Radiation Dose from Diagnostic Imaging in Oncology Patients:

Is there any problem?

D Tack

Epicura, Ath, Baudour, Hornu

COI

- Honorarium for conference:
  - <This is an invited conference with honorary>
- Participation to an « Advisory Board » :
  - <No>
- Sponsored clinical studies
  - <None>
- Consulting honoraries :
  - <None>
- Sponsored Travel-Congresses :
  - <None>

Objectives

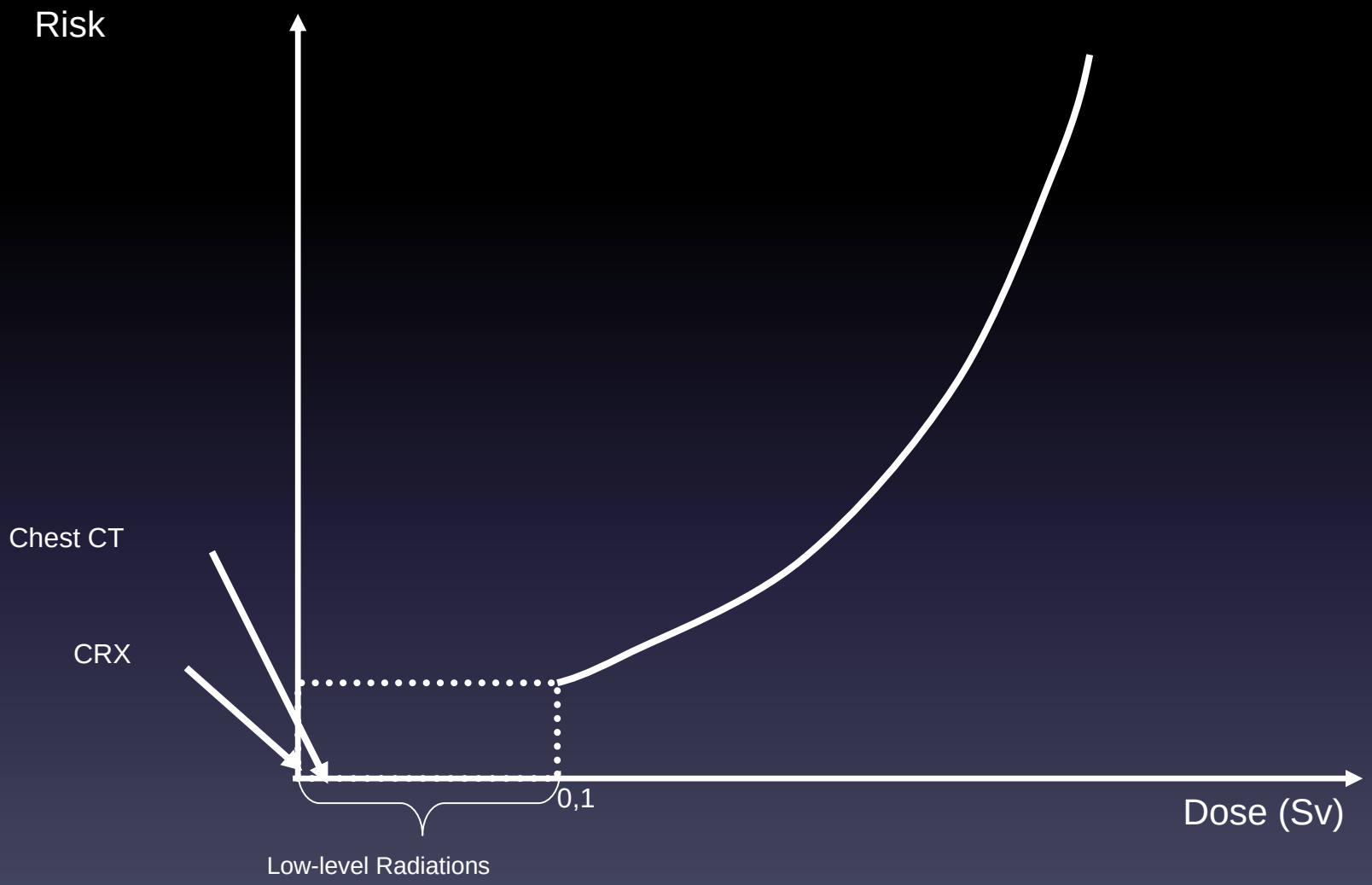
1. Fundamentals of radiation risk quantification
2. Radiations Risks specific to oncology patients
3. Benefit/Risks in Screening
4. Justification in Oncology (Guidelines)
5. Optimization

Fundamentals of Radiation Risk Quantification in Medical Imaging

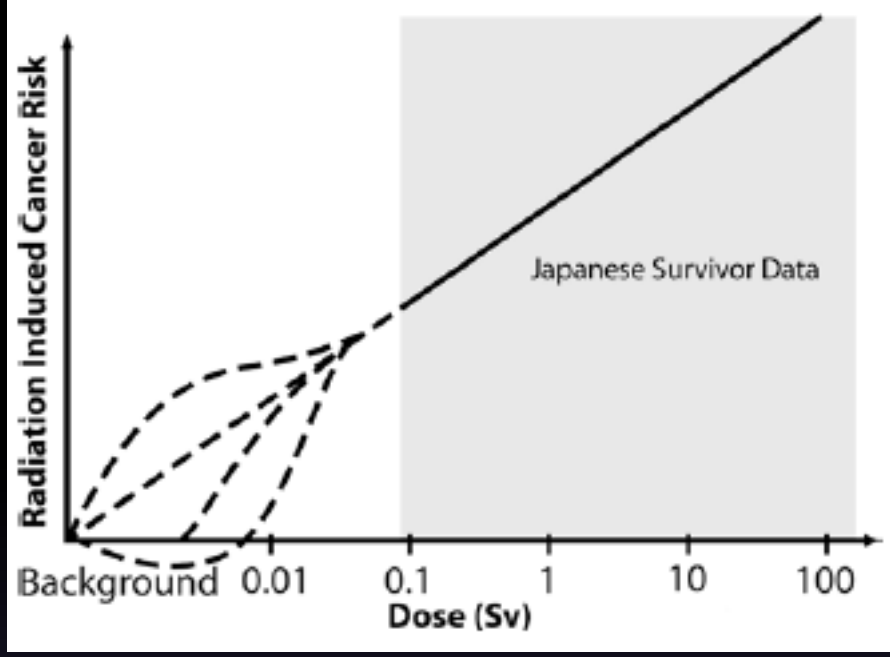
- As standard radiography, CT use X-rays
- Toxicity of ionizing radiations is cumulative
- Estimations of toxicity are mainly based on the history of nuclear energy (military and medical)
- Stochastic (long term) risk = risk of carcinogenesis
- No carcinogenesis was observed below 0,1 Sv

Cohen BL, AJR 2002; 179: 1137-1143
IRCP 60, Pergamon press 1990
IRCP 103, Pergamon press 2008
Tubiana et al, Radiology. 2009;251(1):13-22.
Little et al, Radiology 2009;251(1) 6_12

Low-level Radiations



Radiation Risks of Medical Imaging: Fact and Fantasy



- Risk quantification in the low-level radiation field (0.1 - 10 mSv) results from extrapolations from high doses > 100 mSv
- Linear no-threshold model *,**

* Tubiana, Radiology 2009;251:13-22

** Brenner N Engl J Med 2007;357:2277–2284

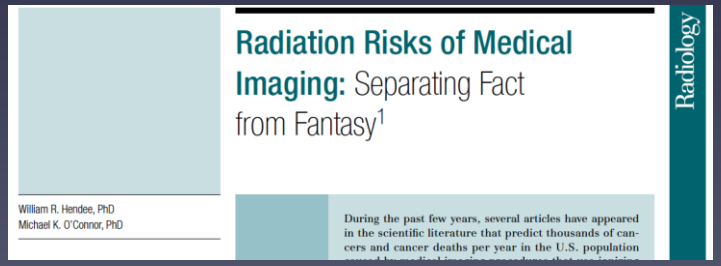
Linear No-Threshold

- Yearly cancer predictions:
  - 40 000 in the US
  - 2000 in Germany
  - 200 in Begium

LNT model: Thousands of predicted death

- What are the data that led to these numbers, and how dependable are these data?
- How firm or speculative are these predictions?
- How much attention should be given to them?

Radiology 2012;264:312-321


Radiation Risks of Medical Imaging: Separating Fact from Fantasy[1]

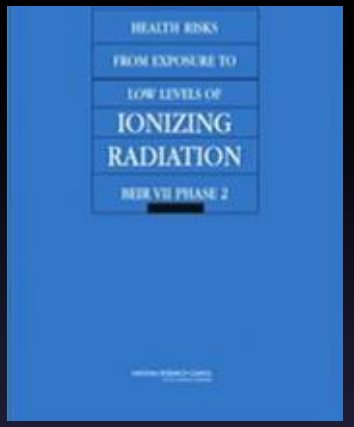
William R. Hendee, PhD
Michael K. O'Connor, PhD

During the past few years, several articles have appeared in the scientific literature that predict thousands of cancers and cancer deaths per year in the U.S. population

Radiology

LNT or not LNT?

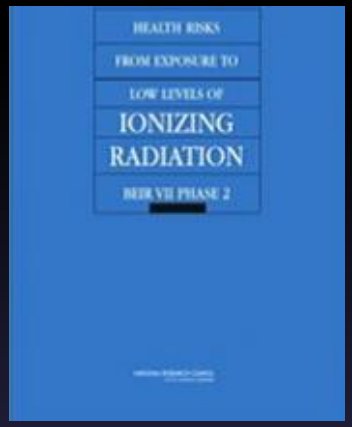
A. Epidemiological studies



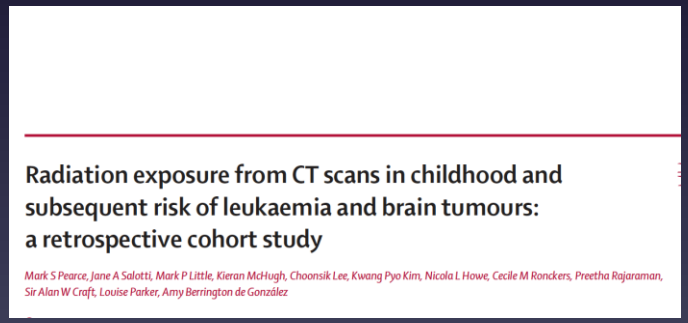
A. Biological studies

A Epidemiological studies

- A1: BEIR VII

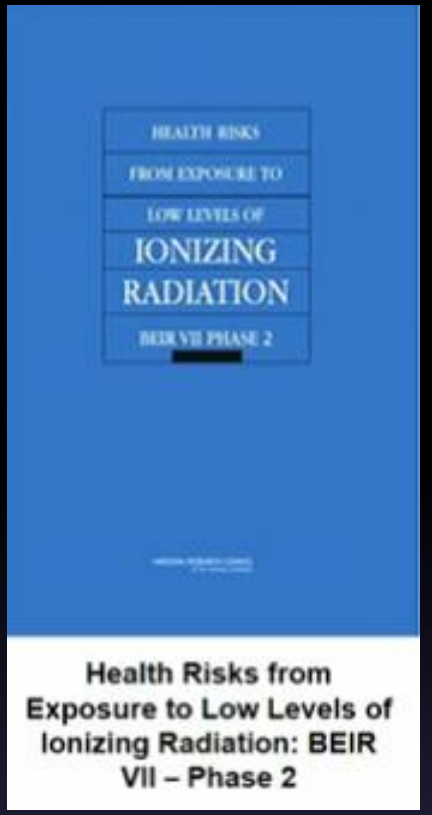


- A2: Studies on Pediatric CT


Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study

Mark S Pearce, Jane A Salotti, Mark P Little, Kieran McHugh, Choonsik Lee, Kwang Pyo Kim, Nicola L Howe, Cecile M Ronckers, Preetha Rajaraman, Sir Alan W Craft, Louise Parker, Amy Berrington de González

A1: BEIR VII report



1. Atomic bomb survivors (Hiroshima-Nagasaki)(Radiation Effects Research Foundation) RERF
2. Workers in Nuclear Plants
3. Accidental radiation

   Three-Mile-Island, Tchernobyl

   Radiological series
4. Data from medical radiation sources

Radiology 2012;264:312-321

RERF →BEIRVII report

- It is from the summary tables of radiation risk in the BEIR VII report that projections of cancer incidence and death are made for medical exposures
- RERF data received by far the greatest emphasis

A/ RERF Program

- 120 000 survivors of atomic blasts
  - 93 000 exposed to radiation
  - 27 000 residents absent from the cities at the time of explosions
- Average dose to exposed individuals: 200 mSv

RERF Program

- Dose distribution among 93 000 exposed.
  - 0 – 5 mSv: 37000 subjects
  - 5 – 100 mSv: 32000 subjects
  - 100 – 2000 mSv 17000 subjects

RERF Program

- Dose distribution among 93 000 exposed.
  - 0 – 5 mSv: 37000 subjects
  - 5 – 100 mSv: 32000 subjects
  - 100 – 2000 mSv 17000 subjects
- Statistical evidence of increased incidence of various cancers in individuals receiving 100 mSv whole body dose or more

RERF Program

- At less than 100 mSv, it is not possible to identify an increased incidence of cancer with any degree of statistical confidence compared with the normal incidence of cancer in the unexposed populations.

2: Data From Nuclear Plants workers

- Studies of 500 000 occupationally exposed workers in the nuclear industry over many years even demonstrated reduced cancer in the exposed individuals, a result termed the "healthy worker effect".

- The BEIR VII report largely excludes all of these studies from its analyses on the basis that they are unsuited to the development of population-based risk estimates.

3: Accidents - Data from Chernobyl, Three-Miles-Island and Medical Sources

- No or few effects were observed (?????)
  - increased thyroid cancer in children exposed in utero downwind of Chernobyl,
- Increased likelihood of cancer in persons receiving multiple doses of radiation from an extended series of medical procedures (high cumulated doses).
- All these effects are associated with relatively high radiation doses to specific organs

4. Medical Radiation for Diagnostic and Therapeutic Purposes

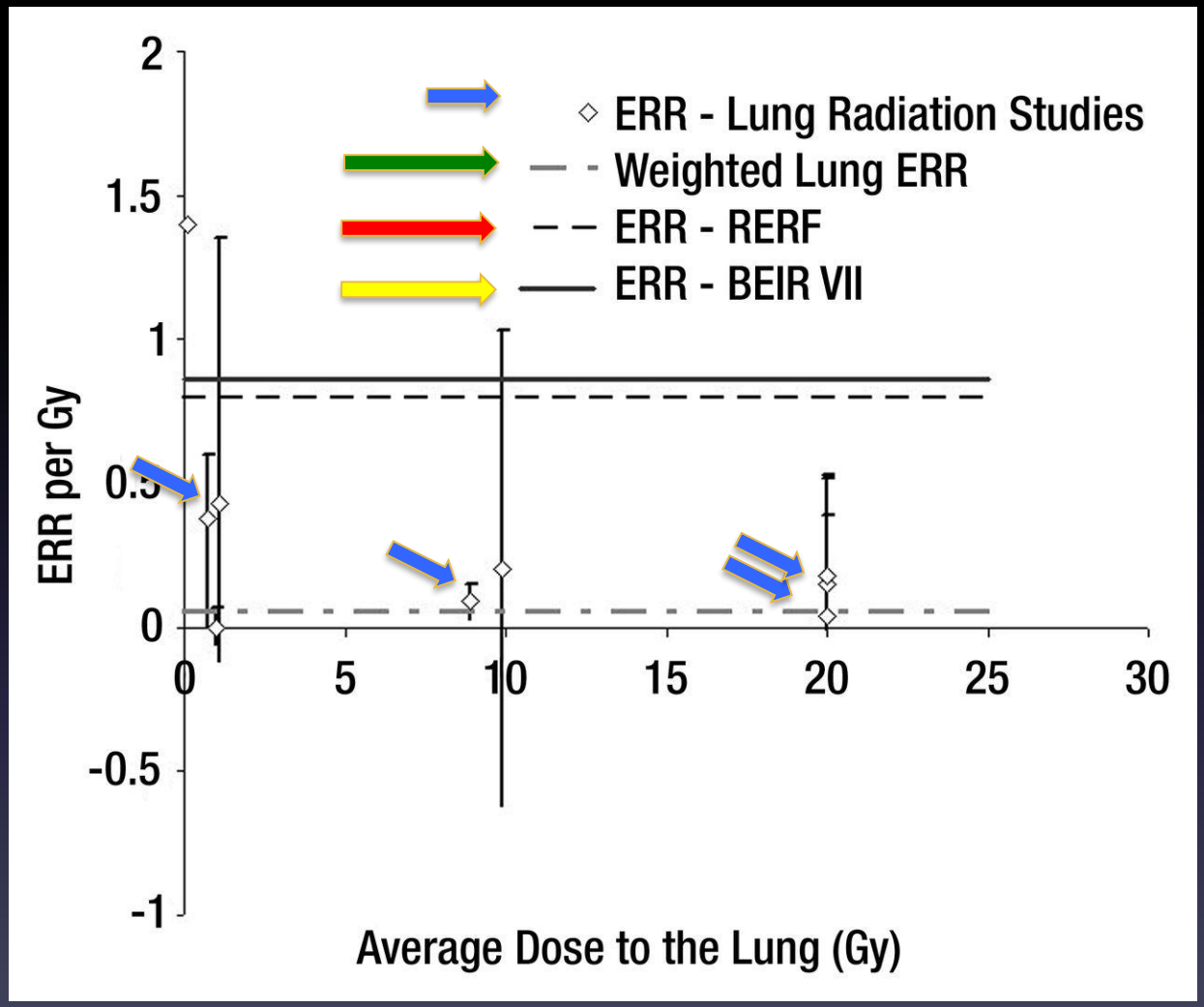
- Various studies that document increased cancer incidence in the lung and breast from radiation administered usually for therapeutic purposes (Treatment of Lymphoma).

Risk Quantification According to Radiation Dose.

- For a given radiation dose, in a perfect world, all studies would yield similar values for the excess risks per gray.

- This was not the case

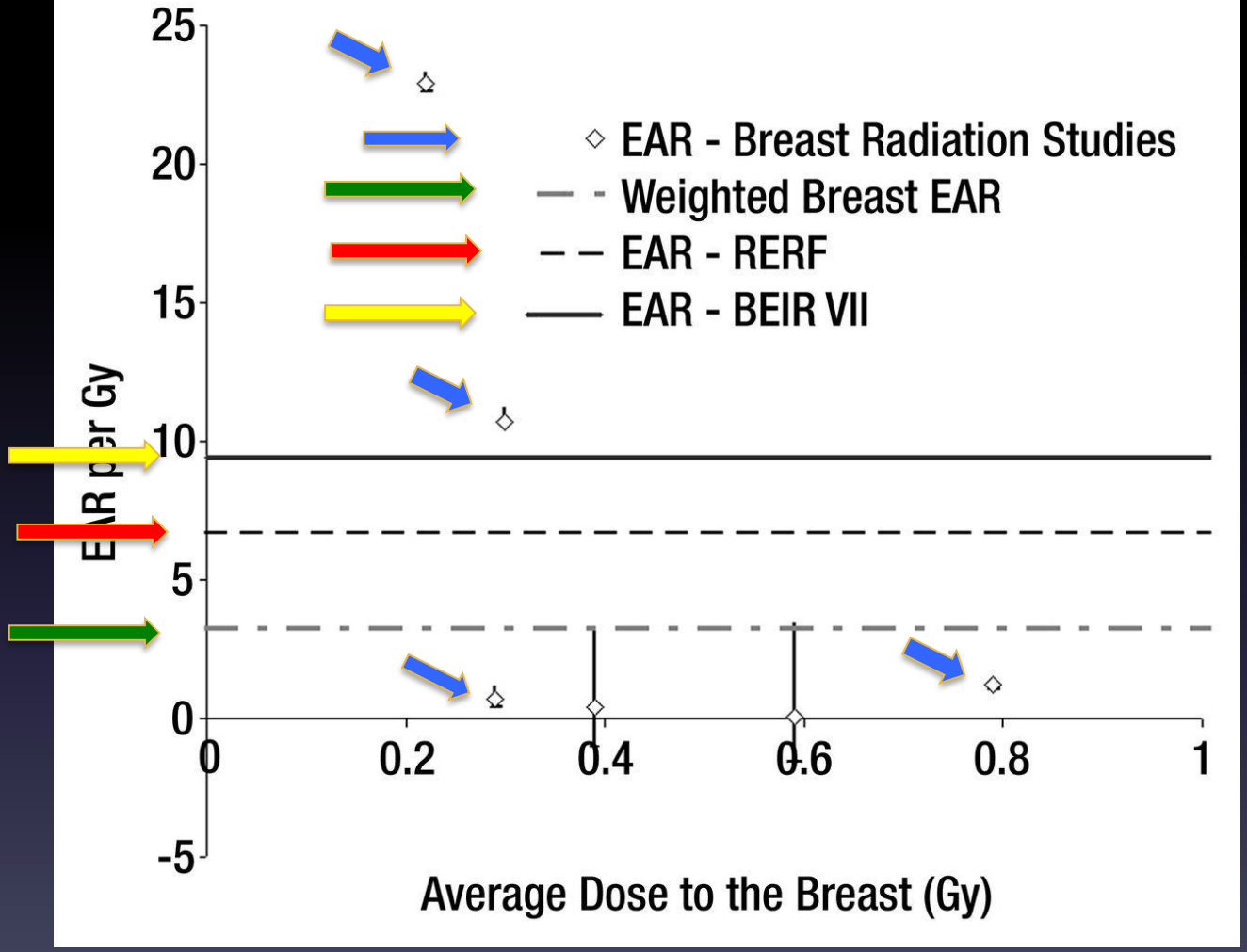
Data points = average values of excess relative risk per Gray (ERR) from individual studies (BEIR VII)



Hendee W R , O'Connor M K Radiology 2012;264:312-321

Radiology

Graph shows risk estimates from medical studies of radiation to the breast. Data points = average values of excess absolute risk (EAR) from individual studies (BEIR VII



Hendee W R , O'Connor M K Radiology 2012;264:312-321

Radiology

BEIR VII Risk Models: ERR vs EAR

- Furthermore, the BEIR VII committee uses two risk models as the foundation for estimating the likelihood of radiation-induced cancer, the ERR and the EAR

BEIR VII Risk Models

- The Excess Relative Risk (**ERR**) is the rate of disease in the exposed population divided by the rate of disease in an unexposed population minus 1.0

BEIR VII Risk Models

- The Excess Abslute Risk (**EAR**) is the rate of disease in an exposed population minus the rate of disease in an unexposed population.

LAR

- Risk factors from these models are incorporated into a final risk model, the **lifetime attributable risk (LAR)** model, to compute a risk estimate for the likelihood of radiation-induced cancer over the lifetime of individuals.

LAR model

- LAR model has been used to predict cancer incidence and deaths in populations of individuals exposed to medical radiation.

LAR Model: Uncertainties

- Given that both models ERR and EAR are based on the same data, one might anticipate reasonable agreement between them.

- This is not the case.

ERR versus EAR in LAR Model Male Patients

Cancer Site	Male Patients		
	LAR Based on Relative Risk Transport*	LAR Based on Absolute Risk Transport†	Combined and Adjusted by DDREF[15]
Stomach	25	280	34 (3, 350)
Colon	260	180	160 (66, 360)
Liver	23	150	27 (4, 180)
Lung	250	190	140 (50, 380)
Breast			
Prostate	190	6	44 (< 0, 1860)
Uterus			
Ovary			
Bladder	160	120	98 (29, 330)
Other	470	350	290 (120, 680)
Thyroid	32	No model	21 (5, 90)
Sum of site-specific estimates	1400	1310‡	800
All solid cancer model**	1550	1250	970 (490, 1920)

# of expected deaths by cancer / 100 000 individuals exposed to 100 mSv

ERR versus EAR in LAR Model Female Patients

Cancer Site	Female Patients		
	LAR Based on Relative Risk Transport*	LAR Based on Absolute Risk Transport†	Combined and Adjusted by DDREF‡§
Stomach	32	330	43 (5, 390)
Colon	160	110	96 (34, 270)
Liver	9	85	12 (1, 130)
Lung	740	370	300 (120, 780)
Breast	510 (not used)	460	310 (160, 610)
Prostate			
Uterus	19	81	20 (< 0, 131)
Ovary	66	47	40 (9, 170)
Bladder	160	100	94 (30, 290)
Other	490	320	290 (120, 680)
Thyroid	160	No model	100 (25, 440)
Sum of site-specific estimates	2310#	2060#	1310
All solid cancer model**	2230	1880	1410 (740, 2690)

# of expected deaths by cancer / 100 000 individuals exposed to 100 mSv

LAR < ERR or EAR …

- Clearly one or both models are in error.
- Because of the paucity of data, unfortunately, it is not possible to determine which model is more accurate.

BEIR VII committee

- The BEIR VII committee resolved the differences between ERR and EAR models by combining estimates from them by using the following expression:
- LAR = *p* . LAR (ERR) + (1 - *p*) LAR (EAR)

- where *p* is determined by the views and opinions of the committee members.

Caution in BEIR VII report

- BEIR VII report states further that the "…range of plausible values for lifetime risk is consequently labeled a '**subjective confidence interval'** to emphasize its' [*sic*] dependence on the opinions of the committee in addition to direct numerical observation"

LAR of Solid Cancer Incidence

Cancer Site	Male Patients			Female Patients		
	LAR Based on Relative Risk Transport*	LAR Based on Absolute Risk Transport†	Combined and Adjusted by DDREF‡§	LAR Based on Relative Risk Transport*	LAR Based on Absolute Risk Transport†	Combined and Adjusted by DDREF‡§
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Note.—Rep… …ta in parentheses are subjective 95% confid…

*Linear esti…

†Linear esti…

‡Estimates … …st, and thyroid, relative risk transport was given a weight of 0.7 and absolute risk transport was given a weight of 0.3. These weights were reversed for lung cancer. Models for breast and thyroid cancer were based on data that included Caucasian …

§Including u… …ed age is not included except for the all solid cancer model.

‖Includes th…

#Includes b…

**Estimates based on model developed by analyzing life span study incidence data on all solid cancers excluding thyroid cancer and nonmelanoma skin cancer as a single category (table 12-1).

Expected number of Solid Cancers (LAR)

With subjective confidence interval

For 100 000 individuals exposed to 100 mSv

Liver Expected : 12 – 95% CI: 1 – 130

Prostate Expected : 44 – 95% CI: < 0 – 1860

Hendee W R , O'Connor M K Radiology 2012;264:312-321

BEIR VII statement

- Many articles using BEIR VII report data omit to acknowledge the limitations of BEIR VII and accept its risk estimates as scientific fact rather than as a consensus (averaged) opinion of a committee.

RERF – Ongoing Study

- Furthermore ….

RERF – Ongoing studies Update < 2012

RADIATION RESEARCH 177, 229–243 (2012)
0033-7587/12 $15.00

DOI: 10.1667/RR2629.1

Studies of the Mortality of Atomic Bomb Survivors, Report 14, 1950–2003: An Overview of Cancer and Noncancer Diseases

Kotaro Ozasa,[a,1] Yukiko Shimizu,[a] Akihiko Suyama,[a] Fumiyoshi Kasagi,[a,b] Midori Soda,[a] Eric J. Grant,[a] Ritsu Sakata,[a] Hiromi Sugiyama[a] and Kazunori Kodama[c]

[a] *Department of Epidemiology and* [c]*Chief Scientist, Radiation Effects Research Foundation, 5-2 Hijiyama-koen, Minami-ku, Hiroshima, 732-0815, Japan; and* [b] *Institute of Radiation Epidemiology, Radiation Effects Association 1-9-16, Kaji-cho, Chiyoda-ku, Tokyo, 101-0044, Japan*

Radiation Research 2012: 243, 229-243

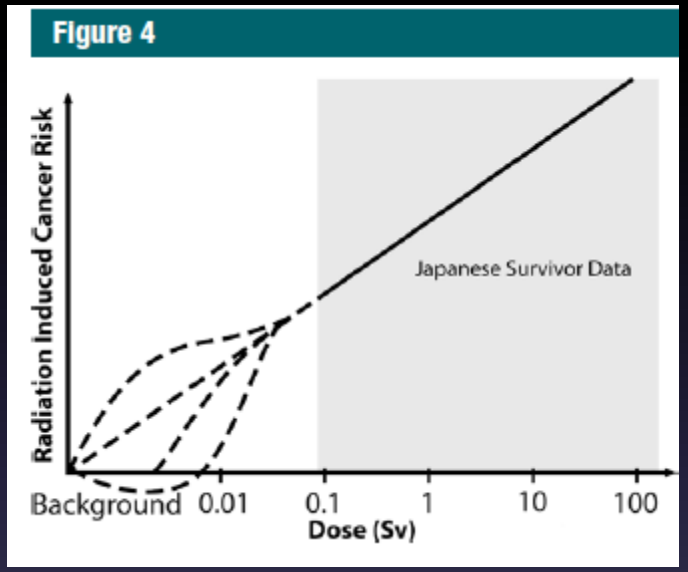
Osaza et al Data

- It is standard practice (e.g., in the BEIR VII report) to claim:
  - « RERF data are consistent with the LNT model »
  - « low-dose radiation can increase the risk of cancer »
- However, the latest update to the RERF by Ozasa et al.
  - Is qualitatively different from earlier such reports
  - shows lower than expected cancer rates in the 0.3–0.7 Gy dose region

Curvature of the Dose Response Relashionship.

TABLE 7
Change in Dose–Response Curvature For Excess Relative Risk (ERR) of Solid Cancer in The range of 0–2.0 Gy by Observation Period

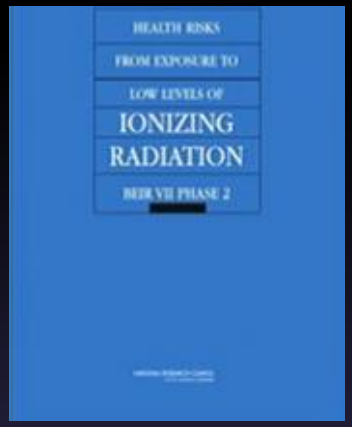
	1950–1985	1950–1995	1950–2003
Curvature (θ)[a]	0.20	0.40	0.81
95% CI[b]	(−0.23, 3.2)	(−0.09, 3.2)	(0.08, 8.6)
Significance (*P*)[c]	0.50	0.16	0.02



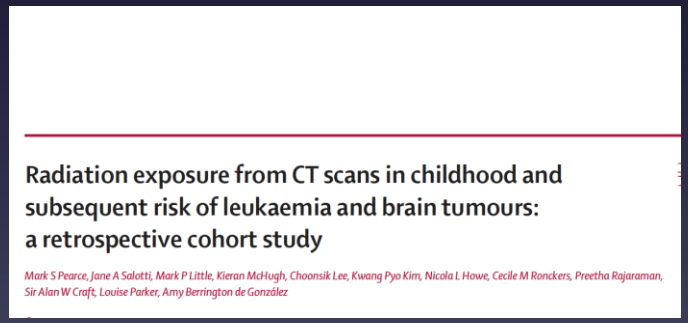
The observed curvature of the dose-risk relashionship in the lower dose range cannot be explained with the LNT model but is consistent with the radiation **hormesis** model

A Epidemiological studies

- A1: BEIR VII



- **A2: Studies on Pediatric CT**


Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study

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A2: Epidemiological Studies on Pediatric CT

- Several Authors attempt to prove the direct increase in cancer risks from CT
- The target population is pediatric.
- Secondary aim is to prove the LNT model

Pearce MS et al. **Lancet** 2012;380(9840):499–505
Mathews JD et al. **BMJ** 2013;346:f2360
Huang WY et al. **Br J Cancer** 2014;110(9):2354–2360

Epidemiological Studies

Pearce, Lancet 2012

Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study

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- 3.18 fold Cancer Risk if Brain CT with > 30 mGy

www.thelancet.com Published online June 7, 2012 DOI:10.1016/S0140-6736(12)60815-0

Matthews JD et al. BMJ 2013; 346

BMJ

BMJ 2013;346:f2360 doi: 10.1136/bmj.f2360 (Published 22 May 2013)

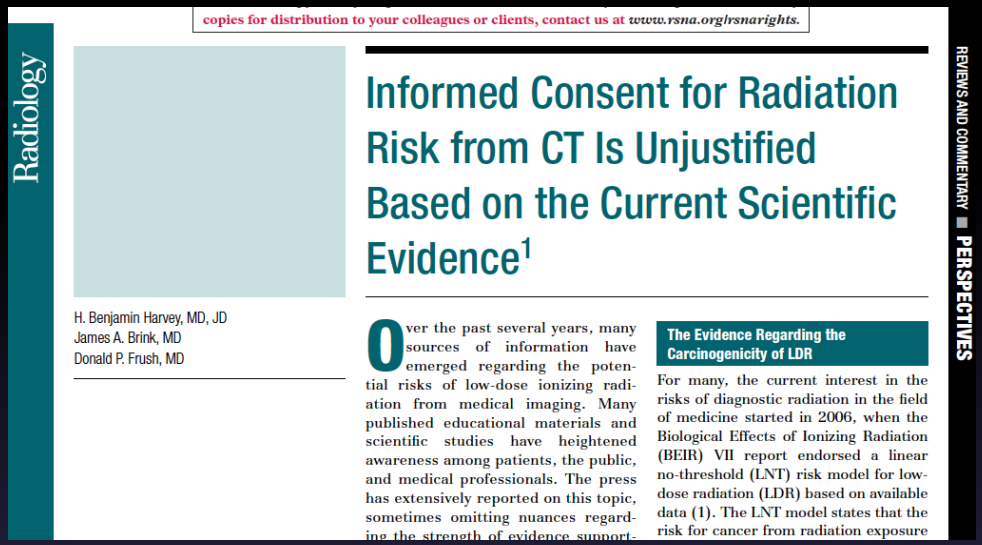
RESEARCH

Cancer risk in 680 000 people exposed to computed tomography scans in childhood or adolescence: data linkage study of 11 million Australians

John D Mathews *epidemiologist*[1], Anna V Forsythe *research officer*[1], Zoe Brady *medical physicist*[1 2], Martin W Butler *data analyst*[3], Stacy K Goergen *radiologist*[4], Graham B Byrnes *statistician*[5], Graham

- Excess risk for leukemia and solid cancers
- « Dose response relashionship. » - LNT model

Current Scientific Evidence …?



Radiology

Informed Consent for Radiation Risk from CT Is Unjustified Based on the Current Scientific Evidence[1]

H. Benjamin Harvey, MD, JD
James A. Brink, MD
Donald P. Frush, MD

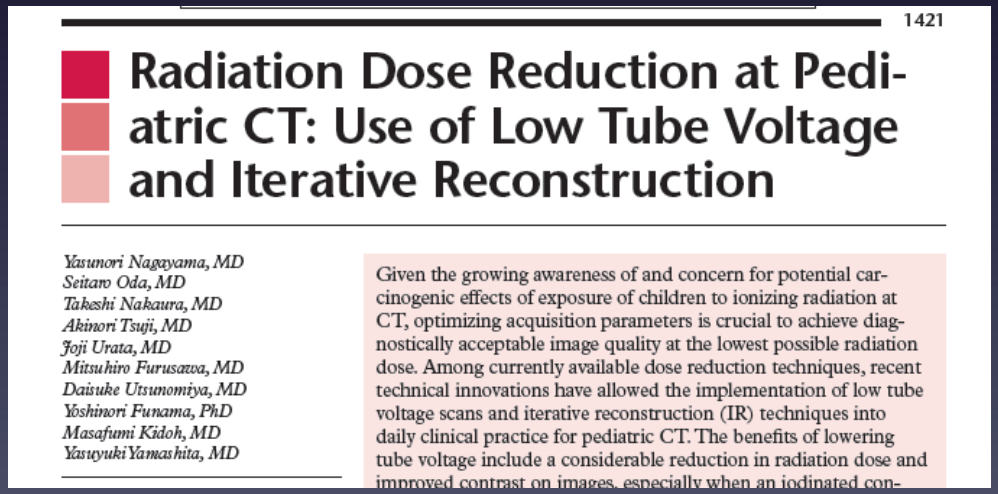
Over the past several years, many sources of information have emerged regarding the potential risks of low-dose ionizing radiation from medical imaging. Many published educational materials and scientific studies have heightened awareness among patients, the public, and medical professionals. The press has extensively reported on this topic, sometimes omitting nuances regarding the strength of evidence support-

The Evidence Regarding the Carcinogenicity of LDR

For many, the current interest in the risks of diagnostic radiation in the field of medicine started in 2006, when the Biological Effects of Ionizing Radiation (BEIR) VII report endorsed a linear no-threshold (LNT) risk model for low-dose radiation (LDR) based on available data (1). The LNT model states that the risk for cancer from radiation exposure

REVIEWS AND COMMENTARY ■ PERSPECTIVES

Harvey HB et al.
Radiology 2015; 275(2): 321–325



Radiation Dose Reduction at Pediatric CT: Use of Low Tube Voltage and Iterative Reconstruction

Yasunori Nagayama, MD
Seitaro Oda, MD
Takeshi Nakaura, MD
Akinori Tsuji, MD
Joji Urata, MD
Mitsuhiro Furusawa, MD
Daisuke Utsunomiya, MD
Yoshinori Funama, PhD
Masafumi Kidoh, MD
Yasuyuki Yamashita, MD

Given the growing awareness of and concern for potential carcinogenic effects of exposure of children to ionizing radiation at CT, optimizing acquisition parameters is crucial to achieve diagnostically acceptable image quality at the lowest possible radiation dose. Among currently available dose reduction techniques, recent technical innovations have allowed the implementation of low tube voltage scans and iterative reconstruction (IR) techniques into daily clinical practice for pediatric CT. The benefits of lowering tube voltage include a considerable reduction in radiation dose and improved contrast on images, especially when an iodinated con-

Nagayama Y et al.
Radiographics 2018; 38(5): 1421-1440.

The studies by Pearce et al and Matthews et al . lacked a control group

- failed to account for pediatric medical conditions that would confound the study results
- failed to detect a known association between leukemia incidence and these conditions
- Typical condition: patients with Down syndrome, genetic syndromes and immune deficiencies have a greatly increased risk for childhood leukemia and increased exposure to diagnostic imaging

Huang, W-Y et al. BJC 2014

FULL PAPER

BJC

British Journal of Cancer (2014) 110, 2354–2360 | doi: 10.1038/bjc.2014.103

Keywords: computed tomography; radiation-induced cancer; brain tumour; leukaemia; cohort study

Paediatric head CT scan and subsequent risk of malignancy and benign brain tumour: a nation-wide population-based cohort study

W-Y Huang[1,2], C-H Muo[3], C-Y Lin[4], Y-M Jen[1], M-H Yang[2,5], J-C Lin[1], F-C Sung[3,6] and C-H Kao[*,6,7]

[1]Department of Radiation Oncology, Tri-Service General Hospital, National Defense Medical Center, Taipei, Taiwan; [2]Institute of Clinical Medicine, National Yang-Ming University, Taipei, Taiwan; [3]Management Office for Health Data, China Medical University Hospital, Taichung 404, Taiwan; [4]Department of Radiation Oncology, Chang Gung Memorial Hospital, Taoyuan, Taiwan; [5]Division of Hematology-Oncology, Department of Medicine, Taipei Veterans General Hospital, Taipei, Taiwan; [6]Graduate Institute of Clinical Medicine Science and School of Medicine, College of Medicine, China Medical University, Taichung, Taiwan and [7]Department of Nuclear Medicine and PET Center, China Medical University Hospital, Taichung, Taiwan

Background: To evaluate the possible association between paediatric head computed tomography (CT) examination and increased subsequent risk of malignancy and benign brain tumour.

Methods: In the exposed cohort, 24 418 participants under 18 years of age, who underwent head CT examination between 1998 and 2006, were identified from the Taiwan National Health Insurance Research Database (NHIRD). Patients were followed up until a diagnosis of malignant disease or benign brain tumour, withdrawal from the National Health Insurance (NHI) system, or at the end of 2008.

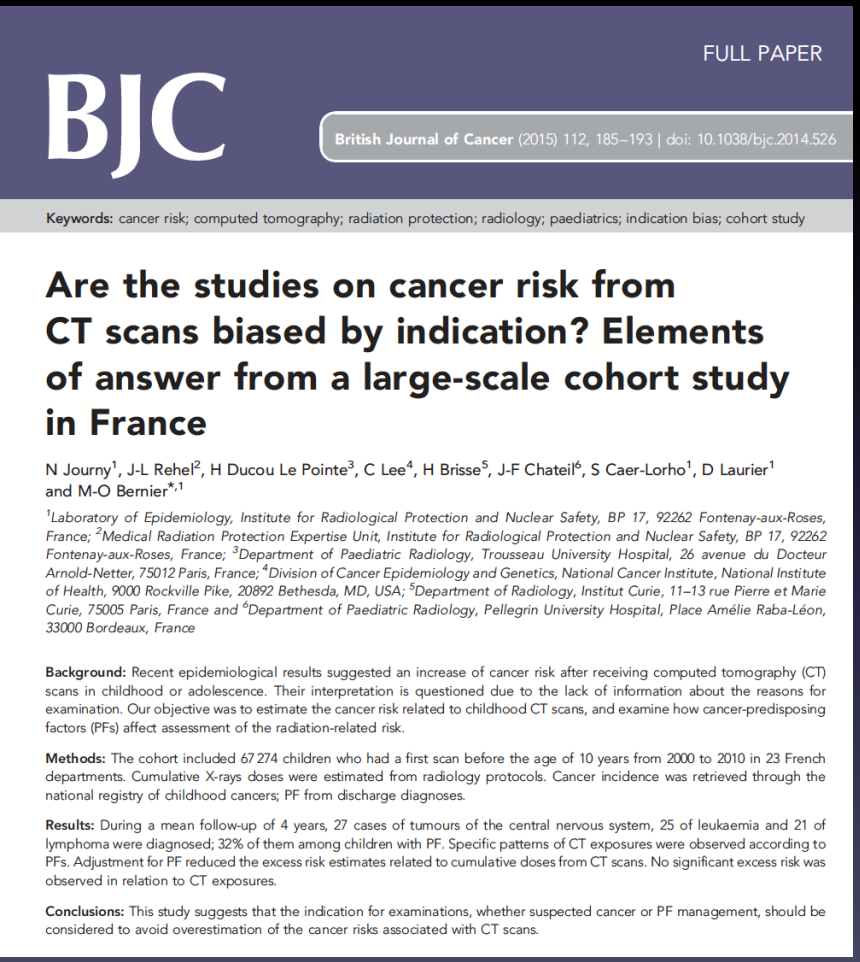
Results: The overall risk was not significantly different in the two cohorts (incidence rate = 36.72 per 100 000 person-years in the exposed cohort, 28.48 per 100 000 person-years in the unexposed cohort, hazard ratio (HR) = 1.29, 95% confidence interval (CI) = 0.90–1.85). The risk of benign brain tumour was significantly higher in the exposed cohort than in the unexposed cohort (HR = 2.97, 95% CI = 1.49–5.93). The frequency of CT examination showed strong correlation with the subsequent overall risk of malignancy and benign brain tumour.

Conclusions: We found that paediatric head CT examination was associated with an increased incidence of benign brain tumour. A large-scale study with longer follow-up is necessary to confirm this result.

In contrast, the Taiwanese study excluded children with disorders that might increase cancer risk, including Down syndrome, and demonstrated no increased risk for leukemia

But … small increase in benign brain tumors

Journy L et al. BJC 2015



FULL PAPER

BJC

British Journal of Cancer (2015) 112, 185–193 | doi: 10.1038/bjc.2014.526

Keywords: cancer risk; computed tomography; radiation protection; radiology; paediatrics; indication bias; cohort study

Are the studies on cancer risk from CT scans biased by indication? Elements of answer from a large-scale cohort study in France

N Journy[1], J-L Rehel[2], H Ducou Le Pointe[3], C Lee[4], H Brisse[5], J-F Chateil[6], S Caer-Lorho[1], D Laurier[1] and M-O Bernier[*,1]

[1]*Laboratory of Epidemiology, Institute for Radiological Protection and Nuclear Safety, BP 17, 92262 Fontenay-aux-Roses, France;* [2]*Medical Radiation Protection Expertise Unit, Institute for Radiological Protection and Nuclear Safety, BP 17, 92262 Fontenay-aux-Roses, France;* [3]*Department of Paediatric Radiology, Trousseau University Hospital, 26 avenue du Docteur Arnold-Netter, 75012 Paris, France;* [4]*Division of Cancer Epidemiology and Genetics, National Cancer Institute, National Institute of Health, 9000 Rockville Pike, 20892 Bethesda, MD, USA;* [5]*Department of Radiology, Institut Curie, 11–13 rue Pierre et Marie Curie, 75005 Paris, France and* [6]*Department of Paediatric Radiology, Pellegrin University Hospital, Place Amélie Raba-Léon, 33000 Bordeaux, France*

Background: Recent epidemiological results suggested an increase of cancer risk after receiving computed tomography (CT) scans in childhood or adolescence. Their interpretation is questioned due to the lack of information about the reasons for examination. Our objective was to estimate the cancer risk related to childhood CT scans, and examine how cancer-predisposing factors (PFs) affect assessment of the radiation-related risk.

Methods: The cohort included 67 274 children who had a first scan before the age of 10 years from 2000 to 2010 in 23 French departments. Cumulative X-rays doses were estimated from radiology protocols. Cancer incidence was retrieved through the national registry of childhood cancers; PF from discharge diagnoses.

Results: During a mean follow-up of 4 years, 27 cases of tumours of the central nervous system, 25 of leukaemia and 21 of lymphoma were diagnosed; 32% of them among children with PF. Specific patterns of CT exposures were observed according to PFs. Adjustment for PF reduced the excess risk estimates related to cumulative doses from CT scans. No significant excess risk was observed in relation to CT exposures.

Conclusions: This study suggests that the indication for examinations, whether suspected cancer or PF management, should be considered to avoid overestimation of the cancer risks associated with CT scans.

In a retrospective cohort study from France, 67,724 children who underwent their first CT study before the age of 10 years showed no significant increased cancer risk from CT when adjusted for cancer-predisposing factors.

Reverse Causation

- Reverse causation occurs when CT scans are performed because of initial signs or symptoms of cancer.
- This cancer later may be assumed to be the consequence of CT, rather than the reason for the scan.
- To minimize this bias, the exclusion interval (ie, lag time) from the time of CT exposure to cancer diagnosis was set at **1–5 years**.
- This period may have been **too short** to exclude reverse causalities completely

Walsh L et al. , **J Radiol Prot** 2014;34(1):E1–E5

CT Induced Cancers in Children

- All studies suffer from
  - Lack of precise dose registering
  - Lack of registering clinical indications (cancers themselves not excluded).
- New European Project on 1 000 000 children (EPI-CT) - Int J Environ Res Public Health 2013;10(2):717–728

LNT or not LNT?

A. Epidemiological studies

A. Biological studies

Cancer Risk Quantification for LLR

- Basis: any single particle of radiation hitting a single DNA molecule can initiate a cancer.
- The probability of such a cancer initiation is proportional
  - to the number of such hits,
  - to the number of particles of radiation,
- Thus the risk is proportional to the dose: this is the “linear no-threshold” model (LNT).

Basics of LNT model: DSBs

- DNA double strand breaks (DSBs) are considered as responsible for cancer induction*
- DSBs can be quantified in cell cultures after low doses down to zero dose*
- DSBs can be quantified in human WBCs and increase after one MDCT examination **
- DSBs count also increases after Iodine injection *** and after any stress (infection, physical exercise ….)

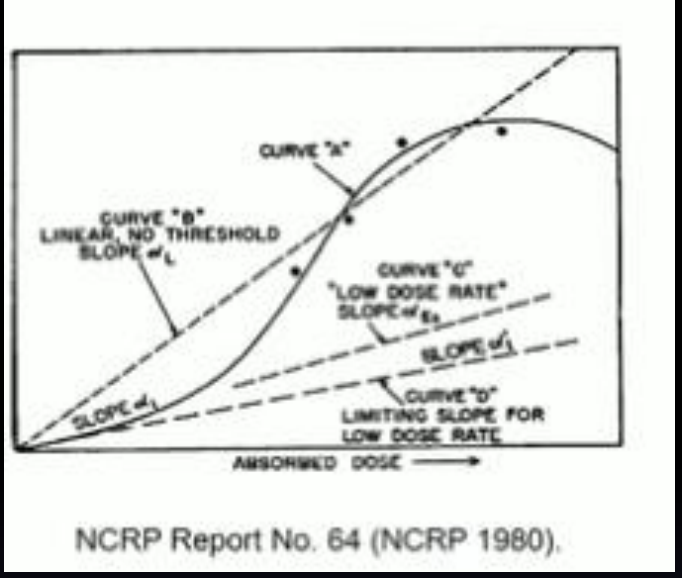
* Chadwick KH, Leenhouts HP. Risks from Ionizing radiations in Radiation Dose Fron Adult and Pediatric MDCT. Springer Berlin ISBN 3-540-28888-0

** Rothkamm K et al, Radiology January 2007 242:244-251

*** Grudzenski et al. Radiology 2009 253:706-714

LNT at Biological Level.

- The problem with the LNT is that factors other than initiating events affect carcinogenesis.
- Human bodies have biologic defense mechanisms that prevent almost all initiating events from developing into a fatal cancer
- In addition, substantial evidence exists that low-level radiation may even be protective against cancer—a view known as hormesis.

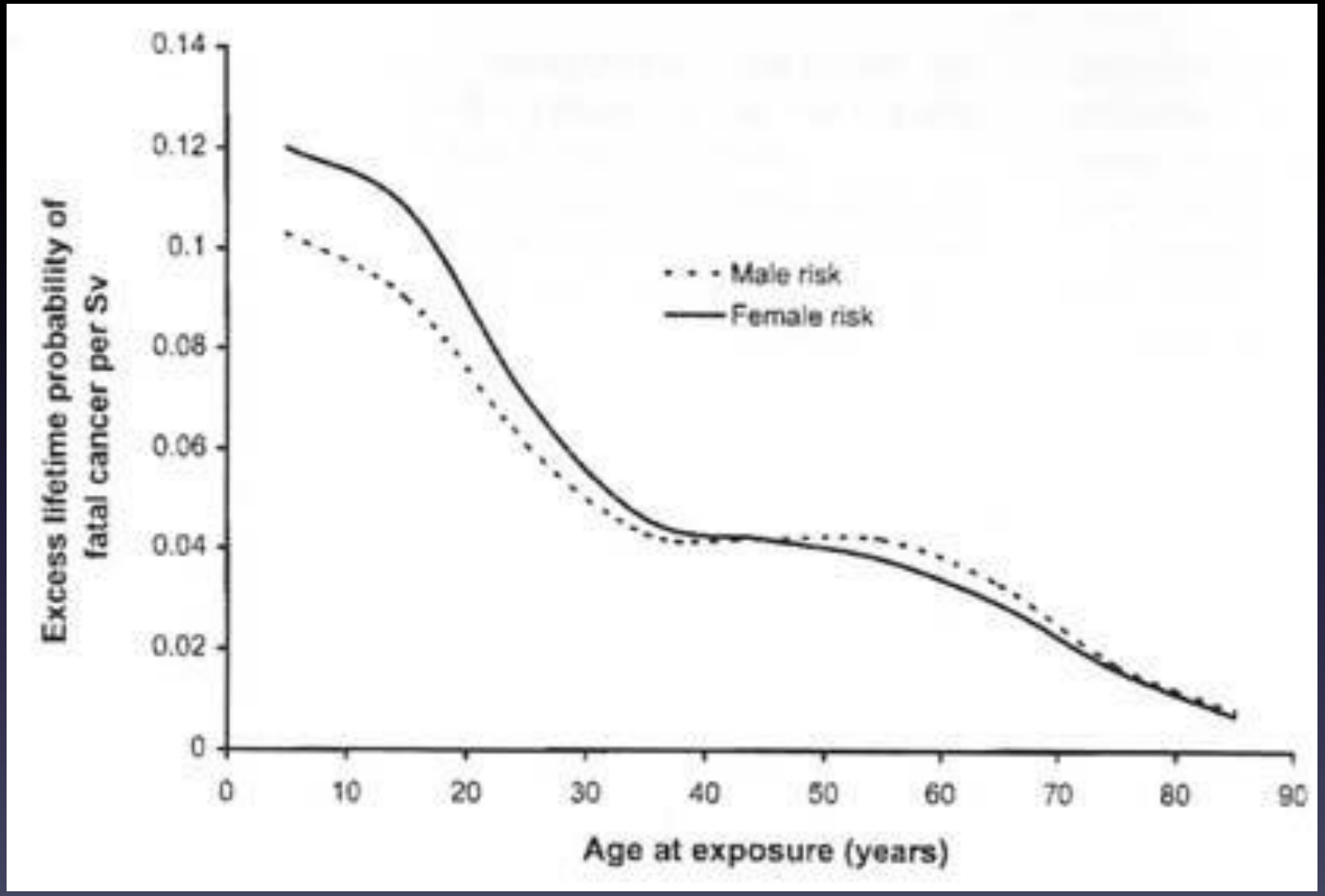


NCRP Report No. 64 (NCRP 1980).

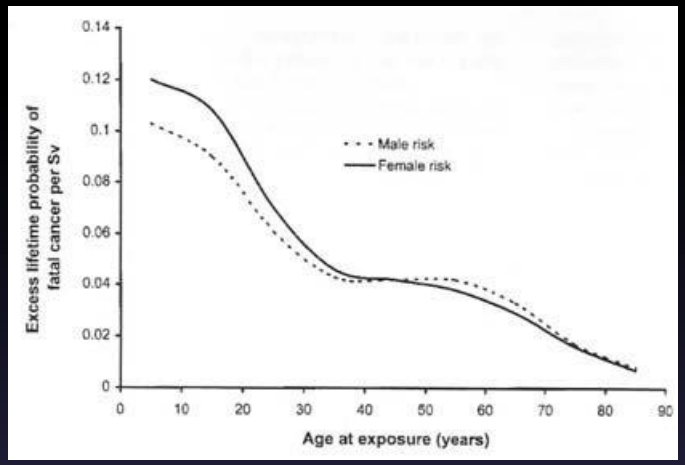
Take Home message
Radiation protection

- The LNT model reached large consensus among authorities
- Conservative approach (precautionary principle)
- Any radiation should be justified and minimized.

Risks Specific to Oncology Patients



Risks Specific to Oncology Patients



- Radiation Risks decrease with age
- Delay > 10 years to develop solid cancers
- Cancer risk increases with age

Radiation Protection in Oncology Patients

- It makes sense if
  - Life expectancy is not reduced (thyroid, gonads, leukemias..)
  - Cancer patients are young
- Debatable
  - New therapies incucing long survivals

- https://www.xrayrisk.com/calculator/calculator-normal-studies.php
- Risk calculations based on the LNT and the BEIRVII - LAR method (overestimations).
- Not to be used for individual patients but only for population-based calculations

X-RAY RISK

Promoting responsible imaging
through patient and provider education

CT Chest-Abdomen-Pelvis
23 year old male
4 examens

Study:	**Chest, Abdomen and Pelvis CT**	
Gender:	Male ● Female ○	
Age at Time of Study:	23	(years)
Number of Exams:	4	
Effective Dose:	21.000	(mSv)
DLP (Optional for CT):	250	(mGy · cm)

Calculate | Add This Exam to your Report

Total Effective Dose:	18	(mSv)	
Additional Cancer Risk:	0.19125	(%)	**1 in 523**
Baseline Cancer Risk:	44.9	(%)	
Baseline + Additional Risk:	45.0912	(%)	

X-RAY RISK

Promoting responsible imaging
through patient and provider education

CT Chest-Abdomen-Pelvis
21 year old female
4 examens

Study:	**Chest, Abdomen and Pelvis CT**	
Gender:	Male ○ Female ●	
Age at Time of Study:	21	(years)
Number of Exams:	4	
Effective Dose:	21.000	(mSv)
DLP (Optional for CT):	250	(mGy · cm)

Calculate | Add This Exam to your Report

Total Effective Dose:	18	(mSv)	
Additional Cancer Risk:	0.32612	(%)	**1 in 307**
Baseline Cancer Risk:	37.5	(%)	
Baseline + Additional Risk:	37.8261	(%)	

CT Chest-Abdomen-Pelvis
83 year old male
4 examens

Study:	**Chest, Abdomen and Pelvis CT**	
Gender:	Male ● Female ○	
Age at Time of Study:	83	(years)
Number of Exams:	4	
Effective Dose:	21.000	(mSv)
DLP (Optional for CT):	250	(mGy · cm)

Calculate | Add This Exam to your Report

Total Effective Dose:	18	(mSv)	
Additional Cancer Risk:	0.03673	(%)	**1 in 2723**
Baseline Cancer Risk:	44.9	(%)	
Baseline + Additional Risk:	44.9367	(%)	

Add This Exam to your Report

To learn more about how these calculations are made, see the About page.

Take home message in oncology patients:

- Whatever the exam and the patient's age or gender, the additional risk from CT is negligible.

Belgian Law< FANC EU2013/57 Directive

Published Feb 20, 2020, effective March 1, 2020

FEDERALE OVERHEIDSDIENST BINNENLANDSE ZAKEN EN FEDERAAL AGENTSCHAP VOOR NUCLEAIRE CONTROLE

[2020/200179]

13 FEBRUARI 2020. — Koninklijk besluit betreffende de medische blootstellingen en blootstellingen bij niet-medische beeldvorming met medisch-radiologische uitrustingen

VERSLAG AAN DE KONING

Sire,

Wij hebben de eer ter ondertekening van Uwe Majesteit een koninklijk besluit voor te leggen betreffende de medische blootstellingen en blootstellingen bij niet-medische beeldvorming met medisch-radiologische uitrustingen.

De ontwerptekst van het besluit werd voor advies voorgelegd aan de daartoe bevoegde adviesinstanties.

De Raad van State verleende op 16 oktober 2019 het advies nr. 66.588/3 op basis van art. 84 § 1, eerste lid, 2°, van de gecoördineerde wetten op de Raad van State.

1. Inleiding

SERVICE PUBLIC FEDERAL INTERIEUR ET AGENCE FEDERALE DE CONTROLE NUCLEAIRE

[2020/200179]

13 FEVRIER 2020. — Arrêté royal relatif aux expositions médicales et aux expositions à des fins d'imagerie non médicale avec des équipements radiologiques médicaux

RAPPORT AU ROI

Sire,

J'ai l'honneur de soumettre à la signature de Votre Majesté un arrêté royal relatif aux expositions médicales et aux expositions à des fins d'imagerie non médicale avec des équipements radiologiques médicaux.

Le projet a été soumis pour avis aux instances d'avis compétentes.

Le Conseil d'Etat a donné le 16 octobre 2019 son avis n° 66.588/3 en application de l'article 84, § 1er, alinéa 1er, 2°, des lois coordonnées sur le Conseil d'Etat.

1. Introduction

Belgian Law< FANC
EU2013/57 Directive

d) elke blootstelling bij niet-medische beeldvorming met medisch-radiologische uitrustingen die niet kan worden gerechtvaardigd is verboden.

d) toute exposition à des fins d'imagerie non médicale avec des équipements radiologiques médicaux qui ne peut être justifiée est interdite.

Any exposure that cannot be fustified is forbidden

§ 3. Voor de keuze en de rechtvaardiging van radiodiagnostische onderzoeken of interventionele radiologie, nemen de verwijzende persoon en de practicus de van kracht zijnde nationale richtlijnen medische beeldvorming, bedoeld in artikel 25, in acht, evenals de stralingsdoses die worden opgelopen bij de beoogde onderzoeken.

§ 3. Pour le choix et la justification d'examens radiodiagnostiques ou en radiologie interventionnelle, la personne référente et le praticien prennent en considération les recommandations nationales en vigueur en matière d'imagerie médicale visées à l'article 25, ainsi que les doses de rayonnement provoquées par les examens envisagés.

Any imaging request has to take guidelines in medical imaging into consideretaion

Belgian Law< FANC
EU2013/57 Directive

Art. 4.

Medische blootstellingen moeten voldoende netto voordeel opleveren wanneer het totale potentiële diagnostische of therapeutische voordeel, waaronder begrepen het directe voordeel voor de gezondheid of de levenskwaliteit van de persoon die de blootstelling ondergaat en het maatschappelijke voordeel, wordt afgewogen tegen de individuele schade welke de persoon die de blootstelling ondergaat, kan ondervinden, rekening houdend met de doeltreffendheid, de voordelen en de risico's van beschikbare alternatieve technieken die hetzelfde oogmerk hebben maar die geen of minder blootstelling aan ioniserende stralingen met zich meebrengen.

Art. 5.

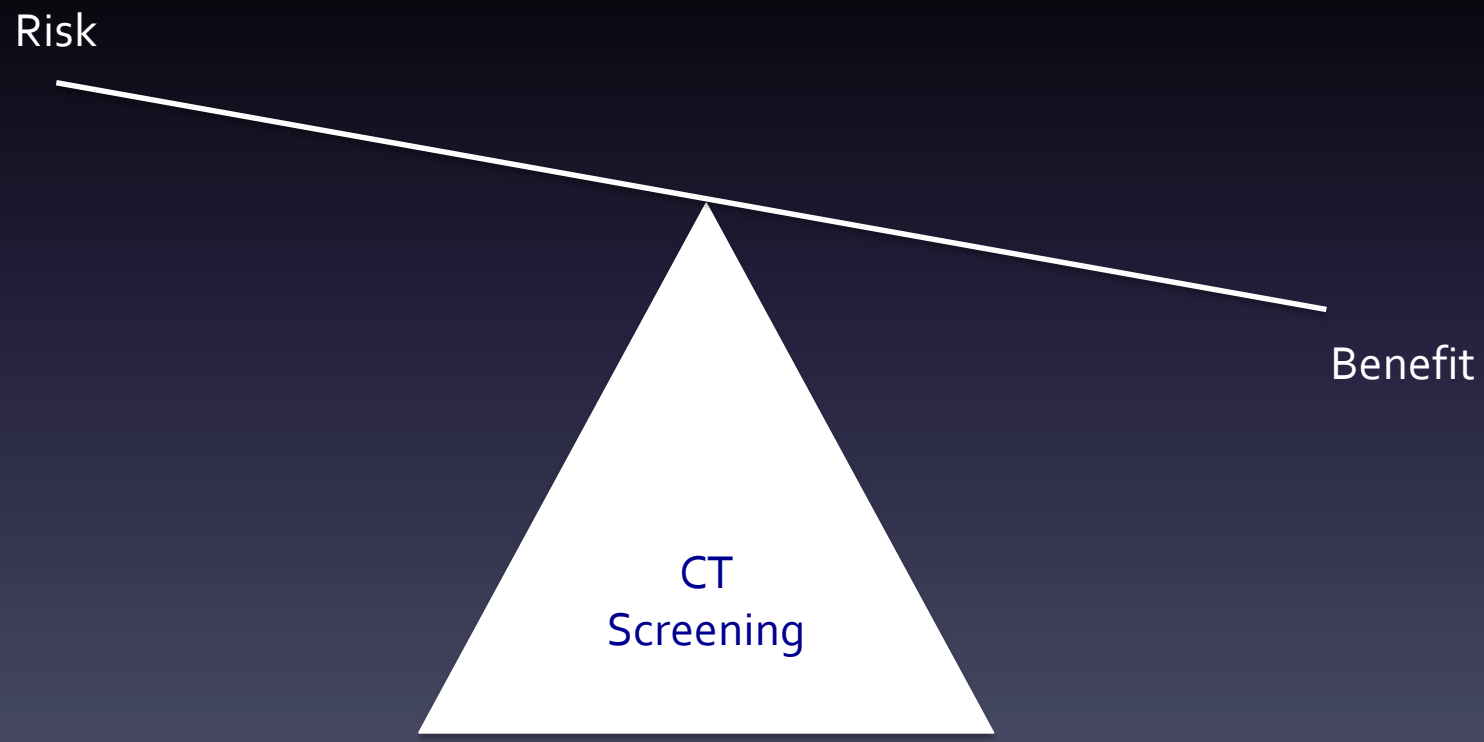
Art. 4.

Les expositions médicales doivent présenter un avantage net suffisamment grand, quand on compare les avantages diagnostiques ou thérapeutiques potentiels globaux qu'elles procurent, en ce compris les avantages directs pour la santé ou la qualité de vie de la personne concernée et les avantages pour la société, par rapport au détriment individuel que l'exposition pourrait provoquer, en tenant compte de l'efficacité, des avantages et des risques que présentent d'autres techniques disponibles visant le même objectif mais n'impliquant aucune exposition ou une exposition moindre aux rayonnements ionisants.

Art. 5.

Any exposure must be associated with a benefit either for the patient or for the population and or civil society.

Benefit must outweigh Radiogenic Risk



B/R in routine clinical practice

- Benefits and risks must be compared though the number of saved *vs.* lost lives. … !
- In routine clinical practice,
- Radiation doses are supposed to be very low
- Benefits are supposed to be much larger
- but have never been and cannot be calculated

Screening

- The balance beween riks and benefit can be calculated (saved vs lost lives)
  - Mammography
  - **Lung cancer screening**

Model for B/R estimation: Lung Cancer Screening

- 1,4 million deaths per year worldwide
- Fewer than 15% detected at stage I
- Stage I : 5-years survival: 70%
- Advanced stages: 5-years survival: <10%
- Screening of at risk asymptomatic population

Benefit *vs.* Risks in Lung CS

RESEARCH

Exposure to low dose computed tomography for lung cancer screening and risk of cancer: secondary analysis of trial data and risk-benefit analysis

Cristiano Rampinelli,[1] Paolo De Marco,[2] Daniela Origgi,[3] Patrick Maisonneuve,[4] Monica Casiraghi,[5] Giulia Veronesi,[5,6] Lorenzo Spaggiari,[5,7] Massimo Bellomi[1,7]

[1]Department of Medical Imaging and Radiation Sciences, European Institute of Oncology, Milan, Italy
[2]Medical Physics School, University of Milan, Milan, Italy
[3]Division of Medical Physics, European Institute of Oncology, Milan, Italy
[4]Division of Epidemiology and Biostatistics, European Institute

ABSTRACT

OBJECTIVE

To estimate the cumulative radiation exposure and lifetime attributable risk of cancer incidence associated with lung cancer screening using annual low dose computed tomography (CT).

DESIGN

Secondary analysis of data from a lung cancer screening trial and risk-benefit analysis.

mSv for women. According to participants' age and sex, the lifetime attributable risk of lung cancer and major cancers after 10 years of CT screening ranged from 5.5 to 1.4 per 10 000 people screened, and from 8.1 to 2.6 per 10 000 people screened, respectively. In women aged 50-54, the lifetime attributable risk of lung cancer and major cancers was about fourfold and threefold higher than for men aged 65 and older, respectively. The numbers of lung cancer and major cancer cases induced by 10 years of screening in our

BMJ 2017;356:j347 | doi: 10.1136/bmj.j347

Cosmos Study, Italy

- MDCT in heavy smokers
- Age > 50 years
- 5203 subjects
- Annual MDCT for 10 consecutive years
- Recalls for suspicions findings with LDCT and PET/CT

BMJ 2017;356:j347 | doi: 10.1136/bmj.j347

Table 2 | Median cumulative organ dose and effective doses for screening and recall low dose CT scans and PET CT scans at baseline, 3rd, 5th, and 10th screening round

	Men				Women			
	Baseline	3rd year	5th year	10th year	Baseline	3rd year	5th year	10th year
No of participants	3439	3056	2768	1850	1764	1527	1352	884
Effective dose (mSv)	1.0	3.0	5.2	9.3	1.4	4.2	7.2	13.0
Organ dose (mGy):								
Breast	—	—	—	—	2.5	7.6	13.0	23.3
Bladder	0.0	0.1	0.1	0.2	0.0	0.1	0.1	0.2
Colon	0.2	0.7	1.2	2.2	0.2	0.6	1.1	2.0
Oesophagus	1.4	4.5	7.7	13.6	1.8	5.6	9.5	16.9
Gallbladder	1.5	4.6	7.9	14.0	1.3	4.2	7.2	12.9
Heart	2.1	6.8	11.5	20.5	2.5	7.6	13.0	23.2
Kidney	1.9	5.9	10.1	18.0	1.8	5.6	9.7	17.4
Liver	1.9	6.1	10.4	18.4	2.1	6.6	11.2	20.0
Lung	2.3	7.1	12.2	21.7	2.7	8.3	14.2	25.3
Ovaries	—	—	—	—	0.1	0.2	0.3	0.6
Marrow	0.8	2.5	4.3	7.6	0.9	2.8	4.7	8.4
Skeleton	1.4	4.3	7.4	13.3	1.7	5.3	9.1	16.5
Spleen	2.0	6.1	10.5	18.6	2.2	6.8	11.7	20.9
Stomach	1.9	5.9	10.0	17.9	2.0	6.1	10.4	18.7
Thyroid	0.2	0.6	1.1	1.9	0.5	1.6	2.8	5.2
Uterus	—	—	—	—	0.1	0.2	0.3	0.5

BMJ 2017;356:j347 | doi: 10.1136/bmj.j347

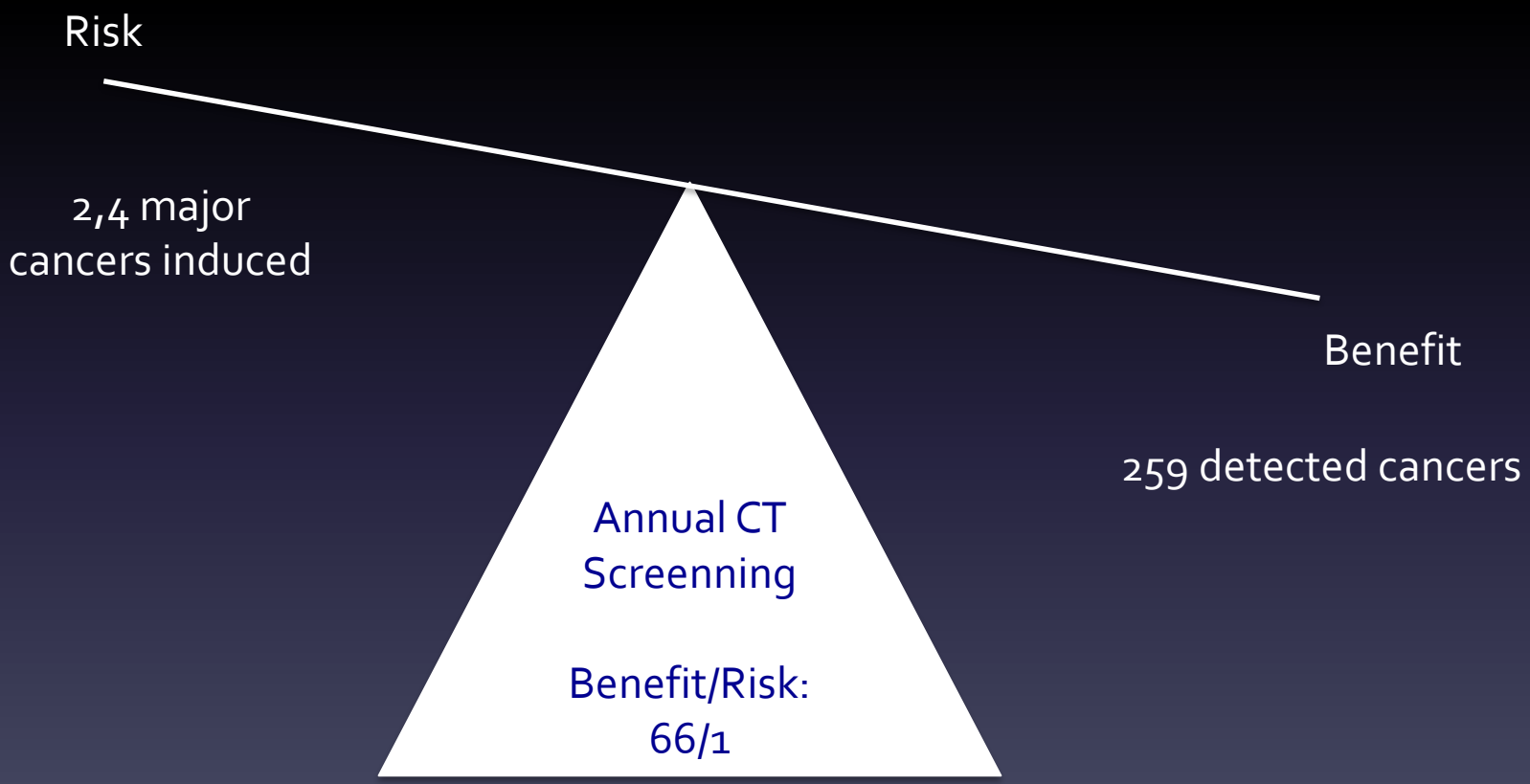
Table 3 | Number of lung cancers detected after 10 years of CT screening and number of estimated lung and major cancers associated with radiation exposure, according to age and sex of COSMOS trial participants

Participant age and sex at start of screening	No of participants	No of lung cancers detected	No of estimated radiation induced lung cancers (LAR/10 000)	No of estimated radiation induced major cancers* (LAR/10 000)
50-54				
Male	1153	35 (1 in 33)	0.24 (2.1)	0.43 (3.7)
Female	606	19 (1 in 32)	0.33 (5.5)	0.49 (8.1)
55-59				
Male	1114	56 (1 in 20)	0.21 (1.9)	0.38 (3.4)
Female	611	31 (1 in 20)	0.31 (5.1)	0.44 (7.2)
60-64				
Male	716	54 (1 in 13)	0.12 (1.7)	0.22 (3.0)
Female	345	13 (1 in 27)	0.16 (4.5)	0.21 (6.2)
≥65				
Male	456	41 (1 in 11)	0.07 (1.4)	0.12 (2.6)
Female	202	10 (1 in 20)	0.08 (3.8)	0.10 (5.1)
All ages, both sexes	5203	259 detected	1.5 induced	2.4 induced

LAR=lifetime attributable risk.
*Cumulative LAR for cancers of the stomach, colon, liver, lung, bladder, thyroid, breast, ovaries, uterus, or leukaemia.

BMJ 2017;356:j347 | doi: 10.1136/bmj.j347

Radiogenic Risk vs. Benefit



NLST Study

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*

ABSTRACT

NEJM 2011;365(5):2643-2653

NLST, USA

- LDCT vs. PA chest in heavy smokers (>30 P-Y)
- Age 55-74 years
- 53 454 subjects (26 722 LDCT)
- Baseline imaging + 2 annual follow-up.
- Septembre 2002 – April 2004

NEJM 2011;365(5):2643-2653

NSLT: Dose Quantification

Medical Physics and Informatics • Original Research

Body Size–Specific Organ and Effective Doses of Chest CT Screening Examinations of the National Lung Screening Trial

Choonsik Lee[1]
Michael J. Flynn[2]
Phillip F. Judy[3]
Dianna D. Cody[4]
Wesley E. Bolch[5]
Randell L. Kruger[6]

OBJECTIVE. We calculated body size–specific organ and effective doses for 23,734 participants in the National Lung Screening Trial (NLST) using a CT dose calculator.

MATERIALS AND METHODS. We collected participant-specific technical parameters of 23,734 participants who underwent CT in the clinical trial. For each participant, we calculated two sets of organ doses using two methods. First, we computed body size–specific organ and effective doses using the National Cancer Institute CT (NCICT) dosimetry program, which is based on dose coefficients derived from a library of body size–dependent adult male and female computational phantoms. We then recalculated organ and effective doses using dose coefficients from reference size phantoms for all examinations to investigate poten-

AJR 2017 May;208(5):1082-1088..

NSLT Risk Quantification

TABLE 3: Median Dose for Major Organs From One CT Screening Examination by Body Mass Index (BMI)[a] Group

Dose	Underweight[b] (*n* = 215 Participants)	Normal Weight[c] (*n* = 6550 Participants)	Overweight[d] (*n* = 10,182 Participants)	Obese[e] (*n* = 6787 Participants)
$CTDI_{vol}$ (mGy)	3.02	3.10	3.40	3.81
Organ dose (mGy) based on participant body size				
Brain	0.06	0.06	0.06	0.06
Lens	0.04	0.04	0.05	0.07
Salivary glands	0.59	0.60	0.66	0.74
Thyroid	6.42	6.41	6.48	6.34
Esophagus	3.93	3.60	3.21	2.95
Thymus	4.70	4.35	4.08	3.81
Lungs	4.93	4.56	4.19	3.90
Breasts	4.56	4.21	4.31	4.28
Red bone marrow	1.79	1.46	1.29	1.25
Effective dose based on participant body size (mSv)	2.80	2.37	2.19	2.10
Organ dose (mGy) based on reference body size				
Thyroid	6.17	6.18	6.68	7.12
Esophagus	3.40	3.59	3.73	4.15
Thymus	4.07	4.33	4.45	4.99
Lungs	4.28	4.33	4.70	5.03
Breasts	3.65	3.69	4.32	4.78
Red bone marrow	1.48	1.48	1.60	1.72
Effective dose based on reference body size (mSv)	2.29	2.31	2.52	2.71

AJR 2017 May;208(5):1082-1088..

NLST Induced Cancers

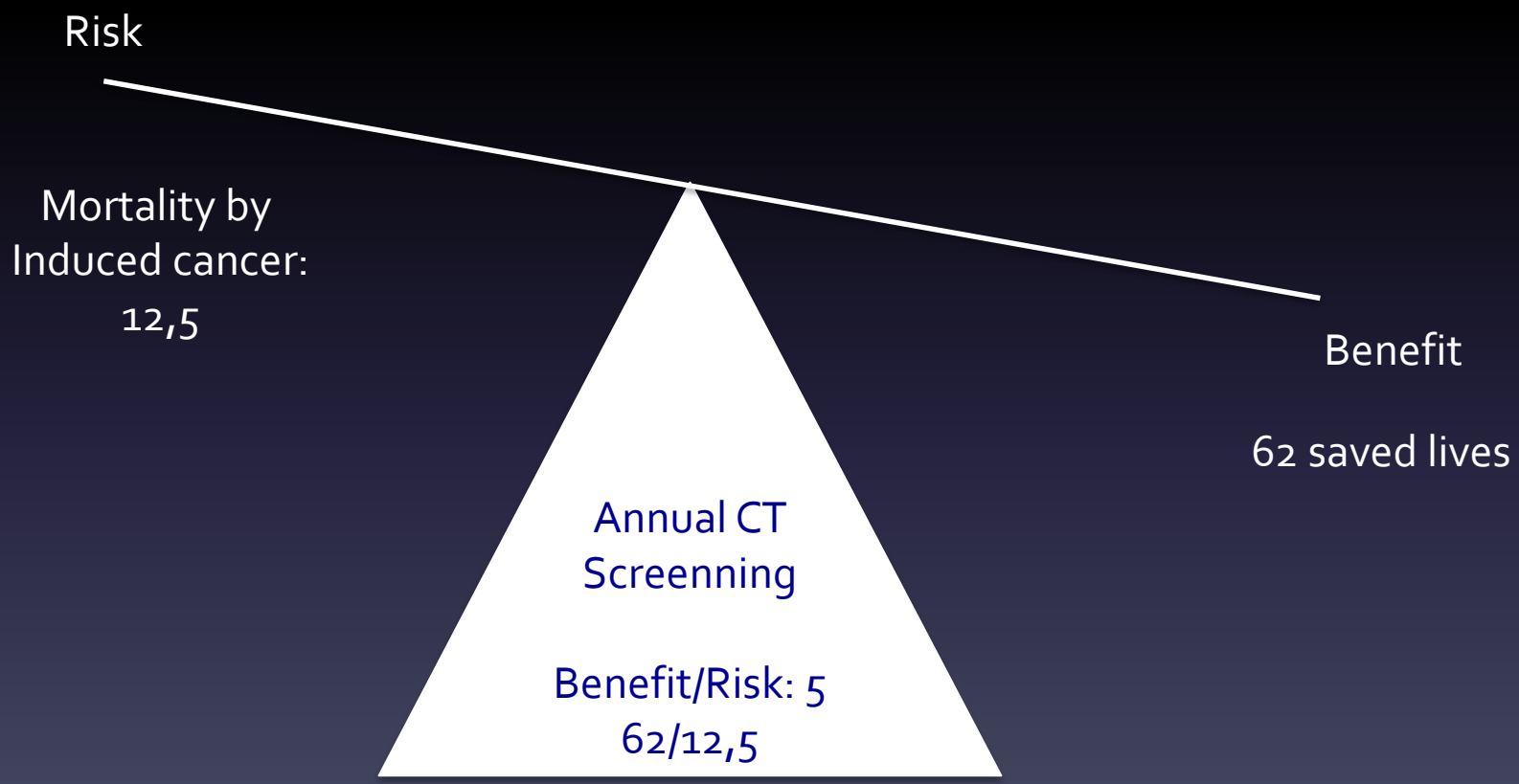
- 2,5 mSv x 100 000 = 250 Sv
- Normalized Risk: 5 deaths / 100 Sv
- Total induced death by cancer: 12,5 deaths

NLST Benefits

- 247 deaths / 100 000 in the LDCT group
- 309 deaths / 100 000 in the radiography group
- 62 saved lives by LDCT / 100 000

N. L. S. T. (2011). NEJM, *365*(5), 2643–2653

Radiogenic Risk vs. Benefit



Doses reduce over time

- NLST - CT Dose (2004) : 2,5 mSv
- COSMOS: CT Dose (2014): 1,0 mSv
- Nowadays: ULDCT= 0,1 – 0,3 mSv

Nelson Trial (Be/NL)

- 26% mortality reduction in men
- 60% mortality reduction in women
- Less repeated scans than in NLST
- B/R should be much higher than 5

Should I optimize in Oncology patiients?

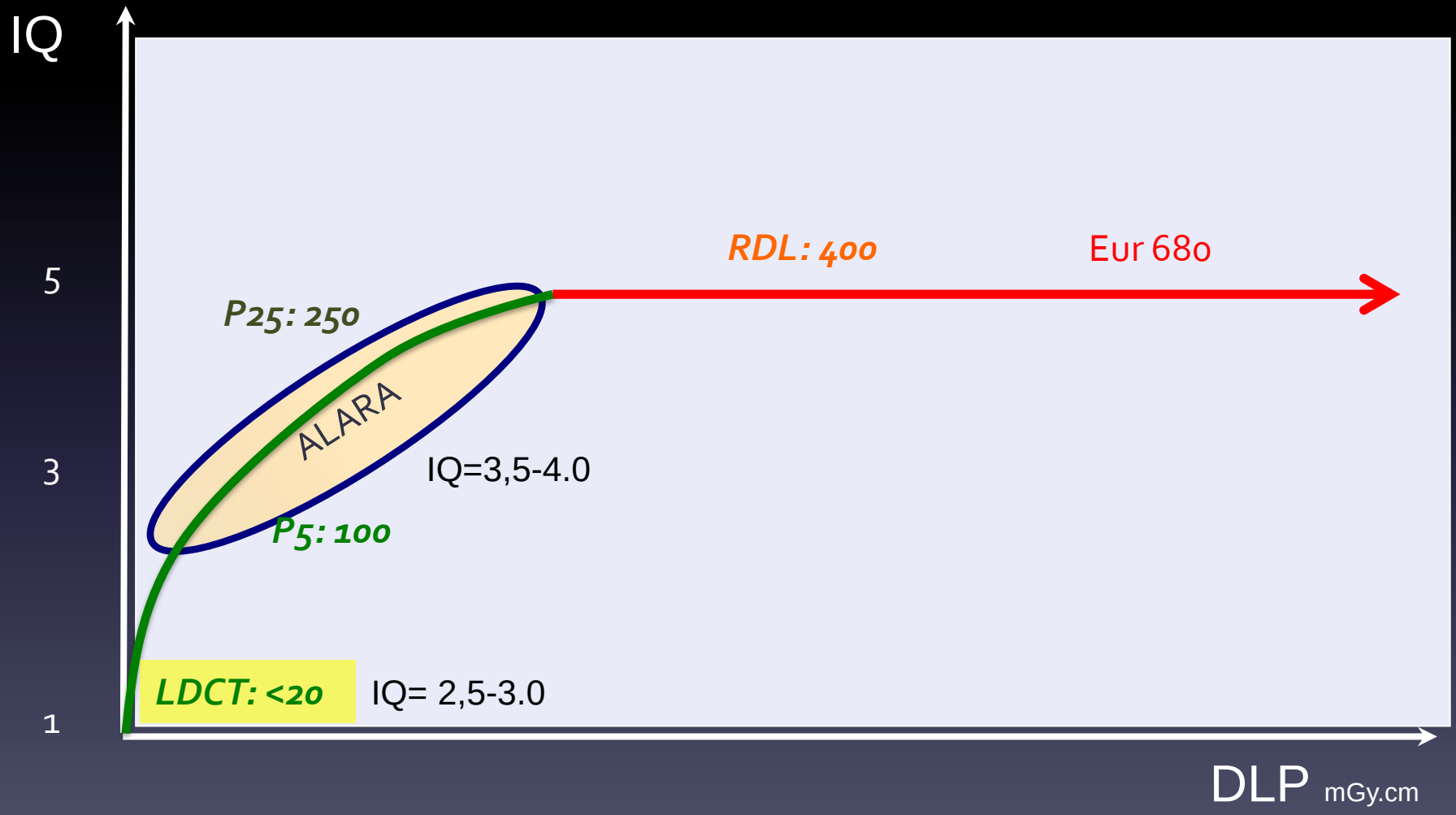
- Life expectancy can be high
  - Lymphoma
  - New therapeutic approaches in carcinoma
- Focus on young patients.

Optimization

- In screening, 'ULTRA-LOW-DOSE' CT
- In diagnosis:
  - Low-dose (reduced image quality) for FU of lymphoma, testis carcinoma (young patients)
  - For all other, keep image quality at a good level

(Level 3,5 to 4 of a 5-point Likert Scale)

Image Quality *vs* Dose



Aged Oncology patients

- Image quality is the main goal
- No need to big compromises

With Siemens scanners, aim to be lower than P25 FANC values

- Chest: DLP < 100 mGy.cm (P25=170) *
- Abdomen: < 200 mGy.cm (P25=320) *
- Th-Abdo-Pel: < 300 mGy.cm (P25=320 in 1 phase and P25 < 480 if multiphase) *

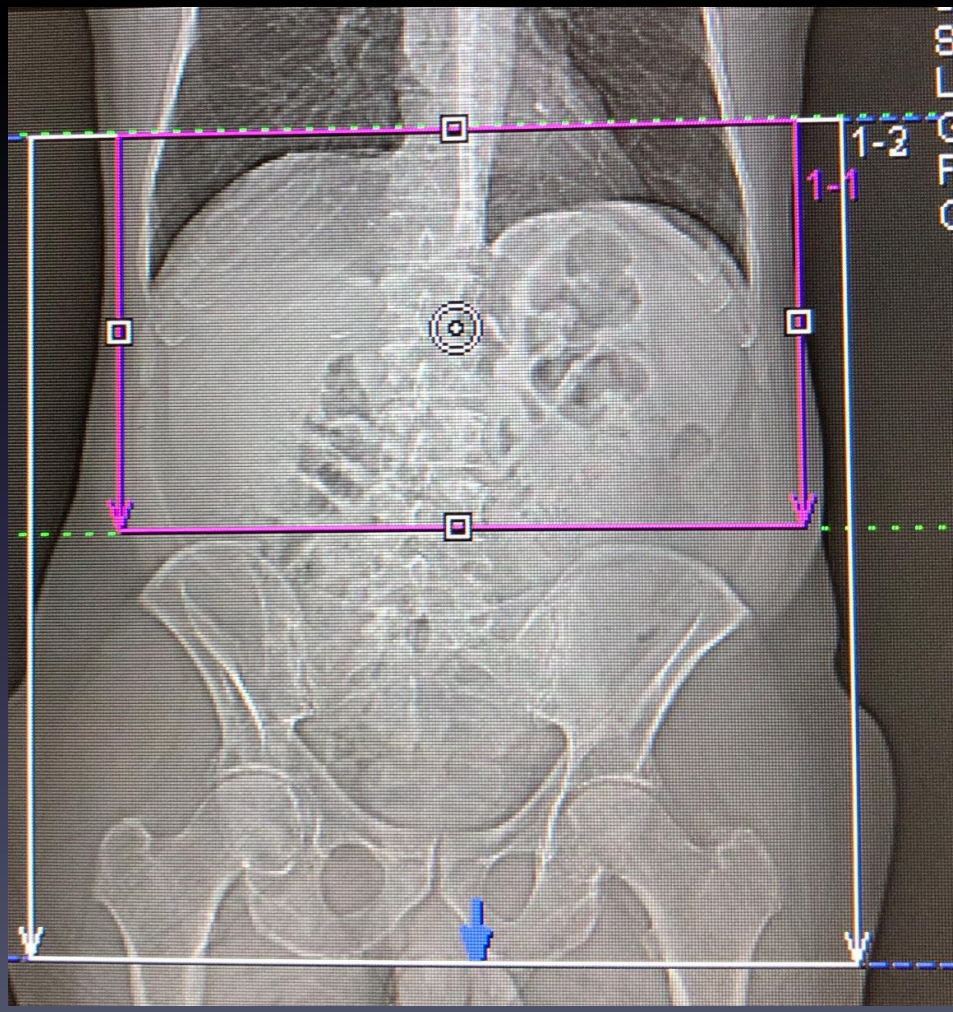
* Median value of samples of data > 300 – 400 exams according to Taylor et al. European Radiology 2017

Technical Advices to be used

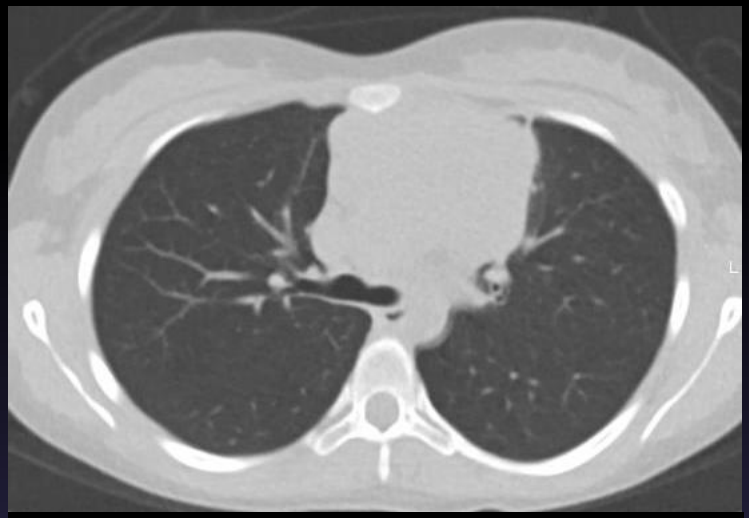
- AEC (CareDose) switched on
- ATPS (Care KV) on
- Recon WITH Iterative techniques
- Unenhanced: Use Sn filters
- Iodine enhanced: focus image quality on the liver (green lines)

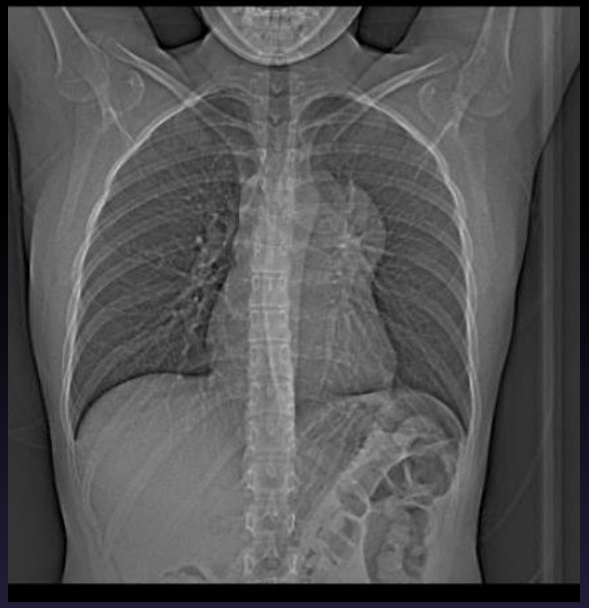
Image Quality according to Z axis

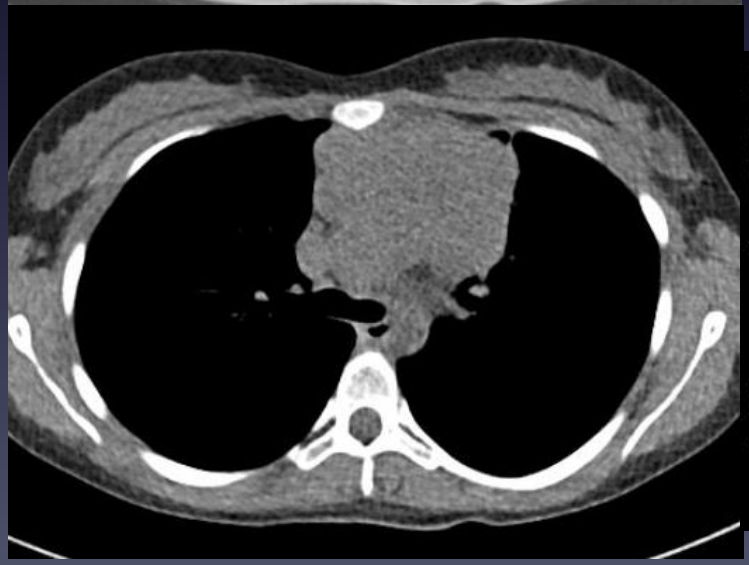
- Standard mAs on the liver (Highest IQ) – green lines
- 1/2 mAs on Pelvis (lower IQ but OK
- Global dose reduction >30% for abdomen-pelvis acquisitsions
- To be used for Chest-Abdo-Pelvis as well



ULD CT in Lymphoma: 27 years-old woman with cough for 2 month. Dyspnea.







29-Jan-2020 10:16

Ward:
Physician: Dr TACK
Operator: DEVOS V

Total mAs 600 Total DLP 13 mGycm

	Scan	kV	mAs / ref.	CTDIvol* mGy	DLP mGycm	TI s	cSL mm
Patient Position F-SP							
TopoThorax	1	Sn100	48 mA	0.01 L	0.5	2.4	0.6
Thorax	2	Sn100	52 / 81	0.40 L	12.5	0.33	0.6

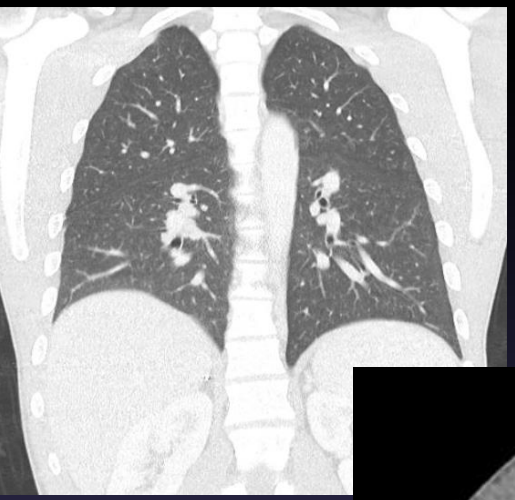
Total mAs 600 Total DLP 13 mGycm

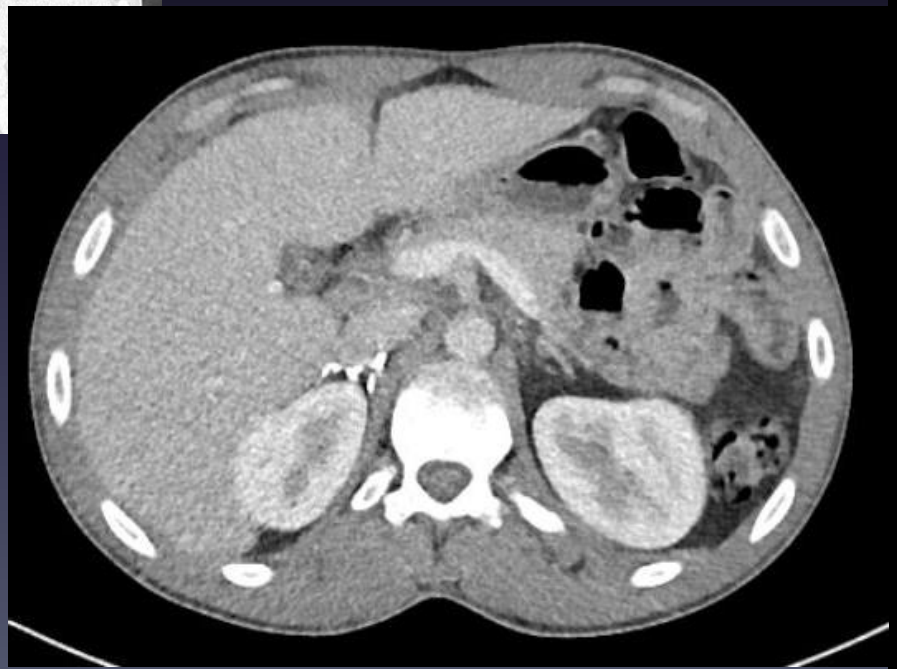
	Scan	kV	mAs / ref.	CTDIvol* mGy	DLP mGycm	Tl s	cSL mm
Patient Position F-SP							
TopoThorax	1	Sn100	48 mA	0.01 L	0.5	2.4	0.6
Thorax	2	Sn100	52 / 81	0.40 L	12.5	0.33	0.6

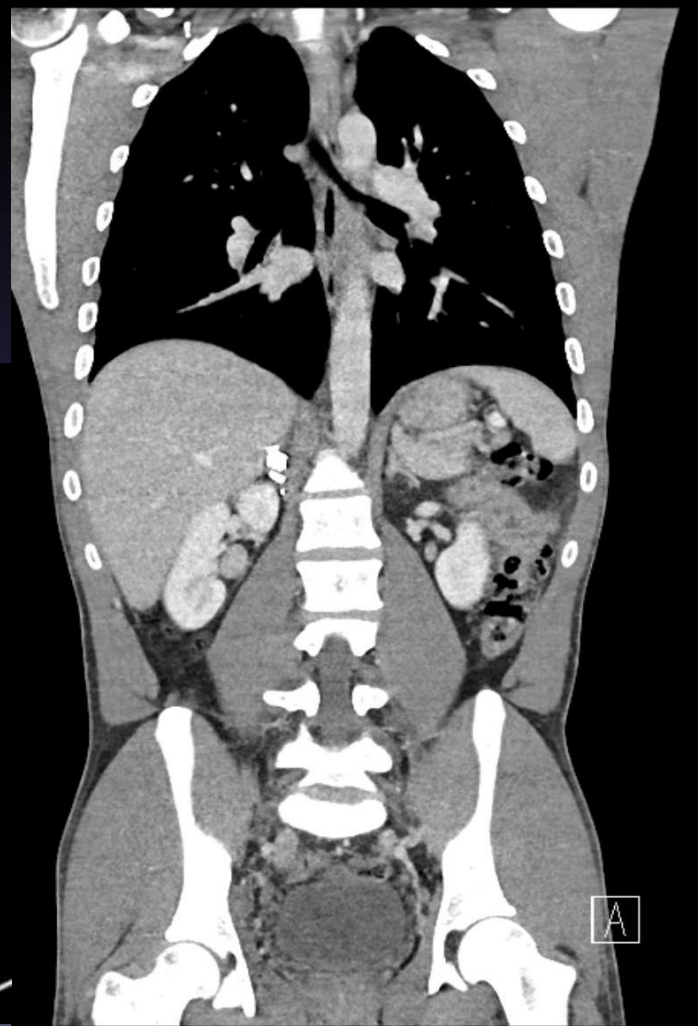
1 line for each x-ray exposure
Dose from topogram converted into DLP
Sn100 means Tin Filter (unenhanced CT only)
L means large CTDI phantom, 32 cm in diameter (body)
S phantom only for brain

*: L = 32cm, S = 16cm

Low-Dose Chest-Abdomen-Pelvis in FU of Operated Right Adrenal Carcinoma in a 25 year—old-man weighting 63 Kg.







Low-Dose Chest-Abdomen-Pelvis in FU of Adrenal Carcinoma in a 25 year—old-man weighting 63 Kg.

Total mAs 1146 Total DLP 131 mGycm

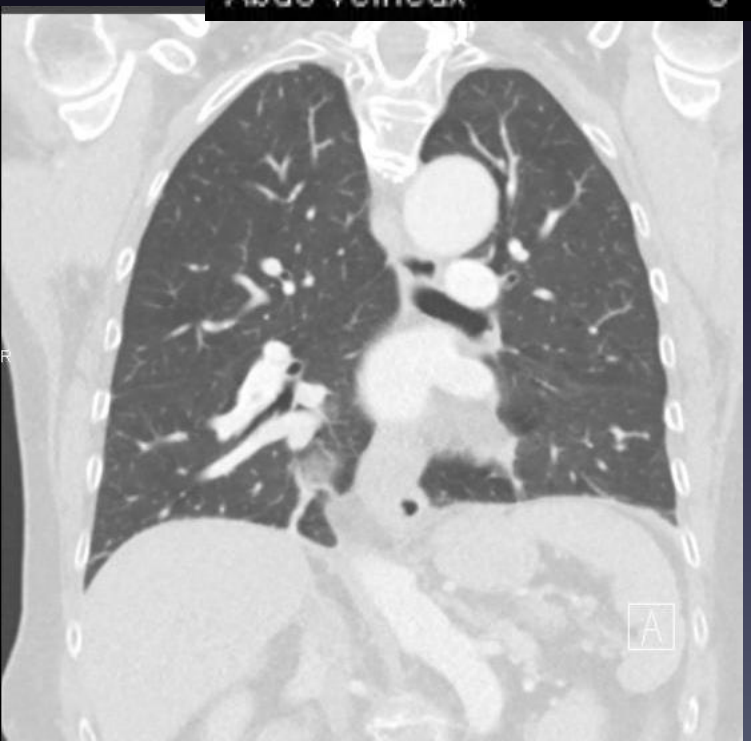
	Scan	KV	mAs / ref.	CTDIvol* mGy	DLP mGycm	TI s	cSL mm
Patient Position H-SP							
Topogram	1	100	42 mA	0.10 L	6.1	6.5	0.6
ThoraxAbdomen	2	100	53 / 97	2.12 L	124.9	0.5	0.6

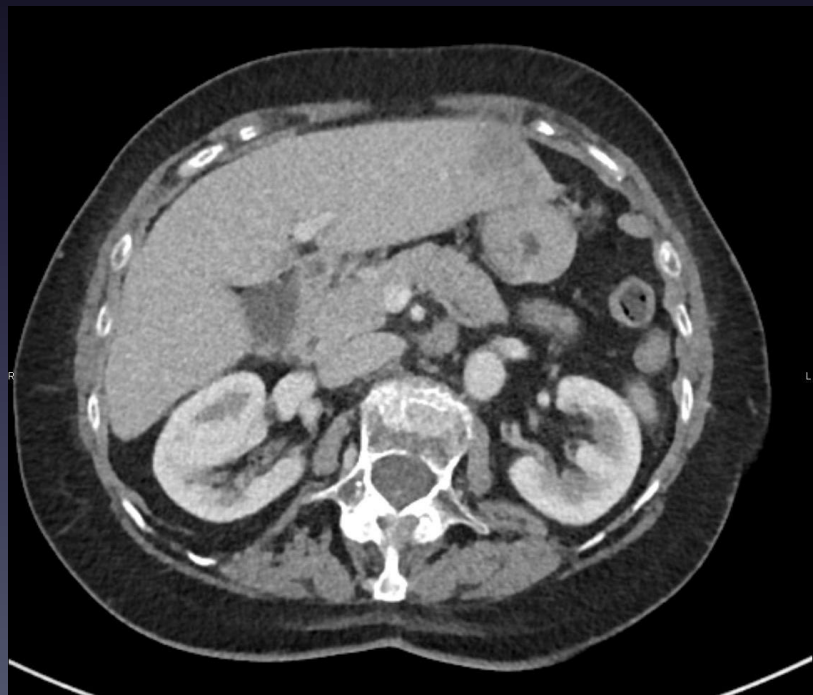
Iodine enhanced: no use of Tin Filters

FU of Liver Mets – 76 Kg
2 phase exam – P25 = 480 mGy.cm

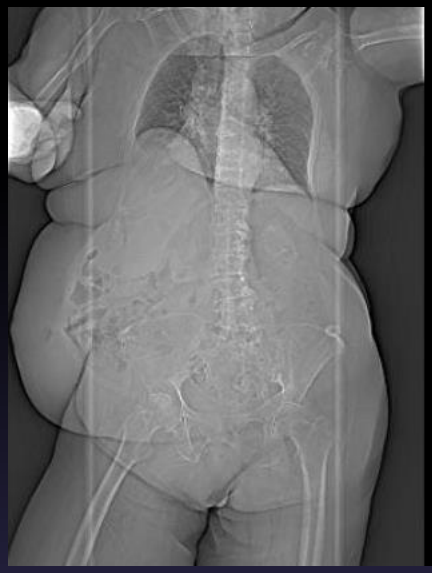
Total mAs 2209 Total DLP 279 mGycm

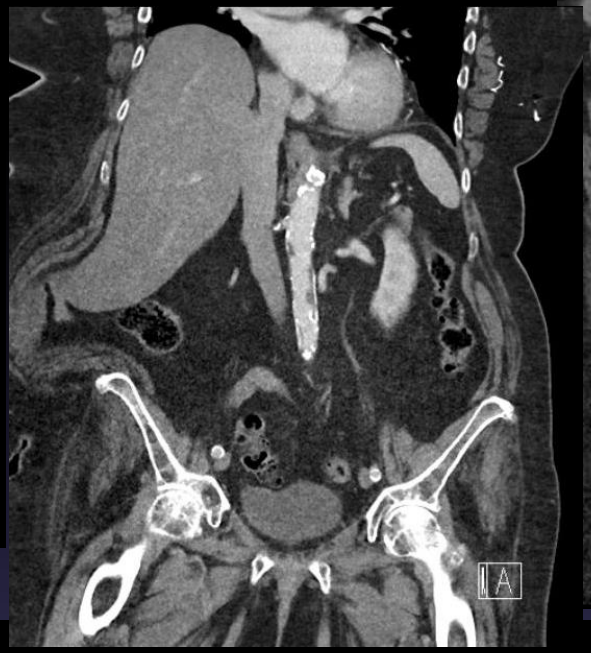
	Scan	kV	mAs / ref.	CTDIvol* mGy	DLP mGycm	TI s	cSL mm
Patient Position H-SP							
Topogram	1	100	42 mA	0.10 L	6.6	7.0	0.6
Thorax +C	2	100	65 / 83	2.57 L	93.2	0.33	0.6
Abdo Veineux	3	100	118 /152	4.67 L	179.4	0.5	0.6

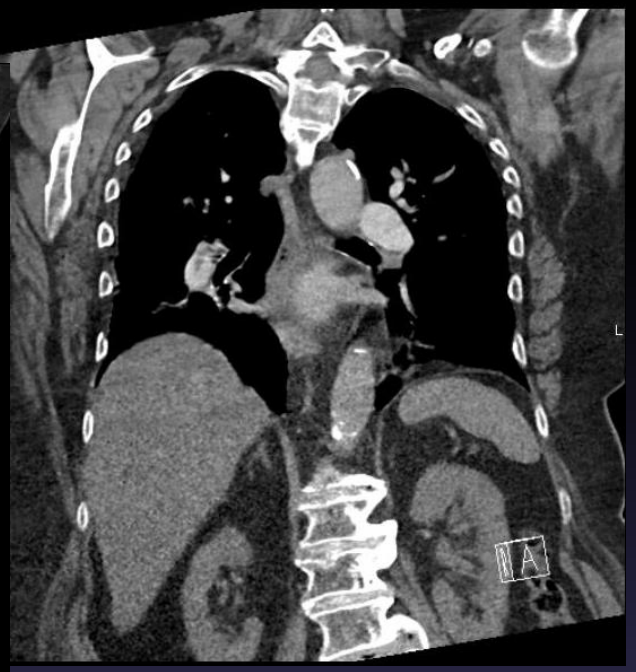




FU colon carcinoma in Obese Patient
Two--phase acquisition



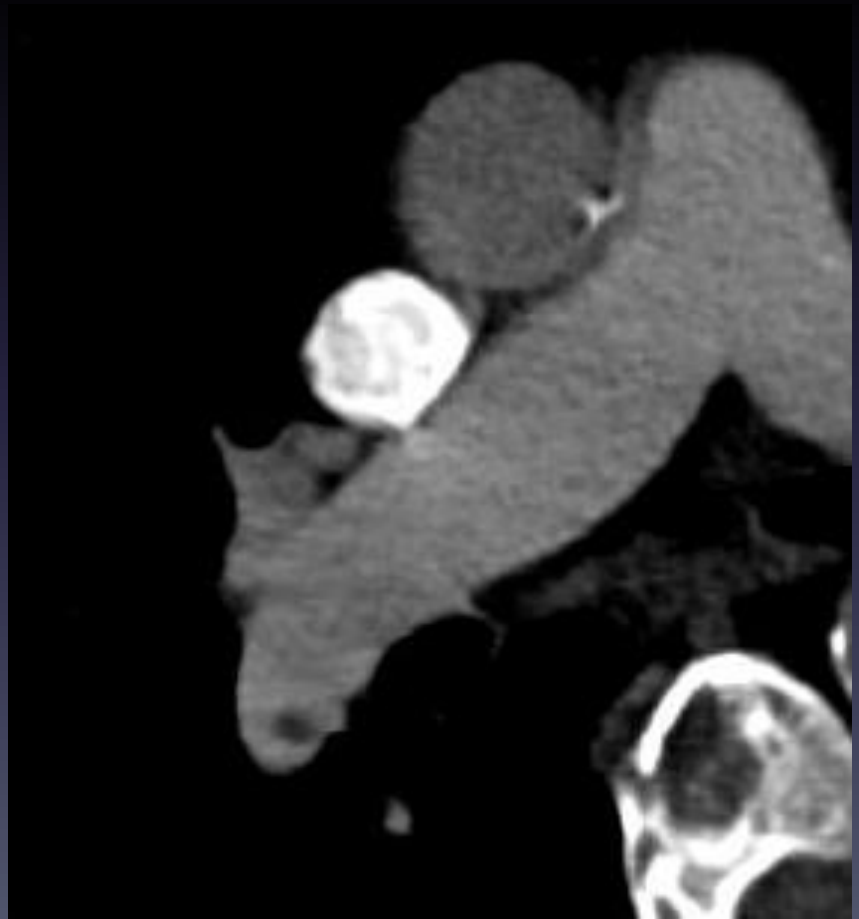


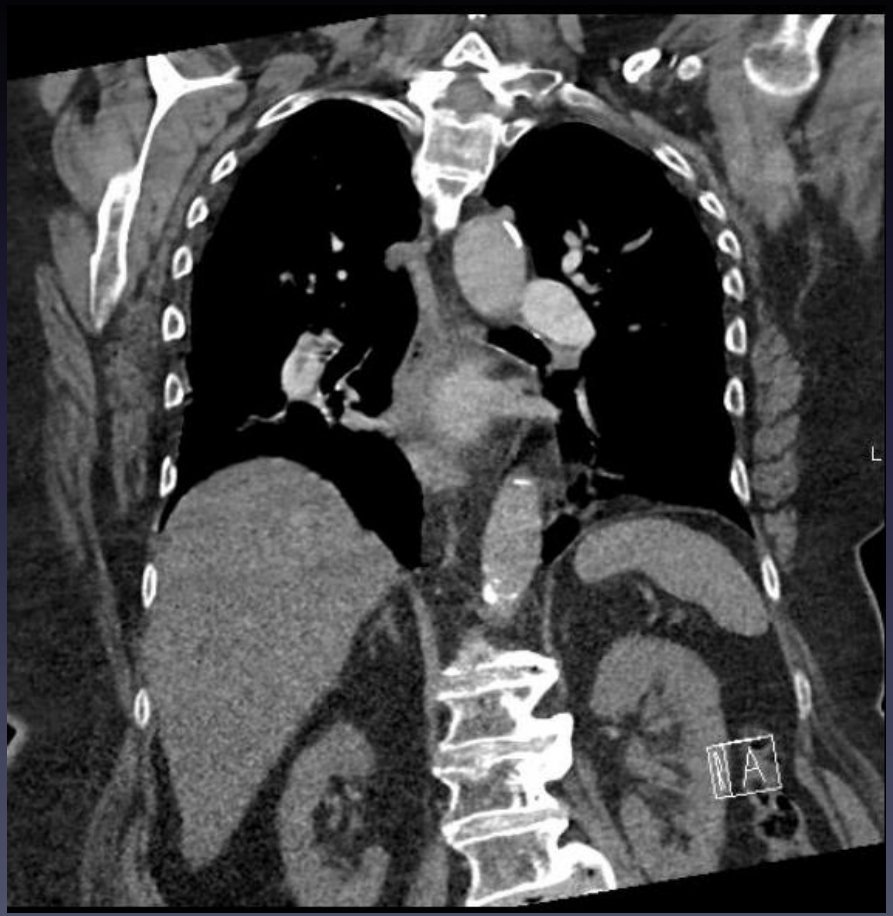


Total mAs 3551 Total DLP 786 mGycm

	Scan	KV	mAs / ref.	CTDIvol* mGy	DLP mGycm	TI s	cSL mm
Patient Position H-SP							
Topogram	1	120	41 mA	0.16 L	4.0	2.7	0.6
Topogram	2	120	42 mA	0.16 L	12.5	7.8	0.6
Thorax +C	3	120	114 / 60	7.74 L	333.0	0.33	0.6
Abdo Veineux	4	120	126 /110	8.55 L	436.5	0.5	0.6

FU colon – Obese
Added value of biphasic protocol
= pick-up pulmonari emboli!





Summary

- Irradiation: Linear-no-threshold model: debatable
- Absolute risks in CT are VERY LOW
- Benefit/Risk ratio in screening: very high
- Image oncology patients:
  - Image quality is main goal (i.e.in old patients)
  - ULDCT in young cancer patients
  - Optimization: < P25 is an easy goal with Siemens scanners