

EC Breakout Session, 05.12.2012, Bonn

***Revision of the Euratom Basic Safety
Standards and Beyond:***

Asymptomatic Individuals

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Medical Exposures: 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**:

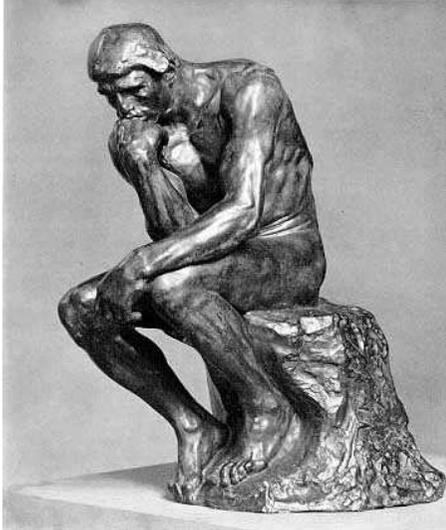
CT-screening exams of lung, colon or whole body („manager check-up“)

* *opportunistic screening*

IHA Using CT: Radiat. Protection Concerns

- 1.) 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.
- 2.) 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.
- 3.) 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.

IHA Using CT: Benefit



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

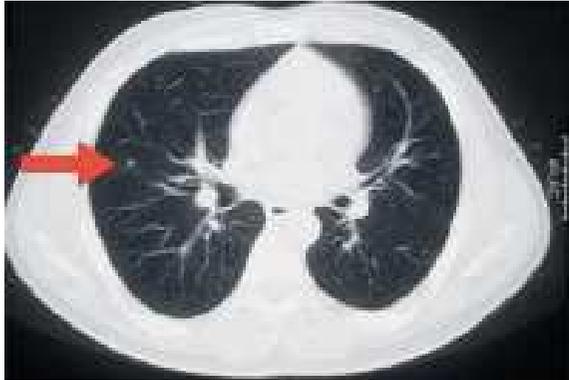
Whole-Body CT Screening

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.

IHA Using CT: Benefit



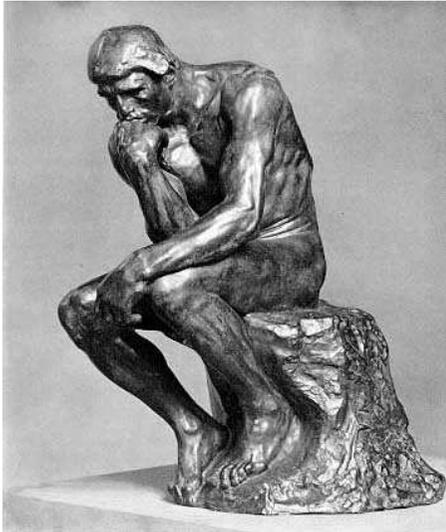
At present, scientific evidence for the benefit from CT screening is vague:

Lung CT Screening



There are **prospective randomized controlled trials** on the efficacy of CT screening as a tool in **reducing disease related mortality**.

IHA Using CT: Benefit

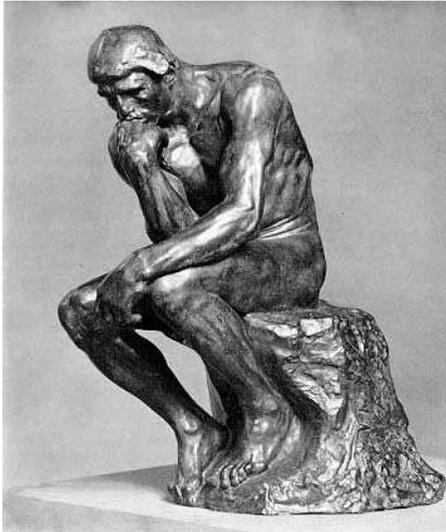


Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening

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

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

IHA Using CT: Benefit



International workshop on randomized lung cancer screening trials.
State of the art in Europe after early conclusion of the US National Lung
Screening Trial



The European Lung Cancer Trials

The PISA Position Statement
Pisa, Italy, March 4th 2011

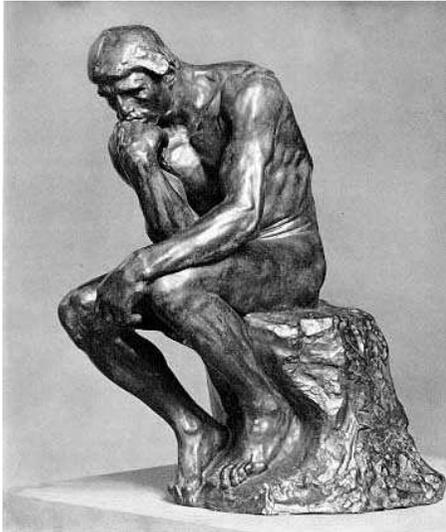


In light of the positive results of the NLS Trial, the **European Randomized CT Screening (EUCT)** investigators held a workshop in **Pisa** (Italy)

- to achieve consensus and
- to develop a strategic plan of action

with regard to the implementation of CT screening in Europe.

IHA Using CT: Benefit



International workshop on randomized lung cancer screening trials.
State of the art in Europe after early conclusion of the US National Lung Screening Trial



The European Lung Cancer Trials

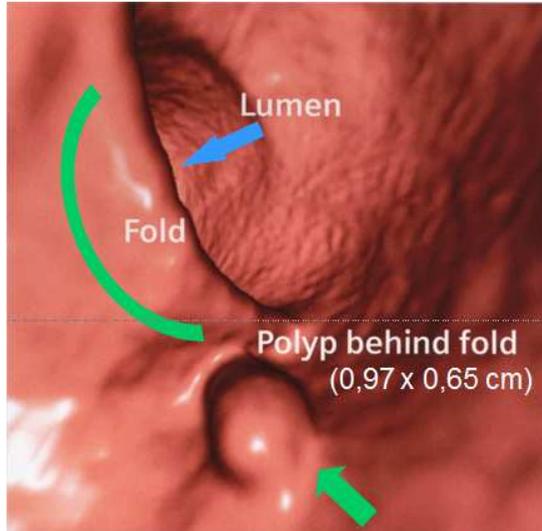
The PISA Position Statement
Pisa, Italy, March 4th 2011



Pisa Position Statement:

- there are many questions to be answered before lung cancer screening with low dose CT can be recommended to millions of current and former smokers,
- a recommendation in favor of screening for lung cancer should **not rely on one single study.**

IHA Using CT: Benefit



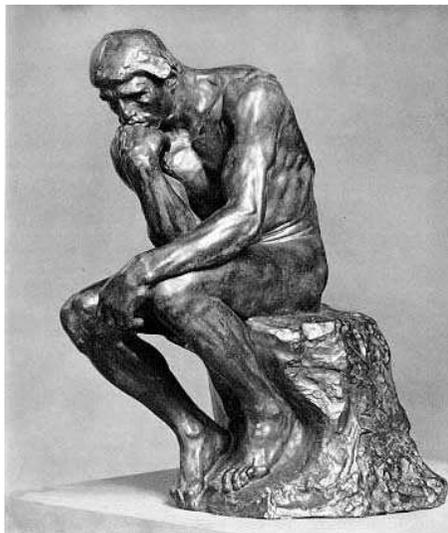
At present, scientific evidence for the benefit from CT screening is vague:

Colorectal CT Screening

M. Macari, A.J. Megibow.
Positive CT Colonography after Negative Colonography.
Somatom Sessions, No 13, 22-23 (2003)

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

IHA Using CT: Benefit



CA

A Cancer Journal for Clinicians

Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: A Joint Guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology*†

CRC: colorectal cancer screening

CTC: CT colonography

The expert panel concludes that there are **sufficient data** to include CTC as an **acceptable option for CRC screening**:

- **average-risk adults** who would benefit from screening but either **decline** colonoscopy or are **not good candidates** for colonoscopy for one or more reasons,
- to commence screening at **age 50 years**,
- to repeat exams **every 5 years**.

IHA Using CT: Quality Assurance



Strahlenschutzkommission

Geschäftsstelle der
Strahlenschutzkommission
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D-53048 Bonn

Recommendation of the German Radiation Protection Commission (SSK), 2006: Requirements for the Justification of Individual Health Assessment Using X-Rays

The Radiation Protection Commission recommends:

individual health assessments shall be performed only on the base of consensus guidelines from scientific societies,

taking into account the following points:

IHA Using CT: 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 of scans (reporting system)
- management of findings (additional testing / treatment)
- training and education
- documentation und evaluation of important *outcome parameters*

for hardly any of these requirements adequate protocols are yet established and standardized

IHA Using CT: 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 of scans (reporting system)
- management (additional parameters)
- training
- documentation
- evaluation of outcomes

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

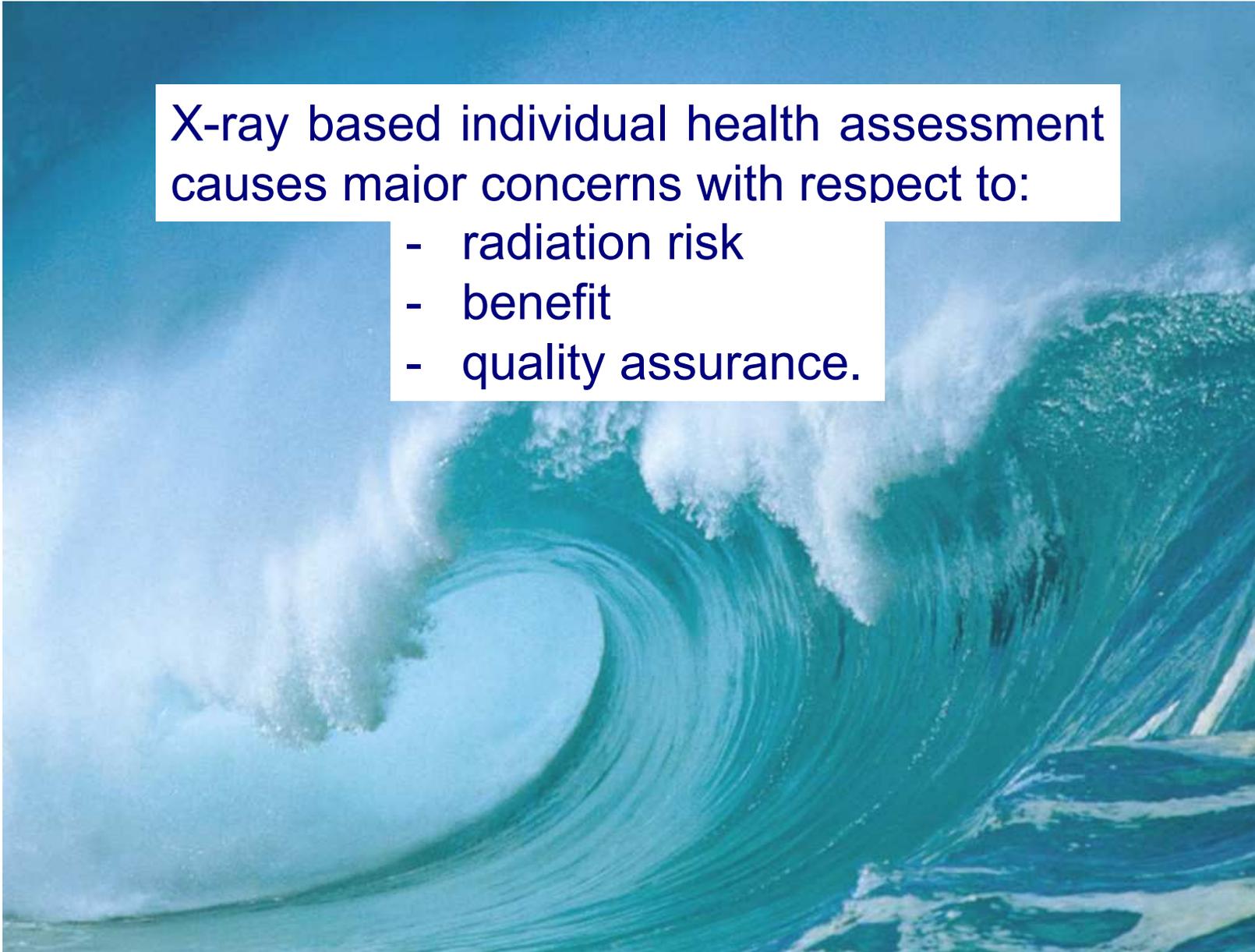
finished and standardized

ts

IHA Using CT: Summary

X-ray based individual health assessment causes major concerns with respect to:

- radiation risk
- benefit
- quality assurance.



IHA Using CT: HERCA

HERCA 

Heads of the European Radiological
protection Competent Authorities

“Position Paper on Screening“, 2012

(1) X-ray based individual health assessment is particularly **challenging the principle of justification** on a number of levels, i.e.:

- generic level,
- individual level.

(2) It is a remarkable progress, that the **Euratom Basic Safety Standards Directive**, in its draft presented for opinion of the European Economic and Social Committee, clearly addresses this issue.

EC-BSS, Article 54, Number 5



EUROPEAN COMMISSION

Proposal for a

COUNCIL DIRECTIVE

Brussels, 29.9.2011
COM(2011) 593 final

2011/0254 (NLE)

laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation

Draft presented under Article 31 Euratom Treaty for the opinion of the European Economic and Social Committee

Any medical radiological procedure on an **asymptomatic individual**, to be performed for the **early detection of disease**,

- shall be part of a **health screening programme**, or
- shall require **specific documented justification** for that individual
 - by the **practitioner**, in consultation with the **referrer**,
 - following **guidelines** from **relevant professional bodies** and **competent authorities**.

HERCA-Position Paper on Screening, 2012



To transform this requirement into national legislation in the EU member states, a **thorough discussion** is needed as to

- whether X-ray based individual health assessment shall be included **at all within national legislation**, and if so,
- what **range of obligations** have to be imposed on the process of justification for this type of X-ray application.

HERCA-Position Paper on Screening, 2012

Hereby, at least, the following requirements are essential:

- ▶ the individual health 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,
- ▶ a demanding programme concerning training and education is well established, and
- ▶ adequate measures concerning documentation and evaluation are set in place.

Thank you for your attention !



| Verantwortung für Mensch und Umwelt | ■ ■ ■ ■ ■ ■ ■