



# Handbook for SHEA-Sponsored Expert Guidance, Consensus, and Guideline Documents

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## Purpose and Scope

The SHEA Guidelines Committee (GLC) has created this document to assist SHEA-sponsored writing groups in applying a consistent and rigorous methodology in the creation of guidelines, expert guidance documents (EGs), and consensus statements.

This Handbook is a living document that will be updated at the discretion of the GLC. The first version of this Handbook was published on the SHEA website in January 2016, and does not apply to documents developed prior to that date. It was revised by its authors in January 2017, August 2019, and December 2021. This Handbook was reviewed and formally approved by the GLC and the SHEA Board of Trustees in October 2015, January 2017, August 2019, and January 2022.

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## Introduction

- SHEA-sponsored documents that provide recommendations regarding the practice of infection prevention and control, healthcare epidemiology, and antibiotic stewardship fall into the three broad categories: guidelines, expert guidance documents (EGs), and expert consensus statements (ECSs). Other types of documents are defined in **Appendix 1**, but this Handbook does not guide their development.
- The literature review process utilized by a specific document is determined based on its category, which is identified at the time the document is commissioned; however, the category may be revised after the initial literature review to accommodate for the nature and quality of existing literature on the topic. Category changes need to be reviewed and re-approved by the GLC, Publications Committee, and SHEA Board of Trustees.
- In addition to guidelines, EGs, and ECSs, SHEA members may at times author documents that do not formalize practice recommendations, e.g., documents that reflect SHEA's position on statements issued by other organizations that are relevant to healthcare epidemiology, or documents on current topics of importance. These can follow one of the document formats outlined in **Appendix 1** or another format at the discretion of the appropriate SHEA committee and SHEA Board of Trustees. The development of such documents is beyond the scope of this Handbook.

## Definitions: Guidelines and Expert Guidance Documents

### Guidelines

Similar to other clinical guidelines, development of comprehensive guidelines in healthcare epidemiology will be considered for relevant topics of priority for which an appropriate body of literature exists, as determined by the GLC and SHEA Board of Trustees. Topics on which SHEA has previously published guidelines will be considered for continuation in the existing format. If a new guideline is written by SHEA, it will employ Grading of Recommendations Assessment, Development and Evaluation (GRADE) or a comparable methodology.

SHEA emphasizes the value of multisociety guidance and encourages collaboration between the society and partnering organizations, both to lend expertise, review, and endorsement to such projects, and also to support creation of multidisciplinary, widely-vetted, consistent, and concise guidance for the benefit of stakeholders in healthcare.

## **Expert Guidance Documents (EGs)**

EGs provide practice recommendations in the absence of availability of literature to support a formal guideline, and follow one of the following formats:

### ***Special Topic EGs***

Special topic EGs are:

1. Important in provision of safe, effective healthcare
2. Developed for topics of relatively narrow scope that lack the level of evidence required for a formal guideline developed using the GRADE or a similar methodology.

EGs utilize the literature review process outlined in this Handbook (see page 10) without grading of evidence levels for individual recommendations.

An EG is based on a synthesis of limited evidence, theoretical rationale, current practices, practical considerations, writing group opinion, and consideration of potential harm. Depending on the topic, the document may also be informed by a survey of SHEA membership and/or the SHEA Research Network (SRN).

### ***Compendium Format***

The compendium format is based on the “Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Settings: 2022 Updates,” and aims to provide practical, relatively concise guidance based largely on previously published guidelines. The compendium format:

1. Generally, addresses topics that are broad in scope
2. Includes recommendations supported by evidence within a specific topic area
3. May also provide recommendations based on expert opinion
4. Includes recommendations based on previously published healthcare-associated infection (HAI) prevention guidelines
5. Categorizes recommendations into essential practices that should be adopted by all acute care hospitals and additional approaches for use in locations and/or populations where HAIs are not controlled after full implementation of essential practices
6. Summarizes implementation strategies for the recommendations
7. Utilizes the literature review process outlined in this Handbook, rather than GRADE or a comparable methodology (see page 10)
8. Includes appropriate level of evidence assigned to each recommendation (see Appendix 3).

## **Consensus Statements and White Papers**

### ***Expert Consensus Statement (ECS)***

An ECS is intended to give a “rapid response” on a time-sensitive topic. It may provide recommendations and rationale, but development does not involve a systematic literature search. ECSs:

1. Address time-sensitive topics, with development completed in less than 6 months
2. Are fewer than 15 submitted pages (MS Word, double spaced, not including references and tables)
3. Do not require or adhere to the literature search process outlined in this Handbook (see page 10)
4. Utilize the expert consensus process outlined in this Handbook (see page 12)

## White Paper

The white paper format is generally utilized to summarize SHEA's recommendations on healthcare epidemiology program-related practices (e.g., infrastructure, business cases, quality outcomes and metrics, etc.)

It does not or adhere to the literature search process outlined in this Handbook (see page 10) or other rigorous literature review process. Details on white paper generation are outside the scope of this Handbook.

## Additional Definitions

This Handbook provides general definitions for additional formats outside the scope of this Handbook in **Appendix 1**.

## Topic Proposal Process

SHEA-sponsored topic proposals are submitted to the GLC via completion of a Manuscript Proposal Form (see **Appendix 2**) by individuals and groups including but not limited to: Board of Trustees, members of the GLC, SHEA committees, and SHEA special interest groups, and partnering organizations. The GLC and subsequently the Board of Trustees will choose topics for development based upon perceived interest, need, target patient population guideline audience, and available resources. If existing guidelines or expert guidance documents from other specialty organizations or national agencies cover the same topic, the submitted Manuscript Proposal Form should provide clearly stated justification. Approval of topics includes vote by the GLC<sup>1</sup>, and approval by the SHEA Board of Trustees.

## Pre-Approval Requirements

- If the document will be submitted to *Infection Control and Hospital Epidemiology* (ICHE) or *Antimicrobial Stewardship and Healthcare Epidemiology* (ASHE), the manuscript proposal must be evaluated by the SHEA Publications Committee prior to Board approval for its appropriateness for publication in a SHEA journal.
- Collaborative projects that involve joint publication by other societies' journals or other publication type require:
  - A memorandum of understanding (MOU) signed by all involved organizations and reviewed by the SHEA GLC, Publications Committee, Board of Trustees, and the Editors of ICHE and/or ASHE, as appropriate.
  - Agreements between the societies and their respective publishers. One publisher may assume the lead as copy editor and publisher so that each article that is co-published in each journal is identical in content.
  - Agreements between the societies and their respective publishers on the means to disseminate the work with regard to the article's presentation on websites, social media, and other means of publicity.

## Manuscript Development Queue

### Guidelines and Expert Guidance Documents

Per the SHEA Strategic Plan (2022-2027), the GLC should aim to have 3 SHEA-sponsored guidelines or EGs published in ICHE or ASHE each year. The manuscript development process outlines a 32-month development process (see **Appendix 4**), with 8 manuscripts in development at any one time (see **Appendix 5**).

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<sup>1</sup>Approval is determined by a simple majority of the committee; however, any dissenting votes are discussed within the committee with the aim of reaching full consensus.

## Expert Consensus Statements and White Papers

ECSs and white papers do not follow the systematic literature review process detailed in the Handbook. Both types of documents may include recommendations.

- Expert consensus statements are meant to address a need to “rapidly respond” to an issue and are developed over approximately 6 months or less.
- White papers are developed in the process outlined in the **Appendix 4**, omitting 10 months for the systematic literature search, and so are developed in 24 months or less.

**Important note:** Neither of these documents are factored into the queue for expert guidance document and guideline publication in SHEA journals; however, prior to approval of a manuscript proposal for a new expert consensus document or white paper, staff and subsequently the Board must assess how their development may affect the manuscript queue, and de-prioritize other manuscripts on the queue and/or allocate additional resources as needed.

## Adjudicating Priority of Development and Publication

Manuscript proposals are evaluated by and approved or not approved by the GLC, Publications Committee, and the Board of Trustees. The GLC typically initiates guidelines and expert guidance manuscripts 4 years in advance of their publication. Manuscript proposals that may affect the existing manuscript queue:

- May be flagged by the Publications Committee and Board of Trustees for potential to affect the manuscript queue, requiring de-prioritization of other manuscripts and/or additional resources
- May require the authors or submitting committee to provide additional information that justifies the change to the queue, de-prioritization of other manuscripts, and/or additional resources
- Individuals who serve on the writing panels whose documents are under consideration, and also serve on a SHEA leadership group responsible for approval of changes, should recuse themselves from these decisions.

## Expert Consensus Statements

These documents require approval of a manuscript proposal by the GLC, Publications Committee, and Board of Trustees. Because of their rapid development (<6 months), expert consensus statements may be added to the current portfolio of documents in development. Prior to approval, SHEA will assess their effect on the manuscript queue, the need for additional resources to support their development, and the ability to procure those resources. Requests for additional resources require approval by the Board of Trustees.

## White Papers

These documents require approval of a manuscript proposal by the GLC, Publications Committee, and Board of Trustees. White papers should be incorporated with a 24-month timeline into the existing manuscript queue, as 1 of 8 documents in development, or with additional resources as needed to increase the number to 9. These documents are required to undergo the same approval process, including potential changes to the queue and increases in resources.

## Publication Considerations

- If SHEA pursues publication in ICHE or ASHE, the submitted document, references, tables, and figures must be double spaced, sans serif 11-point font, with normal margins and may not exceed 50 pages in this format.
- In general, SHEA-sponsored guidelines and guidance papers are published outside of a paywall, meaning that they can be accessed by non-subscribers to the journal at no extra cost to the authors, the society, or the reader. Exceptions may be made.
- Joint publication and other considerations are outlined above in “Topic Proposal Process.”

## Timeline/Process Overview

The process is outlined in **Appendix 4**.

In general, authors have 32 months from acceptance of a guideline or EG manuscript proposal by the Publication Committee to final submission of the manuscript for publication. The status of all manuscripts that have been approved for creation is reviewed by the GLC and Publications Committee. Projects that exceed a 32-month timeline may require re-approval.

The timeline may differ depending on the type of document, topic, and stakeholders involved. Potential alterations to the timeline should be assessed during the manuscript proposal phase and incorporated into the queue.

Refer to **Appendix 4** for components of the review process.

## Writing Panel Composition

The average panel consists of 8-15 members who will meet regularly via video conference, and may meet in person at the SHEA Spring Conference or IDWeek.

The manuscript proposal form (see **Appendix 2**) requires that the submitting committee or authors include:

1. Chairs and co-chairs. Those who submit manuscript proposals may list themselves or others as chairs. If others are listed, they should obtain approval from potential chairs/co-chairs before submission.
2. Panel members (i.e. authors; prior approval not needed). Proposed panel members may be identified from responses to the annual "Call for Volunteers," past volunteer history in SHEA, demonstration of subject matter expertise, and/or experience with the process of developing similar documents.
3. Partnering organizations who will be invited to nominate representatives (prior approval not needed).

Manuscript proposal forms, which include potential panel members and composition, are confirmed by the GLC, Publications Committee, and Board of Trustees Panel.

*As of December 2021, SHEA is assembling a Diversity, Equity, and Inclusion taskforce to identify priorities for the society. The authors will revise this section upon receiving recommendations from the taskforce.*

To the extent possible, ethnic, racial, geographic, profession, practice setting, education level, and gender diversity should be considered. In addition, the panel should include:

- Clinicians with expertise in the topic area(s) in question
- A pediatrician, whenever the management of pediatric contexts or children may be considered
- Antimicrobial and/or diagnostic stewards, whenever the procurement, allocation, prescribing, de-escalation, or other considerations related to testing and/or treatment may be considered
- Clinicians working in community-based healthcare
- In addition, the panel may include individuals with the following expertise:
  - Microbiology
  - Nursing
  - Long-term care
  - Ambulatory care
  - Primary care

- Subspecialty that has a unique interest in the topic under consideration
- Hospital medicine
- Others as appropriate (e.g. patient/public advocate)
- Early in the manuscript development process, the GLC encourages panels to invite stakeholder organizations (**Appendix 4**) to participate. This may take two forms:
  - Joint development: developing a guideline jointly entails having co-chairs from each organization and having equal formal representation on the panel. *Joint publication is a separate consideration, and generally is discouraged for SHEA-sponsored documents.*
  - Endorsement:
    - Review of the end-product by the stakeholder organization OR
    - The addition to the panel of a member from the potential endorsing organization and then review of the final product by the stakeholder organization

## SHEA Conflict of Interest Policy

SHEA agrees with the Institute of Medicine report that conflict of interest (COI) is, “a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.”<sup>2</sup> The primary interests of concern include “promoting and protecting the integrity of research, the welfare of patients and the quality of medical education.” The secondary interest “may include not only financial gain but also the desire for professional advancement, recognition for personal achievement and favors to friends and family or to students and colleagues.”

On an annual basis or as updates arise, all authors of guidelines, expert guidance documents, and other SHEA-sponsored documents must disclose financial relationships and organizational affiliations that pose potential conflict of interest.

Relationships that must be disclosed include:

- Employment/service
- Advisory/consultant role
- Ownership interests (including stock or stock options, except when invested in a diversified fund not controlled by the covered individual)
- Honoraria (e.g. speakers’ bureaus; honoraria for a talk/presentation about the clinical aspects of a disease)
- Research funding
- Patent
- Expert testimony
- Participation on a governmental or other committee (e.g. IOM) that may preclude accurate representation of the society’s views
- Other remuneration (e.g. the value of trips, travel, gifts, or other in-kind payments not directly related to research activities)

A statement of in a manuscript “nothing to disclose” means that the individual has no financial or non-financial relationships with any proprietary entity related to healthcare.

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<sup>2</sup> <http://www.ncbi.nlm.nih.gov/books/NBK148591/>



## COI Review

The chair(s) of the writing panel and the SHEA GLC Chair and Vice/Past Chair provide initial review of disclosures and flag any disclosures requiring further consideration by the Conflict of Interest Review Committee to determine whether actual conflicts exist and identify opportunities for management to mitigate any real or perceived “undue influence” caused by such financial relationships.

Anyone with a conflict of interest is required to submit a management plan. The management plan is a self-identified action plan provided by any member who discloses an external commercial financial relationship. It is intended to clarify disclosed relationships and offer a guide for SHEA governance and the execution of balanced work. The management plan will be approved by the Conflict of Interest Review Committee.

Disclosures are shared with the writing panel and panel members are responsible for stating updates to their fellow members at the start of each meeting.

Authors’ COI disclosures are included in the published manuscript under “Acknowledgements.”

## Indemnification and Copyright

Authors of SHEA-sponsored documents that are approved by the SHEA Board of Trustees are covered from individual liability by the SHEA insurance policy.

A statement is included in guidelines, EGs, white papers, and ECSs that, “no guidance document can anticipate all clinical situations and this paper is not meant to be a substitute for individual clinical judgment by qualified professionals.”

SHEA retains the copyright for all SHEA-sponsored manuscripts. The society adheres to the copyright policy of its official journal, *Infection Control and Hospital Epidemiology* (ICHE):

[http://journals.cambridge.org/images/fileUpload/documents/ICE\\_ctf.pdf](http://journals.cambridge.org/images/fileUpload/documents/ICE_ctf.pdf). If a manuscript is published externally, Publications Committee and Board of Trustees approval will be sought through an official letter of agreement with the other publication.

## Systematic Literature Search and Review

This process applies to expert guidance documents only. Guidelines will follow the methodology of GRADE, or similar. White papers and expert consensus statements do not adhere to a systematic literature search and review.

To ensure consistency and minimize potential for bias, the methods regarding search strategy and study selection will be determined before data collection starts.

The principles of transparency, consistency, and recordkeeping underpin the literature search and review process.

1. **Scope.**
2. **Questions.** SHEA writing panels develop the set of question(s) the manuscript will aim to answer prior to development of a search strategy. Questions may take the form of PICO (population, intervention, control, and outcome), but need not to, as the nature of infection prevention literature does not provide each element for the questions that these documents. The questions set the scope of the document and maintain the framework for its content.
3. **Search Strategy.**
  - a. SHEA hires a consultant medical librarian to develop search strategies for EGs based on the questions identified by the panel. The writing panel reviews and approves the search strategy. The librarian is responsible for de-duplicating articles if multiple search strategies were used and/or if more than one

database was used. The Methods section of the manuscript will disclose that a medical librarian's help was sought.

- b. The medical librarian follows these parameters:
  - a. **Database.** At the minimum, the recommended database for the literature review is MEDLINE (can be assessed through PubMed or Ovid). Other databases such as EMBASE, CINAHL, Cochrane Database of Systematic Reviews can be used to augment the literature search with agreement among the members of the writing group. If additional databases are used by one member of the writing group, the rest of the writing group should use the same database(s). If additional databases are used, these will be explicitly described in the document text.
  - b. **MeSH (medical subject heading).** [Official MeSH terms](#) should be used as much as possible to conduct the search. Non-MeSH terms are permissible as long as the search strategies are congruent.
  - c. **Time Period.** Prior to the librarian's search strategy(s) development, the writing panel will set a reasonable time period from which articles will be selected based on previously published guidance and relevance of evidence to current practice. If a document has previously been published by the GLC, the literature review should generally date from the time the last search was current. The Methods section will document the dates incorporated by the search.
  - d. **Publication Language.** Only English language articles will be included in any documents published by the GLC.
  - e. **Publication Type.** Only full-length articles should be included in any publications produced by the GLC. **Exclusions.** Potential reasons for exclusion include:
    - i. Outside the scope of the document, as determined during the first phase of development
    - ii. Wrong: language, setting, treatment, disease, diagnostic process, comorbidity, age group, sample size, lab study, sex, duration, intervention, procedure, or administration route
    - iii. Insufficient or unacceptable (as agreed upon *a priori*): study design, intervention data, randomization, control, design, data analysis
    - iv. Inaccessible full text article
    - v. Lack of peer review. SHEA does not include in its search yields, and thus does not include as references in its manuscripts, scientific abstracts (such as those published during professional conferences), unpublished research and trials, manuscripts that have not undergone some form of peer review, and articles published after the timeframe of the search yield.
  - f. **Methods and resources not utilized as part of SHEA's systematic literature search and review process.**
    - i. Review of the reference lists contained within review articles or other publications may be used only to determine if the literature search performed was complete. Use of review articles and other publications as a source for articles may bias the writing group by including articles that have been cited before and not including articles that would have been discovered by conducting a thorough literature search.
    - ii. Unpublished, or articles that have not been peer reviewed, including scientific abstracts (such as those published during professional conferences), unpublished research or trials, and articles falling outside the timeframe utilized by the search strategy(s).
    - iii. Findings of research articles that are outside the scope of the document, even if the article was included within the search yield, should not inform the guidance portion of the manuscript (recommendations, rationale, and assessment of evidence level, if applicable).
  - g. **Exceptions.**

- i. On occasion, if/when the panel deems it necessary to include journal article(s) that were not part of the literature search conducted to answer a question(s), the panel will separate and disclose the citations for those articles in the manuscript. Articles may be added:
      - i. If they are published after the completion of the literature search and essential to include in the document, as determined by the panel, or
      - ii. If the panel agrees that a required thorough literature search failed to identify the relevant article.
    - ii. The panel may also consider that in some cases, when decided in advance based on the topic, the search may be expanded into resources outside the above listed databases. This may include “grey literature” such as federal, state, and non-governmental resources (e.g. CDC, AHRQ, WHO, MSF).
- c. The restrictions defined above apply to the guidance portion of the document, i.e., recommendations, rationale, and evidence level, if applicable. Additional relevant information that does not qualify for inclusion in the guidance portion of the document may be included in the background or discussion of the document and/or in a section on “future research needs,” or similar. **Recordkeeping.**
  - i. The questions, search strategy records, and PRISMA may be included as an unpublished appendix that can be accessed electronically at the discretion of the writing group and/or publisher.
  - ii. The methods and results of the literature search will be retained by the SHEA office.
- d. **Primary Review.** Upon receipt of the article yield, two members of the writing group independently (blind) review the title and/or abstract of each paper to identify when predetermined eligibility criteria are not met. For transparency and accuracy, SHEA uses an abstract management service to keep a record of all papers and publications that are identified by the search and to facilitate primary and secondary/full text review.  
If disagreement occurs between two members on whether an article should be included, a third member or the chair of the panel will adjudicate conflicts.
- e. **Secondary/Full Review.** The resulting list of articles that have not been excluded after the primary review will be reviewed in full by at least two members, who could be the same two members who conducted the primary review. This secondary review will determine which articles/papers are suitable for inclusion and will inform the background and recommendations for the document. If there is disagreement between the two members on suitability for inclusion in the document, a third member or chair will review the article in question.
- f. **Updating the Literature Search.** If a manuscript project is delayed by 6 months or more, the panel may request that the librarian run the same search strategy(s) utilized for the initial literature search. If this occurs, the screening will occur by one member per title/abstract via the abstract management service to obtain the full text articles that may potentially be added to the document.
- g. **Submission to national or international guidelines databases.** If SHEA determines that it will submit the manuscript to a national or international guidelines database, authors will create an evidence table for articles included in the final manuscript (**Appendix 7**). This table does not need to be published with the manuscript.

## Consensus

Unique to EGs and ECSs is a formalized process for reaching panel consensus. Recommendations are listed with rationale statements that take into account relevant evidence as well as the consensus of the group. Consensus around recommendations and rationale is determined via an anonymous ranking and comment period. Recommendations and rationale statements that do not receive 100 percent agreement are discussed. If full consensus is not achieved, dissenting opinions are included. This process may be utilized by white papers that include recommendations.

# Review and Approval Process of SHEA-Sponsored Guidelines and EGs

## Internal and External Review

The GLC Chair will ask for at least two primary reviewers from the committee who will review and provide written comments using a standardized review form. Generally, reviews should be completed within a 2 to 4-week time frame, or in the case of external documents, best efforts should be made to conduct the review within the timeframe requested by the sponsoring organization. The full GLC also has the opportunity to review and provide comments on the document at this time as well, either through presentation of the reviews and ensuing discussion or outside the formal review.

Comments received from the GLC are forwarded to the writing panel chair for incorporation into the draft as deemed appropriate. Within 2-4 weeks, the writing panel chair should provide the revised document draft with the response to each of the comments made indicating if applicable where and why reviewer recommendations were included, and why others were not. Staff will then send the revised document and responses to the comments back to the GLC for review.

GLC support for a guideline/EG is demonstrated by a vote of the full committee conducted by email ballot or via conference call vote (any writing group members or those with a relevant conflict of interests are recused from voting). Simple majority of the full committee constitutes approval/disapproval. The final recommendation of the GLC is forwarded with the draft document to the SHEA Board of Trustees for final review and approval.

This process of review and approval by the Guidelines Committee and the Board of Trustees serves as the official peer review for SHEA-sponsored guidelines and expert guidance documents submitted for publication in ICHE.

Refer to **Appendix 1** for the groups responsible for review and approval of other types of SHEA-sponsored documents.

## Stakeholder Review

This process is outlined in further detail in **Appendix 4**. Efforts to obtain stakeholder review depend on the topic and circumstances around the SHEA-sponsored document.

When a stakeholder organization is involved in the development of a SHEA guideline or EG at the onset or is identified later in the process as a potential endorser, SHEA staff will solicit their input and endorsement as follows:

An electronic request is sent that includes an endorsement form, the draft manuscript and a form for comments. The organization that SHEA is seeking endorsement from has the opportunity to provide comments and suggested revisions within a reasonable timeframe (4 weeks). The organization is provided with the following options for their level of endorsement:

- X organization endorses the guideline as written
- X organization endorses the guideline and suggests the attached comments for consideration
- X organization does not endorse the guideline, with specification as to whether the topic is outside the scope of the organization or if it is disagreement with the content

If an organization is able to complete the review within the reasonable and agreed upon timeframe, the organization will be acknowledged within the manuscript; however, if the organization is not able to meet the deadline, the manuscript will continue through the review process and the organization may be acknowledged on the SHEA website.

Comments from stakeholder organizations (if applicable) are forwarded to the writing panel chair, who will review and incorporate them into draft as deemed appropriate. The action taken for each comment/recommendation and the

rationale will be documented on the review form. Not all recommendations must be accepted, but the rationale should be documented.

### **Periodic Review of Guidelines and EGs**

Maintaining guideline and expert guidance content that is up-to-date is a challenge that requires commitment of resources to monitor the emerging literature and scientific consensus to determine whether or not a guideline should be revised, or if it has become obsolete.

On average, guidelines and EGs are reviewed on a 4 year rotation. The “Compendium of Strategies to Prevent HAIs in Acute Care Settings” is reviewed every 5 years. Situations in which a guideline or expert guidance document might be updated include substantive changes in:

- the evidence on existing benefits and harms
- the outcomes that were considered important
- available interventions
- the evidence or consensus that current practice is optimal
- the values placed on outcomes
- the resources available in healthcare

As with internal and external document reviews, the GLC Chair will ask for at least two primary reviewers from the committee who will review and provide written comments using the review form. Generally, reviews should be completed within a 2–4-week time frame. The full GLC also has the opportunity to review and provide comments on the document at this time as well.

In addition to determining whether new evidence or developments exist in the field that potentially invalidate the current recommendations, the GLC should discuss the need for new recommendations within the context of the current guideline that may have been previously excluded for various reasons, or that have arisen in the interim.

Once the decision has been made to update a guideline or EG, an expert panel will be convened. The expert panel may include many of the preceding panelists, but the final composition may be different than the original group. As with new guideline panels, membership is reviewed and approved by the GLC chair and included in the manuscript proposal form approved by the GLC and Board of Trustees. All panel chairs and members must comply with the current SHEA conflict of interest disclosure policies.

The process for conducting a full update, including the review and approval of the manuscript, is the same as outlined in this Handbook for SHEA-sponsored guidelines and EGs.

Guidelines or EGs undergoing revisions will be flagged on the SHEA website to indicate that an update is in progress.

The Guideline Committee can recommend retirement of documents that have become obsolete. These will be maintained on the SHEA website on a different page than current guidelines and EGs.

## Appendix 1: Definitions of SHEA-Sponsored Documents

Development, review, and publications processes as outlined in the Handbook apply to guidelines and EGs. Development of other manuscript types are beyond the scope of this Handbook.

### Peer Reviewers of SHEA-Sponsored Submitted ICHE or ASHE

<p>The SHEA Guidelines Committee and Board serve as the peer reviewers for:</p> <ul style="list-style-type: none"> <li>• Compendium</li> <li>• Guidelines</li> <li>• Expert Guidance Documents (EGs)</li> <li>• Expert Consensus Statements (ECSs)</li> </ul>	<p>The SHEA Publications Committee and Board serve as the peer reviewers for:</p> <ul style="list-style-type: none"> <li>• Knowledge, Skills, Abilities (KSA)-style papers</li> <li>• White Papers</li> <li>• Commentaries</li> </ul>
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Type of Manuscript	Definition	Overseen by	Reviewed by	Peer Reviewer (applicable to SHEA-sponsored documents submitted for publication in ICHE)	Example
Brief	Clarification or update to existing guideline, white paper, position paper	Relevant committee (Guidelines, Education, Research, PPGA, etc.)	<ul style="list-style-type: none"> <li>• Overseeing committee</li> <li>• Board</li> </ul>	N/A	<p>SHEA Response to Institutions' Implementation of 2010 Guideline for Healthcare Workers Infected with Bloodborne Pathogens, October 2014</p> <p><a href="http://www.shea-online.org/Portals/0/PDFs/10_2014_Bloodborne_Pathogens_Public_Letter.pdf">http://www.shea-online.org/Portals/0/PDFs/10_2014_Bloodborne_Pathogens_Public_Letter.pdf</a></p>
Compendium*	Synthesis of evidence for the prevention of key HAIs with intervention, special	GLC	<ul style="list-style-type: none"> <li>• GLC</li> <li>• Board</li> <li>• Expert Panel</li> <li>• Advisory Panel</li> <li>• External participants (Partners, endorsing and sponsoring orgs)</li> </ul>	GLC, Board	<p>Yokoe DS, Anderson DJ, Berenholtz SM, Calfee DP, Dubberke ER, Ellingson KD, et al. A Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals: 2014 Updates. Am J Infect Control. 2014;42(8):820-8. <a href="#">Compendium of Strategies to</a></p>

	precautions, and implementation strategies		<ul style="list-style-type: none"> <li>• Publications Committee: identification of potential critical issues related to publications process or considerations with potential to affect impact factor</li> </ul>		<a href="https://www.cambridge.org/core">Prevent HAIs in Acute Care Hospitals (cambridge.org)</a>
Expert Guidance*	Guidance based on systematic literature review and consensus of experts (internal or external)	GLC	<ul style="list-style-type: none"> <li>• GLC</li> <li>• Board</li> <li>• External participants</li> <li>• Publications Committee: identification of potential critical issues related to publications process or considerations with potential to affect impact factor</li> </ul>	GLC, Board	Rowe TA, Jump RLP, Andersen BM, Banach DB, Bryant KA, Doernberg SB, Loeb M, Morgan DJ, Morris AM, Murthy RK, Nace DA, Crnich CJ. Reliability of nonlocalizing signs and symptoms as indicators of the presence of infection in nursing-home residents. <i>Infection Control &amp; Hospital Epidemiology</i> . Cambridge University Press; 2020;:1–10.
Guideline*	Evidence-based guidance (internal or external) conducted via GRADE or similar methodology	GLC	<ul style="list-style-type: none"> <li>• GLC</li> <li>• Board</li> <li>• External participants</li> <li>• Publications Committee: identification of potential critical issues related to publications process or considerations with potential to affect impact factor</li> </ul>	GLC, Board	Stuart Johnson, Valéry Lavergne, Andrew M Skinner, Anne J Gonzales-Luna, Kevin W Garey, Ciaran P Kelly, Mark H Wilcox, Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of <i>Clostridioides difficile</i> Infection in Adults, <i>Clinical Infectious Diseases</i> , Volume 73, Issue 5, 1 September 2021, Pages e1029–e1044, <a href="https://doi.org/10.1093/cid/ciab549">https://doi.org/10.1093/cid/ciab549</a>
Expert Consensus Statement*	Recommendations based on non-systematic literature review and	GLC	<ul style="list-style-type: none"> <li>• GLC</li> <li>• Board</li> <li>• External participants</li> </ul>	GLC, Board	Multisociety statement on coronavirus disease 2019 (COVID-19) vaccination as a condition of employment for healthcare personnel. Weber DJ, Al-Tawfiq JA, Babcock HM, Bryant K, Drees M, Elshaboury R, Essick K, Fakih M, Henderson DK,

	consensus of experts (internal and/or external)		Publications Committee: identification of potential critical issues related to publications process or considerations with potential to affect impact factor		Javaid W, Juffras D, Jump RLP, Lee F, Malani AN, Mathew TA, Murthy RK, Nace D, O'Shea T, Pettigrew E, Pettis AM, Schaffzin JK, Shenoy ES, Vaishampayan J, Wiley Z, Wright SB, Yokoe D, Young H. Infection Control & Hospital Epidemiology. Cambridge University Press; 2021;:1–9. <a href="https://doi.org/10.1017/ice.2021.322">https://doi.org/10.1017/ice.2021.322</a>
KSAs	Knowledge, skills, and abilities charts and/or articles	Relevant committee	<ul style="list-style-type: none"> <li>• Overseeing committee</li> <li>• Education Committee</li> <li>• Publications Committee</li> <li>• Board</li> </ul>	Publications Committee, Board	Cosgrove SE, Hermsen ED, Rybak MJ, File TM, Parker SK, Barlam TF, et al. Guidance for the knowledge and skills required for antimicrobial stewardship leaders. Infect Control Hosp Epidemiol. 2014;35(12):1444-51.
Position Paper	Society or collaborative statement regarding regulatory and public policy actions	PPGA	<ul style="list-style-type: none"> <li>• PPGA</li> <li>• External participants</li> <li>• Board</li> </ul>	N/A	Revised SHEA Position Paper: Influenza Vaccination of Healthcare Personnel. Talbot TR, Babcock H, Caplan AL, Cotton D, Maragakis LL, Poland GA, Septimus EJ, Tapper ML, Weber DJ. Infection Control & Hospital Epidemiology. Cambridge University Press; 2010;31(10):987–995.
White Paper	Society or collaborative statement regarding institutional or administrative policy, or statements about the state of the field	Relevant committee (Guidelines, Education, Research, PPGA, etc.)	<ul style="list-style-type: none"> <li>• Overseeing committee</li> <li>• Publications Committee</li> <li>• Board</li> <li>• External participants</li> </ul>	Publications Committee, Board	Akinboyo IC, Zangwill KM, Berg WM, Cantey JB, Huizinga B, Milstone AM. SHEA neonatal intensive care unit (NICU) white paper series: Practical approaches to Staphylococcus aureus disease prevention. Infection Control & Hospital Epidemiology. Cambridge University Press; 2020;41(11):1251–1257.
Commentary	Expert opinion/editorial related to guideline, white paper, or position paper	Relevant committee (Guidelines, Education, Research, PPGA, etc.)	<ul style="list-style-type: none"> <li>• Overseeing committee</li> <li>• Publications Committee</li> <li>• Board</li> <li>• External participants</li> </ul>	Publications Committee, Board	Morgan DJ, Deloney VM, Bartlett A, Boruchoff SE, Camargos Couto R, Oji M, et al. The expanding role of the hospital epidemiologist in 2014: a survey of the Society for Hospital Epidemiology of America (SHEA) Research Network. Infect Control Hosp Epidemiol. 2015;36(5):605-8.

\* This document applies only to these formats.



## Appendix 2: Manuscript Proposal Form

Draft title:	
Submitted by:	
Lead authors:	
Contributing SHEA authors:	
Contributing representatives from partnering organizations:	
Possible external consultants:	
Intention to submit to ICHE or ASHE:	
Intention to publish in other journals:	
Type of document based on the level of available evidence: <ul style="list-style-type: none"> <li>• <b>Expert guidance or compendium-style document</b> (systematic literature search and consensus process per Handbook; 32-month development)</li> <li>• <b>Expert consensus statement</b> (rapid development, no systematic literature search, consensus process per Handbook; 6-month development)</li> <li>• <b>White paper</b> (may include recommendations, but does not utilize a systematic literature search (e.g. NICU White Paper Series); 24-month development)</li> <li>• <b>Guideline</b> (GRADE or similarly methodology requiring adequate level of literature to achieve document’s purpose; development TBD)</li> <li>• <b>Other</b></li> </ul>	
Target HCP audience:	
Target patient population:	

Issue in question:	
Objectives:	
In 1-2 sentences, please explain why this document needs to be developed now.	
For considerations for internal consistency, are there existing SHEA-led or multisociety guidelines on this topic? (e.g. current SHEA and/or partnering organizations' recommendations, including IDSA, APIC, PIDS, AORN, and others; SHEA or external guidelines/guidance being updated or in development)	
For awareness of broader context, are there guidelines by other societies on this topic?	
Is there perceived or documented variation in practice:	
Current level of evidence available:	
What is the potential to affect decision-making, clinical outcomes, and/or reduction in practice variation (high, moderate, minimal, or low)?	
Estimated page count (submissions to ICHE not to exceed total of 50 double spaced pages 11 pt. font, including references and appendices that will be published by the journal (unless otherwise specified <i>a priori</i> ). Supplementary material can be linked to within the document via the SHEA website.)	
Estimated month of submission:	
Reviewers in addition to SHEA:	
Intended endorser invitations:	

## Appendix 3: Recommendations and Evidence Classifications

Based on: Update to the CDC and the HICPAC Recommendation Categorization Scheme for Infection Control and Prevention Guideline Recommendations

### Terminology

Type	Definition	Evidence Level	Implied Obligation	Wording	Example Terms
<b>Recommendation</b>	When authors are confident that benefits of the recommended approach clearly exceed the harms (or, in the case of a negative recommendation, that the harms clearly exceed the benefits).	<ul style="list-style-type: none"> <li>In general, high- to moderate-quality evidence (see "Aggregate Quality of Evidence" below); OR</li> <li>Lesser evidence or expert opinion when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms; OR</li> <li>When required by federal law.</li> </ul>	HCP/facilities "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.	<ul style="list-style-type: none"> <li>Specifies the setting and population to which the recommendation applies (e.g., adult patients in intensive care unit settings)</li> <li>Declarative verbs, e.g., use, perform, maintain, replace</li> </ul>	should; should not; recommended; is recommended; recommends against; is not recommended; is indicated; is not indicated
<b>Conditional Recommendation</b>	When authors determine that benefits of the recommended approach are likely to exceed the harms (or, in the case of a negative recommendation, that the harms are	<ul style="list-style-type: none"> <li>In general, may be supported by either low-, moderate- or high-quality evidence (see "Aggregate Quality of Evidence") below:</li> <li>There is high-quality evidence, but the benefit/harm balance is not clearly tipped in one direction</li> </ul> <p>The evidence is weak enough to cast doubt on whether the recommendation will consistently lead to benefit</p> <ul style="list-style-type: none"> <li>The likelihood of benefit for a specific patient population or clinical situation is</li> </ul>	<ul style="list-style-type: none"> <li>HCP/facilities "could," or could "consider" implementing the recommended approach.</li> <li>The degree of</li> </ul>	Specifies the setting and population to which it applies when relevant, including select settings (e.g., during outbreaks), environments (e.g., ICUs),	consider; could; may; may consider

	likely to exceed the benefits).	<p>extrapolated from relatively high-quality evidence demonstrating impact on other patient populations or in other clinical situations (e.g., evidence obtained during outbreaks used to support probable benefit during endemic periods)</p> <ul style="list-style-type: none"> <li>• The impact of the specific intervention is difficult to disentangle from the impact of other simultaneously implemented interventions (e.g., studies evaluating “bundled” practices)</li> <li>• There appears to be benefit based on available evidence, but the benefit/harm balance may change with further research</li> <li>• Benefit is most likely if the intervention is used as a supplemental measure in addition to basic practices</li> </ul>	<p>appropriateness may vary depending on the benefit vs. harm balance for the specific setting.</p>	<p>populations (e.g., neonates, transplant patients)</p>	
<b>No Recommendation</b>	Made when there is both a lack of pertinent evidence and an unclear balance between benefits and harms	N/A	N/A	"No recommendation can be made regarding..."	N/A

## Quality of Evidence

*Used for compendium-style documents.*

<b>High</b>	Highly confident that the true effect lies close to that of the estimated size and direction of the effect, e.g. when there are a wide range of studies with no major limitations, there is little variation between studies, and the summary estimate has a narrow confidence interval.
<b>Moderate</b>	The true effect is likely to be close to the estimated size and direction of the effect, but there is a possibility that it is substantially different, e.g. when there are only a few studies and some have limitations but not major flaws, there is some variation between studies, or the confidence interval of the summary estimate is wide.
<b>Low</b>	The true effect may be substantially different from the estimated size and direction of the effect, e.g. when supporting studies have major flaws, there is important variation between studies, the confidence interval of the summary estimate is very wide, or there are no rigorous studies.

# Appendix 4: 32-Month Expert Guidance Development

Subject to change according to topic, publisher schedule, or other factors.



## Appendix 5: Manuscript Queue

Based on the 2022 SHEA Strategic Plan goal of 3 published EGs per year over 5 years, with an estimated 32-month development per document, there will be:

- 8 writing panels at one time.
- A new writing panel beginning every 4 months.

The bracketed text indicates what information should be added to show specific manuscripts' development stages.

Note: Each manuscript is broken into 4-month intervals. These do not represent specific stages, but are included to help calculate how changes may affect the queue. The top cell of a manuscript's column represents the start of the manuscript's development, and the bottom cell represents its publication.

		Manuscripts in Development																	
	Mo.	[title]	[title]	[title]	[title]	[title]	[title]	[title]	[title]	[title]	[title]	[title]	[title]	[title]	[title]	[title]	[title]		
<i>This column indicates 12-month intervals starting at Year 1 of the strategic plan. This first section represents the multi-year development prior to the start of the strategic plan.</i>	Jun-Sept	1-4																	
	Oct-Jan	5-8	1-4																
	Feb-May	9-12	5-8	1-4															
	Jun-Sept	13-16	9-12	5-8	1-4														
	Oct-Jan	17-20	13-16	9-12	5-8	1-4													
	Feb-May	21-24	17-20	13-16	9-12	5-8	1-4												
	Jun-Sept	25-28	21-24	17-20	13-16	9-12	5-8	1-4											
<b>Year 1</b>	Oct-Jan	29-32	25-28	21-24	17-20	13-16	9-12	5-8	1-4										
	Feb-May		29-32	25-28	21-24	17-20	13-16	9-12	5-8	1-4									
	Jun-Sept			29-32	25-28	21-24	17-20	13-16	9-12	5-8	1-4								
<b>Year 2</b>	Oct-Jan				29-32	25-28	21-24	17-20	13-16	9-12	5-8	1-4							
	Feb-May					29-32	25-28	21-24	17-20	13-16	9-12	5-8	1-4						
	6-9						29-32	25-28	21-24	17-20	13-16	9-12	5-8	1-4					
<b>Year 3</b>	Oct-Jan							29-32	25-28	21-24	17-20	13-16	9-12	5-8	1-4				
	Feb-May								29-32	25-28	21-24	17-20	13-16	9-12	5-8	1-4			
	Jun-Sept									29-32	25-28	21-24	17-20	13-16	9-12	5-8	1-4		
<b>Year 4</b>	Oct-Jan										29-32	25-28	21-24	17-20	13-16	9-12	5-8	1-4	
	Feb-May											29-32	25-28	21-24	17-20	13-16	9-12	5-8	
	Jun-Sept												29-32	25-28	21-24	17-20	13-16	9-12	
<b>Year 5</b>	Oct-Jan													29-32	25-28	21-24	17-20	13-16	9-12
	Feb-May														29-32	25-28	21-24	17-20	13-16
	Jun-Sept															29-32	25-28	21-24	17-20
<b>Year 6</b>	Oct-Jan															29-32	25-28	21-24	

## Appendix 6: SHEA Guidelines, Compendium, and EG Review and Comment Period

Action	Applies to	Participants
1. Draft finalized by writing group	EGs, compendium format, guidelines	Writing panel
2. Draft posted for comment to hidden page on SHEA website that includes online review form.	Guidelines only	<ul style="list-style-type: none"> <li>• External Reviewing Organizations (beyond representatives on writing panel)</li> <li>• SHEA members via SHEA News</li> </ul>
3. Draft posted to SHEA News	EG, compendium format, guideline	<ul style="list-style-type: none"> <li>• Staff</li> <li>• GLC</li> <li>• Coauthoring organizations</li> <li>• PPGA and other relevant SHEA committees</li> </ul>
4. Invitation to review emailed to coauthoring organizations.	EG, compendium format, guideline	<ul style="list-style-type: none"> <li>• Staff</li> <li>• GLC</li> <li>• Coauthoring organizations</li> <li>• PPGA and other relevant SHEA committees</li> </ul>
5. Decision regarding endorsement due by external organizations, SHEA committees.	EG, compendium format, guideline	External organizations
6. Comments provided to authors for response; updates to document.	EG, compendium format, guideline	Writing panel
7. Finalized document and responses to comments sent to SHEA and co-authoring or endorsing organizations for consideration for final approval.	EG, compendium format, guideline	<ul style="list-style-type: none"> <li>• Writing panel (the full writing panel to approve of the final version)</li> <li>• Staff</li> <li>• GLC (vote to recommend approval to the Board)</li> <li>• SHEA Board (vote on final approval)</li> <li>• SHEA Publications Committee (identification of potential critical issues related to publications process or considerations with potential to affect impact factor)</li> <li>• Coauthoring organizations</li> </ul>



8. If applicable, document submitted for CDC clearance at the same time as final approval by authoring organizations.	Compendium format, guidelines	CDC
9. Document submitted for publication with endorsing organizations acknowledged.	EG, compendium format, guideline	Staff, ICHE

1. The decision to endorse a guideline or guidance document is the decision of the organization considering the document.
2. External organizations reviewing a SHEA-sponsored document should highlight and notify the SHEA staff contact of changes necessary for endorsement before the end of the comment period.
3. Draft includes:
  - a. "DRAFT" watermark
  - b. Header with "not for distribution"
  - c. Clear section headers, sub-headers, tertiary headers
  - d. Staff contact
4. Standard comment form:
  - a. Official name (if organization)
  - b. Reviewer's name/email or organization's name/email
  - c. Open field for submission of: header, sub-header, tertiary header
  - d. Option for organization to submit endorsement.

## Appendix 7: Acronyms

ASHE	Antibiotic Stewardship & Healthcare Epidemiology (SHEA journal)
CDC	Centers for Disease Control and Prevention
ECS	Expert consensus statement
EG	Expert guidance
GLC	SHEA Guidelines Committee
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HICPAC	Healthcare Infection Control Practices Advisory Committee (CDC)
ICHE	Infection Control and Hospital Epidemiology (SHEA journal)
PPGA	Public Policy and Government Affairs Committee
SRN	SHEA Research Network