

Methodology quality and grading recommendations in cancer screening guidelines: a systematic review

Jiang Li (✉ lij0515@sina.com)

Cancer Hospital Chinese Academy of Medical Sciences & Peking Union Medical College

Li Ni

Cancer Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College

Yao Pengtao

Cancer Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College

Tong Yajing

Lanzhou University

Yang Min

Cancer hospital, Chinese Academy of Medical Sciences & Peking Union Medical College

Chen Yaolong

Lanzhou University

Feng Xiaoshuang

Cancer Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College

Lv Zhangyan

Cancer Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College

Wang Xiaoqin

Lanzhou University

Yang Kehu

Lanzhou University

Dai Min

Cancer Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College

Chen Wanqing

Cancer Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College

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Abstract

Introduction: Cancer prevention and screening guidelines are ideally suited to the task of providing high-quality and effective screening in clinical practice. We systematically reviewed cancer screening guidelines for recommended cancer prevention and screening interventions, in order to provide recommendations for development and implementation of high-quality guidelines.

Methods: We included cancer screening and prevention recommendations mainly on lung, breast, gastric, liver, colorectal, and prostate from Pubmed, Embase, Web of Science, China Knowledge Resource Integrated Database, Wanfang Data, SinoMed, and then searched in other organizations' website and database such as the United States Preventive Services Task Force, the American Cancer Society, the American College of Physicians, the National Comprehensive Cancer Network, the National Institute for Health and Care Excellence, European Society for Medical Oncology, and the National Guidelines Clearinghouse until June 30, 2018. An abstraction form to code information according to AGREE II was made and four researchers completed separately. The primary outcome was each recommendation's quality; the second outcome was benefit-harm "comparability" rating, based on how benefits and harms were presented.

Results: There are no high-quality guides in the 19 guides because each domain 3 didn't reach 60 points, and only 2 guides scored above 50 points. 10 recommendations 9 guidelines were included, year from 2010 to 2018. The majority of guidelines (67%) were supported by a systematic review and that most guidelines had explicit criteria for rating the quality and strength of evidence (64% and 73%, respectively). 7 guidelines clearly mentioned benefits and harms, and 2 only mentioned relevant content. Four of the 55 recommendation statements we reviewed presented the benefits of the intervention in terms of a relative risk reduction (larger number) while presenting the harms in terms of an absolute risk reduction (smaller number).

Conclusions: Our findings led us to consider potential contributors to the lack of clarity in guidelines. We recommend the use of "summary of findings" tables, an approach proposed in a series of papers from the GRADE guidelines group, as the best method of summarizing and presenting outcome information.

Introduction

Clinical practice guidelines (CPG) are systematically developed statements to assist practitioner and patient decisions about appropriate healthcare in specific clinical circumstances. The Institute of Medicine's standards for guideline development identifies that "a clear description of potential benefits and harms should be provided for each recommendation in a clinical practice guideline"[1]. They are intended to facilitate more consistent, effective and efficient medical practice, and improve health outcomes [2, 3]. CPGs aimed at directly influencing patient, clinician and policy maker decision making. They are also becoming the basis of quality of care measures that are likely to affect urologist reimbursements with pay for performance measures on the horizon [4–6].

Although clinicians' perceptions about the magnitude of benefits and harms help shape their recommendations when discussing cancer screening with patients. It is useful and necessary for clinicians if guidelines are in good quality and reliability. When the qualities of clinical guidelines are not presented in a balanced fashion, testing and treatment decisions can be adversely affected [7].

However, there are not any evidence-based guidelines in cancer screening in China presented and guided[8]. How these important clinical resources present recommendations has not been previously evaluated and extended to cancer screening in China. In order to know the quality of the guidelines in cancer screening and give the recommendations to Chinese guideline makers, we systematically examined how guidelines present quality information according to AGREE II and RIGHT.

Methods

We set an investigative group including 16 researchers and assistants on training, searching, evaluating, discussing guidelines and drafting the manuscript. The group had a kick-off and arrangement meeting in April 2018. The group leader (LJ) and creators in-chief (DM, CWQ, SHC, CYL) discussed the implementation process. During the meeting, the search strategy prepared for guidelines related to cancer screening pre-retrieved in the United States Preventive Services Task Force (USPSTF) and decided the final version.

We included the target cancer whether the incidence and mortality was within the top ten from the International Agency for Research on Cancer database and most concerned[9]. We also documented whether life-years or quality-adjusted life-years lost because of the target cancer were mentioned. Finally, lung, breast, gastric, liver, colorectal, and prostate cancer screening guidelines were decided to evaluate in our systematic review.

Source of materials

For the purposes of this study, all recent clinical practice guidelines/ recommendations for organizations around the world were search electronically in Pubmed, EMBASE, Cochrane Library, Web of Science, and other English databases and China Knowledge Network, Wanfang Database, China Biomedical Literature Database, etc.. Then we group reviewed and retrieved USPSTF, American Cancer Society (ACS), (International Agency for Research on Cancer (IARC), Guideline International Network (GIN), China Guidelines Clearinghouse (CGC), until June 30, 2018.

We included guidelines with sufficient evidence reported based on systematic review and meta-analysis and scaled by Grading of Recommendations Assessment, Development and Evaluation (GRADE) or any other evidence scaled tools. All guidelines/recommendations discussing the high-risk evaluation, technology, benefits and harms of cancer screening with population/patients were also included as "positive recommendations" "positive guidelines". We excluded statements with insufficient evidence, focusing solely on behavioral counseling or children/adolescent populations. Recommendations/guidelines often can appear in multiple forms including summary, document, and published manuscript within a medical journal. We'd better to find and evaluate the most complete version available. If several versions of a guidelines/ recommendations from an organization were available, we formally reviewed only the most recently published version.

Instruments

All methodological quality of guidelines were assessed by the AGREE II instrument within six main domains: 1) scope and purpose; 2) stakeholder involvement; 3) rigor of development; 4) clarity of presentation; 5) applicability; and 6) editorial independence. Each domain is divided into smaller categories called items, with a minimum of 2 items (domain 6) and a maximum of 8 items (domain 3), for a total of 23 items with the total score 84.[10]

Selection of Specific Recommendations

Two (LJ and CYL) trained four research assistants (WD, WXQ, YPT, and TYJ) using the “Screening for Lung Cancer: Systematic Review to Update the U.S. Preventive Services Task Force Recommendation” available from the USPSTF. After training, they can review the eligible guideline documents in their entirety, including abstracts and online appendices and tables, to abstract each specific recommendation within the document. LJ and CYL also trained these four assistants how to use the AGREE II instrument in Chinese and English versions. They also needed to complete the online AGREE II overview tutorial and practice exercise.

We pilot-tested the tool’s use in two separate sets of the guideline before the entire evaluation and grading. Each assistant independently scored the guidelines using the AGREE II items and then assigned an overall quality rating to the guidelines using the same 7-point scale. They also indicated whether: recommended its use by clinicians for practice, recommended its use with some modifications, or did not recommend its use. When assistants met problems, they would discuss with the PI and creators in-chief timely. Two (LJ and LN) then reviewed each recommendation/guideline to ensure all were correct.

Data Extraction and Management

Two assistants (LJ and YM) used the software Endnote X to manage and storage the full text of each eligible recommendation/guideline. The goal of this study was to evaluate the quality especially the method using by guideline developers. Two research assistants (WXQ and FXS) used a standardized form which was discussed and made by creators in-chief to retrieve quality information according to AGREE II and both quantitative and qualitative data from each guideline/recommendation independently. Then two (LJ and CYL) reviewed the abstracted information to check the extraction. Differences were highlighted and resolved by other group researchers, consulting the guideline document as needed.

Grading of the items and domains

The AGREE II user manual was used by appraisers to refer to the criteria for each item. A grade was assigned for each item using a 7-point scale indicating the level of agreement with each statement about the methodological quality of the guidelines/ recommendations. A score of 1 was given if none of the criteria for an item were met or the item was reported very poorly, while a score of 7 was given for an item if it met all the criteria and was well reported. The domain score was calculated using the sum of the item scores in a given domain and transforming the number into a percentage of the maximum score that domain could obtain. For this review, a high quality guidelines/recommendations required a score of 60% for rigor of development (domain 3) as well as 60% in any two other domains. Discrepancies were resolved by consensus after discussion among reviewers.

Analysis

We used descriptive statistics (eg, means, standard deviations, frequencies) to summarize the guideline data and the quality information based on AGREE II. The quality by guideline type, guideline year, and target cancer to evaluate for any patterns that might emerge were tabulated.

All assessments were based on the published full text versions of the guidelines/recommendations and on any supporting documentation as referenced. For our hypothesis we performed descriptive statistics and nonparametric tests using SAS 9.4 to calculate the intraclass correlation and the variation for each of the 23 AGREE II questions as a measure of interrater reliability. Intraclass correlation was considered poor, fair, good and excellent for values in the range of less than 0.4, 0.40 to 0.59, 0.60 to 0.74 and 0.75 to 1.0, respectively.

Results

Summary and Characteristics of Guidelines

Finally, 10 recommendations or consensus, 9 guidelines were included. Table 1 showed them with a variety of different cancers for screening, publication (updated) years, guideline titles, organizations, whether based on systematic review or meta-analysis, whether using GRADE, whether considering benefits and harms etc. The correlation was reported 0.81.

Table 1
Summary and Characteristics of Guidelines

Cancer type	Guidelines	Year	Published agencies	High-risk / target population	Screening approach	Systematic review/meta-analysis	Grade of evidence	benefits and harms
Lung cancer	China national lung cancer screening guideline with low-dose computed tomography (2015 version)	2015	NHFPC of China	aged 50–74 years, 20 pack-year smoking history, quit within the past five years	low-dose computed tomography (LDCT)	systematic review	No	Yes
	Chinese guidelines for screening lung cancer with low-dose spiral CT in China (2018 edition)	2018	NHFPC of China	Aged 50–74 years; Smoking 20 packs a year, or quitting for 5 years.	LDCT	Yes	No	Yes
Breast cancer	Guidelines for diagnosis and treatment of breast cancer of China anti-cancer association (2017 edition)	2017	Chinese Anti-cancer Association(CAA)	Clear genetic predisposition of breast cancer, patients with pre-existing atypical ductal or lobular hyperplasia in situ (LCIS) of the breast	Mammography, or combined ultrasound	No	No	Yes
Gastric cancer	Consensus on early gastric cancer screening and endoscopic diagnosis and treatment in China (April 2014, Changsha)	2014	Chinese Medical Association(CMA)	over 40 years old, people in areas with high incidence of gastric cancer, Hp infection, previously suffered from chronic atrophic gastritis, gastric ulcer, gastric polyp, residual stomach after surgery, hypertrophic gastritis, malignant anemia and other pre-gastric cancer diseases, first-degree relatives of patients with gastric cancer;	Pepsinogen(PG), gastrin-17, Upper gastrointestinal barium meal examination, endoscopy	Review	No	Yes
	Gastric cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up	2016	ESMO Guidelines Committee	No clear	endoscopy, CT	No	YES(adapted from US Public Health Service Grading System)	No
	Consensus on early gastric cancer screening procedures in China (draft) (2017, Shanghai)	2017	National clinical research center for digestive diseases, CMA	≥ 40 years old and meets any of the following criteria: 1.Population in areas with high incidence of gastric cancer;2.Hp-infected;3.Previously suffered from chronic atrophic gastritis, gastric ulcer, and other pre-gastric cancer diseases;4.First-degree relatives of patients with gastric cancer	New gastric cancer screening scoring system, serum pepsinogen, endoscopic screening	No	No	Yes
liver cancer	Asian Pacific Association for the Study of the Liver consensus recommendations on hepatocellular carcinoma	2010	The Asian Pacific Association for the Study of the Liver (APASL)	cirrhotic patients with HBV and HCV as candidates for surveillance at the present moment	ultrasonography (US) and a-fetoprotein (AFP) every 6 months, or CT, MRI	systematic review	Yes(according to the Oxford system)	No

Cancer type	Guidelines	Year	Published agencies	High-risk / target population	Screening approach	Systematic review/meta-analysis	Grade of evidence	benefits and harms
	EASL–EORTC Clinical Practice Guidelines: Management of hepatocellular carcinoma	2012	EASL–EORTC	Cirrhotic patients, Non-cirrhotic subjects, Treated viral chronic hepatitis	ultrasonography	Review	Yes(GRADE)	NO
	Guidelines for Diagnosis and Treatment of Primary Liver Cancer in China (2017 Edition)	2017	NHFPC of China	older than 40 years	Ultrasonography, CT, MRI	No	No	Yes
Colorectal Cancer	Consensus on screening, diagnosis and treatment of early colorectal cancer and precancerous lesions in China	2015	CMA	All patients with hematomogenous stool, black stool, anemia, weight reduction and colorectal cancer alarm symptoms and 50 ~ 74 years old patients without colorectal cancer alarm symptoms	High-risk questionnaire, fecal occult blood, colonoscopy,	Review	No	Yes
	Colorectal Cancer Screening for Average-Risk Adults: 2018 Guideline Update from the American Cancer Society	2018	American Cancer Society (ACS)	45 years	Colonoscopy(Every 10 y), CTC(Every 5 y), FS(Every 10 y)	Yes	Yes (GRADE)	Yes
Prostate Cancer	Consensus of prostate cancer screening	2017	CAA	Man at age > 50;Men aged > 45 with a family history of prostate cancer; Men 40 years old > with baseline PSA > 1 micron/L	PSA	Review	No	Yes
	Prostate cancer screening with prostate-specific antigen (PSA) test: a clinical practice guideline	2018	BMJ Rapid Recommendations team	men without a previous diagnosis of prostate cancer	prostate-specific antigen testing	Yes	Yes (GRADE)	Yes
	Screening for Prostate Cancer US Preventive Services Task Force Recommendation Statement	2018	USPSTF	70 years and older	PSA-based screening	systematic review	No	Yes
Cervical cancer	2012 Updated Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors	2012	American Society for Colposcopy and Cervical Pathology	No clear	colposcopy and cytology at 6-month intervals	Yes	Yes (modification)	Yes
	Screening for Cervical Cancer US Preventive Services Task Force Recommendation Statement	2018	USPSTF	21 to 29 years	cervical cytology, or primary hrHPV testing, or both	systematic review	Yes(GRADE)	Yes

Cancer type	Guidelines	Year	Published agencies	High-risk / target population	Screening approach	Systematic review/meta-analysis	Grade of evidence	benefits and harms
Esophageal cancer	Consensus of experts on early esophageal cancer screening and endoscopic diagnosis and treatment in China (2014, Beijing)	2014	CMA, CAA	over 40 years old, from areas with high incidence of esophageal cancer, upper gastrointestinal symptoms, family history of esophageal cancer, patients with precancerous esophageal diseases or precancerous lesions	endoscope	Review	No	No
	Chinese consensus : Screening, diagnosis and treatment of early esophageal squamous cell carcinoma and precancerous lesions (2015, Beijing)	2015	CMA	40 to 74 years old and people with unknown family history	Risk factor questionnaire, gastroscopy	Review	No	Yes
Endometrial cancer	Consensus on screening and early diagnosis of endometrial cancer (draft)	2017	Expert committee on endometrial cancer screening	age \geq 45 years, diabetes, obesity, hypertension, no history of use of sex hormones antagonized by progesterone, polycystic ovary syndrome.	Vagina colour to exceed	No	No	No

Of the 19 guides included, there are 11 guides from China, 4 from the US, 3 from Europe, and 1 from Asia Pacific. Five articles were prepared by the government and the rest were prepared by research institutions. Among the guides, the earliest was the 2010 guide, which focused on nearly two years. The guide covers lung cancer, breast cancer, gastric cancer, liver cancer, colorectal cancer, prostate cancer, cervical cancer, esophageal cancer, endometrial cancer. The system guide method was used in the development of 8 guides, and 6 guides were used for previous studies. General review, the remaining guidelines do not mention related methods. Only four guides used GRADE for evidence quality grading, and three used other evidence grading methods or revised existing grading methods. 14 guides refer to benefits and harms that take into account the screening program.

Methodological quality evaluation results

The quality of the 19 guides included in the study was not high, and the average score of only 2 guides was 50. See Table 2. The methodological quality of the guides from China was poor, especially in the scores of Fields 3 and 6. Few guidelines can use a systematic approach to the retrieval and selection of evidence and fail to perform external expert reviews. In the disclosure of conflicts of interest, China's guidelines have not yet formed a sense of reporting relevant content.

Table 2
Methodological quality evaluation results

Cancer type	Guidelines	Domain1	Domain2	Domain3	Domain4	Domain5	Domain6	Average score
Lung cancer	China national lung cancer screening guideline with low-dose computed tomography (2015 version)	31	6	16	25	15	48	24
	Chinese guidelines for screening lung cancer with low-dose spiral CT in China (2018 edition)	50	21	21	42	21	15	28
Breast cancer	Guidelines for diagnosis and treatment of breast cancer of China anti-cancer association (2017 edition)	0	0	3	28	13	0	7
Gastric cancer	Consensus on early gastric cancer screening and endoscopic diagnosis and treatment in China (April 2014, Changsha)	11	7	4	17	8	0	8
	Gastric cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up	7	7	19	67	19	23	24
	Consensus on early gastric cancer screening procedures in China (draft)(2017, Shanghai)	10	10	4	28	14	0	11
liver cancer	Asian Pacific Association for the Study of the Liver consensus recommendations on hepatocellular carcinoma	6	14	18	57	25	8	21
	EASL – EORTC Clinical Practice Guidelines: Management of hepatocellular carcinoma	29	40	16	50	35	21	32
	Guidelines for Diagnosis and Treatment of Primary Liver Cancer in China (2017 Edition)	3	10	13	7	21	35	15
Colorectal Cancer	Consensus on screening, diagnosis and treatment of early colorectal cancer and precancerous lesions in China	26	7	3	31	18	4	15
	Colorectal Cancer Screening for Average-Risk Adults: 2018 Guideline Update from the American Cancer Society	50	63	54	79	54	50	58
Prostate Cancer	Consensus of prostate cancer screening	36	22	29	33	23	17	27
	Prostate cancer screening with prostate-specific antigen (PSA) test: a clinical practice guideline	25	35	29	31	21	77	36
	Screening for Prostate Cancer US Preventive Services Task Force Recommendation Statement	40	38	36	58	35	52	43
Cervical cancer	2012 Updated Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors	61	19	26	89	19	19	39
	Screening for Cervical Cancer US Preventive Services Task Force Recommendation Statement	64	44	57	58	55	56	56
Esophageal cancer	Consensus of experts on early esophageal cancer screening and endoscopic diagnosis and treatment in China (2014, Beijing)	13	7	2	22	11	8	11
	Chinese consensus : Screening, diagnosis and treatment of early esophageal squamous cell carcinoma and precancerous lesions (2015, Beijing)	21	18	2	32	4	10	15
Endometrial cancer	Consensus on screening and early diagnosis of endometrial cancer (draft)	10	13	2	10	5	0	7

Discussion

The guidelines included in this study are evenly distributed around the world, including China, Asia Pacific, the United States, Europe and other countries and regions. The guides are published by professional organizations, such as academic associations, associations, and national research institutions, and are highly authoritative. Among the guide development agencies, the larger USPSTF and the Chinese Medical Association of China and the China Anti-Cancer Association. Although the time span is large, it is more concentrated in the past two years. The average of 3.6 years of publication, the information is outdated, and some areas of the guidelines have not been well updated, so even the quality of the guide is better. High, but the release or update time is too long, and its guiding role in clinical practice will be greatly reduced [11]. Each guideline elaborates on the target population or high-risk groups, and satisfies the basic conditions for the publication of the guidelines, but the scientific nature of the research is uneven. Only a small number of guidelines can systematically collect, screen, and evaluate existing literature using systematic review methods, and develop clinical guidelines with evidence-based medicine

support. A small number of guidelines evaluate the evidence that is included in order to facilitate readers to make trade-offs, but only a few guidelines. In the future development of guidelines, scholars need to do more in terms of systematic reviews and evidence grading.

As a basis for the development of medical and health work, the quality directly affects the quality of health care services and plays an important role in the health service system [12]. In addition to the content related to the systematic review, there are still many problems in the included guidelines. The ultimate goal of the guide is to benefit the target population, but the 14 guidelines do not take into account the views and choices of the target population and lack ethical support. The purpose of the development guide is to serve health practice and to provide specific and practical guidance, so applicability is one of the important indicators of the evaluation guide. Only 3 of the included guides refer to comments or tools for applying recommendations, and 11 guides report potential related resources when applied, and the overall applicability is not high. Guideline development requires a certain amount of funding to be successfully completed, and conflicts of interest between funders and guideline developers become the most common source of bias in the guideline development process, and guidance as a guiding document for health practice must be objective and independent. So disclosure of conflicts of interest in the development of guidelines is increasingly important to improve the transparency of the guidelines. Only 9 of the 15 guides reported funding sources and conflicts of interest, and most Chinese guidelines did not mention conflict-related content.

Presenting high-quality quantitative estimates is possible for the cancer prevention services we reviewed. One reason may be a belief among guideline developers that recommendations should be as simple as possible. However, that reasoning does not justify omitting this information from the text and appendices. Another reason might be a fear among guideline developers that too much transparency may lead individual clinicians and patients to decide against utilizing a preventive service when guideline developers believe the service is valuable. Finally, there may be a belief that from a population perspective any cancer screening or prevention service with a statistically significant improvement in mortality is worthwhile. More broadly, the GRADE group now recommends that guideline developers present much quality table. The guidelines reviewed in this study were largely written prior to these GRADE recommendations. It is possible that future cancer screening and prevention guidelines may put more emphasis on the way benefits and harms are presented. Ideally, our study will motivate guideline developers to consistently include outcome summary tables similar to the ones the GRADE group recommends.

Prior to quantifying estimates of absolute effect for different outcomes, guideline groups must identify what the important outcomes are and determine the quality of evidence for each outcome. Determining estimates of absolute effect for each important outcome is a critical next step. The focus of our paper is how guidelines present these outcome estimates.

This paper focuses on how benefits and harms are presented to clinicians. An in-depth discussion of the extent to which clinicians should present numerical information to patients and how best to communicate this information to patients is beyond the scope of this paper. It is often argued that patients do not understand numbers and thus it might be better to avoid providing risk information as it might be too confusing. However, there are many articles that have provided advice on how to make complicated risk statistics easier for patients (and likely their providers) to understand.

Although absolute effects are difficult to know precisely, firm recommendations should not be made without guideline developers and clinicians at least estimating how big the absolute benefits and harms are most likely to be. Groups recommending interventions for asymptomatic individuals should strive to clearly present absolute estimates for the chance of benefit and harm. The GRADE approach for creating summary of findings tables within guidelines-which includes how to present measures of absolute effect for both benefits and harms-could help standardize this task. Without access to transparent risk information on all clinically important outcomes, clinicians and policy makers cannot properly judge the trade-offs. Moreover, without such information clinicians cannot fully engage patients in true shared decision-making.

Declarations

Ethics approval and consent to participate

An ethical exemption were applied.

Consent to publish

The "consent to publish" was submitted as additional supporting files.

Availability of data and materials

This section was presented within the additional supporting files.

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Conflict of interest

None.

Authors' contributions

Li J, Li N and Chen WQ have the idea. Yao PT, Tong YJ, Yang M, Lv ZY, Wang XQ and Feng XS searched the database and extracted data. Yang KH, Dai M and Chen YL checked and approved the manuscript.

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