MEDICAL SCREENING: RP ETHICS AND UNCERTAINTIES IN JUSTIFICATION AND IMPLEMENTATION

Science aspects: the radiologist point of view

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**Table 1**

The World Health Organization’s 10 principles of screening

1. The condition sought should be an important health problem
2. There should be an accepted treatment for patients with recognized disease
3. Facilities for diagnosis and treatment should be available
4. There should be a recognizable latent or early symptomatic stage
5. There should be a suitable test or examination
6. The test should be acceptable to the population
7. The natural history of the condition, including development from latent to declared disease, should be adequately understood
8. There should be an agreed policy on whom to treat as patients
9. The cost of case-findings (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole
10. Case finding should be a continuing process and not a 'once and for all' project
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Main question for the radiologist in case of screening with Ionizing Radiation (IR):

✓ how to measure the real benefit of the examination with IR?

✓ does the examination changes prognosis, survivor and quality of life of the patient?

✓ witch is biological cost of IR in screening programme?

✓ How to communicate the biological cost
**Is screening for breast cancer with mammography justifiable?**

_Peter C Gøtzsche, Ole Olsen_

**Interpretation** Screening for breast cancer with mammography is unjustified. If the Swedish trials are judged to be unbiased, the data show that for every 1000 women screened biennially throughout 12 years, one breast-cancer death is avoided whereas the total number of deaths is increased by six. If the Swedish trials (apart from the Malmö trial) are judged to be biased, there is no reliable evidence that screening decreases breast-cancer mortality.

*Lancet* 2000; *355*: 129–34
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Is Mammographic Screening Justifiable Considering Its Substantial Overdiagnosis Rate and Minor Effect on Mortality?

Karsten Juhl Jørgensen, MD

Radiology 10.1148/radiol.11110210
The time has come to reassess whether universal mammographic screening should be recommended for any age group because the declines in breast cancer mortality can be ascribed mainly to improved treatments and breast cancer awareness; we have seen that screening has only a minor effect on mortality (if any). Equally important, overdiagnosis has profound human costs because it increases rates of mastectomy and death. For these reasons, we question the justification for mammographic screening.
Scenarios for different outcomes of screening mammography. (A) Screening is ineffective. (B) Screening is effective. (C) Screening leads to overdiagnosis. (D) Screening leads to overdiagnosis that causes death from side effects of treatment.
Figure 3 Different estimates of overdiagnosed women and saved lives from breast cancer in different meta-analyses and trials.

Euroscreen: estimates derived from a review of observational studies, where estimates of mortality reduction from case-control studies are included [32]. UK Independent review: estimates on relative effect derived from randomized trials of mammography screening and applied to UK national rates for women aged 55 to 79 years [22]. UK Observational: estimates based on 31% overdiagnosis [19] and 13 to 17% reduction in mortality from breast cancer [35] and applied to the observed incidence of invasive breast cancer (women aged 50 to 69 years) and mortality (women aged 55 to 74 years) in the UK in 2007 [34]; this resulted in 2 to 3 prevented deaths from breast cancer. Cochrane review: estimates from the randomized trials of mammography screening [9]. The Cochrane review does not assume the effect of mammography screening to last for 20 years as is assumed in the other estimates, but relates to what was observed in the randomized trials [9].

DOI 10.1186/s13058-015-0525-z
Figure 5 Twenty year risk for diagnosis of, and death from, breast and prostate cancer with and without screening in the United Kingdom [49].

Displayed are 20-year absolute risks for incidence (including overdiagnosis) and mortality with and without screening. Overdiagnosis is set to 45% for prostate cancer and 22% for breast cancer, respectively (age 50 to 69 years). Mortality reduction is set to be 20% for both cancers (age 55 and 74 years). For prostate cancer, the estimates are based on the observed incidence and mortality in 1998 (before any widespread use of prostate-specific antigen (PSA)) and for breast cancer in 2007 (latest data available).
Computed tomography colonography versus colonoscopy for the diagnosis of colorectal cancer: a systematic review and meta-analysis

Therapeutics and Clinical Risk Management 2018:14 349–360

types was −0.02 (with a 95% CI between −0.04 and −0.00) in favor of OC. CTC is an option for CRC screening in asymptomatic patients. However, as CTC was inferior in detecting ACN, it should not replace OC, which remains the gold standard.
Imaging and Screening for Colorectal Cancer with CT Colonography

Perry J. Pickhardt, MD

http://dx.doi.org/10.1016/j.rcl.2017.06.009

are appropriately addressed. Nonetheless, this promising screening test remains grossly underused. This review of the technical and interpretive approaches used by one successful CTC screening program may serve as a roadmap to other groups looking to get involved.
Coronary Calcium Score and Cardiovascular Risk

doi.org/10.1016/j.jacc.2018.05.027

statins and aspirin. CAC testing in asymptomatic populations is cost effective across a broad range of baseline risk. This review summarizes evidence concerning CAC, including its pathobiology, modalities for detection, predictive role, use in prediction scoring algorithms, CAC progression, evidence that CAC changes the clinical approach to the patient and patient behavior, novel applications of CAC, future directions in scoring CAC scans, and new CAC guidelines. (J Am Coll Cardiol 2018;72:434–47) © 2018 by the American College of Cardiology Foundation.
# Coronary Calcium Score and Cardiovascular Risk

## Central Illustration
Proposed Decision-Making Approach to Selective Use of Coronary Artery Calcium Measurement for Risk Prediction

<table>
<thead>
<tr>
<th>Patient’s 10-year ASCVD risk estimate plus coronary artery calcium (CAC) score to guide statin therapy</th>
<th>&lt;5%</th>
<th>5-7.5%</th>
<th>&gt;7.5-20%</th>
<th>&gt;20%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consulting ASCVD risk estimate alone</td>
<td>Statin not recommended</td>
<td>Consider for statin</td>
<td>Recommend statin</td>
<td>Recommend statin</td>
</tr>
<tr>
<td>Consulting ASCVD risk estimate + CAC</td>
<td>Statin not recommended</td>
<td>Statin not recommended</td>
<td>Statin not recommended</td>
<td>Recommend statin</td>
</tr>
<tr>
<td>If CAC score = 0</td>
<td>Statin not recommended</td>
<td>Consider for statin</td>
<td>Recommend statin</td>
<td>Recommend statin</td>
</tr>
<tr>
<td>If CAC score &gt; 0</td>
<td>Statin not recommended</td>
<td>Consider for statin</td>
<td>Recommend statin</td>
<td>Recommend statin</td>
</tr>
</tbody>
</table>

**Does CAC score modify treatment plan?**
- **×** CAC not effective for this population
- **✓** CAC can reclassify risk up or down


The figure shows a modified approach to the guideline-based decision making by incorporating a consideration of coronary artery calcium (CAC) testing to reclassify a patient’s risk up or down where it would make a clinically important change in the clinical decision. Adapted with permission from Nasir et al. (90).
Radiation exposure and coronary artery calcium scans in the society for heart attack prevention and eradication cohort

The International Journal of Cardiovascular Imaging
https://doi.org/10.1007/s10554-018-1431-0

A total of 82,214 participants were included within the study. The data related to age, gender, body mass index (BMI) and ethnicity. The mean radiation amongst all 82,214 participants was 1.03 mSv, a median dose of 0.94 mSv. The
Lung Cancer Screening: Advantages, Controversies, and Applications

doi.org/10.1177/107327481402100102

becomes standard care. These uncertainties include the cost effectiveness of screening, the radiation risks, adverse events from additional diagnostic testing, the effects of false-positive results, the ability to reproduce the results of trials in clinical practice, and the effects of screening on smoking cessation rates. Such uncertainties should be further explored.
Multimodal lung cancer screening using the ITALUNG biomarker panel and low dose computed tomography. Results of the ITALUNG biomarker study


What’s new?
Low-dose computed tomography (LDCT) for lung cancer screening is associated with a high frequency of detection of pulmonary nodules of uncertain clinical significance. Here, to better identify high-risk individuals, LDCT was combined with biomarker detection as part of ITALUNG, an LDCT lung cancer screening trial in Italy. The ITALUNG Biomarker Panel (IBP), consisting of plasma DNA quantification, loss of heterozygosity, and microsatellite instability, showed high sensitivity for lung cancer detection at baseline screening. Specificity increased to 89% with the multimodal approach, suggesting that combined use of LDCT and IBP can significantly improve the effectiveness of lung cancer screening.
Multimodal lung cancer screening using the ITALUNG biomarker panel and low dose computed tomography. Results of the ITALUNG biomarker study


Prior to the translation of this approach into screening practice, the performance, protocol and diagnostic accuracy of multimodal screening should be tested in other lung cancer screening trials which have a comparable biobank of sputum and blood samples and, further, in a new prospective study of high risk subjects selected for LDCT by means of the ITALUNG biomarker panel.
DIRECTIVES

COUNCIL DIRECTIVE 2013/59/EURATOM
of 5 December 2013

laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom

"clinical responsibility" means responsibility of a practitioner for individual medical exposures, in particular, [justification]; optimisation; clinical evaluation of the outcome; cooperation with other specialists and staff, as appropriate, regarding practical aspects of medical radiological procedures; obtaining information, if appropriate, on previous examinations; providing existing medical radiological information and/or records to other practitioners and/or the referrer, as required; and giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate;
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SYSTEM OF RADIATION PROTECTION

Article 5

General principles of radiation protection

Member States shall establish legal requirements and an appropriate regime of regulatory control which, for all exposure situations, reflect a system of radiation protection based on the principles of justification, optimisation and dose limitation:
Patient centring and scan length: how inaccurate practice impacts on radiation dose in CT Colonography (CTC).

MATERIALS AND METHODS. CTC studies of a total of 199 patients coming from two different referral Hospitals were retrospectively reviewed. Two parameters have been considered for the analysis: patient position in relation to gantry isocenter and scan length related to the area of interest. CTDI vol and DLP were extracted for each patient. In order to evaluate the estimated

CONCLUSION. Radiographers and radiologists need to be aware of dose variation and noise effects on vertical positioning and overscanninig. More accurate training need to be achieved even so when exam protocol vary from general practice.
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CHAPTER VII
MEDICAL EXPOSURES
Article 55

Justification

1. Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.
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Complete written/oral information about dose exposure in CT: is it really useful to guarantee the patients’ awareness about radiation risks? Sergio Salerno

To determine the better communication form of the dose bill to patients, the answers given to seven questions common to both pre-CT and post-CT surveys were compared (Table 5):

Our study proved a small interest of patients in the knowledge of CT dose parameters, when information is provided soon before/after having been submitted to CT examinations.
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Specific justification for medical radiological procedures to be performed as part of a health screening programme are carried out by the competent authority in conjunction with appropriate medical scientific societies or relevant bodies.

Any medical radiological procedure on an asymptomatic individual, to be performed for the early detection of disease, is part of a health screening programme, or requires specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from relevant medical scientific societies and the competent authority. Special attention shall be given to the provision of information to the individual subject to medical exposure, as required by point (d) of Article 57(1).
There is a place in healthcare for screening programme with IR using Multi Detector Computed Tomography (MDCT)?

We have to go back to justification, optimization (of techniques and resources) we need referral guidelines and

**ALARA**
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There is future for MDCT screening combined with biomarkers in cancer disease?

There is future for MDCT screening for coronary disease? Is biologically and economically costly justified?

Should we re-target age for mammography screening?

Witch one is the best way to inform the patients on IR (risk vs benefit)?
Appropriateness

Risk vs Benefit: The code of appropriateness

- **B>>>R**
  - I (appropriate indication)

- **B>>R**
  - IIa (probably appropriate)

- **B≥R**
  - IIb (possibly appropriate)

- **R≥B**
  - III (inappropriate)

AHA-ACC-ESC Guidelines 2007
Addressing Overutilization in Medical Imaging

William R. Hendee, PhD, Gary J. Becker, MD, James P. Borgstede, MD, Jennifer Bosma, PhD, William J. Casarella, MD, Beth A. Erickson, MD, C. Douglas Maynard, MD, James H. Thrall, MD and Paul E. Wallner, DO

can be reduced. In August 2009, the American Board of Radiology Foundation hosted a 2-day summit to discuss the causes and effects of the overutilization of imaging. More than 60 organizations were represented at the meeting, including health care accreditation and certification entities, foundations, government agencies, hospital and health systems, insurers, medical societies, health care quality consortia, and standards and regulatory agencies. Key forces influencing overutilization were identified. These include the payment mechanisms and financial incentives in the U.S. health care system; the practice behavior of referring physicians; self-referral, including referral for additional radiologic examinations; defensive medicine; missed educational opportunities when inappropriate procedures are requested; patient expectations; and duplicate imaging studies. Summit participants suggested several areas for improvement to reduce overutilization, including a national collaborative effort to develop evidence-based appropriateness criteria for imaging; greater use of practice guidelines in requesting and conducting imaging studies; decision support at point of care; education of referring physicians, patients, and the public; accreditation of imaging facilities; management of self-referral and defensive medicine; and payment reform.
How we manage radiation protection in our country
Royal College of Radiologists

**iRefer: Making the best use of clinical radiology**

Denis Remedios and Bethan France on behalf of the RCR Guidelines Working Party
Contact: Bethan France, bethan_france@rcr.ac.uk
Thank you for attention