



German recommendations on self-referred asymptomatic patients

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Justification for using ionisation radiation

reasonable suspicion of disease

Health Screening Programme

Self-referral and self-presentation of asymptomatic persons

doctors role

recommendations

legal framework



Legal Situation in Germany – Radiation Protection Ordinance and the X-ray Ordinance

Only a radiological practitioner with adequate training (technical competence) in radiation protection is authorised to perform X-ray examinations or treatments. Any such application must serve a medical purpose, i.e. there must be reasonable suspicion of disease. The radiological practitioner must furthermore carry out an individual justification, i.e. he has to review whether the health benefits for the use of X-rays outweigh the radiological risk, and whether there are other options with comparable health benefits with no or lesser radiation exposure.



Health Screening Programme



Criteria for approval of health screening programmes

- The examination should have a sufficiently high positive predictive value as well as a sufficiently high negative predictive value.
- The examination is acceptable for the patient (exposure, costs).
- There is no other procedure for examination available with a lower risk than that of ionising radiation.



Prerequisites for an effective screening

- The individual risk profile is known or can be precisely defined.
- The severity of the suspected disease justifies an early detection measure.
- The disease to be detected in an asymptomatic stage must have a sufficiently high prevalence to ensure the effectiveness of the examination.
- The disease must be at a stage in which it does not yet show symptoms but can be detected.
- Effective therapies, which improve the prognosis when applied at an early stage and/or the quality of life of the patient, exist in principle for this disease.



Requirements for consistent quality assurance

- advice and clarification for interested persons,
- distinguishing between persons suitable for an examination and those who do not benefit from it,
- standards for equipment,
- examination,
- assessment of the examination including validation,
- recommendations for further diagnostic measures to confirm and classify diagnosis (clarification) and for suitable treatment where necessary,
- documentation and evaluation.



European regulations

European Basic Safety Directive

"Any medical radiological procedure on an asymptomatic individual, intended to be performed for 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."



Individual Health Assessment



Potential advantages

- improved probability of cure or survival of persons through treatment at an early stage,
- improved quality of life for patients through an early-stage treatment that imposes less strain,
- reassurance in the case of (correct) negative findings and improved quality of life (exclusion diagnosis).



Potential disadvantages

- overdiagnosis, i.e. early detection of a disease that will not cause medical problems during the patient's lifetime.
- reducing quality of life if a diagnosis or treatment is simply brought forward without offering a better prognosis or quality of life,
- incorrect positive findings causing unnecessary anxiety and unnecessary further diagnostic measures and treatments, including their side effects and complications,
- incorrect negative findings providing false reassurance and potential delay of new diagnosis if symptoms occur,
- potential harm to health through radiation exposure.



Under which circumstances could individual early
detection be permissible

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Possible Applications for individual early detection

- CT or MR colonography (virtual colonoscopy),
- low dose CT of lung for smokers,
- X-ray mammography for women outside approved screening programmes.



Justification of an individual health assessment has to be based on

- the medical history of the person and, if necessary, physical examination ,
- drawing up an individual risk profile
- comprehensive information and advice on benefits, risks and undesired side effects as well as diagnostics for clarification where necessary
- severity and course of suspected disease, options for valid diagnostics and treatment
- highest quality standards regarding implementation, findings and decision on further procedures
- comprehensive documentation of measures
- accompanying evaluation of examination



Conclusion:

An individual health assessment using X-rays for the early detection of severe diseases should be carried out exclusively on the basis of agreed guidelines of scientific expert bodies, which take into account the above-mentioned criteria.



Thank you for your attention