Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Scoping review for the development of guidelines for the justification of medical radiological procedures on asymptomatic individuals

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About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory body established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

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- **Regulating social care services** — The Chief Inspector of Social Services within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
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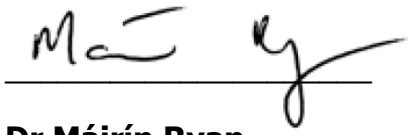
Foreword

Ionising radiation is increasingly being used in both the diagnosis and treatment of disease, and innovations in this area have the potential to improve the health and well-being of patients. The risks to a person receiving a medical exposure to ionising radiation are generally low. However, all medical exposures to ionising radiation carry some risk.

The European Union Basic Safety Standards for the Protection Against Dangers from Medical Exposure to Ionising Radiation (Euratom) were initially transposed into Irish law under SI 256 in January 2019.[1, 2] These regulations named HIQA as the competent authority for medical exposure to ionising radiation. One requirement under the regulations is the publication of guidelines on the specific justification of medical radiological practices on asymptomatic individuals for the early detection of disease, but not as part of a health screening programme.

The purpose of this report is to describe a scoping review undertaken by HIQA to identify and summarise national and international guidelines that relate to the use of medical exposure to ionising radiation (MEIR) on asymptomatic individuals for the purpose of early disease detection, but not as part of a health screening programme. The findings from this scoping review were used by HIQA to inform the development of guidelines in Ireland.

Work on this document was undertaken by the Ionising Radiation Evidence Review Team from the HTA Directorate in HIQA. A multidisciplinary MEIR Expert Advisory Group, convened by HIQA to support its work in this area, provided feedback on this document. HIQA would like to thank the Evidence Review Team, the members of the Expert Advisory Group and all who contributed to the preparation of this document.



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Key: HIQA – Health Information and Quality Authority; HSE – Health Service Executive; NCCP National Cancer Control Programme.

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*Dr Paula Byrne left HIQA in 2022

Conflicts of Interest

None declared.

Table of contents

List of tables

List of figures

List of abbreviations used in this report

CT	computed tomography
COMARE	Committee on the Medical Aspects of Radiation in the Environment
DEXA	dual energy X-ray absorptiometry
EAG	expert advisory group
EU	European Union
IHA	individual health assessment
HERCA	Heads of the European Radiological Protection Authority
HTA	health technology assessment
HIQA	Health Information and Quality Authority
IR	ionising radiation
MEIR	medical exposure to ionising radiation
PICo	population, interest, and context
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
PRISMA-ScR	PRISMA extension for scoping reviews
SI	Statutory Instrument
SSK	Strahlenschutzkommission (The German Commission on Radiological Protection)
UK	United Kingdom
US	United States of America
WHO	World Health Organization

Plain language summary

While the risks are generally considered to be low, all medical exposures to ionising radiation (for example, X-rays or CT scans) carry some risk. Under Irish law, HIQA must publish guidelines for justifying procedures that involve medical exposure to ionising radiation in people who have no known disease or symptoms and where they are not part of a national health screening programme. National screening programmes are government-funded services that look for early signs of disease in people who have no known disease or symptoms, and include screening services such as BreastCheck. Justification means making sure that the benefits outweigh the risks involved. Justification is particularly important when the person has no known disease or symptoms (that is, they are asymptomatic) and the medical exposure to ionising radiation is for screening purposes.

This report was the first step in the development of these Irish guidelines. It presents a scoping review of relevant national or international guidance or guidelines that could be useful in the Irish context. The medical literature was searched for relevant documents as well as the websites of radiological professional bodies and the Departments of Health in a number of countries.

Six relevant documents were found from the searches. Three of the documents were from the UK, one was from Germany, one was from the World Health Organization and one was from a European radiological organisation. A number of key themes or principles were identified from these documents.

HIQA used this work to develop guidelines for screening of asymptomatic individuals involving ionising radiation. HIQA consulted with experts and patients or patient advocates as part of this process.

Key Points

Aims and scope

- HIQA is required to publish guidelines on the specific justification of medical radiological procedures on asymptomatic individuals for the early detection of disease which are not part of a health screening programme.
- To inform the development of these guidelines, HIQA undertook a scoping review to identify national and international guidelines that may be relevant to the Irish context.

Methods

- This scoping review included a search of Medline and Embase as well as an extensive grey literature search for guidelines, guidance or recommendations available nationally or internationally on the medical exposure to ionising radiation on asymptomatic individuals.

Results

- Six relevant documents were identified: one position paper, two reports, one set of recommendations and two guidance documents. Three were from the UK, one from Germany, one from a European organisation and one from the World Health Organization.
- There were several key themes or principles common to most documents. These were that screening for asymptomatic individuals should:
    - be conducted according to guidelines of relevant scientific and professional bodies
    - be individually justified by the radiological medical practitioner and or the referring medical practitioner
    - include an assessment which concludes that the benefits are balanced against the risks; the risks should include consideration of radiation detriment as well as potentially misleading or inaccurate results
    - include an assessment clearly defining the risk profiles of those expected to benefit from screening or individual health assessment
    - only be done after consideration of the integration of results of examinations into an established care pathway

- include a quality assurance programme along the whole screening chain, including the technical equipment, the performance and interpretation of scans, and the management of findings
- include adequate measures concerning documentation and evaluation
- only be considered after ensuring that adequate information about both potential benefit and harm is provided to the individual, including the implications of possible findings
- only occur if there are no examination methods with a better risk/benefit profile than that of the available application of ionising radiation.

- Other, less common themes identified included:
  - providing appropriate support to the asymptomatic individual following test results; the acceptability of the test; training and education of staff; issues of legality; and best practice for the transfer of data.

Discussion and conclusions

- A number of high-level principles were identified in this scoping review that should be considered when screening asymptomatic individuals. HIQA used these principles, in conjunction with public and expert consultation, to inform the development of guidelines for screening asymptomatic individuals using ionising radiation.

1 Background

Ionising radiation (IR) is used in both the diagnosis and treatment of disease. Technological developments in IR have led to improved patient outcomes due to better, faster diagnosis and more effective treatment. However, there are concerns that some technologies are overused with the potential that, for some individuals, the harms exceed the potential for benefit.[3-5] While the risks of using IR in screening are generally considered to be low, all medical exposure to ionising radiation (MEIR) carries some risk. One of the main risks associated with MEIR is the increased risk of developing cancer. Other risks include the possible detrimental impact of misleading or inaccurate results from a radiological procedure on an individual.

The European Union (EU) Directive 2013/59/Euratom (Basic Safety Standards for Protection against Dangers Arising from Exposure to Ionising Radiation) Regulations 2018[1] was transposed into Irish law on 8 January 2019 by Statutory Instrument (SI) 256.[2] These Regulations named HIQA as the competent authority for medical exposure to ionising radiation.

Regulation 8(1) of the SI requires that:

> *A person shall not carry out a medical exposure unless it (a) shows 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, and (b) takes into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.*

MEIR typically is used, either for diagnostic or therapeutic purposes, in symptomatic individuals. However, MEIR can also be used to screen asymptomatic individuals who may be at risk of developing disease, with the intention of early diagnosis, thereby improving outcomes. BreastCheck, the National Breast Screening Programme in Ireland, is an example of where MEIR is used within an approved national programme. However, recognising that such use can occur outside of screening programmes, Regulation 8(6) of the SI requires that:

> *The Authority shall, after consultation with the relevant professional body or bodies, publish guidelines on the specific justification of medical radiological procedure on an asymptomatic individual, performed for the early detection of disease but not as part of a health screening programme.*

For the purpose of this review, an asymptomatic person is defined as a person with no known disease or symptoms. As an asymptomatic person presenting for a radiological procedure is not always a patient in the traditional sense, in this review the term 'asymptomatic individual' is used.

The purpose of this scoping review was to identify national or international guidance, guidelines or recommendations for the medical use of ionising radiation on asymptomatic individuals for the purpose of early detection of disease, but not as part of a national screening programme.

1.1 Overall approach

A standing multidisciplinary MEIR expert advisory group (EAG) has been convened by HIQA comprising representation from key stakeholders. A full list of the membership of the EAG is available in the acknowledgements section of this report and includes the relevant professional bodies as outlined in the regulations. The terms of reference for the EAG are published on the HIQA website.

This scoping review was prepared as the first step in the development of national guidelines. The findings from this report were presented and discussed with the MEIR EAG and were used to inform the next stages of the guideline development process.

2 Description of technology

2.1 What is Medical Exposure to Ionising Radiation (MEIR)?

Ionising radiation (IR) has sufficient energy to remove electrons from atoms and break chemical bonds, and is used in a beneficial way in medicine for the diagnosis and treatment of disease. This is referred to as medical exposure to ionising radiation (MEIR).

IR has the potential to cause harm to human tissue, including skin burns, loss of hair, and an increased risk of cancer. Justification and optimisation are core

principles of radiation protection that have been developed to minimise the harms to individuals from medical exposure to ionising radiation. Justification is a process of demonstrating that there is sufficient net benefit associated with a radiation exposure.[6, 7] This takes into account the efficacy and potential benefits of the exposure, the possible risks associated with the exposure, and any alternatives that may be available. Optimisation means that doses of IR should be kept as low as can be reasonably achieved, consistent with the purpose of the exposure.[8] Dose limitation is another principle of radiation protection, which aims to limit the dose to staff and members of the public by ensuring that the total exposure received is kept below the relevant dose limits.[6]

Only the use of MEIR on asymptomatic individuals for the purpose of diagnosing disease or identifying those at a higher risk of disease were within scope for this report. Other medical imaging techniques, such as ultrasound and magnetic resonance imaging (MRI) that do not involve IR were therefore considered outside the scope of this report.

3 Screening and current use of the technology

3.1 Screening asymptomatic individuals in Ireland

Screening involves testing defined populations to look for undiagnosed conditions or risk factors. The intent of a screening programme can be to:

- reduce mortality by early detection and early treatment of a condition
- reduce the incidence of a condition by identifying and treating its precursors
- reduce the severity of a condition by identifying people with the condition and offering effective treatment
- increase choice by identifying conditions or risk factors at an early stage in a life course when more treatment/management options are available.[9, 10]

Formally recognised programmes typically have a robust evidence base, are supported by professional bodies and are subject to stringent quality control and appraisal throughout their operation. These measures ensure that the benefits to the population screened outweigh the harms.

The use of IR for the early detection of disease in asymptomatic individuals generally falls into two groups: national screening programmes and other types of screening which are not part of a national screening programme (for example, individual health assessments (IHAs)), or opportunistic screening. Under the current regulations, screening outside of a national screening programme is only permitted when the

procedure is justified, evaluated and documented by the medical practitioner on a case-by-case basis.[11, 12]

National screening programmes are set up on the basis that the benefits of screening a particular group of people outweighs the potential harm. The use of IR within these programmes is thus considered to be 'justified' at a population level. BreastCheck is an example of a national screening programme in Ireland which uses IR.[13]

In contrast, IHA (or opportunistic screening) is a type of screening which involves asymptomatic individuals, but is not part of a formal screening programme. It may be conducted to alleviate presenters' anxiety coupled with a practitioners' willingness to perform examinations, and there is a risk that this may be based on a poor or absent evidence base, and in the absence of any relevant risk factors in the individual's history.[9] In accordance with Regulation 8(1) of SI 256, practitioners must not carry out a medical exposure unless there is a net benefit and they have taken into account the efficacy, benefits and risks of alternative techniques.[2]

Examples of screening that are not a part of a national programme include:

- an employer offering IHA in the form of whole body computed tomography (CT) scans as part of an annual health check
- use of mammography in age groups not included in BreastCheck
- the use of CT in coronary artery calcium scoring (for the investigation of coronary artery plaques)
- use of dual energy X-ray absorptiometry (DEXA) for evaluation of bone density.

3.2 What are the potential benefits and harms of screening?

Screening programmes are intended to identify disease or those at higher risk of a disease at an early, more treatable stage and therefore be beneficial to health. However, potential harms need to be considered along with the benefits of screening, especially in the context of ionising radiation, as only a few of those screened will have the condition — although all participants are exposed to the potential harms of ionising radiation. Screening tests are never 100% accurate and some people will test positive who do not have the condition (false positives) and some will test negative who do have the condition (false negatives). Both of these outcomes are associated with harm. Those who receive false positives from screening often suffer anxiety over the result and undergo further testing or procedures before it is clear they do not have the condition that is being tested for.

There can be financial implications for these additional tests, and time potentially missed from work. For those who receive a false negative result, the harm is often the result of delayed diagnosis.[14] Even in a successful screening programme there is potential for harm through under or over diagnosis and over treatment.[10, 15, 16] This can lead to additional unnecessary expenditure in the healthcare system as well as reducing public confidence in screening.[14] Harms can be thought of in four categories: physical effects, psychological effects, financial strain and opportunity cost.[17]

The use of medical imaging has been shown to have increased substantially over the last two decades,[3] with US-based studies showing low-value screening, testing or procedures costing billions of dollars.[18]

Other screening, even when privately funded, has implications for the publicly funded healthcare system due to the cost of follow-up for those who have a positive screening test, and the potential for opportunity cost. In other words, there are concerns that low-value care, generated by IHA, could divert funding from forms of care that would have a larger effect on all-cause mortality and morbidity, or from providing necessary care to those who are ill.

In 1968, the WHO commissioned a report titled *Principles and practice of screening for disease*. This report contained a list of principles, the Wilson and Jungner criteria, to be considered before implementing a screening programme.[19] The National Screening Advisory Committee has published criteria in line with the Wilson and Jungner criteria which are used to appraise the viability, effectiveness and appropriateness of screening programmes in Ireland.[20]

4 National and international guidance review

4.1 Aim and scope of review

The aim of this scoping review was to identify and describe any national or international guidelines, guidance or recommendations relevant to the review question, described below. Condition-specific guidelines or guidance as well as guidance around organised screening programmes were considered outside the scope of this review. The findings from this scoping review were used to inform the development of evidence-based guidelines in Ireland for the justification of medical radiological procedures on asymptomatic individuals for the early detection of disease, but not as part of a health screening programme.

4.2 Methodology

4.2.1 Review question

As outlined in Table 1, this scoping review question was formulated according to the Population, Intervention and Context (PICo) framework. This scoping review sought to answer the following question:

- What international or national guidelines, recommendations or guidance documents regarding the use of MEIR in asymptomatic people, outside of established screening programmes, exist that might be applicable to the Irish healthcare system and or which can assist HIQA in developing guidelines?

The PICo of this research question are presented in Table 1.

Table 1: PICo for scoping review research question

Population	Asymptomatic individuals of any age without known disease
Intervention	Any medical exposure to ionising radiation for the purpose of detecting disease or risk factor early
Context	Asymptomatic screening; individual health assessments; opportunistic screening; risk-based screening. Exclude: o records relating to national screening programmes o condition-specific guidelines, guidance or recommendations o ionising radiation exposure for non-medical purpose o documents which are not a guideline, statement, recommendation or guidance document

	○ non-English documents where a suitable translation cannot be obtained ○ documents where the full text cannot be retrieved.

4.2.2 Search strategy and study selection

The number of documents identified at each stage of the scoping literature search were documented in a PRISMA diagram.

After consultation with an information specialist, the literature databases were searched from January 2013 to December 2022 to identify publications that were relevant to the review question and arose after the 2013 EU directive 2013/59/Euratom. The searches were conducted in Medline and Embase using combinations of words and phrases for 'diagnostic tests', 'asymptomatic', 'ionising radiation' and 'guidelines'. The search terms used and details of the search conducted can be found in Table A1 in Appendix 1. The reference lists of relevant publications were searched with no date limitations. In addition, the first five pages were searched for a Google and Google Scholar search to identify any relevant grey literature. Grey literature sources, as listed in Table A2 in Appendix 1, were searched using combinations of these words and phrases with no date limitations.

Following this initial search, a targeted grey literature search was conducted focusing on websites from professional bodies, health technology assessment (HTA) agencies and departments of health within a number of selected countries as well as international health organisations (Table A2 in Appendix 1). An iterative approach to country selection was adopted in this scoping review. At a minimum, English-speaking, developed countries were included due to their relevance to the Irish situation including UK, the US, Canada, Australia and New Zealand. As the regulation came from an EU directive, Germany, Finland and a number of international and European organisations were also included (Table A2 in Appendix 1). In addition, other relevant countries were added to this selection in an iterative manner, based on the included studies in the systematic search of the literature.

After removal of duplicates, one reviewer reviewed titles and abstracts as per the inclusion and exclusion criteria. Where uncertainty existed, the record was reviewed by a second person. All potentially eligible records included in full-text screening were independently reviewed by two reviewers, with any disagreements resolved through discussion. All records excluded after full-text screening were reported along with their reason for exclusion.

4.2.3 Data extraction and risk of bias assessment

Data extraction was performed by one person and checked by a second, with any disagreements resolved by discussion. The data extraction template (Table A3 in Appendix 1) was trialled on two documents initially.

For data management purposes, the results of the search were exported to Covidence (www.covidence.org) and the screening was completed using this software.

As the aim of this scoping report was to provide an overview of the existing guidelines, guidance, statements and recommendations on this topic regardless of the methodological quality or risk of bias, the documents identified were not appraised for quality.

4.2.4 Data synthesis and presentation

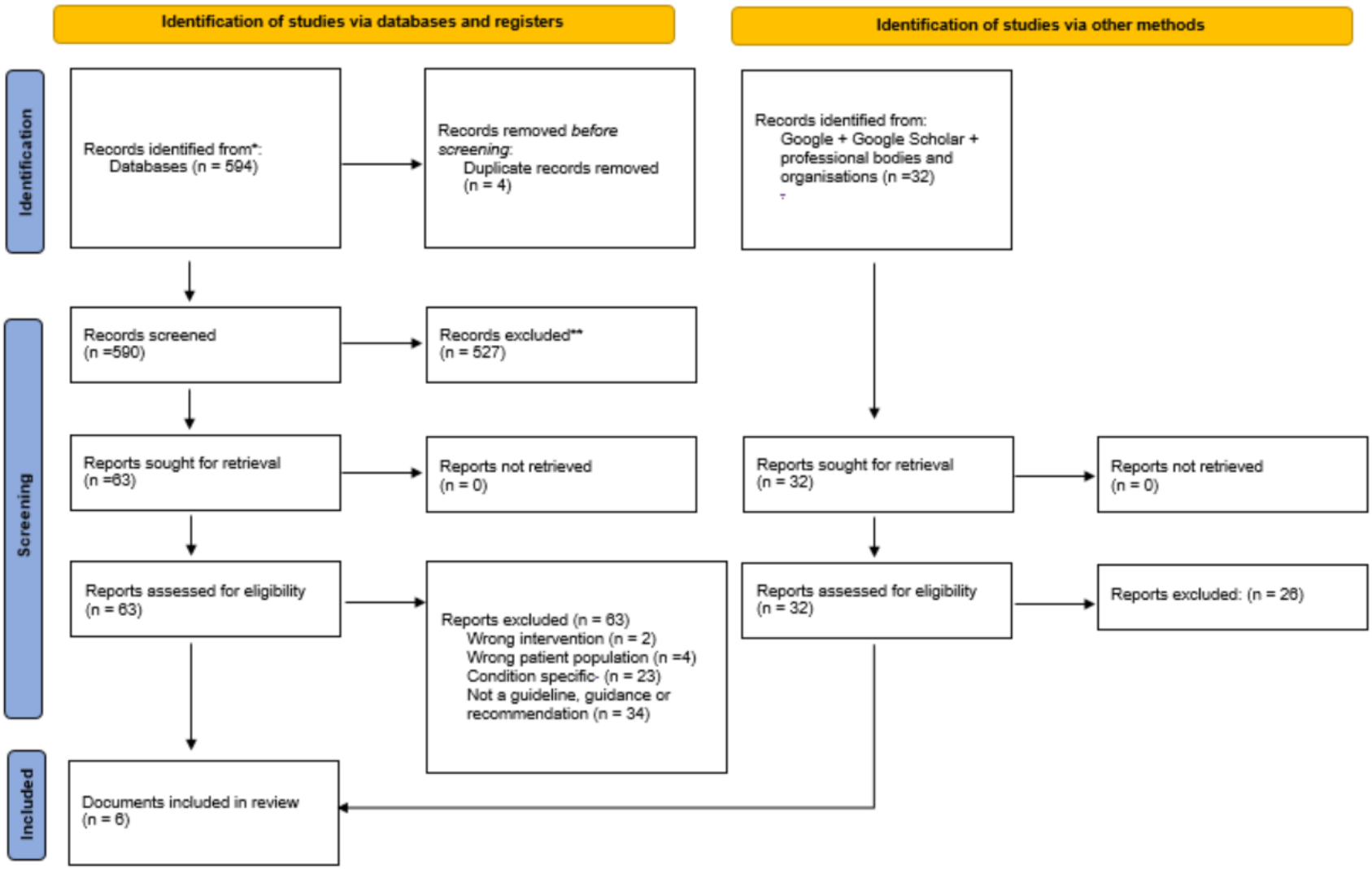
The included guidelines, guidance, recommendations and statements documents are described narratively with common concepts grouped by themes. These identified themes were used to develop guidelines in this area.

4.3 Results

4.3.1 Search results

A total of 594 records were identified through database searching and a further 32 from grey literature searches. After full text review, six documents were included in this scoping review (see Figure 1).

Figure 1: PRISMA flow diagram for search



4.3.2 Characteristics of included records

Six documents were included in the scoping review (Table 2). These included one position paper,[21] two reports,[22, 23] one set of recommendations,[24] and two guidance documents.[10, 25] Three were from the UK,[22, 23, 26] one from Germany,[24] one was from a pan-European organisation (Heads of the European Radiological protection Authority (HERCA),[21] and one was from an international organisation (the World Health Organization, WHO).[10] The three UK documents were from a Committee on the Medical aspects of Radiation in the Environment (COMARE), the Department of Health, and the Royal College of Radiologists. The German recommendations came from the German Commission on Radiological Protection, the Strahlenschutzkommission (SSK).

In most of the documents, screening of asymptomatic individuals was in the context of IHAs,[10, 21, 23, 26] while there was also a reference to opportunistic screening,[21] screening in the 'wellness' area[24] and personally initiated scanning of asymptomatic individuals.[22] One document laid out general principles that applied to IHAs and screening programmes in general.[10]

Four of the documents referred to any or multiple types of medical imaging with ionising radiation,[10, 21, 24, 26] while two focused on CT scans.[22, 23] The dedicated focus on the use of CT scans in this context likely originates from the fact that CT is associated with a relatively high radiation dose (for example, compared with plain X-ray).

Table 2: Summary of included studies

Author Year of publication Country Document link	Title Type of document	Type of IR	Recommendations/principles
HERCA **2012** **Europe** Document link	Position paper on screening (Exposure of asymptomatic individuals in healthcare) Position paper	Any, but mainly focuses on CT	Requirements: Screening asymptomatic individuals should: ▪ be based on consensus guidelines ▪ be embedded in a screening algorithm ▪ include a clearly defined risk profile of the individuals expected to benefit ▪ provide important information including information on both potential benefit and potential risk and harm ▪ include a quality assurance programme along the whole screening chain ▪ include well-established training and education programmes ▪ include adequate documentation and evaluation.
Committee on Medical Aspects of Radiation in the Environment (COMARE) **2007** **UK** Document link	The impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals Advice to Department of Health (Twelfth Report)	CT	Recommendations: 1. Department of Health should review commercial CT services and consider regulating them against agreed standards (referral processes, justification and optimisation and submission of agreed datasets to the regulator) 2. Services should provide comprehensive information regarding eligibility, dose and risk 3. Rates of false negative and false positive findings should be independently audited and explained 4. Any further investigations that may be required should be discussed 5. Commercial CT services should have robust and confidential mechanisms to integrate results into an established care pathway. Transfer of medical data must be discussed with and agreed by patients prior to medical exposures 6. Services offering whole body CT scanning of asymptomatic individuals should cease 7. If CT is not the modality of choice, it should not be made available for the assessment of asymptomatic individuals.
Radiation	Requirements for the	Any	Recommendations:

Protection Commission[24] **2006** **Germany** Document link	justification of individual early detection examinations with ionizing radiation: Recommendation of the Radiation Protection Commission		▪ the treating doctor with the necessary specialist knowledge in radiation protection must indicate that the health benefit of an application outweighs the radiation risk ▪ the severity of the suspected illness justifies an early detection measure and be detected at the asymptomatic phase ▪ effective forms of therapy exist and are available in the healthcare system, which improve the prognosis and or the quality of life of those affected if used early ▪ the examination has a sufficiently high positive predictive value and a sufficiently high negative predictive value ▪ the examination is acceptable for the person to be examined (stress, costs) ▪ there are no other examination methods with a lower risk than the application of ionising radiation available ▪ the following are taken into account: ○ anamnesis, if necessary physical examination ○ creation of an individual risk profile ○ detailed information and advice on benefits, risks and undesirable side effects as well as any necessary diagnostic tests ○ highest quality requirements regarding implementation, diagnosis and determination of the further process ○ comprehensive documentation of the measures. ▪ there is an accompanying evaluation of the study ▪ individual early detection examinations are carried out exclusively on the basis of coordinated guidelines from scientific specialist societies that take the above points into account.
WHO **2020** **Europe** Document link	Screening programmes: a short guide	Not specified	Recommendations: For multiphasic, individual health assessments, health checks or a bundle of tests, each test should be subject to that same stringent criteria used to determine whether to start a screening programme and be provided in a way that fulfils the following criteria: ▪ the screening test is part of a pathway of care ▪ the eligible population is defined according to evidence based on the balance of benefits versus harm ▪ the test is offered systematically, based on a register of the eligible population using a call and recall system

			▪ decisions about an individual's care are based on evidenced protocols and guidelines ▪ the screening service use quality standards based on evidence ▪ an information system is in place linked to population registries.
Department of Health **2014** **UK** Document link	Justification of Computed Tomography (CT) for Individual Health Assessment Expert Working Party Report	CT	Recommendations: Ethical, scientific, logistical, psychological and financial considerations should be taken into account, including: ▪ the provision of information, including the significant likelihood of false positive findings where the probability of disease is low ▪ the provision of detail on possible findings (whether clinically significant or not), potential risks, possible further investigations and where and how these would be conducted ▪ the support provided when results of scans are positive or indeterminate ▪ the impact or otherwise of negative findings on those who have unhealthy lifestyles ▪ the logistical arrangements for transfer of data into the individual's healthcare record ▪ the mechanisms in place to develop an evidence base for justification of CT examinations for asymptomatic individuals with varying risk factors ▪ the relationship between the healthcare professional acting as referrer for the procedure and the practitioner justifying that the scan should be undertaken.
Public Health England, The British Institute of Radiology, Institute of Physics and Engineering in Medicine, The Royal College of Radiologists & The	IR(ME)R Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine Guidance document, (focusing largely on the implementation of the regulations)	Any	Recommendations: ▪ The exposure must be justified, prior to the exposure, by a practitioner who must ensure there is a net benefit from the exposure ▪ The practitioner must have regard in particular to any guidelines issued by appropriate medical scientific societies, relevant bodies or the secretary of state. ▪ The employer and practitioner must hold the appropriate license A number of considerations should be taken into account, for example: ▪ Will the exposure contribute to, or change, the individual's healthcare management?

Society & College of Radiographers **2020** **UK** Document link			▪ Has the referrer provided enough relevant clinical information to be able to justify the exposure? ▪ Has the referrer provided enough information to be able to definitively identify the patient? ▪ Is the exposure likely to answer the clinical question being asked? ▪ What relevant previous imaging is available? ▪ Are there alternative techniques that will answer the question but do not involve ionising radiation?

4.3.3 Thematic analysis

There were a number of themes or principles common to the documents included in this review. Table A4 in Appendix 2 describes these themes in detail. In summary, the included documents recommend that screening of asymptomatic individuals or IHAs should:

- be conducted according to guidelines of relevant scientific and professional bodies[10, 21, 22, 24, 26] or should be individually justified by the radiological medical practitioner and or the referring medical practitioner[22-24, 26]
- be undertaken in the context of a quality assurance programme[10, 21, 24] that includes the whole screening chain, including the technical equipment, the performance and interpretation of scans, and the management of findings[10, 21, 22, 24]
- include adequate measures concerning documentation and evaluation
- integrate results of examinations into an established care pathway that includes support for individuals when scan results are positive or indeterminate[10, 22-24]
- clearly define the risk profiles or eligibility criteria of those expected to benefit from screening or IHA[21-24, 26]
- ensure that the benefits are balanced against the risks,[10, 22-24] not only from the radiation detriment, but also from potentially misleading or inaccurate results[22, 23]
- ensure that adequate information about potential benefit and potential risk and harm is provided to the individual,[21-24] including implications of possible findings[23]
- only occur if there are no examination methods with a better risk/benefit profile than that of the available application of ionising radiation.[24, 26]

Recommendations for screening or IHA in asymptomatic individuals that appeared in only one document included:

- tests should have a sufficiently high positive predictive value and a sufficiently high negative predictive value[24]
- it should only be done if the examination is acceptable for the person to be examined (stress, costs)[24]
- it should incorporate risk profiles of those expected to benefit from screening or IHA in established screening and follow-up algorithms[21]
- there should be adequate staff training and education[21]
- IHA CT should only be offered by expert clinicians who are able to explain the risks and benefits[23]
- legal considerations must underpin the use of CT in IHA[23]

- testing should include a mechanism for the development of an evidence base for justification of CT examinations for asymptomatic individuals with varying risk factors[23]
- consideration should be given to the impact or otherwise of negative findings on those who have unhealthy lifestyles[23]
- there should be adequate measures for the transfer of patient data[23]
- consideration should be given to the relationship between the healthcare professional acting as referrer for the procedure and the practitioner justifying that the scan should be undertaken[23]
- it should not be done if relevant previous imaging is available
- it should only be done if the exposure is likely to answer the clinical question being asked[26]
- it should only be done if the exposure will contribute to, or change, the individual's healthcare management.[26]

5 Discussion

5.1 Summary of findings

Following a systematic search of databases and a targeted grey literature search, six documents were identified that were relevant to this review question. From these documents, a number of themes or principles emerged.

Firstly, the use of guidelines from relevant scientific and professional bodies when using CT or other ionising radiation-based imaging on asymptomatic individuals was recommended. Secondly, while it was advised that all exposures to ionising radiation should be justified regardless of whether the person is symptomatic or asymptomatic, it was noted that such justification is much more difficult in the case of asymptomatic individuals.[23] One document outlined a number of questions a practitioner should consider when justifying an exposure, including the availability of sufficient clinical information, the implications of findings for the individual's health management and whether there was any previous imaging available[26] (Table A4 in Appendix 2). As justification is defined as demonstrating that the benefits of IR outweigh the harms, most of the documents recommended that this net benefit be demonstrated.

All included documents discussed the use of eligibility criteria or risk profiles as part of the process, with risk factors considered in place of symptoms, and four mentioned the importance of having care pathways in place for those being screened outside of an organised programme.[10, 22, 23, 26] Another common theme was the importance of providing information to the asymptomatic individual about the benefits, risks and limitations of the procedure.[21-24] In addition, a number of documents mentioned quality assurance and the importance of documentation and evaluation of any service.[10, 21, 22, 24]

5.2 The findings in context

Most of the documents identified focused on IHA. Malone et al. described a WHO consultation on the justification of CT for IHA of asymptomatic individuals,[9] and distinguished two types of IHAs. Firstly, there is IHA which may have an incomplete but evolving evidence base to justify the procedure. In this case, known risk factors may be present, thus justifying the procedure for some subgroups. This type of IHA may at some point develop into an approved screening programme should more evidence emerge in support of its use in this population. In contrast, a second type of IHA comprises one with limited or no evidence base or risk profile to suggest that the examination is worth doing. It may be opportunistic or it may be driven by the presenter or health professional and is difficult to justify.[9] The participants in the

WHO consultation identified six aspects of IHA that should be considered: terminology; risk communication and dialogue for presenters and professionals; guidelines and clinical audit; social, ethics, public health and resource considerations; education and training of professionals and public; and future framework and regulatory considerations. A number of the topics identified in the WHO consultation were also featured in this scoping review.

The COMARE report from the UK provides four useful examples of common types of CT scans which are currently not part of a screening programme and would be considered to be IHAs in the UK. The evidence base for these is discussed along with criteria that should be considered when deciding if the use of ionising radiation can be justified.[22] The COMARE report includes recommendations for lung cancer screening, colon cancer screening, and coronary heart disease screening using CT. Of note, they recommend that whole-body CT screening of asymptomatic individuals should cease.

In Germany, only mammography screening has been approved for the early detection of breast cancer with the federal office considering the use of low-dose CT for early detection of lung cancer.[27] However, it has been reported that screening for a number of different conditions using IR is being offered commercially and illegally in Germany.[9, 27]

The WHO and the International Atomic Energy Agency made a joint position statement called the 'Bonn Call for Action' which consisted of 10 actions to improve radiation protection in medicine in the next decade. The first action in this statement was to "Enhance the implementation of the principle of justification" and as part of this action "further develop criteria for justification of health screening programmes for asymptomatic populations (for example mammography screening) and for medical imaging of asymptomatic individuals who are not participating in approved health screening programmes (for example the use of CT for individual health surveillance)".[28] However, no official criteria could be found that had been developed in response to this position statement.

5.3 Strengths and limitations of review

This scoping review used a comprehensive search strategy, including extensive grey literature search, which was carried out after consultation with an information specialist. The review took a high-level approach in order to identify themes and principles which may have meant that important principles or themes from documents published by professional clinical groups that were condition-specific were missed as they were considered beyond the scope of this review.[29, 30] Although an extensive grey literature search was undertaken, it is possible that

relevant documents from other countries outside of the targeted grey literature search may have been missed. The quality of the documents identified was not assessed due to the overall aim of this review, which was to identify any and all literature on the topic; it is possible the included documents were of low quality. While three of the six documents identified were from the UK, these documents shared common themes with the other national and international documents.

5.4 Ethical concerns

Concerns around patient safety when using medical imaging often focus around the radiation protection framework, including professional development, regulation, and safety culture.[31] Medical ethics includes values such as dignity and autonomy (of the individual); non-maleficence and beneficence (do no harm and do good); justice (be fair); prudence and precaution (keep in mind long-term risks of actions); and honesty and transparency, with the application of these values leading to the consideration of patient-centred care, shared-decision making and a fair and equitable resource allocation throughout the health system.[9, 31]

In the context of IHAs, the examination may be opportunistic and the decision may be based on balancing the value of individual autonomy with the concept of 'do no harm'.[9] It is important that all costs and resources of IHAs be considered, including the management of incidental, equivocal and false positives, as these costs may end up being diverted from the public healthcare system and from patients who may have a greater need. It may be assumed that consideration of justification and optimisation before the use of medical imaging using ionising radiation is enough to address any moral issues, but this may not always be the case. The World Health Organization has recently produced a policy document on ethics in medical radiological imaging which suggests consideration of these ethical values will help integrate ethics into the framework for medical radiation protection.[31] The International Commission on Radiological Protection is currently developing a report on the ethical aspects of the use of radiation in medicine.[32]

5.5 Conclusions

The aim of this scoping review was to identify relevant documents to aid HIQA in developing guidelines as per its legal obligation under SI 256, as amended. Established scoping review methods were followed and six documents were identified that outlined a number of principles that should be considered or implemented when screening asymptomatic individuals. These concerned the use of established guidelines, the importance of weighing potential benefits against potential harm (that is, justification), the use of eligibility criteria, the provision of full information for the person undergoing the procedure, as well as consideration of

quality assurance, documentation, and evaluation. Some documents detailed specific information, actions or standards that should be required before ionising radiation is used in screening asymptomatic individuals.

The findings of this scoping review, in conjunction with public and expert consultation, were used by HIQA to inform the development of guidelines for screening asymptomatic individuals using IR.

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Appendix 1

Table A.1 Search as run in Medline (EBSCO)

# number	Query
1	AB (Screening* OR (diagnos* N3 (test* OR screening* OR examination*)) OR "individual health assessment*" OR detection N1 test* OR (direct-to-consumer N2 (screening* OR test*))) OR TI (Screening* OR (diagnos* N3 (test* OR screening* OR examination*)) OR "individual health assessment*" OR detection N1 test* OR (direct-to-consumer N2 (screening* OR test*)))
2	(MH "Early Diagnosis+") OR (MM "Diagnostic Tests, Routine") OR (MM "Direct-To-Consumer Screening and Testing")
3	(MH "Mass Screening+")
4	S1 OR S2 OR S3
5	AB (Asymptomatic OR nonsymptomatic OR non-symptomatic OR symptom-free OR symptom-less OR symptomless OR pre-symptomatic OR presymptomatic) OR TI (Asymptomatic OR nonsymptomatic OR non-symptomatic OR symptom-free OR symptom-less OR symptomless OR pre-symptomatic OR presymptomatic)
6	(MH "Asymptomatic Diseases+")
7	S5 OR S6
8	AB (ionising OR ionising) AND AB radiation
9	TI (ionising OR ionising) AND TI radiation
10	AB (ionisation OR ionization) OR TI (ionisation OR ionization)
11	AB (Fluoroscop* OR Radiolog* OR irradiat* OR radioactive OR radionuclide* OR "radioactive nuclide*" OR radioisotope* OR "radioactive isotope*" OR radiopharmaceutical) OR TI (Fluoroscop* OR Radiolog* OR irradiat* OR radioactive OR radionuclide* OR "radioactive nuclide*" OR radioisotope* OR "radioactive isotope*" OR radiopharmaceutical)
12	(MH "Radiation, Ionizing+")
13	AB (mammography OR mammogram*) OR TI (mammography OR mammogram*)
14	AB ("computed tomography" OR "positron emission tomography" OR "PET scan" OR "CT scan" OR "CAT scan") OR TI ("computed tomography" OR "positron emission tomography" OR "PET scan" OR "CT scan" OR "CAT scan")
15	AB x-ray* OR TI x-ray*

# number	Query
16	S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15
17	PT (guideline or consensus development conference) OR AB (position statement* or policy statement* or practice parameter* or best practice*) OR TI (position statement* or policy statement* or practice parameter* or best practice*) OR AB (standards or guideline or guidelines) OR TI (standards or guideline or guidelines) OR AB consensus* OR TI consensus*
18	AB (recommendation* OR "guideline recommendation*") OR TI (recommendation* OR "guideline recommendation*")
19	(MM "Critical Pathways") OR (MH "Clinical Protocols+") OR (MM "Consensus") OR (MH "Consensus Development Conferences as Topic+") OR (MH "Guidelines as Topic+") OR (MM "Health Planning Guidelines") OR (MM "Clinical Decision Rules")
20	S17 OR S18 OR S19
21	S4 AND S7 AND S16 AND S20
22	S4 AND S7 AND S16 AND S20

Table A2. Grey literature search

Sites searched	URL
General sites	
Google Scholar and Google	https://scholar.google.com/, https://www.google.ie
International Organisations	
World Health Organization	www.who.int/en
European Network for Health Technology Assessment	https://www.eunethta.eu/
European Commission	https://ec.europa.eu/health/home_en
International HTA database (INAHTA)	https://database.inahta.org/
Guidelines International Network	https://g-i-n.net/
Selected countries for targeted grey literature search	
Australian	
Australian National Health and Medical Research Council	https://nhmrc.gov.au/about-us/publications
Royal Australian College of General Practitioners	https://www.racgp.org.au/
Imaging Pathways (government Western Australia)	https://radiologyacrossborders.org/diagnostic_imaging/
Canada	
British Columbia Guidelines Advisory Committee (GAC) Recommended Clinical Practice Guidelines	https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/msp/committees/guidelines-and-protocols-advisory-committee-gpac
Canadian Agency for Drugs and Technology in Health	http://www.cadth.ca
Canadian Association of Radiologists	https://car.ca/
Canadian Medical Association Infobase	https://joulecma.ca/cpg/homepage

Objective Health Canada	https://objectivehealth.ca/
Germany	
Federal Institute for Drugs and Medical Devices	www.bfarm.de
Association of the Scientific Medical Societies, Germany	https://www.awmf.org/
Ireland	
Department of Health (including National Clinical Guidelines)	health.gov.ie
Health Service Executive (HSE)	www.hse.ie
The Irish Health Repository (Lenus)	www.lenus.ie
National Cancer Control Programme HSE	https://www.hse.ie/eng/services/list/5/cancer/
Faculty of Radiologists and Radiation Oncologists, RCSI	www.radiology.ie/
Finland	
Stuklex	https://www.stuklex.fi/en/ls#regulatory2
Council for Choices in Health Care in Finland (COHERE Finland)	https://palveluvalikoima.fi/en/council-for-choices-in-health-care-in-finland
New Zealand	
New Zealand Guidelines Group	https://www.nzgp-webdirectory.co.nz/WEB+DIRECTORY/CLINICAL+INFORMATION/GUIDELINES+NEW+ZEALAND.html
Best Practice Advocacy Centre New Zealand	https://bpac.org.nz/guidelines/ – website no longer active
United Kingdom (UK)	
COMARE	https://www.gov.uk/government/groups/committee-on-medical-aspects-of-radiation-in-the-environment-comare
The Royal College of Radiologists	https://www.rcr.ac.uk

National Institute for Health and Care Excellence (NICE)	https://www.nice.org.uk/guidance
Guidelines and Audit Implementation Network / The Regulation and Quality Improvement Authority	https://www.rqia.org.uk/what-we-do/improve/programme-closure-clinical-audit,-qi-and-clinica/
NHS Evidence (incorporating Scottish Intercollegiate Guidelines Network (SIGN) & Guidelines International Network (GIN))	www.evidence.nhs.uk – website no longer active
Department of Health and Social Care	https://www.gov.uk/government/organisations/department-of-health-and-social-care
United States	
Agency for Healthcare Research and Quality	https://www.ahrq.gov/
Food and Drug Administration	https://www.fda.gov/regulatory-information/search-fda-guidance-documents
American College of Physicians	https://www.acponline.org/
US Preventive Services Task Force	www.uspreventiveservicestaskforce.org
National Academy of Medicine	https://nam.edu/

Table A3: Data extraction template

First Author/ Organisation Year of Publication Country/Region Data source(s), URL	Title of Guideline/Guidance Type of guideline, guidance	Type of Ionising Radiation	Guidance based on evidence? If yes state type of evidence	Details of guidelines Included definition/type of asymptomatic screening Essential requirements/principles of screening in this group Recommendations

				Any other useful information

Appendix 2

Table A4 Thematic analysis of included documents

Themes identified from data extraction	
Theme	Quote from document
IHAs/early detection examinations should be conducted according to guidelines of relevant scientific and professional bodies	**5 out of 6 documents had reference to this theme**
	"IHA is based on consensus guidelines of relevant scientific and professional bodies."[21]
	"The Radiation Protection Commission therefore recommends that individual early detection examinations are carried out exclusively on the basis of coordinated guidelines from scientific specialist societies."[24]
	"Decisions about an individual's care are based on evidenced protocols and guidelines"[10]
	"We recommend that the Department of Health should review this situation (commercial CT services) and consider regulating these services against agreed standards. Any regulation should address and provide guidelines on appropriate referral processes, justification and optimisation of CT scans."[22]
	"Regulation 11(3)(c) states that the practitioner must justify the exposure as having shown sufficient net benefit and must have regard in particular to any guidelines issued by appropriate medical scientific societies, relevant bodies or the secretary of state. This applies to all asymptomatic individuals including exposures for IHAs."[26]
Justification	**4 out of 6 documents had reference to this theme**
	"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…"[22]
	"In each case, the Radiation Protection Ordinance (StrlSchV) and the X-ray Ordinance (RöV) require a justifying indication, i.e. an examination by the treating doctor with the necessary specialist knowledge in radiation protection, that the health benefit of an application outweighs the radiation risk. The justifying indication for the use of ionizing radiation for the early detection of a disease must not be based solely on the wishes of the patient, who usually lacks the specialist knowledge to be able to weigh up the advantages and disadvantages of the examination. Rather, the indication may only be based on the state of medical knowledge according to coordinated

	recommendations and guidelines of the scientific professional societies and after reviewing all relevant factors."[24]
	"IR(ME)R 2000 includes a number of requirements but prominent are the key radiation protection principles of justification and optimisation. For individual health assessment…justification is also more difficult because the benefit for asymptomatic individuals may be significantly less than for patients, due to the limited evidence base to support the investigation and the potential increased detriment from false positive results which would require further investigation."[23]
	"The exposure must not be carried out unless it has been justified, prior to the exposure, by a practitioner who must ensure there is a net benefit from the exposure. When justifying an exposure, there are a number of considerations for practitioners to take into account. Some examples are: ▪ will the exposure contribute to, or change, the individual's healthcare management? ▪ has the referrer provided enough relevant clinical information to be able to justify the exposure? ▪ has the referrer provided enough information to be able to definitively identify the patient? ▪ is the exposure likely to answer the clinical question being asked? ▪ what relevant previous imaging is available? ▪ are there alternative techniques that will answer the question but do not involve ionising radiation?"[26]
Benefits vs harms	**5 out of 6 documents had reference to this theme**
	"Procedures can only be justified if the individual for whom the exposure is proposed will receive a predictable benefit that outweighs the detriment, or if there is an overall net benefit to society. In all cases these benefits must be balanced against the risks, not only from the radiation detriment but also from potentially misleading or inaccurate results."[22]
	"The severity of the suspected illness justifies an early detection measure"[24]
	"The eligible population is defined according to evidence based on the balance of benefits versus harm"[10]
	"The benefit v detriment balance is different for a patient with symptoms compared to an asymptomatic individual."[23]
	"Justification is the process of weighing up the expected benefits of an exposure against the possible detriment of the associated radiation dose."[26]
Eligibility and risk profile	**5 out of 6 documents had reference to this theme**
	"Justification of an exposure for an IHA may consider risk factors rather than symptoms."[26]
	"We recommend that all such services should provide comprehensive information regarding eligibility criteria and the dose and risk of the initial CT scan"[22]

	"The risk profile of the individuals expected to benefit from the assessment is clearly defined"[21]
	"Essential prerequisites for effective secondary preventive measures within the meaning of early disease detection are:[24] 1. The individual risk profile is known or can be precisely defined 2. The severity of the suspected illness justifies an early detection measure 3. The disease can be detected at an asymptomatic stage 4. The disease has a phase that does not yet lead to symptoms (preclinical phase), but in which it can already be detected by an examination 5. In principle, effective forms of therapy exist for the disease and are available in the healthcare system, which improve the prognosis and/or the quality of life of those affected if used early. [sic] Individual early detection examinations can only be justified if the following aspects are taken into account: Anamnesis, if necessary physical examination Creation of an individual risk profile based on agreed guidelines from scientific professional societies" [24]
	"The mechanisms in place to develop an evidence base for justification of CT examinations for asymptomatic individuals with varying risk factors"[23]
Presenter informed about benefits, risks and limitations	**4 out of 6 documents had reference to this theme**
	"…the individual shall have been informed about the estimated benefits, risks and limitations of the procedure." [22] "Asymptomatic individuals undergoing CT scanning will require information on radiation risks, the potential for diagnostic error, the likelihood of further investigations being required, and any risks associated with subsequent scans. They will also require advice on how any follow-up should be undertaken, and how to integrate any findings from the examination with existing care pathways."[22]
	"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."[21]
	"It is necessary to provide interested persons with scientifically sound information about early detection examinations. The aim should be to enable the person concerned to assess the advantages and disadvantages of an early detection examination using ionizing radiation. She should also be familiar with the course of the investigation and should be informed that further measures may arise from the result. This information is necessary not only to be able to decide for or against a particular investigation, but also to be aware of the chain of measures that may follow."[24]

	"Medical laypersons often have misconceptions about their personal risk profile and the advantages and disadvantages of earlier diagnosis and/or treatment of a disease. For this reason, detailed advice based on coordinated guidelines with regard to the individual risk of disease should be provided before individual early detection examinations are carried out; this should not only describe details of the respective examination, but also contain the possible advantages and disadvantages of the positive as well as negative findings."[24]
	"While legal considerations must underpin the use of CT in individual health assessment, a range of additional factors, which might be considered as ethical, scientific, logistical, psychological and financial, should be taken into account including: a. The extent of provision of information for potential clients before appointments are made, including the significant likelihood of false positive findings where the probability of disease is low. b. The detail provided on possible findings (whether clinically significant or not), potential risks, possible further investigations and where and how these would be conducted."[23] "Summary recommendation: Information packs on the risks and benefits of CT for IHA, detailing in lay persons' language the limitations, and the risks and benefits of IHA should be made available to individuals prior to undergoing CT scanning." [23]
Specific recommendations	**3 out of 6 documents had reference to this theme**
	"We recommend therefore that services offering whole body CT scanning of asymptomatic individuals should stop doing so immediately. We recommend that where there is evidence that CT is not the modality of choice for diagnostic purposes, then it should not be made available for the assessment of asymptomatic individuals"[22]
	"Summary recommendations: ▪ IHA CT should only be offered by expert clinicians (radiologists and respiratory physicians), able to explain the risks and benefits of CT for IHA. ▪ Information packs on the risks and benefits of CT for IHA, detailing in lay persons' language the limitations, and the risks and benefits of IHA should be made available to individuals prior to undergoing CT scanning."[23]
	"COMARE stated that services providing whole-body CT scanning of asymptomatic individuals should stop doing so immediately. It went on to provide recommendations that should be followed for CT scanning of asymptomatic individuals for specified areas/conditions. Any exposure made as part of an IHA must follow all the requirements for IR(ME)R, including compliance with the employer's procedures for referral, justification, optimisation and evaluation in the same way as any other medical or non-medical exposures."[26]

Quality assurance	**3 out of 6 documents had reference to this theme**
	"A demanding quality assurance programme along the whole screening chain is ensured, which has to include the technical equipment, the performance an interpretation of scans, and the management of finding"[21]
	"Highest quality requirements regarding implementation, diagnosis and determination of the further process"[24]
	"All screening services within a screening programme agree on and use the standards (there are quality standards based on evidence that are followed by screening providers)"[10]
Documentation and evaluation	**4 out of 6 documents had reference to this theme**
	"Adequate measures concerning documentation and evaluation are set in place."[21]
	"Comprehensive documentation of the measures accompanying evaluation of the study"[24]
	"It (DoH) should also require that providers of CT services should submit agreed datasets to the regulator regarding the rate of reported findings. The rates of false negative and false positive findings associated with CT scanning of asymptomatic individuals should be independently audited and explained. In particular, the range of further investigations that may be required to confirm initial findings and the risks associated with subsequent scans if recommended, should be discussed."[22]
Care pathways	**4 out of 6 documents had reference to this theme** "We recommend that commercial CT services should have well-developed, robust and confidential mechanisms for integrating the results of their examinations into an established care pathway, including the availability of scans and data relating to any individual scanned in formats consistent with NHS information technology programmes."[22] "In principle, effective forms of therapy exist for the disease and are available in the healthcare system, which improve the prognosis and/or the quality of life of those affected if used early"[24] "Each test should be part of a pathway of care"[10] "The importance of the transfer of data from individual health assessments into the healthcare record and subsequent influence of the care pathway has already been highlighted, but there may be legal considerations to this as well as ones relating to good medical practice."[23]
Less common themes	
Screening algorithm	"IHA is embedded in a well-established screening algorithm"[21]

Legal concerns	"Employer and practitioner must hold the appropriate license" [26] "While legal considerations must underpin the use of CT in individual health assessment, a range of additional factors, which might be considered as ethical, scientific, logistical, psychological and financial, should be taken into account."[23]
Optimisation	"For individual health assessment, optimisation of imaging should be no more complex than it is for procedures undertaken for diagnostic purposes, as long as the procedure is limited to specific suspected pathology in a restricted area of the body. Where the procedure is less closely defined, and is being used as a trawl for a range of possible diagnoses, optimisation will be more difficult."[23]
Ethical, financial and other considerations	"While legal considerations must underpin the use of CT in individual health assessment, a range of additional factors, which might be considered as ethical, scientific, logistical, psychological and financial, should be taken into account."[23] "The support provided to individuals when results of scans are positive or indeterminate. The impact or otherwise of negative findings on those who have unhealthy lifestyles. The logistical arrangements for transfer of data into the individual's healthcare record. The mechanisms in place to develop an evidence base for justification of CT examinations for asymptomatic individuals with varying risk factors."[23]

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