



# Handbook for SHEA-Sponsored Guidelines, Expert Guidance Documents, Consensus Statements, and Practice Statements

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## Table of Contents

<b>Purpose and Scope</b> .....	3
Authorship of the Handbook .....	3
<b>Introduction</b> .....	4
<b>Definitions of Guidelines, Expert Guidance Documents, Consensus Statements, and Practice Statements</b> .....	5
Guidelines .....	5
Expert Guidance Documents .....	5
Consensus Statements .....	6
Practice Statements .....	6
Additional Definitions .....	6
<b>Proposal Process</b> .....	6
Requirements for Collaborative Documents .....	7
Manuscript Development Queue .....	7
Adjudicating Priority of Development and Publication .....	7
Publication Considerations .....	8
<b>Process Overview</b> .....	8
<b>Writing Panel Composition</b> .....	8
Inclusive Guiding Principles .....	9
Patient Engagement .....	9
<b>SHEA Conflict of Interest Policy</b> .....	10
COI Review .....	10
<b>Indemnification and Copyright</b> .....	11
<b>Systematic Literature Search and Review</b> .....	11
<b>Inclusion of Products, Services, or Treatments</b> .....	13

- Consensus** ..... 14
- Review and Approval** Process of Guidelines and Expert Guidance Documents ..... 14
  - Internal and External Review ..... 14
  - Review by Interested Parties and Groups..... 15
  - Periodic Review of Guidelines and Expert Guidance Documents..... 15
- Appendix 1: Definitions of SHEA-Sponsored Documents ..... 17
  - Peer Reviewers of SHEA-Sponsored Documents Submitted ICHE or ASHE ..... 17
- Appendix 2: Expert Guidance Proposal Form ..... 20
- Appendix 3: Consensus Statement Process Guide ..... 22
  - Consensus statement requirements..... 22
  - Proposal ..... 22
  - Development..... 23
    - Round 1 ..... 23
    - Round 2 ..... 24
    - Round 3 ..... 25
  - Approval, publication, dissemination ..... 25
  - Consensus Statement Proposal Form ..... 26
- Appendix 4: Compendium Recommendations and Evidence Classifications ..... 28
  - Terminology ..... 28
  - Quality of Evidence ..... 29
- Appendix 5: Development Checklists ..... 30
  - 32-Month Expert Guidance Checklist ..... 30
  - 22-Month Practice Statement Checklist ..... 33
  - 6-Month Consensus Statement Checklist ..... 35
- Appendix 7: Review and Comment Period ..... 37
- Appendix 8: SHEA Writing Panels – Author Responsibilities ..... 38
- Appendix 9: SHEA Inclusive Language Policy ..... 42
  - Introduction ..... 42
  - General principles ..... 42
  - Terminology ..... 42
    - Those who work in healthcare..... 42
    - Visitors ..... 43
    - Person-first and identify-first language ..... 43

Gender .....	43
Race and ethnicity.....	44
Age .....	44
Interested persons and groups .....	44
Practice statement.....	45
Resources.....	45
Appendix 10: Acronyms .....	45

## 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 for the development of guidelines, expert guidance documents, consensus statements, and practice 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 for the practice of infection prevention and control (IPC), healthcare epidemiology, and antibiotic stewardship fall into the four broad categories:
  1. Guidelines
  2. Expert guidance documents
  3. Consensus statements
  4. Practice statements
- The category of a recommendations-based document determines the literature review process used. The category 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.
- Consensus statements are developed according to the process defined in **Appendix 3**.
- Other types of documents are defined in **Appendix 1**, but this Handbook does not guide their development. Documents that do not formalize evidence-based or consensus-based recommendations but reflect SHEA's position on relevant issues or time-sensitive documents on topics of importance, 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 of Guidelines, Expert Guidance Documents, Consensus Statements, and Practice Statements

SHEA emphasizes the value of multi-society documents and encourages collaboration to create multidisciplinary, widely vetted, consistent, and concise recommendations for the benefit of all interested parties and groups in healthcare.

### Guidelines

- Priority topics for which an appropriate body of literature exists, as determined by the GLC and SHEA Board of Trustees, may be evaluated for the guideline format.
- If a guideline is written by SHEA, it will employ Grading of Recommendations Assessment, Development and Evaluation (GRADE) or a comparable methodology.
- Topics on which SHEA has previously published guidelines will be considered for continuation in the existing format or conversion to the expert guidance format.

### Expert Guidance Documents

Expert guidance documents provide practice recommendations in the absence of availability of literature to support a GRADE-based guideline.

### Expert Guidance

- Important in provision of safe, effective healthcare
- 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.
- Utilize the literature review process outlined in this Handbook (see **page 10**) without grading the evidence for individual recommendations.

An expert guidance document 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 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 largely based on previously published guidelines. The compendium format:

- Generally, addresses topics that are broad in scope
- Includes recommendations supported by evidence within a specific area
- May also provide recommendations based on expert opinion
- Includes recommendations based on previously published healthcare-associated infection (HAI) prevention guidelines
- Categorizes recommendations into:
  - a. Essential practices that should be adopted by all acute care hospitals
  - b. Additional approaches for use in locations and/or populations where HAIs are not controlled after full implementation of essential practices.
- Summarizes implementation strategies for the recommendations

- Utilizes the literature review process outlined in this Handbook, rather than GRADE or a comparable methodology (see **page 11**)
- Includes appropriate level of evidence assigned to each recommendation (see **Appendix 3**).

### Consensus Statements

A consensus statement 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. Consensus statements:

- Address time-sensitive topics, with development completed in less than 6 months
- Are fewer than 15 submitted pages (MS Word, double spaced, not including references and tables)
- Do not require or adhere to the literature search process outlined in this Handbook (see **page 11**)
- Utilize the expert consensus process outlined in this Handbook (see **page 13**)

### Practice Statements

The practice statement format (previously called the “white paper” format) summarizes views on healthcare epidemiology program-related practices (e.g., infrastructure, business cases, quality outcomes and metrics, etc.)

It does not adhere to the literature search process outlined in this Handbook (see **page 11**) or other rigorous literature review process.

### Additional Definitions

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

## Proposal Process

Guidelines, expert guidance documents, consensus statements, and practice statements require approval of a manuscript proposal by the GLC, Publications Committee (if proposing publication in a SHEA journal), and Board of Trustees. 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, SHEA special interest groups, and partnering organizations. The GLC and subsequently the Board of Trustees will choose topics for development based on perceived interest, need, target population, audience, and available resources. If existing guidelines or expert guidance documents from other specialty organizations or agencies cover the same topic, the submitted Manuscript Proposal Form should provide clearly stated justification for pursuing a SHEA-led document on the topic.

Approval of topics depends on a vote by the GLC,<sup>1</sup> approval of appropriateness for SHEA journals (when relevant) by the Publications Committee, and approval by the SHEA Board of Trustees.

The 2022-2027 SHEA Strategic Plan specifies the GLC should oversee the publication of 3 recommendations-based documents (guideline, expert guidance, consensus, or practice statements) in SHEA journals every year for 5 years.

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<sup>1</sup>Approval is determined by a simple majority of the committee. Dissenting votes are discussed within the committee with the aim of reaching unanimous consensus.

## Requirements for Collaborative Documents

Collaborative projects that involve joint publication with other societies 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 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

- The manuscript development process outlines a 32-month development for guidelines and expert guidance documents (see **Appendix 5**). Up to 8 manuscripts may be in development at any one time.
- Expert consensus statements are meant to address a need to “rapidly respond” to an issue and are developed over approximately 6 months or less.
- Practice statements are developed in the process outlined in **Appendix 5** in 24 months or less and omit 10 months for the systematic literature search employed by expert guidance documents.

## Adjudicating Priority of Development and Publication

Manuscript proposals are evaluated by and approved by the GLC, Publications Committee, and the Board of Trustees every other year. The GLC typically initiates guidelines and expert guidance manuscripts 4 years in advance of their publication.

If a manuscript proposal could affect the existing manuscript queue, it may:

- Be flagged by the Publications Committee and Board of Trustees for potential to require de-prioritization of other manuscripts and/or additional resources
- Require that those who propose the manuscript 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, who also serve on a SHEA leadership group responsible for approval of changes, should recuse themselves from these decisions.

### *Consensus Statements*

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.

### *Practice Statements*

Practice statements, which follow a 22-month timeline, will be added to the existing manuscript queue. These documents are required to undergo the same approval process, including potential changes to the queue and increases in resources.

## Publication Considerations

- All submissions to ICHE and ASHE must be double spaced, sans serif 11-point font, with normal margins and may not exceed 50 pages in this format. Exceptions are considered by the Publications Committee on a case-by-case basis.
- In general, SHEA-sponsored guidelines and guidance papers are published outside of a paywall for at least 6 months following their publication date. This means that they can be accessed by non-subscribers to the journal at no extra cost to the authors, the society, or the reader in order to promote the uptake of recommendations for patient and healthcare personnel safety. Exceptions may apply.
- Joint publication requirements are outlined above in “Topic Proposal Process.”

## Process Overview

The timeline is outlined in **Appendix 5**.

In general, authors have 32 months from acceptance of a guideline or expert guidance manuscript proposal by the Publications Committee to final submission of the manuscript for publication. The GLC and Publications Committee periodically will review the status of all manuscripts that have been approved. Projects that exceed a 32-month timeline may require re-approval. Consensus documents should be developed within 6 months of proposal approval. Practice statements should be developed within 24 months of proposal approval.

The timeline may differ depending on the type of document, topic, and interested parties and groups involved. Potential alterations to the timeline should be flagged with the GLC, and potentially Publications Committee and Board of Trustees, notified.

Refer to **Appendix 7** for components of the review process.

## Writing Panel Composition

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

The manuscript proposal form (see **Appendix 2**) requires that the submitters 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 via a call for applications, following approval of the proposal, from responses to the annual “Call for Volunteers,” past volunteer history in SHEA, for known subject matter expertise as demonstrated with publications, and/or experience with the process of developing similar documents.
3. **Partnering organizations** will be invited to nominate representatives (prior approval by nominees is not needed).

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



## Inclusive Guiding Principles

SHEA writing panels adhere to the SHEA Inclusive Guiding Principles, developed by the SHEA Diversity, Equity, and Inclusion Committee. These principles aim to:

*“Actively implement strategies that incorporate diversity, equity, and inclusion principles to foster a sense of belonging, facilitate innovative solutions, and enhance decision-making”*

These guiding principles specify parameters for gender, race and ethnicity, geography (rural settings), professional roles (non-physician members), primary practice setting (community-based, ambulatory, LTC, correctional health, and Indian Health Service), and years in practice. These principles are updated annually. Those selecting writing panel members should request and use the most recent version of the Inclusive Guiding Principles document when developing the panel’s roster.

Those selecting writing panel members should also consider areas of specialization (pediatrics, stewardship), as listed below. In addition, the panel should include:

- Clinicians with expertise in the topic area(s) in question
- Pediatrician(s), 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
- 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 interested parties and groups (**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 interested parties and groups OR
    - The addition to the panel of a member from the potential endorsing organization and then review of the final product by interested parties and groups

## Patient Engagement

SHEA writing panels may engage patient interest groups in the scoping and review phases during the development of guidelines, expert guidance documents, consensus statements, and practice statements. The groups the SHEA writing panels work with on these phases of document development will depend on the topic(s) intended to be covered by the document. These groups may include but are not limited to: National Patient Safety Foundation/IHI, Peggy Lillis

Foundation, MRSA Foundation, MRSA Survivors Network, Sepsis Alliance, Empowered Patient Coalition, The Institute for Patient- and Family-Centered Care, Patient Safety Movement Foundation, Alliance for Safety Awareness for Patients. Patient advocacy groups interested in working with SHEA on guidelines and guidance development should contact [info@shea-online.org](mailto:info@shea-online.org).

## **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>

1. The primary interests of concern include “promoting and protecting the integrity of research, the welfare of patients and the quality of medical education.”
2. 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, consensus statements, and practice statements must disclose financial relationships and organizational affiliations that pose potential conflict of interest. They also must detail a management plan that includes recusal and other appropriate actions when issues arise that are relevant to one or more of their disclosures.

Relationships that must be disclosed include:

- Employment/service
- Advisory/consultant role, especially for involvement in the marketing (versus research) arm
- Ownership interests (including stock or stock options, except when invested in a diversified fund not controlled by the covered individual), especially those issued for involvement in the marketing (versus research) arm
- 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 “nothing to disclose” in a manuscript means that the individual does not have any financial or non-financial relationships, or primary or secondary interests, which could compromise professional judgment and considerations related to the content of the specific document.

## **COI Review**

The chair(s) of the writing panel and GLC flag 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.

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

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, expert guidance documents, practice statements, and expert consensus statements 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. Practice statements 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. This process and the rationale will be shared with writing groups at an introductory meeting by writing group chair, SHEA staff or GLC chair.

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 all questions. 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 expert guidance documents 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:

- i. **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.
- ii. **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.
- iii. **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.
- iv. **Publication Language.** Only English language articles will be included.
- v. **Publication Type.** Only full-length articles should be included. **Exclusions.** Potential reasons for exclusion include:
  - a. Outside the scope of the document, as determined during the first phase of development
  - b. Excluded based on: language, setting, treatment, disease, diagnostic process, comorbidity, age group, sample size, lab study, sex, duration, intervention, procedure, or administration route
  - c. Insufficient or unacceptable (as agreed upon *a priori*): study design, intervention data, randomization, control, design, data analysis
  - d. Inaccessible full text article
  - e. 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. Commentary/editorials
  - g. Case studies
- vi. **Methods and resources not utilized as part of SHEA's systematic literature search and review process.**
  - a. 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.
  - b. 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).
  - c. 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).
- vii. **Exceptions.**

- a. 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.
  - b. 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.
  - d. **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.
  - e. **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.
  - f. **Secondary/Full Review and Extraction.** The resulting list of articles that have not been excluded after the primary review will be reviewed in full, evenly divided among members of the panel, who will complete a custom extraction form to document the study type, population, and relevance to specific PICO questions and the topic in general. 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.
  - g. **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.
4. **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. This table does not need to be published with the manuscript.

## Inclusion of Products, Services, or Treatments

1. If a recommendation discusses healthcare products, services, or treatments, it will use generic names.
2. Recommendations and their rationale will not refer to organizations whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

3. To the best of a writing panel's ability, the panel will identify if any of the draft recommendations depend on the use of products, services, or treatments known to be highly vulnerable to discontinuation, shortages, or lack of supply.
  - a. The panel will evaluate these recommendations and consider the known vulnerabilities for their potential effect(s) on implementation of the recommendation as written.
  - b. If the panel decides that vulnerable products, services, or treatments should be included, the document will acknowledge the availability or supply issues that the panel considered.

## Consensus

Unique to expert guidance documents and consensus statements is a formalized process for reaching panel consensus. Recommendations are listed with rationale statements that consider relevant evidence as well as the consensus of the group. Voting and discussion of recommendations should occur in tandem with reviewing the rationale with evidence. Consensus around recommendations and rationale is determined via an anonymous ranking and comment period. Consensus thresholds will follow the Consensus Statement Process Guide (see **Appendix 3**):

- Consensus:  $\geq 80\%$  agreement after first vote
- Revote:  $< 80\%$  agreement
  - Majority opinion:  $> 50\%$  agreement
  - No recommendation:  $< 50\%$  agreement. Positions that were considered are included in remarks drafted by the lead authors

## Review and Approval Process of Guidelines and Expert Guidance Documents

### 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.

Guidelines, expert guidance, and other documents considered by SHEA for endorsement should only use generic names to discuss products, services, or treatments in their recommendations and rationale. Likewise, the recommendations and rationale statements in these documents should not refer to organizations whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

GLC support for a guideline/expert guidance document 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). A 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.

### **Review by Interested Parties and Groups**

This process is outlined in further detail in **Appendix 4**. Efforts to obtain review by interested parties and groups review depend on the topic and circumstances around the SHEA-sponsored document. See Patient Engagement (page 9) for more information about engaging patient interest groups.

When interested parties and groups are involved in the development of a SHEA guideline or expert guidance document 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 can 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 interested parties and groups (if applicable) are forwarded to the writing panel chair, who will review and incorporate them into the 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 Expert Guidance Documents**

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 expert guidance documents 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 expert guidance document, 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 expert guidance documents.

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

The Guideline Committee can retire documents that have become obsolete. These will be maintained on the SHEA website on a different page than current guidelines and expert guidance documents.



## Appendix 1: Definitions of SHEA-Sponsored Documents

Development, review, and publications processes as outlined in the Handbook apply to guidelines, expert guidance documents (including Compendium documents), consensus documents, and practice statements. Development of other manuscript types are beyond the scope of this Handbook.

### Peer Reviewers of SHEA-Sponsored Documents 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>• Briefs</li> <li>• Compendium</li> <li>• Guidelines</li> <li>• Expert Guidance Documents</li> <li>• Consensus Statements</li> <li>• Practice Statements (with practice recommendations)</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>• Practice Statements (no practice recommendations)</li> <li>• Commentaries</li> </ul>
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Type of Manuscript (*indicates documents governed by this Handbook)	Definition	Overseen by	Reviewed by	Peer Reviewer (applicable to SHEA-sponsored documents submitted for publication in ICHE)	Example
Brief	Clarification or update to existing document (guideline, practice statement, position paper)	Relevant committee (GLC, Education, Research, PPGA, etc.)	<ul style="list-style-type: none"> <li>• Overseeing committee</li> <li>• Board</li> </ul>	N/A (published online)	<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 and current guidelines for the prevention of HAIs with intervention, special precautions, and implementation strategies	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> <li>• Publications Committee: identification of potential critical issues related to publications process or considerations with potential to affect impact factor</li> </ul>	GLC, Board	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="https://www.cambridge.org/core">Compendium of Strategies to 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. Infection Control & Hospital Epidemiology. 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> </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

			<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>		<p>Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of Clostridioides difficile Infection in Adults, Clinical Infectious Diseases, 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></p>
Consensus Statement*	Recommendations based on non-systematic literature review and consensus of experts (internal and/or external)	GLC	<ul style="list-style-type: none"> <li>• GLC</li> <li>• Board</li> <li>• External participants</li> </ul> <p>Publications Committee: identification of potential critical issues related to publications process or considerations with potential to affect impact factor</p>	GLC, Board	<p>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, 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 &amp; 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></p>
KSA	Knowledge, skills, and abilities 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	<p>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.</p>

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 (published online)	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.
Practice Statement*	Society or collaborative statement summarizing views on healthcare epidemiology program-related practices, administrative policy, or statements about the state of the field. It does not adhere to the literature search process outlined in this Handbook (see <b>page 10</b> ) or other rigorous literature review process.	Relevant committee (GLC, 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 if it does not include practice recommendations, Guidelines Committee if it does include practice recommendations; 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, practice statement, or position paper	Relevant committee (GLC, 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, Camagros 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: Expert Guidance Proposal Form

Draft title:	
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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 journal(s):	
Type of document based on the level of available evidence: <ul style="list-style-type: none"> <li>• <b>Expert guidance or compendium format</b> (systematic literature search and consensus process per Handbook; 32-month development)</li> <li>• <b>Practice statement</b> (may include recommendations, but does not utilize a systematic literature search (e.g. NICU White Paper Series); 22-month development)</li> <li>• <b>Guideline</b> (GRADE or similarly methodology requiring adequate level of literature to achieve document’s purpose; duration determined after approval and identification of resources)</li> </ul>	
Target HCP audience:	
Target patient population:	
Issue in question:	
Objectives:	
Why does this document need to be developed?	
Are there existing <i>SHEA-led or co-led</i> recommendations on this topic?	
Are there recommendations by <i>other societies</i> on this topic?	
Is there perceived or documented variation in practice?	
What is your estimate of currently available level of evidence?	
What is the potential for this document to affect decision-making, clinical outcomes, and/or reduction in practice variation?	
Estimated page count (submissions to ICHE not to exceed total of 50 double spaced pages in MS Word, 11 pt. font, not including references and appendices. Supplementary material can be linked to the document.	

Reviewers in addition to SHEA:	
Intended endorser invitations:	
Estimated month of submission:	
Derivative products (e.g. patient, pocket guides, Medscape slides):	

## Appendix 3: Consensus Statement Process Guide

### Consensus statement requirements

<b>Topic eligibility</b>	<ul style="list-style-type: none"> <li>• Relevant to infection prevention or antimicrobial stewardship</li> <li>• Affecting patient and/or healthcare personnel (HCP) safety</li> <li>• Best practices guidance does <i>not</i> currently exist (within SHEA or by other organizations)</li> <li>• Time-sensitive: urgent (e.g., needed within 6 months) and/or relevant for a short period of time and with evolving evidence (e.g., pandemic, specific outbreak)</li> <li>• Limited evidence: high levels of heterogeneity in estimated effects (i.e., a major study could upend what is currently known) and no large or definitive study (e.g., multicenter RCT) exists or is in progress</li> <li>• Practice variability: general uncertainty related to the topic and approaches vary among similar settings</li> </ul>
<b>Frequency</b>	1 statement every 6 months (timing will be a consideration for approval of petition to GLC)
<b>Format</b>	<ul style="list-style-type: none"> <li>• &lt;10 MS Word pages (double spaced, 4-7 published pages)</li> <li>• ≤10 specific questions with recommendations, % approval, relevant remarks (no narrative rationale), and citations</li> <li>• Front matter with intro/preface, methods, intended use disclaimer, recommendations, disclosures</li> </ul>
<b>Follow-up, review, and updates</b>	<ul style="list-style-type: none"> <li>• Debrief after finalization with electronic survey of panel members to seek input, improvements, ideas</li> <li>• Reviewed every 5 years by the writing panel for state of the literature to determine whether statement will be: <ul style="list-style-type: none"> <li>a. Retired: statement no longer meets eligibility criteria</li> <li>b. Updated: statement meets eligibility criteria (begin with 3-round Delphi and same panel composition, replacing members who are no longer available)</li> <li>c. Upgraded: statement is recommended for conversion to expert guidance or guideline (document will transfer over to follow expert guidance or guidelines process, including formation of writing panel)</li> </ul> </li> </ul>

### Proposal

Step	Lead(s)	Action(s)
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1	Proposal authors (2-4 SHEA members)	Submit to GLC the manuscript proposal form (template provided), specifying: 1. Expertise/views to be represented (perspectives/views, areas of expertise, individuals with that expertise, relevant SHEA groups (committees/interest groups) and external organizations that should be represented) 2. Central issue, practice variation, state of the evidence 3. Maximum 30 questions potentially needing recommendations
2	GLC	1. Reviews proposal 2. Votes whether to approve 3. Nominates additional members or representative groups (committees, SIGs, other organizations) and refines/adds to questions 4. If approved, notifies Publications Committee and Board Executive Committee of the intent to proceed with proposal
3	Publications Committee and Board EC	1. Provide input into panel nominees and questions
4	Proposal authors	2. Make revisions following GLC, Publications, and Executive Committee feedback 3. Contact relevant SHEA groups and external organizations for input into concept 4. Make additional revisions per additional groups' feedback
5	Headquarters and GLC chairs	1. Review changes by proposal authors 2. Submit final proposal to Board for approval
6	Board	Approves or does not approve proposal for development

## Development

Assembly of 20-person panel with 2 leads (completion of 1 electronic ranking form by GLC)

Step	Leads(s)	Action(s)
1	GLC	Complete <i>Panel Ranking Form</i> to identify top 20 panel members from nominees by panel submitters, Publications, Board, committees, SIGs, external organizations. Note: organizational representatives vote on behalf of their individual views but are included on the panel to provide perspectives of organization as needed.
2	Board	Identifies 2 lead authors (first and last or second authors of consensus statement) from the 20 panel members
3	Headquarters	Sends invitations with author guidelines and COI form
4	COI Committee	Reviews panel members' disclosures, management plans, and determines criteria for recusal

## Round 1

**Call 1 agenda** (1.5 hours)

1. Welcome, introductions
2. Individual disclosure and group discussion of known and potential biases, norms for recusal
3. Review, discussion, and refinement of set of questions in final proposal

**Offline work between call 1 and call 2** (completion of 2 electronic votes by panel)

Step	Lead(s)	Action(s)
1	Headquarters	Develops and distributes to full panel <i>Questions Vote 1</i> with questions from proposal
2	Full panel	Completes <i>Questions Vote 1</i> to narrow proposal questions to the top 15
3	Headquarters	Develops and distributes to full panel <i>Questions Vote 2</i> of top 15 questions
4	Full panel	Completes <i>Questions Vote 2</i> to narrow questions to top 10
5	Headquarters and lead authors	<ol style="list-style-type: none"> <li>1. Based on final 10 questions, identify five 4-person subgroups to handle 2 questions each</li> <li>2. Notify panel members of subgroup assignments</li> </ol>
6	Subgroup members	<ol style="list-style-type: none"> <li>1. Individually conduct and document non-systematic database literature searches (e.g., PubMed, Cochrane). Panel members should consider alternative forms of evidence to RCTs (e.g., case control studies, modeling studies)</li> <li>2. Identify “grey literature” (not available through major literature databases, e.g., governmental documents)</li> <li>3. Confer electronically or over calls to draft:               <ol style="list-style-type: none"> <li>a. Recommendations</li> <li>b. Remarks based on literature findings, practice considerations, experience, feasibility/implementation</li> <li>c. Citations</li> <li>d. Note: subgroups may submit up to 3 recommendations options if they cannot achieve internal agreement</li> </ol> </li> <li>4. Submit drafts to SHEA staff two weeks before Call 2</li> </ol>
7	Headquarters and lead authors	<ol style="list-style-type: none"> <li>1. Copyedit recommendations, remarks, citations</li> <li>2. Circulate combined questions and recommendations to full panel</li> </ol>

## Round 2

**Call 2 agenda** (2 hours)

1. Disclosures of known and potential biases
2. Subgroup presentations
3. Full group discussion of recommendations

**Offline work between call 2 and call 3** (completion of 1 electronic vote by panel)

Step	Lead(s)	Action(s)
1	Headquarters	Creates and distributes to full panel <i>Recommendations Vote</i> (electronic survey with comment fields)



2	Full panel	Completes <i>Recommendations Vote</i> . When >1 recommendation option is presented, simple majority prevails
3	Headquarters	Distribute results of <i>Recommendations Vote</i>
4	Subgroups	1. Adjust recommendations based on comments 2. Submit revised recommendations to SHEA staff 2 weeks before call 3
5	Lead authors	Develop front matter

### Round 3

**Call 3 agenda** (2-4 hours; completion of 1-2 live electronic votes by panel)

1. Subgroups present and full group discusses *only* the updated recommendations
2. Full group (quorum of 2/3 of panel in attendance) completes *Finalization Vote 1* (electronically, live)

Consensus	≥80%. If not unanimous, votes published with % agreement and n
<i>Finalization Vote 2</i> (electronic live vote)	<80% agreement. Regardless of outcome of <i>Finalization Vote 2</i> , final votes published with % agreement and n
Majority opinion	>50% agreement after <i>Finalization Vote 2</i>
No recommendation	≤50% agreement after <i>Finalization Vote 2</i> Positions that were considered are included in remarks, drafted by lead authors

Thresholds based on [ACCORD guideline for reporting consensus-based methods](#)

### Approval, publication, dissemination

Step	Lead(s)	Action(s)
1	Headquarters	1. Assembles and finalizes draft with EndNote reference list 2. Submits draft to GLC and Publications 3. Submits draft to represented external organizations 4. Communications and marketing: a. Develops dissemination plan, including PR b. Provides promotional text for external organizations
2	GLC, Publications Committee, external organizations	Vote on approval and submits only comments with copyedits that do not change meaning OR edits that would result in non-approval of manuscript
3	Full panel	Reviews comments flagged as potentially leading to non-approval of manuscript and submits responses and revised document to external organizations, GLC, and Publications for final decision
3	GLC	Recommends approval to the Board
4	Board	Votes to approve manuscript

5	Headquarters	<ol style="list-style-type: none"> <li>1. Adds endorsing organizations' statement</li> <li>2. Submits to journal</li> <li>3. Facilitates proofs review</li> <li>4. Communications and marketing: implement dissemination plan</li> </ol>
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## Consensus Statement Proposal Form

<b>Proposal review</b> <i>(completed by Headquarters)</i>		<b>Date of submission by proposal authors</b>	<b>Date returned to authors</b>
1	<b>Guidelines Committee</b> (reviews proposal, provides feedback on writing panel configuration and questions, declines or provides preliminary recommendation to proceed)		
2	<b>Proposal authors</b> <i>(revise per GLC feedback)</i>		
3	<b>Publications Committee</b> and <b>Board Executive Committee</b> (considers preliminary recommendation to proceed/not proceed by GLC, provides feedback on writing panel configuration and questions (see tables below))		
4	<b>Proposal authors</b> <i>(revise per Publications Committee and Board EC feedback; share with proposed groups (see table below); incorporate feedback)</i>		
5	<b>Headquarters</b> and <b>Guidelines Committee Chairs</b> (review revised proposal, make final recommendation to Board regarding approval)		
6	<b>Board of Trustees</b>	<b>Date of approval:</b>	

<b>Proposal Submission</b> <i>(completed by proposal authors)</i>	
<b>Title and authors</b>	
<b>Preliminary title</b>	
<b>Proposal author(s)</b> (name(s) and email(s))	
<b>Affiliated committee or group</b> (if applicable)	
<b>Topic eligibility</b>	
Will the consensus statement be relevant to infection prevention, antimicrobial stewardship, or both?	
Does current guidance or guidelines for best practices exist on this topic (by SHEA or other organizations)?	
Is the topic time sensitive (e.g., needed within ~6 months, relevant for a short period of time,	

needed for patient or HCP safety in the context of evolving evidence (e.g., pandemic or emerging pathogen))?	
Is there practice variability (general uncertainty related to the topic or varied approaches among HCP in similar settings)?	
What is the current state of the evidence for the topic?	
Can the topic be addressed with the consensus statement format? <ul style="list-style-type: none"> <li>• Development within 6 months</li> <li>• Recommendations identified with non-systematic literature evaluation and 3-round Delphi process conducted over 3 Zoom meetings</li> <li>• &lt;10 MS Word pages (4-7 published pages)</li> <li>• ≤10 distinct questions and recommendations, each with % final panel agreement, relevant remarks (no narrative rationale), and citations</li> </ul>	
<b>Proposed writing panel</b>	
Needed expertise	
Involvement of SHEA groups (committees, special interest groups)	
External organizations	<ul style="list-style-type: none"> <li>• List organizations to involve with representatives and endorsement/approval</li> </ul>
Authors	<ul style="list-style-type: none"> <li>• Maximum 20 suggested individual authors</li> </ul>
<b>Proposed questions</b>	
1-30	<ul style="list-style-type: none"> <li>• 30 questions maximum, suggested by proposal's authors for inclusion in consensus statement (questions will undergo Delphi electronic voting to be narrowed to 10)</li> <li>• <i>PICO-style: description of <b>p</b>opulation or <b>p</b>atient; <b>i</b>ntervention to help population; <b>c</b>omparison or alternative to intervention; <b>o</b>utcome desired from intervention)</i></li> </ul>

## Appendix 4: Compendium 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>Essential 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.	Specifies the setting and population to which the recommendation applies (e.g., adult patients in intensive care unit settings)  Declarative verbs, e.g., use, perform, maintain, replace	should; should not; recommend; is recommended; recommends against; is not recommended; is indicated; is not indicated
<b>Additional 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 likely to exceed the benefits).	<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: <ul style="list-style-type: none"> <li>There is high-quality evidence, but the benefit/harm balance is not clearly tipped in one direction</li> <li>The evidence is weak enough to cast doubt on whether the recommendation will consistently lead to benefit</li> </ul> </li> <li>The likelihood of benefit for a specific patient population or clinical situation is extrapolated from relatively high-quality evidence demonstrating impact on other patient</li> </ul>	HCP/facilities "could," or could "consider" implementing the recommended approach.  The degree of appropriateness may vary depending on the benefit vs. harm balance	Specifies the setting and population to which it applies when relevant, including select settings (e.g., during outbreaks), environments (e.g., ICUs), populations (e.g., neonates,	consider; could; may; may consider

		<p>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>	for the specific setting.	transplant patients)	
<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 5: Development Checklists

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

### 32-Month Expert Guidance Checklist

Month and Phase	Steps	Meetings and votes
<b>Before month 1</b> <i>Topic proposal</i>	1. Topic proposal	
	2. GLC review	
	3. Proposal ranking survey	<b>Electronic vote</b> (GLC and Board)
	4. Manuscript proposal drafted and submitted	
	5. Review by Publications Committee	
	6. Review by Board	
	7. Manuscript queue updated	
	8. Editor/Editorial Team informed of planned manuscript	
<b>Month 1</b> (1 month) <i>Panel assembly</i>	9. Staff planning	
	10. Chair invitations	
	11. Author invitations	1 call (chairs)
	12. Organizational representative invitations	
	13. Roster	
	14. Review of COI by chair(s)	1 call (chairs)
	15. Review of flagged disclosures by COI Committee	1 call (chairs and COI Committee, if needed)
<b>Months 2-3</b> (2 months) <i>Scope, themes, outline</i>	16. COI added to roster	
	17. Planning call	1 call (chairs)
<b>Months 4-8</b> (5 months) <i>Questions</i>	18. Draft scope, themes, outline and finalize outline	2 calls (panel)
	19. Identify questions (max 10), time period, databases, terms	3 calls (panel)
	20. Panel finalization and approval of questions table	<b>Electronic vote</b>
	21. Revisions	1 call (panel, if needed)
<b>Months 9-15</b> (7 months)	22. Send questions and criteria to librarian	
	23. Librarian reviews search strategy with panel	1 call (panel)

<i>Literature search and review</i>	24. Abstract screening	2 calls (panel): • 1 Covidence instruction • 1 check-in
	25. Chairs resolve conflicts	1 call (chairs)
	26. Review of preliminary findings, confirm author assignments	1 call (panel)
	27. Full text review and extraction	2 calls: • 1 Covidence instruction • 1 check in
<b>Months 16-18</b> (3 months) <i>Writing</i>	28. Draft recommendations and rationale	4 calls (subgroups), 3 calls (panel)
	29. Draft background and front matter	2 calls (chairs)
<b>Months 19-23</b> (5 months) <i>Consensus</i>	30. Panel review of recommendations	2 calls (panel)
	31. Preliminary vote	<b>Electronic vote</b>
	32. Revisions	2 calls (panel)
	33. Panel vote on full manuscript	<b>Electronic vote</b>
<b>Months 24-29</b> (6 months) <i>External review</i>	34. GLC, Publications; partnering organizations; potential endorsers	
	35. Submission to CDC Clearance if applicable	
	36. Revisions	1 call (chairs), 2 calls (panel)
	37. GLC vote; Publications (no vote)	
	38. Board and leadership review; endorsement request	
	39. Finalization	
<b>Months 30-32</b> (3 months)	40. Submission to ICHE or ASHE	
<i>Submission and publication</i>	41. Submission for pocket guide development	
	42. Proofs	1 call (chairs)
	43. Publication	
<b>32 months</b>	<b>43 steps</b>	<ul style="list-style-type: none"> <li>• <b>Chairs:</b> 24-26 calls</li> <li>• <b>Panel members:</b> 22-23 calls</li> <li>• <b>4 electronic votes</b></li> </ul>





## 22-Month Practice Statement Checklist

Month and Phase	Steps	Meetings and votes
<b>Before month 1</b> <i>Topic proposal</i>	1. Topic proposal	
	2. GLC review	
	3. Proposal ranking survey	<b>Electronic vote</b> (GLC and Board)
	4. Manuscript proposal drafted and submitted	
	5. Review by Publications Committee	
	6. Review by Board	
	7. Manuscript queue updated	
	8. Editor/Editorial Team informed of planned manuscript	
<b>Month 1</b> (1 month) <i>Panel assembly</i>	9. Staff planning	
	10. Chair invitations	
	11. Author invitations	1 call (chairs)
	12. Organizational representative invitations	
	13. Roster	
	14. Review of COI by chair(s)	1 call (chairs)
	15. Review of flagged disclosures by COI Committee	1 call (chairs and COI Committee, if needed)
	16. COI added to roster	
<b>Months 2-3</b> (2 months) <i>Scope, themes, outline</i>	17. Planning call	1 call (chairs)
	18. Draft scope, themes, outline and finalize outline	2 calls (panel)
<b>Months 4-5</b> (2 months) <i>Questions</i>	19. Identify questions (max 10), time period, databases, terms	2 calls (panel)
	20. Panel finalization and approval of questions table	<b>Electronic vote</b>
	21. Revisions	1 call (panel, if needed)
<b>Months 6-8</b> (3 months) <i>Literature search and review</i>	22. Subgroup literature review via PubMed, Cochrane, and/or Embase (2 databases preferred)	
	23. Full text review	
<b>Months 9-10</b> (2 months) <i>Writing</i>	24. Draft recommendations and rationale	3 calls (subgroups), 1 call (panel)
	25. Draft background and front matter	1 call (chairs)

<b>Months 11-14</b> (4 months) <i>Consensus</i>	26. Panel review of recommendations	2 calls (panel)
	27. Preliminary vote	<b>Electronic vote</b>
	28. Revisions	2 calls (panel)
	29. Panel vote on full manuscript	<b>Electronic vote</b>
<b>Months 15-19</b> (5 months) <i>External review</i>	30. Submission to GLC, Publications; partnering organizations; potential endorsers	
	31. Submission to CDC Clearance if applicable	
	32. Revisions	1 calls (chairs), 2 calls (panel)
	33. GLC vote; Publications (no vote)	
	34. Board and leadership review; endorsement request	
	35. Finalization	
<b>Months 20-22</b> (3 months)	36. Submission to ICHE or ASHE	
<i>Submission and publication</i>	37. Submission for pocket guide development	
	38. Proofs	1 calls (chairs)
	39. Publication	
<b>22 months</b>	<b>39 steps</b>	<ul style="list-style-type: none"> <li>• <b>Chairs: 17-19 calls</b></li> <li>• <b>Panel members: 14-15 calls</b></li> <li>• <b>4 electronic votes</b></li> </ul>

## 6-Month Consensus Statement Checklist

Month and Phase	Steps	Meetings and votes
<b>Before month 1</b> <i>Topic proposal</i>	1. SHEA members (2-4) submit proposal form to GLC	
	2. GLC reviews proposal, comments, and votes whether to proceed	<b>Verbal or electronic vote</b> (GLC)
	3. Authors revise	
	4. Publications Committee and Board Executive Committee review, comment, and vote whether to approve	<b>Verbal or electronic vote</b> (Publications and Board Executive Committee)
	5. Authors revise	
	6. Board of Trustees votes whether to approve	
<b>Month 1</b> (1 month) <i>Panel assembly</i>	7. GLC completes panel ranking form to narrow to 20 panel members	<b>Electronic ranking survey</b>
	8. Board identifies two lead authors from among those listed in the proposal	
	9. Headquarters sends invitations with author guidelines and COI form	
	10. COI Committee reviews disclosures and management plans, criteria for recusal	
<b>Month 2</b> (1 month) <i>Questions</i>	11. Review, discussion, and refinement of set of questions in final proposal	1 call (1.5 hours, panel)
	12. Questions Vote 1 to narrow to top 15	<b>Electronic vote</b>
	13. Questions Vote 2 to narrow to top 10	<b>Electronic vote</b>
	14. Lead authors create 5 4-person subgroups to handle 2 questions each and assign questions	
<b>Months 3-4</b> (2 months) <i>Literature review and drafting</i>	15. Subgroups individually conduct and document non-systematic database literature searches on topic (e.g., PubMed, Cochrane, Embase), including alternative forms of evidence to RCTs (e.g., case control studies and modeling studies)	
	16. Subgroups individually identify “grey literature” (e.g., governmental documents)	
	17. Subgroup members draft recommendations, remarks based on literature findings (subgroups may submit up to 3 recommendations if members cannot reach internal agreement)	
	18. Subgroups submit drafts to SHEA staff 2 weeks before call to be copyedited and shared with panel by headquarters staff	
	19. Full group review of recommendations	1 call (2 hours, panel)
	20. Recommendations Vote. When >1 recommendation is presented, simple majority rules	<b>Electronic vote</b>
	21. Headquarters distributes aggregate results of Recommendations Vote	

	22. Subgroups revise recommendations based on vote and comments	
	23. Subgroups submit revised recommendations 2 weeks before call	
	24. Lead authors develop front matter	
<b>Month 5</b> (1 month) <i>Consensus</i>	25. Consensus voting: a. Electronic consensus Vote 1 i. Consensus for $\geq 80\%$ . If not unanimous, votes published with % agreement and n ii. $< 80\%$ moves to finalization Vote 2 b. Electronic finalization consensus Vote 2 i. Majority opinion for $\geq 50\%$ agreement ii. No recommendation for $< 50\%$	1 call (2-4 hours, panel) <b>Electronic votes</b> (1-2, live)
<b>Month 6</b> (1 month) <i>Approval, publication, dissemination</i>	26. Headquarters assembles and finalizes draft, including EndNote reference list	
	27. Headquarters submits draft to GLC, Publications, represented organizations	
	28. Headquarters (communications and marketing) develop PR and dissemination plan	
	29. GLC, Publications, external organizations vote on approval	
	30. Full panel responds to comments flagged as potentially leading to non-approval	
	31. GLC recommends/does not recommend approval to the Board	
	32. Board votes on manuscript	
	33. Headquarters submits to journal, facilitates proof review, implements dissemination plan	
<b>6 months</b>	<b>33 steps</b>	<b>Chairs and panel: 3 calls, 6.5 hours</b> <b>7 electronic votes</b>

## Appendix 7: Review and Comment Period

1. The decision to endorse a guideline or guidance document is the decision of the organization that is considering the document.
2. Organizations reviewing a SHEA-sponsored document should indicate in the appropriate column on the review form changes that are necessary for endorsement.
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.

Action	Applies to	Participants
1. Draft finalized by writing group	Expert guidance documents, 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	Expert guidance documents, 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.	Expert guidance documents, 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, relevant SHEA committees.	Expert guidance documents, compendium format, guideline	External organizations

6. Comments provided to authors for response; updates to document.	Expert guidance documents, 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.	Expert guidance documents, 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.	Expert guidance documents, compendium format, guideline	Staff, ICHE

## Appendix 8: SHEA Writing Panels – Author Responsibilities

Role	Responsibilities	Listed in Manuscript
First Author/Lead Author (Chair)	<p>As relevant to the manuscript, guide and facilitate decision-making related to content, with other lead author(s):</p> <ul style="list-style-type: none"> <li>• Lead calls and guide discussion over calls and email: <ul style="list-style-type: none"> <li>○ Respond to comments/questions from authors regarding manuscript</li> <li>○ Delegate responses to appropriate authors if unable to respond</li> <li>○ Facilitate consensus process among panel members for recommendations, in accordance with <a href="#">SHEA process</a></li> </ul> </li> <li>• In collaboration with the staff liaison: <ul style="list-style-type: none"> <li>○ Draft manuscript proposal</li> <li>○ Select panel participants (with input from SHEA leadership, as relevant)</li> <li>○ Adhere to appropriate SHEA <a href="#">manuscript development process(es)</a></li> <li>○ Develop agenda for meetings and leading calls</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• First in author block</li> <li>• May also be corresponding author</li> </ul>

	<ul style="list-style-type: none"> <li>• Commit to and support adherence by panel to deadlines and milestones</li> <li>• Commit to and adhere to allocation of resources (staff, budget) as approved by the Board at the outset of the project</li> <li>• Decide and communicate how steps will be accomplished among members of the panel (e.g., handoffs from one milestone to the next).</li> <li>• Serve as primary author of manuscript's Introduction</li> <li>• Thoroughly review of document for accuracy of content (staff will lead formatting decisions): <ul style="list-style-type: none"> <li>○ Upon combination of draft sections</li> <li>○ Upon revisions following external review</li> <li>○ Prior to submission for publication</li> <li>○ Upon receipt of proofs</li> </ul> </li> <li>• Serve as spokesperson for media/PR, if pursued</li> <li>• Review press release, if developed</li> </ul>	
Last Author/Senior Author (possible co-chair)	<ul style="list-style-type: none"> <li>• Support and assist the first author in the areas described above</li> <li>• Coordinate with first and second authors to assume/delegate responsibilities for reasonable burden among authors</li> <li>• Determine with lead authors and staff how steps will be accomplished among members of the panel (e.g., handoffs from one milestone to the next).</li> <li>• Contribute as author of manuscript's Introduction</li> <li>• Commit to and support adherence by panel to deadlines and important milestones for progress</li> <li>• Commit and adhere to allocation of resources (staff, budget) as approved by the Board at the outset of the project</li> <li>• Thoroughly review of document for accuracy of content: <ul style="list-style-type: none"> <li>○ Upon combination of draft sections</li> <li>○ Upon revisions based on external review</li> <li>○ Prior to submission to journal</li> <li>○ Upon receipt of proofs</li> </ul> </li> <li>• Coordinate with second author regarding interim responsibilities if first author is not available</li> <li>• Potentially participate as spokesperson for media/PR, if pursued</li> </ul>	<ul style="list-style-type: none"> <li>• Last in author block</li> <li>• May also be corresponding author</li> </ul>
Second Author (possible co-chair)	<ul style="list-style-type: none"> <li>• Support and assist the first author in the areas described above</li> <li>• Coordinate with first and senior authors to assume/delegate responsibilities for reasonable burden among authors</li> <li>• Determine with lead authors and staff how steps will be accomplished among members of the panel (e.g., handoffs from one milestone to the next).</li> </ul>	<ul style="list-style-type: none"> <li>• Second in author block</li> <li>• May also be corresponding author</li> </ul>

	<ul style="list-style-type: none"> <li>• Contribute as author of manuscript’s Introduction</li> <li>• Commit to and support adherence by panel to deadlines and milestones</li> <li>• Commit and adhere to allocation of resources (staff, budget) as approved by the Board at the outset of the project</li> <li>• Thoroughly review of document for accuracy of content: <ul style="list-style-type: none"> <li>○ Upon combination of draft sections</li> <li>○ Upon revisions based on external review</li> <li>○ Prior to submission to journal</li> <li>○ Upon receipt of proofs</li> </ul> </li> <li>• Coordinate with senior author regarding interim responsibilities if first author is not available</li> <li>• Potentially participate as spokesperson for media/PR, if pursued</li> </ul>	
Corresponding Author	<ul style="list-style-type: none"> <li>• Institution should have a read-and-publish agreement with Cambridge</li> <li>• Complete required forms for journal where manuscript is accepted</li> <li>• Report correspondence with journal to staff lead</li> <li>• Thoroughly review proofs and share revisions with staff, fellow authors, and/or additional partners as appropriate</li> <li>• Work with staff lead to submit, review, and approve proof revision(s)</li> <li>• Respond to inquiries related to the manuscript’s content</li> </ul>	<ul style="list-style-type: none"> <li>• May be first, second, or senior author</li> </ul>
Lead Authors (as group: first, second, and last/senior)	<ul style="list-style-type: none"> <li>• Conflict resolution during abstract and full-text screenings (if relevant)</li> <li>• Collaborative leadership decision-making</li> <li>• Commitment to and support for adherence by panel to deadlines and milestones</li> </ul>	<ul style="list-style-type: none"> <li>• As above</li> </ul>
Subgroup Lead(s)	<ul style="list-style-type: none"> <li>• Schedule and lead subgroup meetings during writing phase (SHEA can provide a Zoom link if needed)</li> <li>• Solicit updates on subgroup members' progress</li> <li>• Commit to and support for adherence by subgroup to deadlines and milestones</li> <li>• Raise issues with staff/lead authors as needed</li> </ul>	<ul style="list-style-type: none"> <li>• Alphabetical between leading authors, or preceding subgroup authors</li> </ul>
Panel Members (usually the authors)	<ul style="list-style-type: none"> <li>• Complete, as assigned and relevant to the manuscript: <ul style="list-style-type: none"> <li>○ Abstract review</li> <li>○ Full text review</li> <li>○ Article extraction</li> <li>○ Manuscript section drafts</li> <li>○ Citations, in the format defined by SHEA staff</li> </ul> </li> <li>• Provide full text references as PDFs or URLs, if not part of the literature identified by a SHEA literature search</li> </ul>	<ul style="list-style-type: none"> <li>• Alphabetical between leading authors</li> </ul>



	<ul style="list-style-type: none"> <li>• Commit to deadlines and milestones</li> </ul>	
Organizational Representative	<ul style="list-style-type: none"> <li>• Communicate and establish organization’s process for inclusion of representative as an author, review, approval, and endorsement</li> <li>• As an author: <ul style="list-style-type: none"> <li>○ Adhere to author guidelines.</li> <li>○ Provide expert input as well as insight into the organization’s views, resources, etc.</li> <li>○ Establish with writing panel and represented organization expectations of representation, i.e., whether their vote will be their individual view or will represent the organization.</li> </ul> </li> <li>• If a representative without pursuing authorship, self-determine participation in order to achieve aim of organization’s involvement (approval, endorsement, etc.) according to timeline.</li> <li>• Liaise with organization represented to keep it apprised of progress.</li> </ul>	<ul style="list-style-type: none"> <li>• Author block, alphabetical</li> <li>• Listed with organization in Methods</li> </ul>
Staff Lead	<ul style="list-style-type: none"> <li>• Develop manuscript proposal with panel lead(s) and put into process for review</li> <li>• Identify panel invitees with panel lead(s)</li> <li>• Provide SHEA documents detailing standard SHEA processes for manuscript proposal, literature review, writing, external review, submission, publication, dissemination and promotion</li> <li>• Guide panel leads and members in adherence to SHEA processes</li> <li>• Primary contact for librarian and other consultants (e.g. EndNote consultant, copyeditors) and Cambridge</li> <li>• Development of reference list (potentially in collaboration with consultant); provide instruction in advance for authors to notate references</li> <li>• Format manuscript to conform with SHEA and ICHE/ASHE</li> <li>• Facilitate external review, as appropriate for the manuscript</li> <li>• Facilitate endorsement by partnering organizations, as appropriate for manuscript</li> <li>• Submit manuscript to ICHE or ASHE</li> <li>• Coordinate with PR firm for media activities in collaboration with appropriate SHEA staff</li> </ul>	<ul style="list-style-type: none"> <li>• Alphabetical in author block if provided substantial contributions to writing</li> <li>• In Acknowledgements if oversaw effort but did not write</li> </ul>
Librarian	<ul style="list-style-type: none"> <li>• Develop search strategy based on manuscript’s approved questions</li> <li>• Obtain staff and panel’s approval for search strategy(s)</li> <li>• Run search strategy (adapted as needed for each specific database) in at least two databases</li> <li>• Perform first exclusions based on defined criteria</li> <li>• Provide lead staff with included and excluded EndNote file, PRISMA file</li> </ul>	<ul style="list-style-type: none"> <li>• In Acknowledgements</li> </ul>

## Appendix 9: SHEA Inclusive Language Guide

### Introduction

The evolution of language in any field warrants periodic efforts to establish consensus and provide guidance for the nomenclature it uses for the clarity, consistency, and usability of its communications. This is especially important for those that inform decisions made for healthcare safety and patient care.

The Handbook Task Force developed this guide for SHEA expert guidance, guidelines, research manuscripts, and other written materials. It focuses on the terminology and phrasing that is relevant to SHEA and feasible for its authors to adhere to consistently in the workflow of manuscript development.

This guide does not address all possible scenarios. The topics that SHEA covers will evolve, as will the nomenclature. Given the challenges in providing comprehensive examples that may go out of date for certain areas, this document recommends that authors and other participants seek further information through reputable sources as needed for writing projects.

This document will be reviewed and revised on a periodic basis. It adheres to the [SHEA Diversity, Equity, & Inclusion Pledge](#).

### General principles

- As appropriate, provide definitions for clarity.
- Be appropriately specific for the purpose of the work and able to explain the reasoning for specificity or differentiation.
- Choose terminology and phrasing that is respectful of a person's individual identity. When uncertain, seek reputable sources for prevailing approaches.
- Be sensitive to labels. When using descriptors, do not make assumptions. Use consistent phrasing. Include appropriate corollaries to avoid implying a "norm" and an "exception."
- When citing or describing a study that did not apply these principles, use the terminology and phrasing from that study when needed to inform the guidance document or guideline.

### Terminology

#### Those who work in healthcare

- For all paid and unpaid persons who serve in healthcare settings and whose primary intent is to protect or improve health, use **healthcare personnel (HCP)** (CDC). When needed, collectively HCP also may be referred to as the **healthcare workforce**.
- For HCP who do *not* work in clinical care spaces, use **non-clinical healthcare personnel (non-clinical HCP)**.
- For HCP who work in clinical care spaces, use **clinical healthcare personnel (clinical HCP)**. As needed for the communication, clinical HCP may be further differentiated as:
  - Patient-interacting HCP

- Prescribing HCP: persons who have authority (independently licensed or as authorized by their employer) to make treatment decisions for patients
- Non-patient interacting HCP.

## Visitors

- For people who enter a healthcare facility, but are *not* patients, HCP, or persons in non-health related roles (e.g., restaurant employees), use **visitors**.
- To specify a visitor who is a primary source of support for the patient’s activities of daily living (ADL), labor and delivery, or a procedure and recovery, use **support person or primary caregiver** (use the term most appropriate for the population and situation being discussed).
- To convey a visitor’s potential exposure due to close or sustained contact with a patient who has a communicable disease, use **time or proximity-based definitions specific to the infectious agent**, rather than “household contact.” For conciseness, after defining the time or proximity-based conditions that constitute exposure to the infectious agent, the authors may subsequently use “**close contact**,” while including the definition in the communication.

## Person-first and identity-first language

- Describe people in ways that maintain their integrity as individuals. Use terms that are broadly inclusive unless specificity is needed for the purpose of the communication.
- Before beginning the communication, identify conditions and situations that may be relevant to the populations and scenarios discussed (e.g., illness, disease, living situation, sexual activity or identity, gender identity, language, ethnicity, citizenship status):
  - In general, **recognize a person before their condition or situation**. Often, this may be conveyed as “a person with…” or “a person experiencing…” or “a person who is…”
  - **Exceptions apply:**
    - If a person prefers a different phrase to describe themselves, use that phrase instead.
    - Certain groups may prefer identity-first language. Per APA, in these cases, it is permissible to use either a person-first or identity-first phrasing or a mix until the group clearly states preference for one approach.
  - Many examples and variations of person and identity-first language exist; seek reputable sources for preferred phrasing.
- In general, **do not describe people by sexual activity**. If a communication needs to refer to sexual activity(s), describe the body part(s) used in that activity (e.g., persons who have anal receptive intercourse). Use prevailing approaches that have been identified from reputable sources.

## Gender

- The same principles of person-first and identity-first language apply: communications should respect a person’s identity as an individual.
- Similarly, before beginning the project, identify what may be relevant to the populations and scenarios that will be discussed. When uncertain, use reputable sources to identify prevailing approaches to inclusive terminology and phrasing.
- Use individuals, persons, or people to refer to human beings. “Persons” may be used to emphasize that individuals make up a collective group.
- Use gender-inclusive occupational nouns such as “chair” or “chairperson” (NIH).
- Use gender as an adjective, not a noun (e.g., female person).

- When referring to someone with a pronoun, use the singular gender-neutral (they/them) (APA, HHS), unless it is demonstrably necessary to differentiate.
- Use “gender” and “sex assigned at birth” classifications appropriately:
  - Gender refers to a person’s social identity
  - In general, avoid “sex” or “sex assigned at birth.” When demonstrably necessary to the project, apply person-first phrasing, such as “people who were raised female/male” (SAGE).
  - As of writing this guide, “transgender” and “gender nonconforming” are generally agreed upon terms (SAGE).
- Avoid assumptions and apply phrasing consistently. E.g., if you refer to people who are transgender, the include the corollary (“people who are cisgender”) (SAGE).
- When referring to pregnancy, birth, and lactation, refer to [ACOG](#), AAP, or similar reputable sources, for preferred terminology. In general, use gender-neutral terminology (e.g., “pregnant person” or “lactating person”, not “pregnant woman” or “lactating mother”).

### Race and ethnicity

- Avoid describing race and ethnicity as biological factors. Inclusion of racial or ethnic information should be relevant to the purpose of a project. When included, provide the reason the information is reported (e.g., to exhibit systemic disparities). Do not report race and ethnicity information in isolation ([JAMA](#)).
- If included among collected data, provide a way for people to self-identify their race and ethnicity.
- Use racial and ethnic terms as adjectives, not nouns.
- Be aware of the relevance of geographic influence and regionalization in the origins of terms. If uncertain, seek information from reputable sources.
- Capitalize the names of races, ethnicities, and tribes ([JAMA](#)).

### Age

- For individuals 18 and older, use specific ages or age ranges rather than descriptors. Adult age ranges are not standard and have been variably defined. Use specific ages or age ranges even for commonly used terms (e.g., “pregnant person over the age of 35” or “persons over the age of 65” instead of “geriatric pregnancy,” “advanced maternal age,” and “older adults.”)
- Check AAP for commonly accepted definitions for age categories of pediatric patients (e.g., neonate, infant, child, adolescent). If choosing a term different than those specified by AAP, explain why.

### Interested persons and groups

For groups and individuals who may be interested or affected by a decision or action, use “**interested persons and groups**,” rather than “stakeholders” or “working partners.” “Stakeholders” is no longer favored due to historic connotations, and working partners may not convey the breadth of those relevant to implementation of a decision or action.

## Practice statement

The term “practice statement” replaces “white paper” as a categorization of document that summarizes views on healthcare epidemiology and antimicrobial stewardship program-related practices (e.g., infrastructure, business cases, quality outcomes and metrics, etc.). It does not adhere to the literature search process outlined in this Handbook (see **page 10**) or other rigorous literature review process.

## Resources

<a href="#">CDC Preferred Terms for Select Population Groups &amp; Communities</a>
<a href="#">AAFP</a>
<a href="#">Agency for Healthcare Research and Quality Priority Populations</a>
<a href="#">American Psychological Association APA Style: Bias-Free Language</a>
<a href="#">APA DEI Language Guidelines</a>
<a href="#">Health Resources &amp; Services Administration</a>
<a href="#">JAMA</a>
<a href="#">NIH person-first language</a>
<a href="#">SAGE Publications</a>
<a href="#">SAGE inclusive communications</a>

## Appendix 10: Acronyms

ASHE	Antibiotic Stewardship & Healthcare Epidemiology (SHEA journal)
CDC	Centers for Disease Control and Prevention
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