General Remarks

1 Evidence-Based Imaging Test Selection

Introduction

One approach to clinical diagnosis is the probabilistic approach (hypothetico-deductive method). With this approach, diagnosis involves establishing a pre-test probability for each differential diagnosis based on a clinical evaluation (history of present illness and physical findings), then calculating a post-test probability based on the test results. These steps constitute the procedure for evidence-based diagnostic procedures, and much has been written about them in recent years.[1-3] The approach of diagnostic inference is also currently becoming more widely adopted and being practiced by medical students and during the training of medical residents. It is hoped that diagnostic imaging and test selection based on theory will be practiced by many clinicians in the future and result in optimal and rapid diagnosis.

Evidence-based imaging test selection

The concept of testing and treatment thresholds is used in determining whether a test is indicated (Fig. 1). This is the idea that a test is first indicated if the diagnosis or treatment plan would change based on the test results. Before a test is requested, it is important to estimate the pre-test probability, gain an understanding of the characteristics of the test to be requested, and consider whether the test is indicated by taking into account factors such as whether a decision to begin treatment will be made and whether a differential diagnosis can be excluded based on the results. This will likely reduce the number of unnecessary screening tests and confirmatory tests performed just to be safe. Test or treatment thresholds vary greatly depending on the risk of procedures, (high thresholds for highly invasive tests and treatments, low thresholds for tests and treatments that are easy to administer, inexpensive, and minimally invasive). Consequently, whether a test is indicated is based on whether the diagnosis or treatment will change depending on the test results. As a specific example, consider coronary artery CT. If the patient is a young adult with no risk factors and no symptoms suggestive of ischemic heart disease (pre-test probability close to 0) but is concerned about angina pectoris and wishes to have a CT test, considering the radiation exposure from coronary artery CT, the possibility of an adverse reaction to the contrast agent, and the cost of the test, the risks of testing would outweigh the benefits, and the test would therefore not be indicated. On the other hand, if the patient had anginal pain, and angina pectoris was suspected based on electrocardiography, percutaneous coronary intervention (PCI) would be indicated regardless of the CT results (treatment threshold is exceeded). A CT test would therefore be unnecessary, because a catheter intervention ought to be selected from the outset. Thus, coronary artery CT would be most strongly indicated for patients at moderate risk.

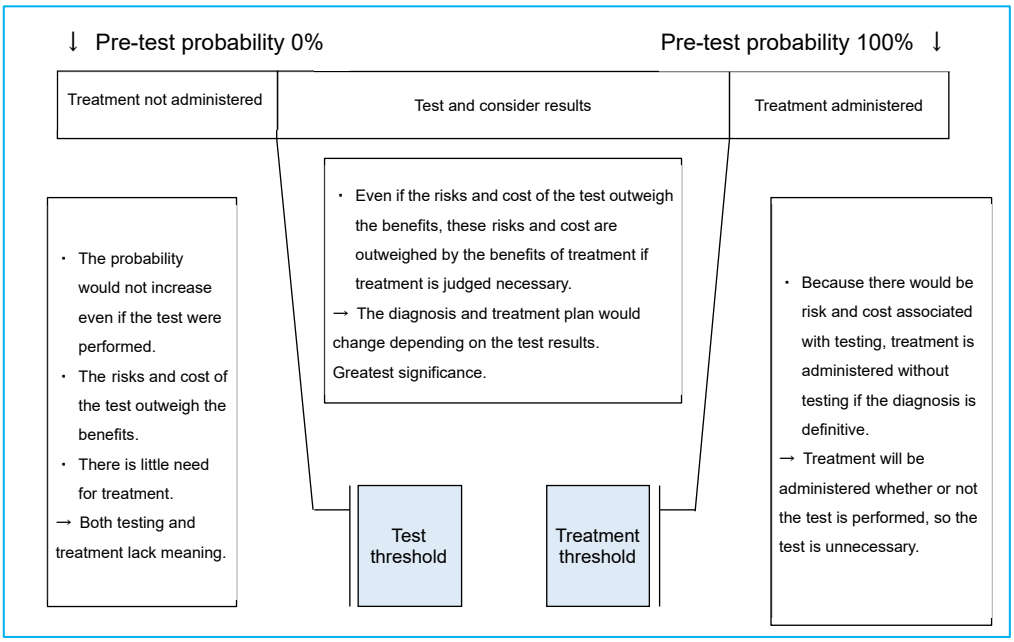

Figure 1. Test and treatment thresholds

The Japanese Circulation Society's diagnostic guidelines for chronic coronary artery disease (2018 revised edition) indicate the testing recommendation grades for each condition.[4)] However, many of the items are assigned a recommendation class of III (not useful; see table), and whether a test is indicated needs to be considered according to the condition (recommendation classes: I. there is evidence or a broad consensus that the procedure or treatment is effective and useful; II. the evidence and opinions regarding the effectiveness and usefulness of the procedure or treatment are inconsistent; IIa. based on the evidence and opinions, it is highly likely that the procedure or treatment is effective and useful; IIb. the effectiveness and usefulness of the procedure or treatment are not well established by the evidence and opinions; III. the procedure or treatment is not effective or useful, and there is evidence or a broad consensus that it is occasionally harmful.)

Diagnostics is the process through definitive diagnosis in patients undergoing initial examination. Currently, many imaging procedures are performed as a treatment adjunct (e.g., surgery support) and to evaluate treatment efficacy; these procedures need to be considered separately from those performed for initial diagnosis.

Table　Recommendations and evidence levels for coronary artery CT

1)　If asymptomatic

	Recommendation Class	Evidence Level	MINDS Recommendation Grade	MINDS Evidence Classification
Risk stratification based on coronary artery calcium score (CACS)				
No chest pain, low CAD risk group	III	C	C2	VI
No chest pain, moderate CAD risk group	II a	A	B	II
No chest pain, high CAD risk group	II a	A	B	II
Stenotic vessel(s) detected by X-ray CT				
No chest pain, low CAD risk group	III	C	C2	VI
No chest pain, moderate CAD risk group	III	C	C2	VI
No chest pain, high CAD risk group	II b	C	C1	VI

2)　If angina pectoris or CAD suspected based on clinical presentation

	Recommendation Class	Evidence Level	MINDS Recommendation Grade	MINDS Evidence Classification
Stenotic vessel(s) detected by X-ray CT				
If chest pain is present, low CAD risk group, and exercise is difficult or exercise ECG is difficult to evaluate	I	A	A	I
If chest pain is present, moderate CAD risk group, and exercise is difficult or exercise ECG is difficult to evaluate	I	A	A	I
If chest pain is present, high CAD risk group, and exercise is difficult or exercise ECG is difficult to evaluate	II a	B	B	II
If coronary spastic angina is strongly suspected	III	C	C2	VI
If unstable angina/non-ST-elevation myocardial infarction is suspected				
Low-to-moderate risk group (no ECG changes, blood chemistry tests negative)	II a	B	A	II
High-risk group (ECG changes present, blood chemistry tests positive)	III	C	D	VI

3)　Combination with other tests

	Recommendation Class	Evidence Level	MINDS Recommendation Grade	MINDS Evidence Classification
Coronary artery CT as a combined test				
If exercise ECG evaluation is difficult	I	A	B	III
When stress MPI indicates mild perfusion abnormality or is difficult to evaluate	II a	B	B	III
Myocardial ischemia detected by stress CTP				
When coronary artery CT is difficult to evaluate or indicates stenosis of moderate or greater severity	II a	B	B	II
Myocardial ischemia diagnosed by stress CTP alone	II a	B	B	II
Infarct imaging by late imaging				

As alternative method if SPECT or MRI cannot be performed	II b	C	C1	IVa

4) Other scenarios in combination with other tests

	Recommendation Class	Evidence Level	MINDS Recommendation Grade	MINDS Evidence Classification
Examination for coronary lesions as cause of heart failure	II b	B	C2	VI
Follow-up after revascularization				
Post-CABG evaluation	II a	B	B	I
Post-PCI (> 3-mm stent)	II a	B	B	IVa
Post-PCI (≤ 3-mm stent)	II b	B	D	IVa
Evaluation of sites of percutaneous old balloon angioplasty (POBA), directional coronary atherectomy (DCA), or rotablator treatment	II a	B	C1	VI
Preoperative evaluation for cardiac great vessel surgery	II a	B	B	IVb
Preoperative evaluation for noncardiac surgery	II b	C	C2	IVb
Kawasaki disease coronary lesion (aneurysm)	II a	C	C1	IVb
Congenital coronary artery malformation	I	B	B	I
Screening test during health checkup	III	C	C2	VI

Japanese Circulation Society: JCS 2018 Guideline on Diagnosis of Chronic Coronary Heart Diseases, https://www.j-circ.or.jp/cms/wp-content/uploads/2020/02/JCS2018_yamagishi_tamaki.pdf (accessed on July 1, 2020)
http://www.j-circ.or.jp/cms/wp-content/uploads/

In addition, one approach for reducing unnecessary tests is to promulgate clinical prediction rules concerning test indications. Specific examples include the Canadian Assessment of Tomography for Childhood Head injury (CATCH rule)[5] for determining whether CT is indicated for childhood head injuries and the Ottawa Ankle Rules[6] for minor trauma. If numerous clinical studies are conducted using these clinical prediction rules, and studies that provide strong evidence accumulate, it may become possible to use the rules effectively to limit the number of patients who require tests. In Japan, few studies of clinical prediction rules have been conducted. It is expected that many such studies will be conducted and evidence accumulated in the future.

Evidence-based differential diagnosis

This method involves estimating the pre-test probability based on symptoms and physical findings and calculating the post-test probability based on the test results. That calculation is performed as shown below using the likelihood ratio for each test.

post-test odds[*1] = pre-test odds × likelihood ratio[*2]

[*1] Odds: The ratio of the probability of an event happening to that of a different event. It is calculated as follows: odds = probability / (1−probability). For a probability of 10%, the odds would be 0.1 / (1−0.1) = 0.101. For a probability of 50%, the odds would be 0.5 / (1−0.5) = 1.

[*2] Likelihood ratio: expresses how many fold a positive test result increases the pre-test odds to reach the post-test odds. It is calculated as follows: likelihood ratio = sensitivity / (1−specificity).

In considering a differential diagnosis, it is important to understand whether the pre-test probability (odds) can be correctly predicted and the characteristics of the test. Broadly speaking, the characteristics of tests are of the following 2 types, and their use needs to be distinguished according to the circumstances, such as when a definitive diagnosis or diagnosis of exclusion is desired.

Sensitive/negative rule out (SnNout): If the result of a highly sensitive test is negative, the condition can be ruled out.

Specific/positive rule in (SpPin): If the result of a test with high specificity is positive, it can be considered definitive.

If the likelihood ratio for a test is ≥ 10 or ≤ 0.1, the result will be a large and often conclusive change from the pre-test probability to the post-test probability. The likelihood ratio for a test with sensitivity and specificity of 90% each would be calculated as follows: likelihood ratio = 0.9 / (1−0.9) = 9. Therefore, a test with equal or greater sensitivity and specificity would be highly useful in differential diagnosis. Conversely, in the case of a test with a low likelihood ratio, a result based on the pre-test probability is often the only result, and the characteristics and purpose of the test must therefore be carefully considered.

In diagnostic imaging, a high diagnostic accuracy rate is required for diseases in which a diagnosis is established based on imaging findings (e.g., aneurysm, artery dissection), regardless of the pre-test probability.

New tests

As advances are made in diagnostic imaging systems, the number of new tests and imaging methods is increasing by the day. The relationship between the new tests and existing tests was summarized by Bossuyt et al., as shown in Fig. 2.[7)]

As the figure indicates, the circumstances in which a new test emerges and the number of tests does not increase are the replacement or triage scenarios, which effectively reduce the number of subsequent tests. Currently, many new tests are thought to be add-on tests. Although it is important to increase findings with new tests, clinical studies are needed in order to accumulate the evidence needed to determine whether performing new tests reduces the number of other tests.

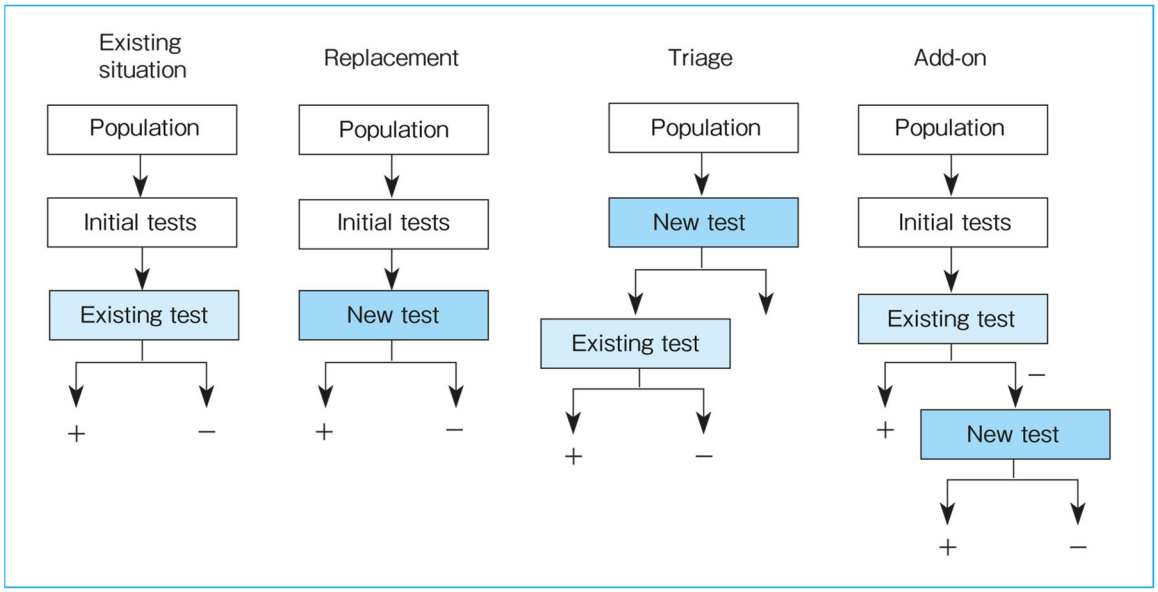

Figure 2. Relationships between indications for new tests and existing tests (excerpted from reference 7).

Secondary source materials used as references

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5) Osmond MH et al: CATCH: a clinical decision rule for the use of computed tomography in children with minor head injury. CMAJ 182 (4): 341-348, 2010
6) Bachmann LM et al: Accuracy of Ottawa ankle rules to exclude fractures of the ankle and mid-foot: systematic review. BMJ 326 (7386): 417, 2003
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2 Developing Diagnostic Imaging Guidelines

The concept behind the new clinical practice guidelines

As indicated in the preface of the guidelines, the present diagnostic imaging guidelines were developed based on the MINDS Guide for developing Clinical Practice Guidelines issued in and after 2014.[1,2] The method used to develop clinical practice guidelines has advanced continuously. A significant difference from the previous method is the introduction of the GRADE (grading of recommendations assessment, development and evaluation) system, a relatively new method of guideline development.[3] In the current version, we changed the target audience from board-certified diagnostic radiologist specialists to general practitioners, who order imaging procedures.

Moreover, the definition of clinical practice guidelines shifted from "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances"[4] to "statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options." Thus, this definition clarified several key concepts such as the SR, overall evaluation, and balancing benefits and harms.[1] In the area of therapeutic options, guideline development based on the GRADE system has been established, while in the diagnostic options, guideline development is still in its early days with trials and errors. A small number of GRADE-based clinical practice guidelines, such as the clinical practice guidelines for breast cancer (diagnosis and epidemiology volumes) were used as references[5].

Forming clinical questions (CQs)

The CQs represent important points for decision-making by patients and healthcare personnel (more accurately, determine key clinical issues, and extract the components of questions that should be addressed) that consist of the following components.

- P: The patient situation, population, or problem of interest
- I/C: The main intervention and a comparison intervention
- O: The clinical outcome (benefits and harms)

The new method of guideline development emphasizes the balance between benefit and harm.[1,2] Benefit refers to the anticipated effectiveness. Examples of harm include adverse events, the cost burden, and the physical and mental burden. Outcome encompasses both benefit and harm.

The previous diagnostic imaging guidelines (2016 edition) included a total of 171 CQs. Because it would be difficult to re-examine all of the CQs based on the new method, and because they included indisputable

information that could be regarded as standard and questions that, although important, had little supporting evidence, we decided to follow the above-mentioned clinical practice guidelines for breast cancer and organize the CQs of the previous edition accordingly. Questions that could be regarded as standard information and test methods were classified as background questions (BQs), and those for which there were insufficient data to raise them as CQs, but that were considered important issues for the future, were classified as future research questions (FQs). The remaining CQs were controversial ones. For these CQs, quantitative or qualitative SRs were performed based on evidence, and recommendations were determined after voting took place in the panel meeting. This process was conducted at the start of the development of the guidelines and then repeated during the course of the work. Depending on the amount and consistency of the evidence obtained, original CQs were changed to FQs.

An SR is a comprehensive review of the research that pertains to CQs, in which studies of the same type are summarized, analyzed, and integrated while risk of bias is assessed. The steps involved evaluating the individual studies, then evaluating the summarized results as the body of evidence.

Appraisal of diagnostic imaging studies

Under the conventional view focusing on treatment research of the primary source of evidence, evidence from randomized, clinical trials (RCTs) was considered the strongest, and that from cross-sectional studies, which many studies of diagnostic imaging are classified, was regarded as relatively weak. With the new method of developing guidelines, secondary studies such as properly performed meta-analyses are given higher standing. Those showing a high probability of effectiveness and a large effect are considered correct, and if multiple studies show an effect in the same direction, the findings are regarded as having a high probability of being correct. The fact that cross-sectional studies are not considered to be of lower quality can be considered an advantage for the field of diagnostic imaging.

The steps to a recommendation

The steps involved in developing clinical practice guidelines are indicated in Fig. 1. For the CQs, an SR plays an important role. In the SR, a comprehensive review of the research is performed, and studies of the same type are analyzed and integrated while bias is assessed.

The SR involves a rigorous standardized comprehensive search and critical appraisal of peer-reviewed articles related to specific health problems (clinical questions). The evidence based on an SR is superior to that based on individual studies because: (1) the risk of bias is reduced; (2) suitable to see overall trends and variability; and (3) the evidence level is higher than with individual studies. However, it should be kept in mind that these advantages depend on the quality of the articles used. An SR is not always the same as a meta-analysis. A meta-analysis refers to a statistical method of integrating data from multiple studies and the article written following this method, alternatively referred to as a quantitative SR. It is an effective

method when the individual studies, even if small, show a similar trend, and significant differences are seen when the data from the studies are integrated. It is also useful for detecting publication bias, which occurs when only studies with positive results are published. However, integrating the data is meaningless if the number of studies is small, with small sample sizes, with wide variability, or with studies of inconsistent quality. In such cases, the more appropriate method is a qualitative SR, in which no meta-analysis is performed, but rather the data from each original study are shown and summarized.

1. Procedure for performing an SR

The SR process can be divided into the 4 steps shown in Fig. 2 (1) to (4) below.

① Literature search and screening

The literature search was based on PubMed and used sources such as the Cochrane Database, and the guidelines of relevant academic societies in Japan and other countries were used as secondary sources. Because keywords related to articles on diagnostic imaging do not necessarily have a high rate of coverage by MeSH terms, concurrent hand searches of citations from guidelines and reviews were also performed in parallel. The individuals in each field subcommittee who were responsible for CQs and SRs selected the CQs, example search queries, keywords, and important articles, supported by the specialist from the Japan Medical Library Association in performing a comprehensive literature search, which yielded a list of several hundred references. The individuals responsible for SRs then reviewed the titles and abstracts and narrowed down the candidate articles

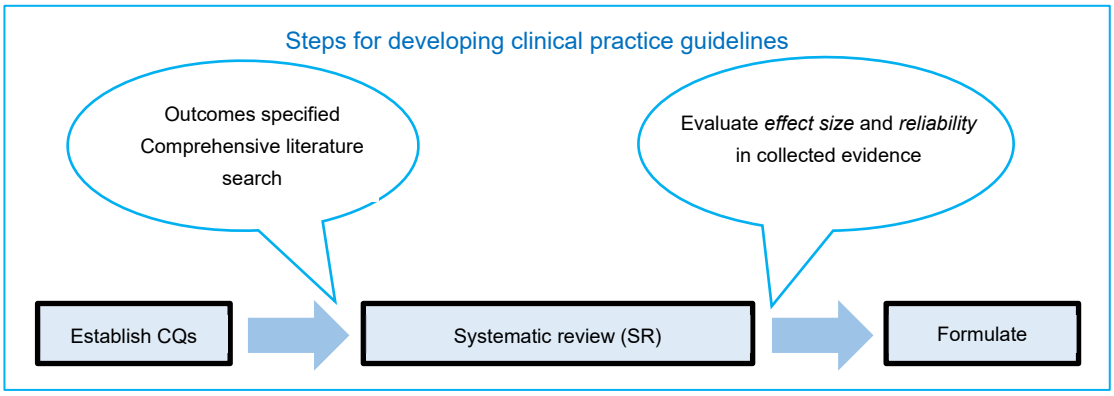

Figure 1. Steps for developing clinical practice guidelines

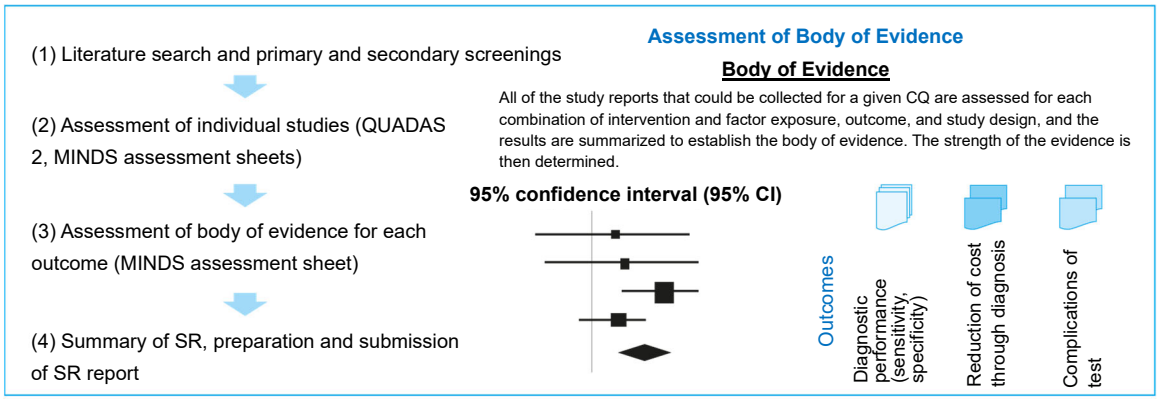

Figure 2. The 4 steps of the SR process

② Assessment of individual studies

The assessment of individual studies involves reading each article and assessing the reliability of the evidence. The evaluated points are as follows:

- Risk of bias: e.g., selection bias;
- Indirectness = external validity/generalizability: Differences between study populations (e.g., original CQ concerns the Japanese population, and the evidence is data from the American population); Inconsistency: variability seen in effect depending on the report;
- Imprecision: small sample size and wide confidence intervals;
- Other types of bias: e.g., publication bias.

Using the QUADAS 2 assessment sheet (revised tool for the Quality Assessment of Diagnostic Accuracy Studies 2)[6], these points were assessed for the individual studies, and the results were recorded on a sheet for individual studies, shown below (Fig. 3).[7]

③ Assessment of the body of evidence

This process involves assessing the evidence for each outcome while referring to the assessment sheets for individual studies. Although many of the main items also apply to individual studies, the main points of this assessment are those such as the consistency of the outcomes. If necessary, a meta-analysis is performed, and the results for the integrated data are examined for any significant differences.

④ SR report preparation

An SR report is written in light of the above-mentioned results. The report is prepared according to the template provided on the MINDS website.

2. Formulating recommendations

The summarized recommendations are formulated with reference to the SR report. In the case of a CQ, the aim at this stage is to form a consensus regarding the final recommendation. During this process, a panel meeting is held to gain an understanding of the report and ask questions, and assess the balance of benefits and harms (Fig. 4). However, different from the previous conference system, methods for determining the recommendation by a vote, such as the Delphi process, which more fairly reflects the opinions held, are currently being promulgated. In this way, recommendations are finally determined at the 4 levels indicated below.

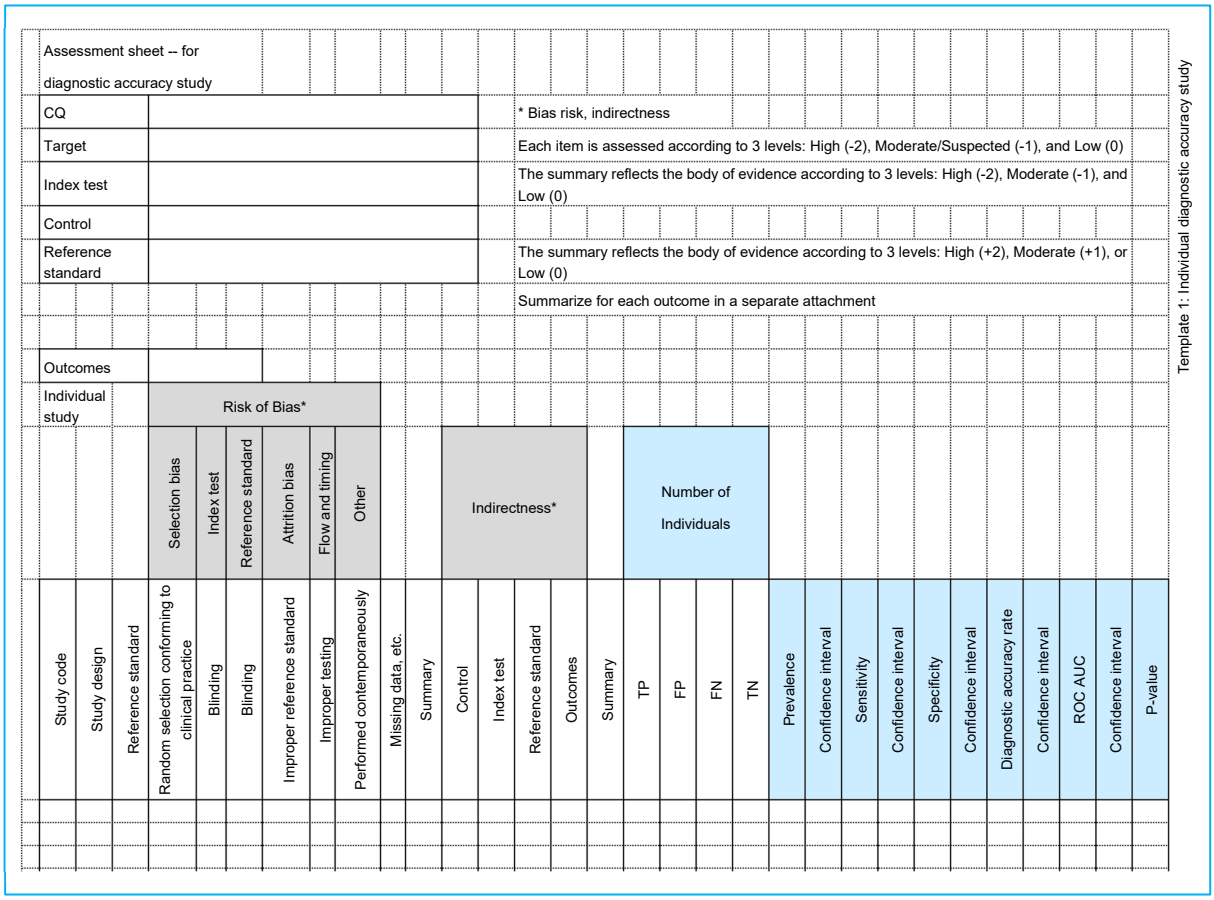

Figure 3. Individual study assessment sheet

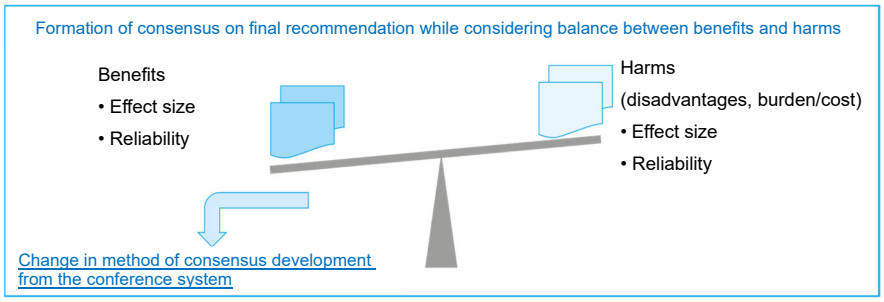

Figure 4. Determination of recommendation that takes into account balance between benefits and harms

- Strong recommendation: perform
- Weak recommendation: perform
- Weak recommendation: do not perform
- Strong recommendation: do not perform

Purpose of panel meeting

Based on the results of the SR conducted for the CQ, a statement of the following form is established: "performing XX is strongly/weakly recommended." Following discussion, an anonymous vote is ultimately taken. In view of the specialized nature of each field, voting on the diagnostic imaging guidelines was conducted at the level of the subcommittee for each field. In addition, 1 or 2 general practitioners associated with each field (non-diagnostic radiologists) were asked to participate in the discussions so that adequate consideration was given to comprehensibility and validity from the perspective of the clinician. Specifically, the following provisions were adhered to during the process.

1. Voter requirements

(1) Qualified as a voter (varies depending on the CQ)

• Not a committee member involved in the SR

• Outside committee member

(2) Unqualified as voters (varies depending on the CQ)

• An individual involved in the SR

• An individual with a COI (including academic COIs)

2. Requirements for a meeting to serve as a venue for discussion to establish recommendation ("panel meeting" below)

The participants are voters, non-voters, and the individual(s) who developed the SR (in the case of multiple individuals, one can participate as a representative). The meeting can be held online.

3. Panel meeting

A common understanding of the SR results is established, and any unclarified issues are resolved. Aspects such as any negative effects and social impacts of the test not covered in the SR are also discussed. After the meeting concludes, an anonymous vote is taken.

- If either choice (perform/do not perform) receives half or more of the vote, and the other choice receives less than 20% of the vote, the former choice is recommended.
- If agreement of 70% or greater is reached in the vote, the strength of the recommendation is determined.
- If agreement of 70% or greater is not reached, the results are announced, and a revote is taken.
- Up to 2 revotes are taken. If that is insufficient to come to a decision, the judgement is “no recommendation.”

Due to restrictions on mobility related to the COVID-19 pandemic, all meetings related to the 23 CQs in 8 areas on the current revision were held online, in accordance with the above-mentioned provision. Outside committee members also participated. In fact it was easier to adjust the schedule online. Although the meetings placed heavy demands on the field committee chairs and the individuals in charge of SRs, they allowed the views of outside committee members to be heard directly, allowing these views to be reflected when preparing the text of the recommendations.

Acknowledgments

Finally, many experts provided advice during the development of the present guidelines, which used a new method that incorporated the GRADE system. Specifically, they were the individuals indicated below. We are deeply grateful for their assistance.

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Hiroji Iwata and Takayoshi Uematsu from the Japanese Breast cancer Society

The experts responsible for the guidelines of the Japan Society of Clinical Oncology

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3 CT and MRI in the Radiological and Medical Services in Japan

The efficiency of healthcare services in Japan

When the quality of medical services in Japan is measured by international rankings, I am probably not the only one who is embarrassed by the magnitude of variation in the ranking among items. Medical services in Japan have made remarkable achievements in mean life expectancy and in the infant mortality rate, which are among the best in the world. People's access to medical services is generally satisfactory. Despite some regional differences, patients in urban regions can access any medical organization's department at a low cost. Such superficial achievements are often cited as grounds for justification of the status quo, but favorably evaluating the whole based on selected items with good results permanently denies opportunities to reform weaknesses. In reality, data that question the efficiency of medical services in Japan are abundant. First, concerning the cost, the number of visits to medical facilities per patient is the highest in Japan (Fig. 1). It has the highest number of hospital beds (Fig. 2),[Footnote1] and the cost of drug prescriptions as a percentage of medical expenditures is in the higher bracket (Fig. 3). In terms of the number of CT/MRI systems per capita, Japan ranks 1st in the world, towering above other countries (Fig. 4A, B). As a result, it has been noted that medical radiation exposure is conspicuously high among the OECD member countries (discussed later). On the other hand, the number of CT/MRI tests per system is the lowest among the Group of Seven industrialized nations.[2)] If Japan's total medical expenditure per population is still relatively low despite such inefficiency (Fig. 5), it would be natural to think that it is due to low unit prices of medical services.

Problems that the status quo causes for Japanese society

As observed above, there seem to be inefficient areas in medical services in Japan that need improvement. Then, what effects do such weaknesses exert on medical services in Japan? Regarding radiological and medical services, this question boils down to an increase in medical radiation exposure, delay of implementation of necessary examinations, and deterioration of the clinical skill of physicians in various clinical departments. Because of the good access to medical services, outpatient clinics of medical organizations (particularly those of middle-sized or large hospitals) are always crowded beyond the capacity of physicians assigned to outpatient care, allowing the mocking phrase, "waiting for 2 hours, treated in 5 minutes". I would venture to say, taking the risk of being misunderstood, that the low cost of each visit is a cause of the high frequency of patient consultations (i.e., high patient-regulated

Footnote 1: Despite having the largest number of hospital beds, Japan encountered problems in coping with severe pneumonia related to the COVID-19 pandemic in spring 2020, because the number of beds available for acute care, particularly in ICUs, was less than half the number in the United States and Germany.[1)]

demand).[Footnote2] Patients' preference for large hospitals and the lowest number of physicians among OECD countries contribute to this situation as well (Fig. 6). As a result, in outpatient clinics, each physician must see 30 or sometimes 50 patients until evening without even taking a break for lunch. An outpatient physician is required to reach some conclusion about the diagnosis and treatment within 10 minutes for each patient on the initial visit. The physician performs a medical interview and physical examinations, determines an examination plan, explains the plan to the patient, obtains consent, explains the results to the patient coming back after the examinations, shows possible diagnoses, explains the treatments, obtains consent, and performs them all within 10 minutes. The fact that medical actions are performed in Japan in such a short time can never be understood by physicians in Western countries. If the situation is explained to them, they would reply that it is impossible to make a diagnosis and prescribe treatment in such a short time (without mistakes). Patients demand an increasingly higher quality of medical services, so their tolerance for medical errors is diminishing. Physicians inevitably rely on diagnostic imaging modalities such as CT and MRI to quickly reach some conclusion or treatment plan without overlooking any pathologies. The physicians are also prompted to eliminate buds of medical errors, though their possibility may be low, by resorting to broadly targeted treatments, such as the prophylactic administration of anti-influenza virus agents or antibiotics even when spontaneous cure is expected. The same prescriptions are continued for patients on revisits, and follow-up examinations are repeated without carefully talking to the patients or re-evaluating their medications. Thus, radiological investigations, which are originally supportive diagnostic procedures, have been transformed into low-cost automatic diagnostic devices in busy outpatient clinics. The medical fee reimbursement system may also be promoting orders based on "conditioned reflexes," not based on a well-thought-out medical plan. The fees for outpatient care are paid on a fee-for-service basis, and payments are made even when a physician orders examinations without carefully evaluating their indications, possibly contributing to an increase in examinations that are unlikely to be necessary. However, if such practice becomes routine, the waiting time for necessary examinations is prolonged. If the number of tests performed increases, outpatient visits would further increase. That is because, as the testing load increases, the radiology department and the diagnostic radiologists become extremely busy. Consequently, wait times for tests increase, test reports are delayed, and patients are notified of the test results during a return visit at a later date. Particularly in the last ten years, rapid advances have been seen in the increases in the number of detector rows in CT systems and the speed of MRI systems.[Footnote3)] Consequently, the number of images produced per patient has increased exponentially, while the number of diagnostic radiologists has increased only linearly.[5)] If a test is performed with no

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Footnote 2: Due to the COVID-19 pandemic in spring 2020, people were asked to refrain from seeking nonessential and non-urgent medical care. During this period and for several months after, the number of patients seeking outpatient treatment at clinics and medical institutions throughout the country dropped sharply, resulting in economic difficulties.[3)] This suggests that a form of the medical fee system that can sustain healthcare during such times needs to be explored by calculating the number of outpatients that would normally be expected to use a facility.

Footnote 3: In the 5 years from 2013 to 2017, 6,103 CT systems were newly installed in Japan. However, less than 2.2% were systems with detectors having ≤ 16 rows. During the same 5-year period, 2,632 MRI systems were installed, but only 16% had a magnetic field strength of < 1.5 T.[4)] Thus, the CT and MRI systems newly installed in the previous 5 years were largely high-performance systems that are capable of high-speed imaging.

consideration given to whether it was indicated, the diagnostic radiologist must at least glance through all of the images before arriving at a diagnosis of “no finding” or “normal.” In addition, for diagnostic devices to be constantly available, even minor medical facilities are required to install them. This increases the number of CT/MRI devices, and the installation of devices in excessive numbers leads to a low utilization level and poor maintenance. Efforts to increase the degree of utilization under such circumstances result in hospital-induced demand, i.e., the use of devices in patients for whom the examination may be unnecessary and even for the general public.

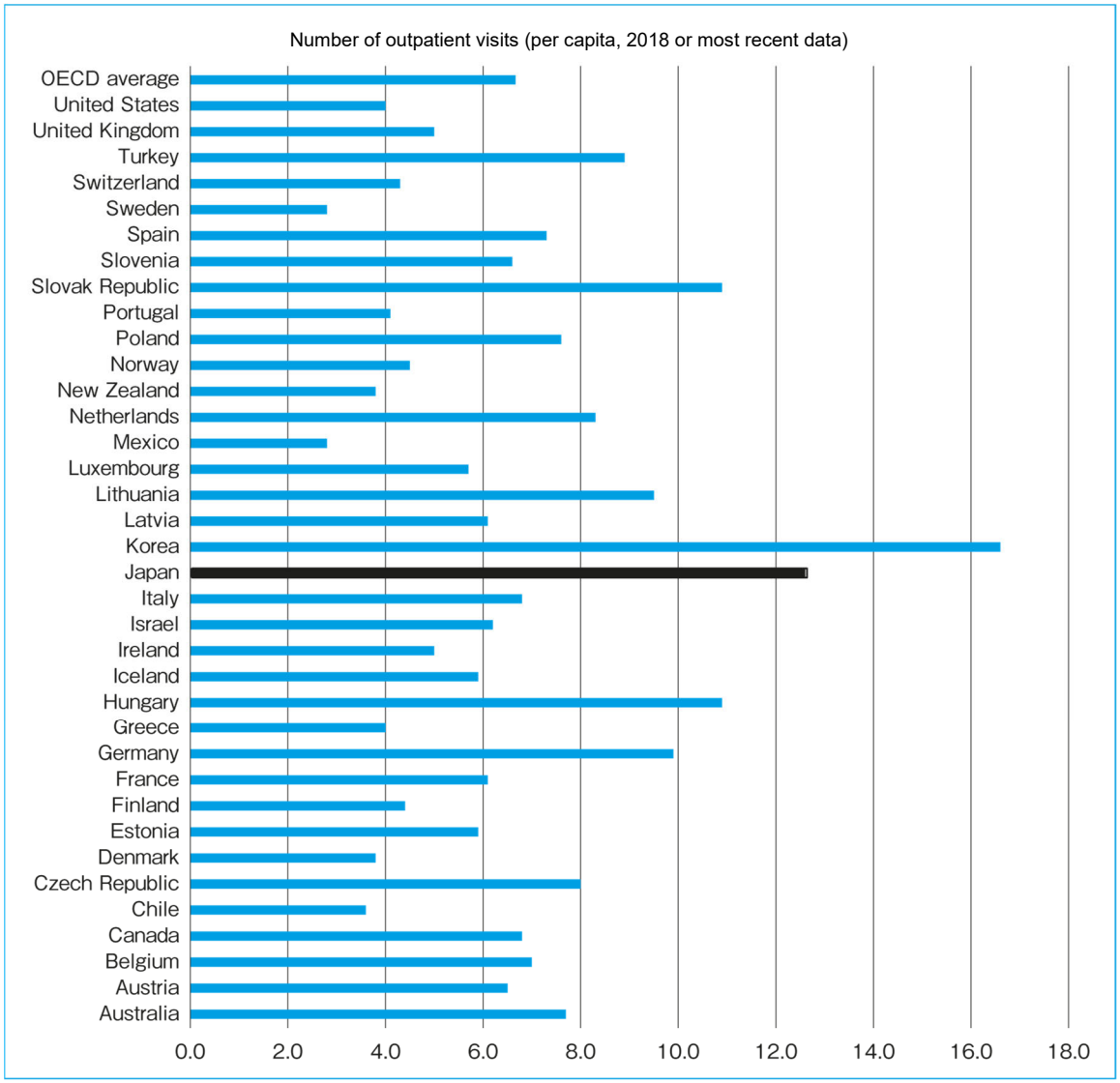

Figure 1. Number of outpatient visits per capita (OECD Health Statistics 2018 or most recent data)

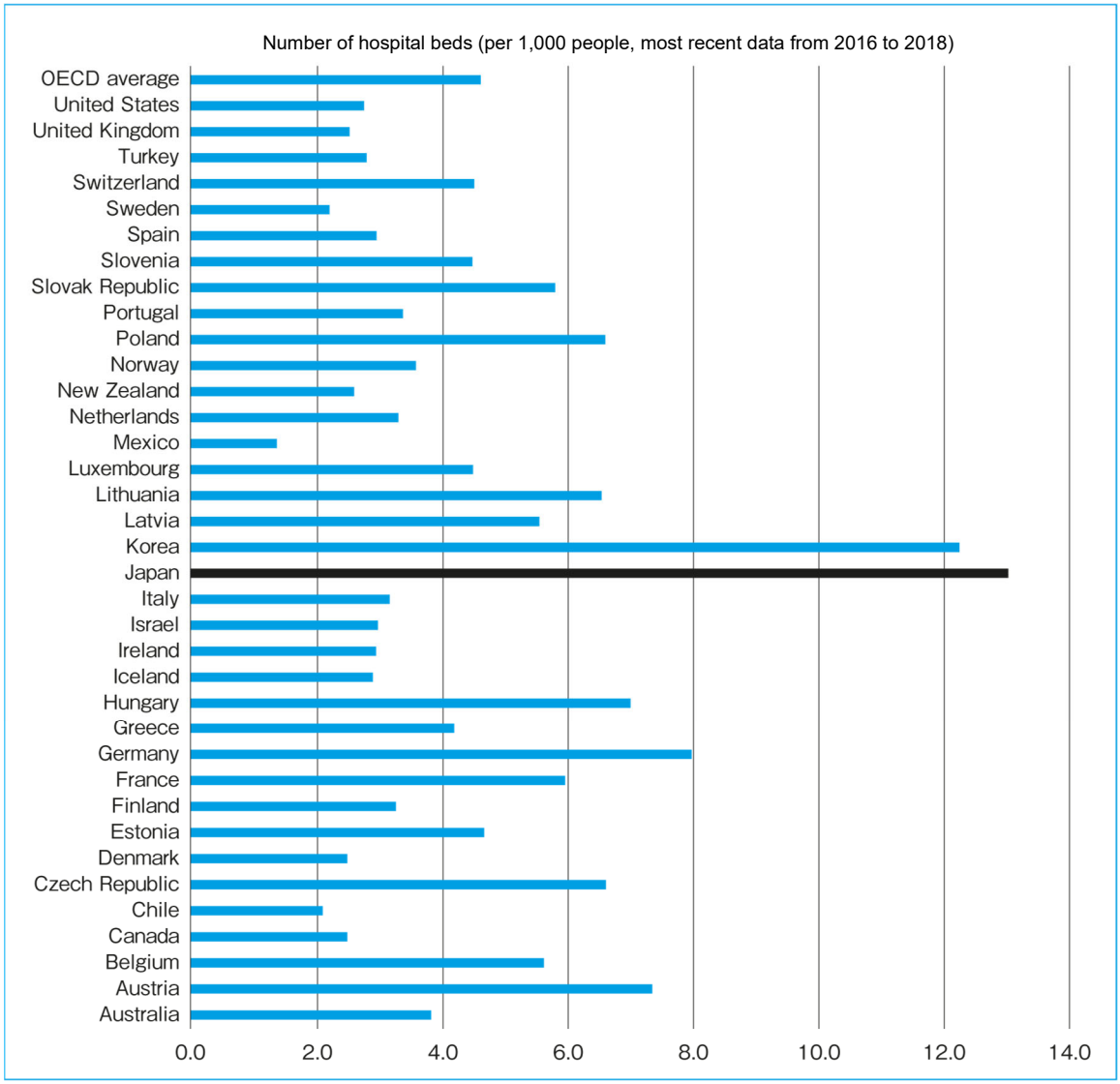

Figure 2. Number of beds per 1,000 people (OECD Health Statistics 2018 or most recent data)

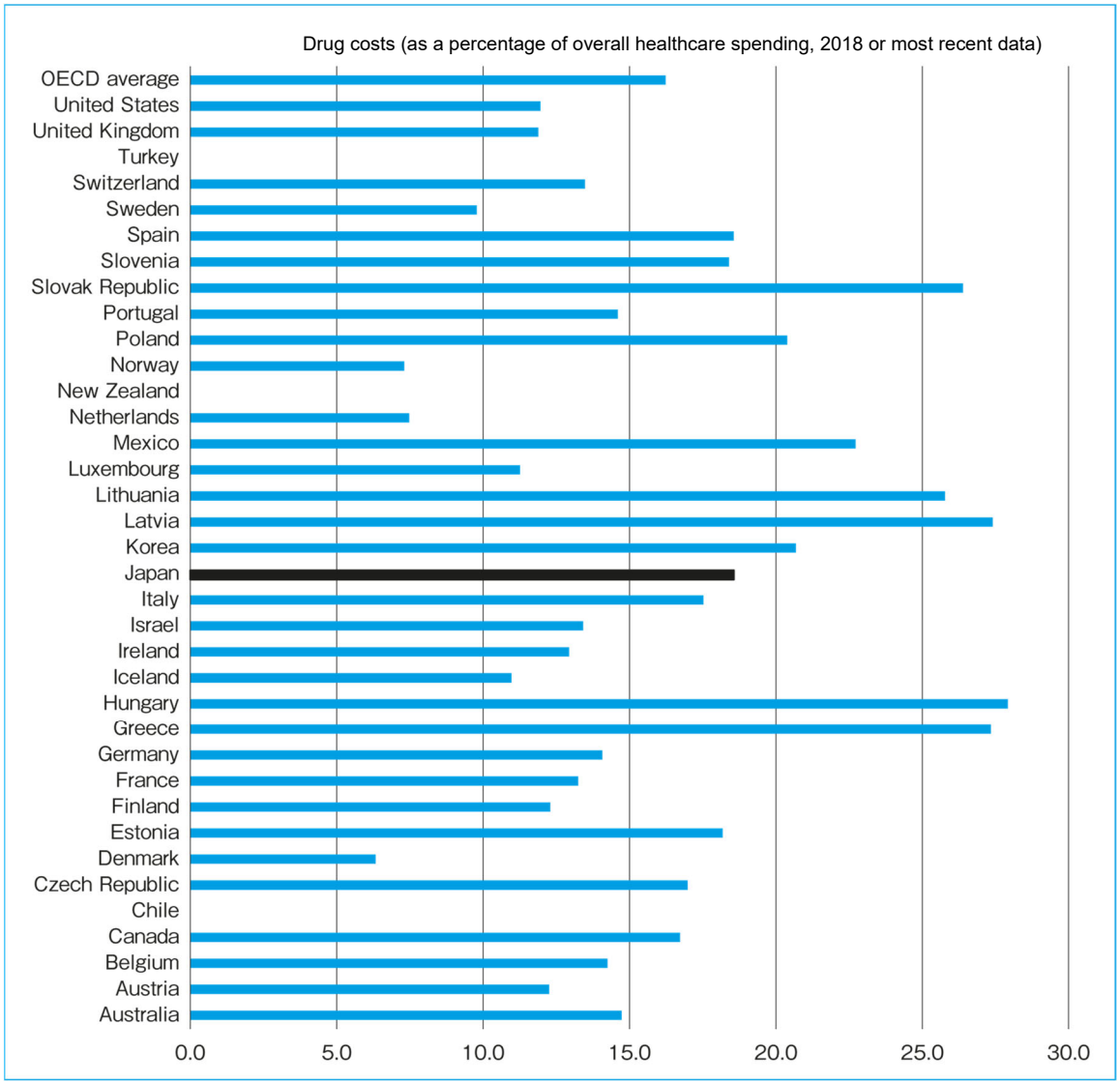

Figure 3. Expenditures for drugs and medical expendables (%; relative to total medical expenditures, 2018 or latest)

"Assembly-line"-like orders for CT/MRI and failed communications

In recent years, physicians in some departments have failed to read radiology reports or have not passed on information satisfactorily, resulting in delays that have left patients with advanced diseases. Thirty-seven such incidents were reported between January 2015 and March 2018 alone.[6)] Factors contributing to this problem include poor communication by healthcare professionals and the overwhelming increase in the volume of information provided by CT and MRI tests. The information provided in radiology reports is wide-ranging and sometimes goes beyond the specialties of the departments that request tests. In cases where the results reported are not anticipated at the time of the orders or beyond the understanding of the specialty, it can be surmised that there will be an incident involving an inadequate response by the

requesting physician who falls short or poor information transfer between the relevant specialties. However, although such incidents cannot be eliminated, they can be gradually decreased through measures such as introducing an IT system to handle unread radiology reports and adding a new unit to monitor this as a hospital function. More than half of the national university hospitals have already implemented such efforts or are considering doing so.[7] There may be opportunities to arrange conditions in the future toward a policy whereby the attending physician shares all chart information, including radiology reports, with the patient so they can double-check each other, as in the United States. However, it will be necessary to thoroughly consider the misunderstandings and other harmful effects that could arise if patients obtain reports that are still in a form intended for healthcare professionals.

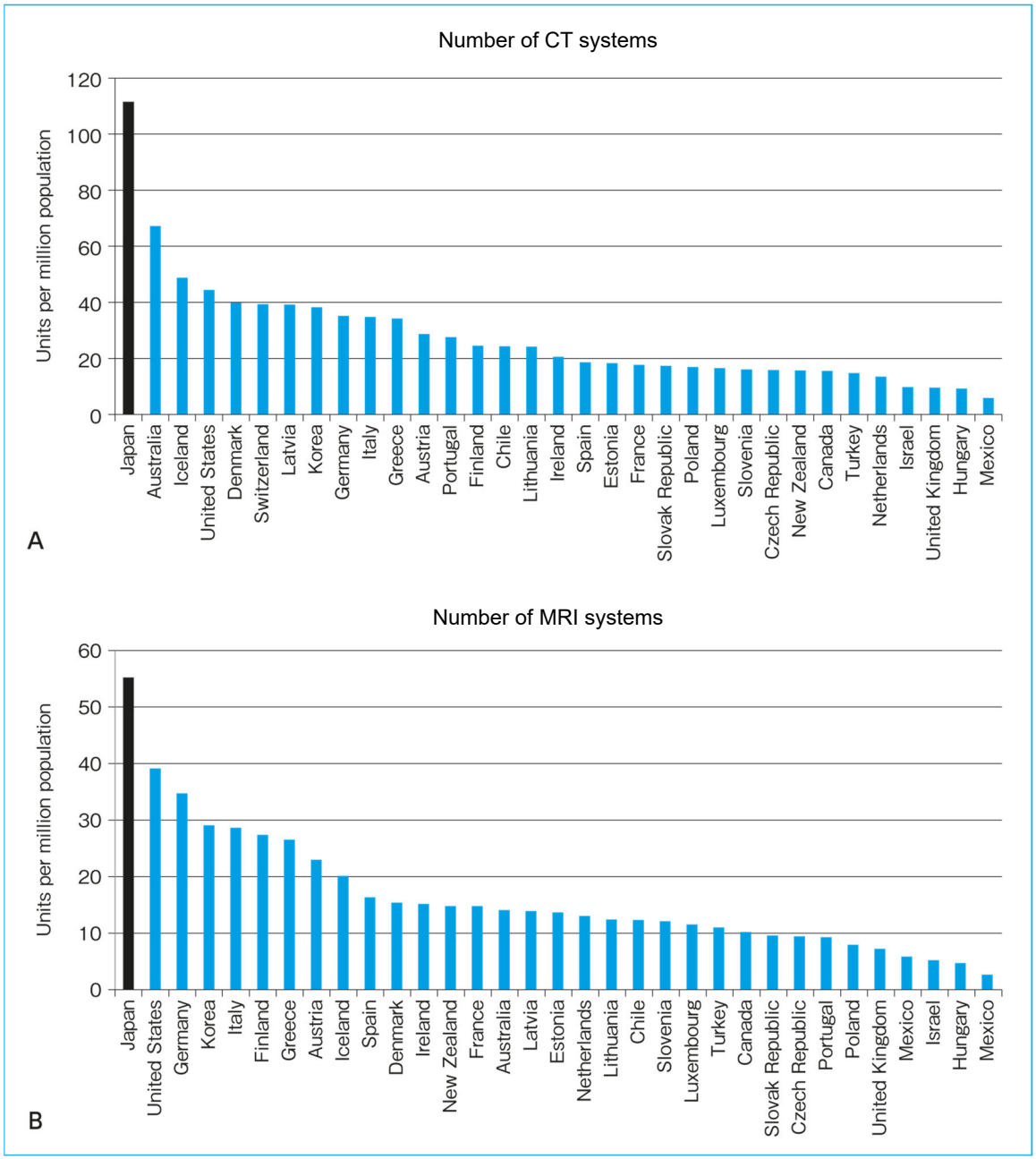

Figure 4. Numbers of installed CT (A) and MRI (B) devices (OECD Health Statistics 2018 or most recent data)

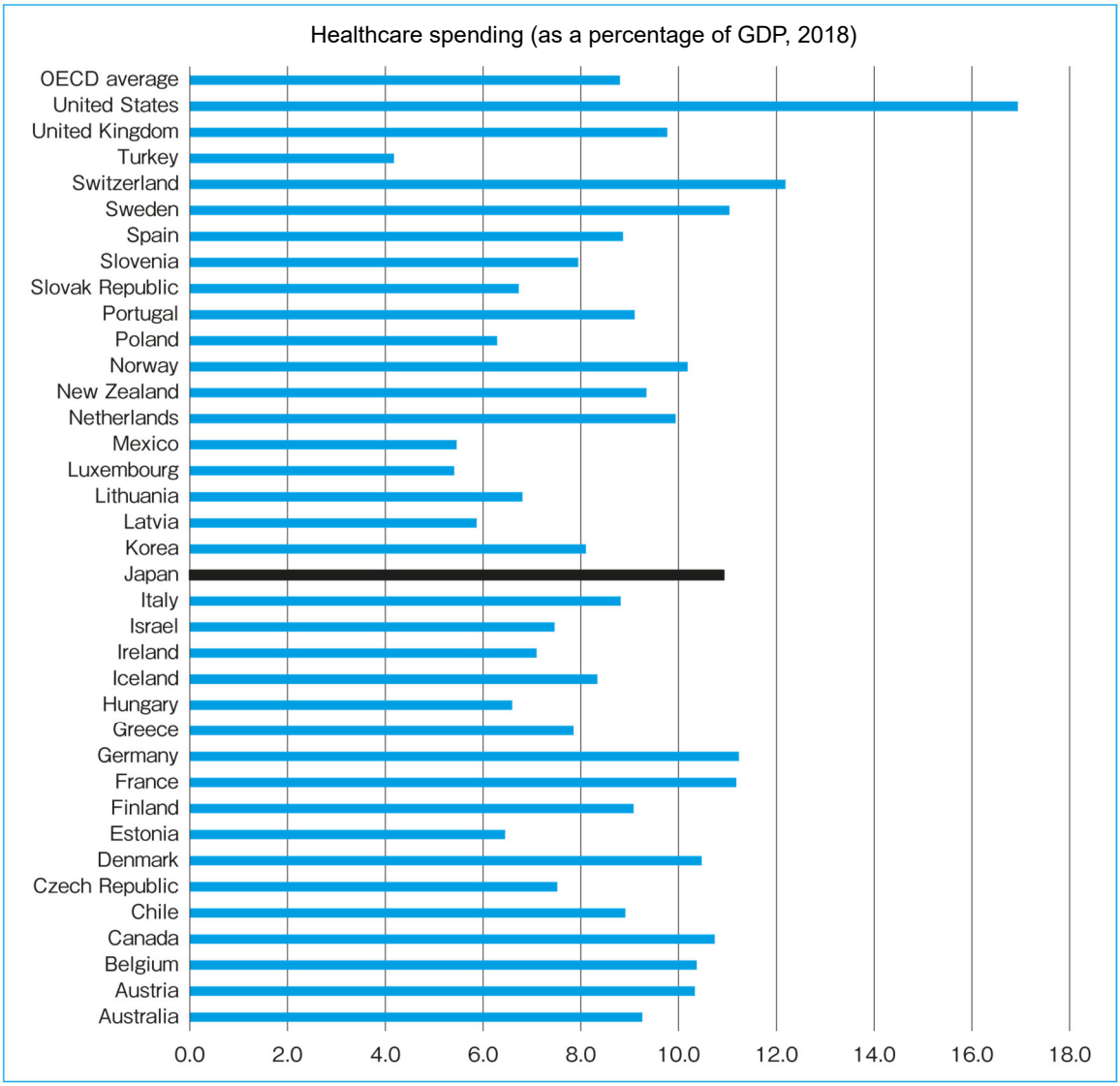

Figure 5. Medical expenditures (relative to GDP) (OECD Health Statistics 2018 or most recent data)

The trap of cost increases due to uniform control of medical fees and the necessity of redistribution of resources for improvements in efficiency

As observed above, efficiency cannot be improved as expected from attempts to reduce costs by across-the-board cuts of medical fees. This paradox is the "trap of cost increases due to uniform control of medical fees." Unquestionably, the national budget allocated to medical services is limited, and state finance is critical due to long-standing economic stagnation. If such uncontrolled increases in the number of imaging examinations continue, the government would reasonably be tempted to cut the budget for diagnostic imaging uniformly. Indeed, fees for CT and MRI examinations have been repeatedly cut at each revision of fees for medical services. However, many studies in Japan and abroad have demonstrated that the policy to reduce reimbursement of medical fees universally is a double-edged sword that ironically

invites increases in medical costs by provoking demand.[8-10)] In Japan, such uniform reduction of fees for examinations and drugs is accompanied by the risk of promoting excessive use of drugs and diagnostic tools, including CT. If wasteful medical expenditures are difficult to eradicate in Japan, the medical administration may be caught in the "trap of cost increases due to uniform control of medical fees." In taking measures to improve the efficiency of medical services, it is necessary to evaluate the causes of the excessive use of drugs and diagnostic devices as mentioned above and to remove fundamental reasons. In advanced countries such as Japan, the days when the efficiency of medical services was measured simply in terms of quantity are gone. We are in the era of quality-oriented assessment of medical services. Regarding radiological and medical services, policies ensure the highest payment when: (1) based on appropriate testing indications, (2) a roadmap to mildly invasive and accurate diagnoses with minimum radiation exposure is drawn by a specialist in diagnostic imaging; (3) a suitable system that has undergone quality control (QC) is used to (4) perform testing based on an appropriate testing plan; (5) a qualified diagnostic radiologist performs an appropriate diagnosis; (6) treatment is administered based on that diagnosis; and (7) the patient is rehabilitated through the shortest process possible. This will likely require a redistribution of healthcare resources to provide appropriate incentives for such practices.

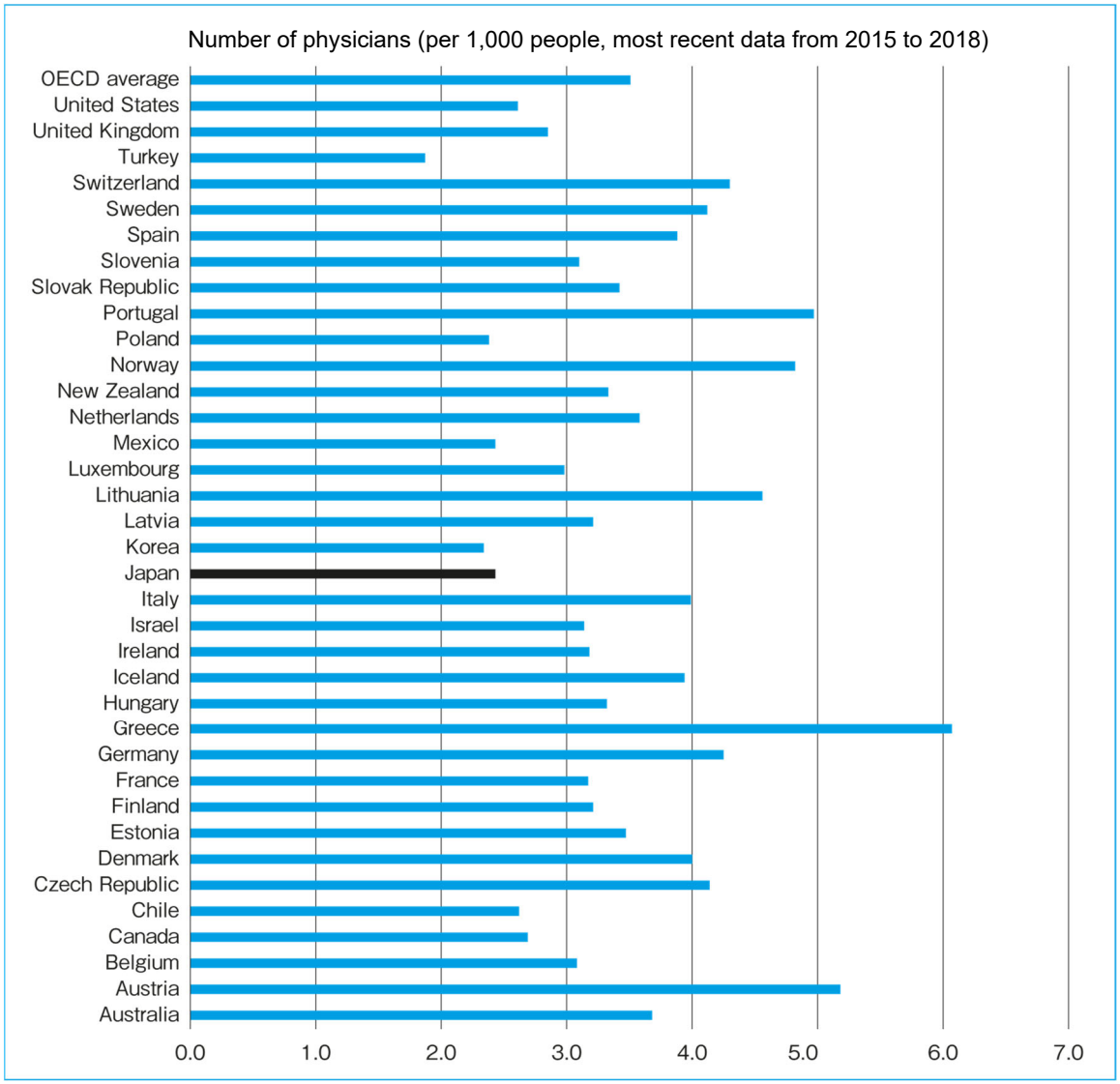

Figure 6. Number of physicians per 1,000 people (OECD Health Statistics 2018 or most recent data)

Excessive examinations and increases in medical radiation exposure

The proper use of diagnostic imaging by physicians is highly desirable from the perspective of the diagnostic radiologist. Needless to say, the use of radiation, particularly in CT, has contributed significantly to improving the public's health. However, the overuse of radiation for the aforementioned reasons and tests performed using obsolete imaging systems or based on flawed testing plans may also have adverse effects on healthcare. An article by de González et al. published in *The Lancet* in 2004 showed that diagnostic X-ray use in Japan was the highest among OECD-member nations, and that the risk of developing cancer was also increased.[11] The article received front-page newspaper coverage,[12] causing anxiety about medical radiation exposure in members of the public. In response to the public's reaction, a symposium on medical radiation exposure was held at the 63rd General Conference of the Japan

Radiological Society in 2004. The results were summarized in the chairperson's statement.[13] Following the Fukushima nuclear power plant accident in Japan, the public's concern about the health hazards of low-dose radiation exposure increased further. Consequently, with the assistance of international institutions and organizations, diagnostic reference levels (DRLs) for optimizing radiological protection in medicine were released to the public in 2015 to implement evidence-based radiation protection.[14] The establishment of DRLs by countries is now becoming a requirement of medical radioprotection internationally. In 2017, the Science Council of Japan (Radiology and Clinical Testing Subcommittee of the Clinical Medicine Committee) published proposals to reduce medical radiation exposure from CT tests. The points raised expanded on the 2004 statement of the Japan Radiological Society and advocated for the following. A redoubling of our constant effort is needed to bring about these changes.

(1) To monitor the status of CT practice in Japan and facilitate the use of DRLs

(2) To promote radiation protection training

(3) To clarify the indications for CT examinations

(4) To develop low-radiation-dose, high-performance CT systems to replace conventional ones

Conclusion

Medical services in Japan, which appear to be making considerable achievements at a low cost, also have weak areas and may be improved further by their correction. If radiological and medical services account for a large part of this inefficiency, we are bound to be more serious about improving the situation.

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4 Contrast Media Safety

Summary of the 2018 Guidelines on the Use of Iodinated Contrast Media in Patients with Kidney Disease

Introduction

Diagnostic imaging using iodinated contrast media is an essential type of test in routine clinical practice and yields an abundance of useful information. However, the use of contrast media in patients with decreased renal function carries a risk of contrast-induced nephropathy (CIN), making guidelines for such use necessary. Consequently, the 2012 Guidelines on the Use of Iodinated Contrast Media in Patients with Kidney Disease were jointly published by 3 academic societies: the Japan Radiological Society, which represents the specialists who use contrast media; the Japanese Circulation Society; and the Japanese Society of Nephrology, which represents the specialists who treat kidney disease.[1)]

Although the guidelines have been widely used, a number of new study results were reported 5 years after the guidelines were published. In addition, contrast-related guidelines in Europe and the United States were revised, and the 2016 Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline for Acute Kidney Injury (AKI) was published for kidney disease that meets the diagnostic criteria for AKI.[2)] Consequently, the 3 Japanese societies jointly revised their previous guidelines and released the 2018 Guidelines on the Use of Iodinated Contrast Media in Patients with Kidney Disease.[3)]

Because the previous version of the guidelines, published in 2012, were developed according to the methods recommended in the 2007 edition of the MINDS guidelines, any revisions of the previous CQs were developed according to the methods recommended in those guidelines. Some CQs and newly added CQs were developed according to the methods recommended in the 2014 and 2017 editions of the Minds Manual for Guideline Development.[4,5)] Consequently, it should be kept in mind that the 2018 guidelines use a mix of 2 types of evidence and methods of assessing recommendations.

This document excerpts and lists strongly radiology-related CQs and their answers from the 2018 Guidelines on the Use of Iodinated Contrast Media in Patients with Kidney Disease.

Definition of contrast-induced nephropathy

○ **How is contrast-induced nephropathy (CIN) diagnosed?**

CIN is generally diagnosed if the serum creatinine (SCr) level increases by ≥ 0.5 mg/dL or ≥ 25% from the previous level within 72 hours after administration of an iodinated contrast medium. Because CIN is a type of AKI, it is also evaluated using the diagnostic criteria for AKI. Based on the KDIGO diagnostic criteria for AKI, CIN is diagnosed in the following cases: the SCr level increases by ≥ 0.3 mg/dL from the previous level within 48 hours after iodinated contrast medium administration; the SCr level increases ≥

1.5-fold from a baseline value determined within the previous 7 days or the predicted baseline value; or urine volume decreases to < 0.5 mL/kg/h for 6 hours.

Rather than remaining constant, renal function is affected by diet, exercise, and changes in body fluid volume, and drugs that inhibit renal tubular secretion of creatinine increase the SCr level. In addition, increased SCr levels are seen due to creatinine absorption resulting from the ingestion of cooked meat and supplements that contain creatinine. Consequently, the following points should be kept in mind.

(1) Diurnal variations in SCr levels of approximately 10% may occur.
(2) SCr levels increase with vigorous exercise or ingestion of large amounts of meat and decrease when protein intake is restricted.
(3) Cimetidine and trimethoprim may reduce renal tubular creatinine excretion and increase SCr levels.

Risks and patient evaluations

(1) Are patients with chronic kidney disease (CKD) at increased risk of CIN?
CKD (eGFR < 60 mL/min/1.73 m^2) is a risk factor for CIN. However, the risk of CIN varies depending on the route of contrast medium administration and the patient's condition.

(2) Does aging increase the risk of CIN?
Aging is a CIN risk factor.

(3) Does diabetes mellitus increase the risk of CIN?
Diabetes mellitus with CKD (eGFR < 60 mL/min/1.73 m^2) is a risk factor for CIN. However, whether diabetes mellitus in the absence of CKD is a CIN risk factor is unclear.

(4) Does continued use of a diuretic increase the risk of CIN?
It is unclear whether continuing to take an oral diuretic increases the risk of CIN.

(5) Does the prophylactic use of a diuretic increase the risk of CIN?
The prophylactic use of a diuretic does increase the risk of CIN and is therefore not recommended.

(6) Does biguanide increase the risk of lactic acidosis?
A transient decrease in renal function resulting from administration of an iodinated contrast medium poses a risk of lactic acidosis. If an iodinated contrast medium is administered, it is recommended that appropriate measures, such as temporarily withdrawing biguanide antidiabetic drugs, be taken after considering the CIN risk, except during an emergency test.

(7) Is the risk of CIN increased by having a single kidney?
The evidence that having a single kidney increases the risk of CIN as compared with having 2 kidneys is unclear.

Types of contrast media

(1) Is there a difference between iso-osmolar and low-osmolar contrast media with respect to the risk of CIN?

No difference has been seen between iso-osmolar and low-osmolar contrast media with respect to the frequency of CIN.

(2) Are there differences between different types of low-osmolar contrast media with respect to the risk of CIN?

Although no definite conclusions have been drawn regarding the risk of CIN with different types of low-osmolar contrast media, no differences in CIN frequency have been reported to date.

(3) Does invasive contrast medium administration (intraarterial) increase the risk of CIN more than non-invasive administration (intravenous)?

There is currently no evidence that intraarterial contrast medium administration is an independent risk factor for CIN. However, there have been many reports of a higher incidence of CIN with invasive (intraarterial) administration than with non-invasive (intravenous) administration. Because differences in the patients' underlying diseases (e.g., diabetes mellitus and chronic nephropathy) may be behind these reports, careful administration that takes into account factors such as the patient's underlying disease is required, particularly when performing invasive (intraarterial) administration.

Testing and treatment with intraarterial contrast media administration

(1) How can one differentiate between decreased renal function caused by CIN and that caused by cholesterol embolization?

Although decreased renal function caused by CIN can usually be differentiated from that caused by cholesterol embolization based on symptoms and test findings, such differentiation can occasionally be difficult.

(2) Does CIN increase cardiovascular events?

The incidence of cardiovascular events is high in patients with CIN.

Tests using intravenous contrast media administration

(1) Is there an increased risk of CIN resulting from contrast CT in CKD patients?

The likelihood of CIN occurring after contrast medium administration is low in CKD patients with an eGFR $\geq$ 30 mL/min/1.73 m^2. Even with an eGFR $\geq$ 30 mL/min/1.73 m^2, however, it is important to thoroughly evaluate CIN risk factors. When performing contrast CT in a CKD patient with an eGFR < 30 mL/min/1.73 m^2, it is recommended that considerations such as the risk of CIN be explained to the patient and that appropriate precautions be taken as necessary.

(2) Is there an increased risk of CIN resulting from contrast CT in intensive care patients or patients receiving emergency outpatient care?

There is little evidence of an increased risk of CIN resulting from contrast CT in intensive care patients or patients receiving emergency outpatient care. However, these patients have a high risk of AKI regardless of whether they are administered a contrast medium. It is therefore recommended that such patients be given a thorough explanation regarding AKI and CIN and that appropriate precautions be taken when contrast CT is performed.

(3) Does reducing the dose of contrast medium used in contrast CT reduce the risk of CIN?

Reducing the dose of contrast medium used in contrast CT may reduce the risk of CIN. Particularly in patients at high risk of CIN, use of the lowest dose of contrast medium that will preserve diagnostic performance is recommended.

(4) Is there a recommended imaging method to use when the dose of contrast medium used in contrast CT is reduced

When the contrast medium dose is reduced, it is recommended that low-tube-voltage imaging and iterative reconstruction be used in combination in facilities where this is possible.

(5) Does repeating contrast CT testing in a short period of time increase the risk of CIN?

Repeating contrast CT in a short period of time (24 to 48 hours) is not recommended because the risk of CIN may increase.

Preventing CIN: fluid infusion

(1) Is physiological saline administration recommended to prevent CIN?

Administering physiological saline intravenously before and after a contrast study is recommended to prevent CIN in patients with CKD, who are at risk of CIN.

In terms of effectiveness in preventing CIN, a 0.9% physiological saline solution, which is an isotonic infusion, is superior to 0.45% physiological saline, a hypotonic infusion. Consequently, the use of an isotonic infusion is recommended.

(2) Is drinking water recommended to prevent CIN?

There is insufficient evidence regarding whether drinking water alone has an inhibitory effect on CIN comparable to that of intravenous fluid infusion. To prevent CIN, substantial measure such as fluid infusion is recommended more highly than hydration with drinking water alone.

(3) Is sodium bicarbonate (baking soda) administration recommended to prevent CIN?

Because sodium bicarbonate (baking soda) administration may inhibit CIN, administration of baking soda solution is recommended when infusion time is limited. When administering sodium bicarbonate (baking soda), use an isotonic preparation.

Preventing CIN: hemodiafiltration

○ Is hemodiafiltration recommended after contrast medium administration to prevent CIN?

The use of hemodiafiltration after contrast medium administration to prevent CIN does not reduce the risk of CIN and is therefore not recommended. It is particularly recommended that hemodialysis not be performed.

Treatment of CIN

(1) Is administration of a loop diuretic recommended to treat CIN?

The evidence that loop diuretic administration to treat CIN inhibits the progression of renal dysfunction is weak, and such administration may instead be deleterious. It is therefore not recommended.

(2) Is fluid therapy recommended to treat CIN?

Fluid therapy to treat CIN is not recommended except when a decrease in body fluid volume is seen.

(3) Is acute blood purification therapy recommended to treat CIN?

There is no evidence that acute blood purification therapy administered after the onset of CIN improves the prognosis of renal function. It is therefore not recommended to improve the prognosis of renal function.

Acute blood purification therapy is strongly recommended as a lifesaving measure if the patient's general condition is strikingly poor as a result of abnormal fluid volume or an electrolyte or acid-base imbalance. This is not limited to AKI resulting from CIN. The timing of the start of blood purification therapy should be determined after broadly considering the patient's clinical status and pathophysiology.

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5 Effects of Medical Radiation Exposure in Diagnostic Imaging and of Electromagnetic Fields in MRI

Introduction

Because ionizing radiation and electromagnetic fields (nonionizing radiation) have biological effects, diagnostic imaging is a medical practice associated with invasiveness. All healthcare practitioners should recognize this and perform these tests with the aim of maximizing their benefits for the patient.

Medical radiation exposure in diagnostic imaging

1. Fundamental views

Because the ionizing radiation used in diagnostic imaging has biological effects, the appropriate principles of radiological protection must be strictly adhered to, even though the purpose of the testing is its effective medical use. The 3 principles of radioprotection are justification, optimization, and dose limit. However, setting dose limits for patients could constrain radiological and medical services by, for example, limiting testing and interventional radiology (IVR) procedures, thereby undermining the benefits to the patient. Consequently, radiological protection is addressed based on the principles of justification and optimization.[1)] Moreover, the physician bears responsibility for the practice of radiological and medical services and is therefore obligated to ensure safety. The Enforcement Regulations on the Medical Care Act (Order of the Ministry of Health and Welfare), the revision of which went to effect in April 2020, requires each facility with X-ray systems to formulate policies for the safe use of radiation for patients and to strengthen its safety management. Stronger steps need be taken to address radiation safety, using for reference the Guidelines for Safety Management Systems Concerned with Radiation for Medical Use and Reference Material for Guidelines on the Safe Use of Radiation for Medical Use, which were published by the Japanese Society of Radiation (http://www.radiology.jp/member_info/guideline).

The justification principle in radiation medicine means that the benefits obtained from radiation use outstrip the risks of radiation exposure. The optimization principle means that unnecessary radiation exposure is avoided during justified uses of radiation medicine, that the doses used ensure maximum benefit to the patient, and that this takes place in an environment that fosters a culture of safety.

Methods of justification and optimization in diagnostic imaging are described in specific terms below. To justify exposing a patient to radiation, an indication for testing or IVR is needed, and the patient's consent must be obtained. Optimization means ensuring that imaging radiation doses and radiopharmaceutical doses take into account the diagnostic reference levels (DRLs) (www.radher.jp/J-RIME/report/JapanDRL2020_jp.pdf) indicated for each clinical practice guideline or

procedure and maximize the benefit to the individual patient. The procedures for managing patient radiation exposure in accordance with these principles are (1) to (4) below (Fig. 1).

(1) Conclude that a radiological test or IVR, such as CT or nuclear medicine, is medically essential.
(2) Based on the medical records, confirm that the procedure does not duplicate another procedure.
(3) The patient understands the need for the test or IVR and consents to it.
(4) The test is performed using imaging conditions and a dose appropriate to the circumstances of the individual patient.

Needless to say, these points are premised on the performance of quality assurance/quality control (QA/QC) for the system, with the assistance of radiology technologists. When attempting to reduce the radiation dose, one should pay attention to ensuring that lesions are well visualized and that the image quality is such that it does not place undue demands on the diagnostic radiologist, who performs many diagnostic imaging studies on a daily basis. In addition, if the radiopharmaceutical used in a nuclear medicine test is excreted through the urinary tract, encouraging the patient to urinate frequently will directly reduce the patient's radiation dose.

2. Classifications of radiation exposure

In the field of radioprotection, radiation exposure is classified as medical, occupational, and public exposure. In addition to the exposure of the patient himself or herself, which was discussed in the preceding paragraph, medical radiation exposure includes the exposure of family members and caregivers as a result of providing care for a patient and the exposure of subjects who volunteer for biomedical research. Although no regulatory dose limits for medical radiation exposure have been established, a dose of ≤ 5 mSv during a single treatment period has been indicated in notifications as a reference standard for those who provide care for patients.[2)] Although such reference levels are referred to collectively as dose constraints, they lack the enforceability of dose limits. Dose constraints can be determined to suit the circumstances of the individual. For example, when considering the return home of a pediatric patient who has received internal radiation therapy, consideration of the patient's mental anxiety from spending time separated from family members should take precedence over ensuring strict compliance with the dose constraints for the family members.

Volunteers for biomedical research are essential for the advancement of medicine. During drug development, the pharmacokinetics of the drug must be understood, and when a diagnostic imaging system is developed, it is finally evaluated by imaging volunteers. When a study is begun, effort is made to ensure not only compliance with clinical ethics, but also to ensure that the principles of justification and optimization are adhered to in using radiation. Although dose constraints have not been specifically defined, it would be desirable for the Japan Radiological Society to formulate a radioprotection proposal for diagnostic imaging based on the proposal set forth for the radioprotection of biomedical research volunteers

by the Radiological Protection Committee of the Japanese Society of Nuclear Medicine (http://www.jsnm.org/archives/649). The targets are generally participants in clinical trials, clinical studies, and clinical research in patients. However, when used to compare accuracy with that of other new testing methods, in addition to dose controls, specific limits on the number of tests (number of subjects) are needed. For studies involving healthy volunteer subjects, the ages of the participants and their previous participation in studies must be taken into account. The use of pregnant women and children as subjects should be avoided unless absolutely necessary. When the subjects are volunteer patients, testing should be limited to methods that are expected to directly or indirectly benefit the individual participants.

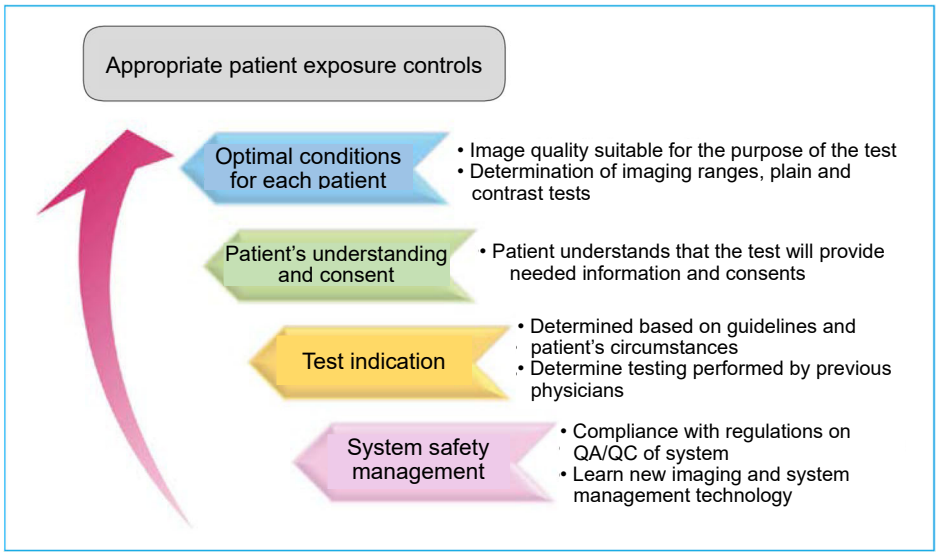

Figure 1. Principles of medical radiation exposure management

The optimal dose for lesion detection and disease treatment is managed for each patient. It is important to train healthcare staff to be able to implement these steps with an awareness of radiation safety.

3. Dose evaluation

To evaluate the dose of medical radiation exposure in diagnostic imaging, the index generally used for each testing method is used. For general imaging and fluoroscopy, the entrance surface dose for the patient's skin (units: mGy) is used. For CT, the CT dose index volume (CTDIvol, units: mGy) and dose length product (DLP, units: mGy·cm) are used. In nuclear medicine, the administered radioactivity dose (units: MBq) is used. In nuclear medicine, the dose can be determined before testing. However, it is difficult to measure radiographic indices for each patient. Consequently, in compliance with the medical safety quality controls and training stipulated in the Enforcement Regulations on the Medical Care Act, the accuracy of the index values displayed by systems is ensured through periodic training in dose measurement using the established methods and in operating skills.[3)]

If radiation exposure from a radiation source will occur, the effective dose used in radiological protection is evaluated in advance at the planning stage and used for safety considerations. It is also used as a regulatory value, such as a dose limit, to determine whether safety was ensured after the plan was

implemented. However, although the International Commission on Radiation Protection (ICRP) recommends using the effective dose as the basic radiation protection dose, it has also stated that it should not be used to retrospectively estimate the risk of probabilistic effects for specific individuals or for epidemiological evaluation of physical exposure.[1)] The biggest reason for this is that the risk of carcinogenic probabilistic effects, which is the basis of the tissue weighting factor, largely depends on age and sex. To evaluate medical exposure risk, use of the doses absorbed by the individual tissues and organs (units: Gy) that are irradiated has been proposed. Although the effective dose is easy to determine and has been used in many medical reports that compare doses, its accepted use in medicine is limited to evaluations in the following cases: (1) a different diagnostic test or IVR procedure is used; (2) a similar technology or procedure is used in a different hospital or country; or (3) different technologies are used for the same medical test. The fact that cancer risk depends largely on age and sex also must be considered in these cases. After the accident at the Fukushima Daiichi Nuclear Power Plant, the mass media reported the results of various tests using the effective dose and often erroneously compared it with the exposure dose of residents, which created confusion among patients. Rigor therefore needs to be applied when using the effective dose.

Effects of electromagnetic fields in MRI

With MRI, the effects of static magnetic fields and electromagnetic radiation are taken into account. In environments with extremely strong static magnetic fields, symptoms such as erythrocyte deformation and, in individuals who move back and forth between locations with electromagnetic radiation, lightheadedness occur. However, these changes do not occur with the use of systems with a magnet strength ≤ 3 T, which are the systems used in routine medical care. The specific absorption rate (SAR) is considered an effect of the electromagnetic radiation in MRI. The SAR refers to the radiofrequency power that is absorbed by the body per unit mass (W/kg), and it is associated with increases in core temperature. It is proportional to the square of the magnetic field strength, the square of the high-frequency magnetic field strength, the radiofrequency (RF) pulse duty cycle, the square of the radius of the cross-section of the patient, and the electrical conductivity of tissues (largely affected by the brain, blood, liver, and cerebrospinal fluid, slightly by adipose tissue and bone marrow). As in the case of the absorbed dose for X-ray examinations, the SAR is an index than cannot be measured in the course of routine medical care. It is therefore determined using the operating modes that are displayed by the system for each imaging condition and guaranteed by the manufacturer (normal, the first-level controlled, and second-level controlled operating modes). The standard is to use imaging conditions within the normal operating mode to ensure safety and allow no possibility of causing physiological stress to the patient. However, when a system ≥ 3 T is used and image quality is sought, the first-level controlled operating mode, which is defined as a mode that could cause extreme physiological stress in the patient, may easily be reached. This is addressed by considering what is clinically necessary and changing the imaging condition settings so that, for example, the smallest possible flip angle (FA) is used, the number of slices is limited, and the repetition time (TR) is increased.

For MRI examinations in pregnant women, the possible developmental effects of increasing SAR, such as developmental delay in the fetus, are considered, rather than the risk of pediatric cancer or teratogenicity, as in the case of ionizing radiation. However, there have been almost no findings that provide a basis for determining safety and risk with systems of ≤ 4 T.[4] Consequently, the view of the Japanese Society for Magnetic Resonance in Medicine is that, if nonionizing radiation imaging other than MRI (ultrasound) is considered inadequate, and MRI testing is considered so essential that it is used as an alternative to ionizing radiation imaging (e.g., X-ray and CT), then there is no obstacle to performing MRI in pregnant women. When an MRI test is medically necessary, it is performed after it has been confirmed that the patient has been given accurate information about the test and has agreed to it.

MRI carries a risk of burns resulting from conduction currents (eddy currents) on the body surface, and steps must therefore be taken to avoid creating a circuit (loop) that facilitates current flow. When water from sweating functions as a conductor, burn incidents have been reported in which the cause was resistance to conduction currents (eddy currents) that occurred as a result of point contact of the bore, coil, or part of the subject's body. Thus, a lack of knowledge regarding the electromagnetic field environment often leads directly to a medical accident. Engaging in continuous training that, as part of the education and training stipulated in the Enforcement Regulations on the Medical Care Act, emphasizes safety so that precautions are taken when a system is operated is the most effective means of avoiding the effects of electromagnetic radiation.

All healthcare practitioners must recognize the risks of core temperature increases and eddy current formation on the body surface that are associated with the electromagnetic field of MRI, and exercise judgement that conforms to the diagnostic radiology principles of justification and optimization for imaging conditions that exceed those of the normal operating mode.

Conclusion

The use of radiation and radioactive materials has contributed to advances in fields ranging from medicine to manufacturing to agriculture. These are the results of effectively using the properties of radiation that give it its ability to sterilize, alter the links between molecules, induce cellular mutagenicity, and damage tissue. When using it, however, effort must be made to use it safely by taking appropriate radiation protection measures based on the knowledge that radiation and radioactive materials are carcinogenic in humans.[1]

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6 The Medical Accident Investigation System and Radiological and Medical Services

Introduction

The Medical Accident Investigation System was included in the revised Medical Care Act as a measure to prevent medical accidents and took effect in October 2015. When an accident occurs, the medical institution carries out an internal investigation and reports the accident to the Medical Accident Investigation and Support Center, a private third-party agency. The center then performs a case analysis and conducts an investigation to prevent recurrence. The center forms technical analysis committees to address the various circumstances that cause in-hospital deaths, organizes and analyzes accident information, and prepares written proposals for prevention of recurrence of medical accidents. As of 2020, the center had published recommendations for 12 items (Table 1). One such set of proposals, based on an analysis of deaths related to diagnostic imaging in emergency medicine, was compiled as proposal set no. 8 in April 2019.[1)] In the present document, that proposal is analyzed from the perspective of a radiologist. There is also an additional note regarding radiological and medical services other than emergency diagnostic imaging, especially interventional radiology (IR), which is related to the Medical Accidents Investigation System.

Table 1. Proposals for prevention of recurrence of medical accidents

No. 1	Analysis of deaths related to complications of central venous puncture: Part 1
No. 2	Analysis of deaths related to acute pulmonary thromboembolism
No. 3	Analysis of deaths related to injection-induced anaphylaxis
No. 4	Analysis of deaths related to early post-tracheotomy dislodgement or aberration of a tracheostomy tube
No. 5	Analysis of deaths related to laparoscopic cholecystectomy
No. 6	Analysis of deaths related to nasogastric intubation performed for nutrient administration
No. 7	Analysis of deaths related to non-positive pressure ventilation (NPPV) and tracheostomy positive-pressure ventilation (TPPV) in general and long-term care units
No. 8	Analysis of deaths related to diagnostic imaging in emergency medicine
No. 9	Analysis of deaths related to head injuries caused by falls occurring during hospitalization
No. 10	Analysis of deaths related to pretreatment for procedures such as colonoscopy
No. 11	Analysis of deaths related to liver biopsy
No. 12	Analysis of deaths related to thoracentesis

Proposals based on analysis of deaths related to diagnostic imaging in emergency medicine

The analysis included 12 patients who were concluded to have died without having undergone proper diagnostic imaging and interpretation or having received an appropriate clinical decision. They were among 15 patients whose deaths were suspected of being related to emergency diagnostic imaging and whose cases were analyzed in detail. These 15 patients were selected from 851 hospital internal investigation

reports filed between October 2015 and October 2018. The analysis results were compiled as 6 proposals (Table 2).

Table 2. Proposals based on an analysis of deaths related to diagnostic imaging in emergency medicine

Proposal 1	Significance of imaging procedures in emergency medicine and key findings
Proposal 2	Information-sharing when an imaging procedure is requested
Proposal 3	Checking images acquired for emergency outpatient care
Proposal 4	Additional imaging procedures and judgments regarding hospitalization or returning home
Proposal 5	Checking diagnostic imaging reports and incidental findings
Proposal 6	Establishing adequate in-hospital systems

1. Specific proposals and their explanations

(1) Proposal 1: Significance of imaging procedures in emergency medicine and key findings

With emergency medicine imaging procedures, interpreting radiographic images with urgent, life-threatening diseases (killer diseases) in mind is more important than making a definitive diagnosis. Pay particular attention to imaging findings of slight bleeding due to a head injury, impending rupture of aortic aneurysm and aortic dissection, and the appearance of free gas from intestinal perforation.

Diagnostic radiologists are required to detect subtle findings of the killer diseases mentioned above. Image interpretation during an emergency requires a proactive approach to detecting such findings, regardless of the clinical presentation. It requires recognizing that detecting killer diseases outside the purview of the attending physician is the responsibility of the diagnostic radiologist.

(2) Proposal 2: Information-sharing when an imaging procedure is requested

Physicians who request imaging procedures should share information with radiology technologists and radiologists by clearly indicating on the request form about the patient's clinical symptoms and suspected disorder and any specific disorders they wish to rule out.

Although this proposal is mainly concerned with sharing information with radiology technologists, it also applies to radiologists responsible for emergency image interpretation. Naturally, information-sharing does not mean a unidirectional flow of information from the attending physician to the radiology department. It also requires radiologists to convey information about highly urgent findings. In addition, the following points must be confirmed: that the images have subsequently been examined in detail, such as on the following morning; and a final diagnostic imaging report has been prepared and that information on any incidental findings of the type referred to in proposal 5 has been shared.

(3) Proposal 3: Checking images acquired for emergency outpatient care

Not just the attending physician, but rather multiple physicians, including senior staff and radiologists, check the images from their own perspective and share information on the findings. If a radiology technologist can detect urgent findings during the radiological procedure in an emergency outpatient clinic,

he or she promptly provides this information to the interpreting physician. Using information communication technology (ICT) to obtain interpretations from outside radiologists is also useful.

In relation to this proposal, there have been cases in which a radiologist in an outside hospital was not notified despite the presence of a remote diagnosis system for emergency image interpretation in the hospital, and an important finding was overlooked as a result. Remote diagnosis systems have begun to be adopted by medical institutions, along with a lack of familiarity with such systems. Cases have been reported in which the radiologist, who is normally busy with interpretations in daily work, was not contacted out of a reluctance to wake him or her up late at night with an interpretation request. To avoid this systemic error, both the emergency physician and the hospital should understand that mistakes in emergency diagnostic imaging carry a significant risk of medical accidents. The radiologists have an important role in making the hospital system work.

(4) Proposal 4: Additional imaging procedures and judgments regarding hospitalization or returning home

If killer diseases cannot be ruled out based on the initial imaging procedure, additional procedures such as non-contrast CT and contrast CT are performed. Continue with adequate imaging diagnosis until such diseases are definitively ruled out. It is important that healthcare personnel share information on any symptoms observed during this time.

In the emergency care setting, it is recommended that having a single individual decide whether a patient should return home be avoided to the extent possible and that a radiologist be consulted about imaging. There have been 2 cases in which new findings emerged after the patient was sent home, but unfortunately the information was not shared, resulting in the patient's death. These cases showed the importance of information-sharing among healthcare personnel, particularly the importance of radiologists sharing information with attending physicians.

(5) Proposal 5: Checking diagnostic imaging reports and incidental findings

An individual is designated to take responsibility for ensuring that the diagnostic imaging reports that are prepared following emergency care can be checked. With regard to abnormal findings detected incidentally in testing not performed as the initial test (incidental findings), it is important that those that need to be addressed by the attending physician be communicated by a radiologist.

In 2018, cases in which lung cancer was missed because diagnostic imaging reports were neglected stirred controversy and prompted discussions about creating report-checking systems. In 2 of these emergency cases, reports that were issued at a later date had not been shared. Details regarding report-checking will be left to other articles. However, in the emergency medicine setting, radiologists need to adopt a posture of actively sharing information.

(6) Proposal 6: Establishing adequate in-hospital systems

The following systems are established: a system of training in the differentiation of killer diseases in emergency medicine; a support system for attending physicians working in emergency medicine; and a system that can ascertain whether diagnostic imaging reports that contain important findings are checked and the response to such reports. It is hoped that these systems will foster a culture in which all healthcare personnel are proactively involved in the safety of imaging procedures and accurate diagnosis.

This proposal and proposal 1 are the most important proposals. Based on a thorough understanding of the fact that emergency medicine is an extremely busy environment where important imaging findings can easily be overlooked, medical, radiology, medical information, and medical safety departments need to collaborate in establishing systems suitable for the circumstances at each facility.[2)]

2. Expectations (suggestions) for organizations such as academic societies and companies

These proposals include requests for support and leadership from organizations such as academic societies and companies with respect to the challenges related to emergency diagnostic imaging that medical institutions address. First, with regard to training in emergency diagnostic imaging, the involvement of the Japan Radiological Society and Japanese Association for Acute Medicine is needed in sharing the importance of emergency diagnostic imaging and promoting training in this area. In the area of undergraduate education, the Ministry of Education, Culture, Sports, Science and Technology needs to add training in explaining imaging findings that involve killer diseases to the learning objectives for diagnosis and treatment using radiation of its medical education model and core curriculum. In addition, as a safety measure for electronic medical records systems, a mechanism for checking diagnostic imaging reports needs to be made a standard feature. Finally, progress in developing diagnostic imaging support systems using artificial intelligence, an examination of the effectiveness of emergency interpretation by diagnostic radiology specialists, and a move toward revising medical fees are recommended. Several reports have summarized how clinical decisions for acute abdomen have changed based on a radiologist's CT report.[3-5)] Amid the demand for value-based medicine, it is hoped that the importance of emergency diagnostic imaging, in the sense that it increases the value of radiological and medical services, will be recognized.

Medical accident investigation other than emergency diagnostic imaging in radiological and medical services

The matters examined in medical accident investigations conducted for radiological and medical services are not limited to emergency diagnostic imaging, but also concern regular radiographic interpretation. In addition, interventional radiology (IR), like a surgical procedure, always carries the potential for a fatal medical accident. It requires responses that differ from those for normal diagnostic radiology work. These include providing the patients and their families with information appropriate for a selected IR procedure, determining whether a procedure is indicated based on shared decision-making agreed to by consent,

providing a postoperative explanation, and establishing a record of the procedure in the manner of operative notes. IR is an important branch of radiological and medical services that can contribute greatly to the entire hospital as a means of avoiding circumstances that can result from medical accidents, such as postoperative accidents and obstetrical hemorrhage. It is important for attending physicians in each department to recognize the efficacy of IR, and this entails establishing an in-house system as described above in Proposal 6 for emergency diagnostic imaging. On the other hand, with salvage therapy by IR, whose purpose is lifesaving, there is the risk of occasionally giving the attending physician and the patient's family unrealistic expectations and pushing ahead with a hopeless procedure. If a case is considered difficult, it is essential that decisions not be made by a single individual, but rather that the indications always be examined by multiple eyes and decisions made calmly.

Summary

Eliminating loss of life caused by a lack of accurate diagnostic imaging is the mission of the radiologist. The whole point of emergency diagnostic imaging is to effectively use information possessed by the attending physician, the radiology technologist taking the images, and the nurses managing the patient and to provide the treatment team with information that is directly linked to treatment. Although it is important to seek to strengthen the systemic aspects of the hospital as a whole, as was described in the proposal section, it is more important to first seek to change how emergency diagnostic imaging is viewed within the radiology department.

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7 Views and Procedures for Pediatric Diagnostic Imaging

Introduction

Unlike adults, children change in both somatotype and normal appearance as they develop. They also differ from adults in the types and frequencies of illnesses that affect them. Consequently, knowledge of children and how to accommodate them is needed for imaging procedures and required of physicians and diagnostic radiologists involved in pediatric care. The discussion in these guidelines focuses on imaging procedures for children that involve radiation exposure. In addition, because imaging procedures in children often require sedation, ensuring safety during examination is also important.

Reducing radiation exposure in imaging procedures of children: Justification and optimization

Needless to say, children have more years of life remaining than adults, and they are therefore more sensitive to the various invasive effects of imaging procedures; thus, more attention must be given to the principles of justification and optimization for children than for adults. A factor that clearly affects children more than adults is the cancer risk associated with radiation exposure, and the type of procedure that results in the highest radiation exposure, number of examinations, and total dose from diagnostic imaging is CT. Although there was no evidence that cancer risk increases with low-dose exposure with CT in the past, a succession of articles has recently been published reporting an increased risk of various types of cancer resulting from CT radiation exposure in children.[1-4] Although the risk for individuals is by no means high, there is clearly an increase in the overall risk of cancer. The diagnostic radiologist should take this seriously and make an effort to justify and optimize CT studies in children.

1. Justifying imaging procedures in children

A report from Europe, where the rate at which CT is controlled by radiologists is considered appreciably higher than in Japan, indicated that 30% of pediatric CT examinations are either unnecessary or could be replaced by a study that does not use radiation (typically ultrasound and MRI).[5] Guidelines are useful for judging the justifiability of an imaging study,[5] and the present guidelines should also be useful for that purpose.

Based on the concept that communication between various disciplines and the patients and their family members is essential for reducing radiation exposure in pediatric diagnostic imaging, the World Health Organization (WHO) compiled a booklet. A Japanese-language version of it (Figure)[6,7] was created by the Japan Network for Research and Information on Medical Exposure (J-RIME), a body formed by relevant academic societies and organizations, particularly the National Institutes for Quantum Science and

Technology and the Japan Radiological Society. Communication among diagnostic radiologists, the physicians requesting imaging procedures, and the patients and their family members is necessary for justification. Before requesting a study, the requesting physician needs to ask himself or herself whether the examination has already been performed, whether it will affect patient management, whether it is truly necessary, whether it is necessary now, whether it is the optimal examination, and whether he or she has clearly explained the need for the examination to the diagnostic radiologist. In Europe and the United States, guidelines for the requesting physician have also been created. In Japan, training and awareness in this area are inadequate, and it is likely almost always the diagnostic radiologist who asks the above questions of the requesting physician. However, a pediatric imaging procedure cannot be justified without making that effort. Although it is the requesting physician who first determines that an examination is indicated, determining whether it is justified is the most important job of the diagnostic radiologist. The diagnostic radiologist's job is not only to interpret images. Particularly for children, the diagnostic radiologist should try to justify testing by thoroughly considering the examination indication, communicating with the requesting physician, and considering whether to perform the examination and whether the information can be obtained by ultrasound or MRI. It is helpful to have as many regular opportunities as possible to talk to requesting physicians, such as during conferences.

Figure. Booklets on communication for radiation risks prepared by the WHO and J-RIME

2. Optimization of pediatric imaging procedures: Reducing exposure and optimal use of contrast media

Optimization of pediatric imaging is undertaken based on the ALARA (as low as reasonably achievable) principle.[8] The WHO has stated in reports that optimization requires communication among diagnosticians, technicians, and medical physicists.[6,7] The move toward reducing exposure doses has gained momentum in Japan in recent years, with J-RIME releasing a revised version of the Diagnostic Reference Levels in Japan (2020 edition).[9] The diagnostic reference levels (DRLs) for pediatric CT are shown in the table below. Because there are differences in facility size, localities, personnel, and the performance of the CT systems that can be used, DRLs are not dose limits. Depending on the procedure, the values can be exceeded if clinically necessary. However, they are indices that enable the identification of facilities that use unusually

high doses or levels that are the same as those used for adults, thereby encouraging optimization. The purpose of DRLs is optimization, not simply dose reduction. Adequate diagnostic information for pediatric CT can usually be obtained with single-phase imaging (e.g., generally non-contrast CT alone for emergency head CT, single-phase contrast alone for usual truncal CT). At facilities that specialize in pediatric care, examinations may be performed at dose settings that exceed the DRLs if necessary, and arterial phase imaging may be added. However, these are performed as the result of optimization for the diagnostic information required by the diagnostician. Moreover, DRLs are indices for facilitating exposure dose optimization and do not take image quality into account at all. Due to concern over exposure, imaging in children is often performed at a dose so low that sufficient information cannot be obtained, and multi-phasic CT imaging is frequently performed with a low single dose, but according to the protocol for each organ in adults. However, even if an examination has been justified, it just results in needless exposure if it cannot provide the necessary information. In addition, it should be recognized that, even if the CT dose index volume (CTDIvol) is below the DRL, the dose length product (DLP) increases 2- or 3-fold if multi-phasic imaging is performed unnecessarily, which is far from optimal. The very fact that the imaging procedures are being performed in children, who are sensitively affected by radiation exposure, means that it is the duty of the diagnostic radiologist to make the best possible use of his or her knowledge.

Table　Diagnostic reference levels in pediatric CT[9)]

Classified by age group

	< 1 year old		1 to < 5 years old		5 to < 10 years old		10 to < 15 years old	
	$CTDI_{vol}$ mGy	DLP mGy・cm	$CTDI_{vol}$ mGy	DLP mGy・cm	$CTDI_{vol}$ mGy	DLP mGy・cm	$CTDI_{vol}$ mGy	DLP mGy・cm
Head	30	480	40	660	55	850	60	1,000
Chest	6 (3)	140 (70)	8 (4)	190 (95)	13 (6.5)	350 (175)	13 (6.5)	460 (230)
Abdomen	10 (5)	220 (110)	12 (6)	380 (190)	15 (7.5)	530 (265)	18 (9)	900 (450)

Classification by weight

	< 5 kg		5 to < 15 kg		15 to < 30 kg		30 to < 50 kg	
	$CTDI_{vol}$ mGy	DLP mGy・cm	$CTDI_{vol}$ mGy	DLP mGy・cm	$CTDI_{vol}$ mGy	DLP mGy・cm	$CTDI_{vol}$ mGy	DLP mGy・cm
Chest	5 (2.5)	76 (38)	9 (4.5)	122 (61)	11 (5.5)	310 (155)	13 (6.5)	450 (225)
Abdomen	5 (2.5)	130 (65)	12 (6)	330 (165)	13 (6.5)	610 (305)	16 (8)	720 (360)

Note 1) Values for a 16-cm phantom shown; values based on a 32-cm phantom also given in parentheses.
Note 2) Imaging range for abdomen extends from the upper abdomen to the pelvic region.

(Japan Network for Research and Information on Medical Exposure (J-RIME): Diagnostic Reference Levels in Japan, 2020 edition, p5, 2020 http://www.radher.jp/J-RIME/report/JapanDRL2020_jp.pdf)

The appropriate use of contrast media is also important for the optimization of diagnostic imaging. With both CT and MRI, additional information may be obtained using contrast media. However, contrast media result in adverse reactions, and gadolinium contrast media deposition has recently been shown to occur in human tissue.[10,11] Therefore, an important responsibility of the diagnostic radiologist is to rigorously determine whether contrast media use is necessary. At present, the only adverse event in humans reported in association with tissue deposition of free gadolinium from contrast media has been nephrogenic systemic fibrosis (NSF). However, because gadolinium contrast media were first marketed only 35 years ago, the indications for its use should be more rigorously considered for children, who have more years yet to live. See section 4, Contrast Media Safety, for information on safety and precautions.

Safety measures for children in diagnostic imaging

The radiologists responsible for clinical care in the diagnostic imaging department puts in place safety measures for adverse reactions to contrast media, but ensuring the safety of pediatric patients who are sedated for an imaging procedure is also important. In MRI laboratories, a strong magnetic field is always present, requiring that measures be taken to address emergencies, including measures to prevent secondary accidents. A helpful reference source is the 2020 edition of the Joint Recommendation on Sedation during MRI Examination by the Japan Pediatric Society, the Japanese Society of Pediatric Anesthesiology, and the Japanese Society of Pediatric Radiology.[12] Preparing the facilities (e.g., plumbing), monitors, and emergency items in various sizes tailored to the different physique of children in diagnostic imaging departments and establishing emergency backup systems are also useful measures for addressing adverse reactions to contrast media.

Conclusion

Imaging procedures must not be performed thoughtlessly in children, who still have long to live. Inappropriate imaging test occurs because justification and optimization are not properly performed. Making use of our knowledge as pediatric or diagnostic imaging specialists and mutually cooperating to perform the necessary examinations safely and under optimal conditions is the duty and responsibility of those of us involved in healthcare.

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