DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

X Congresso Regional Latino Americano IRPA de Proteção e Segurança Radiológica

April 11, 2015, Buenos Aires, Argentina

INDUSTRY OPINION ON IMPROVEMENTS IN RADIATION PROTECTION CULTURE IN MEDICINE

DOSE REDUCTIONS FOR VIRTUAL COLONOGRAPHY (CT) AND LUNG CANCER SCREENING WITH LOW-DOSE CT

Richard A. Frank, MD, PhD
DITTA WHO Working Group Leader

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Key Topics

Disclosures

What is DITTA?

Key Players in Radiation Protection

Importance of standards

Examples; CT Dose in Screening for Cancer

Industry Opinion; Success Factors in Radiation Protection

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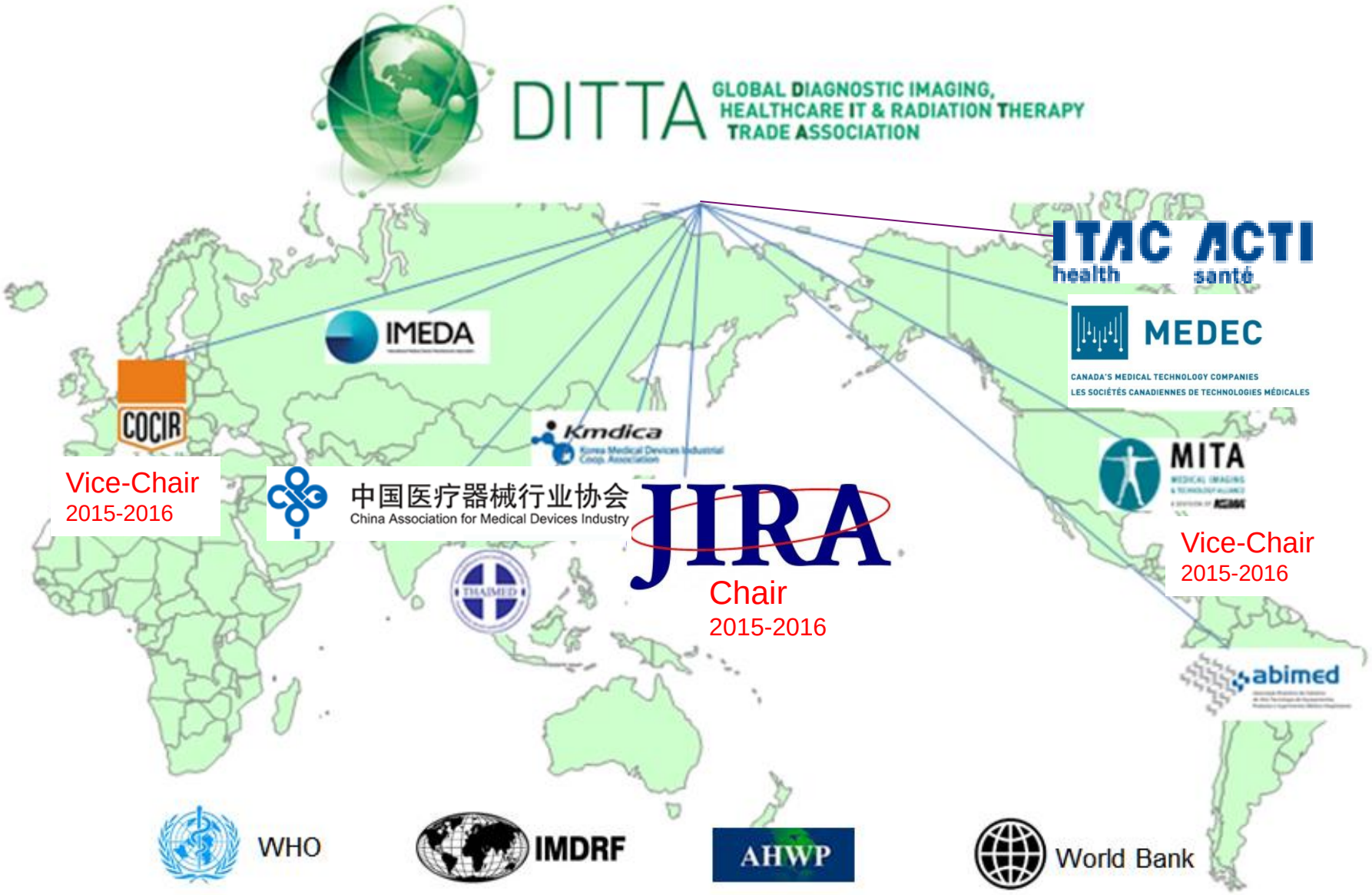
DISCLOSURES

- Richard A. Frank, MD, PhD
  - is employed by Siemens Healthcare USA as the Chief Medical Officer and
  - is an active member of the DITTA WHO Working Group.

- DITTA represents the global diagnostic imaging, healthcare IT, radiation therapy and radiopharmaceutical manufacturers.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UPDATES ABOUT DITTA

Granted NGO status by WHO

Established formal liaison with AHWP*

Expanded Working Groups:

- Mirroring the International Medical Device Regulators' Forum (IMDRF)
  - Regulated Products Submissions (RPS)
  - Unique Device Identification (UDI)
  - Medical Device Single Audit Proposal (MDSAP)
  - Software as a Medical Device (SaMD)
- Environmental WG; working toward the Basel Convention
- World Bank WG; for World Bank Procurement Policies
- Refurbishment WG; Standards for refurbishment/refurbished products
- New! 2 groups created recently: 1 on standards + 1 on WHO activities

* Asian Harmonization Working Party

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INDUSTRY SUPPORTS REDUCTION IN UNNECESSARY EXPOSURE

- Expand and integrate appropriateness criteria into physician decision-making;
- Create national dosage registries to ensure longitudinal tracking of dose levels across patients;
- Adopt standardized storage of diagnostic imaging and radiation therapy information in EMR;
- Explore the expansion of mandatory accreditation for advanced imaging facilities;
- Work with professional societies to establish minimum standards for training and education for hospital and imaging facility personnel who perform medical imaging exams and deliver radiation therapy treatments;
- Develop enhanced operational safety procedures and checklists to reduce medical errors;
- Expand and standardize reporting of medical errors associated with medical radiation across stakeholders in a manner that is transparent for patients, families and physicians; and
- Champion the ALARA principle, which stands for “as low as reasonably achievable.” This principle of radiation dose management and optimization is incorporated into all imaging procedures and technologies, and is mandated by nearly all regulatory bodies and licensing agencies, including the Nuclear Regulatory Commission.

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KEY PLAYERS IN RADIATION DOSE REDUCTION INITIATIVES EXAMPLES PER CATEGORY

- **Professional Societies**
  - AAPM (American Association of Physicists in Medicine)
  - ACR (American College of Radiology: Image Wisely, Image Gently)
  - ASRT (American Society of Radiologic Technologists)
  - European Society of Radiology (Eurosafe Imaging)
- **Industry Associations**
  - MITA (Medical Imaging & Technology Alliance)
  - COCIR – European Trade Association
  - JIRA – Japanese Trade Association
- **Domain Knowledge Experts**
  - CRCPD (Conference of Radiation Control Program Directors)
  - Mayo Clinic, Washington University
- **Government Agencies**
  - FDA (Food and Drug Administration)
  - HERCA (Heads of European Radiological protection Competent Authorities)
  - JCAHO (The Joint Commission on Accreditation of Health Care Organizations)
  - NCRP (National Council on Radiation Protection and Measurements)
  - IAEA (International Atomic Energy Agency)
  - IEC (International Electrotechnical Commission)

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RADIATION DOSE MITIGATION STANDARDS

- NEMA XR 25 (2010): *Computed Tomography Dose Check*
- NEMA XR 26 (2012): *Access Controls for Computed Tomography: Identification, Interlocks, and Logs*
- NEMA XR 27 (2012): *X-ray Equipment for Interventional Procedures User Quality Control Mode*
- NEMA XR 28 (2013): *Supplemental Requirements for User Information and System Function Related to Dose in CT*
- NEMA XR 29 (2013): *Standard Attributes on Computed Tomography (CT) Equipment Related to Dose Optimization and Management*

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TECHNOLOGY INNOVATION IN CT DOSE REDUCTION AND MANAGEMENT

- Automatic Exposure Control (AEC)
- Wider coverage detectors
- “Shutter” modes
- Advanced electronics
- **Dedicated pediatric image acquisition protocols**
- **CT Dose Check**
- **Dose Display and Record/DICOM Radiation Dose Structured Report (RDSR)**
- **Iterative reconstruction**

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INDUSTRY PARTNERSHIPS PEDIATRIC DOSE REDUCTION

Collaborate with radiologists, medical physicists, technologists and regulators to develop and implement radiation dose standards and patient safety features on medical devices.

FDA Collaboration ; The FDA awarded MITA (a DITTA member) its "Leveraging/Collaboration Award" in 2012 for developing a collaborative network aimed at reducing unnecessary pediatric radiation exposure, the "Image Gently" campaign

Image Gently

MITA partnered with the Alliance for Radiation Safety in Pediatric Imaging to establish the "Image Gently" campaign to educate medical professionals and parents about ***image acquisition protocols*** **that can reduce dose for children.**

Image Wisely

MITA also supports the "Image Wisely" campaign, which focuses on reducing unnecessary exposure for adults.

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STANDARD XR – 25
CT DOSE CHECK

Industry-wide commitment to more expansively address patient safety in medical imaging by including new radiation dose safeguards

An alert to CT machine operators when recommended radiation dose – as determined by hospitals and imaging centers – will be exceeded

Provides a clear indication to health care providers when radiation dose adjustments made for a patient's exam would result in delivering a dose higher than the facility's pre-determined dose threshold for routine use

Known as a "reference dose," this dose threshold level at which the new alert will appear is set by clinicians

The NEMA standard requirement has been reflected in IEC60601-2-44: 2012

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KEY INTERNATIONAL STANDARD

IEC 60601 Medical Electrical Equipment – Part 2-44

Particular Requirements for the basic safety and essential performance of X-ray Equipment for Computed Tomography

Used in development of DICOM CT Radiation Dose Structured Report (RDSR)

http://medical.nema.org/medical/dicom/final/sup127_ft.pdf

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ITERATIVE RECONSTRUCTION CT DOSE REDUCTION IN COLONOGRAPHY

Validation of Dual-Source Single-Tube Reconstruction as a Method to Obtain Half-Dose Images to Evaluate Radiation Dose and Noise Reduction: Phantom and Human Assessment Using CT Colonography and Sinogram-Affirmed Iterative Reconstruction (SAFIRE)

Joel G. Fletcher, MD, Katharine L.R. Grant, PhD,† Jeff L. Fidler, MD,* Maria Shiung, BA,* Lifeng Yu, PhD,* Jia Wang, PhD,† Bernhard Schmidt, PhD,‡ Thomas Allmendinger, PhD,‡ and Cynthia H. McCollough, PhD**

Objective: To evaluate a method for obtaining half-dose CT images for observer studies evaluating lower-dose CT.

Methods: Phantoms of varying sizes were scanned at multiple tube potentials using dose-matched dual-source (DS) and single-source (SS) protocols. Images from single-tube reconstruction of DS data were compared with SS images acquired at half-original $CTDI_{vol}$. Thirty patients underwent supine SS and dose-matched prone DS CT colonography (CTC). Half-dose prone images were reconstructed with sinogram-affirmed iterative reconstruction (SAFIRE). Two radiologists scored image quality on 2-dimensional (2D) and 3D images.

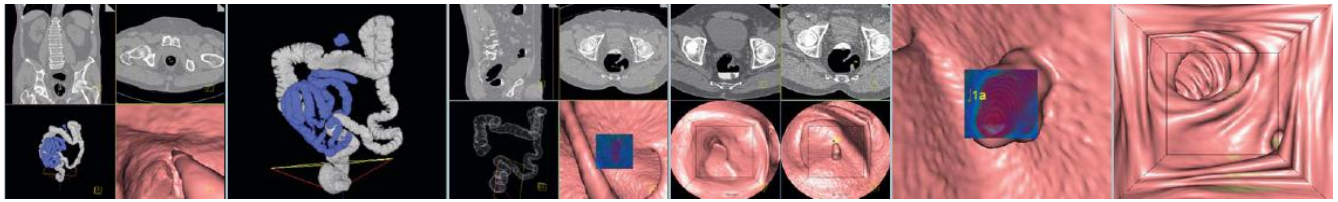
Results: Image noise was similar between half-dose SS images and DS images reconstructed from one tube only with tube potential of 120 kV or more for phantoms 40 cm or smaller ($P < 0.05$). For both readers, the patients' CTC image quality scores were more than 84% concordant between SS or DS CTC images, and half-dose–prone CTC images with SAFIRE had 84% or more concordance with routine-dose CTC except for 3D image noise.

Conclusions: In appropriately sized patients, DS acquisition with single-tube reconstruction can create half-dose images, permitting comparison to full-dose images. For CTC, there is comparable image quality

CT contributes almost one half of the total radiation exposure from medical use,[5] there is considerable public and scientific concern regarding potential associated risk of radiation-induced malignancy.[1,6]

Radiation dose is particularly important in CT colonography because screened patients are asymptomatic, and there is consequently a greater imperative to minimize the risk of this examination, including radiation dose.[4,7,8] Berrington de González et al[9] recently evaluated CT colonography benefit versus risk, taking into account CTC dose levels, and used comparative modeling with 3 colorectal cancer microsimulation models. They found the benefit-to-risk ratio to be high (ie, between 24:1 and 35:1),[9] echoing earlier work performed by Brenner et al.[10]

Advances in CT technology have led to the development of numerous techniques for reducing radiation dose.[11–15] Several approaches also exist for reducing image noise to improve the image quality of low-dose CT images, including iterative reconstruction, iterative noise reduction methods involving projection space, image and projection-space denoising, and noise reduction kernels and filters.[16–18] Flicek et al[19] recently reported



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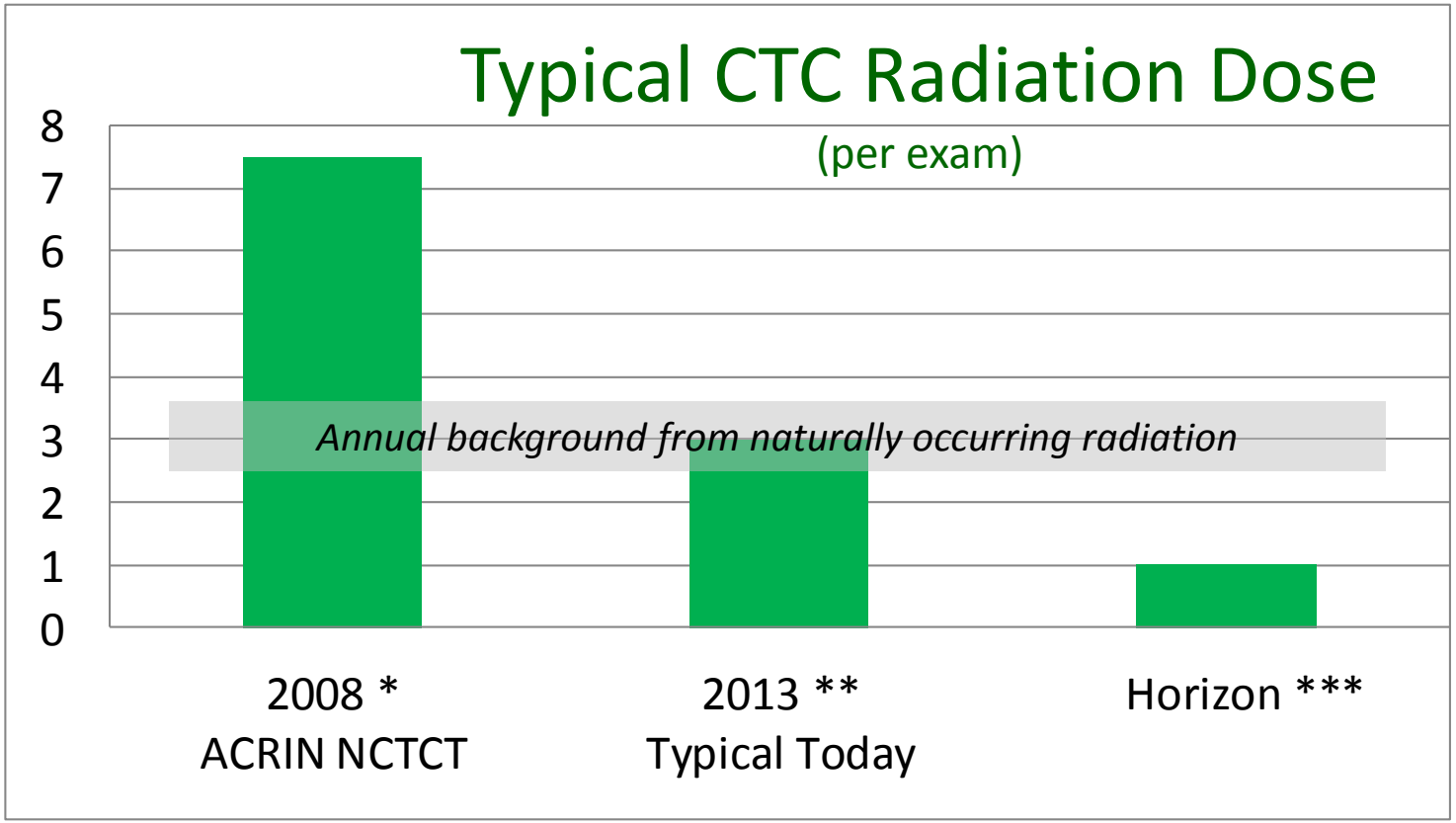
FDA JOINT GASTROENTEROLOGY-UROLOGY PANEL AND RADIOLOGICAL DEVICES PANEL SEPTEMBER 9, 2013



** 2008 ACRIN NCTCT- Berrington de González A, Kim KP, Knudsen AB, et al. Radiation-related cancer risks from CT colonography screening: a risk-benefit analysis. AJR 2011; 196:816–823*

***2013 – Yee J, Keysor KJ, Kim DH. The time has arrived for national reimbursement of screening CT colonography. AJR Am J Roentgenol. 2013 Jul;201(1):73-9.*

****2013 – Chang KJ, Yee J. Dose reduction methods for CT colonography. Abdom Imaging. 2013 Apr; 38(2):224-32.*

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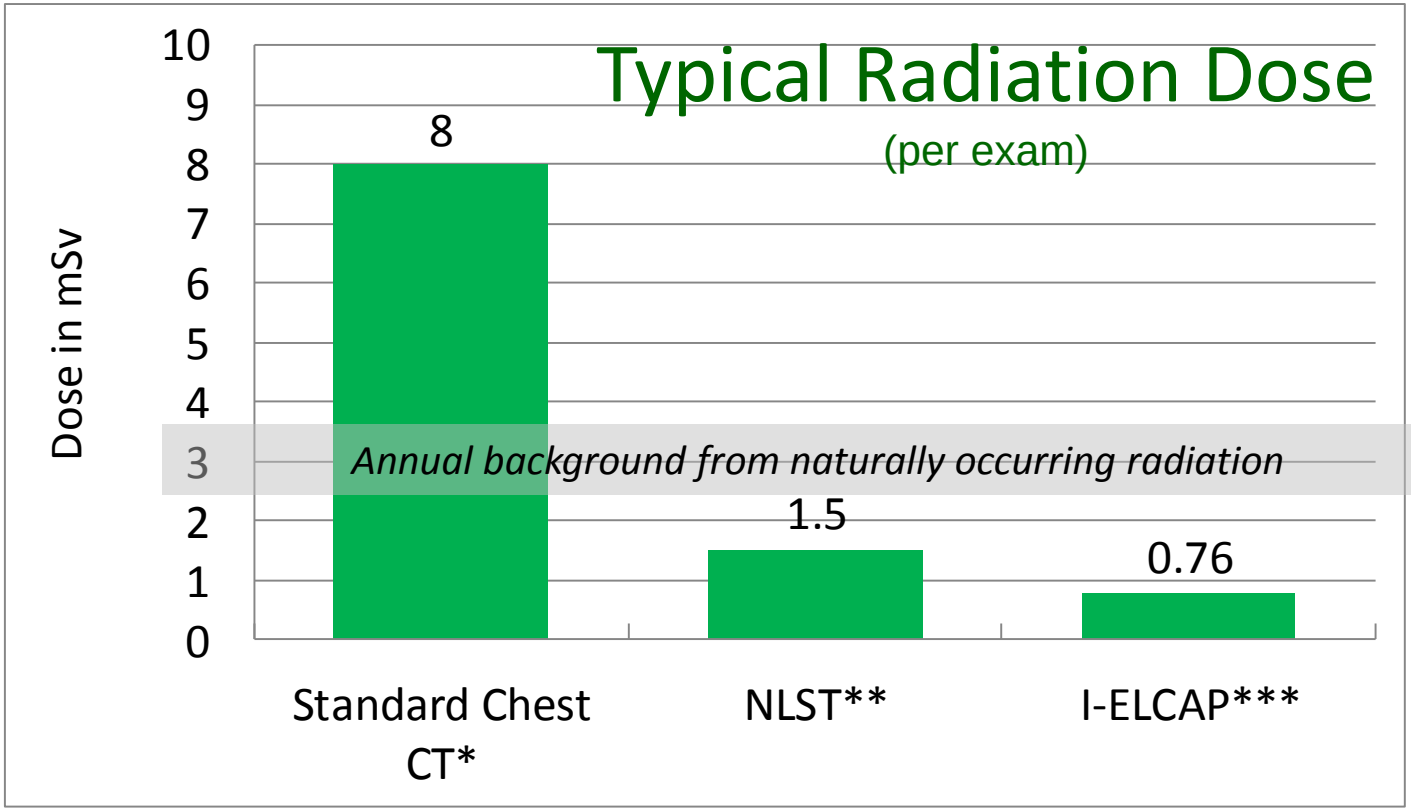
CENTERS FOR MEDICARE & MEDICAID SERVICES MEDICARE EVIDENCE DEVELOPMENT AND COVERAGE ADVISORY COMMITTEE APRIL 30, 2014



** 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.*

***Aberle DR, Adams AM, Berg CD, Black WC, Clapp JD, Fagerstrom RM, et al; National Lung Screening Trial Research Team. Reduced lung-cancer mortality with low-dose computed tomographic screening. N Engl J Med. 2011; 365:395-409*

**** Data on file at I-ELCAP.*

International Early Lung Cancer Investigators. "Survival of Patients with Stage I Lung Cancer Detected on CT Screening." The New England Journal of Medicine. 2006; 355:1763-1771.

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The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 AUGUST 4, 2011 VOL. 365 NO. 5

Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening

The National Lung Screening Trial Research Team*

N Engl J Med 2011;365:395-409.

RESULTS

The rate of adherence to screening was more than 90%. The rate of positive screening tests was 24.2% with low-dose CT and 6.9% with radiography over all three rounds. A total of 96.4% of the positive screening results in the low-dose CT group and 94.5% in the radiography group were false positive results. The incidence of lung cancer was 645 cases per 100,000 person-years (1060 cancers) in the low-dose CT group, as compared with 572 cases per 100,000 person-years (941 cancers) in the radiography group (rate ratio, 1.13; 95% confidence interval [CI], 1.03 to 1.23). There were 247 deaths from lung cancer per 100,000 person-years in the low-dose CT group and 309 deaths per 100,000 person-years in the radiography group, representing a relative reduction in mortality from lung cancer with low-dose CT screening of 20.0% (95% CI, 6.8 to 26.7; P=0.004). The rate of death from any cause was reduced in the low-dose CT group, as compared with the radiography group, by 6.7% (95% CI, 1.2 to 13.6; P=0.02).

Press releases

Return to Newsroom

National Coverage Determination (NCD) for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)

Date 2015-02-05

Title National Coverage Determination (NCD) for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)

Contact press@cms.hhs.gov

National Coverage Determination (NCD) for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)

Today the Centers for Medicare & Medicaid Services (CMS) issued a final national coverage determination that provides for Medicare coverage of Screening for Lung Cancer with Low Dose Computed Tomography (LDCT). The coverage is effective immediately.

"This is the first time that Medicare has covered lung cancer screening. This is an important new Medicare preventive benefit since lung cancer is the third most common cancer and the leading cause of cancer deaths in the United States," said Dr. Patrick Conway, chief medical officer and deputy administrator for innovation and quality for CMS.

Medicare will now cover lung cancer screening with LDCT once per year for Medicare beneficiaries who meet all of the following criteria:

- they are age 55-77, and are either current smokers or have quit smoking within the last 15 years;
- they have a tobacco smoking history of at least 30 "pack years" (an average of one pack a day for 30 years); and

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INDUSTRY OPINION - ROLES

Industry

Innovate and build safe products to serve patient needs

Set standards, train operators, enable others' initiatives

Professional & Accrediting Societies

Accredit sites, train & certify users, manage registries

Maintain & promote appropriate use criteria

Providers

Hire and train qualified staff and monitor performance

Maintain safe facilities and deliver appropriate care efficiently

Government

Ensure access by populations to health benefits of innovation

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INDUSTRY OPINION

1. Each must play their complementary role
2. Standards drive quality and value
3. Dose reduction enables population health
4. Safety innovation needs rewarding

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QUESTIONS AND DISCUSSION

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THANK YOU

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ONGOING DOSE REDUCTION LUNG CANCER SCREENING

- Nakajo C, Heinzer S, Montandon S, et al. Chest CT at a dose below 0.3 mSv: impact of iterative reconstruction on image quality and lung analysis. Acta Radiol. 2015 Apr 2. (ePub ahead of print)

  "CONCLUSION: Chest CT performed at effective **doses below 0.3 mSv** may be used to confidently diagnose lesions greater than 4 mm … "

- Ebner L, Bütikofer Y, Ott D, et al. Lung Nodule Detection by Microdose CT Versus Chest Radiography (Standard and Dual-Energy Subtracted). *Am J Roentgenol*. 2015;4:727-35.

  "CONCLUSION: Microdose CT is better than the combination of chest radiography and dual-energy subtraction for the detection of solid nodules between 5 and 12 mm at a lower **dose level of 0.13 mSv**. … These preliminary results indicate that microdose CT has the potential to replace conventional chest radiography for lung nodule detection."

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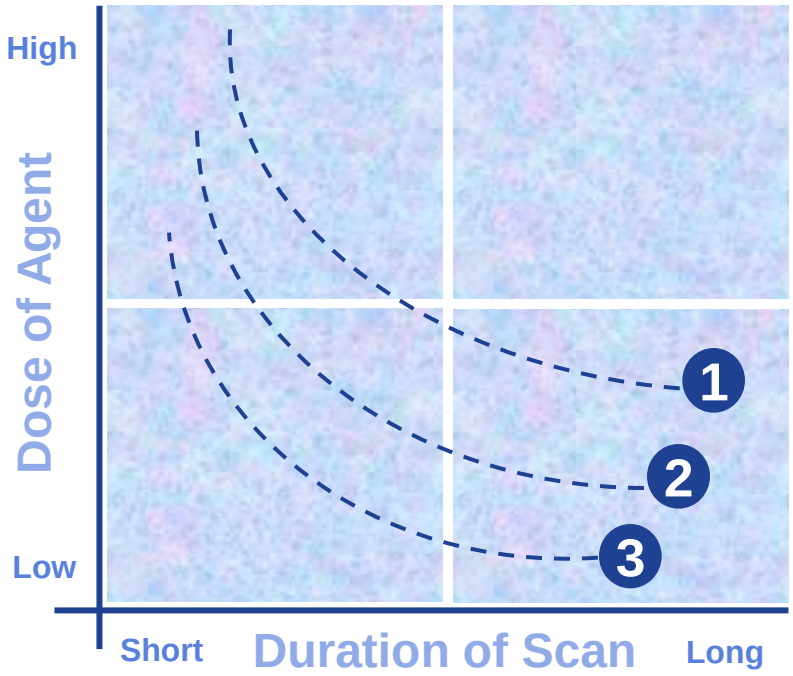
DOSE REDUCTION ENGINEERING INNOVATION IN IMAGE ACQUISITION

Counts = Quality = k



Innovation in efficiency of image acquisition, whether by novel detectors or novel architecture, enables reduced dose = improved safety

Detector	1 = lower
Efficiency	3 = higher

Duvall et al; JNC 2012; 1: 19-27

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