New American Cancer Society Process for Creating Trustworthy Cancer Screening Guidelines

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American Cancer Society (ACS) cancer screening guidelines have high credibility in the United States among the general population and health care professionals and have been cited by policy makers as legal mandates for health insurance companies in many states.1-4 The organization is therefore in an important position to educate these groups about the benefits, limitations, and harms of cancer screening tests. However, there are many other cancer screening guidelines. The National Guidelines Clearinghouse includes a collection of nearly 3000 clinical practice guidelines, with more than 180 guidelines for early detection of cancer.5 Many cancer screening guidelines differ, even when purported to have been based on the same set of evidence.6,7 Those differences can cast doubt on the credibility of both the recommendations and the organizations that produced them.

In March 2011, the Institute of Medicine (IOM) released 2 reports on standards for creating trustworthy clinical practice guidelines, one providing recommendations for how clinical practice guidelines should be created8 and the other providing recommendations for how systematic evidence reviews should be conducted.9 The primary goals of the reports were to motivate guideline developers to use good processes and provide the users of guidelines with metrics to judge their trustworthi-

Guidelines for cancer screening written by different organizations often differ, even when they are based on the same evidence. Those dissimilarities can create confusion among health care professionals, the general public, and policy makers. The Institute of Medicine (IOM) recently released 2 reports to establish new standards for developing more trustworthy clinical practice guidelines and conducting systematic evidence reviews that serve as their basis. Because the American Cancer Society (ACS) is an important source of guidance about cancer screening for both health care practitioners and the general public, it has revised its methods to create a more transparent, consistent, and rigorous process for developing and communicating guidelines. The new ACS methods align with the IOM principles for trustworthy clinical guideline development by creating a single generalist group for writing the guidelines, commissioning independent systematic evidence reviews, and clearly articulating the benefits, limitations, and harms associated with a screening test. This new process should ensure that ACS cancer screening guidelines will continue to be a trustworthy source of information for both health care practitioners and the general public to guide clinical practice, personal choice, and public policy about cancer screening.

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ness. Those reports have defined new standards for how guidelines should be developed to increase their inherent quality while ensuring their trustworthiness in the eyes of clinicians, the public, and policy makers. To continue to deserve high levels of public trust, the ACS must demonstrate that it is using a transparent and trustworthy process for creating and communicating guidelines for cancer screening.

During 2010, in parallel with the work of the IOM, the ACS was also engaged in evaluating its own process for creating cancer screening guidelines. Early that year, the ACS Board of Directors appointed the ACS Guidelines Process Workgroup to review the methods used by the ACS and other organizations to create such guidelines and recommend any needed improvements. Throughout 2010, the workgroup met to develop its recommendations, and after the IOM reports were released in March 2011, the workgroup refined its recommendations so the ACS process would be consistent with the latest standards for clinical practice guideline development. This Special Communication summarizes the new process the ACS will use for developing and communicating cancer screening guidelines.

How the ACS Formerly Created Cancer Screening Guidelines

Historically, ACS staff and volunteer leaders have appointed ad hoc cancer screening guidelines groups, which have varied in size and composition, typically including many relevant specialists joining with other members who are experts in cancer treatment, epidemiology, and primary care. Although this approach has resulted in highly credible and clinically useful guidelines, there have been problems. First, any guideline developed by a group heavily represented by a particular subspecialty that advises greater use of a procedure delivered by that subspecialty could be devalued by the perception of conflict of interest. Second, the composition of ACS screening guideline committees and their methods have varied across different guidelines. Third, although the ACS has usually produced guidelines of its own, it has sometimes produced guidelines with other professional organizations. Such collaboration can reduce differences between guidelines, but joint guideline development usually involves longer periods, varying methods, and the risk of appearance of professional conflicts of interest by organizations representing particular medical specialties. Fourth, in the past, the volunteer experts and staff developing specific ACS cancer screening guidelines have presented the critical evidence, discussed it, and then variously summarized it in the written guidelines. Although the guidelines have been based on scientific evidence and in recent years the ACS has commissioned systematic evidence reviews, the methods for reviewing the evidence have not followed a defined, consistent process. Fifth, it has been difficult for guideline users to understand why ACS guidelines sometimes differ from those of other organizations because the ACS guidelines have not included full discussions of the reasons for those differences.

New Process for Creating ACS Cancer Screening Guidelines

The ACS will continue to develop guidelines for cancer screening to meet the needs of clinicians, the general public, and policy makers and has redefined its policies and practices for their development in accordance with the following 8 principles for trustworthy clinical guidelines development, as recommended by the IOM (TABLE).

Transparency. This article defines the process the ACS will use for creating and communicating cancer screening guidelines. This method and full protocols will be posted on the ACS Web site, including timelines for all cancer screening guidelines planned and in development. Transparency can also be achieved through collaboration and communication. Although the ACS will not produce these guidelines in partnership with other organizations, it will solicit timely input and comment from relevant professional and interest groups on final drafts before publication.

Conflicts of Interest. Conflicts of interest regarding personal and organizational finances are already managed carefully by the ACS. The more difficult issue in cancer screening guideline development is the management of professional conflicts of interest, in which advice can be perceived as exceeding evidence to promote greater use of a procedure provided by members of a particular specialty. Although the clinical expertise of specialists is a critical ingredient in any guideline, the self-interest of a specialty group may either influence judgments or create the appearance of such influence and thereby adversely affect the credibility of a guideline. The IOM determined that because subspecialists have economic conflict, they should not be directly involved in the final process of guideline writing.

Group Composition. The ACS approach will separate the process of receiving expert input from that of writing the guideline, providing the guideline writing group with appropriate specialty expertise while protecting it from the appearance of professional conflict of interest. The ACS Board of Directors will appoint a single group, the ACS Cancer Screening Guidelines Development Group, to create all ACS cancer screening guidelines. This group will supervise or commission the review of evidence, consider the opinions of expert clinical consultants, transform that evidence into an estimation of clinical benefits and harms, and then write the guideline. The group will be composed of 12 members appointed for 5-year terms, including 1 patient advocate, who will promote the rights of the patient in shared decision making. The remaining 11 members will be generalist health care professionals and clinical and population health care professionals with expertise in the interpretation of evidence regarding benefits, limita-
tions, and harms of clinical interventions. The ACS Cancer Screening Guidelines Development Group will invite content-specific input from expert subspecialists for each guideline to help inform their process of interpretation of evidence, but these ad hoc advisors will not be directly involved in guideline writing. All members of the group, as well as the ad hoc advisors, will regularly disclose publicly any potential conflicts of interest.

Systematic Evidence Review. In evidence gathering, the process of conducting a systematic review has been defined as an essential component of a credible guideline development process.\(^8,9\) The ACS will develop contractual relationships with experienced authors who have conducted systematic reviews, who will be charged to objectively summarize the evidence and estimate benefits and harms, using methods consistent with IOM committee standards. Decisions about the scope of the systematic review will be made by the ACS Cancer Screening Guidelines Development Group at the outset of the process for each guideline, and all commissioned reviews should adhere to the methodology standards as defined by the IOM.\(^9\) In some cases, the commissioned review can simply build on an existing systematic review, which is common practice by guideline developers. Although empirical evidence is always preferable, the ACS guidelines process will use decision modeling when appropriate. In some instances, authoritative models might be available for use and modification by the ACS, and in other instances, the group will commission modeling for specific purposes. Statistical modeling can directly inform guidelines by projecting outcomes in some situations for which definitive evidence is not available to answer specific questions. Decision models are useful to estimate benefits and harms to inform screening recommendations when empirical data are lacking for different clinical screening scenarios that have not been tested in trials.

Grading the Strength of the Recommendations. The ACS Cancer Screening Guidelines Development Group will formally grade the strength of its recommendations. Many methods are used for such grading, and variation in grading schemes across different guidelines is a source of confusion by guideline users. The IOM guideline committee report pointed to the need for better standardization across guideline groups nationally in the schemes that are used.\(^8\) The ACS group will therefore carefully evaluate the methods used for evidence grading by other guideline groups so that the scheme it adopts will be similar, as well as consistent with IOM standards.

Articulation of the Recommendations. An important aspect of explaining the rationale for a recommendation is the clear articulation of both benefits and harms associated with any recommended procedure. Comparing the benefits vs harms of screening (eg, reduced risk of death vs discomfort, anxiety, or medical complications) is difficult because clear evidence of their magnitude may not be available and they are measured with different met-

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### Table. Standards for Clinical Practice Guidelines: Institute of Medicine (IOM) Recommendations and American Cancer Society (ACS) Process

<table>
<thead>
<tr>
<th>Standards</th>
<th>IOM Recommendations</th>
<th>New ACS Process for Cancer Screening Guideline Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transparency</td>
<td>The process and funding of guideline development should be completely specified.</td>
<td>This article defines the new ACS process, and all ongoing and planned work in cancer screening guideline production and revision will be posted on the ACS Web site.</td>
</tr>
<tr>
<td>Conflicts of interest</td>
<td>Conflicts of interest include commercial, institutional, professional, and intellectual conflicts, all of which must be openly declared. Members should divest conflicting financial relationships.</td>
<td>ACS guideline developers will publicly declare financial and intellectual conflicts, and all will be expert generalists to avoid the appearance of professional conflicts.</td>
</tr>
<tr>
<td>Group composition</td>
<td>The guideline group should include multidisciplinary methodological experts, clinicians, and patient advocates.</td>
<td>Guidelines will be developed by a 12-person panel of multidisciplinary experts in clinical screening, including a patient advocate.</td>
</tr>
<tr>
<td>Systematic review of evidence</td>
<td>The guidelines should be based on a systematic literature review that meets the standards set by the IOM.(^9)</td>
<td>ACS will commission high-quality and independent systematic evidence reviews to serve as the basis for all guidelines.(^9)</td>
</tr>
<tr>
<td>Grading strength of recommendations</td>
<td>For each recommendation, the text should explain the evidence and the reasoning, explain the balance of benefits and harms, and indicate the level of confidence in the recommendation.</td>
<td>ACS will be explicit about harms, as well as benefits, and will develop a grading scheme to rate confidence in recommendations that will be consistent with methods used by other organizations.</td>
</tr>
<tr>
<td>Articulation of recommendations</td>
<td>Recommendations should be clearly stated and actionable.</td>
<td>ACS guidelines will be written for audiences of primary care clinicians, the general public, and policy makers.</td>
</tr>
<tr>
<td>External review</td>
<td>The draft guidelines should be posted for public comment, and the final guidelines should be revised as appropriate before peer review.</td>
<td>Before publication, all draft guidelines will be vetted by relevant experts, organizations, and societies, and any differences will be explicitly discussed in the published guideline.</td>
</tr>
<tr>
<td>Updating</td>
<td>Guidelines should be updated when new evidence could result in modifying the recommendations.</td>
<td>ACS guidelines will be briefly updated as needed, and at a minimum at least annually online with relevant new studies, and rewritten every 5 years.</td>
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RICS. The objective of a guideline, which is to clearly compare benefits and harms to justify a recommendation, requires comparison of outcomes that can be based on qualitatively different scales. Thus, any conclusion about the net balance of benefits and harms will always be in part a values-based judgment. Reports of ACS guidelines will describe explicitly, and quantitatively when possible, the benefits and harms of screening. A clear description of the information and values that have affected recommendations will help the ACS to assist both clinicians and the general public in making their own decisions about cancer screening. When the ACS recommendations differ from those of other organizations, the ACS will articulate those differences and the reasons for the differences. The ACS guidelines will be submitted for publication in peer-reviewed journals that reach primary care audiences. As is its current practice, the ACS will also create online postings and other publication products to communicate guidelines to clinicians and the general public. Any new systematic evidence reviews or statistical models conducted to support ACS guidelines will be peer reviewed and published in parallel with the guidelines themselves, either online by the ACS or in a peer-reviewed journal.

**External Review.** Before submission of manuscripts reporting ACS guidelines for peer review and publication, each ACS cancer screening guideline will undergo a formal review process that includes opportunities for national and international experts, as well as professional organizations, to provide review and comment, and records will be kept of responses to those reviews. The published guidelines will then also summarize the opinions and provide a thoughtful discussion of reasons for any differences to assist guideline users with their personal, practice, and policy decisions. Furthermore, the overall process of ACS cancer screening guideline development and the influence of ACS guidelines will be evaluated periodically by an independent advisory group who will report to the ACS Board of Directors about the overall clarity, utility, and influence of ACS cancer screening guidelines.

**Updating.** New evidence is accumulating continuously on cancer screening, so individuals overseeing the ACS cancer screening guidelines must constantly consider the relevance of new information and update guidelines periodically and as needed. There will be a formal review and rewriting of every ACS cancer screening guideline at least every 5 years. The ACS will also perform an informal yearly update of the scientific evidence and update more frequently as needed, depending on the emergence of influential new evidence.

**Comment**

This new ACS process for creating cancer screening guidelines is consistent with new national standards for the creation and communication of clinical practice guidelines. The key features of the new ACS process are a consistent and rigorous process for guideline development, a single generalist expert group to develop all guidelines, use of systematic reviews of the evidence as the scientific basis for each guideline, increased attention to explicit comparisons of benefits and harms, review by other experts and organizations before publication, and increased attention to guideline communication and evaluation.

Managing professional conflicts of interest was identified as a major challenge by the IOM because health care professionals may be regarded as having a conflict simply because the guideline they develop may influence the use of procedures that provide a source of income for them and their professional colleagues. The question of who should develop guidelines was one of the most intensively discussed issues in deliberations of the ACS workgroup, in particular regarding the role of generalists and methodologists vs the role of clinical subspecialists. Although the analyses of particular screening decisions should be informed by the best clinical judgment, tension can exist between specialty expertise and freedom from conflict of interest. With this background, the ACS needed to develop a process that uses specialists’ valuable clinical expertise while avoiding real or perceived conflict. The ACS Cancer Screening Guidelines Development Group will benefit from the advice and input of specialists in particular types of cancer by giving them an advisory role only rather than having them take part in the actual guideline writing. The intent of this approach is to ensure that the group has access to and considers all relevant and current evidence, including factors influencing clinical decision making by experts.

The creation of a separate process for systematic review will also be a new process for the ACS but will make the guidelines process more consistent with the new IOM standards. The guidelines development group will provide detailed specifications to authors of the systematic reviews to define the specific evidence questions and types of evidence that should be reviewed and summarized and then will use that evidence as the basis of guidelines. Although modeling has limitations when the underlying evidence is weak or ambiguous, it can provide useful estimates of benefits and harms that might be expected from specific clinical screening scenarios, such as alternative screening frequencies, for which direct evidence is lacking. The group may therefore sometimes commission modeling to estimate the benefits vs harms for specific clinical screening protocols.

Another important new feature of the ACS process is prepublication peer review, which will offer an opportunity for other experts and other groups to comment and then to highlight any important differences. In adopting this approach, the ACS will be acting in accord with many organizations that operate at the interface between science, policy, and the public. Although the ACS may develop guidelines that differ from those of other organizations, soliciting
input before final publication will increase the likelihood of achieving broad consensus. The final ACS guideline can then discuss any important differences with other guidelines in terms of either evidence interpretation or values. This communication will be increasingly important to the US public as the nation proceeds with health care reform and as cancer screening choices involve increasingly complex scientific, financial, and psychological factors. With increasing scrutiny about value in health services, clear and trustworthy communication about cancer screening benefits, limitations, and harms from a national organization other than a services payer will be especially important.

This new process should ensure that ACS cancer screening guidelines will be a trustworthy source of information for both health care practitioners and the general public and guide clinical practice, personal choices, and public policy about cancer screening.

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REFERENCES

Every gun that is fired, every warship launched, every rocket fired signifies, in the final sense, a theft from those who hunger and are not fed, those who are cold and are not clothed. . . . This is not a way of life at all, in any true sense. Under the cloud of threatening war, it is humanity hanging from a cross of iron.

—Dwight D. Eisenhower (1890-1969)