging	CDI	41
	Community Health Network	CHN	8
	Children’s Mercy Hospitals and Clinics	CMH	2
	City of Hope	COH	1
	Einstein Medical Center	EMC	4
(*)	University of Duisburg-Essen	ESN	4
	East Texas Medical Center	ETMC	9
	Emory Health System	EU	11
	Henry Ford Health System	HFH	9
	Huntsville Hospital	HH	5
	Miami Children’s Hospital	MCH	1
	Mount Sinai Health System	MSH	1
	Maastricht University Medical Center	MUMC	1
(*)	Olive View – UCLA Medical Center	OVMC	1
	John Radcliffe Hospital, National Health Services	OXF	3
	San Francisco Veteran’s Administration Health Care System	SFVA	1
	St. Joseph Health System	SJHS	7
(*)	St. Luke’s International Hospital	SLIH	3
	University of Virginia Health System	UVA	2

## **F. UCSF Radiation Dose Registry**

A secure central CT radiation dose registry, the UCSF Radiation Dose Registry (UCSF-RDR), has been created at UCSF to pool data across the collaborating institutions and facilities. This registry was funded by a separate research contract from the Patient Centered Outcomes Research Institute (PCORI). Each institution or facility pools data from consecutive CT scans performed at their institution or facility on their local server, and these data are transferred and pooled at UCSF. All facilities that contribute to the registry currently use Radimetrics - a web-based, medical imaging, radiation dose-monitoring software product owned by Bayer that quantifies the radiation delivered in CT scans. Radimetrics links to medical image archiving and communication systems to collect examination information and CT dose data delivered. Data come from the output of individual scanners using DICOM (Digital Imaging and Communications in Medicine) headers and structured reports on scanners when available, or optical character recognition if necessary. Data are collected for each radiating event (series). Monte Carlo simulation estimates absorbed and effective doses. The software also collects the image for calculating size-specific doses. These details allow valid, nuanced, and readily understandable metrics to be assembled for radiation dose within each facility.

The radiation data stored within the CT examination file (stored in DICOM data) are pooled directly from the machines where the CT scans are performed, or from the PACS (Picture Archiving and Communication Systems) where the scans are reviewed and stored on the local Radimetrics instance. The data are stripped of identifiers and in real time are then submitted to the UCSF-RDR. All identifying information, other than study date and time, is stripped or obfuscated, prior to submission to the registry. The data now stored in the registry allow us to access facility-specific radiation dose data on all consecutive CT examinations conducted at each of the collaborating facilities.

## **G. Institutional and Facility Surveys**

Several surveys will be administered to each facility to understand the organizational factors that may influence their dependence on other facilities within

their overall umbrella healthcare institution and thus how they will be randomized in the trial, and to assess institutional factors and facility factors that might influence dose indices and implementation of dose optimization following audits.

We will administer two types of surveys to capture facility-level characteristics:

1) structural and organizational aspects of each facility's CT imaging work flow (organizational survey)

2) cultural and behavioral aspects of each facility's approach to CT imaging, especially as regards patient safety, quality improvement, power and decision-making, etc. (implementation survey)

We administered the organizational survey prior to randomizing facilities. This survey collected information on structural and organizational patterns at our various facilities, including their size and type, numbers of personnel of different types (e.g. CT technologists, physicists, radiologists, residents, administrators, etc.), number of CT scanners, number of CT imaging protocols, how often protocols are reviewed, and who has the authority to change them. The organizational survey includes a combination of quantitative and qualitative questions.

We will administer our implementation (or "cultural") survey four times over the course of the study. This survey will collect information on imaging and operational practice patterns that could affect dose levels and abilities or willingness to change doses. The implementation survey includes a series of likert-scale questions that ask respondents for their opinions about practice patterns at their facility. Collectively we anticipate that trends across a number of conceptual "domains" could have correlational and predictive power related to CT dose.

We will use the surveys to understand and measure facility-level characteristics as they pertain to CT imaging. The second primary purpose of the surveys is to assess how facility-level characteristics correlate with CT dose levels at baseline. For example, are their systematic relationships between the number of CT imaging protocols at a facility and their CT dose levels.

The third primary purpose of the surveys is to assess how facility-level characteristics predict changes in CT dose levels throughout our study. For example, we might hypothesize that facilities with a strong "culture" of continuous quality improvement or CT protocol reassessment could experience greater reductions in CT dose in response to the interventional components of our study.

### **G.1 Organizational Survey**

We are including 116 individual facilities in the project. While several individual facilities might be owned or run by a single umbrella organization (healthcare institution), they all could function similarly (collectively) or differently (independently), or two could function jointly and a third separately.

The primary unit of comparison will be the individual facility. The primary unit for randomization will be the facility cluster, referring to a group of facilities within a healthcare institution that have a high degree of integration so that separate randomization would not be possible without contamination. We identified 84 facility clusters.

#### Determining facility clustering:

Highly integrated facilities within a single institution (e.g. with technologists, radiologists, and physicists moving freely between facilities/hospitals and sharing process for CT) will be considered a single facility "cluster" for the purpose of determining our randomization units. On the other hand, independently functioning facilities within a single system will be treated as separate facility clusters for the purpose of randomization.

We determined the independence of the facilities using an organizational survey and a derived CT facility independence index. The organizational survey highlights important features at each healthcare institution that we anticipate could influence how radiation doses relate to CT practices. We surveyed parent institutions and their component facilities, asking questions designed to gauge how much they functioned independently from their parent system, and

whether they should be considered clustered with other facilities for the purpose randomization.

Organizational survey questions that we used to derive the CT facility independence index focused on the processes used to develop CT protocols, sharing radiology personnel, sharing best practices, and requiring external approval on protocols. Using a 7-point scale (scored from 0 to 6 points), facilities with a higher score were deemed to be more independent than facilities with a lower score. Facilities that scored 3 points or higher were considered independent (i.e. little sharing of process or staff, with significant internal decision making on protocols). When facilities were considered "dependent" (scoring lower than 3 points), they were grouped with the other facilities in their parent institution with which they identified the sharing of staff and practices, forming a facility cluster.

Facilities will be randomized in the trial by facility cluster (the group of facilities considered dependent on another). However, the primary unit of comparison to assess the impact of the interventions will be the individual facility. When reports are provided to each facility, they will be shown the doses at their own facility, their own doses in comparison to all other facilities that are part of their umbrella institution, and in comparison to other all other facilities in the trial.

## **G.2 Institutional and Facility Implementation Surveys and Interviews**

Since we are implementing the strategies in highly diverse environments, we will study institutional and facility factors associated with doses at baseline and change in dose after the different interventions. The goal is to understand the hospital environments and cultures that are conducive to adopting strategies to improve doses. We will assess the relationship between hospital characteristics (such as readiness for change, and hierarchical arrangement of how CT protocol decisions are made) and the likelihood of the interventions succeeding to lower and optimize doses.

Surveys and interviews will be conducted at each facility because decision-making, organizational culture, and details of how CT protocols are set can differ between facilities even if they share staff and processes. For example, we will survey facility and radiology leaders to understand personal priority for optimizing CT radiation doses, perceived value of audit reports, perceived barriers to improvement, and relevant quality improvement strategies in development or implementation. We will ask the radiology administrative leader about training of personnel performing CT scans and proportion done outside normal workdays. We will ask about their reasons for purchasing Radimetrics, its use thus far, whether it has met expectations, and its impact on CT practice. We also will ask questions about the culture of quality improvement. The survey will include questions from the CPCQ, PPC-RS.

When assessing the relationship between survey results and success/failure of implementation, each facility will be considered separately.

We will ask collaborators to engage organizational leaders at their facilities, including at a minimum a non-radiology health system leader, chief radiologist, lead CT technologist, radiation safety expert, and departmental administrator. Leaders will participate in surveys and ultimately help implement systems-based strategies (such as locking CT protocols).

We will use an adapted PPC-RS from the National Committee for Quality Assurance that focuses on practice system infrastructure. This will include assessment of factors involved in dose management (e.g., systematic review of individual case dosages, department policies to standardize dosage, radiologist and technologist agreements to follow policies, processes to address staff who do not achieve dosage improvements, staff and patient education about radiation risks, etc.). The follow up surveys will try to include, at minimum, a radiologist and technologist from each facility.

### **G.3. Administration of the Surveys**

Upon agreement to participate in the study, each healthcare facility was sent a link to complete an organization survey, and a request to provide a graphical depiction of

their organizational structure. Each facility within the institution was asked to complete a questionnaire to provide further context about their relationship with the larger parent institution and other facilities within their institution. The questionnaire focus on staff composition, protocol development and maintenance, making changes to protocols, level of practice sharing, and commitment to dose optimization. Upon completion, questionnaires were returned to study coordinators, who reviewed and followed up with facilities whenever further information or clarification was necessary.

Once the study begins, we will email invitations to complete a REDCap (Research Electronic Data Capture) survey in year 1, prior to the beginning of the RCT. The survey invitation will be sent to an authority in the radiology department: the site lead champion, radiologists and technologists at baseline. REDCap surveys will again be sent to each hospital periodically (after the simple audit and prior to the multicomponent intervention, and 4-6 months and then 12 months after the multicomponent intervention) to inquire whether the recommended CT improvements were implemented and/or remain in place. The radiologists and technologists will be invited to participate in our REDCap survey. We will offer incentives, in the form of raffle drawings for prizes, to those who complete the survey within the given time periods.

## **H. Study Population and Unit of Analysis**

CT doses will be measured at the examination (i.e., encounter) level. Because examinations from the same machine, facility, and institution are structurally nested (hence non-independent), we will use appropriate statistical techniques to account for this correlational structure.

### **H.1 Included Patients and CT Examinations**

We will include consecutive patients who undergo a diagnostic CT at a participating facility from November 2015 to December 2018. We will include CT scans of the head, chest, and

abdomen and pelvis. As an exploratory analysis, we will also evaluate combined chest/abdomen/pelvis (CAP) exams.

## **H.2 Excluded Patients and CT Examinations**

- Patients over the age of 99 years will be excluded.
- Musculoskeletal (i.e., spine and extremity) CT scans will be excluded because the methodology for assessing their doses is less developed, and organ doses and cancer risk are lower for these examinations.
- CT scans of combined areas (other than combined chest/abdomen/pelvis) will be excluded because of the complexity of estimating dose.
- CT scans conducted at external institutions and sent to the Picture Archiving and Communication System (PACS) systems of the participating facilities will be excluded because these do not reflect CT practices at participating facilities.
- CT scans performed to guide radiation therapy will be excluded
- CT combined with Positron Emission Tomography (PET-CT) scans will be excluded.
- CT scans used to guide procedures and biopsies will be excluded.

## **H.3 CT Examination / CT Encounter as the primary unit of dose assessment**

Data will be assembled from the UCSF-RDR for patient level variables and CT examination (more clearly conceptualized as an encounter) level variables. An encounter is a complete CT study, which can include imaging of more than one anatomic area and can also include several irradiating events (such as a scan with intravenous contrast and a scan without intravenous contrast). The unit of CT dose assessment will be the examination (encounter) and include all irradiating events that occurred as part of the examination. If a patient undergoes two or more scans as part of that examination (encounter) – for example a scan with contrast and a scan without contrast – the dose metrics will be combined and summed for that examination (encounter).



## **H.4 Survey and Interview Participants**

We will ask collaborators from each institution to identify individuals from each facility to participate in the surveys and interviews. We will ask the collaborators to engage organizational leaders at their facilities, including where possible a non-radiology health system leader, chief radiologist, radiologist, lead CT technologist, technologist, radiation safety expert, medical physicist and departmental administrator. Some of the participating facilities are very small (i.e. have only a single employee such as a radiology technologist), whereas others are large, and thus the number of available individuals varies. The individuals who participate in surveys will also ultimately help implement successful strategies (such as locking CT protocols).

## **I. Randomization**

The unit of randomization will be the facility cluster. Facilities will be randomly assigned to one of three tracks that determine the timing of when they receive the audits, in-person meeting, and multicomponent intervention. Randomization will be conducted using matching<sup>169,170</sup> and re-randomization<sup>171</sup> to ensure balance based on the following facility-level factors:

- 1) Total number of scans between December 1, 2015 and March 20, 2016. (measure of volume)
- 2) Total number of pediatric scans in the same time period.
- 3) Mean DLP of Abdomen, Chest, and Head scans in the same time period (to account for dose)
- 4) Proportion of Abdomen, Chest, and Head scans over benchmark (75th percentile of DLP) in the same time period.
- 5) Proportion of Abdominal Diameters that fall in the 1st-5th (quintile) size categories of overall population (to account for patient size)
- 6) Geographic location (Asia, Europe, West US, South US, Midwest US, Northeast US)
- 7) Time zone
- 8) A number of other facility characteristics based on self report including whether facility is:
  - A children's hospital
  - In the U.S.
  - Academic
  - A trauma center
  - Public / Private
  - Community hospital
  - Acute care facility
  - Tertiary referral hospital
  - Outpatient imaging facility

We will also apply these two additional conditions:

- 1) All facilities of the same "facility cluster" must be in the same track.
- 2) All facilities in a given track must be able to participate in phone calls at reasonable work hours, defined as 7 am – 5 pm local time. This means that some geographic locations cannot be in the same track.

A biostatistician not affiliated with UCSF, nor with other collaborators on this project, will perform the randomization.

## **J. Study Variables**

Data will be assembled via the UCSF-RDR for patient-level variables and CT examination-level variables and through surveys of each participating facility to assess facility - and institutional-level variables.

### **J.1 Patient-level Variables**

The patient-level variables of age and sex and anatomic area imaged will be extracted from the Radiology Information System (RIS) and PACS through the Radimetrics software and are available in the UCSF-RDR. A mid-scan diameter extracted from the CT image will be used as a surrogate for patient size and weight.

### **J.2 Examination/encounter-level Variables**

The specific protocol used for every imaging examination is recorded within the RIS and PACS and will be imported to the central server by Radimetrics. Anatomic area definitions will include head, neck, chest, abdomen/pelvis, combined chest/abdomen/pelvis (CAP), spine (cervical, thoracic, and lumbar), and extremity (although only some will be used in this study as described above). We will also develop and validate approaches for defining these anatomic areas using other collected variables, such as study description and protocol name. Setting (inpatient, outpatient, emergency department [ED]), time/day when examination was

conducted (time of day, day of week, and month), equipment (machine manufacturer, model and year), will be extracted from Radimetrics and used to assess as potential confounders.

### **J.3 CT Dose Metrics**

The radiation dose data will be assembled and stored for each radiation event. Radimetrics extracts direct measures of dose for each radiating event from the CT reports (CTDIvol and DLP) and calculates effective dose. Radiation dose indices will include effective dose, CTDIvol, and DLP. Our primary outcome measure will be effective dose. CTDIvol and DLP will be analyzed as secondary outcomes.

Assessing diagnostic accuracy is outside the scope of this project. However, we will ask radiologists on surveys about their satisfaction with image quality as part of the pre- and post-intervention interviews and surveys and will assess the association between satisfaction and dose.

### **J.4 Calculated Variables**

Dose indices will be assessed and presented graphically and in tabular format. They will be calculated prior to and following the simple audit report and the multicomponent intervention. The dose indices will be stratified by age (child, adult), anatomic area (head, chest, abdomen/pelvis, combined chest/abdomen/pelvis), and machine manufacturer and model, as well as geographically, e.g. by U.S. and non-U.S. location. Diagnostic reference levels (DRLs) will be created overall at baseline across all facilities using the interquartile range (IQR) and 75<sup>th</sup> percentile. The proportion of examinations above benchmarks will be calculated against fixed thresholds created during a single baseline period.

## **K. Study Endpoints and Planned Analyses**

### Endpoints:

The primary outcome is effective dose.

The Secondary outcomes include two other dose metrics, CTDIvol and DLP.

During each time period and within each anatomic area, we will assess the mean dose and the proportion of examinations above the baseline 75<sup>th</sup> percentile benchmarks (see above), for each facility. We will only assess doses in children if a facility has at least 12 examinations for at least one machine within at least one anatomic area during the audit period.

#### Planned analyses:

##### Primary Analysis

###### 1. Effective dose.

Time frame (see Section M for details):

Baseline 1: 9-12 months prior to simple audit;

Follow-up 1: 3-6 months following 4 weeks washout after simple audit;

Baseline 2: 2-6 months prior to multicomponent intervention;

Follow-up 2: 3-6 months following 2 weeks washout after multicomponent intervention;

Within each anatomic area, the mean effective dose and the proportion of CT scans with an effective dose over the benchmark during the Follow-up period will be compared to doses during the Baseline period. The benchmark for each anatomic area is defined as the 75<sup>th</sup> percentile of the dose distribution during Baseline 1.

##### Secondary Analysis

###### 1. Volumetric Computed Tomography Dose Index (CTDIvol).

Time frame and comparisons same as for Effective dose described above

###### 2. Dose Length Product (DLP).

Time frame and comparisons same as for Effective dose described above

### 3. Delayed effects: Effective dose, CTDIvol, DLP

Time frame (see Section M for details):

Baseline 1: 9-12 months prior to simple audit;

Follow-up 1: 3-6 months following 4 weeks washout after simple audit;

Baseline 2: 2-6 months prior to multicomponent intervention;

Follow-up 2 : 3-6 months following 2 weeks washout after multicomponent intervention;

Follow-up 3 : 12-15 months after multicomponent intervention

Within each anatomic area, the mean effective dose and the proportion of CT scans with an effective dose over the benchmark during Follow-up period 3 will be compared to doses during the Baseline periods prior to each intervention and the Follow up periods after each intervention.

### 4. Facilitators and Barriers associated with Effective dose and successful and failed implementation of dose optimization

We will use a linear mixed model analyses of changes in dose, and we will use mixed-methods approaches to identify facility-level factors (assessed through surveys of participating facilities) associated with effective dose levels and facilitators and barriers associated with successful and failed implementation of dose optimization (i.e., improvements of doses during Follow-up periods 1, 2, and 3 relative to Baseline periods 1 and 2).

## **L. Study Arms (Tracks)**

The study will divide facility clusters into three separate tracks. Each facility will first receive the simple audit, followed later by the multicomponent intervention, and will be staggered as to when they begin each intervention. Two of the three randomized tracks will be invited to participate in an in-person meeting, which will be timed to coincide with the audit for one of

the tracks and to coincide with the multicomponent intervention for one of the tracks. The third track will serve as a control (i.e., no in-person meeting). This will permit assessing whether the in-person meeting enhances the impact of the audit and/or multicomponent intervention.

### **L.1 Audit**

Audits will be sent to each facility summarizing their own doses and comparing them to the other facilities in their randomized track. The audits will be stratified by anatomic area and age group (adult/child) using each of the identified dose metrics. Facilities will be provided dose metrics in comparison to other facilities in their facility cluster, the healthcare institution, and overall compared with other facilities in their track and in the entire study. The audits will summarize data from a time period prior to provision of the audits and multicomponent interventions.

Each audit report will compare the facility against other facilities within their institution and to the other facilities/institutions in the study. The comparison will be made based on mean as well as median radiation doses, and the proportion of examinations above the baseline 75<sup>th</sup> percentile of radiation dose. Results will be provided both unadjusted and adjusted for patient size (using mid scan diameter as a surrogate for patient size). The audit reports will include descriptive tables and figures showing protocol-specific measures of radiation dose, outcome metrics indicating how their radiation doses rank against other facilities, stratification of results by age and anatomic area and results by the machine make and model. The audits will also provide information on patients who received very high doses.

After facilities receive the initial audit report, there will be a four-week (“washout”) period where facilities will have time to make changes to their imaging processes. For example, facilities can hold staff meetings or make any changes that could lead to dose optimization prior to when we assess their doses the next time. Facility leads will be responsible for developing plans for using audit data for quality improvement with our targeted suggestions; for example, meeting with technologists to review protocols or modifying existing protocols for a particular

anatomical area. This phase will test whether complete, comparative data alone can effect changes in dose levels.

Audit reports will be sent to “facility lead champions” (as requested/noted by the site PI) and facilities will be encouraged to share the information broadly with other contributors to radiologic practices at their facility or institution.

## **L.2. Multicomponent Intervention**

The multicomponent intervention will, in addition to the audit reports, provide a more detailed, tailored, facility-specific feedback (more detailed audit report) that will match the information provided on the audits to workable interventions and actionable suggestions for lowering doses. For example, not only will high dose protocols be identified, but also facilities will be provided with guidance on technical parameters that they could alter to match the performance of the best performing facilities. Further, the multicomponent intervention will include an invitation to participate in quality improvement collaborative calls where facilities will meet via teleconference regularly (weekly over 8 weeks) to learn about quality improvement and share experiences and challenges with adopting the various practices that we are promoting. These regular meetings between a UCSF established Change Team and a hospital created Implementation Team will help guide the implementation of the key aspects of the intervention.

Facilities will receive recommendations targeted to performance, which will be sent to individuals, identified by the PI at each facility, but will ideally include facility leads, heads of radiology departments, and Implementation Team leaders. Recommendations will focus on specific, alterable, technical factors (e.g., scan length); specific protocols to use more or less frequently (e.g. multiphase protocols); protocol modifications based on cross-facility analyses, etc. Recommendations will be tailored to the facilities practices. The audit reports will be a starting point for discussions about strategies and techniques to improve CT dose levels.

### Change/Implementation Team meetings and Quality Improvement Collaboratives:

The University of California based Change Team includes physicists, lead technologists,

radiologists, an administrator with extensive experience in departmental change who will be the liaison to facilities, and a leader in implementation research who knows how to implement change. Our facility lead champions will assemble local Implementation Teams based on the facility structure (e.g., who makes decisions about protocols or monitors legal issues). Members of the Change Team will advise facility leads on the creation of the Implementation Team. Implementation Teams will use baseline audit results to convey the importance of CT quality improvements to a broad audience. Change Teams will work with Implementation Teams (within the context of the RCT) to standardize practice, for example by showing the impact of organizational changes, creating disincentives for deviation, and providing monthly call access to physicists, technologists, or radiologists who can guide improvements. We will also regularly consult with our partners (including chief physicians, radiologists, and technologists) to understand what does and does not work and why. Close engagement of health care delivery staff as full partners will help to overcome critical implementation barriers. Examples of barriers might include CT systems that are too old to generate doses comparable to newer machines; or facilities that have so many protocols for imaging a single area that technologists cannot use them all in an optimized way; or that radiologists insist on multiphase or multi-sequence CT protocols without appreciating that those protocols are no longer considered state-of-the-art or understanding their impact on patient dose. These challenges each require different solutions and engagement of different individuals. Some facilities may be more resistant to change than others. We anticipate that comparative performance data combined with group assessment of the most effective strategies will be the strongest tools for local champions to encourage change. Thus, we will work with facility lead champions to collect and present appropriate dose metric data that will encourage action by senior hospital leadership.

Many of the facilities do not have experience in conducting quality improvement activities. We have engaged the Institute for Clinical Systems Improvement (ICSI) to provide background education on quality improvement to help our facilities create appropriate expectations and change team members.

Facilities receiving the multicomponent intervention will meet via WebEx online conferencing



with other groups in their randomization cluster to share experiences (Quality Improvement calls) weekly. Change and Intervention Teams will participate in these calls. Each meeting will include physicists and radiologists who will answer technical questions and provide specific examples and strategies for effective dose management. Topics will include change strategies such as development and application of standardized procedures and protocols. Facilities will report concerns and barriers for group problem solving and guidance. Leaders in implementation sciences will provide concrete suggestions for changing practice. Shared data from the groups in the cluster will allow the best performers to describe how they achieved goals and give low performers concrete steps toward more effective action. Collaborative implementation is an ideal strategy for pooling experience. Educational materials will be offered and encouraged in these collaborative meetings. During each WebEx conference, we will keep track of the number of participants from each facility who attend, the number of questions that are asked by each facility or comments that are made, and the sharing of specific cases as a way to score the relative engagement of individuals from each facility in the quality improvement collaboratives.

As with the audit intervention, the facilities will be responsible for determining how to use the provided advice to improve performance.

## **M. Timeline and Timeline of Assessments**

The facilities will be divided into three tracks (i.e. randomization groups), each containing approximately 37 facility clusters. Most facility clusters include a single facility, while some clusters will include several facilities that are integrated in how they perform CT. Tracks will receive interventions in a sequentially staggered fashion, with their order determined randomly (see below).

### **M.1. Graph of timeline (also included with attachments)**



In order to assess whether improvements in dose occur at or persist over a longer time period; we will compare doses 12-15 months after completion of the multicomponent intervention with baseline doses and doses after the simple audit and the multicomponent interventions.

## **N. Statistical Analysis**

### **N.1 Quantitative Analyses**

For each trial phase, we will compare radiation doses from a baseline period before that intervention starts with doses in a post intervention period, separated by a “washout” period during which facilities should have adequate time to a) absorb the feedback and messages from the intervention, and b) implement changes in scanning practices if and how they so choose.

The pre-audit/intervention and post-audit/intervention periods will vary in length of time according to: a) which type of intervention (simple or multicomponent), and b) which track (randomization group) the facilities are in. Please see Section M for details.

The primary outcome measure will be effective dose. Secondary outcomes will be CTDIvol and DLP. For each anatomic area studied and each dose metric, we will compare the mean dose and the percentage of CT examinations with dose levels above the baseline 75<sup>th</sup> percentile benchmark threshold. Dose metrics may be transformed (e.g., by applying the natural logarithm) prior to modeling the mean dose if necessary to meet linear model assumptions.

We will model mean doses (possibly transformed) using hierarchical linear regression and will model the percentage of doses above the threshold using hierarchical logistic regression, controlling for underlying time trends and for facility-level and patient-level covariates that could influence dose (e.g., facility size, patient age or sex, etc.). We will include random effects for machine, facility, and facility cluster to account for correlation among scans performed on the same machine, within the same facility, and/or within the same cluster of facilities. We will evaluate the effect of audit vs. no feedback on CT dose by testing whether dose levels decrease in the follow-up period after the audit vs. during the baseline period prior to the audit. We will use a similar approach for the multicomponent intervention but will include all periods in the

model, comparing post intervention to both original (pre-simple audit/intervention) baseline and new (pre-multicomponent audit/intervention) baseline after completion of the final collaborative calls of the multicomponent audit/intervention. We will use a similar approach for assessing delayed and/or longer-term changes by analyzing doses 12-15 months following the multicomponent intervention in comparison to doses in the earlier periods.

We will also compare the multicomponent intervention and simple audit effects to determine which is more effective. We will also compare how participation in the in-person meeting impacts the effects of the simple audit and multicomponent intervention by including interactions with an effect of in-person meeting and the particular intervention. Each facility will act as its own control, and we will control for underlying time trends, which are estimable because of the stepped-wedge design.

## N.2 Mixed methods qualitative and quantitative analyses

The organizational survey includes a combination of quantitative and qualitative questions. We will examine these questions using standard descriptive statistics. We will assess the relationship between facility-level characteristics as assessed through the surveys and dose levels (baselines as well as changes in dose), using responses to our facility surveys using mixed methods approaches. In order to make the analysis more robust we will construct domains using the survey questions. The first step in constructing these "domains" is to use exploratory factor analysis (EFA) to identify groups of questions that simultaneously correlate highly with each other but not to the point of redundancy. We will then combine the questions within each of these groups, or domains, to form composite domain scores (i.e. measures) that will become continuous predictive variables, combined with structural facility-level variables from the first survey and with patient-level variables (e.g. age, size, etc.) for a series of linear models that assess how these facility- and patient-level measures relate to: a) baseline dose levels and b) changes in dose levels after the interventions in our study.

Our final statistical models of dose and changes in dose will use primary (facility-level, scanner-level, and patient-level) analytical variables derived directly from our Radimetrics database, in

combination with facility-level characteristics derived from our two surveys. We will use the same hierarchical modeling approaches as described above to estimate the relationships between our predictors (facility-level, scanner-level, patient-level, and various interventions) and dose measures.

## **O. Sample Size**

Statistical power depends on between-class coefficient of variation (standard deviation between facilities divided by average prevalence per facility). Based on prior research, we expect these values to vary between 0.4 and 1.1, depending on anatomical region and response metric. With 84 unique clusters, reflecting 116 facilities, to be randomized and at least 27-28 scans per facility for each anatomical region and age group (adult/children), in each measurement period, we will have an 80% power to detect a change of 5 percentage points (from 25% to 20%) in percentage of examinations with doses above the benchmark after the intervention versus baseline, using a two-sided significance level of 5%. The exceptions to this are children's head scans, which only require 15 scans per facility in each measurement period to achieve the same power with 84 clusters. We expect each facility to contribute, on average, at least 60 scans per day. With each measurement period being at least 1 month it is very likely 80% power will be surpassed. The effect of multicomponent intervention is expected to be greater than the effect of auditing; thus, the same sample size would also be sufficient in detecting the significance of multicomponent intervention.

## **P. Ethical Considerations and DSMB**

The primary ethical concern for the project relates to loss of confidentiality for the participating facilities and institutions. We will do everything we can to maintain the confidentiality of the facilities. Through the project we may identify individuals who have received exceedingly high radiation exposures. These will be reviewed with the Data Safety Monitoring Board (DSMB) to determine what course of action, if any, is necessary. We will be interviewing staff at many of our facilities. Potentially they might disclose views that could be perceived as negative by their

peers or supervisors. All of the survey results will be kept confidential and will not be reported back to the individual facilities so that the results cannot be linked to an individual or even to a facility or institution.

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## **R. APPENDICES**

### **R.1. Variable List - Survey**

#### **Facility-Level Variables**

##### Organization Location

Geographic location (U.S., non U.S.; Geographic region of the U.S.)

Population size of community where facility located

##### Organization Structure

Services provided (hospital/inpatient, emergency, ambulatory, other)

##### Type of Facility

Academic/Teaching Hospital

Trauma Center (Level 1, 2, or 3)

Public Hospital

Community Hospital

Private Hospital

Acute Care Facility

Primary Cancer Facility

Pediatric Hospital

Tertiary Referral Hospital

Outpatient Imaging Facility

##### Payer mix

Racial and ethnic breakdown of patients

##### Staffing and Capacity

Number of radiologists

Number of technologists

Number of CT machines

Number of medical physicists

##### CT Protocols (instructions)

Number by anatomic area



Who establishes them, who can modify them

Manufacturer (protocols pre-set on machines)

Organizational leadership

Medical Physicist (one for the org.)

Medical Physicist (at the particular hospital)

Radiology site

Lead radiologists

Any individual radiologists

Head Technologist

Technologist performing exams

Other

Are protocols locked

How often are protocols reviewed and updated

Facility Practice Sharing

Activities focused on optimization

Status of ongoing efforts on optimization

## **R.2. Variable List – Dose Registry Variables**

### **Patient-Level Variables**

Sex

Age

Size (mid scan diameter)

Indication for imaging (derived)

### **CT examination-level variables (each examination/encounter may include 1 or more radiating events/ imaging acquisitions)**

Time of examination (date, day of the week, time of the day)

Machine (make, model)

Study description

Protocol name

Scan region(s):

Dose parameters of each imaging acquisition

Average mAs

Average kVp

Scan length

Pitch

Collimation

Scan thickness

CTDIvol for each imaging acquisition

DLP for each imaging acquisition

Effective Dose for each imaging acquisition

CTDIvol (average, weighted by scan length) for each examination

DLP (sum) for each examination

Effective Dose (sum) for each examination

**R.3 Parental Organizational Survey (pdf attached)**

**R.4 Sublevel Organizational Survey (pdf attached)**

**R.5 Implementation Survey (pdf attached)**

**R.6 Timeline (pdf attached)**