

Original Article

## The Standardized Development Method of the Japanese Guidelines for Cancer Screening

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**Background:** To reduce cancer mortality, effective screening should be implemented properly. In Japan, the Research Group for Cancer Screening developed screening guidelines; however, the development process was not well established.

**Methods:** Based on the development processes of other guidelines, an original method, unique to Japan, was established to develop the Japanese cancer screening guidelines.

**Results:** The guideline development process involved the following steps: topic selection, development of the analytic framework, systematic literature review, translation to recommendations, consultation and publication. Mortality reduction related to cancer screening was evaluated using both direct and indirect evidence. To select appropriate articles, an analytic framework for cancer screening program with key questions was developed. Direct evidence was defined as a single body of evidence that established the linkage between screening and health outcomes such as mortality and incidence. The use of indirect evidence to determine the level of evidence was limited to situations where test accuracy could be compared with that of a method whose evidence was supported by randomized, controlled trials. Eight levels of evidence were defined based on the study design and quality. The benefits of each screening modality were determined based on the level of evidence according to the results of the systematic review. Balancing the benefits and harms, five grades of recommendation were formulated for population-based and opportunistic screening. After organized consultations, three types of guidelines were published.

**Conclusion:** We developed a unique, standardized method for developing cancer screening guidelines in Japan. Based on this process, previously developed cancer screening guidelines have been revised.

*Key words:* cancer screening – guideline – mortality reduction – population-based screening – opportunistic screening

### INTRODUCTION

Cancer control is a major issue, the goal of which is to reduce the burden of the disease. In 2006, the Cancer Control Act,

which was aimed at reducing the incidence and mortality associated with cancer in Japan, was approved. Cancer screening programs are one of the effective strategies for reducing mortality; however, to achieve this goal, evidence-based screening programs need to be implemented properly.

As well as clinical practice guidelines, cancer screening guidelines can assist physicians and other health professionals and policy-makers to make effective decisions.

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In 2001, the research group for cancer screening funded by the Ministry of Health and Welfare in Japan recommended the following six cancer screening programs (the Hisamichi reports) (1): gastrofluorography for gastric cancer, fecal occult blood testing (FOBT) for colorectal cancer, a combination of chest radiography and sputum cytology (focused on high-risk group) for lung cancer, Pap smear for cervical cancer, a combination of physical examination and mammography for breast cancer and hepatitis virus markers for hepatocellular carcinoma. Although the Hisamichi reports were based on the evidence for cancer screening, they were, in some respects, immature as guidelines. The details of the development process, including the systematic review process, were not standardized. Although the recommendations were not graded, the level of evidence was shown based on the method used in the US Preventive Task Force (USPTSF) 2nd edition. However, the method used to evaluate the efficacy of cancer screening was limited to the study design (2). Since there are insufficient rules for guideline development, different conclusions could be reached with respect to each of the cancer screening programs.

A good guideline should be the product of an established process. Details about the process of guideline development have been published by several guideline development institutes in the US and Europe (3–7). To promote evidence-based screening in Japan, there is a need to standardize the development method of cancer screening guidelines and to disseminate appropriate information through the guidelines.

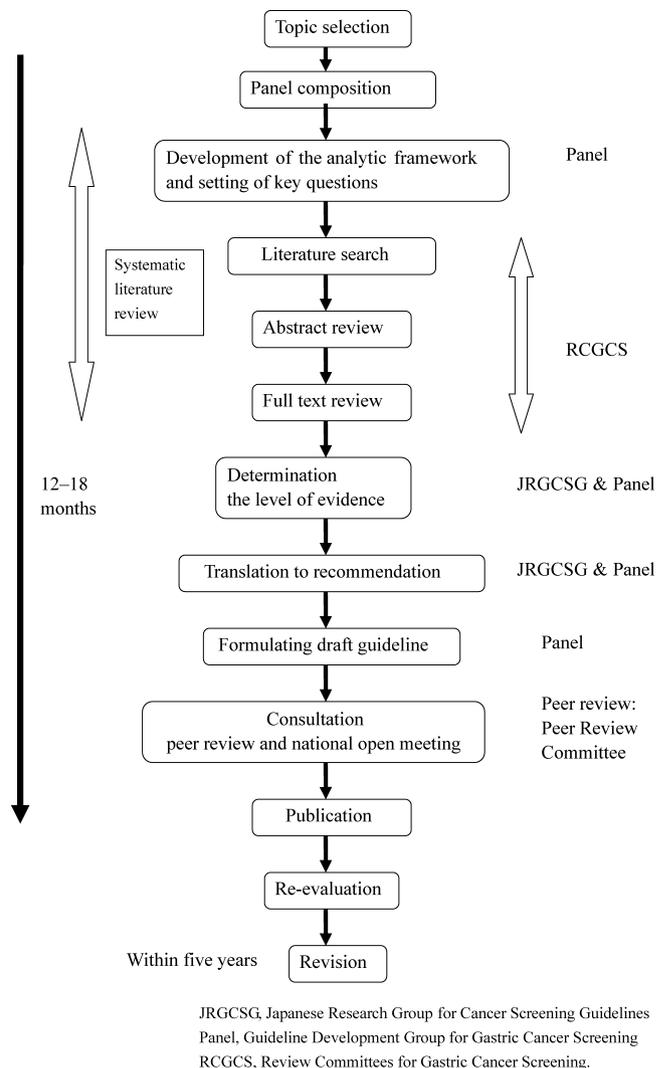
## METHODS

To clarify the evidence related to each cancer screening program, the new guideline development process was standardized. The USPTSF (3), the Scottish Intercollegiate Guideline Network (SIGN) (4) and the Appraisal of Guidelines, Research and Evaluation in Europe instrument (AGREE) (8) were used as the primary sources of information. On the basis of these guideline development processes, an original method, unique to Japan, was created for the evaluation of cancer screening programs.

## RESULTS: A STANDARDIZED METHOD FOR GUIDELINE DEVELOPMENT

### OUTLINES

Our guidelines target the public, health professionals working in cancer screening programs and policy-makers. An outline of our guideline development process is shown in Fig. 1; it includes topic selection, panel composition, development of the analytic framework and setting of key questions, systematic literature review (literature search, abstract review and full text review), determination of the level of evidence, translation to recommendations, formulation of the draft guideline, consultation (peer review and national open meeting) and publication of the guideline. Overall, these processes require 12–18 months. All of the guidelines are scheduled for revision within 5 years, so that new evidence can be incorporated.



**Figure 1.** Cancer screening guideline development process.

meeting) and publication of the guideline. Overall, these processes require 12–18 months. All of the guidelines are scheduled for revision within 5 years, so that new evidence can be incorporated.

### TOPIC SELECTION

The topics of the cancer screening guidelines deal with the current population-based screening programs: colorectal, gastric, lung, breast and cervical cancer screening. In every screening program, several methods that have been used for cancer screening are evaluated. Then, a schedule is developed to assess the common screening programs used by certain local municipalities and in various clinical settings (e.g. prostate cancer screening using prostate specific antigen).

### PANEL COMPOSITION

The members of the guideline development group (Panel) include physicians working in cancer screening programs,

researchers including epidemiologists and health economists and board members of the Japanese Research Group for the Development of Cancer Screening Guidelines (JRGCSG). A systematic literature review is conducted by the members of the review committees, including the members of the Panel, for each specific cancer screening program. The recommendations are assessed in conjunction with the board members of the JRGCSG.

ANALYTIC FRAMEWORK

An analytic framework demonstrates the chain of logic that must be supported by evidence that links screening to improved health outcomes. Both the USPTSF and the Community Guide use an analytic framework to select evidences (3,7). We use basically the same flowchart to evaluate the cancer screening programs (Fig. 2). If needed, the flowchart is modified so as to be appropriate to the Japanese context. This could be a useful tool for mapping out the plan used to evaluate each screening program, which guides the search for evidence. For each stage of the analytic framework, key questions are prepared; these questions must be clear and focus on the main issues related to each stage of the analytic framework. The key questions are based on the population, intervention, comparison and outcome format.

DETERMINATION OF THE LEVEL OF EVIDENCE

Direct and indirect evidences are used to evaluate mortality reduction related to cancer screening. Direct evidence is defined as a single body of evidence that establishes the

connection between screening and health outcomes, such as mortality and incidence (mainly late-stage cancer) (Fig. 2, arrow 1). Direct evidence could be provided by randomized, controlled trials (RCTs) and observational studies such as cohort and case-control studies. Other studies that provide indirect evidences are selected based on the key questions related to other stages of the analytic framework (Fig. 2, arrows 2-8). Intermediate outcomes are often used as indicators of efficacy, but they are not direct measures of mortality reduction; studies that use intermediate outcomes may be useful for offering indirect evidence of efficacy. The use of indirect evidence to determine the level of evidence was limited to situations where the test accuracy could be compared with methods for which the evidence was supported by RCTs. However, the presence of harmful effects of screening and treatment is a significant factor for deciding the recommendation grade. Data from studies that dealt with the key questions of the analytic framework are collected (Fig. 2, arrows 4 and 6).

LITERATURE SEARCH

A systematic literature review is performed to identify articles relevant to assessing specific cancer screening programs. Literature searching is done from 1985 to the present using MEDLINE, EMBASE, CINAHL, the Cochrane Collaboration Library, the Database of Abstracts of Reviews of Effectiveness and the Japanese Medical Research Database (Igaku-Chuo-Zasshi). At a minimum, both MEDLINE and Igaku-Chuo-Zasshi are searched. A manual search of key journals related to cancer screening, mainly

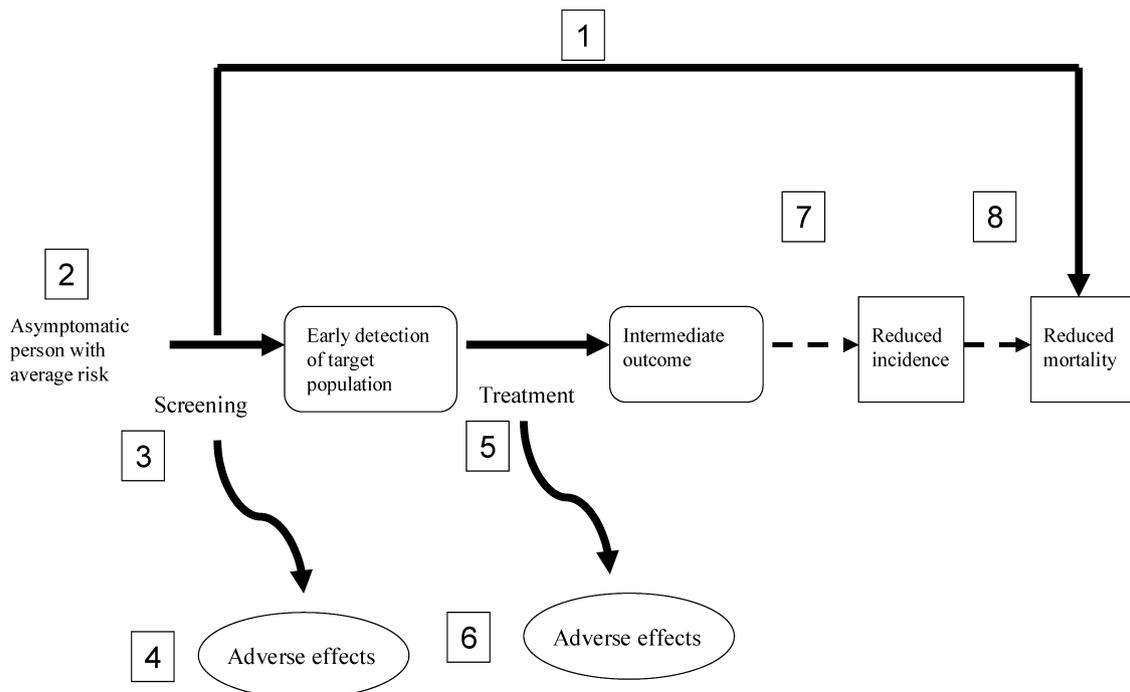


Figure 2. Analytic framework and key questions.

published in Japan, is performed. In addition, reference lists of the Hisamichi reports, as well as other systematic reviews and guidelines dealing with the same topic, are identified and included as needed.

#### LITERATURE REVIEW (ABSTRACT AND FULL TEXT REVIEW)

The abstracts of all articles identified by the literature search are reviewed. Each abstract is independently evaluated by two members of the review committee to assess the evidences. The articles for which the abstracts meet the inclusion criteria of both reviewers are retrieved. If the reviewers do not agree on the assessment of a particular article, then adoption of the article is discussed at a meeting of the guideline development group. The main inclusion criteria are: (i) original article, not including abstracts or meeting/conference proceedings; (ii) the target group studied in the article must be limited to asymptomatic persons with an average risk, not symptomatic patients and (iii) the article adequately answers the key questions. The reports dealing solely with detection rates in a local area or in a clinical setting are excluded.

Once the articles have been selected for full text review, independent reviewers appraise the quality of each article using a checklist for each study design. The checklist is a modified version of SIGN (4), which is used to evaluate the efficacy of cancer screening program. There are seven types of checklists: systematic review, RCT, case–control study, cohort study, test accuracy, ecological and time-series studies and others. Case series studies regard to harm are evaluated using the ‘other’ checklist. Each checklist item is scored using five categories: adequately addressed (score 4), addressed (score 3), poorly addressed (score 2), not reported (score 1) and not applicable. Articles with a total score of >60% are adopted. Although these criteria are the basic requirement for selecting adequate articles, low-quality articles could be chosen if there is a general lack of evidence on the topic. Although most studies concerning harms tend to be low quality (e.g. case series), these studies could be accepted in the absence of other evidences.

#### LEVEL OF EVIDENCE

For each key question of the analytic framework, the body of evidence for each screening method is summarized in an evidence table. Evidence is obtained from studies that evaluate mortality reduction as a result of cancer screening. There are eight levels of evidence based on the study design and quality (Table 1). The level of evidence of the SIGN (4) was modified. The highest level of evidence is considered to be a high-quality RCT; expert opinion is considered to provide the lowest level of evidence. Although the most relevant study is considered to be an RCT, the level of evidence is divided into three levels based on the quality of the study. Ecological and time-series studies are limited due to attenuating effects or difficulties in controlling confounding

factors; however, in both the UK National Institute for Clinical Excellence [presently, National Institute for Health and Clinical Excellence (NICE)] public health guidelines and the Community Guide (6,7), these studies have been defined as providing significant evidence. In our guidelines, ecological and time-series studies are considered to provide the same level of evidence as medium-quality case–control and cohort studies. The use of indirect evidence to determine the level of evidence is limited to situations where the test accuracy can be compared with that of methods for which evidence is supported by RCTs.

#### DEFINITION OF CANCER SCREENING PROGRAMS

There are two types of screening: population-based and opportunistic screening. The features are summarized in Table 2. In Japan, as in most countries, both types of cancer screening are prevalent (9). Although the aim of both screening programs is to reduce cancer mortality, they are different in many aspects, particularly with respect to their significance in the anti-cancer strategy. Population-based screening programs have been mainly conducted as a preventive policy in local municipalities with government support. Organized screening, which is considered to be an ideal system of population-based screening, involves centralized responsibility for the program’s process, such as registration for eligibility, quality assurance follow-up and evaluation. In this regard, population-based screening in Japan has not matured as organized screening. There has been firm evidence that organized screening could achieve mortality reduction from the corresponding cancer. In contrast, opportunistic screening depends on individual members of the public requesting screening or their health advisors recommending it. This type of program is also common and has been conducted using various modalities in clinical settings, even when there is insufficient evidence for efficacy. In addition, quality assurance is lacking in opportunistic screening. Therefore, this type of screening is generally not preferred as a screening strategy to reduce mortality.

#### TRANSLATION INTO RECOMMENDATION

On the basis of balance of benefits and harms, recommendations are formulated. The benefit of each screening modality is determined based on the level of evidence. In contrast, the harms, including the false-negative rate, the false-positive rate and the burden for cancer screening participants, are compared among the various methods. If there is a serious issue relating to harms, any recommendation should be tempered by considering the impact of the harm.

Five grades of recommendation are defined and applied for the two types of screening (Table 3). Since there is sufficient evidence, both Grade A and B recommendations could be directly applied to the target population as both population-based and opportunistic screening programs. However, a Grade D recommendation implies that the method should not

**Table 1.** Level of evidence

Level	Study design	Language
1++	RCT	High-quality RCTs with a very low risk of bias. Overall consistency of the results is needed.
	Systematic review	High-quality meta-analysis or systematic review of RCTs
1+	RCT	Medium-quality RCTs with a low risk of bias. Overall consistency of the results is needed.
	Systematic review	Medium-quality meta-analysis or systematic review of RCTs, case-control or cohort studies.
	Combination based on selected studies by each stage on analytic framework	Medium-quality RCTs dealing with an important stage of the analytic framework and high-quality case-control or cohort studies
1-	RCT	Low-quality RCTs with a high risk of bias
	Systematic review	Low-quality systematic review of RCTs, case-control or cohort studies with a high risk of bias
2++	Cohort study/case-control study	High-quality case-control or cohort studies with very low risks of bias, confounding or chance and a high probability that the relation is causal. Overall consistency of the results is needed
2+	Cohort study/case-control study	Medium-quality case-control or cohort studies with a low risk of bias, confounding or chance and a moderate probability that the relation is causal. Overall consistency of the results is needed
	Time-series/ecological study	Well-conducted time-series or ecological study studies. Overall consistency of the results is needed
	Combination based on selected studies by each stage on analytic framework	RCTs dealing with an important stage of the analytic framework and several studies concerning test accuracy and survival rate, etc at various stages of the analytic framework
2-	Cohort study/case-control study	Low-quality case-control or cohort studies with a high risk of confounding, bias, or chance and a high probability that the relation is not causal
	Time-series/Ecological study	Low-quality time-series or ecological studies
	Combination based on selected studies by each stage on analytic framework	Several studies concerning test accuracy and survival rate, etc at various stages of analytic framework
3	Non-analytic study	Case reports, case series, etc
4	Expert opinion	

RCT, randomized controlled trial

**Table 2.** Comparison of population-based and opportunistic screenings\*

Screening program	Population-based screening**	Opportunistic screening
Aim	Reduce cancer mortality at the population level	Reduce cancer immortality at the individual level
Provider	Decision-maker for health plan of local municipalities and workplace	Variable
Outline	Public service for prevention	Spontaneous medical services in clinical settings
Target population	Specified: all members limited to specific age range.	Variable: limited to asymptomatic person
Screening test	Method to reduce mortality from specific cancer: chosen based on the cancer screening guidelines by local municipality and workplace	Variable: chosen based on individual preference***
Sensitivity of test	The most sensitive test may not be chosen	The most sensitive test is usually chosen
Specificity of test	High specificity is important for reducing unnecessary work up of false-positive results and associated adverse effects	High specificity is less important at individual level
Quality assurance	Continues monitoring	Not be monitored
Available financial resources	Limited at the population level in relation to the politics of health spending, taking into account all aspects of health care	Limited at the individual level
Benefits	Maximized for the population within available resources	Maximized for the individual
Harms	Minimized for the population to avoid	Not necessarily minimized

\*The table was customized for the Japanese situation based on the article by Miles et al. (*Cancer* 2004;101:1201-13).

\*\*Organized screening is conducted systematic invitation based on specific target and monitoring for quality. In Japan, population-based screening is still in its early stages as a form of organized screening.

\*\*\*In opportunistic screening, the screening method should be chosen based on the cancer screening guidelines. If this is impossible, the benefits and harms of specific cancer screening programmes must be explained.

**Table 3.** Recommendation grades

Recommendation	Population-based screening	Opportunistic screening	Level of evidence
A	The JRGCSG strongly recommends the use of the method based on sufficient evidence which evaluated mortality reduction from the specific cancer by cancer screening	The JRGCSG strongly recommends the use of the method based on sufficient evidence that evaluated mortality reduction from the specific cancer by cancer screening	1++/1+
B	The JRGCSG recommends the use of the method based on fair evidence that evaluated mortality reduction from the specific cancer by cancer screening	The JRGCSG recommends the use of the method based on fair evidence that evaluated mortality reduction from the specific cancer by cancer screening	2++/2+
C	The JRGCSG recommends against the use of the method.	The JRGCSG judges that this method could be used; both adequate risk management and informed consent about harms are needed.	1++/1+ 2++/2+
D	The JRGCSG recommends against routine use based on sufficient evidence.	The JRGCSG recommends against routine use based on sufficient evidence.	1++/1+ 2++/2+
I	The JRGCSG recommends against routine use due to insufficient evidence.	The JRGCSG recommends against routine use due to insufficient evidence. If the patient requests, decision-making should be done at the individual level based on appropriate information.	1-/-/3/4

JRGCSG, Japanese research group for cancer screening guidelines

be used for either population-based or opportunistic screening programs. A grade C recommendation implies that the method should not be used for population-based screening; although there is sufficient evidence, important harms that cannot be ignored could occur. Thus, considering the balance of the benefits and the harms, these could not be recommended for population-based screening. However, a Grade C recommendation implies that the method could be used in clinical settings if both adequate risk management and informed consent about the harms were assured. Programs for which there is insufficient evidence are graded as I; they are not recommended for routine population-based screening or as screening methods in clinical settings, although the decision to undergo screening could be made at the individual level based on appropriate information provided by health professionals in clinical settings.

The guideline development group and all members of the JRGCSG are involved in allocating the recommendation grades. All members must agree with the recommendation; any major issues discussed in the meeting are noted in the guidelines.

#### FORMULATING GUIDELINE

A draft guideline is prepared based on the recommendation of the Research Group for Cancer Screening Guidelines. The members of the Panel for each guideline program write the draft. The draft is evaluated by peer reviewers and at a national open meeting. All guidelines are reviewed in draft form by eight independent referees from two expert groups: an expert group dealing with screening, diagnosis and treatment for the specific cancer and another specialty group,

such as general practitioners or experts in public health, disease management, epidemiology and health technology assessment. For peer reviews, the AGREE instrument (8) and the checklist proposed by the Conference on Guideline Standardization (10) were modified to evaluate the cancer screening guidelines. Questions about the appropriateness of the level of evidence and the recommendation grade were added. A 27-item checklist is used for peer review. The draft guideline is available on our web site (Promoting Evidence-based Cancer Screening: <http://canscreen.ncc.go.jp/>) for a limited period prior to official publication. The Research Group for Cancer Screening Guidelines holds a national open meeting to discuss each draft guideline. Taking into account the comments received, the appropriateness of the recommendation is discussed and the guideline is refined.

#### PUBLICATION

The guidelines are published in several forms. The full text version contains the recommendations, details of how they were developed and information about the evidence on which they were based. The concise version includes the recommendations and short comments about the evidence. The non-specialist version is mainly targeted at public health nurses who work in local municipalities; it can be easily understood and can be used to provide information to cancer screening participants. All of the guidelines are posted on the following website: Promoting Evidence-based Cancer Screening and Research Center for Cancer Prevention and Screening, National Cancer Center (<http://ganjoho.ncc.go.jp/pro/index.html>).

## DISCUSSION

Cancer screening guidelines are required to promote effective cancer screening to primarily achieve mortality reduction from a specific cancer, or to reduce the incidence of late-stage cancer in some cases, such as cervical cancer screening. In Japan, the Research Group for Cancer Screening Guidelines refined the development process for cancer screening guidelines. Compared with previous reports, the Japanese Guidelines for Cancer Screening development process has certain unique characteristics. Our guidelines include a system of recommendation grading that is divided into population-based and opportunistic screening programs. It provides a consistent and transparent process for evaluating cancer screening based on a standardized method. Using the recommendations, effective cancer screening programs can be developed.

Screening program requirements differ among countries due to differences in the incidence and mortality of specific cancers. Although global evidence is a preferable starting point for evaluating the efficacy of a particular screening test, local evidence is needed to determine what should be done in a specific setting (11). In Japan, gastric and lung cancer screening are major issues due to the high incidence and mortality of these cancer (12). Although an RCT is considered to be the most reliable study design to evaluate cancer screening, the results of these studies are limited to screening for specific cancers. Thus, we also use evidence obtained from case-control and cohort studies conducted in Japan. Additionally, indirect evidence is used to formulate recommendations; however, the use of indirect evidence is strictly limited to the situation where the accuracy of a new screening method can be compared with that of an established method that is supported by RCTs. For example, this process was followed for determining the recommendation for immunological FOBT. The efficacy of chemical FOBT screening was evaluated by three RCTs. However, the evidence for the efficacy of immunological FOBT was considered weak, because the efficacy was evaluated by observational studies. On the basis of this process, the accuracy of both tests was compared to assess the value of immunological FOBT screening. Thus, immunological FOBT screening could be adopted as a Grade A recommendation.

The recommendations grading systems are based on the best available evidence. If the evidence is strong, the process should be straightforward, and the evidence should translate directly into recommendations. However, when there is disagreement among the members of the guideline development group, a consensus must be reached. For several guidelines, if there is poor evidence, formal consensus methods are adopted (13,14). Using a formal approach that is explicit and transparent, it is possible to trace how the group reached a decision. In contrast, the GRADE group defined a new system that takes into account the study design, study quality, consistency and directness (15). We experienced no difficulties in our process of grading the

recommendations; however, a clear process is needed that considers all of these methods to ensure that difficulties can be resolved.

Despite the use of the latest methods, our guideline development process does have certain limitations. First, economic evaluations are not used to determine recommendations. NICE clarified the need to introduce health policy from the perspective of health economics (6). It is important to consider costs when developing guidelines, because resources are always limited (16). An economic analysis can provide useful information for improving health outcomes in an environment with limited resources. Secondly, service user involvement needs to be considered. Although several comments from the general public can be received at the national open meetings, the opportunity for service user involvement is limited in our process. On the other hand, many clinical guidelines have included patient involvement (3,17). Thirdly, to promote informed decision-making for cancer screening, a version of the guidelines that is accessible to the public needs to be developed (18,19).

Finally, our guideline development process does not deal with issues surrounding implementation. Evidence-based medicine requires evidence-based implementation (20). In Japan, population-based screening has not matured due to a lack of key elements required for organized screening. It is impossible to reduce mortality from a specific cancer without an appropriate implementation system that includes quality assurance. Implementation of a guideline should be monitored and evaluated through clinical audit (4). A monitoring system could be conducted that would be limited to population-based screening programs. The European Community Guidelines defined performance indicators for mammography screening (21); they have been used to assess the implementation of cancer screening programs (22,23). Thus, appropriate performance indicators need to be developed for the quality assurance of cancer screening programs that are based on our guidelines.

To reduce cancer mortality, effective screening is required that is based on the cancer screening guidelines. Recommendations based on a rigorous process of guideline development are needed. We standardized the original method that was used for the development of the Japanese Guidelines for Cancer Screening. Based on this method, colorectal, gastric and lung cancer screening guidelines were revised. Nevertheless, the development process needs to be refined further based on international collaboration of guideline development and its applicability to the Japanese Guidelines for Cancer Screening.

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## Conflict of interest statement

None declared.

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## JAPANESE RESEARCH GROUP FOR DEVELOPMENT OF CANCER SCREENING GUIDELINES

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