Early Detection of Diseases by Radiological Imaging: New Legal Situation and Evaluation of Service Offers using CT Examinations as an Example

Früherkennung von Krankheiten mittels radiologischer Bildgebung: Neue Rechtslage und Bewertung von Leistungsangeboten am Beispiel von CT-Untersuchungen

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ABSTRACT

Background Radiological imaging offers promising prospects for the early detection of diseases. In Germany, the legal framework for such examinations was created by the Radiation Protection Law, which entered into force on December 31, 2018. Under this law, each specific type of radiodiagnostic screening of non-communicable diseases needs an approval on a generic level (permission) by a federal statutory ordinance, defining the specific requirements and conditions. It is the aim of the present paper, (i) to present in detail the new legal situation and (ii) to assess actual service offers for the screening of asymptomatic persons using CT examinations as an example.

Method In February 2019, radiology institutions in Germany illegally offering on the Internet CT examinations for the screening of lung and colon cancer or coronary artery disease were identified. For each type of examination, 50 pertinent websites were evaluated particularly regarding the general information on the offered screening examination and the concrete procedure.

Results In the vast majority of cases, the information provided on the websites was inadequate and disproportionately emphasized the benefits over the risks of the screening examination. Moreover, the offers differed substantially with respect to the age and risks factors of potential participants, the frequency of examinations, the screening procedure, and the diagnostic workup.

Conclusion The evaluated service offers strongly substantiate the need to define requirements and conditions regarding radiological screening examinations by statutory ordinances, in order to ensure an informed decision of potential screening participants as well as the benefit versus the risks of the procedures.

Key Points:
- High-evidence studies prove the benefit of radiological screening for some diseases.
- In Germany, screening examinations are only permissible when stated in a federal statutory ordinance.
- At present, only mammography screening for breast cancer is permitted in Germany.
- CT screening examinations currently being conducted in Germany do not fulfill the legal and professional requirements.
- A review process has been initiated regarding possible generic approval of lung cancer screening.

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ZUSAMMENFASSUNG

Hintergrund Die radiologische Bildgebung bietet für die Früherkennung von Krankheiten vielversprechende Perspektiven. In Deutschland wurden die rechtlichen Grundlagen für derartige Untersuchungen mit dem Strahlenschutzgesetz geschaffen, das am 31. Dezember 2018 in Kraft getreten ist. Danach bedarf es für jede Art von strahlendiagnostischer Früherkennung nichtübertragbarer Erkrankungen einer generischen Zulassung durch eine Rechtsverordnung, in der die jeweiligen Anforderungen und Bedingungen festgelegt werden. Ziel der vorliegenden Arbeit ist es, 1. die neue Rechtslage vorzustellen und 2. aktuelle Leistungsangebote zur Früherkennung bei asymptomatischen Personen am Beispiel von CT-Untersuchungen zu bewerten.

Methode Im Februar 2019 wurden radiologische Einrichtungen in Deutschland identifiziert, die rechtswidrig CT-Untersuchungen zur Früherkennung von Lungen- und Darmkrebs sowie der koronaren Herzkrankheit im Internet angeboten haben. Pro Fragestellung wurden 50 einschlägige Websites insbesondere zu den vermittelten grundlegenden Informationen zur angebotenen Früherkennung sowie zum konkreten Vorgehen analysiert.

Ergebnisse Die auf den Websites vermittelten Informationen waren in der weit überwiegenden Mehrheit unzureichend und betonten einseitig den Nutzen gegenüber den Risiken der Früherkennung. Darüber hinaus unterschieden sich die Angebote erheblich u. a. bezüglich des Alters und der Risikofaktoren möglicher Teilnehmer, der Häufigkeit der Tests, der Durchführung der jeweiligen Untersuchung sowie der Abklärungsdiagnostik.

Schlussfolgerung Die bewerteten Leistungsangebote belegen nachdrücklich die Notwendigkeit, Anforderungen und Bedingungen an radiologische Früherkennungsmaßnahmen in Rechtsverordnungen festzulegen, um eine informierte Entscheidung potenzieller Teilnehmer sowie den Nutzen gegenüber den Risiken der Maßnahmen zu gewährleisten.

Introduction

Current strategies in the health care sector increasingly target the early detection of frequent, severe, and costly diseases or the detection of their risk factors. In principle, imaging methods can also be used for this purpose. The best-known example is mammography screening for early detection of breast cancer. Based on promising results of recent studies, the use of other radiological screening examinations is currently being discussed [1] and promoted [2]. As a result of the impressive technological advances achieved in recent years, particularly computed tomography (CT) offers promising potential for the early detection of diseases, such as:

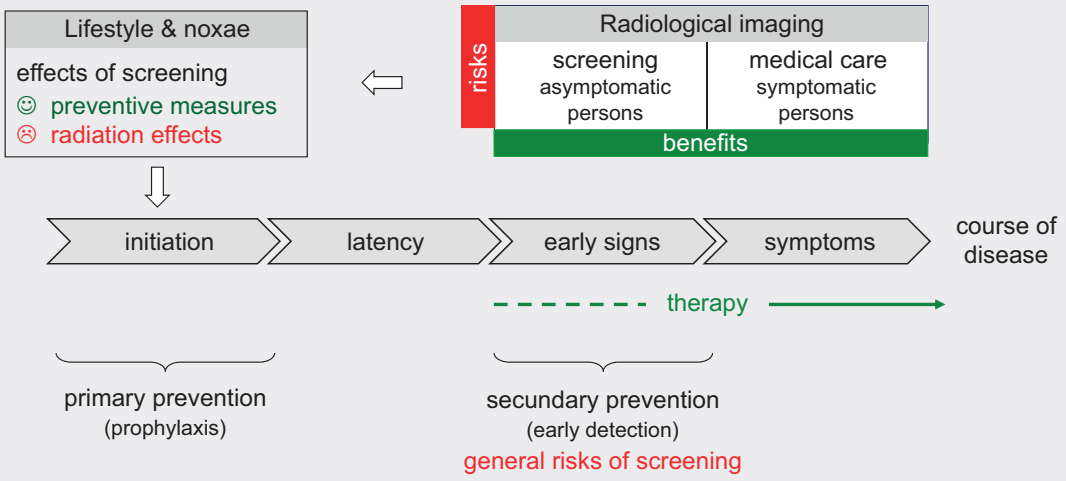
- Lung cancer,
- Intestinal polyps and malignant intestinal tumors,
- Calcifications and stenoses of the coronary arteries.

These examinations are already offered by some practices and clinics in Germany as individual health services in violation of the provisions of the Radiation Protection Law.

There is a semantic as well as technical difference between preventive care (primary prevention) and early detection (secondary prevention) (▶ **Fig. 1**). The goal of preventive care is to prevent, lower the likelihood of, or delay disease. In contrast, the goal of early detection is to detect an already existing disease (e. g. cancer, coronary heart disease) at the earliest stage possible in a person who is still asymptomatic in order to allow earlier treatment that is presumably more effective and gentler. Of course, some types of screening can also include aspects of preventive care. If, for example, adenomatous intestinal polyps are detected by virtual CT colonoscopy, they can be subsequently endoscopically ablated to interrupt the adenoma-carcinoma sequence. A further example is CT calcium scoring for determining the individual risk of heart attack. If the calculated calcium score is slightly elevated, a change in lifestyle, possibly in combination with medication for existing arterial hypertension and/or hyperlipidemia, can prevent the clinical manifestation of coronary heart disease. However, imaging itself always serves solely to detect a disease or its precursors and risk factors and should therefore not be designated as a preventive medical measure, particularly to avoid unreasonable expectations of potential test participants.

While only a small portion of screening participants will benefit from the examinations due to the typically low prevalence of the considered diseases, all participants will be subjected to the risks associated with the test. Therefore, the advantages and disadvantages of early detection listed in ▶ **Table 1** must be carefully weighed by expert committees and every potential test participant must be provided this information in detail so that an informed decision can be made [3]. An important aspect that has to be addressed in the informed consent discussion is the mental stress in the case of a finding requiring clarification. This is particularly relevant, for example, in the case of CT screening for lung cancer since hereby detected pulmonary nodules are frequently observed by CT over several months to assess their growth behavior to determine whether they are malignant. Therefore, the patient must live for an extended period in uncertainty about whether lung cancer is present.

If the screening procedure involves the use of X-rays or a radiopharmaceutical, the requirements for the justification for the examination are particularly high. Therefore, article 55 para. 2 letter h of European Directive 2013/59/Euratom [4] requires “that member states shall ensure that any medical radiological procedure on an asymptomatic individual, to be performed for the early detection of disease, is part of a health screening program, or requires specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from relevant medical scientific societies and the competent authority. Special attention shall be given to the provision of information to the individual subject to medical exposure.” These requirements were implemented in Germany by the Radiation Protection Law that came into effect on December 31, 2018 [5].



▶ **Fig. 1** Contribution of radiological and nuclear medicine imaging to the primary (prophylaxis) and secondary prevention (early detection) of diseases. The aim of early detection is to initiate therapy of diseases at an earlier stage. Some tests may not only allow early detection of diseases but may also have a primary preventive component. For example, when precursors of cancer (e. g., colon polyps) are detected and subsequently removed or when individual risks for developing a severe disease are detected and reduced (e. g., coronary artery calcification). Ionizing radiation used for imaging is itself a potentially noxious agent and thus should be minimized to the greatest extent possible. The basic risks related to all screening procedures are summarized in Table 1.

▶ **Table 1** Advantages and disadvantages of radiodiagnostic screening. Except for the radiation-associated risks, the mentioned aspects also hold true for early detection with MRI and ultrasound.

benefits	damage/risk
for the individual: ▪ treatment is potentially more effective and gentler when the disease is detected at an early stage. ▪ better prognosis or at least longer life expectancy and improved quality of life. ▪ identification of individual disease risks and any resulting preventive care measures such as changes in lifestyle or medication. for the target group or the general population: ▪ reduction of disease-specific mortality. ▪ lower treatment costs in the case of early detection of a disease. ▪ reduction of indirect costs, e. g. by shortening disease-related inability to work (“manager check”).	general aspects: ▪ mental stress until clarification of a nonspecific finding, particularly if several months of follow-up are indicated. ▪ invasiveness of the diagnostic workup. ▪ unnecessary diagnostic workup in the case of a false-positive finding with potentially serious complications and relevant costs. ▪ false sense of security in the case of a false-negative finding. ▪ detection and treatment of a disease that never would have resulted in symptoms or death without treatment (overdiagnosis/overtreatment). additional imaging-specific aspects: ▪ contrast-agent-induced side effects. ▪ radiation-associated risks.

The goal of the present study is to (i) present the new legal regulations in Germany regarding the early detection of non-communicable diseases using radiodiagnostic procedures and (ii) to evaluate in detail representative services offered by radiology institutions on the Internet using the three previously specified CT examinations as examples.

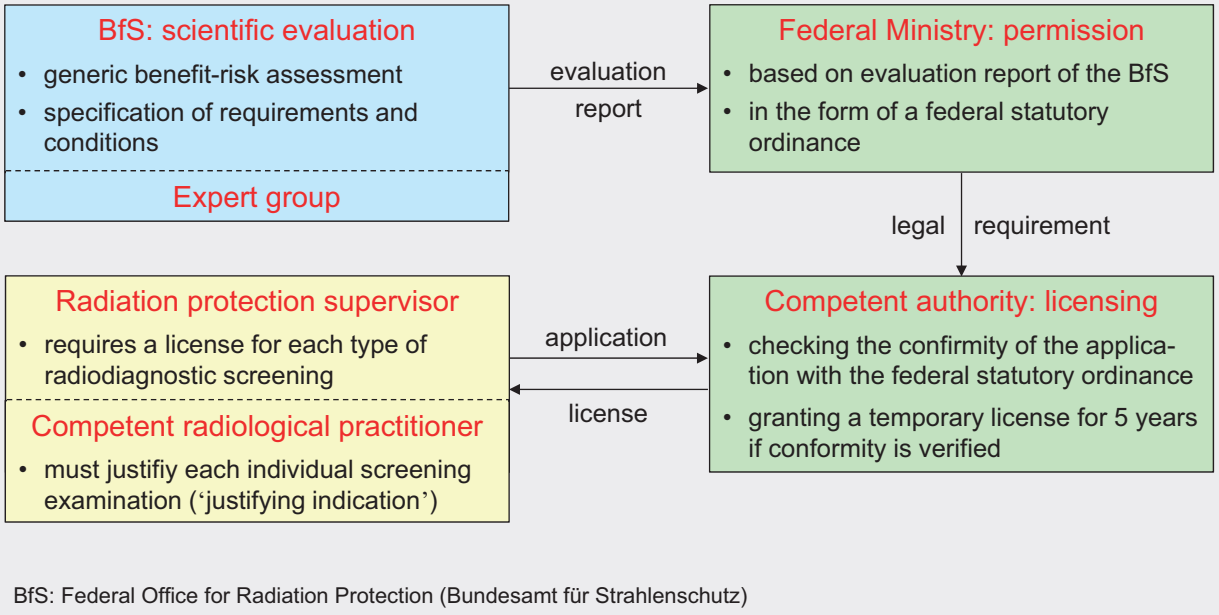
New legal framework for early detection using X-rays and radiopharmaceuticals

Radiation Protection Law [5]

▶ **Fig. 2** provides an overview of the new legal regulations regarding the scientific assessment as well as the permission and licensing of the early detection of non-communicable diseases. These legal regulations and the associated tasks and obligations of the involved parties are discussed in greater detail in the following.

Legal definition (§ 5 para. 16): Early detection refers to the application of X-rays or radioactive substances in the context of medical exposure (see § 2 para. 8 no. 1) for the examination of persons who do not exhibit any symptoms and have no concrete suspicion of disease (asymptomatic persons) in order to detect a specific disease. In contrast to the previous regulations under which exclusively serial X-ray examinations (such as the German mammography screening program) were permitted, the above definition also takes into account individual screening examinations and the use of radiopharmaceuticals in accordance with the EU Directive.

Scientific evaluation by the Federal Office for Radiation Protection (§ 84 para. 3): Radiodiagnostic examinations for the early detection of diseases must be evaluated by the Federal Office for



▶ **Fig. 2** Key elements of the new German radiation protection legislation concerning the early detection of non-communicable diseases by radiodiagnostic examinations as well as the parties involved.

Radiation Protection (Bundesamt für Strahlenschutz, BfS). In collaboration with experts from different disciplines, the risks and benefits of the screening measures must be weighed. The details of the scientific evaluation are defined in a general administrative regulation issued by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety in consultation with the Federal Ministry of Health (see below). The scientific evaluation of the BfS is to be published.

Permission granted by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (§ 84 paras. 1, 2 and 5): Screening examinations are only permissible when explicitly stated in a federal statutory ordinance. Under consideration of the scientific evaluation by the BfS, the statutory ordinance must define which type of early detection is permissible for detecting a disease for a particular group of persons and under which conditions. Only the permissibility of screening examinations in which a scientifically recognized examination method can detect a serious disease at an early stage in order to allow more effective treatment of affected persons may be regulated. If the screening is part of a program, exceptions to the requirement to carry out justification on an individual level according to § 83 para. 3 can be allowed if the type and scope of inclusion criteria render unnecessary a decision about whether and how the screening is to be applied. To date, only mammography has been approved by the Breast Cancer Early Detection Ordinance [6].

Obligation to apply for a license (§ 12 para. 1 nos. 3 and 4 in conjunction with § 14 para. 3 and § 19 para. 2 no. 4; § 16; appendix 2, part B, no. 6 letter d): The use of ionizing radiation or radioactive substances for the early detection of diseases requires a license. To obtain a license, the radiation protection supervisor of a practice or clinic has to submit an application to the relevant competent authority on a regional level. The application must include all necessary information that allows the authority to check whether the requirements of § 14 para. 3 have been met.

Licensing by the competent authority (§ 14 para. 3): A license for a practice according to § 12 para. 1 nos. 3 and 4 in conjunction with early detection may only be granted by the regional competent authority (i) when the considered screening measure is approved on a generic level by a federal statutory ordinance according to § 84 para. 2 (§ 14 para. 3 no. 1) and (ii) when it is ensured that the requirements stated in this ordinance that take into account the state-of-art of medical science will be met in order to achieve the required quality with the lowest possible exposure (§ 14 para. 3 no. 2). The last requirement ensures in particular the specification of provisions that relate, for example, to the definition of the target group, the necessary qualifications of the medical and technical personnel, implementation and evaluation of the examination, diagnostic workup, as well as documentation and evaluation. The maximum term of the license is five years in order to allow adjustments to the state of the art and updating of measures needed for quality improvement.

Breach of law (§ 194 para. 1 no. 1 letter a, para. 2): Breach of law refers to an act in opposition to a federal statutory ordinance based on § 84 para. 2 with intent or negligence. This can be punished by a fine of up to 50 000 Euros if the federal statutory ordinance refers to the provision concerning fines in the Radiation Protection Law for a certain offense.

Fifth Book of the Social Code [7]

When the Radiation Protection Law came into force, a new regulation regarding a check of the assumption of the cost of radiodiagnostic screening examinations by the statutory health insur-

ance funds was added under para. 4a in § 25 section 4 of the Fifth Book of the Social Code "services for detecting health risks and the early detection of diseases". It stipulates that after a federal statutory ordinance according to § 84 para. 2 of the Radiation Protection Law permits a specific type of screening examination, the Federal Joint Committee, the highest decision-making body of the joint self-government in the German health care system, checks within 18 months whether the costs for this examination are to be covered by the statutory health insurance funds in accordance with § 25 para. 1 or 2 of the Fifth Book of the Social Code. Regardless of the decision of the Federal Joint Committee, screening examinations permitted in accordance with the Radiation Protection Law can be provided as individual health services.

General Administrative Regulation Regarding the Scientific Evaluation of Screening Examinations [8]

The general administrative regulation, which is based on the power to issue statutory instruments defined in § 84 para. 3 of the Radiation Protection Law and also came into effect at the end of 2018, defines the methodology for the scientific evaluation of radiodiagnostic screening techniques for the early detection of non-communicable diseases by the BfS. It defines a two-stage process: a preliminary review and a detailed scientific assessment. A multidisciplinary group of experts is involved in both stages. The BfS immediately informs the Federal Joint Committee of the result of a positive preliminary review – including the reason. Prior to conclusion of the scientific assessment, the BfS also requests that the relevant professional and scientific entities as well as patient organizations according to § 140 f of the Fifth Book of the Social Code, provide written comments regarding the assessment. Health economics do not play a role in the two stages. This aspect is first taken into consideration in the assessment by the Federal Joint Committee.

Preliminary review: This first step, which is to be repeated on an event-driven basis or at least annually, is used for the preselection of radiodiagnostic examinations that fulfill the basic requirements for the early detection of diseases and thus qualify for detailed assessment. The following requirements must be examined for plausibility:

- The examination method is recognized according to the current state of medical science.
- The goal of early detection is to detect a serious disease whose spontaneous course typically leads to death or severe impairment of health.
- The disease can be detected at an early stage.
- An effective treatment is established and available at an early stage of the disease.
- A target group can be clearly defined under consideration of risk factors.
- The level of prevalence of the disease is sufficiently high.

If there are multiple screening measures that qualify for detailed assessment, the BfS in coordination with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety determines the order in which they will be processed. The currently available scientific data is an essential criterion here.

Detailed assessment: In the second step, the following aspects are to be evaluated and presented in detail:

- Generic risk-benefit assessment. Benefits and adverse effects of a screening examination are to be evaluated on the basis of a systematic literature search based on the standards of evidence-based medicine. The risk assessment relates in particular to the extent of false-positive or false-negative examination results, the extent of overdiagnosis and overtreatment, and the invasiveness of the diagnostic workup. The radiation risk associated with the examinations is to be assessed on the basis of established age-, sex-, and organ-specific risk models.
- Conditions and requirements. To ensure that the benefit outweighs the risks of radiodiagnostic screening (see ▶ **Table 1**), the target group (inclusion and exclusion criteria), the training and continuing education of personnel, the required equipment (imaging technology), performance of the examination (frequency, time intervals, imaging protocol), reading (scheme, double or reference reading, reading at certified centers), the type and scope of diagnostic workup depending on the finding, documentation, and quality assurance (organizational, technical, and medical aspects) must be defined.

Reassessment: At least every five years, the BfS checks screening examinations approved according to § 84 para. 2 of the Radiation Protection Law to determine whether the state of scientific knowledge has developed further and whether a reassessment or an adjustment of the conditions and requirements is necessary.

Evaluation of service offers by radiology institutions using CT screening as an example

Method

In February 2019, radiology institutions in Germany offering CT for the prevention or early detection of diseases were identified via an Internet search. The search was performed separately for the three diseases named above, namely lung cancer (alternatively: lung or smoker check), colon cancer (virtual colonoscopy or colon check), and coronary heart disease (cardiac or heart check). For each of these three radiodiagnostic tests, 50 relevant websites were analyzed by two persons familiar with the subject independently of one another with respect to the aspects listed in ▶ **Table 2–4**. In the case of a discrepant evaluation regarding one of these aspects, the relevant website was analyzed again together until a consensus was reached.

Results

General aspects

Of the 150 analyzed websites, 110 belonged to practices, 18 to medical centers (some with multiple locations) and 22 to clinics or groups of clinics. Although the Internet search was preformed separately for the three analyzed screening examinations, 17 institutions appeared in two samples and 13 even appeared in all three

▶ **Table 2** Evaluation of the information provided on 50 websites of radiology institutions in Germany regarding the advertised individual CT screening procedures for lung cancer. The figures in the second column indicate the number of websites without details regarding each aspect and the figures in parentheses in the third column indicate those with details.

aspect	details on the website	
	no	yes
target group		
▪ Age	39	older than 40 (3), 50 (2), or 55 (6) years.
▪ risk factors		
smoker	2	mentioned in general terms (39); more than 10 (4) or 30 (4) pack years; ≥ 10 of smoking history (1).
ex-smoker	41	mentioned in general terms (2); more than 10 (5) or 30 (2) pack years.
passive smoker	48	mentioned in general terms (2).
other noxae	44	asbestos (5) and/or other cancer-causing substances (3).[1]
benefits	21	general statement in terms of "earlier equals better" (13); explicit or implicit reference to results of ELCAP [14, 15], NLST [16] or NELSON study (14); benefit not yet definitively proven (1); reference to American guidelines (1).
risks	48	detailed and clear representation (1); given a nonspecific finding, there is a risk of unnecessary interventions in the case of non-standardized workup (1).
radiation exposure	26	trivial (9); plausible with 0.2–1.0 mSv or 1/5 of the average natural radiation exposure per year (4); false (11).
examination		
▪ smoker, frequency	38	annually (8); biennially (1); regularly (3).
▪ ex-smoker, period	45	(regular) examinations over 10 (3) or 15 years (2) after smoking cessation.
▪ contrast agent	28	without (20); possibly with (2).
▪ Breath-hold technique	37	necessary (13).
reading		
▪ incidental findings	50	–
▪ double reading	49	by radiologist and computer-assisted detection (1).
diagnostic workup	42	in the case of a nonspecific finding, one or more CT follow-up examinations at intervals of multiple months, biopsy possibly necessary (7); emphasis on quality-assured and standardized workup (2).[1]
smoking cessation	44	necessity mentioned (5); CT screening as alternative to smoking cessation (1).

[1] Multiple entries.

samples which confirms the general impression that some institutions offer a broad spectrum of radiological screening examinations. Only one website stated that "as of the end of 2018, examinations can only be performed in the case of a concrete indication, i. e., in the case of suspicion of a disease". On all other sites, there was not even a hint of the lack of legal conformity of the offered screening examinations. On the other hand, 94 websites provided information stating that costs are typically reimbursed by private but not by statutory health insurances. In the latter case, the services were therefore offered as individual health services, in some cases at "reduced fixed prices". The key terms used to communicate with and facilitate the understanding of test participants, i. e., prevention, early detection, and preventive care, were used largely synonymously.

The CT equipment used for screening was very heterogeneous according to the concrete information on 106 websites – ranging from older 6-row systems to well-equipped (dual-source) systems of the latest generation, which allow high-quality and dose-saving imaging of moving organs, particularly the heart, due to the very short scan times.

Examination-specific aspects

The results of the Internet search are listed separately for the three analyzed early detection measures in ▶ **Table 2–4**. The general findings are summarized in the following.

Data regarding the age of the target persons was provided only on 40 websites and deviated significantly for the same screening examination. The discrepancy between the age data for virtual colonoscopy and the exisiting age specification for early detection via conventional colonoscopy is notable here. Information on risk factors showed an inconsistent picture: it was either concrete but discrepant (e. g. pack years of (ex-) smokers in lung cancer screening) or so general (colon and heart) that it applied to the majority of persons in the considered age group and thus was not suitable

▶ **Table 3** Evaluation of the information provided on 50 websites of radiology institutions in Germany regarding the advertised individual CT screening procedures for colon cancer. The figures in the second column indicate the number of websites without details regarding each aspect and the figures in parentheses in the third column indicate those with details.

aspect	details on the website	
	no	yes
target group		
▪ age	33	older than 40 (3), 45 (5), 50 (6) or 55 (2) years; already at a young age (1).
▪ general risk factors	31	family predisposition, unhealthy diet (including consumption of meat), excessive alcohol consumption, obesity, inactivity (19).[1]
▪ contraindications to conventional colonoscopy	24	intestinal adhesions, diverticula, inflammation, surgeries, increased risk of bleeding (26).[1]
▪ other aspects	39	refusal to undergo conventional colonoscopy (11).
benefits	19	general statement in the sense of "comparable with conventional colonoscopy" (13); quantitative information regarding study results from [17] among others (16); reference to recommendations or guidelines (2).
risks	47	uncertainty in the case of growths < 5 mm (1), 5 % false-negative findings (1), unnecessary conventional colonoscopy in the case of a false-positive finding (1).
radiation exposure	26	trivial (19); plausible with 2–8 mSv or 1 to 2 times the average natural radiation exposure per year (5).
advantages over conventional colonoscopy	11	no endoscope, pain-free, no sedation, no risk of intestinal perforation, visualization of the entire length of the colon, ability to evaluate deep wall layers and surrounding organs (39).[1]
disadvantages over conventional colonoscopy	25	no polypectomy and/or taking of tissue samples (25), no visualization of inflammatory processes (1), radiation exposure (1), subsequent conventional colonoscopy needed in case of a relevant finding (20)[2]
examination		
▪ frequency	44	every five years (4); depending on the finding, every five years when normal (2).
▪ bowel cleansing	11	necessary (39).
▪ gas insufflation	17	necessary (33).
▪ patient positioning	31	prone position (1), supine and prone position (15), supine and possibly prone position (3).
▪ contrast agent	24	without (5); with (12); possibly with, administration usually with change of position (8); contradictory information (1).
reading		
▪ incidental findings	23	recorded (27).
▪ double reading	44	second opinion from expert if needed (4); by radiologist and computer-assisted detection (2).
diagnostic workup	38	guaranteed since clinic or gastroenterology center (7); in cooperation with external gastroenterologist (5). Additional information: conventional colonoscopy performed if necessary on the same day without repeat bowel cleanse (3).

[1] Usually a number of the specified points.
[2] Multiple entries.

for useful preselection of test candidates to increase the pretest probability.

The benefit of early detection with CT was mostly described as “early equals better” or “comparable with…” if mentioned at all. Concrete results of high-quality studies were provided only on relatively few websites. The risk of false-negative or false-positive findings as well as of overdiagnosis and overtreatment was also rarely addressed.

On the whole, the data on radiation exposure was also inadequate. If this aspect was mentioned at all, statements were often limited to general and trivial information (e. g. low-dose CT, dose today lower than before); concrete dose values were provided on only a small number of websites. The values specified on the websites (and summarized in ▶ **Table 2–4**) always related to a single examination and not to the cumulative dose over a typical screening period of several years. The comparisons used to rate radiation exposure (natural radiation exposure, annual limits for occupationally exposed persons, exposure during air travel, chest X-ray, etc.) were grossly incorrect in some cases. Data regarding the radiation risk was not provided on any website.

The advantages of CT for the early detection of colon cancer compared to conventional colonoscopy and of CT examination of

▶ **Table 4** Evaluation of the information provided on 50 websites of radiology institutions in Germany regarding the advertised individual CT screening procedures for coronary artery calcification and stenoses. The figures in the second column indicate the number of websites without details regarding each aspect and the figures in parentheses in the third column indicate those with details.

aspect	details on the website	
	no	yes
target group		
▪ age	38	men/women older than 40/40 (1), 40/50 (7), 40/55 (1), 45/45 (1), 45/55 (2).
▪ risk factors	9	high blood pressure, elevated blood lipid levels, diabetes, smoking, obesity, inactivity, family predisposition, etc. (41).[1]
benefits	16	general statement that the calcium score correlates with the individual infarction risk (27); reference to studies on the Agatston Score [including 18, 19] (4); reference to recommendations or guidelines (3).
risks	49	unnecessary cardiac catheterization in the case of a false-positive finding (1).
radiation exposure	23	trivial (13); plausible with 0.3–1.0 mSv (5); comparable with or less than natural radiation exposure per year (3); less than in the case of cardiac catheterization (6); false comparison with chest X-ray (1).[2]
advantages compared to cardiac catheterization	8	noninvasive, pain-free, no risk of vascular rupture, no prolonged bed rest, lower radiation exposure compared to cardiac catheterization (36); visualization of soft-tissue changes in the vascular wall as well as of soft and mixed plaque (4); ability to assess myocardium, cardiac chambers, and cardiac valves (2) and pulmonary vessels (2).[1]
disadvantages compared to cardiac catheterization	42	In the case of a finding requiring workup or treatment, cardiac catheterization is usually necessary (8).
examination		
▪ frequency	50	–
▪ CT method[3]	1	calcium scoring (45), contrast-enhanced coronary angiography (43).[2]
▪ cardiol. preliminary testing	36	performed (12), recommended (1), additionally offered (1).
▪ beta blockers	34	required, if pulse too high (16).
reading		
▪ incidental findings	49	recorded (1).
▪ double reading	45	in every case (1), second reading if necessary (4).
diagnostic workup	27	in cooperation with internal (19) or external (4) cardiologists/internists.

[1] Usually a number of the specified points.
[2] Multiple entries.
[3] If both calcium scoring and coronary angiography were offered on a website, it was often not clear whether these are alternative examinations or whether both examinations are performed and if yes in which cases.

the cardiac vessels compared to cardiac catheterization were described in detail on 39 and 42 websites, respectively. In contrast, the disadvantages of these screening examinations, particularly the necessity for conventional colonoscopy or heart catheterization in the case of a screening finding requiring further workup or treatment, were only briefly mentioned on 25 and 8 websites, respectively.

It is especially surprising that there was no standardized procedure among service providers even regarding the performance of the individual examinations. In the case of virtual colonoscopy, the differences related, for example, to the positioning of the person to be examined, the number of CT series, and the necessity for the administration of contrast agent. For the examination of the coronary vessels, both calcium scoring and coronary angiography were usually offered but often without more detailed information as to whether these were alternative or supplementary examinations and according to the criteria used to define the examination protocol in the individual case.

The handling of incidental findings outside the target organ is both ethically and legally sensitive. Therefore, whether the participant would like to be informed of such findings should be defined in writing during the informed consent discussion [9]. Diagnostic assessment of incidental findings was mentioned on 28 of the analyzed websites but as a fact and not as a process to be defined in a common dialog. Preliminary information regarding the possible need for diagnostic workup depending on the concrete screening finding, particularly regarding the type and invasiveness of these measures, the obtaining of a second

opinion, and the cooperation with other disciplines during the workup was provided on distinctly less than half of the websites. The necessity for a standardized and quality-assured diagnostic workup at certified centers, particularly in lung cancer screening, was highlighted on only two websites.

In total, only a few websites provided comprehensive, valid and well-balanced information regarding most, but unfortunately not all, relevant aspects of the particular screening procedure.

Discussion

The new German Radiation Protection Law made it possible to use both X-ray and nuclear medicine imaging techniques for individual screening. However, this requires a generic permission for every type of radiodiagnostic screening examination by a federal statutory ordinance defining the relevant requirements and conditions. The BfS in cooperation with an expert group performs a comprehensive scientific evaluation as the basis for this. In the preliminary review performed for the first time at the beginning of 2019 according to the specifications of the general administrative regulation, it was decided in consensus between the BfS and the expert group as well as in coordination with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety to prioritize a detailed evaluation of low-dose CT for the early detection of lung cancer in smokers due to the availability of several studies of the highest evidence level [10]. At present, however, none of the three CT screening examinations discussed in this study and offered by numerous practices and clinics are approved on a generic level. It is therefore illegal to perform them.

An exception from the necessity to carry out justification on the individual level by a competent radiological practitioner according to § 83 para. 3 in conjunction with § 2 para. 8 no. 1 of the Radiation Protection Law is only provided under the conditions mentioned above, i. e., when screening examinations are performed as part of a program. In contrast, a justification on the individual level must always be carried out while satisfying the requirements and conditions of the federal statutory ordinance in the case of individual screening examinations outside of a program. However, the justifying process does not replace the lack of a permission. Moreover, it must be taken into consideration that the formal necessity for carrying out the justifying process on the individual level has no impact on the question whether the examination is for the purpose of medical care or early detection. The answer to this question is based solely on the health status of the person to be examined: the first case refers to a person with disease symptoms while the latter case refers to an asymptomatic person with a certain risk profile. To ensure a clear delineation between these two categories of persons (e. g. in the case of a gradual transition of a score or laboratory value used to assess the pretest probability from the risk to disease range), the risk profile of screening participants is to be defined as concretely and with as much detail as possible by the inclusion and exclusion criteria specified in the federal statutory ordinance and is then to be individually verified as part of the justifying process.

Since screening is not an urgent measure in the care of a specific individual and is also associated with an individual benefit for only a small portion of participants, there are particularly extensive requirements regarding the provision of information and informed consent in the course of participative decision-making. A potential participant can only make an informed decision if notified in a comprehensive, neutral, and professional manner of the benefits and risks of radiodiagnostic screening, including any alternatives and possible negative consequences (▶ **Table 1**). The information in this regard provided on the evaluated websites was inadequate in the broad majority of cases. In fact, some websites even included irrelevant, suggestive and advertising statements (see info box). Apart from the fact that the offered CT screening examinations are currently not approved on a generic level, there is a concern that these problems are also not addressed in a personal consultation and that the special features of early detection compared to conventional diagnostics in medical care are not sufficiently reflected by service providers. The documented lack of information has been confirmed by the results of a current representative survey among statutory health insurance patients regarding screening measures [11]. According to survey participants, the information needed to make an informed decision was not sufficiently provided by the doctors and the benefits were overemphasized compared to the risks. It may play a role here that physicians “as providers of individual health services” are “biased” [12].

However, the inadequacies shown here are not limited to the information provided to potential test participants but also relate to the procedure itself. As ▶ **Table 2–4** show, the details regarding the age and risk factors of target persons, number and timing of tests, performing of the examinations, and diagnostic workup differ among service providers – if even provided. Thus there are inevitably deviations from the protocols and inclusion criteria used in the published high-quality studies so that benefit-risk assessments derived from these studies cannot be used as evidence of the benefit of different institution-specific protocols [13].

Detailed information regarding the evaluated aspects of the three CT screening examinations was usually available only on some of the 50 websites analyzed for each type of examination so that the relative frequency of the diverging information on individual aspects may not necessarily be representative for the total number of examinations performed in Germany due to the low number of cases. However, the considerable and scientifically unjustifiable discrepancy in central aspects is indisputable. Our Internet evaluation thus clearly demonstrates the need to define standardized and binding regulations in the form of federal statutory ordinances in order to ensure the benefit and quality of radiological screening examinations as well as informed decision-making by potential test participants. Binding requirements regarding the systematic evaluation of the structure, process and outcome quality of screening measures are particularly important here.

INFO BOX

Examples of irrelevant, suggestive or advertising statements regarding CT screening of diseases on the evaluated websites of radiology institutions. The quotes take into account the tenor of the respective website.

- Preventive medical check-ups – individual health services: Color 3 D images allow us to take a virtual journey through your body – your colon, heart, vascular system, and lungs – and to look closely at every nook and cranny without you having to endure unpleasant or painful interventions.
- A preventive care examination … confirms your state of health independent of your family doctor and allows you to get early treatment if needed. Good reason to receive comprehensive preventive care!
- Examinations are allowed to be performed even if they are not covered by your health insurance.
- Not just smokers want to rule out lung cancer.
- Get proactive and do something good for your health: Overview of our preventive care services: …Years of cigarette consumption increase your risk both for cancer and heart attack. That's why we offer a heart-lung check in combination.
- People who are healthy go to the doctor to stay healthy. … Prevent your risk for lung cancer. …An investment in your health is an investment worth making. …Responsible citizens should make their own decision about the benefit of this preventive care service for their personal situation, possibly in coordination with their doctor.
- Avoid primary risk factors, particularly smoking, or at least take advantage of the benefits of modern diagnostic imaging for preventive care.
- Choosing CT-guided virtual colonoscopy instead of conventional colonoscopy will provide you with a comfortable and risk-free alternative with comparable diagnostic reliability. CT-guided diagnostic imaging produces precise images of the intestinal wall and mucosa that allow us to identify findings requiring treatment at the earliest stage.
- CT-guided virtual colonoscopy = gentle comprehensive preventive care – comfortable and risk-free. …CT colonoscopy is the state-of-the-art technique for examining the colon. It combines gentle preparation with a pleasant and quick procedure.
- Particularly when your lifestyle is not one hundred percent "healthy", it is highly recommended to have your personal risk clarified in a timely manner.

Conflict of Interest

The authors declare that they have no conflict of interest.

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