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Society of American Gastrointestinal and Endoscopic Surgeons guidelines development: Clinical Practice Guideline Update Standard Operating Procedure

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Abstract

Introduction The SAGES Guidelines Committee creates evidence-based clinical practice guidelines (CPGs). Updates which incorporate new evidence into the guidelines are necessary to maintain relevance for clinical use. A description of our standard operating procedure for this process is described here, which contributes to SAGES' commitment to producing high-quality clinical recommendations.

Methods This paper outlines the SAGES Clinical Practice Guideline Update Standard Operating Procedure in order to incorporate regular updates to our guideline development process.

Results SAGES has developed an evidence-based, standardized approach in updating current clinical practice guidelines to ensure that physicians and patients have access to the most appropriate recommendations.

Conclusion Societies that promote guidelines within their organization must make an intentional effort to regularly evaluate the relevance of their recommendations. The SAGES Guidelines Update Standard Operating Procedure aims to provide a framework to reliably and systematically review existing guidelines and update them as needed.

Keywords Clinical practice guidelines · Living guidelines · Guideline update · Current guideline · Protocol · Standard operating procedure

The SAGES Guidelines Committee uses a robust process for developing surgical clinical practice guidelines (CPGs) [1]. While the systematic reviews that are conducted for guidelines are comprehensive, they are only as strong as the literature on which they are based. There are approximately 2 million new medical articles published per year worldwide [2]. Surgical literature from 2016 to 2017 accounted for about three thousand published articles, which was significantly increased from ten years prior [3]. This puts pressure on guidelines developers to revisit their recommendations and incorporate pertinent literature that could alter recommendations.

An explicit and regular schedule is necessary for guideline review and revision to ensure that recommendations remain relevant and safe for their end users. The Agency for Healthcare Research and Quality supported a 2001 study which demonstrated that review of guidelines should be conducted every three years [4]. Another study from the Updating Guidelines Working Group in Spain confirmed that one in five guidelines become outdated after three years [4, 5]. On average, a new SAGES-developed guideline takes about a year to develop. The SAGES Guidelines Committee and the Guidelines Update Task Force (GUTF) deemed that

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five years would be too long to revisit guidelines, given that surgical practice can change rapidly with new and changing technologies. Considering the above, SAGES elected to review guidelines every three years (Fig. 1).

There is no clearly accepted single approach to updating systematic reviews and guidelines. An international consensus document was published in 2016 in an effort to provide a framework for maintaining systematic reviews [6]. The Cochrane handbook has built upon this with a dedicated chapter to help guide researchers in their approach to updates [7]. This standard operating procedure aims to outline the SAGES approach to updating guidelines and their maintenance.

Methods

Guideline updates are influenced by the "Updating a review" chapter in the Cochrane Handbook of Systematic Reviews [7]. They are also influenced by the SAGES Guideline Development Standard Operating Procedure (SOP) [1]. The proposed process was developed with the current Guidelines Committee leadership and the GUTF. The chair of the GUTF and the chair of the Guidelines Committee developed this protocol with the input of the guideline research fellows and co-chairs. Different iterations were discussed based on the current SAGES guideline development standard operating procedure, our experience with guideline development methodology, and what we believed would be most effective in providing up-to-date guidelines while still feasible as a volunteer surgical organization.

Results

Step 0: identify guidelines due for review

All guidelines will be re-evaluated at a three-year interval from the last publication date. If there is evidence of disruptive surgical approaches, surgical techniques, technologies, or drugs that could change a guideline, this would also provoke the GUTF to re-evaluate the relevant guideline. In addition, should a SAGES member or the committee become aware of new trials involving new populations or other evidence that could further inform the recommendations, this may also provoke re-evaluation of the current guideline by the GUTF.

Step 1: key questions

The GUTF will contact the senior author of the previous guideline, the Guidelines Committee chair, research fellow, relevant patient representatives, and potentially other experts

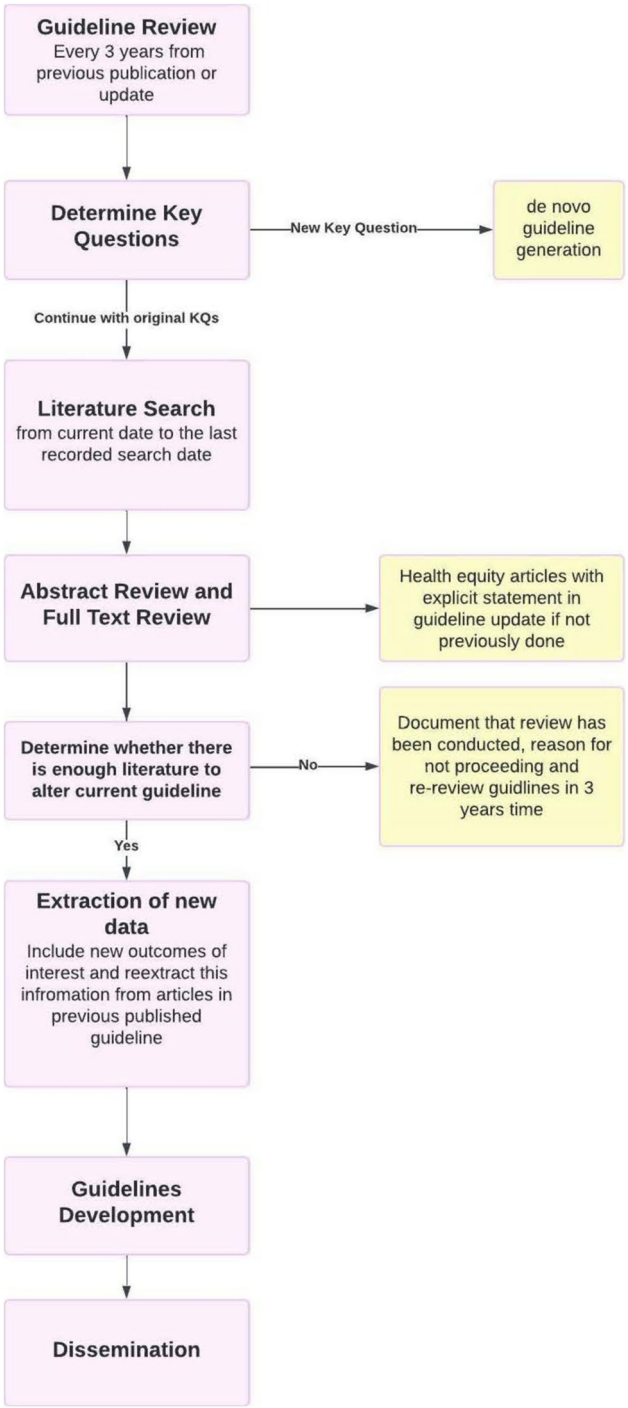

Fig. 1 Summary of the guideline update process created by the SAGES Guidelines Committee and the GUTF. Key questions from the original guideline are evaluated, if new ones are needed then a de novo guideline synthesis process will take place [1]. Otherwise, GUTF will proceed with a literature search using the original search syntax. After full-text review, the criteria in Table 1 will determine the decision to proceed with the update versus stopping

in the field if needed. This small committee will ensure that the key questions (KQs) are still relevant. Experts will be determined by contacting the leads of the relevant SAGES committee group and include a multidisciplinary panel. Experts may include those that have been agreed upon by the formed committee, internal or external, from SAGES. Patient representatives specific to the guideline will also be contacted at this time through the Patient Engagement Task Force to provide their input on outcomes of interest.

New KQs will be generated if new clinical questions have arisen since the last literature review. If a new KQ is agreed upon, then the process would follow de novo guideline generation described in the SAGES Guideline Development SOP [1].

If new outcomes of interest are determined, this will continue through the update process outlined here with some modification, rather than generating a new guideline, as discussed for new KQs. In addition, any question may be excluded at this stage if the question no longer has clinical relevance.

Step 2: literature search

A librarian for the GUTF will conduct a literature search for the selected KQs from the date of the last literature search to the present, using the original search terms.

Step 3 & 4: abstract review and full-text review

The GUTF will review abstracts for inclusion and then proceed with full-text review as described in the SAGES Guidelines Development SOP [1]. In addition, if articles related to health equity in the topic of interest are identified, they will be incorporated to better advise the guideline as described in the SAGES Health Equity SOP [8]. Of note, there will be no calibration phase using Abstrackr, members will begin with abstract and full-text review in Covidence [9, 10].

The GUTF will evaluate the amount of new evidence, including the quality of that evidence, and compare it to the evidence that was used to inform the original guideline. To do this the study design, e.g., randomized trial, will be filtered for in the new search and the trigger for an updated guideline will be made by loosely following Table 1.

The GUTF will then assign articles to relevant KQs and provide a summary of key findings including the number of relevant RCTs and comparative observational studies. Table 1 will be used as a guide to roughly determine whether to proceed with a formal update or only a brief narrative update on the website. This decision will be made with input from the GUTF chair, fellow, Guideline chair, and chair of any relevant, disease-related SAGES committee. If a formal update is decided upon, then members from the original guideline panel will be contacted and asked to participate again. Expanding the panel is also appropriate to multidisciplinary physicians and other guidelines committee members as needed.

Table 1 Decision criteria for a guideline update based on the level of certainty evidence in the original guideline

Certainty of evidence per KQ in original guideline	Triggers in literature search for new project
High	3 RCTs
Moderate	Any of the above OR 1 RCT
Low	Any of the above OR 1 RCT
Very low	Any of the above OR 5 comparative studies
Expert opinion	Any of the above OR Any comparative studies

If the original guideline had high certainty of evidence, then 3 new RCTs must be identified to proceed with an update. Low to moderate certainty of evidence requires at least 1 new RCT to proceed. Very low certainty of evidence requires any RCT evidence or 5 comparative studies to proceed and expert opinion requires comparative data

If it is determined that there is enough literature available to change the current recommendations or could change the strength of current recommendations, then the group will move forward with a formal update and move to data extraction. If it is considered that no recommendations will change, an update will be made on the website describing steps 1–4 for the specific Guideline and outcome of review.

If the previous guideline did not specifically address whether recommendations were applicable to diverse populations with available evidence or did not make a healthy equity statement due to limited evidence, then the guideline will be updated to incorporate the above.

Step 5: data extraction

If after full-text review, it is determined that the current recommendations or strength of the recommendation could change, the GUTF will move forward with full data extraction. Following extraction, an expert panel will be assembled to review the new literature and provide recommendations.

If additional outcomes of interest were identified in Step 1, these will be included in the extraction form in addition to the prior outcomes.

New outcomes will also be extracted from the articles contributing to the previous guideline. This will be limited to RCTs. If no RCTs are available, then only articles with direct comparative evidence utilizing statistical matching will be revisited for extraction of the new outcomes of interest. Based on our experience with guideline development, it is unlikely that low quality evidence would have a large enough

impact to change an active guideline. This reduces resource utilization where futile, contributing to the decision of only using RCTs and direct comparative evidence.

Step 7: data analysis/meta-analysis and follow-up literature search

The statistician will perform an analysis including previous data from the original guideline and merge it with data from the update. A subgroup analysis will also be performed with the most recent literature. This step will otherwise follow the SAGES Guideline Development SOP [1].

If new outcomes have been determined, then these will be analyzed as described in the SAGES Guideline Development SOP [1].

Step 9: guidelines development

If the new evidence is predicted to change the overall recommendation or change the strength of the recommendation, the above panel will be assembled to review the new data (merged with the old data) and amend the guideline as necessary. This will be conducted in accordance with the SAGES Guideline Development SOP [1]. The Patient Engagement Task Force will also be called upon for patient representatives to provide input during this step.

Dissemination

The updated guidelines will be submitted for publication. If a formal update of the guideline is unnecessary, then a small summary of the new literature will be posted online on the SAGES website.

Discussion

Several surgical organizations have made updates to their CPGs over the years [11–15]; however, to our knowledge, we are the first surgical organization to develop a SOP for the process of updating guidelines. SAGES believe that having a dedicated team, Guidelines Update Task Force, and clear procedure for updating guidelines are imperative to ensure the guidelines are current and remain relevant to its membership.

As mentioned by Garner et al. in the 2016 panel for updating systematic reviews, the decision on whether and when to update is a judgment call made for each review [6]. The Cochrane Handbook has also developed a flexible approach to updating guidelines and we understand that this will be an evolving process for the SAGES organization [7].

Despite different approaches, the process of updating a guideline can be resource and time intensive. One group as early as 2001 suggested putting in place continuous prospective processes to help combat the hurdles [16]. This has been coined as "living guidelines" and is the manifestation of a continuous prospective revising process with frequent surveillance of literature and timely incorporation of the new evidence into existing recommendations [17]. While a "living guidelines approach" may be a future direction, SAGES is a volunteer-based organization and at this time, the guidelines that would most benefit from a living guidelines protocol are minimal. Furthermore, surgical data can take longer to collect and accumulate and may require a more substantial amount of time to observe changes. Based on this SOP, all guidelines will be reviewed for update every three years.

SAGES is dedicated to producing quality CPGs and understands that the maintenance of these guidelines is an important part of this process. We believe that the addition of this methodology for updating guidelines will strengthen efficiency, accuracy, and reporting of CPGs to help facilitate evidence-based, high-quality care.

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Declarations

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