

TEP packet includes

Agenda, including location of meeting and times of discussion

Contact Information for UCSF Project team

Meeting Attendee Biographies

TEP Charter

COI blank template

1-page project summary (same that was sent with invite)

Slides of all planned presentations

Background reading

BMJ paper

UCSF Guest Reimbursement Document

All requests must be submitted within 45 days of occurrence

Receipts required for all expense requests

Reimbursement process can take 4 – 6 weeks

## Technical Expert Panel In-Person Meeting Agenda

*Tuesday, February 26, 2019*

Club Quarters Hotel, 839 17th St NW, Washington, DC

*Lafayette Room (2nd Floor)*

Zoom Meeting ID: 427 347 843

<https://ucsf.zoom.us/j/427347843>

8:00 AM	Breakfast, Coffee, & Tea	
8:30 AM	Call meeting to order	Dr. Helen Burstin
8:35 AM	Roll Call	led by Dr. Burstin
8:40 AM	Review and approve TEP Charter	
8:50 AM	Discussion of what constitutes a conflict	
8:55 AM	Introductions and statement of conflicts	
9:30 AM	CMS Merit-Based Incentive Payment System/Medicare Access and CHIP Reauthorization Act (MIPS/MACRA) and cooperative agreement overview	Dr. Reena Duseja
9:50 AM	Discussion	led by Dr. Burstin
10:00 AM	Break	
10:15 AM	NCI Presentation on radiation risk	Dr. Amy Berrington
10:35 AM	Discussion	led by Dr. Burstin
10:50 AM	Variation in CT Radiation Dose	Dr. Rebecca Smith-Bindman
11:10 AM	Discussion	led by Dr. Burstin
11:25 AM	Project overview	Dr. Andy Bindman
11:45 AM	Dose manipulation program/application	
12:00 PM	Lunch	
1:00 PM	Measuring and Quantifying Radiation Dose	Dr. Smith-Bindman
1:15 PM	Risk Adjustment	Dr. Patrick Romano
1:40 PM	Discussion	led by Dr. Burstin
2:30 PM	Measuring and Quantifying Image Quality	Dr. Smith-Bindman
2:45 PM	Discussion	led by Dr. Burstin
3:05 PM	Summary and next steps	Dr. Bindman
3:15 PM	Meeting Ends	

***Thank you for attending - we look forward to your continued collaboration.***

# DR CTQS

## Defining and Rewarding Computed Tomography Quality and Safety

### University of California San Francisco Project Team Contact

Naomi López-Solano  
Radiology Outcomes Research Laboratory  
Department of Radiology and Biomedical Imaging, Box 0628  
University of California, San Francisco  
533 Parnassus Ave., Suite U368E  
San Francisco, CA 94143

[naomi.lopez-solano@ucsf.edu](mailto:naomi.lopez-solano@ucsf.edu)

Ph: 415.502.1370 | Fax: 415.502.2663

### *Meeting Participant Biographies*

#### *CMS presenter*

#### **Reena Duseja, MD, MS**

Dr. Reena Duseja is the Chief Medical Officer of the Quality Measurement and Value-Based Incentives Group in the Centers for Clinical Standards and Quality at the Centers for Medicare and Medicaid Services. In this role, she oversees the measure development and analyses for a variety of CMS quality reporting and value-based purchasing programs. Previously, Dr. Duseja was the Acting Director of the Quality Measurement and Value-Based Incentives Group, and the Director of the Division of Quality Measurement. She is an emergency medicine physician and prior to coming to CMS, was an Associate Professor at the University of California, in San Francisco, in the Department of Emergency Medicine, where she led quality improvement activities in a large county hospital and was awarded funding by NIH to conduct studies related to improving patient care and value for the health system. As a Robert Wood Johnson Clinical Scholar at the University of Pennsylvania, her research focused on quality of care and unintended consequences of measurement. She received her Master's in Science in Health Economics at Wharton, Health Care Management and Economics, at the University of Pennsylvania.

### *TEP Members*

#### *TEP Chairperson*

#### **Helen Burstin, MD, MPH, MACP**

Helen Burstin, MD, MPH, MACP is the Executive Vice President and Chief Executive Officer of the Council of Medical Specialty Societies (CMSS) which represents 43-member specialty societies with collective membership

of almost 800,000 U.S. physician members. CMSS works to support and strengthen specialty societies and catalyzes improvement through convening, collaboration, collective voice and action across specialties. CMSS also provides a proactive platform to assess and address emerging and critical issues across specialty societies that influence the future of healthcare and the patients we serve. Dr. Burstin formerly served as Chief Scientific Officer of The National Quality Forum. Prior to joining NQF, Dr. Burstin was the Director of the Center for Primary Care, Prevention, and Clinical Partnerships at the Agency for Healthcare Research and Quality (AHRQ). Prior to joining AHRQ, Dr. Burstin was Director of Quality Measurement at Brigham and Women's Hospital and Assistant Professor at Harvard Medical School. Dr. Burstin is the author of more than 100 articles and book chapters on quality, safety and disparities. She is a graduate of the State University of New York at Upstate College of Medicine and the Harvard School of Public Health. She completed a residency in primary care internal medicine at Boston City Hospital and a fellowship in General Internal Medicine and Health Services Research at Brigham and Women's Hospital and Harvard Medical School. She is a Professorial Lecturer in the Department of Health Policy at George Washington University School of Public Health and a Clinical Associate Professor of Medicine at George Washington University.

#### **Mythreyi Bhargavan Chatfield, PhD**

Mythreyi Bhargavan Chatfield is the Executive Vice President of Quality and Safety at the American College of Radiology (ACR) where she oversees the accreditation programs, registries, Appropriateness Criteria, and other quality activities. A health economist by training, Dr. Chatfield has been at the ACR for close to 18 years and has held a variety of roles at the organization. Prior to stepping into her current role in 2015, Dr. Chatfield was Director of Registries at the ACR where she designed, analyzed, and reported on quality registries related to radiology. She was involved with the ACR Dose Index Registry since implementation, and worked on measures research papers related to that registry. She continues to work closely with the registries and measure development projects at ACR, providing input on data standards, measure testing, and implementation. In previous roles at the ACR, she conducted research on socioeconomic topics of relevance to radiology, including trends in imaging utilization and costs, variations in healthcare use, and racial and ethnic disparities in access to care.

#### **Niall Brennan, MPP**

Niall was appointed President and CEO of HCCI in June 2017. In this role, he is responsible for all aspects of the HCCI mission, promoting HCCI's research agenda, examining cost trends in U.S. healthcare, ensuring maximal use of the HCCI data resources to enable world class research and analysis by external users, leading HCCI's Medicare Qualified Entity business, and working with state and national policy makers to improve the health care system. He is a nationally recognized expert in health care policy, the use of health care data to enable and accelerate health system change, and data transparency. He has published widely in leading academic journals, including the Journal of the American Medical Association, the New England Journal of Medicine and Health Affairs. Prior to joining HCCI, Mr. Brennan was Chief Data Officer at the Centers for Medicare and Medicaid Services (CMS). He has also worked at the Brookings Institution, the Medicare Payment Advisory Commission, the Congressional Budget Office, the Urban Institute, and PriceWaterhouseCoopers. Mr. Brennan received his MPP from Georgetown University and his BA from University College Dublin, Ireland.

**Jay Bronner, MD**

Jay began his private practice with Radiology Imaging Consultants at Ingalls Memorial Hospital in Illinois and now has more than 25 years of practice experience. He earned his medical degree at Johns Hopkins Medical School, and then completed his internship in Medicine and Surgery at Northwestern Memorial Hospital and Weiss Memorial Hospital in Chicago. Jay returned to Johns Hopkins Hospital completing his Diagnostic Radiology Residency and became the Chief Resident in Radiology followed by Fellowships in Imaging and Neuroradiology both at John Hopkins. In addition to his medical education, Jay earned his MBA at Kellogg School of Management at Northwestern University. He has served as chairman of radiology services at nine hospitals with Radiology Imaging Consultants, CEO Team Radiology a division of Team Health and became CEO of Radiology Imaging Consultants in 2006. Jay joined Radiology Partners in 2013.

**Missy Danforth**

Missy Danforth is the Vice President of Health Care Ratings at The Leapfrog Group, a Washington, DC based, not-for-profit organization representing the nation's largest employers and purchasers of health benefits working to make great leaps forward in the safety, quality, and value of healthcare.

At Leapfrog, Ms. Danforth serves as member of Leapfrog's senior leadership team informing Leapfrog's strategic direction, engaging experts and stakeholders, and analyzing program results to engage purchasers and consumers and to drive safety and quality improvements. Ms. Danforth administers Leapfrog's various measurement and public reporting activities including the Leapfrog Hospital Survey, the Hospital Safety Grade, Leapfrog's Value-Based Purchasing Platform, Leapfrog's new Ambulatory Surgery Center Survey, and emerging ratings programs.

Ms. Danforth serves on the National Quality Forum's Patient Safety Steering Committee, the Consensus Standards Approval Committee (CSAC), and is the co-chair of the Diagnostic Quality Committee. She serves on the Policy Committee of the Society to Improve Diagnosis in Medicine and on the Steering Committee of the Coalition to Improve Diagnosis. She has served on several CMS Technical Expert Panels focused on patient harm. Ms. Danforth is also on the board of PCPI, a membership organization with the goal of bringing the voices of patients and clinicians together to advance the science and practice of measurement and improvement.

**Tricia Elliot, MBA, CPHQ**

Tricia Elliott, MBA, CPHQ is the Director of Quality Measurement at The Joint Commission. Ms. Elliott joined The Joint Commission after over twenty years of experience working in acute care healthcare settings as Executive Director of Service Excellence, Director of Process Improvement, Director of Decision Support, and several other analytic roles. In this position, she ensures the development of scientifically based performance measures that drive improved healthcare outcomes. Ms. Elliott currently directs projects focused on development of standardized electronic clinical quality measures and chart-based measures to support the accreditation and certification processes, and the data receipt process which ensures the application of data quality standards. With this diverse experience, Ms. Elliott is able to contribute comprehensive insight into the selection of measures for the quality improvement of care and safety for patients within healthcare systems.

**Jeph Herrin, PhD**

Jeph Herrin, PhD is Adjunct Assistant Professor in the Yale University School of Medicine and principal researcher for Flying Buttress Associates Ltd. He received his doctorate in mathematical physics from the University of Virginia and has more than 20 years experience as a methodologist in health services research. His primary expertise is in the areas of provider measurement, clustered design and analysis, shared decision making, and health disparities. He currently focuses his research efforts on: cluster randomized studies of interventions to improve the delivery of health care; identifying and mitigating disparities in health care and outcomes; and measuring the quality of care of clinicians, clinician groups, and hospitals.

**Hedvig Hricak M.D., Ph.D., Dr.h.c.**

Hedvig Hricak is Chair of the Department of Radiology at Memorial Sloan Kettering Cancer Center (MSK). She is also member of the Molecular Pharmacology Program of the Sloan Kettering Institute, Professor at the Gerstner Sloan Kettering Graduate School of Biomedical Sciences, and Professor of Radiology, Weill Medical College of Cornell University. She is a member of the National Academy of Medicine of the National Academy of Sciences, Engineering and Medicine (NAS) and holds honorary degrees from both Ludwig Maximilian University, Munich, Germany and University of Toulouse III, Paul Sabatier in Toulouse, France. In recognition of her distinguished work in radiology, she has received the gold medals of the International Society for Magnetic Resonance in Medicine, the Association of University Radiologists, the European Society of Radiology, the Asian Oceanian Society of Radiology, and the Radiological Society of North America. For her research accomplishments and advancement of oncologic imaging she has served on a number of NAS and National Institutes of Health (NIH) advisory boards and councils including the NIH Board of Scientific Counselors, the Scientific Advisory Board of the National Cancer Institute's Board of Scientific Advisors, the Nuclear and Radiation Studies Board of the NAS, and the Advisory Council of the National Institute of Biomedical Imaging and Bioengineering. Dr. Hricak is presently a member of the National Cancer Policy forum. She has served as chair, vice-chair on several NAM and NAS studies including Committee on State of the Science in Nuclear Medicine (Chair), Committee on Tracking Radiation Doses from Medical Diagnostic Procedures (Vice Chair) Committee on Research Directions in Human Biological Effects of Low Level Ionizing Radiation (Chair) and also was a member of the NAM Committee on Diagnostic Error in Medicine.

**Leonard Lichtenfeld, MD, MACP**

Dr. Lichtenfeld has been appointed interim Chief Medical and Scientific Officer for the American Cancer Society effective November 3, 2018. In that role he will have oversight responsibility for the Society's epidemiologic, behavioral and statistical research activities, external grants, medical affairs, and relevant constituent relationships.

He joined the Society in 2001 as a medical editor, and in 2002 assumed responsibility for managing the Society's newly created Cancer Control Science Department. In 2014, Dr. Lichtenfeld entered his current role as Deputy Chief Medical Officer where he has provided extensive support to a number of Society activities. A frequent spokesperson in the media on behalf of the American Cancer Society, Dr. Lichtenfeld has also since 2005 written a widely read blog focused on topics related to cancer. He is board certified in medical oncology and internal medicine and practiced for over 19 years. He has also been engaged in health care policy and numerous

medical professional organizations on a local, state, and national level for most of his professional career.

Dr. Lichtenfeld is a graduate of the University of Pennsylvania and Hahnemann Medical College (now Drexel University College of Medicine) in Philadelphia and completed his postgraduate training at Temple University Hospital, Johns Hopkins University School of Medicine and the National Cancer Institute. He is a member of Alpha Omega Alpha, the national honor medical society and has received several awards including designation as a Master in the American College of Physicians in recognition of his professional accomplishments.

#### **Matthew Nielsen, MD, MS**

Dr. Matthew Nielsen is a tenured associate professor of urology and adjunct associate professor of epidemiology and health policy & management at the University of North Carolina, where he also serves as Associate Director of the UNC Institute for Healthcare Quality Improvement. Alongside his clinical practice in urologic oncology, he has an active research program in clinical epidemiology and delivery system science, and serves as a clinical investigator in the Kaiser Permanente Center for Health Research. He has contributed in leadership roles to multiple national organizations, with the American College of Physicians' High Value Care Task Force and Performance Measurement Committee, the Physician Consortium for Performance Improvement (PCPI), and Chair of the American Urological Association Quality Improvement and Patient Safety Committee.

#### **Debra P. Ritzwoller, PhD**

Debra P. Ritzwoller, PhD, is an economist and Senior Investigator at the Institute for Health Research. Her research focuses on variation in cancer screening, treatment, outcomes and costs in community settings; the impact of insurance benefit design on patient cost-sharing; and cost estimation and cost-effectiveness. Dr. Ritzwoller completed her doctoral training in economics at the University of Colorado, Boulder. As a health economist and health services researcher, she has served as a Principal Investigator or Co-investigator on more than a dozen large, complex, multi-site studies, including several studies conducted within the Cancer Research Network (CRN). Currently, Dr. Ritzwoller is the Principal Investigator (MPI with Chyke Doubeni) of the Lung PROSPR Research Center (Lung-PRC). The long-term goal of this multi-site center grant is to identify critical gaps in the lung cancer screening process and to design innovative, multilevel interventions to reduce lung cancer mortality, particularly among underserved populations. Dr. Ritzwoller is an Adjunct Professor in the Department of Health Systems, Management, and Policy at the University of Colorado School of Public Health and a member of the National Cancer Institute (NCI) Cancer Care Delivery Research (CCDR) Steering Committee. In addition, Dr. Ritzwoller is the mother of a pediatric cancer survivor. Previously, she and her daughter served as Patient/Guardian Stakeholders for a PCORI funded radiation dose registry project (Smith-Bindman PI).

#### **Lewis G. Sandy, MD, FACP**

Lewis G. Sandy MD FACP is Executive Vice President, Clinical Advancement, at UnitedHealth Group (NYSE: UNH) a diversified health care company dedicated to helping people live healthier lives and helping make the health system work better for everyone. UnitedHealth Group offers a broad spectrum of products and services

through two distinct platforms: UnitedHealthcare, which provides health care coverage and benefits services; and Optum, which provides information and technology-enabled health services. At UnitedHealth Group (UHG) he focuses on clinical innovation, payment/delivery reform practice and policy, and physician/health professional collaboration. From 2003 to 2007, he served as EVP and Chief Medical Officer of UnitedHealthcare. From 1991 to 2003, he served as VP and EVP of The Robert Wood Johnson Foundation, the nation's largest philanthropy dedicated solely to health. Prior to this, he was a physician executive at the Harvard Community Health Plan in Boston, Massachusetts. An internist with over 20 years in practice, Sandy received his B.S. and M.D. degrees from the University of Michigan and an M.B.A. degree from Stanford University. He was a faculty member, fellow and RWJF Clinical Scholar at the University of California, San Francisco, and served his internship and residency at the Beth Israel Hospital in Boston. He serves on a number of Boards and Advisory Groups, including the Board of the National Quality Forum (NQF) and Panel of Health Advisors for the Congressional Budget Office (CBO). He is a senior fellow of the University of Minnesota School of Public Health, Department of Health Policy and Management.

#### **Suzanne Schrandt, JD**

Suz Schrandt, JD, is the Director of Patient Engagement at the Arthritis Foundation where she works to infuse the lived experience of patients into the Foundation's projects and strategies. Schrandt previously served as Deputy Director of Patient Engagement for Patient-Centered Outcomes Research Institute (PCORI), where she helped to launch the Institute's patient engagement infrastructure and several key efforts including the Engagement Rubric and Engagement Officers. Schrandt's patient engagement focus stems from her own rheumatological diagnosis at age 14. Since then, she has been involved with myriad patient and clinician education and advocacy initiatives. Schrandt's prior posts include roles in health and disability law and policy, genetic discrimination, and public health. Schrandt is current chair of the ISPOR North American Patient Representative Roundtable and a member of the FDA's inaugural Patient Engagement Advisory Committee.

#### **James Anthony (Tony) Seibert, PhD**

Tony Seibert, PhD, is a professor of radiology at University of California Davis Health in Sacramento, California. He is a medical physicist who has practiced at the medical center in diagnostic radiology for 36 years and has participated in the clinical quality control and quality assurance efforts for advanced diagnostic imaging equipment, including implementation, protocol development and dose assessment in computed tomography. Dr. Seibert has taught radiology residents and biomedical engineering graduate students throughout his career, and is an author of the widely used textbook, *The Essential Physics of Medical Imaging*. He contributes to research in the department and participates as co-investigator of the development and translation of a dedicated breast CT scanner at UC Davis. For the University of California DOSE (Dose Optimization and Standardization Endeavor) project, he interacted with Dr. Rebecca Smith-Bindman and the assembled research team to develop dose monitoring tools, to evaluate protocols, and to develop training and education sessions for safe use of CT. This was followed by providing consultant services for the UCSF PCORI and Partnership for DOSE projects. From a professional perspective, Dr. Seibert has served as President of the American Association of Physicists in Medicine (2010-2012) and the Society for Imaging Informatics in Medicine (2004-2006). He currently serves as a Governor of the American Board of Radiology.



**Arjun Venkatesh, MD, MBA, MHS**

Dr. Venkatesh is an Assistant Professor and Director of Performance Improvement in the Department of Emergency Medicine at Yale University. He is also Scientist at the Yale Center for Outcomes Research and Evaluation. He is funded by the NIH and AHRQ to study health system outcomes and efficiency, and he is supported by CMS as co-Principal Investigator of the Emergency Quality Network (E-QUAL) and for the development of the Overall Hospital Quality Star Ratings. He has published over 70 peer-reviewed papers and is senior editor of The Evidence book series. He is national leader within SAEM and ACEP and he serves on expert panels for the NQF, AHRQ and CMS.

**Todd C. Villines, MD, FACC, FAHA, FSCCT**

Dr. Todd C. Villines is a Professor of Medicine at the Uniformed Services University School of Medicine in Bethesda, Maryland. He is an actively practicing cardiologist on faculty at the Walter Reed National Military Medical Center where he has served for more than 5 years as the Cardiology Fellowship Program Director and for the past 10 years as the Director of Cardiovascular CT and Cardiovascular Research. Dr. Villines is the current Chair of the American College of Cardiology (ACC) Imaging Section and Leadership Council, the Immediate Past President of the Society of Cardiovascular CT (SCCT), and the Immediate Past Chair of the ACC Federal Cardiology Section and Leadership Council. He is the current Executive Editor of the Journal of Cardiovascular Computed Tomography.

**Kenneth C. Wang, MD, PhD**

Kenneth C. Wang, MD, PhD is the MRI section chief at the Baltimore VA Medical Center, and an adjunct assistant professor of diagnostic radiology at the University of Maryland School of Medicine. He is a member of the Radiological Society of North America (RSNA) Radiology Informatics Committee, where he serves as the chairman of the RadLex Steering Committee, as well as the liaison to the RSNA 3D Printing Special Interest Group. Dr. Wang earned his BS, MS and PhD degrees in electrical engineering from Stanford University, and his medical degree from the University of California, San Francisco. He completed his radiology residency and a musculoskeletal radiology fellowship at Johns Hopkins Hospital, and an informatics fellowship at the University of Maryland. His research interests include radiologic applications of semantic computation, shoulder and ankle imaging, 3D printing and MR neurography.

*Ex officio federal representatives for the TEP*

**Amy Berrington, DPhil**

Dr. Amy Berrington is the Branch Chief and Senior Investigator in the Radiation Epidemiology Branch at NCI. She is an internationally recognized expert in the potential cancer risks from medical radiation exposures. Dr Berrington is co-PI of the UK Pediatric CT scans cohort, which was the first epidemiological study to suggest a

direct link between CT scans and subsequent cancer risk. She currently also leads studies on the risk of second cancer after proton therapy and other emerging radiotherapy techniques. The goal of her research program is to quantify the potential cancer risks to enable an assessment of the risks and benefits of these medical exposures. Dr Berrington is currently a member of the NAS Nuclear and Radiation Studies Board and has served on many national and international radiation committees. Originally trained in mathematics/statistics she has a DPhil in Cancer Epidemiology from Oxford University. Before joining NCI in 2008 she held faculty positions at Oxford and then Johns Hopkins University.

### **Mary C. White, ScD**

Mary C. White, ScD, is Chief of the Epidemiology and Applied Research Branch in the Division of Cancer Prevention and Control at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia. For nearly three decades, Dr. White has led the development, implementation, and translation of population-based health research at CDC. She has published and lectured widely on topics related to the control of asthma, cancer, and other chronic diseases, the risks associated with exposure to air pollution and hazardous substances, and the interpretation of scientific evidence for public health. In her current position, Dr. White leads a program of applied research and science dissemination to support CDC programs and partners and advance national priorities in cancer prevention and control. She has helped to expand the agency's activities in primary cancer prevention through a transdisciplinary initiative to explore opportunities for cancer prevention across the lifespan.

### ***UCSF Project Team***

#### **Rebecca Smith-Bindman, MD**

Rebecca Smith-Bindman is Professor of Radiology, Epidemiology and Biostatistics, Obstetrics, Gynecology and Reproductive Medicine, and Health Policy at University of California San Francisco School of Medicine. She graduated from Princeton University with a degree in Engineering, attended UCSF Medical School, and completed her Radiology, Epidemiology and Biostatistics training at UCSF. She is a clinical researcher with expertise in epidemiology, outcomes research, comparative effectiveness research, health services research, and dissemination and implementation sciences focused on imaging. Her research has focused on epidemiological studies evaluating the quality, utilization, accuracy, predictive values and impact of diagnostic testing on patient health, and she has quantified both the risks and benefits of medical imaging when used in different contexts and by different populations. She has led many large multi-institutional research projects. The projects are typically collaborative, involving researchers and clinicians with diverse areas of expertise including radiology, medicine, biostatistics, epidemiology, economics, demography, social sciences, medical informatics, radiation science and dissemination and implementation science. Her research has been published in high impact medical journals including The NEJM, Annals of Internal Medicine, JAMA, The Journal of the National Cancer Institute, and the leading radiology specialty journals such as Radiology and The Journal of the American College of Radiology. Several recent studies have quantified the variation in radiation dose associated with medical imaging and expected impact on cancer outcomes. This work has brought attention to the greater need for standards in imaging. She is currently leading two large, multi-institutional epidemiological projects on

medical radiation funded by the NIH. One project is collecting radiation dose metrics associated with CT from over 150 hospitals in the US, Europe and Asia, and she is testing the impact of providing feedback and education on average and high doses. The second project is a multi-national epidemiological study assessing the risk of cancer associated with medical imaging among 1 million children and 1 million pregnant patients. The study will be the first to quantify the risk of medical imaging including CT among a large cohort of patients, and uses novel methods to accurately estimate dose.

**Andrew Bindman, MD**

Dr. Andy Bindman is a professor of medicine, epidemiology & biostatistics, and a core faculty member within the Philip R. Lee Institute for Health Policy Studies at the University of California, San Francisco. He is a primary care physician who has practiced and taught clinical medicine at Zuckerberg San Francisco General Hospital over 3 decades while also conducting health services research to improve care within the health care safety net. He has been a leader in translating research into policy through several roles he has played within the federal government. He was a health policy fellow on the staff of the US House Energy and Commerce Committee where he contributed to the drafting of the Affordable Care Act (ACA). He worked for several years to implement the ACA as a senior adviser within the US Department of Health and Human Services and as the Director of the Agency for Healthcare Research and Quality. He currently serves as the co-editor in chief of the journal, Health Services Research. Dr. Bindman was elected to the National Academy of Medicine in 2015.

**Patrick Romano, MD, MPH, FACP, FAAP**

Patrick S Romano, MD, MPH currently works at the University of California, Davis. His research focuses on developing, testing, and validating health care quality measures, using outcomes data to improve the quality and effectiveness of health care, and studying the role of physicians and nurses in optimizing quality and safety. His research program is supported by AHRQ and numerous California agencies, and has resulted in over 186 peer-reviewed publications. He now serves as Co-Editor in Chief of Health Services Research (HSR), an official journal of AcademyHealth published by the Health Research & Educational Trust, and as Director of Quality, Safety, and Comparative Effectiveness Research Training in Primary Care (QSCERT-PC), a T32 primary care research training program supported by HRSA.

**Naomi López-Solano, CCRP**

Naomi López-Solano is a Certified Clinical Research Professional and the Project Manager for DR CTQS. She has been with UCSF for over 10 years and has worked with Dr. Smith-Bindman's research group since 2014. She successfully managed two grant-funded projects, including a PCORI funded UCSF International CT Dose Registry that received data from over 150 hospitals and 7 countries and simultaneously managed an NIH-funded stepped wedge clinical trial that involves over 100 hospitals.

# TECHNICAL EXPERT PANEL (TEP) CHARTER

## **Project Title: Defining and Rewarding Computed Tomography Quality and Safety (DR CTQS)**

### **Dates:**

February 2019 – September 2021. First meeting February 26, 2019.

### **Project Overview:**

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of California San Francisco to develop a measure of CT image quality and radiation safety. The project is a part of CMS's MACRA/Measure Development for the Quality Payment Program. The contract name is "DR CTQS: Defining and Rewarding Computed Tomography Quality and Safety". The contract number is 1V1CMS331638-01-01. As part of its measure development process, CMS asks measure developers to convene groups of stakeholders and experts who contribute 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 that on the one hand image quality standards are preserved while on the other, 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 seeking input from a broad group of 15-20 stakeholders to develop a set of recommendations to assist CMS in implementing a radiology quality and safety measure as a part of the Merit Based Incentive Payment System (MIPS) and potentially any CMS related Alternative Payment Method (APM) programs. 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 helps 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 to monitor and reduce radiation dose in the context of 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. As such, individuals participating on the TEP should 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 to meet three times per year either in-person or via a webinar.

#### **Date Approved by TEP:**

February 26, 2019

#### **TEP Membership:**

Niall Brennan, MPP; Health Care Cost Institute

Kenneth Wang, MD, PhD; University of Maryland, Baltimore

Mythreyi Bhargavan Chatfield, PhD; American College of Radiology

Matthew Nielsen, MD, MS; UNC Gillings School of Global Public Health

Arjun Venkatesh, MD, MBA, MHS; Yale School of Medicine

Todd Villines, MD, FSCCT; Uniformed Services University School of Medicine in Bethesda, Maryland

Jay Bronner, MD; Radiology Partners

Hedvig Hricak, MD, PhD; Memorial Sloan Kettering Cancer Center

Debra P. Ritzwoller, PhD; Patient Representative

J. Anthony Seibert, PhD; University of California, Davis

Lewis G. Sandy, MD, FACP; UnitedHealth Group

Tricia Elliott, MBA, CPHQ; Joint Commission

Missy Danforth; The Leapfrog Group

J. Leonard Lichtenfeld, MD, MACP; American Cancer Society, Inc.

Helen Burstin, MD, MPH, FACP; Council of Medical Specialty Societies

Jeph Herrin, PhD; Flying Buttress Associates, Ltd.

M. Suzanne Schrandt; Patient Representative

Amy Berrington, Dphil; Federal Representative (non-voting member)

Mary White, ScD; Federal Representative (non-voting member)

## 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](mailto:Naomi.Lopez-Solano@ucsf.edu)

## **Defining and Rewarding Computed Tomography Quality and Safety (DR CTQS)**

The focus of the proposal is to develop a quality measure for Computed Tomography (CT) that focuses on image quality and radiation dose. The goal is to create a quality measure for CT to ensure that on the one hand image quality standards are preserved while on the other, 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.

As a result of the proposed work, we will provide a fully developed, specified, and tested quality measure that we will submit to NQF for endorsement for it to be used in the Medicare Quality Payment Program. The measure will be designed to apply to radiologists, as well as a growing number of other physicians (e.g. orthopedists, emergency physicians, urologists) who perform (not just order) CTs as a part of their work. The measure will be modelled on one used to assess radiation dose in children that has already received NQF endorsement.

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 who will serve on a Technical Expert Panel (TEP) to increase use, usability, and measure value while minimizing burden on clinicians. 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). Some data from PACS are already prioritized for clinical use and are pulled from these radiology records into the electronic medical records. Radiation dose information is currently not routinely accessed or stored in a consistent fashion. In order to facilitate measure reporting, we will establish a means for health care organizations and clinicians to electronically capture the information necessary for the quality measures in a way which can allow them to review their own data, receive detailed feedback with actionable suggestions, and report it to CMS in a way which limits the burden on them to do anything outside of usual patient care.

The specific steps will include developing a measure which can be used to monitor image quality in the context of minimizing radiation doses. Second, we will test, modify and re-test the performance of the radiation dose and imaging quality measures in a wide variety of settings including urban and rural practices, hospital and community-based practices and medical groups of varying sizes and specialty. Third, we will assess the performance characteristics of the measures when applied to individual clinicians versus groups of clinicians in different specialties and working as a part of the same health care organization. Fourth, we will develop tools that physicians and institutions can use to report their performance on the measures. Fifth, we will partner with key stakeholder groups to submit the measure for NQF endorsement. Finally, we will work with CMS to draft language which can be included in draft and final rulemaking to update the Measure Inventory so that these measures can be used as a part of the Merit Based Incentive Payment System (MIPS) and potentially any CMS related Alternative Payment Method (APM) programs.

# Welcome to the DR CTQS TEP in-person meeting

*Please help yourself to some breakfast and have a seat.  
We will begin promptly at 8:30am*



University of California  
San Francisco



## Technical Expert Panel In-Person Meeting Agenda

**Tuesday, February 26, 2019**  
Club Quarters Hotel, 639 17th St NW, Washington, DC  
Lafayette Room (2nd Floor)

Zoom Meeting ID: 427 347 843 <https://ucsf.zoom.us/j/427347843>

8:00 AM	Breakfast, Coffee, & Tea	
8:30 AM	Call meeting to order	Dr. Helen Burstin
8:35 AM	Roll Call	led by Dr. Burstin
8:40 AM	Review and approve TEP Charter	
8:50 AM	Discussion of what constitutes a conflict	
8:55 AM	Introductions and statement of conflicts	
9:30 AM	CMS Merit-Based Incentive Payment System (Medicare Access and CHIP Reauthorization Act (MACRA)) and cooperative agreement overview	Dr. Reena Duseja
9:50 AM	Discussion	led by Dr. Burstin
10:00 AM	Break	
10:15 AM	NCI Presentation on radiation risk	Dr. Amy Berrington
10:35 AM	Discussion	led by Dr. Burstin
10:50 AM	Variation in CT Radiation Dose	Dr. Rebecca Smith-Bindman
11:10 AM	Discussion	led by Dr. Burstin
11:25 AM	Project overview	Dr. Andy Bindman
11:45 AM	Dose manipulation program/application	
12:00 PM	Lunch	
1:00 PM	Measuring and Quantifying Radiation Dose	Dr. Smith-Bindman
1:15 PM	Risk Adjustment	Dr. Patrick Romano
1:40 PM	Discussion	led by Dr. Burstin
2:30 PM	Measuring and Quantifying Image Quality	Dr. Smith-Bindman
2:45 PM	Discussion	led by Dr. Burstin
3:05 PM	Summary and next steps	Dr. Bindman
3:15 PM	Meeting Ends	

*Thank you for attending - we look forward to your continued collaboration.*

## Roll Call

<b>TEP Chair</b>	Matthew Nielsen, MD, MS
Helen Burstin, MD, MPH, FACP	Debra P. Ritzwoller, PhD
	Lewis G. Sandy, MD, FACP
<b>Members</b>	M. Suzanne Schrandt, JD
Mythreyi Bhargavan Chatfield, PhD	J. Anthony Seibert, PhD
Niall Brennan, MPP	Arjun Venkatesh, MD, MBA, MHS
Jay Bronner, MD	Todd Villines, MD, FSCCT
Missy Danforth,	Kenneth Wang, MD, PhD
Tricia Elliott, MBA, CPHQ	
Jeph Herrin, PhD	<i>Ex officio (non-voting) Members</i>
Hedvig Hricak, MD, PhD	Amy Berrington de Gonzalez, DPhil
J. Leonard Lichtenfeld, MD, MACP	Mary White, ScD

## TEP Charter (1 of 4)

**Project Title: Defining and Rewarding Computed Tomography Quality and Safety (DR CTQS)**

**Dates:** February 2019 – September 2021. First meeting February 26, 2019.

**Project Overview:**  
The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of California San Francisco to develop a measure of CT image quality and radiation safety. The project is a part of CMS's MACRA/Measure Development for the Quality Payment Program. The contract name is "DR CTQS: Defining and Rewarding Computed Tomography Quality and Safety". The contract number is 1V1CMS331638-01-01. As part of its measure development process, CMS asks measure developers to convene groups of stakeholders and experts who contribute 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 that on the one hand image quality standards are preserved while on the other, 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 Charter con't (2 of 4)

### TEP Objectives:

In its role as a measure developer, the University of California San Francisco is seeking input from a broad group of 15-20 stakeholders to develop a set of recommendations to assist CMS in implementing a radiology quality and safety measure as a part of the Merit Based Incentive Payment System (MIPS) and potentially any CMS related Alternative Payment Method (APM) programs. 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 helps 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 to monitor and reduce radiation dose in the context of 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.

## TEP Charter con't (3 of 4)

### Guiding Principles:

Participation on the TEP is voluntary. As such, individuals participating on the TEP should 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 to meet three times per year either in-person or via a webinar.

**Date Approved by TEP:** February 26, 2019

## TEP Charter con't (4 of 4)

### TEP Membership:

Niall Brennan, MPP; Health Care Cost Institute  
 Kenneth Wang, MD, PhD; University of Maryland, Baltimore  
 Mythreyi Bhargavan Chatfield, PhD; American College of Radiology  
 Matthew Nielsen, MD, MS; UNC Gillings School of Global Public Health  
 Arjun Venkatesh, MD, MBA, MHS; Yale School of Medicine  
 Todd Villines, MD, FSCCT; Uniformed Services University School of Medicine in Bethesda, Maryland  
 Jay Bronner, MD; Radiology Partners  
 Hedvig Hricak, MD, PhD; Memorial Sloan Kettering Cancer Center  
 Debra P. Ritzwoller, PhD; Patient Representative  
 J. Anthony Seibert, PhD; University of California, Davis  
 Lewis G. Sandy, MD, FACP; UnitedHealth Group  
 Tricia Elliott, MBA, CPHQ; Joint Commission  
 Missy Danforth; The Leapfrog Group  
 J. Leonard Lichtenfeld, MD, MACP; American Cancer Society, Inc.  
 Helen Burstin, MD, MPH, FACP; Council of Medical Specialty Societies  
 Jeph Herrin, PhD; Flying Buttress Associates, Ltd.  
 M. Suzanne Schråndt; Patient Representative  
 Amy Berrington, Dphil; Federal Representative (non-voting member)  
 Mary White, ScD; Federal Representative (non-voting member)

## What Constitutes a Conflict?

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



## What Constitutes a Conflict?

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


UCSF  
University of  
California, San Francisco



### The Quality Payment Program, the Role of Cooperative Agreements and getting to Meaningful Measures

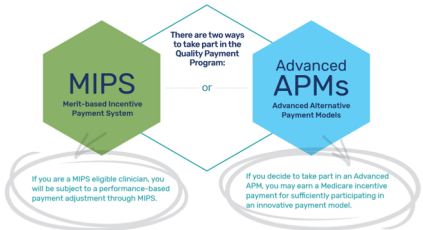
Reena Duseja, MD, MS  
Chief Medical Officer, Quality Measurement and Value-  
Based Incentives Group, CMS


February 26, 2019



## Quality Payment Program

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires CMS by law to implement an incentive program, referred to as the Quality Payment Program:





## Quality Payment Program

Considerations

Improve beneficiary outcomes

Reduce burden on clinicians

Increase adoption of Advanced APMs


Maximize participation

Improve data and information sharing

Ensure operational excellence in program implementation

Deliver IT systems capabilities that meet the needs of users

Quick Tip: For additional information on the Quality Payment Program, please visit [qpp.cms.gov](http://qpp.cms.gov)



## MIPS: Quick Overview


Combined legacy programs into a single, improved program.

Physician Quality Reporting System (PQRS)

Value-Based Payment Modifier (VM)

Medicare EHR Incentive Program (EHR) for Eligible Professionals


MIPS



## MIPS: Quick Overview


*MIPS Performance Categories*

Quality




45% of MIPS Score

Cost




15% of MIPS Score

Improvement Activities



15% of MIPS Score

Promoting Interoperability




25% of MIPS Score

=

100%

of MIPS Final Score

- Comprised of **four** performance categories
- So what? *The points from each performance category are added together to give you a MIPS Final Score*
- The MIPS Final Score is compared to the MIPS performance threshold to determine if you receive a **positive, negative, or neutral payment adjustment**



## MIPS Year 3 (2019) Final

MIPS Eligible Clinician Types

### Year 2 (2018) Final

**MIPS eligible clinicians include:**

- Physicians
- Physician Assistants
- Nurse Practitioners
- Clinical Nurse Specialists
- Certified Registered Nurse Anesthetists
- Groups of such clinicians

➤➤➤

### Year 3 (2019) Final


**MIPS eligible clinicians include:**

- Same five clinician types from Year 2 (2018)

**AND:**

- Clinical Psychologists
- Physical Therapists
- Occupational Therapists
- Speech-Language Pathologists\*
- Audiologists\*
- Registered Dieticians or Nutrition Professionals\*

\*We modified our proposals to add these additional clinician types for Year 3 as a result of the significant support we received during the comment period.



## What is an APM?

Alternative Payment Models (APMs) are new approaches to paying for medical care through Medicare that incentivize quality and value. The CMS Innovation Center develops new payment and service delivery models. Additionally, Congress has defined—both through the Affordable Care Act and other legislation—a number of demonstrations that CMS conducts.

As defined by MACRA, **APMs include:**

- ✓ CMS Innovation Center model (under section 1115A, other than a Health Care Innovation Award)
- ✓ MSSP (Medicare Shared Savings Program)
- ✓ Demonstration under the Health Care Quality Demonstration Program
- ✓ Demonstration required by federal law

**CMS**  
CENTERS FOR MEDICARE & MEDICAID SERVICES

### APMs Overview

- A payment approach that provides added incentives to clinicians to provide high-quality and cost-efficient care.
- Can apply to a specific condition, care episode or population.
- May offer significant opportunities for eligible clinicians who are not ready to participate in Advanced APMs.

**Advanced APMs are a subset of APMs**

**CMS**  
CENTERS FOR MEDICARE & MEDICAID SERVICES

### Advanced APMs

Clinicians and practices can:

- Receive **greater rewards** for taking on some risk related to patient outcomes.

**Advanced APMs** → **Advanced APM-specific rewards** (represented by a dollar sign icon and a 5% badge)

*“So what?”* - It is important to understand that the Quality Payment Program does not change the design of any particular APM. Instead, it creates **extra incentives** for a sufficient degree of participation in Advanced APMs.

**CMS**  
CENTERS FOR MEDICARE & MEDICAID SERVICES

Medicare and CHIP Reauthorization Act (MACRA)

Section 101      Section 102


Advanced Alternative Payment Models (APMs)      Merit-based Incentive Payment System (MIPS)      Measure Development Plan & Annual Report      Measure Development

Quality Payment Program ↔ Clinician Measures

**CMS**  
CENTERS FOR MEDICARE & MEDICAID SERVICES

### CMS Quality Measure Development Plan

- Strategic framework to guide measure development for MIPS and APMs
  - Includes priorities for MACRA-funded clinician measure development
  - Recommends prioritized approaches to close gaps through measure development
  - Identifies guiding principles to drive measure development
  - Sets expectations for MACRA-funded measure developers
- Posted in May 2016 following a public comment period soliciting stakeholder input




### MACRA Cooperative Agreements

- MACRA section 102 authorizes \$75 million in funding\* for measure development and associated activities
- In September 2018, CMS announced 7 cooperative agreements awarded to specialty societies, consumer advocacy groups, educational institutions, independent research institutions, and health systems to fill measure gaps in the Quality Payment Program
- Awardees align closely with specialties prioritized in the MDP and further examined in the 2017 MDP Environmental Scan
  - Oncology
  - Palliative care
  - Orthopedic surgery
  - Psychiatry (2 awards)
  - Pathology
  - Radiology

\*\$15 million each FY 2015–2019, available through end of FY 2022


21



### Future Direction of Measure Development Plan

- Meaningful Measures Initiative as a guiding framework for measure development
- Process used to identify measure gaps
- Measure development principles consistent with current standards
- Human-centered design as an approach to obtain stakeholder input in measure development and other related improvements


22



### A New Approach to Meaningful Outcomes









#### What is Meaningful Measures Initiative?

- Launched in 2017, the purpose of the Meaningful Measures initiative is to:
  - Improve outcomes for patients
  - Reduce data reporting burden and costs on clinicians and other health care providers
  - Focus CMS’s quality measurement and improvement efforts to better align with what is most meaningful to patients



### Meaningful Measures Objectives

Meaningful Measures focus on everyone’s efforts on the same quality areas and lend specificity, which can help identify measures that:

 <p>Address high-impact measure areas that safeguard public health</p>	 <p>Are patient-centered and meaningful to patients, clinicians and providers</p>	 <p>Are outcome-based where possible</p>	 <p>Fulfill requirements in programs’ statutes</p>
 <p>Minimize level of burden for providers</p>	 <p>Identify significant opportunity for improvement</p>	 <p>Address measure needs for population based payment through alternative payment models</p>	 <p>Align across programs and/or with other payers</p>





## Vision for Quality Reporting

**KEY LEVERS**

**Engage Patients and Providers**

- Measures development begins from a person-centered perspective
- Involve patients and caregivers in measure development and public reporting efforts
- Involve first-line health care professionals on the front line are involved in measure development, implementation, and data feedback processes

**Strengthen/Facilitate Interoperability**

- Ongoing, timely information is provided to health care professionals
- Data collection and exchange is low burden
- Quality measure data is fed into planning and implementation of quality improvement initiatives

**Optimize Public Reporting**

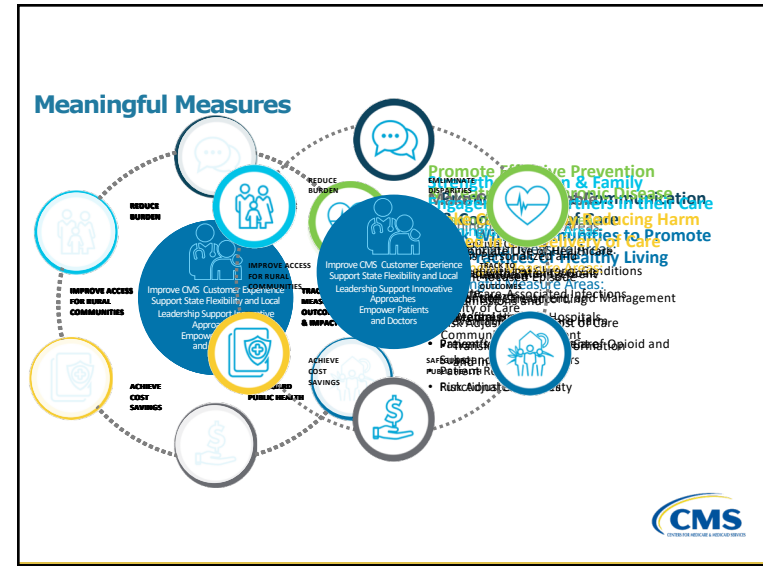

- Relevant, actionable data is accessible to a variety of audiences
- Patients and caregivers have access to data

**Aligned Measure Portfolio**

- An enterprise-wide strategy for measure selection focuses on patient-centered, outcome, and longitudinal measures
- Infrastructure supports development of health IT enabled measures


**Aligned Quality Reporting and Value-based Purchasing**


- Aligned and streamlined policies and processes for quality reporting and value based purchasing programs
- CMS demonstration programs have flexibility to test innovative models, while maintaining a desired end state of alignment with legacy CMS programs

## Meaningful Measures- Key benefits

- Provides a focused conceptual framework to address national healthcare priorities
- Establishes clear objectives for quality measures (e.g., minimize burden)
- Supports consistency between measure development and evaluation activities






**Conceptual Framework Supporting Clinician Specialty Measure Development**


Meaningful Measures Priority/MACRA Domain	Meaningful Measure Area	Allergy/Immunology	Emergency Medicine	Neurology	Physical Medicine and Rehabilitation	Rheumatology
Effective Prevention and Treatment/Clinical Care	Preventive Care					
	Management of Chronic Conditions					
	Prevention, Treatment, and Management of Mental Health					
Making Care Safer/Safety	Prevention and Treatment of Opioid and Substance Use Disorders					
	Risk-Adjusted Mortality					
Communication and Coordination/Care Coordination	Healthcare-Associated Infections					
	Preventable Health Care Harm					
	Medication Management					
Person and Family Engagement/Patient and Caregiver Experience	Admissions and Readmissions to Hospitals					
	Transfer of Health Information and Interoperability					
	Care is Personalized and Aligned With Patient's Goals					

28




**Meaningful Measure Development**

- Appropriate use of opioids and avoidance of harm
- Interoperability and care transitions
- Appropriate use of services
- Patient-reported outcome measures
- Alignment of Quality and Cost Measures to drive toward value



**Ideal Future State for Meaningful Measures**

- Developing more APIs for quality measure data submission
- Prototype the use of the FHIR standard for quality measurement
- Interoperable electronic registries – incentivizing use
- Harmonizing measures across registries
- Timely and actionable feedback to providers
- Working with CMMI on use of artificial intelligence to predict outcomes




**Questions**

Reena Duseja, M.D., M.S.

Chief Medical Officer, Quality Measurement and Value-Based Incentives Group, CMS


Reena.Duseja@cms.hhs.gov

**Discussion on MIPS/MACRA**



University of California  
San Francisco

15 minute Break



University of California  
San Francisco

National Cancer Institute

## Ionizing Radiation & Cancer Risk

Amy Berrington de Gonzalez, DPhil  
Branch Chief & Senior Investigator  
Radiation Epidemiology Branch  
DCEG/NCI/NIH

34

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
National Institutes of Health


## 100+ Years of Radiation Epidemiology

Timeline of Radiation Epidemiology:

- 1895: X-Rays Discovered
- 1900: Skin/Bone Cancer
- 1920s: Radium Dial Painters
- 1930s: Thorotrast Imaging
- 1940s: Radiologists
- 1950s: A-Bomb Data
- 1960s: Medically Treated Populations, Underground Miners (Radon)
- 1970s: Nuclear Workers
- 1980s: Chernobyl
- 1990s: Cancer Survivors (therapy)

## Life Span Study of Japanese Atomic Bomb Survivors

**“Gold Standard”  
of radiation epidemiology**

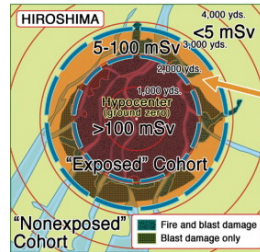


## Life Span Study Cohort

- Survivors within 2.5 km of the bombings (0-4Gy)
- Survivors within 2.5-10 km
- Not-in-city (NIC)

TOTAL PEOPLE 120,321

- Hiroshima and Nagasaki tumor registries (1958-98)
- 22,538 cancers diagnosed
- Dose estimates based on location/shielding



Grant et al. Radiat Res, 2017

## A-bomb: Key Findings after 70 years

What types of cancer?

- Almost all cancers related to radiation
- Red bone marrow, breast and thyroid most radiosensitive tissues

Who is most at risk?

- Children
- But risk elevated for all age-groups

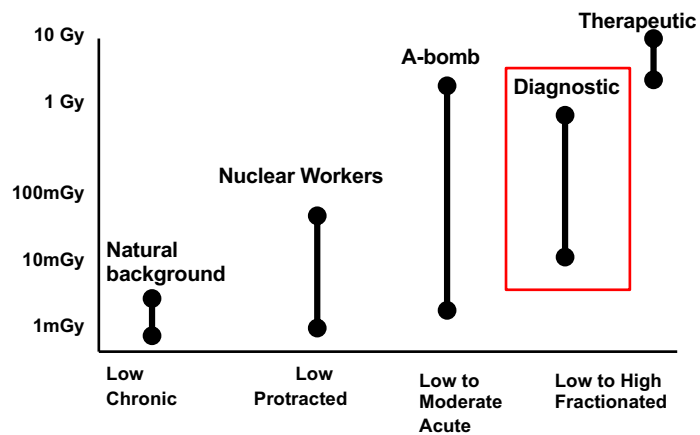
How long does the risk last?

- Risk increased from 2-5 years after exposure
- Remains elevated for entire lifetime

Is there a threshold?

- No
- Dose-response similar for doses <100mGy

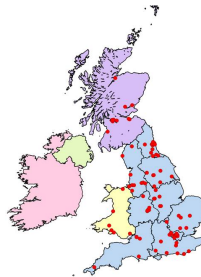
## Wide Range in Radiation Doses & Exposure Patterns



## STUDIES OF DIAGNOSTIC RADIATION EXPOSURES

### NCI-UK Pediatric CT Scan Cohort

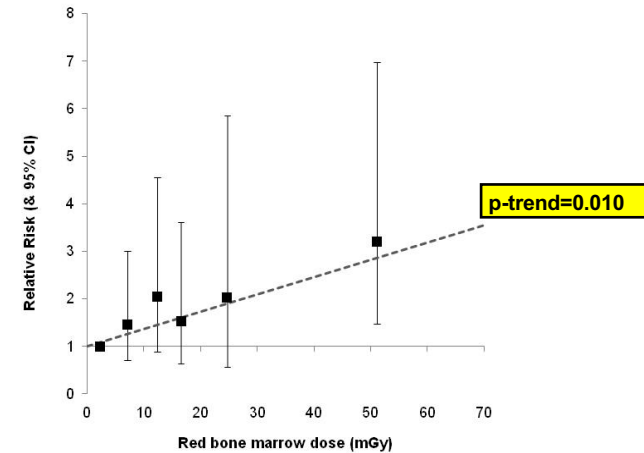
- Radiology Information Systems data from 100+ hospitals
- CT scans aged 0-21 yrs from 1990-2002 (186k children)
- Link to cancer registrations, vital status
- Organ dose estimates for each CT scan
- Leukemia & brain tumors dose-response



Pearce et al (Lancet 2012); Kim et al (Radiat Prot Dosimetry 2012)

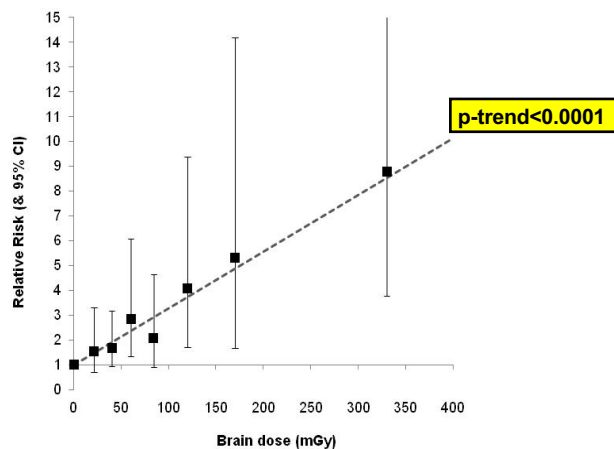
41

### Leukemia and Radiation Dose to Red Bone Marrow



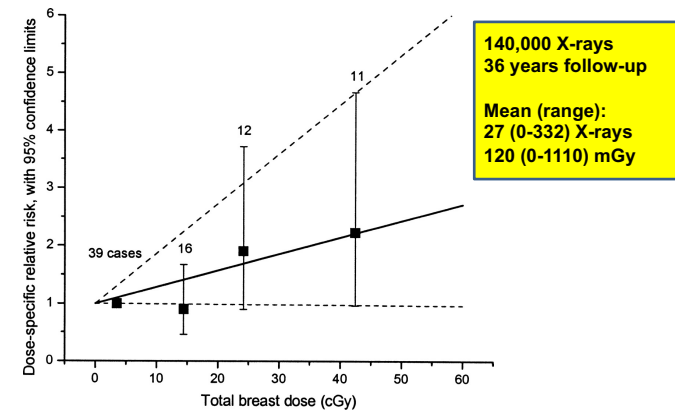
Pearce, ..., Berrington de Gonzalez (Lancet 2012)

### Brain tumors and Radiation Dose to Brain



Pearce, Salotti, Little, McHugh, Lee ..., Berrington de Gonzalez (Lancet 2012)

### Radiation Dose Response for Breast Cancer Multiple Spine X-rays in 3,002 Scoliosis Patients



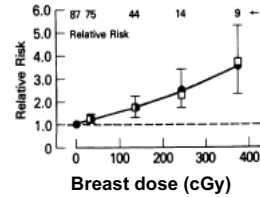
©2008 by American Association for Cancer Research

AAO Cancer Epidemiology, Biomarkers & Prevention

## Tuberculosis & Multiple Fluoroscopies

Massachusetts 4940 women (1925-54)

- Mean dose 0.8Gy (88 exposures)
- 234 breast cancers

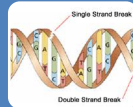


Canadian 31,710 women (1930-1952)

- 688 breast cancer deaths


Boice et al (Radiat Res 1991); Howe and McLaughlin (Radiat Res 1996); Howe (Radiat Res 1995); 45

## Cancer & Radiation: Summary




**Universal carcinogen**

- Causes most types of cancer
- Any age at exposure



**Main sources to general population**

- Diagnostic medical exposures
- Natural background



**Radiation protection of patients**

- Direct evidence of risk from multiple X-rays
- ALARA (as low as reasonably achievable)

## Radiation Risk Discussion




## Variation in Computed Tomography Radiation Dose

Rebecca Smith-Bindman, MD  
The University of California San Francisco




### Background

- Radiation levels U.S.
  - radiation all non imaging sources: 3 mSv / yr
  - radiation from Imaging: 3 mSv / yr
- Radiation doses used for CT are higher than conventional x-rays
  - chest x-ray: 0.01 - .1 mSv
  - chest CT: 5 - 40 mSv
- Growth in CT, and high dose/scan has resulted in 600% increase in radiation dose associated with imaging 20 yrs
- CT Doses in range where there is agreement they should be minimized
- Radiology guiding principle ALARA




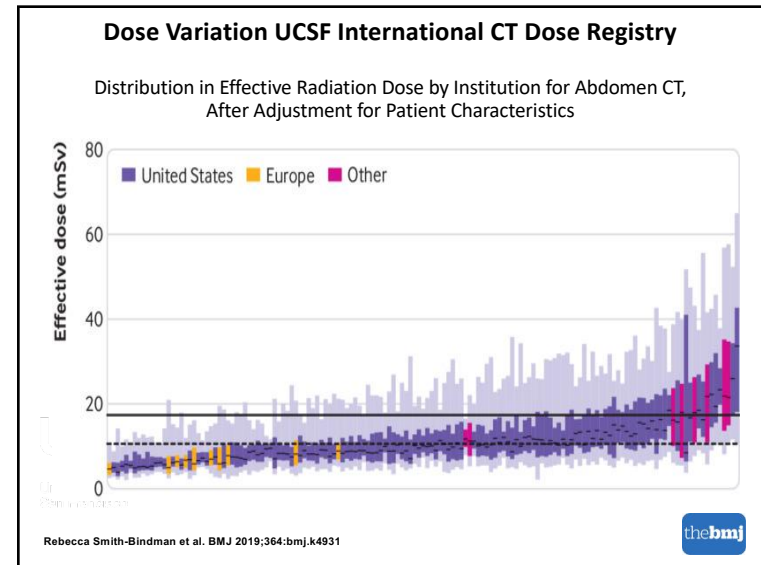
### Radiation Doses for CT

- Doses are highly variable
- Doses are higher than needed for diagnosis
- Doses can be reduced
- Patients are largely unaware of potential risks



### Variation in Radiation Dose

- Significant variation in dose occurs across patients and hospitals and outpatient settings has been identified suggesting a significant quality gap
- The variation is large
- The large variation in dose is not driven by patient, or machine factors, but practice preferences

### Effective Dose for Abdomen CT in Adults (Adjusted for Patient Factors)

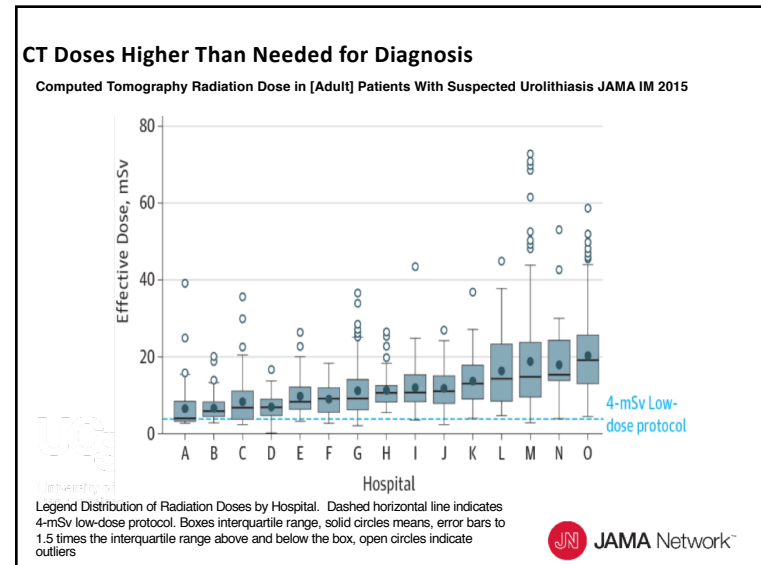
	Mean Dose (SD) mSv		Proportion High Dose CTs
Switzerland	8.3	(4.4)	7
Netherlands	7.0	(4.1)	9
Germany	8.0	(7.1)	4
UK	7.9	(6.0)	9
USA	12.0	(7.9)	22
Israel	18.4	(11.3)	54
Japan	25.7	(16.1)	69

### Causes of the Variation

- Analyzed data included information on patients, reasons for scan, machine manufacturer / model, and information about the hospitals / imaging centers where scans were done
- While radiation doses vary by these factors (and some of the variation is appropriate) none of these factors accounted for the variation between institutions
- Accounting (adjusting) for these factors did not explain differences across institutions
- Essentially all of the variation was due to how machines were used and local choices and protocols for scanning

### Variation in Technical Parameters for Pulmonary Embolism CT All Implemented on a Single Scanner Model (sample)

Country	Effective Dose (mSv)	kVP mean	mAs mean	Pitch mean	Scan length mean	Phase per Study
Switzerland	1.7	103	137	1.5	32	1.0
Germany	1.6	103	109	1.4	33	1.1
USA	1.6	101	92	0.9	30	1.0
USA	3.4	105	81	1.0	16	2.2
USA	5.4	112	201	0.9	29	1.1
USA	7.3	109	132	0.8	37	1.1
USA	9.9	112	265	1.0	21	2.2
USA	12.6	115	199	1.0	43	2.0
USA	20.0	116	190	0.8	41	1.2
USA	32.7	120	211	0.8	41	2.8
<b>Lowest Dose Protocols</b>	<b>1.6</b>	<b>102</b>	<b>113</b>	<b>1.2</b>	<b>32</b>	<b>1.0</b>
<b>Highest Dose Protocols</b>	<b>27.5</b>	<b>119</b>	<b>188</b>	<b>0.8</b>	<b>39</b>	<b>2.7</b>



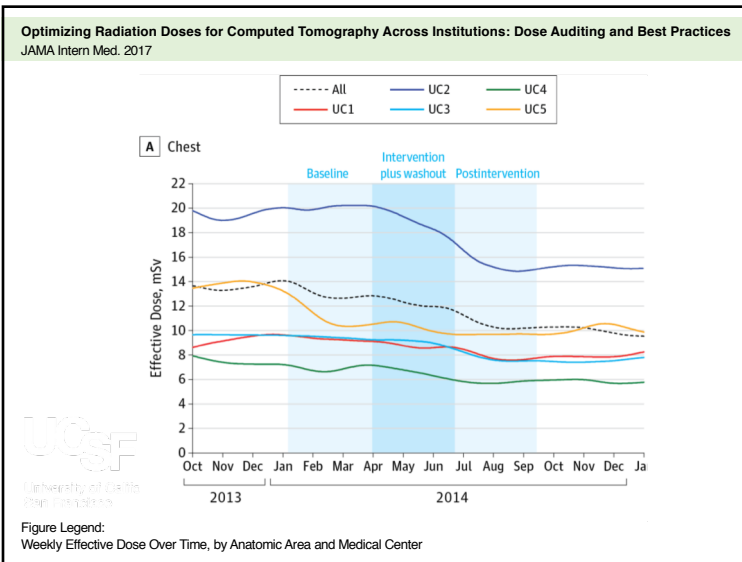


### CT Doses Are Higher Than Needed for Diagnosis

- Diagnostic accuracy can vary by the doses used and CT imaging exams require a minimum dose to ensure image quality so that diagnoses are not missed
- We are routinely using doses higher than needed for diagnoses
- Lowering doses can be done without undermining our ability to make accurate diagnoses
- Both dose variation and interventions showing successful dose reduction show that doses can be reduced without impacting quality

### Efforts to Reduce Doses

- Numerous clinical studies have found through QI efforts, and practice review, that doses can be reduced 50% or more without impacting quality
- Several multi-center studies have shown doses can come down substantially with oversight and use of standards
- UCSF conducted a UC-wide observational study and an RCT each resulted in significantly lowered doses



### RCT to Reduce Doses

- 100 institutions participated in RCT completed December 2017
- The study compared simple audit to a more detailed approach combining audit with education and sharing of best practices
- Following the multicomponent intervention
  - High dose examinations reduced up to 60% (across anatomic areas)
  - Average doses reduced by up to 40%
  - Variation within institutions reduced by 40%
  - MDs reported no change in satisfaction with image quality (all high)

### Discussion of Radiation with Patients

- Patients are rarely informed about radiation or radiation risks
- The risks are typically trivialized when patients ask
- Patients report (when educated and asked) that they want to be informed that medical imaging delivers radiation and want to understand the doses and potential risks
- Debate has focused on whether or not to obtain informed consent, and there is no consensus within radiology that the benefit of informing and educating patients would outweigh potential harms (fear) and work (few radiologists or technologists are prepared to counsel patients)
- Studies of educating patients about radiation have found it leads to reasonable decision making (patients don't defer needed imaging)

### Summary

- There is a safety gap reflected in higher than needed doses as well as unnecessary variation in the doses that are used for CT
- Creating a quality metric (focused on adults) to assess safe CT imaging practices that also ensure quality imaging is the focus of the application
- We will later discuss how to measure radiation dose and image quality in a standardized way to support the development of a quality metric

### Discussion Questions

- Do you believe there is an important health reason to lower radiation doses in the use of CT imaging?
- Do you believe that clinicians can use lower radiation doses to perform CT scans?
- Do you believe there is a role for a quality metric which captures the radiation doses used in performing CT scans?
- What concerns would you have about using lower doses in the performance of CT scans?

*Project Overview*  
**DR CTQS: Defining and Rewarding  
 Computed Tomography Quality and Safety**

Andy Bindman, MD  
 University of California San Francisco

February 26, 2019

**UCSF**  
 University of California  
 San Francisco

## UC Project Team

- Rebecca Smith-Bindman, MD – PI
- Andy Bindman, MD – TEP and implementation
- Patrick Romano, MD, MPH, FACP, FAAP - Risk Adjustment
- Monika Ray, PhD - Risk Adjustment and Artificial Intelligence
- Antonio Westphalen, MD, PhD – Image quality
- Eliot Siegel, MD – Artificial Intelligence
- Marc Kohli, MD – Radiology Informatics
- Naomi López-Solano, CCRP – Project Manager



## Concept

- Develop a composite quality measure which can be linked with financial incentives to minimize the use of radiation in the performance of CT scans to produce high quality images for diagnosis among adults
- Intended to be implemented as a part of the Medicare Quality Payment Program
  - Merit-based Incentive Payment System (MIPS)
  - Alternative Payment Models (APMs)



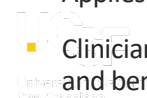
## Approach

- Develop a standardized method for calculating the radiation dose associated with the performance of CT scans
  - head, chest, cardiac, abdomen, pelvis, spine, extremities and combinations
- Develop a standardized method for assessing whether a CT scan exceeds a minimum threshold for image quality
- Establish a maximum risk-adjusted radiation dose standard which takes account of patient characteristics, the scanned anatomical area, and the indication for the scan
  - Provide software for capturing and reporting the calculated risk adjusted radiation dose and image quality assessments



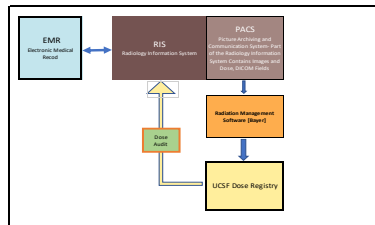
## Principles

- Assessment made of all eligible CT scans (not sampled)
- Measure based on electronic data
- Minimize burden on clinicians
- Applies to all specialties that perform scans
- Applies to all settings where scans performed
- Clinicians can use generated data for self-assessment and benchmarking



## Data Source and Generation of Measure

- EMR – Electronic Medical Record
- RIS – Radiology Information System
- PACS – Picture Archiving and Communication System

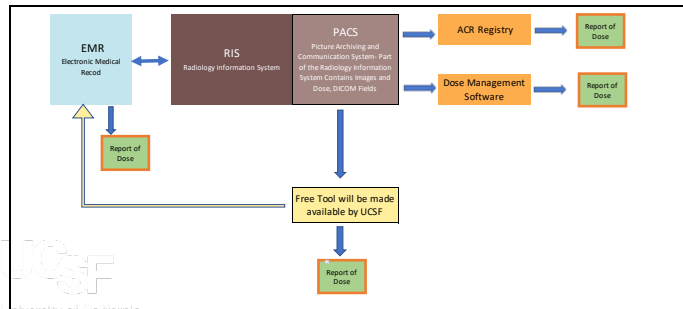


## UCSF International CT Dose Registry

- PCORI funded
- Repository of > 6 million CT scans
- 151 institutions worldwide
- Audit reports
- Platform for randomized trials



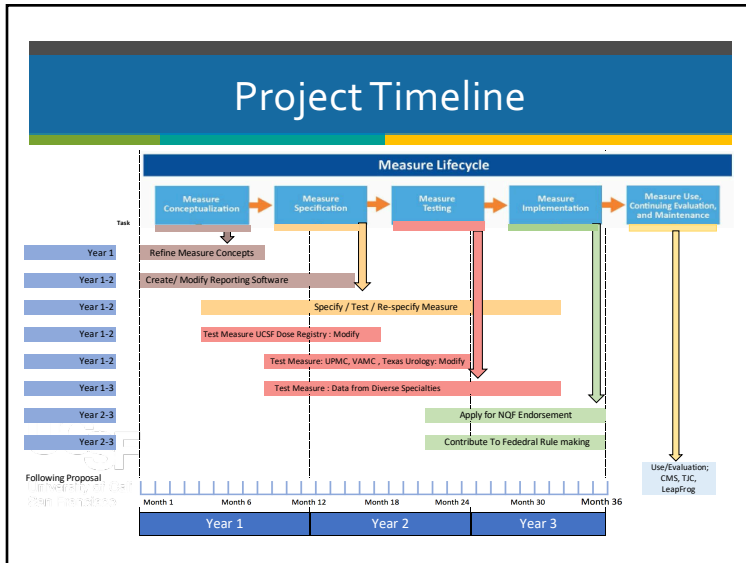
## Alternative Approaches for Generating Quality Measure



## Today's TEP Meeting

- Proposed method for measuring radiation dose
- Proposed method for risk adjustment
- Proposed method for measuring image quality





## Role of the TEP

- Advise on how to specify measure
- Advise on how to test measure
- Advise on how to interpret results of measure tests and to re-specify measure as needed
- Advise on how to implement the measure

University of California  
San Francisco

## Dose manipulation program/application

<http://ctsim-env.bggaezja3.us-west-1.elasticbeanstalk.com/>

**UCSF**  
University of California  
San Francisco


## Measuring and Quantifying Radiation Dose

Rebecca Smith-Bindman, MD  
The University of California San Francisco

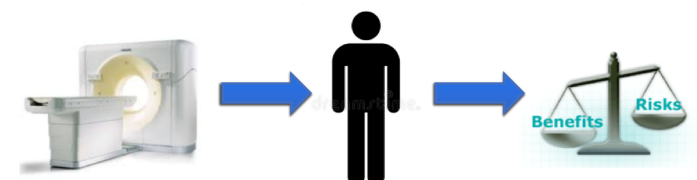
**UCSF**  
University of California  
San Francisco

### Measures of Dose and Unit of Assessment

- What are possible measures (metrics) of radiation dose that can be used to quantify exposures?
- What should be the unit of assessment to assess doses
- The proposed dose measure will be based on an NQF endorsed measure of radiation dose in children (measure #2820) but this new measure will be only apply in adults

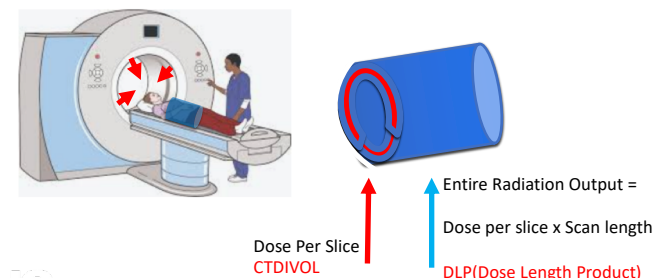


### Estimating Radiation Dose

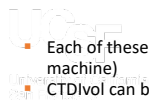


Dose Emitted by Scanner	Dose Absorbed by Patient	Estimate combining Dose with Future Harm (cancer)
This is largely what is decided by organization / radiologist / technologist / system.	This takes into account patient factors and area scanned and is complex to calculate	This takes into account future harms, and can be easy to calculate
Reported by scanners	Calculated	Calculated

### Measures of Dose: Radiation Dose Emitted by the Scanner




- Each of these 2 measures of dose are easily calculated and reported (by the machine)
- CTDIvol can be thought of as the average dose per slice (per fixed scan length)
- DLP reflects the total dose delivered by CT (reflects dose / slice x total scan length)
- By convention, CTDIvol is an average, whereas DLP is a total




### Effective Dose

- Effective dose considers the scanner output and area scanned and estimates the future risk to the patient (cancer) for scan
- This measure is more easily understood by patients and providers, as in the same units as other radiation exposures
- This measure needs to be calculated (not directly reported by CT scanners) and there are different ways to calculate



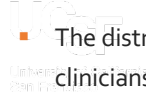
### Proposed Measure of Dose: Dose Length Product (DLP)

- Proposed measure: DLP
- DLP is reported using an industry-wide standard
- Dose can easily be scaled to patient size




### Variation in Dose by Anatomic Area that is Imaged

- Different regions of the body will require different amounts of radiation to generate images
- This is due in part to differences in the density of tissues  
It takes less energy (and dose) to penetrate the lungs compared with the brain
- The distribution of CT scans by anatomical area varies across clinicians and will be incorporated into the quality metric




### Average Dose by Anatomic Area

	CTDI vol	DLP	Effective Dose
Head	59.0	960	2
Chest	17.8	550	11
Abdomen	17.2	960	26
Chest and Abdomen	17.2	1450	40



### Other Factors Which Can Influence Dose

- Even within anatomic area there may be different dose requirements (protocols) based on the clinical questions being asked
- These differences are smaller than the differences by anatomic area and are not standardized
- When we talk about risk adjustment of the quality metric we will discuss whether to adjust for protocol and clinical indications



### Assessing the Appropriateness of The Doses We Calculate

- We are proposing to assess providers' doses within anatomic areas and case-mix adjusting doses across anatomic areas to derive an overall assessment of dose safety
- The assessment of a provider's doses will be evaluated in the context of image quality and benchmarked across all eligible providers.
- We will assess whether the risk-adjusted dose (1) on average exceeds a benchmark; (2) the proportion of scans that exceed the benchmark and (3) the proportion of scans which exceed extreme dose levels (i.e. never events)
- The threshold for acceptable doses would have to be broad to allow for different clinical conditions / expected diagnoses

### Sampling to Calculate Dose and Exclusions

- Dose will be assembled on consecutive CT scans in adult patients for a year
- We will calculate
  - Average doses
  - Proportion of out of range doses
  - Proportion of "never events" above a very high threshold
- Certain specialized exam types (such as CT as part of PET, or for biopsies, surgeries, treatment) will be excluded

## Risk Adjustment

Patrick Romano, MD, MPH, FACP, FAAP  
The University of California Davis



University of California  
San Francisco

## What is Risk Adjustment?

- **IOM's 2006 Performance Measurement report:**
  - "a process that modifies the analysis of performance measurement results by those elements of the patient population that affect results, are out of the control of providers, and are likely to be common and not randomly distributed."
- **National Quality Forum's 2014 Risk Adjustment for SES report:**
  - "statistical methods to control or account for patient-related factors when computing performance measure scores"
- **Iezzoni's 2013 Risk Adjustment for Measuring HealthCare Outcomes:**
  - "aims to account for differences in intrinsic health risks that patients or populations bring to their health care encounters"



## Implications of Risk Adjustment

Risk-adjustment is about performance measurement results that are assessed and/or reported at the level of “accountable entities”

- Most people don’t care about risk-adjustment unless there is a decision-making context for using the information is used (e.g., evaluating radiologic providers)

Risk-adjustment requires data on risk factors and statistical methods

Risk-adjustment is about minimizing confounding

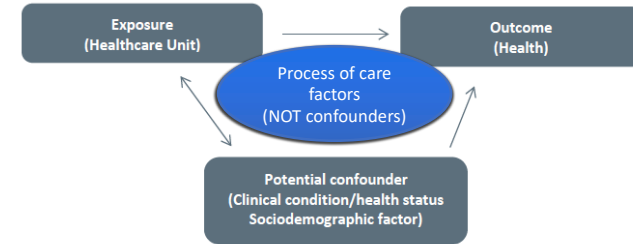
- Confounders are factors that are associated with both the exposure of interest (e.g., provider organization) and the risk of an adverse outcome, but are not caused by the exposure of interest

## When is Risk-Adjustment NOT Necessary?

- When there are no important risk factors “out of the control of providers”:
  - “Never events” that are unambiguous, serious, and virtually always preventable (e.g., radiation dose exceeding “never” threshold)
- When confounding can be eliminated by design:
  - Random allocation, matching, etc. – not applicable here
  - Restriction/stratification (typical approach for process measures; for example, using an appropriate protocol for a particular clinical scenario such as chest CT to rule out pulmonary emboli)

## Confounding

Figure D1. Relationship between exposure, outcome, and potential confounders



Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors  
 NQF TECHNICAL REPORT; August 15, 2014

## lezzoni’s 4 Questions for Risk-adjustment

- Risk of what outcome?
  - Radiation dose length product
  - Effective dose based on future cancer risk
  - Dose exceeding threshold (to be established)
- Over what time frame?
- For what population (“at risk,” “clinically relevant”)?
  - All head, neck, chest, abdomen/pelvis, combined, upper and lower extremity CTs among adults
- For what purpose?
  - Public accountability
  - Drive quality improvement

## How Purpose Informs Risk Factor Selection

Consider the conceptual framework

- Focus on risk factors that plausibly affect the radiation dose needed to generate images that are sufficiently informative, reducing false positive and false negative risks

Compare outcomes across provider organizations for public accountability:

- Focus on risk factors that plausibly differ across providers

Reward performance attainment or improvement:

- Consider social factors to avoid systematically penalizing the most vulnerable providers, **ONLY WHEN APPROPRIATE**

## Considerations in Selecting Risk Factors

Consideration	Example/issue
Clinical/conceptual relationship with the outcome of interest	Need input from TEP
Empirical association with the outcome	Empirically testable
Variation in prevalence of the factor across the measured entities	Do not adjust for extremely rare risk factors (better to exclude from denominator)
Present at the start of care	Do not adjust for CT findings
Not an indicator or characteristic of the care provided (e.g., treatments, expertise of staff)	Do not adjust for machine features or hospital/facility characteristics
Resistant to manipulation or gaming	Do not use check-box for facilities to declare any "indication for high-dose imaging"
Accurate data that can be reliably and feasibly captured	Empirically testable, but need input from TEP
Contributes unique variation in the outcome	Empirically testable
Improve metrics of discrimination and/or calibration	Empirically testable

## Types of Risk Factors (theoretical)

- Genetics (e.g., predisposition to health conditions)
- Demographic characteristics (e.g., age, sex, country of origin)
- Chronic clinical factors (comorbid conditions and severity; physical, mental, cognitive function)
- Acute clinical factors (principal diagnosis, physiologic stability)
- Psychosocial, socioeconomic, and environmental factors (e.g., family, education, occupation, economic resources, health insurance, neighborhood)
- Health-related behaviors and activities (tobacco, diet, physical activity)
- Quality of life, attitudes, and perceptions (health-related quality of life and overall health status; preferences; cultural, religious beliefs, and behavior)


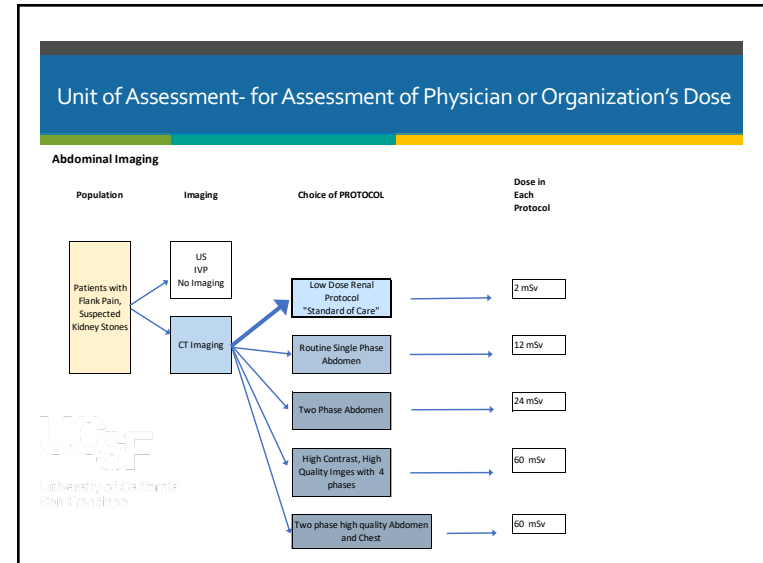
## Risk Factors for CT Dose

- Patient size (average patient diameter across all acquisitions)
- Patient gender/age?
- Anatomic area
- Clinical indications for higher dose imaging
  - There are a few (uncommon) indications for CT that require higher doses

We plan to develop a list of indications where atypically high doses are indicated so that these can be used to adjust the quality metric


### Risk Factors for CT DOSE: Not Included

- Process Factors
  - Machine variables
  - Protocol variables
  - Technical parameters used

### Analytic Approaches

- Multivariable regression
  - Account for clustering of patients within units
  - Hierarchical/mixed models
  - Random effects
  - Shrinkage estimators
- Classification tree approaches
- Machine learning approaches




### Evaluating Risk-Adjustment

National Quality Forum Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement, August 2017

- "an evidence-based risk-adjustment strategy is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care, and has demonstrated adequate discrimination and calibration"

OR

- "rationale/data support no risk adjustment."
- "Risk factors that influence outcomes should not be specified as exclusions."



## Evaluating Risk-Adjustment

- Face/content validity: Does the method adjust for all of the key content domains identified by prior research or expert knowledge?
- Criterion validity: Does the method perform as well as a “gold standard” method based on detailed clinical factors?
- Predictive validity: Does the method have adequate discrimination and calibration in predicting outcomes?
- Construct validity: Does the method behave as expected, based on a previously articulated construct or conceptual framework?
- Attributional validity: Can the method be used to attribute differences in outcomes to differences in processes of care?

## Discussion/Questions

- Do you think that DLP is the right measure of dose? Effective dose?
- Is a judgment of doses outside of range and never doses appropriate?
- Do you think a measure based on anatomy makes sense?
- Do you agree that the key risk factors for risk-adjustment are patient size, anatomic area of imaging, and specific clinical indications for multi-phase or other higher-dose protocols?
- Any specific suggestions regarding how to designate and capture “specific clinical indications for multi-phase or other higher-dose protocols”?
- Do you agree that patient age, gender, and social/economic variables should NOT be considered as risk factors for risk-adjustment?
- How to combine scores across anatomic areas?
- Any suggestions/concerns regarding data capture and validation?

## References

### CMS MAT

- <https://www.emasuretool.cms.gov>

### National Quality Forum

- <http://www.qualityforum.org/Home.aspx>
- [http://www.qualityforum.org/Publications/2014/08/Risk\\_Adjustment\\_for\\_Socioeconomic\\_Status\\_or\\_Other\\_Sociodemographic\\_Factors.aspx](http://www.qualityforum.org/Publications/2014/08/Risk_Adjustment_for_Socioeconomic_Status_or_Other_Sociodemographic_Factors.aspx)

### National Academy of Medicine

- <https://www.nap.edu/read/23635/chapter/1>

### AHA/ACC

- <http://circ.ahajournals.org/content/113/3/456.long>

Iezzoni LI, et al. *Risk Adjustment for Measuring Health Care Outcomes, 4<sup>th</sup> edition*. Health Administration Press: Chicago, 2013.

## Measuring and Quantifying Image Quality

Rebecca Smith-Bindman, MD  
The University of California San Francisco

UCSF

University of California  
San Francisco

## Radiation Dose and Image Quality

- In general, there is an association between dose and image quality
- Radiologists responsibility: to ensure acceptable diagnostic quality
- There is no measure of diagnostic quality
- There is a measure of image "noise" but unclear whether it predicts radiologists' perception of image quality



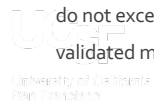
## Proposed Approach To Measure Quality: Satisfaction

- Clinicians interpreting scans are responsible for ensuring the image quality is sufficient for diagnosis
- Clinician satisfaction currently drives practice choices either individually or as a group
- When clinicians are not satisfied with image quality, if it is dose related, their job is to increase the doses used (typical)



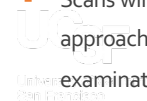
## Automated and Valid Measure of Image Quality

- Goal is to develop an automated and validated measure of image quality
- We propose using radiologist satisfaction with image quality as the referent standard to validate the measure
- Plan to apply the automated and validated measure of image quality in assessing risk-adjusted radiation doses
- Remove from a provider's assessment of radiation doses those scans which do not exceed a threshold of image quality based on the automated and validated measure



## Image Quality Study Design

- We will assemble a large number of CTs with varying doses
- A large sample of radiologists will be asked to rate each case with a gradation score and assess whether adequate for diagnosis
- Paired comparisons of similar anatomical areas using different doses will be ranked relative to one another
- Scans will be then be read by AI software to create an automated approach for characterizing the clinician thresholds (for a diagnostic examination) and preferences and to assess if "noise" can be used as a valid measure of image quality



## Discussion

- Is radiologist satisfaction with image quality a reasonable gold standard?
- Should we have specialists other than radiologists be a part of the gold standard assessment of image quality?
- Is it reasonable to exclude scans that don't meet quality threshold?
- We will be looking for readers from a broad range of practice types to assess the cases we assemble – and are estimating it will take each participant ½ day to review case set. Any ideas for recruitment?

## Summary & 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](http://ctqualitymeasure.ucsf.edu)
- We will be reaching out to you soon to set the date for the next TEP meeting (June?) which will be done as a webinar.
- Reimbursement Request Reminder
- Safe travels!



OPEN ACCESS



# International variation in radiation dose for computed tomography examinations: prospective cohort study

Rebecca Smith-Bindman,<sup>1</sup> Yifei Wang,<sup>2</sup> Philip Chu,<sup>2</sup> Robert Chung,<sup>3</sup> Andrew J Einstein,<sup>4</sup> Jonathan Balcombe,<sup>5</sup> Mary Cocker,<sup>6</sup> Marcos Das,<sup>7,8</sup> Bradley N Delman,<sup>9</sup> Michael Flynn,<sup>10</sup> Robert Gould,<sup>2</sup> Ryan K Lee,<sup>11</sup> Thomas Yellen-Nelson,<sup>12</sup> Sebastian Schindera,<sup>13</sup> Anthony Seibert,<sup>14</sup> Jay Starkey,<sup>15</sup> Saravanabavaan Suntharalingam,<sup>16</sup> Axel Wetter,<sup>17</sup> Joachim E Wildberger,<sup>8</sup> Diana L Miglioretti<sup>18,19</sup>

For numbered affiliations see end of article.

Correspondence to: R Smith-Bindman, School of Medicine, 350 Parnassus Avenue, San Francisco CA 94117, USA; Rebecca.Smith-Bindman@ucsf.edu

Additional material is published online only. To view please visit the journal online.

Cite this as: *BMJ* 2019;364:k4931 <http://dx.doi.org/10.1136/bmj.k4931>

Accepted: 30 October 2018

## ABSTRACT OBJECTIVE

To determine patient, institution, and machine characteristics that contribute to variation in radiation doses used for computed tomography (CT).

## DESIGN

Prospective cohort study.

## SETTING

Data were assembled and analyzed from the University of California San Francisco CT International Dose Registry.

## PARTICIPANTS

Standardized data from over 2.0 million CT examinations of adults who underwent CT between November 2015 and August 2017 from 151 institutions, across seven countries.

## MAIN OUTCOME MEASURES

Mean effective doses and proportions of high dose examinations for abdomen, chest, combined chest and abdomen, and head CT were determined by patient characteristics (sex, age, and size), type of institution (trauma center, care provision 24 hours per day and seven days per week, academic, private), institutional practice volume, machine factors (manufacturer, model), country, and how scanners

were used, before and after adjustment for patient characteristics, using hierarchical linear and logistic regression. High dose examinations were defined as CT scans with doses above the 75th percentile defined during a baseline period.

## RESULTS

The mean effective dose and proportion of high dose examinations varied substantially across institutions. The doses varied modestly (10-30%) by type of institution and machine characteristics after adjusting for patient characteristics. By contrast, even after adjusting for patient characteristics, wide variations in radiation doses across countries persisted, with a fourfold range in mean effective dose for abdomen CT examinations (7.0-25.7 mSv) and a 17-fold range in proportion of high dose examinations (4-69%). Similar variation across countries was observed for chest (mean effective dose 1.7-6.4 mSv, proportion of high dose examinations 1-26%) and combined chest and abdomen CT (10.0-37.9 mSv, 2-78%). Doses for head CT varied less (1.4-1.9 mSv, 8-27%). In multivariable models, the dose variation across countries was primarily attributable to institutional decisions regarding technical parameters (that is, how the scanners were used).

## CONCLUSIONS

CT protocols and radiation doses vary greatly across countries and are primarily attributable to local choices regarding technical parameters, rather than patient, institution, or machine characteristics. These findings suggest that the optimization of doses to a consistent standard should be possible.

## STUDY REGISTRATION

Clinicaltrials.gov NCT03000751.

## Introduction

Radiation doses for computed tomography (CT) vary substantially across patients, institutions, and countries.<sup>1-4</sup> Ionizing radiation is a known carcinogen,<sup>5-10</sup> and CT radiation is associated with increased cancer incidence.<sup>11-14</sup> Therefore, it is important to minimize exposure from medical imaging and reduce unnecessary variation by optimizing examination protocols. Evidence suggests that in many instances, CT doses can be reduced by 50% or more without reducing diagnostic accuracy.<sup>15</sup> However, differences in patient populations and inconsistencies in data collection and analysis have challenged both accurate quantification of dose variations and

## WHAT IS ALREADY KNOWN ON THIS TOPIC

Radiation doses used for computed tomography (CT) are highly variable across patients, institutions, and countries

Lowering patients' exposure to radiation, a known carcinogen, requires an understanding of factors contributing to this variation

Owing to differences in patient populations and inconsistencies in data collection and analysis, accurately quantifying the dose variation or determining whether differences are primarily driven by specific factors has been difficult

## WHAT THIS STUDY ADDS

Variation in doses used for CT scanning across patients is primarily driven by how CT scanners are used, and not to factors related to the patient, institution, or machine

The large variation in doses across countries is mainly attributable to institutional decisions regarding the technical parameters that are used rather than to underlying differences in the patients scanned or the machines used

These findings suggest that optimizing doses to a consistent standard is possible, which will probably require more education of individuals who create protocols for CT, recalibration of image quality expectations targeted to answering the clinical question at hand, and greater sharing of protocols across institutions

determination if variability is driven primarily by patient characteristics (patient size, indications for imaging), institution type (eg, academic, private, trauma facility, or 24 h/day provider of CT), machine factors (eg, machine age, specific manufacturer and model, or use of updated software that permits dose reduction), or regional choices that affect dose optimization or image quality (or both). For example, the European Union collects dose levels in Europe, but differences in definitions and data collection techniques across member states confound the identification of factors that explain the observed variation.<sup>3</sup> To develop optimization activities likely to meaningfully affect CT doses, we must understand the factors that influence them.

Various approaches have been used to optimize CT radiation doses. For example, doses for individual patients can be minimized by refining the scan coverage, altering technical parameters (eg, the machine's x ray tube current) or by techniques such as iterative reconstruction.<sup>16</sup> One widely used approach to standardize radiation doses is the creation of target dose levels<sup>17</sup> or diagnostic reference levels. Levels are defined for groups of patients receiving broadly defined study types with the expectation that under best practices, levels will not be exceeded for average sized patients.<sup>3</sup> Levels are frequently the 75th percentile of the observed dose distribution for a geographical area.<sup>3 18 19</sup> Target doses and diagnostic reference levels are often set locally, on the assumption that dose variation is driven by differences in equipment or patients.<sup>20 21</sup> However, without understanding precise factors behind variation in reported doses, it is unknown whether the setting of target levels locally is needed. For example, if dose variations between localities reflect differences in how CT machines are used rather than differences in underlying patient populations or machine manufacturer or specific models, setting standards and targets locally needlessly complicates optimization activities.

The University of California San Francisco CT International Dose Registry collects data from participating healthcare institutions worldwide that perform CT. In this study, we sought to use registry data to understand factors that influence CT dose, to inform development of dose optimization approaches, and to ultimately investigate the need (or lack of) to localize target levels.

## Methods

### Registry

The University of California San Francisco CT International Dose Registry was created to pool CT dose data from collaborating institutions on 100% of CT scans performed. Radiation and imaging data stored in digital imaging and communications in medicine (DICOM) format are exported onto a local server directly from the CT machines or via the picture archiving and communication systems (PACS) used to review these examinations. Data are stripped of patient

identifying information other than study date and time, and transferred to the dose registry in real time.

### Collaborating institutions

All healthcare institutions that used Radimetrics software (Bayer) in 2015 to monitor medical imaging radiation dose were invited by email to participate in the registry. The registry is a convenience sample and includes data from sites that expressed interest in participating and who were able to complete the logistical requirements of establishing data connections, complete data use agreements, receive institutional review board approval, and agree to complete the study aims. Institutions from seven countries were included.

### Study population

We included diagnostic CT examinations of the abdomen (including any imaging through the abdomen or pelvis), chest, combined chest and abdomen, and head in adults aged 18 years and older between 1 November 2015 and 22 August 2017. Cardiac exams were excluded. The four groups included anatomical areas reflecting about 92% of all diagnostic CT exams during the study period. Spine CT, and exams performed across multiple anatomical areas comprised most of the excluded exams. CT exams for research, radiation oncology guidance, surgical or interventional procedures, or that were part of combined positron emission tomography-CT exams or single photon emission tomography-CT exams were excluded because of expected heterogeneous doses for these study types.

### Variables

Analyses were at the CT examination level, defined as a complete CT study, which could include several CT scans such as with and without intravenous contrast. Statistical analyses were performed separately for each anatomical area.

The analyses adjusted for a range of variables that we hypothesized might be associated with radiation doses. Patient characteristics extracted for each examination were age, sex, and size. Sex and size might be factors because the larger a patient, the greater the doses of radiation that must be used to generate an image equal in quality compared with doses needed in a smaller patient. Patient diameter, the proxy for size, was calculated as the average of the water equivalent diameter from each CT acquisition over the entire imaging range.<sup>22</sup> Age could be important because institutions might lower doses for younger patients. Scanning indication could influence the radiation doses needed, because greater imaging quality might be needed for particular clinical questions, but was known for only a subset of examinations and could not be used to adjust for possible case mix differences across institutions. Instead, differences in dose were assessed by examination time of day, because those taking place at night (between 10 pm and 5 am) should primarily reflect acute imaging.



The type of institution might reflect the types and complexity of the patients seen at that institution, and therefore could predict doses use for imaging. The type of institution was extracted from a survey completed by each institution, which also included trauma center status, whether imaging was provided 24 h/day and 7 days/week (24/7), and self identification as an academic or private institution. Average machine and institutional practice volumes could be associated with dose based on volume-outcome associations described in many other areas of medical practice. Volumes were calculated on the basis of all CT examinations performed on weekdays.

Machine characteristics included manufacturer and model. These factors could be associated with dose because the technical capacity of machines have changed over time. Further, newer machines sometimes offer dose reduction software.

The technical parameters<sup>23</sup> (including x ray tube parameters (kV and mAs), acquisition parameters (pitch and acquired slice thickness), scan length, and number of scans per examination) and CT dose metric parameters (volumetric CT dose index and dose length product) were stored for each CT scan. The volumetric CT dose index reflects the average dose value within a section (slice) of the scanned volume, whereas the dose length product reflects the total emitted radiation imparted to the patient (defined as volumetric CT dose index×scan length). Effective dose, which is proportional to total imparted radiation, is an estimate that accounts for estimated future cancer risk based on irradiated organs. If multiple CT scans were performed during an examination, a weighted average of the technical parameters was used. The number of CT scans did not include localizers or contrast bolus timing scans, although the radiation from the contrast bolus was included in the dose calculations. Effective dose was calculated for each examination by use of the dose length product and published conversion factors.<sup>22</sup>

### Statistical analysis

We calculated descriptive statistics for CT scans by patient, institution, practice volume, machine, and country. The dose metrics of interest were effective dose (mean, standard deviation, median, and interquartile range) and the prevalence of high dose studies, defined as studies whose effective dose exceeded the 75th percentile during the first six months of study (1 November 2015 to 30 April 2016). Variation by less than 50% was considered modest variation.

#### *Variation in radiation doses across institutions and countries and by predictive variables*

We calculated the distribution in radiation doses for abdominal CT by institution and for all anatomical areas by country after adjusting for patient characteristics. The mean effective dose (and standard deviation) and proportion of high dose studies by institution, practice volumes, machine, and country are shown unadjusted and adjusted for patient characteristics to

show how the doses vary by these factors. The adjusted effective dose and adjusted prevalence of high dose examinations were estimated by log-linear regression and logistic regression, respectively.

#### *Multivariate analysis to identify factors that are associated with dose*

To understand the contribution of patient, institution, practice volume, machine, country, and technical factors to the variation of effective dose between machines and countries, we fit a series of log-linear mixed effects models predicting effective dose. We graphically show a series of models displaying how the doses vary across the 290 machines included in the University of California San Francisco CT International Dose Registry. The first model contained no predictors except for a random effect accounting for clustering by machine and showed the average dose for each machine for abdomen CT. The second model added patient characteristics, showing the average dose for each machine after accounting for patient characteristics. Additional predictors were subsequently added to each model so that the final fully adjusted model included all of the predictor variables and log-transformed technical parameters (kVp, mAs, pitch, number of CT scans, scan length, and slice thickness).

To quantify variation in dose across the different machines and the reduction in variation after accounting for each predictor variable, we randomly sampled random effects for 10 000 pairs of machines from the estimated distribution and computed the ratio of the estimates for each pair. We presented the median, 75th percentile, and 95th percentile of these 10 000 bootstrapped ratios as relative doses. The 95% in the relative dose was used to quantify the variation between two randomly selected machines. The larger the ratio between two randomly selected machines, the greater the variation in dose across machines in the registry. A sharp decline in the variability of relative dose among machines and countries after a predictor was added indicates that the predictor accounted for a large amount of the variation. We also computed the expected mean effective dose in each country for each model, also shown in the figures.

The magnitude of the associations between dose and patient, institution, practice volume, machine, and country are also shown. The effect sizes were defined as the multiplicative change in dose for each standard deviation change in the associated covariate; the larger the estimated effect, the more important the variable. Lastly, we showed the effect of the inclusion of technical factors on the observed variation in dose across countries.

#### *Sensitivity analysis*

To remove the potential effect of case mix (that is, different reasons why patients underwent CT), we illustrated the variation in effective doses for one specific imaging indication: suspected pulmonary embolism. We also did a subanalysis for this indication using

data from one machine model (Somatom Definition AS, Siemens Healthineers) to illustrate representative differences in technical parameters chosen by institutions for this indication and on this scanner. The main analyses were repeated using volumetric CT dose index as the outcome, and restricting to single phase CT examinations. We compared doses in the registry to published benchmarks, extracting combined data across age, sex, and size categories.<sup>3 4 24-28</sup> We abstracted effective doses from published reports, or calculated these from dose length product values using published conversion factors.<sup>22</sup>

### Patient and public involvement

Patients were included as stakeholders in the project and contributed as part of in-person meetings and webinars to help guide the project direction.

### Results

During the study period, 151 institutions from seven countries (Switzerland, Netherlands, Germany, United Kingdom, United States, Israel, and Japan) performed just over 2.0 million CT scans on about 1.7 million adults. Examinations were performed on 290 machines from four machine manufacturers and 49 machine models (table 1). Of the included CT scans, about one third were abdomen (n=724 627, 36%), one third head (682 701, 34%), and one third chest (n=515 007, 26%) or combined chest and abdomen (n=83 124, 4%). Numbers of examinations by patient, institution, practice volumes, machine, and country are shown in table 1.

### Factors associated with CT dose

After accounting for patient characteristics, the median effective doses for abdominal CT across institutions ranged from 5 to 32 mSv (fig 1). The distribution in effective dose by country for each anatomical area (fig 2) demonstrated the greatest variation in median doses for abdomen and combined chest and abdomen CT.

The mean effective dose and proportion of high dose examinations by institution, practice volume, machine, and country after adjustment for patient characteristics are shown in table 2 (corresponding unadjusted values in table S1). The adjusted mean effective doses varied modestly (typically by 10-20%; occasionally by up to 40%) by institutional characteristics and practice volumes. For example, mean effective dose for abdomen CTs was 12.1 mSv at trauma centers compared with 12.5 mSv at a non-trauma center (relative dose 0.97 mSv). The adjusted mean effective dose also varied modestly by manufacturer. In contrast with other factors considered, mean doses varied widely across countries, particularly for abdomen, chest, and combined chest and abdomen CT. Mean effective dose for abdomen CT ranged fourfold across countries (7.0 mSv in the Netherlands to 25.7 mSv in Japan), and the relative proportion of high dose studies varied more than 17-fold (4-69%). Variation was similar for effective dose for chest and combined chest and abdomen CT, with fourfold differences in mean

dose across countries. Dose variation in head CT was more modest, with a relative mean dose between the highest dose and lowest dose countries of 1.3 (range 1.4-1.9 mSv).

In the subanalysis of patients who underwent CT for suspected pulmonary embolism scans, the variation in effective dose was substantial across countries (table 2). Mean effective dose ranged from 2.2 mSv to 33.2 mSv, and the relative proportion of high dose studies ranged from 0% to 89% (table 2). Variation in doses across countries were generally greater, rather than reduced, after adjustment for patient factors (table 2v table S1).

### Factors explaining CT dose variation

The multivariable analyses highlighted that most factors considered (patient, practice volumes, machine factors) had only a small effect on the dose variation across different machines in the registry or between the different countries (fig 3, figures S1a-d). For abdomen CT examinations, the unadjusted 95th percentile of relative dose was 2.65, and the mean effective dose ranged from 7.3 mSv in Switzerland and Germany to 15.7 mSv in Israel, reflecting large variation between machines and countries. Subsequent adjustment for patient factors had no effect on relative dose (2.65) and resulted in a small increase (rather than decrease) in the differences in mean dose by country (range of 8.1 to 22.9 mSv). This suggests that despite the effective dose being highly correlated with patient characteristics (specifically patient size; table S1, table 3), patient size does little to explain the variability across machines or countries (fig 3, model 2). Sequential adjustment for institution and machine characteristics also had little effect on relative dose, although these adjustments slightly attenuated dose variation across countries (fig 3, models 3-5).

The final adjustment including the specific technical factors substantially reduced or eliminated large differences in relative dose between machines and reduced or eliminated the large differences across countries. In model 6 (fig 3), the technical factors explained nearly all dose variation (95th percentile relative dose 1.42), and average doses among countries were similar after this final adjustment. Results were similar for the chest, combined chest and abdomen, and the subanalysis for pulmonary embolisms (figures S1a, b, and d). We saw large differences in the relative doses across machines and countries that were reduced or eliminated only after inclusion of the technical parameters. We found less variation in doses for head CT even without adjustment (figures S1c).

### Effect of each predictive factor in multivariable models

Table 3 shows the magnitude of the association between effective dose and patient, institution, practice volume, machine, and country characteristics, based on the multivariate results. Patient size was a significant predictor of mean dose in the fully adjusted multivariable models with large effect sizes; for each

**Table 1 | Characteristics of computed tomography (CT) examinations, institutions, and machines included in analyses**

	CT examinations (n=2 005 459)	Institutions (n=151)	Machines (n=290)
<b>Anatomical area</b>			
Abdomen	724 627 (36)	—	—
Chest	515 007 (26)	—	—
Combined abdomen and chest	83 124 (4)	—	—
Head	682 701 (34)	—	—
<b>Patient characteristics</b>			
Age (years)			
18-29	179 889 (9)	—	—
30-39	177 964 (9)	—	—
40-49	251 366 (13)	—	—
50-59	385 556 (19)	—	—
60-69	439 115 (22)	—	—
70-79	337 904 (17)	—	—
≥80	233 665 (12)	—	—
Sex			
Female	1 056 929 (53)	—	—
Male	948 530 (47)	—	—
Size*			
Smallest	369 967 (20)	—	—
Small	369 938 (20)	—	—
Medium	369 939 (20)	—	—
Large	369 925 (20)	—	—
Largest	369 934 (20)	—	—
<b>Time of scanning</b>			
Daytime	1 783 910 (89)	—	—
Night time	221 549 (11)	—	—
<b>Institutional characteristics†</b>			
Trauma center	790 912 (39)	25 (17)	—
Institution scans 24/7	1 605 234 (80)	64 (42)	—
Academic	967 012 (48)	41 (27)	—
Private	204 962 (10)	12 (8)	—
Machine daily volume			
1-6	112 847 (6)	—	98 (34)
>6-9	108 127 (5)	—	33 (11)
>9-12	157 327 (8)	—	34 (12)
>12-20	583 851 (29)	—	71 (24)
>20-60	1 043 307 (52)	—	54 (19)
Facility daily volume			
1-6	77 001 (4)	58 (38)	—
>6-9	40 386 (2)	13 (9)	—
>9-20	113 142 (6)	20 (13)	—
>20-50	583 408 (29)	32 (21)	—
>50-600	1 191 522 (59)	28 (19)	—
<b>Manufacturer‡</b>			
GE	873 965 (44)	92 (61)	147 (51)
Philips	381 917 (19)	28 (19)	44 (15)
Siemens	552 222 (28)	43 (28)	78 (27)
Toshiba	197 355 (10)	16 (11)	21 (7)
<b>Country</b>			
Switzerland	37 119 (2)	2 (1)	4 (1)
Netherlands	38 034 (2)	1 (1)	5 (2)
Germany	45 599 (2)	4 (3)	7 (2)
UK	61 888 (3)	3 (2)	9 (3)
USA	1 627 834 (81)	133 (88)	253 (87)
Israel	133 031 (7)	5 (3)	5 (2)
Japan	61 954 (3)	3 (2)	7 (2)

Data are number (%). Percentages might not add to 100% owing to rounding. 24/7=24 h/day, 7 days/week.

\*Size could not be calculated for 8% of scans. Based on average scan diameter, abdominal size categories were smallest (<26.6 cm), small (26.6-29.1 cm), medium (>29.1-31.3 cm), large (>31.3-34.2 cm), and largest (>34.2 cm); chest size categories were <25.7 cm, 25.7-28.2 cm, >28.2-30.1 cm, >30.1-32.3 cm, and >32.3 cm, respectively; combined chest and abdomen size categories were <26.2 cm, 26.2-28.6 cm, >28.6-30.6 cm, >30.6-33.1 cm, and >33.1 cm, respectively; and head size categories were <16.4 cm, 16.4-17.0 cm, >17.0-17.4 cm, >17.4-17.9 cm, and >17.9 cm, respectively.

†Institutional characteristics were not mutually exclusive. Institutions can report 0-4 institutional characteristics therefore the total number of institutions does not sum to 151.

‡Machine characteristics were not mutually exclusive. Institutions could have more than one manufacturer's machines and therefore the total number of institutions does not add up to 151.

standard deviation increase in patient size, mean dose increased by 36-47% for chest, abdomen, and combined chest and abdomen CT, and increased by

19% for head CT. We saw only small differences in dose by institutional characteristics; mean doses were slightly but significantly higher for chest and head CT

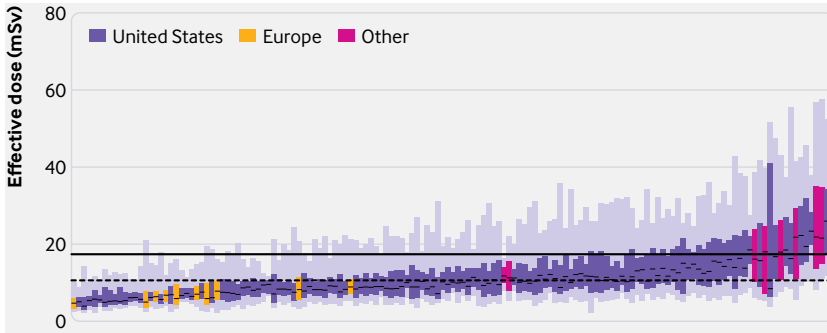


Fig 1 | Distribution in effective radiation dose by institution for abdomen CT, after adjustment for patient characteristics. Each column signifies one institution, ranked by mean effective dose. Light purple columns=5th and 95th percentiles of effective dose; dark purple, pink, and yellow column sections=25th and 75th percentiles of effective dose; lines=medians; horizontal solid line and dashed line=benchmark and target doses for abdomen, defined as the 75th and 50th percentiles of dose for all abdominal scans performed before 30 April 2016

at trauma centers, and head CT doses were higher at private institutions and those with scanning provided 24 h/day and 7 days/week. Most other institutional characteristics were not significantly associated with mean dose.

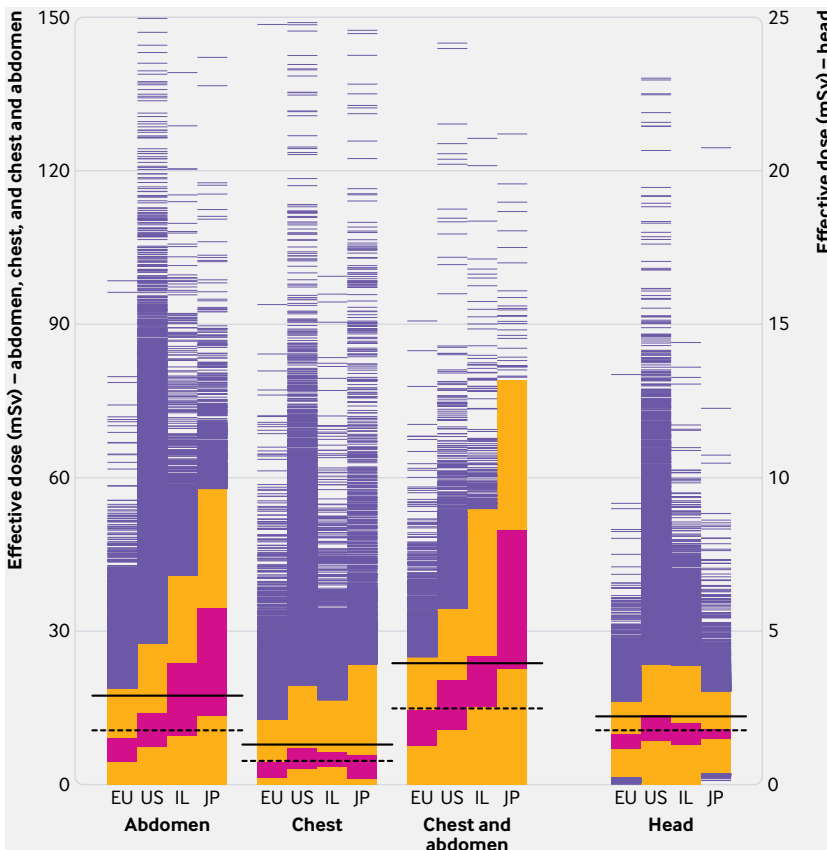


Fig 2 | Distribution of effective radiation dose by country and scan region, after adjustment for patient characteristics. Each column signifies one country or the European Union, with one horizontal line denoting each observation within the country. IL=Israel; JP=Japan; pink lines=within 25th and 75th percentiles; orange lines=two standard deviations from the mean; purple lines=outliers; horizontal solid line and dashed line=benchmark and target doses for each anatomical area, defined as the 75th and 50th percentiles of dose for all scans of that type performed before 30 April 2016

Abdomen, chest, and combined chest and abdomen CT doses did not differ significantly by manufacturer, although machines from Canon Medical Systems (Toshiba) were associated with modestly increased doses for head scans and machines from Siemens were associated with modestly reduced doses for suspected pulmonary embolism scans.

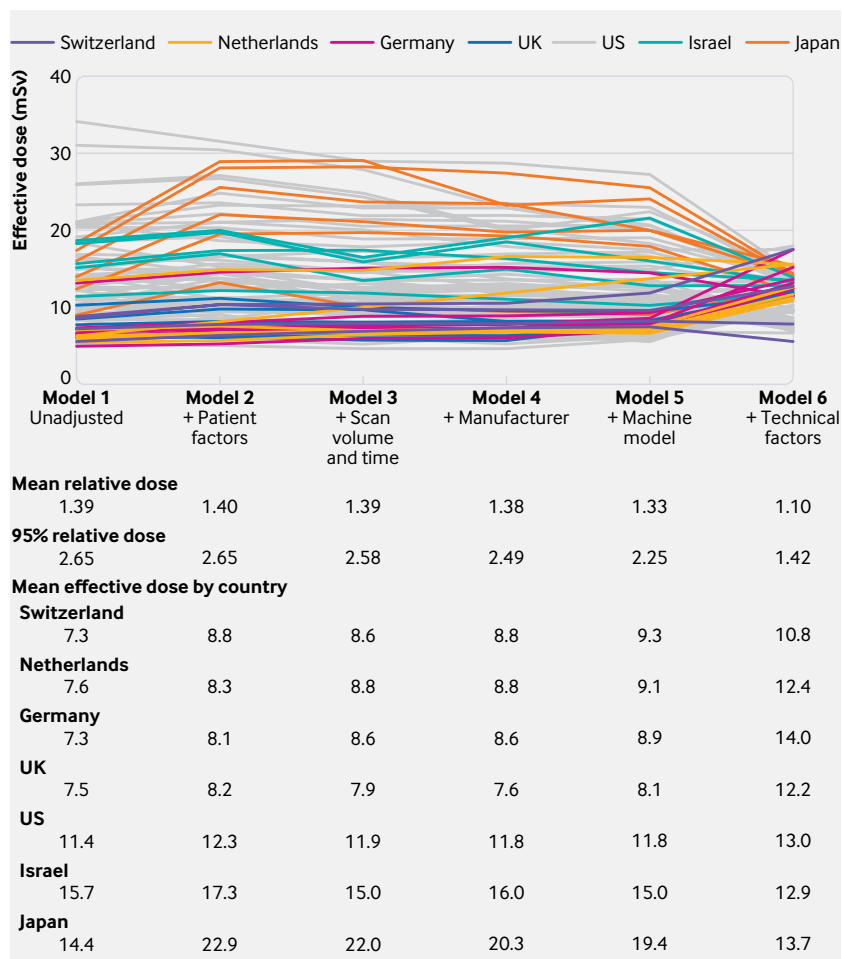
Although most predictive factors had relatively small effects on dose, large differences in dose persisted among countries for abdomen, chest, and combined chest and abdomen CT and for pulmonary embolism CT. The differences among countries was largest for suspected pulmonary embolism CT. We saw no significant differences in mean effective dose by country for head CT after accounting for other factors, suggesting a greater degree of protocol standardization for head imaging. The addition of specific scan parameters to the multivariable models (eg, x ray tube and acquisition parameters; table 4) attenuated or eliminated the differences between countries. This suggests that the differences among countries in the mean doses were not attributable to patient, institution, or machine factors (which all had small effects in table 3), but to the technical parameters.

**Effect of technical parameters on CT dose for one indication**

Subanalysis of one specific indication (suspected pulmonary embolism) highlighted differences in technical parameters chosen by different institutions using the same machine make and model that resulted in the large observed differences in effective dose (table 5). We found a greater than 15-fold difference in mean effective doses between the institutions with the highest tenth versus lowest tenth in dose (mean effective dose 31.0 v 2.0 mSv). Accounting for patient size resulted in a slightly greater difference between the highest tenth and lowest tenth in protocols (mean effective dose 27.5 v 1.6 mSv). Compared with institutions in the highest tenth of effective dose, those in the lowest tenth had a lower adjusted CT dose index (3.8 v 15.9 mGy), tube potential (102 v 119 kVp), tube current (113 v 188 mAs), slice thickness (1.9 v 3.9), number of CT scans per examination (1.0 v 2.7), and had higher pitch (1.2 v 0.8). Thus, as shown for the analyses at the anatomical area level, dose variations in pulmonary embolism CT, even when restricted to the same machine model, were explained by differences in technical parameters rather than patient characteristics.

**Sensitivity analyses**

Results were similar when we used the volumetric CT dose index as the outcome dose metric (results not shown), and when limited to single CT scan examinations (results not shown). The unadjusted doses in the University of California San Francisco CT International Dose Registry were similar to data in the literature (table S2). For example, the published benchmark abdomen dose in Switzerland is 10 mSv, and is 10.3 mSv (95% confidence interval 9.9 to 10.6) in the University of California San Francisco registry.



**Fig 3 | Mean effective radiation dose by machine in abdomen computed tomography (CT) scans, with different levels of adjustment. Model 1=unadjusted results; subsequent adjustments included: model 2, patient characteristics; model 3, institutional characteristics; model 4, machine manufacturer; model 5, machine model; and model 6, technical parameters. Rows=mean relative effective dose and 95th percentile of relative dose for two randomly chosen machines, with mean dose by country at the corresponding level of adjustment within multivariable model. Lines=dose for single machines. For abdomen examinations in model 1, 95th percentile of relative dose was 2.65 and mean effective dose ranged from 7.3 mSv (Switzerland) to 15.7 mSv (Israel)**

## Discussion

### Principal findings

Using an international registry of CT doses, we found large variation in doses across the included countries even after accounting for patient characteristics, numerous institutional characteristics, average machine and institutional practice volumes, and machine factors. The variation in dose persisted when we limited our analysis to one clinical question where the radiation dose requirements would have been the same across the included countries. To better understand reasons for variability between countries, we included technical parameters in multivariable models, the inclusion of which attenuated or eliminated these intercountry differences. These technical factors reflect an intermediate step in which clinical staff make changes that alter dose levels and hence can increase dose variation. Thus, CT dose differences

among countries were not attributable to patient or institutional characteristics or machine manufacturer or model, but were almost entirely associated with how institutions used the machines, presumably reflecting different decisions about technical parameters to yield optimal CT images.

### Comparison with other studies

International efforts to improve radiation safety for medical imaging vary considerably across the included countries, so it is not surprising that we found CT dose differences.<sup>3 24 29 30-36</sup> For example, the EU adopted legislation with mandatory directives about medical radiation exposure from CT where member states are required to establish and promote diagnostic reference levels for CT.<sup>31-34</sup> The US has educational efforts by professional societies, such as the American College of Radiology,<sup>29</sup> and recommendations from government agencies ask institutions to assess their CT doses.<sup>37</sup> However, no US organization is tasked with collecting, monitoring, or reporting CT radiation doses, and no national US legislation sets CT dose standards.<sup>38</sup> Only two US states (California and Texas) have legislation related to CT scanning. In Japan, a consortium group has proposed national diagnostic reference levels, but these have not been widely adopted.<sup>24</sup> In Israel, a few institutions have established diagnostic reference levels, but adoption is not uniform, although currently the ministry of health is considering establishment of a national dose registry.

One approach to optimizing CT doses has been setting benchmarks for optimum target doses. Challenges in setting benchmarks include difficulty in deciding how they should be established—for example, by anatomical area, clinical indication, or protocol<sup>3 24 25 29</sup>—and difficulty in collecting sufficient data to reflect actual practice. The ideal approach to creating benchmarks would likely reflect a compromise, with target dose levels based on broad anatomical areas, supplemented by additional target dose levels for specific clinical indications that have unique contrast and spatial resolution needs not captured by these broad anatomic areas.<sup>39</sup>

Our analysis used broad anatomical areas and considered the entire CT examination for several reasons. Firstly, having fewer categories simplified comparisons across institutions. Secondly, institutional decisions to use particular approaches (eg, single or multiple CT scan examinations) affects the doses delivered, and to stratify results within these narrow categories would mask the primary contributor to dose variation. For example, if an institution routinely uses multiple CT scan examinations to assess pulmonary embolism, this will result in higher radiation doses to their patients compared with facilities that routinely use just one CT scan examination. Assessment of doses within narrowly defined categories of single or multiple phase would mask differences and would not enable identification of institutions whose doses are outside practice norms because they use multiple scan examinations. Furthermore, there are few evidence

**Table 2 | Computed tomography (CT) effective radiation doses and proportion of high dose examinations by institution and machine characteristics, adjusted for patient age, sex, and size**

	Effective dose in CT scan (mSv), by anatomical area									
	Abdomen		Chest		Combined chest and abdomen		Head		Suspected pulmonary embolism	
	Mean (SD)	High dose (%)	Mean (SD)	High dose (%)	Mean (SD)	High dose (%)	Mean (SD)	High dose (%)	Mean (SD)	High dose (%)
<b>Institutional characteristics</b>										
Trauma center, yes	12.1 (8.6)	22	6.9 (7.2)	30	16.6 (10.8)	22	2.0 (1.0)	27	6.6 (6.1)	25
Trauma center, no	12.5 (8.7)	25	5.4 (6.1)	20	15.3 (8.6)	18	1.8 (0.9)	22	6.4 (4.4)	25
Scans 24/7, yes	11.8 (8.3)	20	6.3 (6.6)	26	15.0 (10.1)	19	1.9 (0.9)	25	6.3 (5.2)	24
Scans 24/7, no	14.5 (9.7)	36	5.3 (6.3)	17	16.7 (8.1)	21	1.5 (1.1)	17	8.4 (6.1)	40
Academic, yes	12.2 (8.3)	23	6.4 (7.0)	26	16.4 (9.1)	21	1.9 (1.0)	24	6.3 (4.2)	23
Academic, no	12.4 (8.9)	24	5.6 (6.1)	21	14.5 (9.7)	17	1.8 (0.9)	24	6.8 (6.4)	27
Private, yes	16.2 (10.2)	42	4.6 (5.3)	31	23.2 (14.6)	39	1.9 (1.0)	21	6.5 (5.4)	25
Private, no	11.9 (8.3)	21	6.2 (6.7)	23	15.4 (9.0)	19	1.9 (1.0)	25	7.0 (3.8)	26
<b>Machine daily volume</b>										
1-6	12.2 (8.8)	25	5.3 (6.8)	17	14.0 (7.4)	9	1.5 (1.3)	17	6.7 (5.3)	27
>6-9	11.4 (7.4)	22	5.2 (4.8)	21	13.6 (9.3)	13	1.9 (1.0)	27	7.1 (4.7)	37
>9-12	11.3 (7.9)	21	6.7 (8.5)	23	14.6 (8.3)	17	1.8 (0.8)	17	6.3 (4.6)	20
>12-20	13.0 (9.0)	28	5.9 (7.1)	24	15.0 (9.4)	16	1.9 (0.9)	23	7.3 (7.1)	30
>20-60	12.2 (8.7)	22	6.1 (5.7)	25	16.5 (9.5)	23	1.9 (1.0)	26	6.1 (4.4)	22
<b>Facility daily volume</b>										
1-6	12.3 (8.9)	23	6.3 (6.7)	26	15.9 (9.3)	21	1.9 (1.0)	27	6.3 (5.6)	23
>6-9	12.0 (8.6)	25	5.2 (6.6)	17	14.1 (9.2)	13	1.4 (1.0)	14	7.4 (5.8)	30
>9-20	11.7 (8.6)	24	4.9 (4.9)	20	15.8 (10.1)	19	1.8 (1.0)	23	6.2 (3.9)	27
>20-50	10.5 (8.1)	17	6.2 (8.6)	19	10.3 (5.9)	6	1.7 (1.1)	22	5.0 (3.7)	12
>50-600	12.7 (8.2)	26	5.6 (5.9)	21	16.0 (10.0)	17	1.8 (0.9)	19	7.3 (4.8)	32
<b>Manufacturer</b>										
GE	12.7 (8.7)	26	5.4 (5.5)	19	17.0 (8.6)	23	1.8 (1.0)	19	7.3 (5.1)	31
Philips	12.1 (8.9)	24	5.7 (5.3)	22	14.3 (10.3)	16	1.9 (0.9)	29	6.2 (4.6)	23
Siemens	12.1 (8.3)	22	6.4 (7.7)	26	12.0 (8.3)	11	1.7 (0.8)	17	5.4 (4.5)	16
Toshiba	11.8 (9.1)	17	8.3 (9.0)	42	18.5 (14.2)	26	2.3 (1.0)	49	7.4 (7.4)	33
<b>Country</b>										
Switzerland	8.3 (4.4)	7	1.7 (1.7)	1	13.3 (7.3)	11	1.5 (0.5)	8	2.2 (1.1)	0
Germany	8.0 (7.1)	9	3.4 (5.3)	11	10.0 (8.0)	9	1.4 (0.7)	8	2.4 (2.6)	3
Netherlands	7.0 (4.1)	4	4.7 (5.4)	14	11.8 (4.1)	2	1.4 (0.6)	15	2.2 (1.8)	1
UK	7.9 (6.0)	9	4.1 (3.3)	10	12.5 (5.2)	6	1.5 (0.6)	11	5.5 (4.1)	19
US	12.0 (7.9)	22	6.4 (6.6)	26	16.7 (8.9)	23	1.9 (1.0)	27	6.7 (4.7)	27
Israel	18.4 (11.3)	54	5.8 (5.4)	17	23.7 (15.1)	39	1.8 (1.1)	17	6.2 (5.3)	11
Japan	25.7 (16.1)	69	5.0 (9.3)	20	37.9 (20.6)	78	1.7 (0.7)	11	33.2 (25.0)	89

24/7=24 h/day, 7 days/week; mSv=millisievert; SD=standard deviation.

based guidelines for choosing different approaches to scanning most clinical indications (that is, little data are available to link dose requirements to specific indications or diagnostic accuracy), and thus the use of broad anatomical areas seems most useful. The primary disadvantage of our approach was that grouping of exams by anatomical area precluded accounting for variation in case mix for the few clinical indications that might have unique spatial resolution needs. Inclusion of institutional characteristics in our analyses probably minimized differences by institutions.

A widely held belief is that CT dose standards and benchmarks must be created individually by each hospital,<sup>30</sup> region, or country,<sup>3 40</sup> a tailored approach necessitated by variation in achievable targets that are largely determined by the specific types and models of CT machines used and characteristics of the local patient populations.<sup>20 21</sup> In the EU, large differences in doses across included nations have been reported, which has contributed to the widely held belief that country specific benchmarks must be created.<sup>3 40</sup>

We did not find that dose variation is largely attributable to variation in patient requirements, clinical circumstances, or machine factors. We found that variations persist even when we limited analysis to patients assessed for a specific clinical condition, adjusted for patient factors, and restricted analysis to patients scanned on a single instrument model. Machine make and model are only modest predictors of dose and that substantial variance for each device type. The largest driver of dose variation was how providers or clinical staff chose to set the machine technical parameters, not the machine. Our results suggest that dose variation and outlier doses could be diminished without new equipment, which would require the creation of consistent standards, and to create those standards, the collection of standardized data across all countries similar to the data we include.

Our findings suggest that work is needed to understand why doses vary among users. The variation in radiation dose across countries will reflect the variation in image quality, and user's willingness to accept noisier images. We need to determine

**Table 3 | Multivariable regression results for change in mean computed tomography (CT) effective dose per standard deviation for continuous variables and relative dose for categorical variables. SD=standard deviation; asterisks=P<0.05**

	Effect size (95% CI), by anatomical area of CT scan				
	Abdomen	Chest	Combined chest and abdomen	Head	Suspected pulmonary embolism
<b>Patient characteristics</b>					
Age, years (per SD)	1.01 (1.00 to 1.01)*	0.98 (0.97 to 0.98)*	0.95 (0.95 to 0.96)*	1.04 (1.03 to 1.04)*	0.99 (0.99 to 0.99)*
Sex (male v female)	1.04 (1.04 to 1.05)*	1.13 (1.12 to 1.13)*	1.06 (1.06 to 1.07)*	0.96 (0.96 to 0.97)*	1.09 (1.09 to 1.10)*
Size (per SD)	1.47 (1.46 to 1.47)*	1.36 (1.35 to 1.36)*	1.43 (1.42 to 1.43)*	1.19 (1.18 to 1.19)*	1.41 (1.41 to 1.42)*
Night time scan	0.98 (0.97 to 0.98)*	1.06 (1.06 to 1.07)*	1.06 (1.04 to 1.07)*	1.04 (1.03 to 1.04)*	1.02 (1.01 to 1.03)*
<b>Institutional characteristics</b>					
Trauma center	0.99 (0.90 to 1.09)	1.23 (1.07 to 1.42)*	1.08 (0.93 to 1.25)	1.13 (1.03 to 1.25)*	1.10 (0.96 to 1.26)
Institution scans 24/7	0.87 (0.79 to 0.96)*	1.13 (0.97 to 1.32)	0.97 (0.82 to 1.15)	1.25 (1.13 to 1.39)*	0.93 (0.80 to 1.08)
Academic	0.98 (0.90 to 1.07)	1.10 (0.96 to 1.26)	1.15 (0.98 to 1.35)	1.09 (0.99 to 1.2)	0.99 (0.87 to 1.13)
Private	0.99 (0.81 to 1.21)	0.77 (0.57 to 1.03)	1.13 (0.84 to 1.54)	1.27 (1.01 to 1.59)*	1.11 (0.79 to 1.54)
<b>Volume</b>					
Machine	0.92 (0.87 to 0.98)*	1.03 (0.95 to 1.12)	1.00 (0.93 to 1.09)	1.04 (0.98 to 1.11)	0.97 (0.90 to 1.05)
Facility	1.08 (1.03 to 1.13)*	1.36 (0.92 to 1.06)	0.98 (0.91 to 1.05)	1.01 (0.97 to 1.06)	1.05 (0.99 to 1.12)
<b>Manufacturer</b>					
GE	Reference	Reference	Reference	Reference	Reference
Philips	0.87 (0.74 to 1.01)	0.79 (0.61 to 1.03)	0.85 (0.68 to 1.06)	1.02 (0.86 to 1.21)*	0.89 (0.71 to 1.13)*
Siemens	1.05 (0.92 to 1.20)	0.99 (0.79 to 1.23)	0.90 (0.72 to 1.12)	1.08 (0.94 to 1.25)*	0.75 (0.62 to 0.91)*
Toshiba	1.13 (0.92 to 1.37)	1.21 (0.88 to 1.67)	1.15 (0.87 to 1.53)	1.51 (1.22 to 1.87)*	1.08 (0.82 to 1.41)*
<b>Country</b>					
Germany	Reference	Reference	Reference	Reference	Reference
Netherlands	0.99 (0.71 to 1.39)*	0.71 (0.43 to 1.19)*	1.15 (0.68 to 1.95)*	0.96 (0.66 to 1.39)	1.18 (0.69 to 2.02)*
Switzerland	1.11 (0.77 to 1.61)*	0.38 (0.22 to 0.67)*	1.11 (0.65 to 1.91)*	1.06 (0.71 to 1.58)	1.07 (0.62 to 1.84)*
UK	0.98 (0.72 to 1.33)*	0.82 (0.52 to 1.32)*	1.02 (0.62 to 1.67)*	1.05 (0.74 to 1.48)	1.54 (0.96 to 2.45)*
USA	1.48 (1.17 to 1.86)*	1.07 (0.75 to 1.52)*	1.25 (0.81 to 1.92)*	1.22 (0.93 to 1.58)	2.31 (1.6 to 3.33)*
Israel	2.69 (1.76 to 4.11)*	1.77 (0.93 to 3.37)*	2.28 (1.18 to 4.41)*	1.1 (0.68 to 1.75)	1.86 (0.97 to 3.55)*
Japan	2.73 (1.95 to 3.83)*	0.92 (0.56 to 1.52)*	2.83 (1.61 to 5.00)*	1.18 (0.80 to 1.74)	6.49 (3.72 to 11.35)*

how institutions set up their CT scanning protocols and how to develop consensus about balancing image quality with diagnostic accuracy. Education and collaboration in setting standards could offer the largest effect on optimizing dose.<sup>41 42</sup> Choosing appropriate CT protocol parameters might be less complex than widely believed. Institutions with lower doses shared scanning approaches. These institutions tended to limit the number of protocols, with each relying on the minimum dose required to answer the clinical question. They used multiple CT scanning infrequently, had lower settings for tube current and tube potential, and used higher pitch for most, if not all, imaging indications. The key to protocol optimization is updating physician awareness and

recalibrating expectations about what constitutes a diagnostic CT scan based on better alignment of CT protocol parameter choices with diagnostic image quality requirements.

#### Strengths and limitations

The main advantages of our study are its large size and detailed and standardized collection of data that allowed us to determine potential contributors to radiation dose. This study also had several limitations. The number of participating institutions for each country outside the US was limited so our data cannot be considered representative of any country as a whole. However, country specific doses in our registry are similar to those reported elsewhere,<sup>3 24 25 40</sup> suggesting our estimates are

**Table 4 | Multivariable linear regression results for relative computed tomography (CT) effective dose by country, accounting for all patient, institute, and machine characteristics with and without technical factors. Asterisks=P<0.05**

	Effect size (95% CI), by anatomical area of CT scan (with and without technical factors)									
	Abdomen		Chest		Combined chest and abdomen		Head		Suspected pulmonary embolism	
	Without	With	Without	With	Without	With	Without	With	Without	With
Germany	Reference		Reference		Reference		Reference		Reference	
Netherlands	0.99 (0.71 to 1.39)*	0.88 (0.74 to 1.04)*	0.71 (0.43 to 1.19)*	0.91 (0.72 to 1.15)*	1.15 (0.68 to 1.95)*	1.09 (0.87 to 1.36)	0.96 (0.66 to 1.39)	1.10 (0.92 to 1.30)*	1.18 (0.69 to 2.02)*	1.35 (1.01 to 1.81)*
Switzerland	1.11 (0.77 to 1.61)*	0.64 (0.53 to 0.78)*	0.38 (0.22 to 0.67)*	0.73 (0.56 to 0.94)*	1.11 (0.65 to 1.91)*	0.86 (0.68 to 1.09)	1.06 (0.71 to 1.58)	1.03 (0.85 to 1.25)*	1.07 (0.62 to 1.84)*	1.15 (0.85 to 1.56)*
UK	0.98 (0.72 to 1.33)*	0.84 (0.71 to 0.99)*	0.82 (0.52 to 1.32)*	0.91 (0.73 to 1.14)*	1.02 (0.62 to 1.67)*	1.02 (0.83 to 1.27)	1.05 (0.74 to 1.48)	1.26 (1.06 to 1.49)*	1.54 (0.96 to 2.45)*	1.49 (1.14 to 1.93)*
US	1.48 (1.17 to 1.86)*	0.92 (0.81 to 1.04)*	1.07 (0.75 to 1.52)*	0.92 (0.78 to 1.09)*	1.25 (0.81 to 1.92)*	1.02 (0.85 to 1.23)	1.22 (0.93 to 1.58)	1.08 (0.96 to 1.23)*	2.31 (1.60 to 3.33)*	1.44 (1.18 to 1.76)*
Israel	2.69 (1.76 to 4.11)*	0.95 (0.75 to 1.19)*	1.77 (0.93 to 3.37)*	1.00 (0.73 to 1.36)*	2.28 (1.18 to 4.41)*	1.15 (0.87 to 1.54)	1.10 (0.68 to 1.75)	1.17 (0.93 to 1.48)*	1.86 (0.97 to 3.55)*	1.47 (1.02 to 2.11)*
Japan	2.73 (1.95 to 3.83)*	0.98 (0.83 to 1.17)*	0.92 (0.56 to 1.52)*	0.88 (0.70 to 1.11)*	2.83 (1.61 to 5.00)*	1.27 (1.00 to 1.63)	1.18 (0.8 to 1.74)	0.94 (0.78 to 1.13)*	6.49 (3.72 to 11.35)*	1.70 (1.25 to 2.31)*

**Table 5 | Technical details of computed tomography (CT) protocols included in the registry for suspected pulmonary embolism CT examinations at institutions with Siemens Somatom Definition AS machines. Data are mean (with or without standard deviation), adjusted for patient age, sex, and size; table rows ordered by mean effective dose**

Country	Effective dose (mSv)	Adjusted effective dose (mSv)	CTDI <sub>vol</sub> (mGy)	Adjusted CTDI <sub>vol</sub> (mGy)	X ray tube potential (kVP)	X ray tube current (mAs)	Collimation	Pitch	Scan length (cm)	Slice thickness (mm)	No of CT scans per examination
Switzerland	1.9 (1.0)	1.7 (0.6)	4.4 (2.3)	4.0 (1.7)	103	137	38	1.5	32	1.8	1.0
Germany	2.0 (1.3)	1.6 (0.8)	4.0 (2.2)	3.4 (1.4)	103	109	19	1.4	33	1.9	1.1
US	2.2 (1.1)	1.6 (0.6)	5.0 (2.5)	4.1 (1.6)	101	92	19	0.9	30	2.1	1.0
Switzerland	2.4 (1.3)	2.2 (1.1)	4.9 (2.4)	4.6 (1.9)	109	125	38	1.5	34	1.4	1.0
Germany	2.5 (2.2)	2.3 (2.0)	4.8 (1.9)	4.4 (1.5)	98	146	38	1.2	33	2.3	1.1
US	3.9 (2.2)	3.4 (1.1)	8.5 (4.3)	7.5 (2.5)	105	81	14	1.0	16	5.8	2.2
US	4.2 (2.0)	3.3 (1.2)	8.4 (3.7)	7.1 (2.3)	113	159	38	1.2	34	2.0	1.0
US	4.5 (2.4)	3.8 (1.3)	8.8 (3.3)	7.7 (2.2)	116	261	18	1.1	35	4.2	1.0
US	4.6 (2.9)	3.4 (2.6)	9.1 (1.7)	7.3 (1.4)	120	172	19	1.5	32	1.0	1.0
US	4.6 (2.4)	3.9 (1.4)	9.8 (4.2)	8.8 (2.7)	116	114	19	0.8	32	1.1	1.0
US	4.7 (2.5)	3.8 (1.5)	10.4 (5.1)	9.0 (3.1)	103	175	19	0.9	31	1.5	1.0
US	4.8 (1.7)	3.7 (1.0)	11.2 (3.9)	9.4 (2.1)	118	165	19	1.1	30	2.0	1.0
US	4.8 (3.0)	4.6 (2.4)	8.9 (3.3)	8.8 (2.6)	112	123	19	0.9	33	3.2	1.1
US	4.9 (2.4)	4.0 (1.3)	10.7 (5.0)	9.3 (2.9)	104	179	19	0.9	31	1.5	1.0
US	4.9 (2.5)	5.2 (3.0)	11.6 (6.0)	11.9 (6.4)	107	193	19	1.0	31	1.5	1.0
US	5.5 (3.3)	4.4 (1.7)	12.2 (5.7)	10.5 (3.9)	114	157	19	0.9	31	1.4	1.0
US	5.8 (2.8)	4.7 (1.7)	12.6 (4.6)	10.8 (2.9)	114	163	38	0.8	32	2.0	1.0
US	6.0 (1.9)	5.4 (1.3)	13.8 (5.1)	12.8 (3.8)	112	201	19	0.9	29	2.2	1.1
US	6.9 (3.6)	6.7 (3.5)	14.3 (2.7)	14.2 (2.6)	120	187	19	1.0	32	3.9	1.0
US	6.9 (4.5)	6.8 (3.7)	13.3 (4.2)	13.3 (3.8)	118	152	18	0.9	29	3.7	1.3
US	7.1 (2.9)	7.5 (3.7)	15.2 (5.4)	15.7 (5.4)	120	175	19	0.9	31	3.1	1.1
US	8.0 (6.5)	7.8 (5.6)	16.2 (9.4)	15.8 (6.0)	121	174	38	0.8	30	1.1	1.1
US	8.2 (6.0)	8.2 (6.2)	10.0 (5.4)	10.0 (5.7)	105	172	12	1.0	23	4.0	2.7
US	9.1 (5.5)	7.3 (4.4)	9.3 (4.3)	8.0 (3.4)	109	132	19	0.8	37	2.8	1.1
US	10.5 (1.6)	7.1 (1.9)	22.7 (2.8)	17.1 (3.2)	120	278	14	1.0	16	5.1	2.1
US	11.4 (8.2)	9.9 (6.3)	18.3 (6.5)	16.8 (4.4)	112	265	27	1.0	21	2.9	2.2
US	11.5 (4.7)	9.1 (4.0)	9.5 (3.8)	7.9 (3.2)	111	277	17	1.0	42	4.4	1.9
US	13.4 (4.0)	18.3 (8.0)	51.5 (11.1)	65.9 (25.4)	120	180	19	0.2	19	2.0	1.0
US	15.4 (7.3)	12.4 (2.7)	13.2 (5.8)	10.9 (2.2)	109	200	19	1.0	39	5.0	2.0
US	16.5 (7.5)	12.6 (3.1)	13.4 (5.4)	11.1 (2.8)	115	199	38	1.0	43	2.8	2.0
US	26.2 (17.6)	20.0 (11.3)	16.9 (8.7)	13.8 (6.0)	116	190	38	0.8	41	3.1	1.2
US	29.3 (13.1)	29.7 (7.3)	14.1 (4.7)	14.4 (2.7)	120	161	19	0.9	35	4.0	4.1
US	37.4 (15.4)	32.7 (11.6)	21.3 (6.2)	19.4 (3.6)	120	211	19	0.8	41	4.6	2.8
Lowest tenth in protocols	2.0 (1.1)	1.6 (0.7)	4.5 (2.3)	3.8 (1.6)	102	113	25	1.2	32	1.9	1.0
Highest tenth in protocols	31.0 (15.4)	27.5 (10.1)	17.4 (6.6)	15.9 (4.1)	119	188	26	0.8	39	3.9	2.7

SD standard deviation; CTDI<sub>vol</sub>=volumetric CT dose index.

likely to reflect country norms. We report effective dose, but the results were similar when limited to volumetric CT dose index or to single CT scans. We do not have a measure of image quality and cannot be sure that institutions with the lowest doses had image quality sufficient for diagnosis; however, each institution determined that their protocols provided adequate diagnostic information for their patients.

Our analyses did not include several technical factors associated with dose (eg, use of iterative reconstruction software), but such software, when used in actual practice, has been shown to have only a modest effect on dose.<sup>43</sup> The inclusion of these factors would probably further reduce dose variation. The availability of alternative imaging modalities (eg, magnetic resonance imaging) could affect the case mix of patients who undergo CT, and we did not have information on availability of other imaging modalities. Our report on dose variation for a single indication on a single machine model indicates that some variability might be due to how the machines were configured.

Finally, the institutions included in this registry are a convenience sample of institutions that use Radimetrics dose monitoring software. Institutions that invest in dose monitoring software might systematically differ from institutions that do not, although our doses were similar to published accounts by country. We plan to diversify our CT registry, and invite any institution that would like to participate.

### Conclusions and policy implications

CT scanning doses varied widely across included countries. Variation was chiefly driven by how machines were used, rather than by patient or machine manufacturer or model. Optimizing doses to a more consistent standard should be possible both within and between countries by modifying the decisions made by radiology teams in developing CT protocols for patients. Future research should focus on understanding factors that drive institutions, and scientifically comparing different approaches for optimizing doses.



## AUTHOR AFFILIATIONS

<sup>1</sup>Department of Radiology and Biomedical Imaging Epidemiology and Biostatistics, Obstetrics Gynecology and Reproductive Sciences, Philip R Lee Institute for Health Policy Studies, University of California San Francisco, San Francisco, CA, USA

<sup>2</sup>Department of Radiology and Biomedical Imaging, University of California San Francisco, San Francisco, CA, USA

<sup>3</sup>Department of Demography, University of California Berkeley, Berkeley, CA, USA

<sup>4</sup>Department of Medicine, Division of Cardiology and Department of Radiology, Columbia University Medical Center, New York, NY, USA

<sup>5</sup>Assuta Medical Center, Tel Aviv-Yafo, Israel

<sup>6</sup>Department of Medical Physics, Churchill Hospital, Oxford University Hospitals NHS Foundation Trust, Oxford, UK

<sup>7</sup>Department of Diagnostic and Interventional Radiology, Helios Kliniken Duisburg, Duisburg, Germany

<sup>8</sup>Department of Radiology and Nuclear Medicine, Maastricht University Medical Center, Maastricht, Netherlands

<sup>9</sup>Department of Radiology, Icahn School of Medicine at Mount Sinai, New York, NY, USA

<sup>10</sup>Henry Ford Health System, Radiology and Public Health Sciences, Detroit, MI, USA

<sup>11</sup>Department of Radiology, Einstein Healthcare Network, New York, NY, USA

<sup>12</sup>University of California San Diego, San Diego, CA, USA

<sup>13</sup>Cantonal Hospital Aarau, Aarau, Switzerland

<sup>14</sup>Department of Radiology, University California Davis Medical Center, Sacramento, CA, USA

<sup>15</sup>St Luke's International Hospital, Tokyo, Japan

<sup>16</sup>Department of Diagnostic and Interventional Radiology and Neuroradiology, University Hospital Essen, Essen, Germany

<sup>17</sup>Institute of Diagnostic and Interventional Radiology and Neuroradiology, Essen University, Essen, Germany

<sup>18</sup>Department of Public Health Sciences, University of California Davis School of Medicine, Sacramento, CA, USA

<sup>19</sup>Kaiser Permanente Washington Health Research Institute, Kaiser Permanente Washington, Seattle, WA, USA

**Contributors:** RS-B contributed to obtaining funding, performing literature searches, study design, data collection, data analysis, data interpretation, and writing the manuscript, and is the study guarantor. YW contributed to data analysis, data interpretation, and writing of the manuscript. PC contributed to data collection, data analysis, data interpretation, and writing of the manuscript. RC contributed to data analysis, data interpretation, and writing of the manuscript. AJE contributed to performing literature searches, study design, data analysis, data interpretation, and writing of the manuscript. RG, TY-N, and AS contributed to the study design, data collection, data interpretation, and writing of the manuscript. DLM contributed to obtaining funding, study design, data collection, data analysis, data interpretation, and writing of the manuscript. The remaining authors contributed to data collection, data interpretation and writing of the manuscript. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

**Funding:** Funded by the US National Institutes of Health (R01-CA181191); Patient-Centered Outcomes Research Institute (CD-1304-7043); Centers for Disease Control and Prevention; and the University of California Office of the President, Center for Health Quality and Innovation; Chris Tachibana edited this manuscript, funded by Kaiser Permanente Washington Health Research Institute. Funders had no role in study design, collection, analysis, interpretation, and reporting of data; or decision to publish.

**Competing interests:** All authors have completed the ICMJE uniform disclosure form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) and declare: support from the US National Institutes of Health; Patient-Centered Outcomes Research Institute; Centers for Disease Control and Prevention; and the University of California Office of the President, Center for Health Quality and Innovation for the submitted work; RS-B reports grants from the US National Institutes of Health, Patient-Centered Outcomes Research Institute, Centers for Disease Control and Prevention, and the University of California Office of the President, is on a scientific advisory board, and has given talks for Bayer Healthcare; BND is on a scientific advisory board and has given talks for Bayer Healthcare; AJE has served as a consultant to GE Healthcare, and Columbia University has received support for other research from Toshiba America Medical Systems; MD reports grants and personal fees from Bayer Healthcare, grants and personal fees from Siemens Healthcare, grants from Philips Healthcare, personal fees from Cook Medical, outside the submitted work; AS reports non-financial support

and is on Bayer Healthcare scientific advisory board; JS has given talks for Bayer Healthcare; JEW reports institutional grants from Agfa, Bard, Bayer, GE, Optimed, Philips, Siemens, personal fees (speaker's bureau) from Bayer, Siemens, outside the submitted work; DLM is on an advisory board for Hologic; the remaining authors have nothing to disclose.

**Ethical approval:** The institutional review boards at the University of California San Francisco (and the collaborating institutions) approved the study or relied on the university's approval.

**Data sharing:** No additional data currently available.

The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

- Smith-Bindman R, Lipson J, Marcus R, et al. Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. *Arch Intern Med* 2009;169:2078-86.
- Lukasiewicz A, Bhargavan-Chatfield M, Coombs L, et al. Radiation dose index of renal colic protocol CT studies in the United States: a report from the American College of Radiology National Radiology Data Registry. *Radiology* 2014;271:445-51. doi:10.1148/radiol.14131601
- European Commission. *Diagnostic Reference Levels in Thirty-six European Countries Part 2/2*. Publications Office of the European Union, 2014.
- Parakh A, Euler A, Szucs-Farkas Z, Schindera ST. Transatlantic Comparison of CT Radiation Doses in the Era of Radiation Dose-Tracking Software. *AJR Am J Roentgenol* 2017;209:1302-7. doi:10.2214/AJR.17.18087
- Radiation. *International Agency for Research on Cancer (IARC). Monogr Eval Carcinog Risks Hum* 2012;100:7-303.
- Berrington de González A, Darby S. Risk of cancer from diagnostic X-rays: estimates for the UK and 14 other countries. *Lancet* 2004;363:345-51. doi:10.1016/S0140-6736(04)15433-0
- Board of Radiation Effects Research Division on Earth and Life Sciences National Research Council of the National Academies. *Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2 Washington*. The National Academies Press, 2006.
- Richardson DB, Cardis E, Daniels RD, et al. Risk of cancer from occupational exposure to ionising radiation: retrospective cohort study of workers in France, the United Kingdom, and the United States (INWORKS) [correction in: *BMJ* 2015;351:h6634]. *BMJ* 2015;351:h5359. doi:10.1136/bmj.h5359
- Cardis E, Vrijheid M, Blettner M, et al. Risk of cancer after low doses of ionising radiation: retrospective cohort study in 15 countries. *BMJ* 2005;331:77. doi:10.1136/bmj.38499.599861.E0
- Davies HE, Wathen CG, Gleeson FV. The risks of radiation exposure related to diagnostic imaging and how to minimise them. *BMJ* 2011;342:d947. doi:10.1136/bmj.d947
- Mathews JD, Forsythe AV, Brady Z, et al. Cancer risk in 680,000 people exposed to computed tomography scans in childhood or adolescence: data linkage study of 11 million Australians. *BMJ* 2013;346:f2360. doi:10.1136/bmj.f2360
- Sodickson A. CT radiation risks coming into clearer focus. *BMJ* 2013;346:f3102. doi:10.1136/bmj.f3102
- Pearce MS, Salotti JA, Little MP, et al. Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. *Lancet* 2012;380:499-505. doi:10.1016/S0140-6736(12)60815-0
- Martin DR, Semelka RC. Health effects of ionising radiation from diagnostic CT. *Lancet* 2006;367:1712-4. doi:10.1016/S0140-6736(06)68748-5
- Catalano C, Francone M, Ascarelli A, Mangia M, Iacuzzi I, Passariello R. Optimizing radiation dose and image quality. *Eur Radiol* 2007;17(Suppl 6):F26-32. doi:10.1007/s10406-007-0225-6
- Trattner S, Pearson GDN, Chin C, et al. Standardization and optimization of CT protocols to achieve low dose. *J Am Coll Radiol* 2014;11:271-8. doi:10.1016/j.jacr.2013.10.016
- Goske MJ, Strauss KJ, Coombs LP, et al. Diagnostic reference ranges for pediatric abdominal CT. *Radiology* 2013;268:208-18. doi:10.1148/radiol.13120730

- 18 International Council on Radiological Protection (ICRP). Diagnostic Reference Levels in Medical Imaging, ICRP Publication 135. *Ann ICRP* 2017; 46(1).
- 19 Rosenstein M. Diagnostic reference levels for medical exposure of patients: ICRP guidance and related ICRU quantities. *Health Phys* 2008;95:528-34. doi:10.1097/O1.HP.0000326331.35187.63
- 20 European Society of Radiology. Eurosafe Imaging, EUCLID (European Study on Clinical Diagnostic Reference Levels for X-ray Medical Imaging) 2007. [www.eurosafeimaging.org/euclid](http://www.eurosafeimaging.org/euclid).
- 21 Ormsby EL, Pavlik EJ, van Nagell JR. Ultrasound follow up of an adnexal mass has the potential to save lives. *Am J Obstet Gynecol* 2015;213:657-61.
- 22 Christner JA, Kofler JM, McCollough CH. Estimating effective dose for CT using dose-length product compared with using organ doses: consequences of adopting International Commission on Radiological Protection publication 103 or dual-energy scanning. *AJR Am J Roentgenol* 2010;194:881-9. doi:10.2214/AJR.09.3462
- 23 American Association of Physicists in Medicine. American Association of Physicists in Medicine Report No 96. The Measurement, reporting and management of radiation dose in CT, Report of AAPM Task group 23 of the Diagnostic Imaging Council CT Committee. American Association of Physicists in Medicine, 2008.
- 24 Japan Network for Research and Information on Medical Exposures (J-RIME) and the Japan Medical Imaging and Radiological Systems Industries Association and National Institute of Radiological Sciences. Diagnostic Reference Levels Based on Latest Surveys in Japan — Japan DRLs 2015— 2015. <http://www.iomp.org/sites/default/files/drlhoukokusyoeng.pdf>.
- 25 Kanal KM, Butler PF, Sengupta D, Bhargavan-Chatfield M, Coombs LP, Morin RL. U.S. Diagnostic Reference Levels and Achievable Doses for 10 Adult CT Examinations. *Radiology* 2017;284:120-33. doi:10.1148/radiol.2017161911
- 26 van der Molen AJ, Schilham A, Stoop P, Prokop M, Geleijns J. A national survey on radiation dose in CT in The Netherlands. *Insights Imaging* 2013;4:383-90. doi:10.1007/s13244-013-0253-9
- 27 Treier R, Aroua A, Verdun FR, Samara E, Stuessi A, Trueb PR. Patient doses in CT examinations in Switzerland: implementation of national diagnostic reference levels. *Radiat Prot Dosimetry* 2010;142:244-54. doi:10.1093/rpd/ncq279
- 28 Public Health England. *Diagnostic Radiology: National Diagnostic reference levels*. NDRLS, 2016.
- 29 Dose Index Registry - American College of Radiology. American College of Radiology. <https://www.acr.org/Quality-Safety/National-Radiology-Data-Registry/Dose-Index-Registry>. 2015.
- 30 Joint Commission on Hospital Accreditation. Diagnostic imaging requirements 2015 [https://www.jointcommission.org/assets/1/18/AHC\\_DiagImagingRpt\\_MK\\_20150806.pdf](https://www.jointcommission.org/assets/1/18/AHC_DiagImagingRpt_MK_20150806.pdf).
- 31 European Society of Radiology (ESR). Summary of the European Directive 2013/59/Euratom: essentials for health professionals in radiology. *Insights Imaging* 2015;6:411-7. doi:10.1007/s13244-015-0410-4
- 32 European Commission. *Radiation Protection 109. Guidance on diagnostic reference levels (DRLs) for medical exposures*. Office for Official Publications of the European Communities, 1999.
- 33 European Union. Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom. 1997.
- 34 European Union. Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. 2013.
- 35 Valentin J, International Commission on Radiation Protection. Managing patient dose in multi-detector computed tomography(MDCT). ICRP Publication 102. *Ann ICRP* 2007;37:1-79, iii.
- 36 Committee on Medical Aspects of Radiation in the Environment (COMPARÉ). Sixteenth Report. Radiation dose issues resulting from the use of CT in the UK: Public Health England, 2014.
- 37 US Food and Drug Administration. FDA White Paper: Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging 2010. <https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm199994.htm>.
- 38 Smith-Bindman R. Is computed tomography safe? *N Engl J Med* 2010;363:1-4.
- 39 Loose RWR. Clinical diagnostic reference levels: from concept to impact in clinical practice. Abstract A143, European Congress of Radiology 2017, A-143. *European Congress of Radiology* 2017.
- 40 European Commission. *Medical Protection No 180. Medical Radiation Exposure of the European Population. Part 1/2*. Luxembourg Publications Office of the European Union, 2014.
- 41 Smith-Bindman R, Chu P, Wang Y, Chung R, Einstein A, Miglioretti DL. An international randomized controlled trial of two interventions for reducing doses for computed tomography through audit feedback and sharing best practices. European Congress of Radiology, European Society of Radiology, Vienna, Austria, March 2018.
- 42 Demb J, Chu P, Nelson T, et al. Optimizing Radiation Doses for Computed Tomography Across Institutions: Dose Auditing and Best Practices. *JAMA Intern Med* 2017;177:810-7. doi:10.1001/jamainternmed.2017.0445.
- 43 Smith-Bindman R, Wang Y, Yellen-Nelson TR, et al. Predictors of CT Radiation Dose and Their Effect on Patient Care: A Comprehensive Analysis Using Automated Data. *Radiology* 2017;282:182-93. doi:10.1148/radiol.2016151391

### Web appendix: Supplementary materials

## Certification of Expenses

Expense reimbursement claim for the amount of \$ \_\_\_\_\_

Payable to \_\_\_\_\_

I certify that the expenses were incurred by me on official University business on the dates shown, and no expenses claimed as reimbursable relate to personal or unallowable expenses. I also certify that I did not receive reimbursement from any other source(s) for the expenses claimed. In the event of an overpayment, or if payment is received from another source for any portion of the expenses claimed, I assume responsibility for repaying UC Regents in full for those expenses.

Signature: \_\_\_\_\_

Print Name: \_\_\_\_\_

Date: \_\_\_\_\_

To be completed if UCSF employee signing on behalf of the guest

Signature: \_\_\_\_\_

Print Name: \_\_\_\_\_

Job Title: \_\_\_\_\_

Date: \_\_\_\_\_