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Title: **HERCA WG Medical Applications /
Sub WG “Exposure of Asymptomatic Individuals in Health Care”
– “Position Paper on Screening” –**

Summary: In this position paper the HERCA WG on Medical Applications proposes a clear distinction between screening and radiological procedures as part of an individual health assessment and highlights special requirements for the latter. The impact on the work of radiation protection authorities in Europe is addressed.

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Table of contents

Introduction

- A. *Definition of relevant terms with respect to screening*
 - B. *Special requirements for radiological procedures as part of an individual health assessment*
 - C. *Impact on the work of radiation protection authorities in Europe*
-

HERCA WG Medical Applications / Sub WG “Exposure of Asymptomatic Individuals in Health Care”

– “Position Paper on Screening” –

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Introduction

Over the course of several meetings the HERCA-Working Group (WG) “Medical Applications” has discussed the exposure of asymptomatic individuals in healthcare. In particular, the discussions focussed on the issue of the early detection of severe diseases, by use of X-rays, for those who do not present with symptoms. An important and established example is the use of X-ray mammography to detect early breast cancer and this has traditionally been referred to as screening. An emerging application is the use of computed tomography in a range of circumstances, some of which may be better described as a separate category of medical exposure as they are neither diagnostic nor screening in the accepted sense. The discussions have indicated that it is pivotal to clearly define the relevant terms generally applied and to clearly differentiate these terms from diagnostic examinations used in healthcare.

In this context, it is important to note, that the revision of the Euratom Basic Safety Standards (Euratom BSS) Directive is under way and addresses in particular medical radiological procedures on asymptomatic individuals, intended to be performed for early detection of disease (Draft Proposal 29 September 2011 Article 54(5)). Hereby, two types of examinations of asymptomatic individuals, (that in some cases have both been referred to as screening) are addressed: (1) exposures as part of screening programmes and (2) exposures associated with individual health assessment. On adoption, this directive will have significant implications for and a substantial impact on the work of the radiation protection authorities in Europe.

In this position paper the WG „Medical Applications“ proposes a clear distinction between screening and radiological procedures as part of an individual health assessment and highlights special requirements for the latter. Finally, the impact on the work of radiation protection authorities in Europe is addressed.

A. Definition of relevant terms with respect to screening

1. Healthcare:

Traditionally, health strategies focus on a patient with recognized symptoms or at least with a high likelihood of disease presenting to a medical doctor in a hospital or private practice. If

the medical doctor needs further diagnostic information, he refers the patient to a radiologist performing the adequate X-ray exam. This scenario is usually considered as an exposure with diagnostic benefit, taking place as part of the patient's healthcare and it is expected that such a healthcare episode takes place within a defined clinical pathway.

The IAEA-BSS was approved on 12 September 2011. Draft 4.0 (Para 3.156) states that

- *justification of medical exposure for an individual patient shall be carried out through consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, taking into account,:*
 - (a) *the appropriateness of the request;*
 - (b) *the urgency for the procedure;*
 - (c) *the characteristics of the exposure;*
 - (d) *the characteristics of the individual patient;*
 - (e) *relevant information from previous radiological procedures.*

Similar requirements are included in the European Commission proposal (29 September 2011) at Articles 54, and 56.

2. Screening:

Screening is a significant departure from the clinical model of healthcare, because apparently healthy individuals are offered a test. An effective screening intervention detects either pathology demonstrating risk factors for developing a disease, or the disease itself at an early stage where treatment can improve clinical outcome. The aim is to identify those individuals who are more likely to be helped than harmed by further diagnostic tests or treatment (BMA, 2005).

Concerning screening, two scenarios have tended to be considered together but in fact should be clearly distinguished:

2.1 Screening as part of a programme

Screening programmes systematically invite all members of a certain population to take a screening test. Examples of this are the breast screening programmes in Europe where all women between 50 and 69 routinely receive invitations to have an X-ray mammography.

Screening programmes

- have to be evidence based,
- have to meet stringent quality requirements, taking into account the need to include all parts of the program (i.e. invitation, X-ray devices, performance and reading of X-ray procedure, diagnostic workup, training and education, documentation, evaluation, etc),
- have to be approved by competent national health authorities.

The IAEA-BSS, Draft 4.0 (Para 3.158) claims that

- *justification for radiological procedures to be performed as part of a health screening programme of asymptomatic populations shall be carried out by the health authority in conjunction with appropriate professional bodies.*

Similarly, the draft Euratom BSS refers to these exposures at Articles 54 and 60, requiring specific justification in a similar manner.

Where possible, the risk to the individual associated with any examination performed as part of a screening programme should be low. However, even for well established screening programmes, such as the breast cancer screening programmes, the balance between

benefits and undesired adverse health effects – such as radiation induced cancer or false-positive results and overdiagnosis - is narrow.

In addition, it has to be considered that due to the typically low prevalence of serious diseases in an asymptomatic population, the vast majority of individuals undergoing even a well established screening programme are not affected by the disease. These individuals do not derive a direct health effect, but can only be harmed.

2.2 Opportunistic “screening” or individual health assessment

It is important to differentiate more informal arrangements from formal screening programmes. This scenario, often occurring as a result of patient choice, is usually denoted as “opportunistic screening” or “individual health assessment”. The latter of these terms is preferred as it offers a clearer differentiation.

A range of difficulties exist with examinations for individual health assessment. By definition they apply to individuals and not large populations, and there is typically a lack of evidence to support their use. In addition, lack of follow-up from inclusion of individuals and lack of embedding these examinations within a clinical care pathway does not increase this evidence base. Failure to include these medical exposures within the healthcare pathway seriously reduces their potential benefit and may be considered by some to undermine their justification. The isolation of these services may hinder quality assurance. Information about the tests, their efficacy and the need and conduct of follow-up tests can be poor. In summary, there is potential for a large number of individuals receiving more harm than good, particularly if the individual examination used carries a higher risk and the false positive rate from the examination is high.

With the evolving new technology of multi-slice spiral CT, predominantly CT procedures are discussed in the context of individual health assessment:

- lung CT for early detection of lung cancer, in particular in smokers;
- virtual CT colonoscopy – also denoted as CT colonography - for early detection of intestinal polyps (which might be pre-cancerous lesions) and colorectal cancer;
- CT quantification of coronary artery calcification (which is considered as sensitive marker of arteriosclerosis);
- whole-body CT, particularly for early detection of cancer.

It should be noted that individual health assessment is not restricted to CT alone. X-ray mammography is widely used within the context of individual health assessment – even in countries where officially approved screening programmes are established, and both within the assigned age period and outside of it. CT however is of particular interest as it has been seen to be profitable and commercially viable in a number of countries and this has resulted in aggressive marketing.

Due to the typically low prevalence of serious diseases in an asymptomatic population, it is questionable whether radiological procedures as part of an individual health assessment may be assigned to the healthcare scenario or whether it shall be assigned to a separate scenario somewhere between healthcare and screening programmes.

The latter case may be supported by the IAEA-BSS, Draft 4.0 (Para 3.159) which claims that

- *any radiological procedure on an asymptomatic individual, intended to be performed for early detection of disease but not as part of an approved health screening programme, shall require specific justification for that individual by the radiological medical practitioner and the referring medical practitioner, following guidelines from relevant professional bodies or the health authority. As part of that process the individual shall have been informed about the estimated benefits, risks and limitations of the procedure.*

Again, almost identical requirements are included in the draft Euratom BSS at Article 54.

B. Special requirements for radiological procedures as part of an individual health assessment

With respect to benefit, it has to be kept in mind that, in contrast to X-ray mammography, either no valid data from prospective, randomized clinical studies indicating a significant reduction in cancer mortality due to CT screening are available, or the scientific evidence of such studies and their clinical implications are still controversially discussed in the scientific community¹.

Nevertheless, national guidelines of scientific bodies in particular in UK und USA conclude that there are sufficient data to include some CT procedures, in particular CT colonography, as an acceptable option for cancer “screening”, and cardiac assessment in intermediate risk patients, but – in both cases - only where specific risk factors are sufficient to indicate a reasonable expectation of benefit outweighing detriment.

To cope with these ambiguities, special requirements have to be defined, before the application of X-rays, in particular CT, for the purpose of an individual health assessment in asymptomatic individuals may be considered as an acceptable option from a regulator’s point of view. Hereby, at least, the following requirements are essential:

- the individual health assessment
 - is based on consensus guidelines of relevant scientific and professional bodies, and
 - is embedded in a well-established screening algorithm,
- the risk profile of the individuals expected to benefit from the assessment is clearly defined,
- important information is available to the individual examined so that he can be involved, as an informed person, in the decision to undertake the CT scan; this has to include information on both potential benefit and potential risk and harm, such as false positive rates, follow-on examinations and associated morbidity, radiation dose etc.,
- a demanding quality assurance programme along the whole screening chain is ensured, which has to include the technical equipment, the performance and interpretation of scans, and the management of findings (additional testing / treatment),
- a demanding programme concerning training and education is well established, and
- adequate measures concerning documentation and evaluation are set in place.

Unfortunately, no standardised and optimised protocols and algorithms are yet available concerning the definition of risk profiles of individuals, technical performance of CT, reading and diagnostic workup of suspicious findings, training and education as well as documentation and evaluation. It has to be highly recommended to initiate actions on national and international level addressing these important issues. The role of the radiation protection

¹ In this context, the first results of the National Lung Screening Trial (NLST) have to be taken into account. The NLST was conducted to determine whether screening with low-dose CT could reduce mortality from lung cancer in comparison to chest X-ray radiography. Eligible participants were between 55 and 74 years of age, had a history of cigarette smoking of at least 30 packyears, and, if former smokers, had quit within the previous 15 years. The results indicate a reduction of about 20% in lung cancer mortality with low-dose CT screening as compared to screening using chest radiography. However, a total of 96.4% of the positive screening results in the low-dose CT group and 94.5% in the radiography group were false positive results. In light of the results of the NLST, the European randomized CT screening (EUCT) investigators held a workshop in Pisa (Italy), concluding that 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.

authorities needs to be considered, in conjunction with those authorities and Ministries responsible for health.

C. Impact on the work of radiation protection authorities in Europe

1. Screening programme:

Europe has many long established population screening programmes for breast cancer using conventional and digital mammography for women within well defined age ranges. These may be regionally or nationally based, meet the requirements specified in national and European guidelines and have been investigated following national assessments.

A recent survey undertaken by the WG “Medical Application” reveals that no such population screening programmes exist using CT. But the advent of low dose CT techniques may influence decisions regarding the value of population screening for colorectal and lung disease, where alternative techniques may also have disadvantages (lack of sensitivity, specificity and in some cases significant morbidity and some mortality). Nevertheless, any changes will need strong scientific evidence and costs will play a crucial part.

2. X-ray based individual health assessment:

While the current position in Europe is quite clear concerning screening programmes, the position regarding individual health assessment is not so consistent across Europe. For example, in Germany, available reimbursement data indicate that a significant fraction of X-ray mammographies are performed in asymptomatic women outside the officially approved screening programme and may have to be considered as individual health assessment. In recent years, the advent of commercial services offering CT scans to individuals for the detection of lung, cardiac and colorectal disease has been reported in the USA and in some parts of Europe (e.g. Germany and the UK).

The regulatory control of these practices is not clear. Because of the lack of strong scientific evidence, competent radiation protection authorities are faced with increasing difficulties when deciding whether or not these types of exposures are justified on a generic level, and doctors face similar difficulties regarding justification of exposures of individuals.

While some Member States in the EU have already encountered the issue of individual health assessment in some detail, many other Member States have not yet started to discuss this issue.

For example, in the UK, the Committee on Medical Aspects of Radiation in the Environment (COMARE) provided in its Twelfth Report² some guidance on CT based individual health assessment, making a number of recommendations to the Department of Health in England. These included that whole body examinations and lung scanning were not justified and that colon and cardiac examinations should be restricted to specified patient populations. Other recommendations included a need for additional comprehensive and transparent information to clients.

This report has highlighted the need for further work and in 2011, Great Britain amended its medical exposure regulations to explicitly include individual health assessment. In addition,

² Committee on Medical Aspects of Radiation in the Environment (COMARE) Twelfth Report: The impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals.

the Department of Health intends to provide further guidance in 2012, focussing again on lung, cardiac and colorectal scanning with CT.

At present, in Germany, radiological procedures as part of an individual health assessment are not considered as healthcare. As a consequence, these procedures are not allowed within the scope of the German X-Ray Ordinance. However, the legal base of this point of view is intensively discussed. Albeit the existing legal framework, the German Radiation Protection Commission (SSK), in 2006, produced a number of requirements for the justification of individual health assessments using X-rays³. Furthermore, two workshops were organized by the Federal Office for Radiation Protection (BfS) to address the issue of CT screening in general (2005) and of lung cancer screening in particular (2011). As a consequence, Germany is currently considering whether to explicitly include individual health assessment within an upcoming amendment of its X-Ray Ordinance.

All these activities strongly support the conclusion, that X-ray based individual health assessment is particularly challenging the principle of justification on a number of levels. It is a remarkable progress, that the Euratom Basic Safety Standards (EC BSS) Directive, in its draft presented for the opinion of the European Economic and Social Committee, clearly addresses this issue by stating (Article 54(5)):

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.

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 (see also *Paragraph B* of this paper).

Failure to address these issues may result in a lack of protection for a sector of the population. In addition, from a public health perspective, this discussion may have to address far-reaching questions, such as the socio-economic benefit to the society including the potential non-radiation induced detriment and costs that may follow from investigations as the result of an inconclusive individual health assessment. Last, but not least, the conclusions drawn from these discussions will be strongly influenced by scientific evidence and by technological improvement

In a next step, the need for guidelines on the justification of X-ray based individual health assessment as well as for respective referral criteria will have to be considered. Concerning the latter, one approach might be to substitute risk factors for symptoms and follow the general approach in established referral guidelines. Where possible, the examinations should be included within the individual's healthcare record to ensure that the full benefit of the examination is realized. Furthermore, the interaction between referring medical practitioner and radiological practitioner, carrying out justification, will have to be clarified in the case of individual health assessment.

The WG "Medical Application" considers that HERCA can contribute significantly to this challenging issue by providing a platform for harmonization throughout Europe.

³ Empfehlung der Strahlenschutzkommission. Anforderungen an die Rechtfertigung individueller Früherkennungsuntersuchungen mit ionisierender Strahlung. Verabschiedet in der 208. Sitzung der Strahlenschutzkommission am 11./12. Juli 2006