Statement of the German Roentgen Society, German Society of Neuroradiology, and Society of German-speaking Pediatric Radiologists on Requirements for the Performance and Reporting of MR Imaging Examinations Outside of Radiology

Positionspapier der Deutschen Röntgengesellschaft (DRG), der Deutschen Gesellschaft für Neuroradiologie (DGNR) und der Gesellschaft für Pädiatrische Radiologie (GPR) zu den fachlichen Anforderungen an Durchführung und Befundung von MRT-Untersuchungen außerhalb des Fachgebietes Radiologie

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ABSTRACT

Background Magnetic Resonance Imaging (MRI) is a very innovative, but at the same time complex and technically demanding diagnostic method in radiology. It plays an increasing role in high-quality and efficient patient management. Quality assurance in MRI is of utmost importance to avoid patient risks due to errors before and during the examination and when reporting the results. Therefore, MRI requires higher physician qualification and expertise than any

other diagnostic imaging technique in medicine. This holds true for indication, performance of the examination itself, and in particular for image evaluation and writing of the report. In Germany, the radiologist is the only specialist who is systematically educated in all aspects of MRI during medical specialty training and who must document a specified, high number of examinations during this training. However, also non-radiologist physicians are increasingly endeavoring to conduct and bill MRI examinations on their own.

Method In this position statement, the following aspects of quality assurance for MRI examinations and billing by radiologists and non-radiologist physician specialists are examined scientifically: Requirements for specialist physician training, MRI risks and contraindications, radiation protection in the case of non-ionizing radiation, application of MR contrast agents, requirements regarding image quality, significance of image artifacts and incidental findings, image evaluation and reporting, interdisciplinary communication and multiple-eyes principle, and impact on healthcare system costs.

Conclusion The German Roentgen Society, German Society of Neuroradiology, and Society of German-speaking Pediatric Radiologists are critical with regard to MRI performance by non-radiologists in the interest of quality standards, patient welfare, and healthcare payers. The 24-month additional qualification in MRI as defined by the physician specialization regulations (Weiterbildungsordnung) through the German state medical associations (Landesärztekammern) is the only competence-based and quality-assured training program for board-certified specialist physicians outside radiology. This has to be required as the minimum standard for performance and reporting of MRI exams. Exclusively unstructured MRI training outside the physician specialization regulations has to be strictly rejected for reasons of patient safety. The performance and reporting of MRI examinations must be reserved for adequately trained and continuously educated specialist physicians.

Key Points:

- MR imaging plays an increasing role due to its high diagnostic value and serves as the reference standard in many indications.
- MRI is a complex technique that implies patient risks in case of inappropriare application or lack of expertise.
- In Germany, the radiologist is the only specialist physician that has been systematically trained in all aspects of MRI such as indication, performance, and reporting of examinations in specified, high numbers.
- The only competence-based and quality-assured MRI training program for specialist physicians outside radiology is the 24-month additional qualification as defined by the regulations through the German state medical associations.
- In view of quality-assurance and patient safety, a finalized training program following the physician specialization regulations has to be required for the performance and reporting of MRI examinations.

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ZUSAMMENFASSUNG

Hintergrund Die Magnetresonanztomografie (MRT) ist ein sehr innovatives, aber zugleich komplexes und technisch aufwendiges Verfahren in der Radiologie. Ihr Stellenwert für hochqualitatives und effizientes Patientenmanagement nimmt stetig zu. Die Qualitätssicherung hat in der MRT eine besondere Bedeutung, da Fehler vor und während der Untersuchung oder bei der Befundung schnell zu einem Patientenrisiko führen können. Daher erfordert die MRT eine höhere ärztliche Qualifikation und Expertise als andere bildgebende Diagnoseverfahren. Dies bezieht sich auf die Indikationsstellung, die Durchführung und im Besonderen auf die Auswertung und Befunderstellung. Der Radiologe ist der einzige Facharzt, der schon in der Weiterbildung sämtliche Aspekte der MRT erlernen und in definierter, hoher Anzahl nachweisen muss. Aber auch nichtradiologische Fächer bemühen sich zunehmend, selbstständig MRT-Untersuchungen durchführen und v. a. abrechnen zu dürfen.

Methode In diesem Positionspapier werden auf wissenschaftlicher Basis die folgenden Aspekte zur Qualitätssicherung von MRT-Untersuchungen und Leistungserbringung durch Radiologen und nichtradiologische Fachärzte beleuchtet: Anforderungen an die ärztliche Weiterbildung, Risiken der MRT und Kontraindikationen, Strahlenschutz bei nichtionisierender Strahlung, Anwendung von MRT-Kontrastmitteln, Anforderungen an die Untersuchungsqualität, Bedeutung von Artefakten und Nebenbefunden, Befundung und Erstellung des Befundberichts, interdisziplinärer Austausch und Mehraugenprinzip sowie Auswirkungen auf die Kosten für das Gesundheitssystem.

Schlussfolgerung DRG, DGNR und GPR stehen der Durchführung von MRT-Untersuchungen durch Nichtradiologen im Interesse von Qualitätsstandards, Patientenwohl und Kostenträgern kritisch gegenüber. Die Weiterbildungsordnungen der Landesärztekammern bieten mit der 24-monatigen „Zusatz-Weiterbildung Magnetresonanztomographie“ die einzige kompetenzbasierte und qualitätsgesicherte Weiterbildungsmöglichkeit für Fachärzte außerhalb des Faches der Radiologie. Diese muss als Mindeststandard für die Durchführung und Befunderstellung von MRT-Untersuchungen gefordert werden. Der alleinige Nachweis von Fortbildungen in der MRT ist – ohne entsprechende Weiterbildung – aus Gründen der Patientensicherheit abzulehnen. Durchführung und Befunderstellung von MRT-Untersuchungen müssen adäquat weitergebildeten und kontinuierlich fortgebildeten Fachärztinnen und Fachärzten vorbehalten bleiben.

Background

Magnetic resonance imaging (MRI) occupies a central position in radiological imaging diagnostics, since it offers the best diagnostic significance for many medical questions due to the high soft tissue contrast and very good spatial resolution; thus it is considered the reference standard for many indications. This is especially true for diseases of the brain and spinal cord, musculoskeletal system, upper abdominal organs and heart. Furthermore, MRI does not require ionizing radiation. The great and growing importance of MRI can be substantiated particularly well by two aspects: on the one hand, the method is increasingly included in the guidelines of national and international professional societies, where it often functions as the method of choice or equivalent to other examinations. On the other hand, the number of MRI examinations is steadily increasing. For example, according to the German Federal Office for Radiation Protection (BfS), 142 MRI examinations were performed per 1000 inhabitants in Germany in 2016 [1], corresponding to an annual number of approximately 11.8 million examinations and a 71 % increase in just 9 years. There is no end in sight to this growth trend. MRI is firmly anchored in the awareness of referring physicians[1] and specialist societies outside of radiology and is valued for what it represents today, i. e. a diagnostic method that is indispensable for modern and efficient medical care.

Radiology is responsible for this very positive development. For decades, leaders in the field of radiology have taken care that new technical developments were in demand, advanced in universities, research institutions and industry, and that the resulting innovations were introduced into clinical care on a scientific basis – to meet demand. The acquisition of knowledge, experience and skills in MRI is an integral, significant and mandatory component of the 60-month residency training program in radiology. In addition, according to the current (Model) Specialty Training Regulations ((Muster-) Weiterbildungsordnung, MWBO 2018) of the German Medical Association (Bundesärztekammer BÄK), the field of radiology is the only specialist residency program to explicitly require familiarity with all aspects of medical activity in MRI, i. e. indication, preparation of examination protocols, performance and report preparation [2]. Outside of radiology, the MWBO with the "Supplementary Advanced Training in Magnetic Resonance Imaging" also previously set high requirements for continuing education in MRI. The only exception critically viewed by the German Roentgen Society is the "Supplementary Advanced Training in cardiac magnetic resonance imaging" for specialists in internal medicine and cardiology, which was newly included in the MWBO 2018 and, contrary to the other systematics of the MWBO, requires only 12 months of further education "under authority at continuing education centers".

The undoubtedly high diagnostic value of the MRI method on the one hand, but also in particular the "business" of MRI on the other, have led in recent years in Germany to non-radiological specialists also wanting to perform MRI examinations independently and, above all, to bill them privately. In the following, the German Roentgen Society, the German Society of Neuroradiology, and the Society of German-speaking Pediatric Radiology explain their position on the prerequisites and implications of performing and reporting MRI examinations.

Specialist Training Requirements

Four aspects can be considered with regard to the acquisition of knowledge, experience and skills in the field of radiology and the specialties of neuroradiology and pediatric and adolescent radiology:

1. Indication for the examinations
2. Planning and performing the examinations
3. Reporting of these examinations
4. Indication of potentially necessary follow-up or monitoring examinations.

Due to the complexity of the technology and performance of diagnostics for almost all adjacent specialties with a corresponding variety of expected pathologies, the demands on the trainees are high. This refers to the medical-technical knowledge (here in particular the equipment technology), the expert medical knowledge (especially with regard to the patient and pathology spectrum in MRI) and the ability of a goal-oriented combination of this technical and medical knowledge with respect to the issue or examination situation.

For this reason, the 2018 MWBO explicitly requires all of the above-mentioned sub-aspects of MRI examinations "of all body regions, e. g., CNS, nerves, musculoskeletal system, soft tissues, thorax, heart, abdomen, pelvis, vessels, fetal MRI, MRI interventions" in 3000 documented cases for specialty training in the field of radiology [2]. In addition to this uniquely diverse spectrum of examination regions, the MWBO therefore also requires proof of very high number of examinations performed, which is expressly required and supported by the radiological societies with respect to quality assurance in their area. Expertise in MRI can only be obtained with correspondingly comprehensive knowledge, experience and skills; this applies to the logistical and technical requirements for the application of the method as well as to the indication and, in particular, to the medically necessary, final, high-quality and comprehensible documentation of the results in the form of a report of the findings. The following sections discuss the various aspects of specialty training content in detail.

Outside of the field of radiology, MWBO 2018 defines the following supplementary advanced training for MRI [2]:

1. "Supplementary advanced training for magnetic resonance imaging" for specialty physicians. For this purpose, 24 months of further education must be completed under authority at a training center in the field of radiology; up to 12 months of this can also be completed with a "person authorized to provide further training in magnetic resonance imaging", i. e. does not need to be completed under authority at a training center for radiology. This requires the "indication, performance, and reporting of area-based MRI examinations" on 1000 cases.

1 In the interest of readability, we have refrained from using gender-related wording. Of course, F/M are always intended, even if explicitly only one of the genders is addressed.

2. “Supplementary advanced training in cardiac magnetic resonance imaging” for specialists in internal medicine and cardiology. This requires the “indication, performance and reporting of MRI examinations of the heart and thoracic vessels” on only 500 cases within a 12-month training period “under authority at training centers”, i. e. not fully under authority at a training center in the field of radiology.

A 24-month training period in the field of radiology has so far appeared adequate also to the radiological societies in order to acquire the necessary knowledge, experience and skills in the indication, planning and performance of MRI examinations of a circumscribed specialty to a reasonable extent. If, however, in the case of “Supplementary advanced training in cardiac magnetic resonance imaging”, only 12 months of further training and 500 cases are required, which do not even have to be performed under authorization at a training center in the field of radiology, this can do justice neither to the complexity of the method nor to the quality requirement of a fully comprehensive and conclusive statement spectrum of MRI imaging to be interpreted in the findings report.

Unsupervised indication, planning, performance and reporting of MRI examinations without completion of a supplementary advanced training as defined by the physician specialization regulations is not tolerable under any circumstances and poses a risk to patients for the reasons outlined below. In the interest of patient health, the responsible handling of the potential, but also of the challenges that MRI brings with it, is only possible in the long term with expertise based on the training content required in the MWBO for the field of radiology.

MRI Risks and Contraindications

Modern MR tomographs are highly complex machines that have undergone rapid development since their introduction to clinical medicine. An example of this is the constant increase in field strength. In addition, there are improvements to all components such as coils and gradients with higher performance, so that the conditions also change with regard to the electromagnetic high-frequency and gradient fields. Parallel to the hardware, there has been steady development of software and sequence technology. Taken together, this may improve the diagnostic value of MRI, but potentially poses new, different, or greater risks to patients. A summary of MRI incidents reported to the FDA included 1548 reports over a 10-year period (2008 to 2017) [3].

Implants pose a special challenge with respect to patient safety. The patients to be examined are getting older and, for this reason alone, the number of medical implants is continually increasing. Furthermore, new therapeutic procedures are being developed at a rapid pace, leading to ever new and a growing number of medical devices found in patients undergoing an MRI scan. For example, the current edition of the “Shellock”, the worldwide standard work for MR safety of medical implants, lists nearly 5000 products and evaluates their MR compatibility [4]. Basically, implants are classified as MR-safe, -unsafe, or -conditional, with the latter category requiring that certain conditions be met during the examination, such as lower SAR values (specific absorption rate), special coil configurations, or exclusion of certain body regions. Thus, in many cases, very careful preparation and clarification is required in advance. Examples of the complexity of handling implants in MRI include pacemakers and implantable defibrillators (AICD); improper handling can lead to failures or malfunctions with the risk of life-threatening arrhythmias. According to the DRG position paper, patients can currently be examined by MRI with both “MR-conditional” (conditionally MRI-safe, approved under defined conditions) and “MR-conventional” (relative contraindication, off-label use) pacemaker systems under certain conditions [5]. However, handling of even MR-conditional systems is complex. In any case, a very precise and elaborate check of the system is required beforehand. The major challenges for imaging in such patients are prior reprogramming, adherence to and adjustment of the examination technique parameters (sequences) especially specified by the manufacturer for each system, and instrumental patient monitoring during the examination. All of this requires a great deal of effort, special logistics and expertise.

Potential hazards associated with non-active metallic implants are due to interactions of MRI fields with magnetically active and electrically conductive material. This applies, for example, to ferromagnetic osteosynthesis material and wires or electrodes. Strong mechanical forces and torques can act on the implants in the magnetic field, which can lead to dislocation and heating. Alternating currents can be induced in electrically conductive implants, resulting in heat generation and burns [6].

Patients with tattoos or permanent make-up are now commonplace. Both can also cause burns, although the risk of burns depends on the size of the tattoo and especially the nature of the pigments applied. Older tattoos can contain ferromagnetic iron and iron oxide pigments. Of enormous importance is the prior clarification of metallic foreign bodies such as shell fragments. Analogous to the above, these can heat up or dislocate in the magnetic field and migrate in the tissue. For this reason, they are an absolute contraindication at sensitive body sites, e. g. brain, eye, lung. ▶ **Table 1** lists various implants and foreign bodies that may be contraindications for an MRI examination. It is part of a physician's duties to rule out absolute contraindications beforehand and to weigh the benefits and risks to each patient.

Part of the responsibility for patient safety lies with the technical staff who position the patient and perform the examination – with the need for in-depth training. This includes the following measures to avoid complications, mainly burns: removal of unnecessary metallic objects, avoidance of direct skin-to-skin or skin-to-coil contact, application of only tested and MR-suitable material (e. g. ECG electrodes), removing or covering electrically conductive materials, avoiding crossing or circularly arranging cables.

Overall, it is a challenge even for radiology specialists to keep up with the numerous innovations and maintain an overview. Medical personnel have a great responsibility to identify risks and contraindications in advance of the examination and, in case of doubt, to weigh the risk-benefit ratio. In addition, cooperation between medical and technical staff plays a major role for the benefit of patient safety. Experience is indispensable for this in order to offer the best possible diagnostics on the one hand and

to ensure patient safety under changing conditions on the other. In turn, many years of radiological education of medical residents in a radiology MR department with a heterogeneous patient population is certainly the best guarantee for this.

Radiation Protection

Radiation protection also plays a significant role in MRI which may seem strange at first. Even though the emitted radiation types and waves are non-ionizing radiation and are therefore less in public focus than X-rays or radioactive radiation, they can pose an explicit risk to exposed persons if used improperly. This has consequences for the treatment of patients, medical staff and also those who are examined for non-medical reasons, e. g., for research purposes. The relevant aspects for the application of MRI are regulated in Germany by the Act on Protection against Non-Ionizing Radiation in Human Applications (NiSG) and the Ordinance on Protection against Harmful Effects of Non-Ionizing Radiation in Human Applications (NiSV). According to § 1 para. 1 no. 1, the NiSG applies "to the operation of facilities for the medical application of non-ionizing radiation in medicine and dentistry" and, according to § 1 para. 2 no. 1, covers "electrical, magnetic and electromagnetic fields in a frequency range from 0 Hertz to 300 Gigahertz" [7]. During medical operation of an MR tomograph, the specified limits for non-ionizing radiation (NiSV, Annex 1) are regularly exceeded to ensure image quality and diagnostic significance. In NiSG § 2 (protection in medicine) para. 1–3, the requirements for justifying such an exceedance are defined as follows – in analogy to ionizing radiation: "(1) In the practice of medicine or dentistry on humans, the [...] values specified for certain types of application may only be exceeded during the operation of systems that can emit non-ionizing radiation if an authorized person has provided the justifying indication for this. (2) An authorized person pursuant to paragraph 1 is [...] anyone who is licensed as a physician or dentist [...] and has the necessary expertise to assess the risks to humans of the respective application of non-ionizing radiation. [...] (3) The justifying indication according to paragraph 1 is the decision that and in which way non-ionizing radiation is applied to humans in medicine or dentistry. It requires a finding that the health benefits of applying non-ionizing radiation to humans outweigh its risk." Moreover, according to § 11 of the NiSV, MR scanners may be used even for non-medical purposes "on humans only under the responsibility of a physician with a specialist qualification in the proper operation of magnetic resonance tomographs" [8]. In addition, the Radiation Protection Commission of the German Federal Office for the Environment, Nature Conservation and Nuclear Safety describes the aspects of radiation protection in MRI [9] and published very detailed "Recommendations for the safe use of magnetic resonance methods in medical diagnostics" [10], which includes the sentence: "MR should not be used uncritically, even though it is often the superior alternative".

In MRI, static, low-frequency and high-frequency fields are applied even above the recommended limits, which may result in direct adverse health effects, but also in indirect adverse effects.

▶ **Table 1** MRI contraindications: Medical implants and other foreign bodies that may pose a risk and must therefore be obligatorily checked for MR suitability before the examination. The list is not exhaustive.

type	example
active metallic/ electronic medical implants	cardiac pacemaker/AICD, neuro-stimulators, medicine pumps, cochlear implants, cardiac assist devices
non-active medical implants	osteosynthesis material, aneurysm clips, coils, shunt reservoirs, venous ports, recently implanted stents, event recorders
	surgical skin staples
	central venous catheters/catheters with metal markings, esophageal temperature sensors
	abandoned pacemaker electrodes
non-medical implants or modifications	piercings, tattoos
	metallic jewelry
	metallic make-up
other foreign bodies	metal splinters, shrapnel, projectiles

Basically, the following three different types of non-ionizing radiation pose hazards during the operation of MRI systems:

1. Static magnetic field. Depending on the level of the static magnetic field ("field strength"), dizziness, discomfort and nausea may occur during the patient's entry into the scanner. Particularly relevant is acceleration of ferromagnetic (especially iron) objects in the scanner room, which can fly into the bore of the scanner and cause significant, sometimes fatal injuries to the patient.
2. Electromagnetic HF fields: see section MRI Risks and Contraindications.
3. Gradient fields can cause nerve stimulation and muscle twitching, triggering pain, and in the worst cases, hazardous cardiac arrhythmias.

MRI is therefore not a risk-free method; if used improperly, it harbors potential hazards on several levels and is also relevant from the point of view of radiation protection. According to the recommendations of the Radiation Protection Commission, the ordering of an MR examination "may therefore only be carried out by a physician who can demonstrate special qualification (expertise) in the field of MR examinations. [...] When used on humans, a competent physician must be present at all times" [10].

Use of Contrast Agents: Indications, Contraindications and Hazards

Some MRI examinations require intravenous or intra-articular administration of paramagnetic contrast media to enhance the

meaningfulness of the examination. These contrast agents are almost exclusively small, hydrophilic gadolinium(III)-based chelates. In recent years, concerns have arisen about the long-term safety of these compounds, as tissue deposition of such contrast agents has been detected and is now the subject of ongoing research efforts [11]. Acute, sometimes severe allergic reactions are rarely, but regularly observed [12]. The use of contrast agents requires detailed knowledge of the contrasting behavior of relevant pathologies and requires individual consideration in order to avoid unnecessary administration of contrast while accepting these risks. Patients must therefore be carefully questioned and informed before contrast medium is administered.

The occurrence of allergic reactions depends on the type of contrast agent used, age, sex and admission status of the patients [13, 14]. Patients who have already had allergic reactions to gadolinium (Gd)-based contrast agents are also at high risk (approximately 39 %) for a further allergic reaction with subsequent contrast agent applications, even with drug preparation [15]. Incorrect preparation of the intravenous injection of the contrast agent, which is usually applied by an injector, can lead to incorrect injections outside the vessel (so-called extravasations), the consequences of which can range from temporary pain to necrosis and permanent disability [16].

A serious and permanent side effect of Gd-containing contrast media is nephrogenic systemic fibrosis (NSF), a rare fibrosing disease with a poor prognosis and even severe disability. The condition has been reported exclusively in patients with advanced renal disease and is associated with higher doses and certain types of Gd-based contrast agents [17].

Only in recent years have Gd deposits in the brain been associated with multiple administrations of Gd-based contrast agents. Causality has now been demonstrated, with a higher incidence of such depositions shown for certain classes of contrast agents [18]. However, because the long-term risks of Gd deposits are unknown, the EMA additionally recommended the suspension of authorizations for intravenous linear Gd-based contrast agents in the EU.

The complexity of the proper use of MRI contrast agents in radiological examinations is summarized in a 130-page letter of recommendation from the American College of Radiology, much of which discusses Gd-based contrast agents [19]. This demonstrates the fact that expertise is required for the handling of MRI contrast media in order to use them responsibly and in accordance with the indications and to avoid related hazards to the patient. The MWBO describes handling of MRI contrast agents only in the field of radiology, the sub-specialties of the field and the two above-mentioned supplementary advanced trainings in magnetic resonance imaging.

Utilization of MRI: Quality Requirements

Spatial resolution and signal basically define the image quality of MRI. Both should be as high as possible, but they negatively influence each other, i. e. the higher the resolution, the lower the signal and vice versa. To increase both requires an increase of measurement time which in turn can only be increased to a limited extent, because it defines the time span in which the examined body region must be motionless, so that the partial examination (so-called sequence) does not become useless due to motion blur. This is especially true for organs that can be displaced by breathing, such as the heart or liver, but even the shoulder does not remain completely immobile for minutes. Depending on the clinical issue, it is necessary to choose an imaging protocol that delivers the best results in the tension between resolution/signal and measurement time while allowing the examination to be compared with previous recordings inside and outside the imaging institution. The recommendations of the MR manufacturers can best be used as a basis in this case. Due to the many options in the measurement sequences, which increase with each software update by the manufacturers, and the interdependencies of the parameters, the sequence protocols are always determined in consensus with the most experienced MR radiologists, MR technical assistants and, in larger hospitals, physicists, and adjusted across all available MR scanners. It is not enough to “just be able to drive the car”; one needs in-depth knowledge of how the engine, transmission, chassis, etc. work. This is the only way to ensure consistently high quality while making sensible use of the latest technology.

Perfect image quality is a necessary, but alone not sufficient, prerequisite for correct diagnosis. It is important to understand the pathomorphology of a disease and the corresponding changes in MRI, taking into account the technical options on the part of the scanner and scanning software. For example, pigmented villonodular synovitis (PVNS) may be “invisible” in standard sequences of knee MRI. However, if gradient echo sequences, which are not actually part of standard knee MRI, are added, this condition is easily recognizable [20]. A visually pleasing MRI of the liver may miss the diagnosis of hepatocellular carcinoma (HCC, liver tumor) if the crucial late arterial contrast sequence is missing or measured a few seconds too early or too late [21, 22]. Storage disorders of the heart such as Fabry disease can be missed without T1 mapping sequences in an otherwise perfect cardiac MRI [23, 24].

Artifacts: Occurrence, Detection and Interpretation

Knowledge of “typical artifacts in MRI and their causes” is listed in the MWBO as a separate item for MRI, unlike most other imaging procedures, and is thus a defined part of the radiologist’s specialist training [2]. There are two reasons for this, on the one hand the complexity of the procedure and on the other hand the fact that artifacts in MRI not only impair assessability, but can also mask real pathologies or mimic false pathologies.

Patient-caused and technical artifacts occur with magnetic resonance imaging as with all other imaging modalities, especially respiratory and motion artifacts [25]. Blood flow and pulsation artifacts are also more strongly expressed on MRI. However, the confounding feature in the interpretation of MRI examinations lies in the multitude of possible physical artifacts [26]. These are more important in MRI because this is not a direct imaging technique like, for example, X-ray diagnostics based on the principle of attenuation, but is based on complex physical process steps.

Here, artifacts can be caused by magnetic field inhomogeneities or strongly differing physical properties of neighboring tissues (chemical shift, susceptibility). The signal changes caused by this can, for example, mimic contrast uptake and thus appear as inflammation or a tumor. Other types of artifacts are folding artifacts, where an object outside the field of view is projected into the examination area and can thus be misinterpreted as a tumor, for example. These potential misinterpretations explain the special importance of recognizing and interpreting MR artifacts in the specialist training regulations.

Incidental Findings: Significance, Detection and Interpretation

The occurrence of unexpected incidental findings in MRI examinations has been reviewed in detail in the literature. The early detection of tumors that are not yet symptomatic and discovered as incidental findings is of immense importance for the treatment options of patients. As expected, a survival advantage in asymptomatic patients (incidental detection) was described as early as 1995 using the example of malignant kidney tumors and has since been confirmed many times in the literature [27, 28]. The management of potentially malignant incidental findings poses an enormous risk of avoidable subsequent costs and unique ethical challenges, which are largely borne by the imaging reviewer himself [29].

Whole-body imaging of asymptomatic patient cohorts provides an interesting insight into the frequency of such incidental findings, and demonstrate that a substantial proportion of asymptomatic adults have potentially serious incidental findings on MRI. A total of 17 961 incidental findings were obtained from 6214 examinations in a meta-analysis of 12 studies of non-symptomatic patients who received whole-body MRI as a screening procedure. Of these, 9 % were considered oncologically relevant (potentially malignant), of which 0.5 % were confirmed to be malignant tumors after further evaluation. Only 5 % of patients had no incidental findings on MRI. In 30 % of all subjects, findings were present that required further investigation. In contrast, the overall rate of histologically confirmed malignant tumors was only 1.1 %. The authors concluded from this that MRI studies, when used for screening purposes in the asymptomatic general population, should be performed by experienced radiology specialists familiar with identifying MRI abnormalities and who could provide referral pathways [30]. In some respects, these findings can be equally applied to clinical examinations. In an even more comprehensive meta-analysis of 32 representative studies (27 643 clinically asymptomatic patients), the authors found an incidence of 3.9 % for potentially serious incidental findings and 12.8 % for incidental findings of indeterminate potential severity in brain and body MRI. In this case, approximately 50 % of the potentially serious incidental findings were judged to be suspicious for tumor which required further workup. Although some limitations in comparability were indicated, this analysis also shows that relatively few potentially serious incidental findings also had serious final diagnoses (20.5 %) [31].

A comparison of 20 systematic reviews (from 240 original studies) showed that cardiac MRI in particular has the highest proportion of incidental findings (34 %) among MRI examinations of all body regions. MRI of the spine is on par with MRI of the brain at 22 % [31].

Since the introduction of digital DICOM viewers and picture archiving systems (PACS) in radiology, patient MRIs performed to analyze the spine due to back pain were one of the first groups analyzed for the occurrence of incidental findings. The possibilities of reporting with the aid of PACS led to an increase in detected incidental findings from approx. 4 % to approx. 10 % over an observation period of 5 years with 2500 examinations. Incidental findings in all age groups have been described in the literature. A recent review of 190 MRI examinations of pediatric patients found rates of incidental findings of 21.1 % in the cervical spine, 13.8 % in the thoracic spine, and 22.6 % in the lumbar spine [32]. Park et al. found incidental findings in 8.4 % of examinations of an older age patient population (95 % of patients over 30 years of age) with 1268 patients who underwent MRI of the lumbar spine for evaluation of disc herniation [33]. Another study showed a total of 16.6 % incidental findings outside the spine, including anatomic and developmental abnormalities, in spinal MRIs of 1031 consecutive patients, with the highest percentage occurring in the cervical spine at 25.7 % [29]. Lesions discovered incidentally on cervical spine imaging in the posterior cranial fossa have a high percentage of clinically relevant disease, particularly in children. In this regard, Kozyrev et al. showed that of a group of 70 children with incidentally-found posterior cranial fossa lesions, 56 % required surgery. About 10 % of these lesions turned out to be malignant tumors [34]. In a large retrospective analysis of MRIs of the lumbar spine using an expanded field of view (FoV), the authors identified one or more incidental findings in the abdomen or pelvis in 33.2 % of 2067 examinations, of which 102 (representing 4.9 % of the total population) required further workup. Of the latter, about half were classified as “probably clinically insignificant”, about 10.9 % were classified as “indeterminate”, and 40.1 % were classified as “probably clinically relevant” [35].

On the basis of the studies described, the importance of the reliable assessment of incidental findings with regard to their clinical relevance is obvious. If a finding cannot be reliably assessed due to a lack of expertise on the part of the examiner, further clarification possibly including invasive histological confirmation is often recommended, which not only generates avoidable costs but also poses a risk of complications for the patient. Similarly, a lack of advanced training may result in the failure to recognize unexpected imaging findings, especially if they are located in body regions that were included but are not the target region itself. Only specialists in radiology have expertise in imaging all body regions and pathologies, and therefore have unique experience in handling and assessing incidental findings.

Diagnosis and Preparation of the Findings Report

The core elements of diagnostic radiological procedures performed by a radiologist are the reporting of examination results

and the preparation of a written, specialist report of findings. The findings report documents the results of the examination in a structure that can be archived and, above all, is presented in a form that can be used by the referring physician, who is not qualified to collect the relevant findings on the basis of the images. According to the NiSG/NiSV relevant to MRI, the performance of an MRI examination requires the process steps 1.) Establishing the justifying indication, 2.) Clarification and 3.) Performing the procedure. DIN standard 25 300–1: 2018–05 "Processes in radiology – Part 1: Diagnosis of a imaging or image-based procedure" describes this as follows: "The application of an imaging [...] procedure in human and dental medicine is a process that includes not only collecting the examination results but also evaluating these results. Reporting is understood to be a sub-process in the course of which the examination results are interpreted and at least a written diagnosis report must be drawn up. Furthermore, the communication of the diagnostic reports is part of the diagnostic process" [36]. The findings report is then defined as the "documentation of the part of the medical examination [...] that includes the description of the implementation and the evaluation of the examination results of imaging [...] procedures."

The actual expertise of the specialist in radiology lies in the preparation of the findings report; he spends the vast majority of his working time on it. He carries out the above steps of the process as follows: first of all, the digital image data obtained is carefully assessed with the help of a modern DICOM viewer within a PACS; hundreds to thousands of images are viewed and evaluated in the MRI area. The target region of the issue requires special attention. Nevertheless, the areas outside the target region are then specifically observed again in order to detect incidental findings. Findings considered pathological are collected and descriptively documented. The examiner then compiles the findings into a findings report. Finally, the findings are summarized in an assessment, evaluated and classified in relation to the medical history and the given issue. In the case of unclear findings, this should also include a weighted list of possible differential diagnoses and, if necessary, recommendations for further diagnostic procedures.

In radiology, creation of the findings report and its communication has recently moved more into focus. It must be ensured that the collected findings are transmitted promptly in an understandable, unambiguous and clear form and that an evaluation with probability-based differential diagnoses is carried out, i. e. that the issue is addressed efficiently [37]. The DRG working group on information technology has started an initiative regarding specified structure and standardization in order to take account of the importance of reporting – also in perspective with regard to the increasing demand for structured reporting [38].

With regard to the requirements for the qualification of the assessor, DIN standard 25 300–1:2018–05 defines in clause 6: "The reporting process must be carried out by a person with the necessary qualification to do so. [...] Qualifications are set forth in specialist training regulations and radiation protection laws, among others." [36] (for a definition of qualification refer to section "Specialist Training Requirements" and "Radiation Protection"). The MWBO 2018 requires as competence the "indication, performance and reporting of MRI examinations of all body regions" for the field of radiology with a guideline number of 3000 cases; for supplementary advanced training "Magnetic Resonance Imaging" 1000 cases are required, and for "Cardiac Magnetic Resonance Imaging" 500 cases of heart and thoracic vessels are required [2]. Only in the field of radiology is the "Radiological report preparation, assessment and communication of the result of findings" explicitly required in the necessary competence (experience and skills) under the heading "Communication" in the MWBO 2018. This implies two conclusions. Firstly, the specialist in radiology has the unique experience of preparing MRI examinations due to extensive training and full-time employment in precisely this area during residency and as a specialist. Second, the radiologist is the only specialist who has experience from the beginning in preparing reports for external, non-specialist referring physicians and communicating them. In this way, he is uniquely exposed to the professional exchange with all clinical colleagues on a daily basis. This, in turn, is an aspect of quality assurance that cannot be provided by self-referrers.

The medical requirements presented for the assessment of a diagnostic service are of major importance in the context of medical liability. Since, according to Section 630a (2) of the German Civil Code, medical treatment must be provided in accordance with generally accepted professional standards existing at the time of treatment; it is of decisive importance whether an alleged medical error is classified as an irreproachable diagnostic error, as a misdiagnosis, or as an error in gathering of findings.

A "mere" diagnostic error exists if the treating physician misinterprets findings and therefore does not take the measures required from the professional point of view of his field. On the other hand, a reproachable diagnostic error exists if the correct diagnosis was grossly misjudged or a suspected or working diagnosis was not checked and the diagnosis made as a result no longer appears justifiable from a specialist's point of view. In this case, a gross treatment error with the consequence of a reversal of the burden of proof to the detriment of the physician is to be assumed as a rule. If, on the other hand, the incorrect diagnostic classification of a disease is already due to the fact that the physician did not even collect the findings required by the state of the art in medicine, then an error in the gathering of findings exists [39].

The standard under liability law for a reproachable diagnostic error depends on the standard that the physician must ensure. In principle, when a patient visits a physician, he is entitled to compliance with the standard of good medical care according to the benchmark of an experienced physician in the respective specialty (so-called "specialist standard") [40, 41]. If it is a radiology specialist, this is generally also the governing specialist standard. However, if a doctor uses examination and treatment methods that fall into an outside specialty, he has to guarantee the outside specialty's standard. The starting point for the classification is the training content of the respective specialist training.

Since the implementation of MRI examinations for non-radiological specialists is to be regarded as a non-specialist subject if they have not completed the supplementary advanced training in magnetic resonance imaging, then they do not have to guarantee the specialist standard of their own specialization, e. g. orthopedics and trauma surgery or internal medicine and cardiology, but the standard of the radiology specialist field, in whose specia-

list field the examination and treatment method belongs. This is because MRI is an integral part of the training to become a radiology specialist. In this case, a misinterpretation of collected findings can lead to a treatment error if the diagnostic error becomes causal for the course of the patient's disease.

Interdisciplinary Exchange

Radiology is considered a service-providing, independent specialty at equal footing in a highly interdisciplinary environment and consciously avoids the distinction between "radiologist" and "clinician" because radiology itself is a clinical specialty. Radiology is mentioned in § 2 of Section A of the MWBO as an area of direct patient care. Radiology aims to provide clinically relevant and usable information for therapy and management of the patient in dialog with the referring physicians, which is done more transparently than any other specialty. For each individual patient, the examining specialist in radiology provides the referring physician with both the results of the examination itself and the clinical assessment of the same – in the form of MRI images (PACS, CD, online access, printout, etc.) on the one hand and the written report on the other. In this way each referring physician can get an impression of the images for himself and compare it with the radiologist's assessment, which can lead to diverging opinions regarding the findings, which have to be discussed in dialog. In the hospital, radiologists offer referring colleagues regular demonstrations (synonym: rounds) in which cases are discussed on an interdisciplinary basis using the image presentation. There is no question that these demonstrations are useful and valuable, but they require an enormous amount of time, personnel, and thus financial resources for radiology. Tumor boards, as an example of such demonstrations, have a proven benefit, so the presence of a radiology specialist is mandatory in the vast majority of cases. But other demonstrations also have benefits for patient care by leading to changes in treatment approach; for example, a German study showed that joint discussion in radiology-internal medicine conferences led to a change in the previous diagnosis in 17 % of cases and to a different therapy in 22 % [42].

Interdisciplinary exchange is, so to speak, "in the DNA" of radiology, which gladly enters into a dialog with treating colleagues in order to improve the quality of treatment. In this context, the MWBO 2018 explicitly calls for the "preparation and implementation of radiological demonstrations, interdisciplinary conferences, including tumor conferences" in the field of radiology and is given a benchmark [2]. This interdisciplinary, quality-assuring aspect does not apply in the case of self-referrals by non-radiologists who perform and diagnose the MRI themselves. The "multiple-eyes principle" is thus counteracted.

In the German statutory health insurance system, the "multiple-eyes principle" is prescribed by law as a quality assurance requirement and is implemented by restricting the provision and billing of MRI services to specialists in radiology in accordance with Section 135 (2) Sentence 4 of the German Social Security Code V (in conjunction with Section 4 (1) of the Magnetic Resonance Imaging Agreement of the German National Association of Statutory Health Insurance Physicians) and subjecting them to a general referral requirement. The German Federal Constitutional Court (BVerfG) and the Federal Social Court (BSG) have repeatedly judged the allocation of MRT exclusively to the field of radiology, as constitutional with reference to the "multiple-eyes principle" in the statutory health insurance [43, 44]. The "multiple-eyes principle", which has so far only been legally anchored in the statutory health insurance system, is certainly transferable to the private medical sector, because the referral proviso for the specialties named in Section 13 (4) of the physicians' Federal Blanket Agreement is based, according to the Constitutional Court, on "the special features of a diagnostic medical specialty and the definition anchored in the advanced training regulations" [43].

Cost Increases

Especially in the cost-intensive field of MRI diagnostics, the principle of separation of referring physician and service provider is essential for achieving a high quality of medical care while taking into account the cost efficiency of the health care system. The expansion of MRI diagnostics to other medical specialties will inevitably cause a significant increase in costs due to self-referrals, as has been shown for X-ray diagnostics [45]. For identical diseases, self-referrals increase the number of radiology services per disease case [46–48], physicians with their own X-ray equipment schedule up to 4–5 times more examinations than physicians without their own X-ray equipment [49].

In addition, referring a diagnostic issue to radiology ensures that the most appropriate imaging modality is selected for the respective medical issue. This does not always have to be MRI, which is highly important but in no way replaces all other imaging modalities. Only the radiology specialist has the appropriate training and expertise to make a selection based on all available procedures and may not always choose MR diagnostics, but also use alternative imaging such as computed tomography, X-ray or ultrasound. In addition, the separation of diagnostics and therapy by referral for diagnostic imaging to the radiology specialist allows a second opinion to be obtained on the clinical constellation of findings independent of any interest in performing a particular therapy.

Summary

"Magnetic resonance imaging currently represents the most modern, but at the same time technically most complex cross-sectional imaging procedure in radiology. Quality assurance in MRI is of particular importance because, due to the large number of variable and interdependent measurement parameters, the possibility of error due to artifacts and inadequate performance of the examination is considerably greater than in all other imaging procedures. Therefore, not only technical quality assurance, but above all medical qualifications play a special role in the indication, performance, evaluation and assessment of MRI." This is the preamble of the guidelines of the German Medical Association for quality assurance of magnetic resonance imaging [50], which aptly describes the tenor of this article.

MRI is an established and still very innovative examination method and is the diagnostic reference standard for many indications today. Its importance for high-quality and efficient patient management is steadily growing. This is reflected in the increasing presence of MRI in guidelines as well as in the rising numbers of examinations. For this reason, non-radiological disciplines are increasingly seeking to be allowed to perform MRI examinations independently and, above all, to be allowed to bill for them.

MRI is a very complex and potentially risky method that can pose a hazard to patients, which is not adequately addressed by current case law. Only in the hands of experts is the risk as minimal as perceived and expected by patients; be it with regard to radiation protection, the handling of medical implants or metallic foreign bodies, the application of MRI contrast media, correct patient positioning or the use of suitable materials. Radiology specialists know these risks and necessities from their training and experience and know how to avoid complications as best as possible or how to manage them appropriately. In addition, without this radiological expertise, there is a significant patient risk from incorrect reporting, e. g., due to lack of experience, misinterpretation of artifacts, or overlooking of relevant incidental and coincidental findings.

For decades, MRT has been positioned in radiology and its facultative sub-specialties neuroradiology and pediatric and adolescent radiology. The radiologist is the only specialist who has to learn all aspects of MRI (indication, protocol planning, examination performance, reporting) in the specialist training and has to demonstrate these skills based on a high number of cases. Radiologists work closely with all other clinical specialties to an exceptional degree, perform a wide variety of MRI examinations, and are in constant interdisciplinary communication with their referring physicians with great transparency. Therefore, only they have both the expertise and experience in imaging diagnostics of all body regions and constant contact with an enormously broad spectrum of different pathologies and patients from all disciplines. The professional competence and the highest qualification in all of the sub-areas mentioned lie within radiology. The abolition of the separation of diagnostics and therapy (referring physician – radiologist) by self-assignment contradicts the multiple-eyes principle and will lead to an increase in costs for the health care system.

Bottom line: the German Roentgen Society, the German Society of Neuroradiology and the Society of German-speaking Pediatric Radiology are very critical of the performance of MRI examinations by non-radiologists for the reasons mentioned above in the interest of patient welfare and cost bearers and even consider supplementary advanced training lasting only 12 months without obligatory participation of education authorized in the subject of radiology to be inadequate. The use of MRI without adequate and certified specialist training in accordance with the physician specialization regulations would lead to a massive loss of quality and a risk to patients while at the same time increasing costs. Indication, performance and reporting of MRI examinations must be reserved for appropriately trained and educated specialists.

Conflict of interest

Hunold: Mitglied Deutsche Röntgengesellschaft, Vorstandsmitglied AG Herz- und Gefäßdiagnostik der DRG, Mitglied Bundesverband Deutscher Radiologen, Mitglied European Society of Radiology; Vortragshonorare Fa. Bayer Vital
Bucher: Mitglied Deutsche Röntgengesellschaft, Vorstandsmitglied der AGs Muskuloskelettale Radiologie, Gesundheitspolitische Verantwortung, Uroradiologie und Urogenitaldiagnostik und Forensisch-Radiologische Bildgebung der DRG, Mitglied European Society of Radiology; Travel support Fa. Bayer und Guerbet
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Janka: Mitglied Deutsche Röntgengesellschaft, Vorstandsmitglied AG Muskuloskelettale Radiologie der DRG, Mitglied Bayerische Röntgengesellschaft, Mitglied European Society of Radiology; Vortragshonorare Fa. Siemens Healthineers und Bracco
Fritz: Mitglied Deutsche Röntgengesellschaft, Vorstandsvorsitzender der AG Gesundheitspolitische Verantwortung der DRG
Regier: Mitglied Deutsche Röntgengesellschaft, Vorstandsvorsitzender AG Muskuloskelettale Radiologie der DRG, Mitglied Bundesverband Deutscher Radiologen
Loose: Mitglied Deutsche Röntgengesellschaft
Barkhausen: President elect und Mitglied Deutsche Röntgengesellschaft
Mentzel: Präsident und Mitglied Gesellschaft für Pädiatrische Radiologie, Mitglied Deutsche Röntgengesellschaft
Zimmer: Präsident und Mitglied Deutsche Gesellschaft für Neuroradiologie
Antoch: Präsident und Mitglied Deutsche Röntgengesellschaft

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