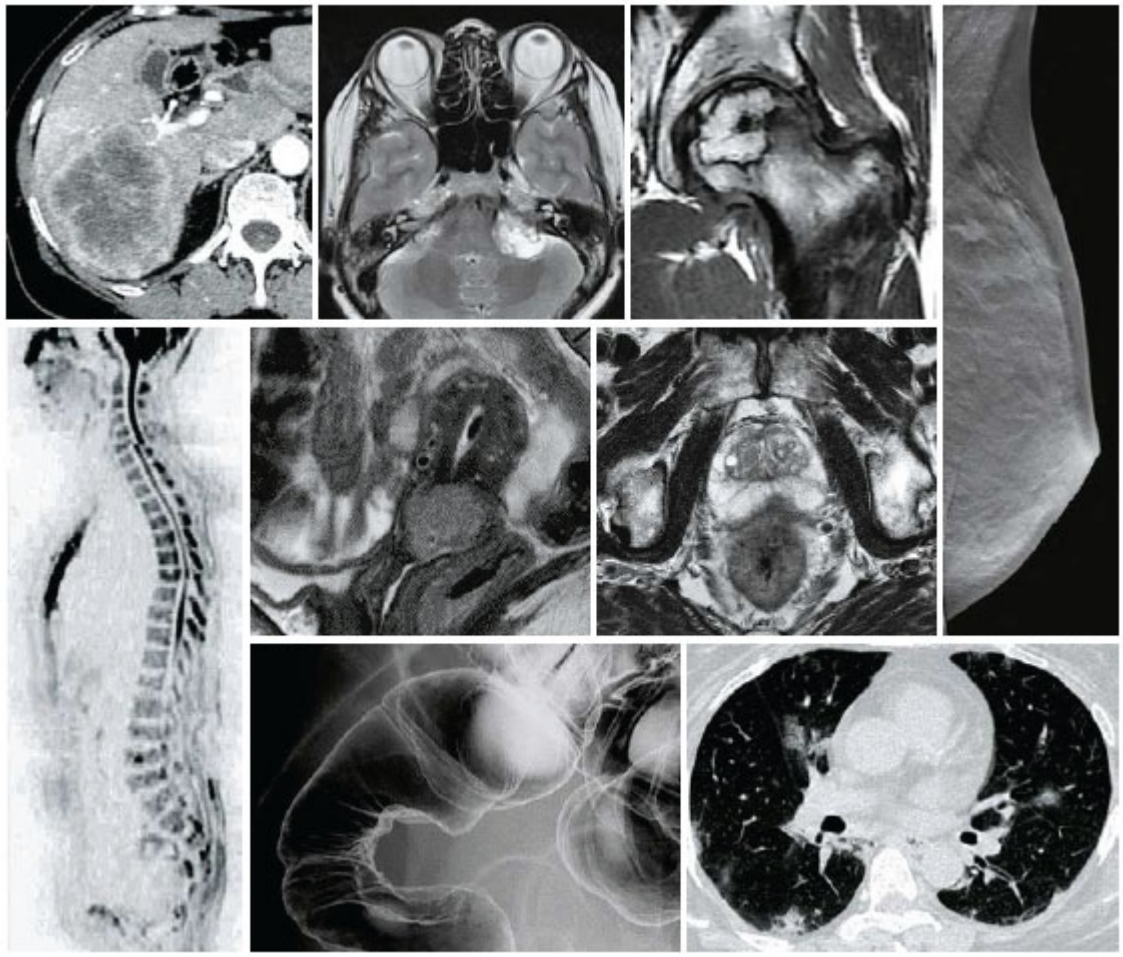
Diagnostic Imaging

Guidelines 2021

Japan Radiological Society



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Introduction

The purpose of the diagnostic imaging guidelines is to ensure that medical care that uses diagnostic imaging is justified, optimized, performed effectively and efficiently, grounded in science to the greatest extent possible, and that its outcome is beneficial to the patient. Since the 2013 edition, the guidelines have been provided in the form of clinical questions (CQs) and recommendation grades for the different fields. Progress in diagnostic imaging has been rapid, and immediately after the 2016 edition was published, work on the next revision began. The current revision was made possible through the efforts of all members of the guidelines committee, particularly the committee chair, Dr. Murayama.

The previous belief about medical research was that the level of evidence from randomized, controlled studies was high, whereas the level of evidence from diagnostic imaging tended to be weak because it was based on cross-sectional studies. Moreover, evidence from imaging procedures for which multicenter, randomized, controlled studies could be performed and that used technology that was already widely used (somewhat older) was considered stronger than evidence from clearly superior, cutting-edge, imaging procedures (e.g., in detecting stroke, CT had stronger evidence than diffusion-weighted MRI). In the rapidly advancing field of diagnostic imaging, this left the impression of being removed from the current reality. Consequently, the Grades of Recommendation Assessment, Development and Evaluation (GRADE) system has been incorporated for the first time to bring the guidelines in line with reality.

Although the target audience for the 2016 edition of the guidelines was mainly diagnostic radiology specialists, the target audience of the present guidelines is general practitioners, who order imaging procedures. Japan has the highest number of CT and MRI systems per capita. On the one hand is the view that the government and citizenry understand the importance of diagnostic imaging, and it is therefore widely used. On the other is the criticism that there is often inadequate justification for imaging procedures, as indicated by the fact that CT exposure in Japan is the highest in the world, and that CT needs to be used appropriately. The number of radiologists per capita is smaller in Japan than in other countries, suggesting that diagnostic imaging guidelines aimed at the general practitioner could play a major role in encouraging the appropriate use of imaging procedures.

A questionnaire survey of radiologists at a training facility for radiology specialists on compliance with the 2016 edition of the diagnostic imaging guidelines showed that, although many procedures were performed according to the recommendations, a considerable number of tests that were not recommended were also performed (Fig.; Kumamaru KK et al: Jpn J Radiol 35: 648-659, 2017). It is hoped that these general practitioner-oriented guidelines will be used widely, and that imaging procedures will be used appropriately, leading not only to improvements in the quality of medical care and outcomes for patients, but also appropriate restraints on medical costs.

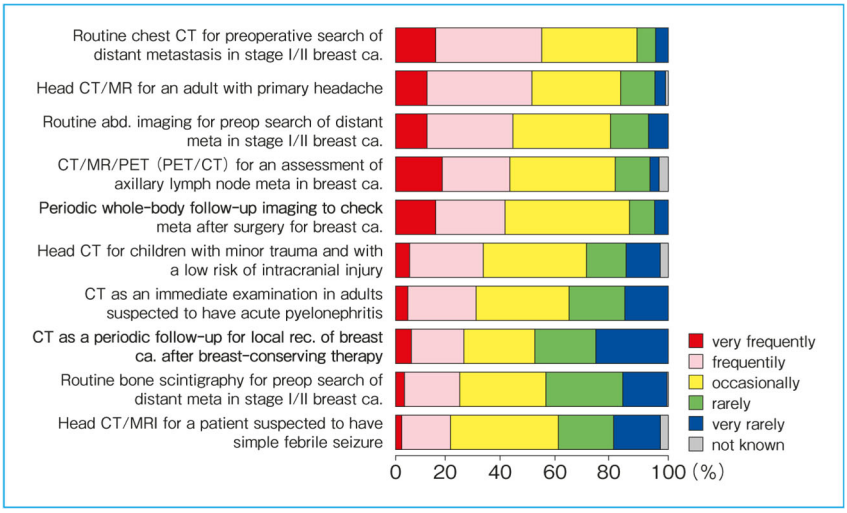

Figure Frequency of non-recommended imaging procedures
(Japan Radiological Society appropriate-use survey, 2017)

September 2021
Shigeki Aoki
President, Japan Radiological Society

Formulation of the 2021 Diagnostic Imaging Guidelines

As with the previous edition (2016 edition), I was appointed a committee chair and engaged in formulating the guidelines. In the 5 years since the previous edition was published, there have been several developments that have had a major impact on the context in which clinical practice guidelines are developed. First, to ensure consistency among the guidelines proposed by the various academic societies, the Japanese Association of Medical Sciences established a clinical practice guidelines management committee, and the societies were required to coordinate their efforts in developing clinical practice guidelines. One aspect of this was disclosing any conflicts of interest on the part of committee members who develop clinical practice guidelines and setting forth a policy stipulating that individuals with commercial conflicts of interests in excess of what is allowed should not serve as a chairperson or member of a guidelines development committee. With regard to the present guidelines, the Japan Radiological Society was notified of the presence or absence of any conflicts of interest held by the individuals who developed the guidelines, and this information was publicly disclosed on the society's website. Another aspect was consolidating the target readership of the clinical practice guidelines. During management committee meetings, the decision was made to target the guidelines at physicians belonging to key academic societies. The previous edition of the diagnostic imaging guidelines was aimed at diagnostic radiology specialists and was developed to serve as a guide for radiologists who provide advice on the usefulness of an imaging procedure when one was requested in the clinical setting. However, the present edition is aimed at physicians affiliated with key academic societies and was developed to serve as a guide when requesting an imaging procedure. In other words, the previous guideline has been changed to information that is more suitable for the medical treatment site.

Moreover, in the previous edition, the recommendation grades took into account evidence-based medicine (EBM) levels based on the MINDS Manual for Guideline Development 2007. For the present edition, a 4-step assessment was performed incorporating the GRADE system (explained in Overview section 2, Preparing the Diagnostic Imaging Guidelines) for the clinical questions (CQs), based on the MINDS Manual for Guideline Development 2017. In the previous edition, grade C1, "procedure recommended, although there is no scientific basis for performing it," was the most common grade, and this was limited to assessments indicating that the procedure could be performed because adequate evidence was lacking. In the present edition, many of these assessments were changed to "weakly recommended" under the GRADE system. In brief, this was because it enabled the assessments to reflect not only the evidence, but also the clinical importance of the procedure.

The many physicians on the subcommittees for the different fields expended considerable effort in developing the present guidelines, starting with the numerous training sessions on the GRADE system held at the headquarters of the Medical Information Distribution Service (MINDS) and extending to development of the background questions (BQs), clinical questions (CQs), and future research questions

(FQs) for each field. In addition, the physicians on the central committee, particularly Dr. Masako Kataoka of Kyoto University and Dr. Yuko Iraha of the University of the Ryukyus, oversaw all aspects of the preparation of the guidelines, from inception to publication. Furthermore, assistance was provided through the publication stage by the physicians who served as advisors, those from other academic societies who provided assessments as outside committee members, and many other physicians. We are deeply grateful to everyone involved.

September 2021

Sadayuki Murayama

Chair, Clinical Practice Guidelines Committee, Japan Radiological Society

Overview of the 2021 Diagnostic Imaging Guidelines

1 Purpose of the guidelines

The purpose of these guidelines is to help ensure that medical care that uses diagnostic imaging is provided effectively, efficiently, and in a manner that benefits the patient in terms of outcomes. The guidelines are based on evidence-based medicine (EBM; i.e., using the latest and best evidence in making diagnostic imaging decisions for the individual patient in a conscientious, clear, and prudent manner) related to diagnostic imaging performed in a variety of fields. Indications for diagnostic imaging and the effectiveness of diagnostic imaging, particularly standard imaging methods, are discussed in detail.

2 Revisions

The diagnostic imaging guidelines were prepared based on EBM methods by the Japanese College of Radiology in 2003 and as a joint project by the Japan Radiological Society and Japanese College of Radiology in 2007 and 2013. Since the 2016 edition ("previous edition" below), the Japan Radiological Society has assumed responsibility for the project and prepared the guidelines based on the MINDS Manual for Guideline Development 2007. The 2021 edition ("present edition" below) represents a major revision that, based on the MINDS Manual for Guideline Development 2017,[2)] incorporates the GRADE system.[3)] The standard imaging methods for each field were updated with the addition of the 3T-MRI and 64-row CT imaging methods. Moreover, in addition to the 9 fields covered in the previous edition, new sections were created for the fields of pediatrics and hematology. Through the previous edition, the target audience was diagnostic imaging specialists. However, the present edition was created with physicians affiliated with key academic societies in mind.

3 Intended users

In developing the present edition, an effort was made to ensure that the content is easy to use for physicians affiliated with the key academic societies, as well as for those who specialize in diagnostic imaging (specialists). It was also intended as a reference for paramedical staff such as radiology technologists.

4 Usage notes

The guidelines strictly represent the guidance considered standard when they were developed. They do not regulate actual medical practice, and they should be used flexibly and in a manner that takes into account the healthcare environment (personnel, experience, facilities, etc.) and the individual patient.

Although the academic society assumes responsibility for the content of the guidelines, responsibility for treatment outcomes lies with those directly providing the medical care. Neither the Japan Radiological Society nor the members of the guidelines development committee bear any responsibility for such outcomes. Use of the guidelines as examination criteria for health insurance or as reference material in medical practice disputes or medical lawsuits would be an obvious deviation from the purpose of clinical practice guidelines.

5 Organization of the present edition and the formulation process

As was mentioned above, the first edition of these guidelines was published in 2003, and revisions have since been made as appropriate. The guidelines, which cover all areas where diagnostic imaging is used, are organized according to 11 fields (14 fields when the digestive organs field is subclassified): neuroradiology, head and neck, chest, cardiovascular, digestive organs (liver, hepatobiliary, pancreas, and gastrointestinal tract), uroradiology, obstetrics and gynecology, breast, musculoskeletal, pediatrics, and hematology. Since the previous edition, the organization responsible for preparing and revising the guidelines has been the Japan Radiological Society, with the society's standing diagnostic imaging guidelines committee actually preparing and revising the guidelines. The guidelines committee consists of central committee members who coordinate and assist in all fields and 14 subcommittees, one for each field.

In implementing the present revision, new committee members were appointed, and the work began in April 2018. At the first guidelines committee meeting (April 2018), the decision was made to prepare the guidelines based on the GRADE system,[3)] which was recommended by the EBM promotion program (MINDS) being implemented by the Japan Council for Quality Health Care. Subsequently, through May 2019, approximately 100 committee members participated in on-demand seminars on preparing clinical practice guidelines organized by MINDS, where they learned about the process of preparing CQs using the GRADE system. At the fourth meeting of the guidelines committee (June 2019), it was decided that each subcommittee would reorganize the 171 CQs of the previous edition by dividing them into CQs, BQs, and FQs and retaining or discarding items or creating new CQs, BQs, and FQs as necessary (see Overview section 2, Developing the diagnostic imaging guidelines). The final CQs, BQs, and FQs for each area were determined by the fifth meeting of the guidelines committee (October 2019). The members of each subcommittee responsible for BQs and FQs began writing, adding articles published through June 2019 to the cited references. However, if an article published after June 2019 provided important findings that were related to a recommendation grade, it was added as appropriate at the discretion of the subcommittee members. The previous edition provided the evidence level proposed by the Oxford EBM Centre for each cited reference. In the present edition, however, because the quality of evidence grade based on the GRADE system[3)] was used (see next section 6), the evidence level for each cited reference was not indicated to avoid confusion. CQ-related literature searches were performed

using the PubMed database, with the assistance of the Japan Medical Library Association. The period searched was January 1, 2016 to June 30, 2019. If the search results were inadequate, the search queries were modified, and additional searches were performed by each subcommittee. The subcommittee members responsible for systematic reviews (SRs) of the CQs selected by each subcommittee participated in an SR workshop for the radiological society (February 2020) organized by Cochrane Japan in order to gain an understanding of the specific tasks involved in SRs. Substantive SR work began in August 2020, when the Japan Medical Library Association finished collecting literature. Between January 2021 and March 2021, the subcommittees met to determine recommendation grades (all meetings held online due to the coronavirus pandemic) and decided on the grade for each CQ. The designated subcommittee members wrote the CQ explanations based on these decisions.

6 Strength of Recommendation, quality of evidence grade (strength), and agreement rate based on the GRADE system

The recommendation strength in the present edition determined the degree to which a procedure was recommended. It was based not only on the scientific evidence presented in the previous edition, but also factors such as the balance between the benefits and harms that result from intervention in routine clinical practice, the consistency of the patients' wishes, and economic considerations. The strength of the evidence was rated on a 4-step scale according to the MINDS Manual for Guideline Development 2017,[2)] with the Clinical Practice Guidelines for Breast cancer 2018 used as a reference (Table 1).[4)] The strength ratings roughly correspond to the recommendation grades of A, B, C1, C2, and D that were used through the previous edition. In the text of the recommendations, the quality of the evidence was indicated according to 4 steps: high, moderate, low, and very low (Table 2). For all of the outcomes specified for each CQ, the recommendation is considered strong in proportion to the strength of the overall evidence. Conversely, the recommendation is considered weak in proportion to the weakness of the evidence. The quality of evidence reflects the extent to which our confidence in an estimate of the effect is adequate to support a particular recommendation.

The reason for indicating the agreement rates (%) in the meetings held to determine recommendations is that a recommendation grade of "weakly recommended," for example, would have different implications if the agreement rate were 100% than if it were 73%. The authors hope that the users will understand that a small number of panel members were leaning toward strongly recommending the procedure or toward weakly recommending not performing it, and to refer to it as useful information in actual diagnostic intervention. In addition, knowing whether the decision was made with a single vote or if agreement was reached after multiple votes enables the user to understand whether there are differences of opinion. In other words, when shared decision-making is practiced in the clinical setting, it would be preferable to share with the patient the fact that there are differences of opinion among specialists before determining the ultimate means of intervention. If agreement was not reached after 3

votes, “agreement not reached” was indicated for the agreement rate. Because the agreement rate indicates where opinions diverged, the authors hope that the users will refer to such information in determining the means of intervention.

Table 1. Strength of Recommendation

Recommendation Strength	Recommendation Text	Recommendation Grade in Previous Edition
1	Strongly recommend performing	A
2	Weakly recommend performing	B, C1
3	Weakly recommend not performing	C2
4	Strongly recommend not performing	D

When both performing and not performing were difficult to recommend, “no recommendation” was indicated.

Table 2. Quality of Evidence Grades (strength) for a recommendation

A: High	We are very confident that the true effect lies close to that of the estimate of the effect.
B: Moderate	We are moderately confident in the effect estimate.
C: Low	Our confidence in the effect estimate is limited.
D: Very Low	We have very little confidence in the effect estimate.

7 Third-party evaluations

In implementing the present revision, third-party evaluations were obtained by sending a draft indicating the standard imaging methods, BQs, CQs, and FQs for each field to the academic societies listed in the third-party evaluation list provided below. For the previous edition, a post-publication third-party evaluation was obtained from MINDS, and a post-publication third-party evaluation will continue to be obtained from MINDS for each revision.

8 Funding sources

The Japan Radiological Society bears the entire cost of preparing and revising these guidelines; no outside funding is provided.

9 Conflicts of interest (COIs)

Publication of these guidelines is approved by the Japan Radiological Society, and the society bears the entire cost of preparing and revising the guidelines. No outside funding whatsoever, such as grants or research funding, has been accepted. In accordance with the society’s COI rules, the conflict-of-

interest status of all committee members involved in preparing the guidelines (members of the central committee and subcommittees and outside committee members) was determined for the previous 3 years. When voting took place in meetings to determine recommendations, the members self-reported any COIs (economic or academic). If a member was disqualified due to a COI, the member abstained from voting on that CQ in an effort to avoid biased opinions. The COI status of each committee member is indicated on the Japan Radiological Society website (http://www.radiology.jp/).

10 Future plans

The guidelines will be published in print by Kanehara & Co., Ltd. and subsequently released on the Japan Radiological Society website.

1) MINDS Clinical Practice Guidelines Selection Working Group, Ed.-in chief: MINDS Manual for Guideline Development 2007. Igaku-Shoin Ltd., 2007.
2) Kojimahara N, et al., Ed.: MINDS Manual for Guideline Development 2017. Japan Council for Quality Health Care, 2017.
3) GRADE: The grading of recommendations assessment, development and evaluation (https://www.gradeworkinggroup.org)
4) The Japanese Breast cancer Society Clinical Practice Guidelines for Breast cancer 2018

Guidelines Development Committee Members

Indicated in Japanese syllabary order for each field

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Third-Party Evaluators

In implementing the present revision, third-party evaluations were obtained by sending a draft indicating the standard imaging methods, BQs, CQs, and FQs for each field to the academic societies listed below. We are deeply indebted to the physicians who were involved in this effort.

The Japan Neurosurgical Society.

Japanese society of neurology

Japanese Society of OtoRhinoLaryngology-Head and Neck Surgery

Japan Society for Head and Neck Cancer

The Japanese Circulation Society

The Japanese Society for Vascular Surgery

The Japanese Respiratory Society

The Japan Lung Cancer Society

The Japan Society of Hepatology

Japan Liver Cancer Association

Japan Biliary Association

Japan Pancreas Society

The Japanese Urological Association

Japanese Breast Cancer Society

The Japanese Orthopaedic Association

The Japan Society of Gynecologic Oncology

The Japan Society of Obstetrics and Gynecology

Japan Pediatric Society

The Japanese Society of Child Neurology

The Japanese Society of Pediatric Surgeons

Japanese Society of Hematology

(legal status omitted)

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11 Nuclear Medicine and Hematology

Abbreviations

Abbreviation	Full Term in English
ADC	apparent diffusion coefficient
AUC	area under the curve * Unless otherwise indicated, the AUC is obtained from ROC analysis in this guideline.
BQ	background question
CHESS	chemical-shift selective
CI	confidence interval
CQ	clinical question
CT	computed tomography
CTA	computed tomography angiography
EOB-MRI	Gd-EOB-DTPA enhanced MRI
EPI	echo planar imaging
ERCP	endoscopic retrograde cholangiopancreatography
ERP	endoscopic retrograde pancreatography
ETL	echo train length
EUS	endoscopic ultrasonography
FA	flip angle
FDG	fluorodeoxyglucose
FLAIR	fluid attenuated inversion recovery
FOV	field of view
FQ	future research question
FSE	fast spin echo
Gd-EOB-DTPA	gadolinium ethoxy-benzyl diethylene triamine penta-acetic acid
GRE	gradient echo
HASTE	half-Fourier single-shot turbo spin echo
HRCT	high-resolution computed tomography
HU	Hounsfield unit
IR	inversion recovery
MDCT	multi-detector row CT
MIBG	meta-iodobenzylguanidine
MIP	maximum intensity projection
MPR	multi planar reconstruction
MRA	magnetic resonance angiography
MRCP	magnetic resonance cholangiopancreatography

Abbreviation	Full Term in English
MRI	magnetic resonance imaging
NEX	number of excitations
PET	positron emission tomography * Unless otherwise indicated, ^{18}F-FDG is used for PET and PET/CT in this guideline.
ROC	receiver operating characteristic
SAR	specific absorption rate
SE	spin echo
SNR	signal-to-noise ratio
SPAIR	spectral attenuated inversion recovery
SPECT	single photon emission computed tomography
SPIR	spectral inversion recovery
SROC	summary receiver operating characteristic
SSFP	steady-state free precession
SSFSE	single shot fast spin echo
STIR	short TI inversion recovery
SUV	standardized uptake value
T	tesla
TE	echo time
TR	repetition time
VR	volume rendering
WL	window level
WW	window width