13th EAN Workshop: ALARA in Medicine

Challenges to Justification and Optimization: Individual Health Assessment Using CT

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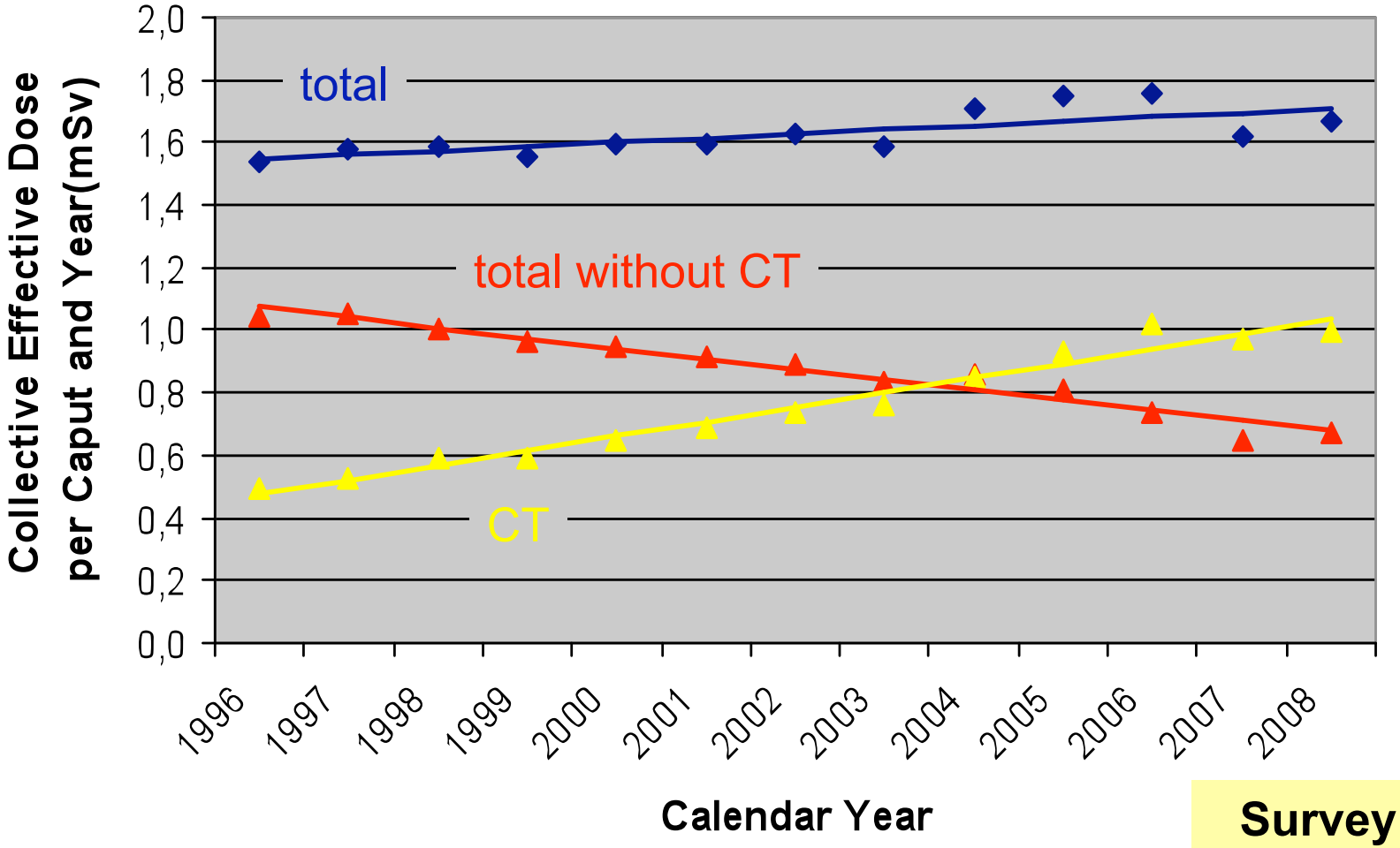
Use of CT: Radiation Protection Concerns

BfS Annual Survey: Medical Exposures in Germany



Survey in 2008:
CT-Contribution
≈ 60%

Use of CT: Radiation Protection Concerns

Organ Dose:

Einstein et al.
JAMA, 2007 Vol 298, No. 3

Doses from 8 CT Coronary Angiography Protocols using a 64-Detector Row Helical Scanner

Sex	ECTCM	Aorta	Effective Dose, mSv	Organ Equivalent Doses, mSv			
				Breast	Lung	Esophagus	Marrow
Femal	No	No	21	77	74	47	13
Male	No	No	15		65	37	10
Femal	Yes	No	14	50	48	30	8
Male	Yes	No	9		42	24	7
Femal	No	Yes	29	80	91	77	21
Male	No	Yes	23		90	63	18
Femal	Yes	Yes	19	52	59	50	14
Male	Yes	Yes	15		58	41	12

Aorta: protocol including a scan of both the heart and aorta
ECTCM: electrocardiographically controlled tube current modulation.

CT organ doses may reach values for which scientific evidence is sufficient to conclude a statistically significant increase of radiation-induced cancers following these exposures.

Use of CT: Radiation Protection Concerns

Concerning the use of CT for screening, special care has to be taken in justifying radiological procedures:

1.) Due to the typically low prevalence of serious diseases in an asymptomatic population, the vast majority of individuals undergoing screening is not affected by the disease.

2.) These individuals do not derive a direct health effect, but can only be harmed
   - either by radiation induced cancer
   - or by adverse health effects such as false-positive results and overdiagnosis.

Use of CT: Scenarios

Scenario #1:
an ***individual patient:***
- ***symptomatic individual***
- ***high prevalence of disease***

undergoing X-rays as part of his own ***medical treatment***
⇒ ***healthcare***

Scenario #2:
a ***target population:***
- ***group of asymptomatic individuals***
- ***low prevalence of disease***

undergoing X-rays as part of an ***approved health screening programme***
⇒ ***breast cancer screening programmes***

Scenario #3:
an ***individual person:***
- ***asymptomatic individual***
- ***low prevalence of disease***

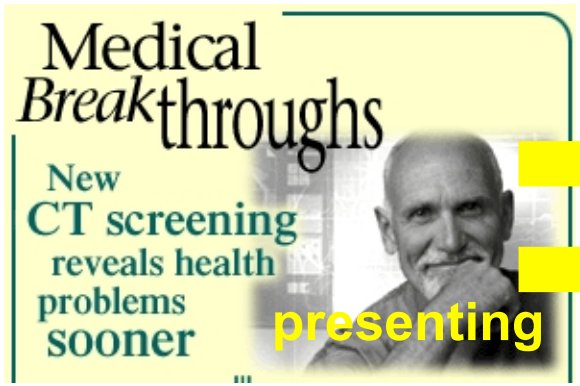
undergoing X-rays for the ***early detection of severe diseases***
⇒ ***individual health assessment*:***
CT-screening exams of lung, colon or whole body („manager check-up“)

**** opportunistic screening***

Bundesamt für Strahlenschutz

Use of CT: Scenarios

Scenario #3: *Individual Health Assessment (IHA)*



presenting

self-presentation

referring

any common interest between both

self-referral

problem: financial incentive

asymptomatic individual

medical practitioner:

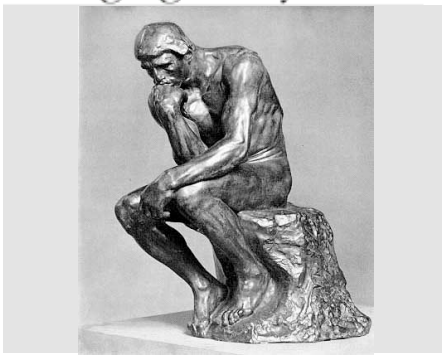
- clinical history
- physical examination
- other clinical testing

radiological practitioner:

- performs **IHA**
- carries out **individual justification**
- ensures **optimisation**

CT Ind. Health Assessment: Advertisement

Imaging for your Health



The emergence of new diagnostic techniques provides the opportunity to detect disease before symptoms are present. We have long known that in certain cases the earlier the detection of the disease, the greater the likelihood of a better outcome. In the past it was necessary to wait for appearance of symptoms before the presence of disease could be confirmed.

But times have changed. We now have the ability to detect disease prior to the onset of symptoms. Through painless, state-of-the-art scanning equipment, we are able to diagnose problems, potential problems or the absence of disease prior to any complaints or symptoms. With this knowledge, our hope is to enhance the patient's chance for living a long, healthy, productive life.

SCREENING EXAMS:

HEART SCAN (EBT CORONARY CALCIUM SCREENING):
Detects and measures coronary arterial calcium (atherosclerosis), the earliest indicator of heart disease.

HEART & BODY ATHEROSCLEROSIS SCREENING:
Adds the measurement of Aortic and Iliac calcification. Includes Body CT, described below.

LUNG CT SCAN:
Can detect lung cancer and other abnormalities of the lungs, including emphysema before it can be detected by lung function tests.

WHOLE BODY CT:
Can detect cancer and other abnormalities in the chest (lungs, aorta & heart), abdomen (liver, kidneys, pancreas, gall bladder, abdominal aorta, adrenal glands, lymph nodes, & spleen) and pelvis (bladder, prostate, ovaries, & uterus) as well as skeletal problems.

BRAIN MRI/MRA:
Early detection of brain abnormalities including tumors, aneurysm and possibly predicting stroke or dementia.

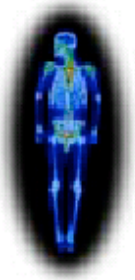
MRI ABDOMINAL/PELVIC:
A radiation free exam of the abdominal and pelvic regions.

BONE DENSITY:
Detects osteoporosis that can lead to fractures.

CAROTID ULTRASOUND:
Identifies blood flow blockages to the brain (stroke risk).

ABDOMINAL AORTIC ULTRASOUND:

SCREENING EXAM PRICE LIST:

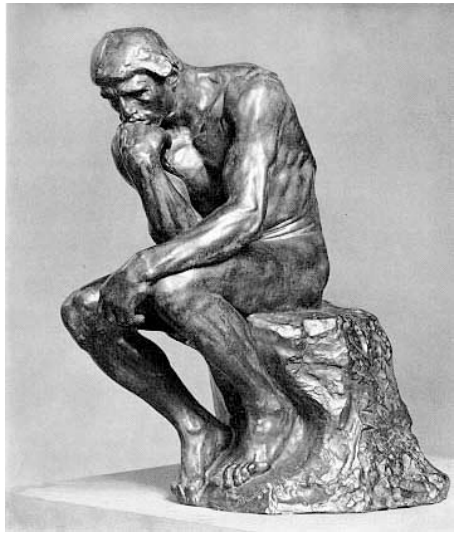


Heart Scan (EBT)	$395.00
Lung Scan (CT)	$395.00
Whole Body CT	$675.00
Brain MRI/MRA	$595.00
MRI Abdomen/Pelvis	$695.00
Bone Density	$125.00
Carotid Ultrasound	$65.00
Abdominal Aortic Ultrasound	$65.00

SCREENING PACKAGES:

Heart/Lung Screening Heart CT (EBT) & Lung CT	$550.00
Heart & Body Screening Whole Body CT & Heart CT (EBT)	$795.00
Heart & Body Atherosclerosis Screening Whole Body CT & Heart CT (EBT) with measurement of whole body arterial calcium	$895.00
Neuro/Stroke Screening MRI/MRA Brain & MRA Neck	$795.00
EBT Non-Invasive Coronary Angiogram/Body Screening EBT Coronary Angiogram & Whole Body CT with contrast	$1495.00
Wellness Screening Whole Body CT, Heart CT (EBT), MRI/MRA Brain & MRA Neck	$1,995.00
Deluxe Screening Heart & Lung EBT, Bone Density, MRI/MRA Brain, MRA Neck,	$2,595.00

CT Individual Health Assessment: Benefit



At present, scientific evidence for the benefit from CT screening is vague:

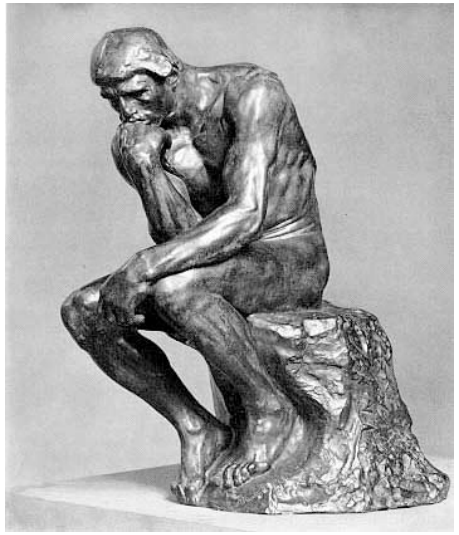
- There are no **prospective randomized controlled trials** reporting the efficacy of CT screening as a tool in **reducing disease related mortality**.

FDA, 2009:

At this time the FDA knows of **no data** demonstrating that **whole-body CT screening**

- ➢ is effective in detecting any particular disease early enough for the disease to be managed, treated, or cured and
- ➢ advantageously spares a person at least some of the detriment associated with serious illness or premature death.

CT Individual Health Assessment: Benefit



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US National Lung Screening Trial (NLST) on 53,000 current and former heavy smokers aged 55 to 74:

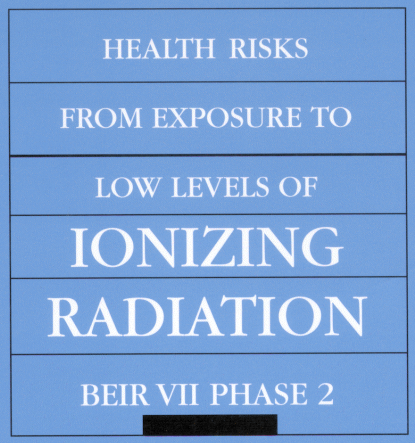
in a press release in **Nov 2010** initial findings were reported:

- participants who received low-dose spiral CT scans had a 20% lower lung cancer mortality risk than participants who received standard chest X-rays,

but yet, no publication in a peer-reviewed journal is available.

CT Individual Health Assessment: Risk

BfS Evaluation: Radiation Risk with CT Screening



BEIR VII:
Biological Effects of Ionizing Radiation, Report 2006

BEIR VII models were applied to estimate **age, gender and organ specific excess lifetime risks** for a **German population** using:

- **German baseline rates for cancer incidence / mortality**,
- **German life table data**, and
- **organ doses** from typical **CT screening procedures:**
  - **lung**
  - **colon**
  - **whole-body**.

CT Ind. Health Assessment: Benefit - Risk

for each CT screening procedure:

required reduction in mortality
to achieve a benefit-risk ratio of at least 10

benefit

risk

CT screening for severe diseases

CT Ind. Health Assessment: Benefit - Risk

Typical Screening Procedures				
male | female	X-Ray Mam-mography [a]	CT-Lung [b]	CT-Colon [c]	CT-Whole Body [d]
required reduction in mortality (%) to achieve a benefit-risk ratio of at least 10	5 (female)	10 21	41 63	20 43

[a]	50-69 years	every 2 years / 10x	exam of both breasts in two views
[b]	50-69 years	annual / 20x	low-dose CT
[c]	50-70 years	every 5 years / 5x	paired exam in supine and prone position
[d]	50-69 years	every 2 years / 10x	

Ind. Health Assessment: Quality Assurance

Recommendation of the German Radiation Protection Commission (SSK), 2006:

Requirements for the Justification of Individual Health Assessment Using X-Rays

- technical equipment
- performance and interpretation (rep
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Screening

- **is not just making some nice pictures,**
- **but is a whole system including many steps, which are strongly correlated with each other**

screening chain

Summary I: Benefit - Risk - Qualitiy

Individual Health Assessment: CT	
valid data from **prosp. randomized controlled trials** indicating a **significant reduction in disease related mortality**:	
are not yet available♦	
radiation risk:	
cannot be considered as negligible	
quality assurance along the whole screening chain:	
is not yet sufficiently established and standardized	

♦ promissing exception: Press Release on NLST Trial. Nov 2011

Summary I: Benefit - Risk - Qualitiy

Individual Health Assessment: CT	Screening Programme: Breast Cancer / X-Ray
valid data from **prosp. randomized controlled trials** indicating a **significant reduction in disease related mortality**:	
are not yet available♦	are available♦
radiation risk:	
cannot be considered as negligible	can be considered as negligible
quality assurance along the whole screening chain:	
is not yet sufficiently established and standardized	is sufficiently established and standardized♣

♦ promissing exception: Press Release on NLST Trial. Nov 2011

♦ International Agency for Research on Cancer (IARC / WHO), 2002

♣ European Guidelines for Quality Assurance in Mammography Screening, 4th Edition, 2006

Summary II: BfS Point of View

Against this background, the BfS concludes that **individual health assessment to early detect serious diseases** by **CT** may - if at all - be considered as appropriate, if at least:

- ► the assessment is
  - based on consensus guidelines of scientific societies,
  - embedded in a well-established screening algorithm,
- ► clearly defined risk profiles exist,
- ► adequate information about both potential benefit and potential risk and harm is provided to the individual,
- ► a demanding quality assurance programme is established along the whole screening chain,
- ► both adequate training & education and adequate documentation & evaluation is ensured,
- ► the problem of self-referral and self-presentation is solved.

Thank you for your attention !

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