



# SHEA Handbook for SHEA-Sponsored Guidelines and Expert Guidance Documents

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## Purpose and Scope

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

This handbook is considered to be a living document and will be updated at the discretion of the GLC. The first version of this Handbook was published on the SHEA website on January 2016, and does not apply to documents developed prior to that date. It was revised in January 2017.

Add revision date

## Authorship of the Handbook

The Handbook was researched and developed by the SHEA Methodologies Task Force:

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This handbook was reviewed and formally approved by the GLC and the SHEA Board of Trustees in October 2015. It was reviewed by the GLC and Board of Trustees in January 2017 and approved with updates.

## Introduction

- All SHEA-sponsored documents that provide recommendations regarding the practice of infection prevention and control, healthcare epidemiology, and antibiotic stewardship will fall into the two broad categories of “Guidelines” or “Expert Guidance Documents” (including special types of expert guidance documents).
- Development of the specific document, and particularly the literature review process, will be based on the identified category.
- The intended document category will be identified at the time the document is initially commissioned; however, because the document category is heavily influenced by the nature and quality of existing literature on a given topic, the category may be subject to revision if

necessary based on the initial literature review. Document category change after initial approval will need to be reviewed and re-approved by the GLC and SHEA Board of Trustees.

- In addition to guidelines and expert guidance documents, SHEA members may at times author documents that do not formalize practice recommendations, e.g., documents that reflect SHEA's position on statements issued by other agencies (e.g., Centers for Disease Control and Prevention) that are relevant to healthcare epidemiology, or documents on current topics of importance (e.g., major outbreak). These can follow one of the document formats outlined in **Appendix 1** or another format at the discretion of the GLC (or other appropriate SHEA committee, e.g., Public Policy and Government Affairs, Antibiotic Stewardship, Education, etc.) and SHEA Board of Trustees. The development of all such documents is beyond the scope of this handbook.

## Definitions: Guidelines and Expert Guidance Documents

### Guidelines

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

SHEA emphasizes the value of multi-society guidelines and encourages collaboration between the society and partnering organizations, both from the perspective of SHEA's lending of expertise, review, and endorsement to such projects, and also from that of the end-users of the guidelines, who benefit from multidisciplinary, widely-vetted, consistent, and concise guidelines achievable through the multi-society approach.

### Expert Guidance Documents (EGs)

Expert guidance documents (EGs) will be developed to provide practice recommendations in the absence of availability of literature to support a formal guideline. SHEA EGs will follow one of the following formats:

#### *Special Topic EGs*

Special topic EGs are 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 systematic methodology, but are important in provision of safe, effective healthcare. As such, systematic grading of the evidence level is not provided for individual recommendations. Each EG is based on a synthesis of limited evidence, theoretical rationale, current practices, practical considerations, writing group opinion, and consideration of potential harm where applicable. Depending on the topic of the EG, a survey of SHEA membership and the SHEA Research Network (SRN) may also be included. Within the document, a summary list of EG recommendations is provided, along with relevant rationale.

This definition is to be included in the front matter of all special topic EGs.

### *Compendium Format*

The compendium format is based on the “Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Settings: 2014 Update.” While a compendium document will generally address topics that are broad in scope and include recommendations supported by evidence, within a specific topic area, the document may also provide recommendations based on expert opinion, including those related to practical aspects of implementation. Further, the compendium format largely includes recommendations based on previously published healthcare-associated infection (HAI) prevention guidelines available from a number of organizations. The aim of the compendium format is to provide a summary of practical, relatively concise guidance based largely on previously published guidelines. While the compendium format does not reflect a complete systematic review of the medical literature per GRADE or a comparable methodology, an expert review panel applies the literature review process outlined in this handbook with an appropriate level of evidence assigned to each recommendation as appropriate. The compendium format is specifically designed for the practice of healthcare epidemiology by categorizing recommendations into either basic practices that should be adopted by all acute care hospitals or special approaches that can be considered for use in locations and/or populations within hospitals when HAIs are not controlled after full implementation of basic practices. Further, the compendium also summarizes strategies on implementation of the recommended strategies.

### *White Paper*

A white paper format is generally utilized to summarize SHEA’s recommendations on healthcare epidemiology program-related practices (e.g., infrastructure, business cases, quality outcomes and metrics, etc.). This format is not covered in the handbook.

### *Additional Definitions*

This handbook provides general definitions for additional formats in **Appendix 1**, but does not address these papers in detail, which are considered beyond the realm of guidelines or guidance documents.

## **Topic Proposal Process**

SHEA-sponsored topic proposals are submitted to the GLC by individuals including but not limited to: Board of Trustees, members of the GLC, SHEA committees, SHEA special interest groups, and partnering organizations via completion of a Manuscript Proposal Form (**Appendix 2**). Topics will be chosen for development based upon perceived interest, need, target patient population and guideline audience, as well as available resources. If existing guidelines or EGs from other specialty organizations or national agencies cover the same topic, the justification for the proposed project should be clearly stated. Approval of topics includes vote by the GLC<sup>1</sup>, and approval by the SHEA Board of Trustees. Prior to final approval of the topic and initiation of the project, the SHEA Publications Committee will be consulted about its appropriateness as a SHEA document. Decisions about how the paper will be reviewed and where the manuscript might be published will be decided prior to approval of the project. Collaborative projects that involve joint publication by journals from other societies or external publication will

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

require a memorandum of understanding (MOU) signed by all involved organizations and reviewed by the SHEA GLC, Publications Committee, Board of Trustees, and the Editor of ICHE before the project is started. Formal representatives from each society may be assigned at this time.

If publication in more than one journal or location on more than website is anticipated, agreements between the societies and their respective publishers should be made at the time that the topic is approved. Publishers will work out mutual agreements, as agreed upon by their societies, so that one publisher assumes the lead as copy editor and publisher and each article that is co-published in each journal is identical in content. Each society and publisher will agree as to the best means to disseminate the work with regard to the article's presentation on websites, social media, and other means of publicity.

In general, SHEA-sponsored guidelines and guidance papers are published free-access, meaning that they can be accessed by non-subscribers to the journal at no extra cost to the authors, the society, or the reader. Exceptions may be made.

## Timeline/Process Overview

The process is outlined in **Appendix 3**.

In general, a final draft of a guideline may be submitted for approval within 2 years of commissioning of the writing group and EGs may be submitted to the committee within 15 months. The timeline may differ depending on the type of document, topic, and stakeholders involved.

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

## Writing Panel Composition

The average panel will consist of 8-12 members who will meet regularly via conference call, and may meet in person at the SHEA Spring Conference or IDWeek. To the extent possible, ethnic, racial, geographic, practice setting, and gender diversity should be considered when identifying potential expert panel members.

In addition, the panel should include:

1. Clinicians with expertise in the topic area in question
2. A pediatrician whenever the management of children may be considered
3. In addition, the panel may include:
  - a. Microbiology
  - b. Nursing
  - c. Infection preventionist
  - d. Long-term care
  - e. Primary care
  - f. Subspecialty that has a unique interest in the topic under consideration
  - g. Hospitalists
  - h. Others as appropriate (e.g. patient/public advocate)

4. Early in the manuscript development process, the GLC encourages panels to invite stakeholder organizations (**Appendix 4**) to participate. This may take two forms:
  - a. Joint development: developing a guideline jointly entails having co-chairs from each organization and having equal formal representation on the panel.
  - b. Endorsement:
    - i. Review of the end-product by the organization
    - ii. The addition to the panel of a member from the potential endorsing organization and then review of the final product by the organization

## **SHEA Conflict of Interest Policy**

SHEA agrees with the Institute of Medicine report on conflict of interest (COI), which defines COI as, “a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.”<sup>2</sup> The primary interests of concern include “promoting and protecting the integrity of research, the welfare of patients and the quality of medical education.” The secondary interest, according to IOM “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, EGs, and other SHEA-sponsored documents must disclose financial relationships and organizational affiliations that pose potential conflict of interest.

Relationships that must be disclosed include:

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

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

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

## COI Review

The SHEA GLC Chair and Conflict of Interest Review Committee reviews disclosures to determine whether actual conflicts exist and identify opportunities for management to mitigate any real or perceived “undue influence” caused by such financial relationships.

Anyone with a conflict of interest is required to submit a management plan. The management plan is a self-identified action plan provided by any member who discloses an external commercial financial relationship (**Appendix 6**). 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.

## Publication of Disclosure Information

Authors’ disclosures are listed in the “Acknowledgements” section of a published manuscript with the following language:

*Potential Conflict of Interest: The following list is a reflection of what has been reported to SHEA. In order to provide thorough transparency, SHEA requires full disclosure of all relationships, regardless of relevancy to the guideline topic. Evaluation of such relationships as potential conflicts of interest is determined by a review process which includes assessment by the SHEA Guidelines Chair, the SHEA Conflict of Interest Committee, and may include the Board of Trustees and Editor of Infection Control and Hospital Epidemiology. The assessment of disclosed relationships for possible COI will be based on the relative weight of the financial relationship (i.e., monetary amount) and the relevance of the relationship (i.e., the degree to which an association might reasonably be interpreted by an independent observer as related to the topic or recommendation of consideration). The reader of these guidelines should be mindful of this when the list of disclosures is reviewed.*

## Indemnification and Copyright

Authors of guidelines and EGs that are approved by the SHEA Board of Trustees are covered from individual liability by the SHEA insurance policy.

A statement should be included in the guideline or EG that no guideline or guidance paper can anticipate all clinical situations and these papers are 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.

## Literature Review/Search

To ensure consistency and minimize potential for bias, the methods regarding search strategy and study selection will be determined before data collection starts. The following are recommended when conducting the review/search for relevant papers or publications:

1. **Recordkeeping.** For transparency and accuracy, keep a record (tabular form preferred) of all papers and publications that are identified by the search. It is also recommended that each time a paper or publication is excluded, the reason for exclusion be recorded in this table. Potential reasons for exclusion are 1) not related to the question at hand, 2) not an acceptable study design as agreed upon a priori, 3) does not compare interventions of interest, 4) improper participant population, and/or 5) not peer-reviewed. Although a medical librarian is not required for conducting literature searches, disclosing that a medical librarian's help was sought for the current literature search is recommended. The methods and results of the literature search will be retained by the librarian (if present) and the GLC. Additionally, this record may be included as an unpublished appendix that can be accessed electronically at the discretion of the writing group and/or publisher.
2. **PICO (population, intervention, control, outcomes).** Whenever possible, generate PICO-style question(s) prior to conducting each literature search. These questions should be discussed among the group of writers. Update or modify the PICO question(s) as necessary.
3. **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. Reviewing the references contained within review articles or other publications is recommended only to determine if the literature search performed was complete. Using review articles and other publications as a source for articles may bias the writing group in including articles that have been cited before and not articles that would have been discovered by conducting a thorough literature search.  

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 the PICO-style question(s), the panel will separate and disclose the citations for those articles in the manuscript. Articles may be added 1) if they are published after the completion of the literature search, 2) upon panel agreement that a comprehensive and systematic literature search per the criteria in this handbook was conducted and the relevant article was not located, or 3) if the timeframe is extended. 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).
4. **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 group uses the same search terms. It is recommended that the writing group agree on the MeSH and search terms to be used before the literature search is undertaken. A record of all MeSH terms used should be kept and should be made available to anyone who wishes to review the search algorithm. In the event that additional MeSH terms are identified during the review process, this will be discussed among the writing group and approved by the writing group leader.

5. **Time Period.** The time period from which articles will be collected is not be limited by this Handbook. It is recommended that the writing group set a time period and agree on it prior to initiating the literature search. This may be updated or modified as long as all members agree to it. If a review/guideline has previously been published by the Guideline Committee, the literature review should generally date from the time the last search was current. The dates incorporated by the search will be documented in the manuscript.
6. **Language and Other Exclusion Criteria.** Only English language articles will be included in any documents published by the GLC. Articles without abstracts may also be excluded from the search via database filters.
7. **Types of Publications.** Only full length articles should be included in any publications produced by the GLC. Scientific abstracts should not be included among the literature used for development of recommendations.
8. **Primary Review.** Once a list of articles is generated, it is recommended that at least two members of the writing group independently review the title and/or abstract of each paper to identify when predetermined eligibility criteria are not met. This may include the study 1) not being related to the question at hand, 2) not comparing interventions of interest, 3) including an improper participant population, 4) not describing an acceptable study design as agreed upon a priori, and/or 5) not being peer-reviewed. If disagreement occurs between two members on whether an article should be included, a third member or the chair of the panel will be asked to adjudicate.
9. **Secondary/Full Review.** The resulting list of articles that have been deemed suitable for inclusion after the primary review will be reviewed in full by at least two members, who could be the same two members who conducted the primary review. This secondary review will determine which articles/papers 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 should review the article in question.
10. **Submission to National Guidelines Clearinghouse.** If SHEA determines that it will submit the manuscript to National Guidelines Clearinghouse, in accordance with NGC's requirements, authors will create an evidence table for articles included in the final manuscript (**Appendix 7**). This table does not need to be published with the manuscript.

## Expert Consensus

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

## Review and Approval Process of Internal Guidelines and EGs

### Internal and External Review

The Guidelines Chair will ask for at least two primary reviewers from the committee who will provide review and written comments using a standardized review form. Generally, reviews should be completed within a 2-4 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.

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 guideline draft with the response to each of the comments made indicating where and why reviewer recommendations were included, and why others were not (if applicable). Staff will then send the guideline and responses to the comments back to the GLC for review.

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

### Stakeholder Review

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

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

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

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

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

Comments from stakeholder organizations (if applicable) are forwarded to the writing panel chair, who will review and incorporate them into draft as deemed appropriate. The action taken for each comment/recommendation and the rationale will be documented on the review form. Not all recommendations must be accepted, but the rationale should be documented.

## Periodic Review of Guidelines and EGs

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

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

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

As with internal and external document reviews, the GLC Chair will ask for at least two primary reviewers from the committee who will provide review and 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 on areas within the context of the current guideline that may have been previously excluded for various reasons, or that have recently arisen.

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

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

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

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

## Appendix 1: Manuscript Definitions (2013)

*This Handbook addresses Guidelines and EGs. Additional manuscript types are beyond the scope of this Handbook.*

Type of Manuscript	Definition	Overseen by	Reviewed by	Examples
Brief	Clarification/update to existing guideline, white paper, position paper	Relevant committee (GLC, Education, etc.)	Relevant committee, Board	SHEA Response to Institutions' Implementation of 2010 Guideline for Healthcare Workers Infected with Bloodborne Pathogens, October 2014  <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>
<b>Compendium</b>	Synthesis of evidence for the prevention of key HAIs with intervention, special precautions, and implementation strategies	GLC	Compendium Format: TBD  2008, 2014 Compendium of Strategies: External participants (endorsing and sponsoring orgs), Advisory and Expert panel, 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="http://www.shea-online.org/PriorityTopics/CompendiumofStrategiestoPreventHAIs.aspx">http://www.shea-online.org/PriorityTopics/CompendiumofStrategiestoPreventHAIs.aspx</a>
<b>Expert Guidance (EG)</b>	guidance based on consensus of experts (internal or external)	GLC	External participants, GLC, Board	Murthy R, Bearman G, Brown S, Bryant K, Chinn R, Hewlett A, et al. Animals in healthcare facilities: recommendations to minimize potential risks. Infect Control Hosp Epidemiol. 2015;36(5):495-516.

<b>Guideline</b>	evidence-based guidance (internal or external) conducted via GRADE or similar methodology	GLC or Partnering Organization	External participants, GLC, Board	Lucas GM, Ross MJ, Stock PG, Shlipak MG, Wyatt CM, Gupta SK, et al. Clinical practice guideline for the management of chronic kidney disease in patients infected with HIV: 2014 update by the HIV Medicine Association of the Infectious Diseases Society of America. Clin Infect Dis. 2014;59(9):e96-138.
KSAs	Knowledge, skills, and abilities charts and/or articles	Education Committee	Education, Publications, Board	Cosgrove SE, Hermsen ED, Rybak MJ, File TM, Parker SK, Barlam TF, et al. Guidance for the knowledge and skills required for antimicrobial stewardship leaders. Infect Control Hosp Epidemiol. 2014;35(12):1444-51.
Position Paper	society or collaborative statement regarding regulatory and public policy actions	PPGA	External participants, PPGA Committee, Board	<a href="http://www.shea-online.org/Policy/PositionsStatements.aspx">http://www.shea-online.org/Policy/PositionsStatements.aspx</a>
White Paper	society or collaborative statement regarding institutional or administrative policy, or statements about the state of the field	Relevant committee (Guidelines, Education, etc.)	External participants, overseeing committee, Publications Committee (as needed), GLC, Board	Perencevich EN, Stone PW, Wright SB, Carmeli Y, Fisman DN, Cosgrove SE, et al. Raising standards while watching the bottom line: making a business case for infection control. Infect Control Hosp Epidemiol. 2007;28(10):1121-33.
Commentary	Expert opinion/editorial related to guideline, white paper, or position paper	Relevant committee (Guidelines, Education, etc.)	External participants, overseeing committee, GLC, 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.

## Appendix 2: Manuscript Proposal Form

<b>Draft title:</b>	
<b>Submitted by:</b>	
<b>Lead authors:</b>	
<b>Contributing SHEA authors:</b>	
<b>Contributing representatives from partnering organizations:</b>	
<b>Possible external consultants:</b>	
<b>Type of document:</b> (e.g. EG, compendium format, guideline)	
<b>Intention to submit to ICHE:</b>	
<b>Intention to publish in other journals:</b>	
<b>Target provider audience:</b>	
<b>Target patient population:</b>	
<b>Issue in question:</b>	
<b>Prevalence/incidence</b> (is issue in question large enough to warrant development of document?)	
<b>Existing guidelines on topic?</b>	
<b>Considerations in internal consistency</b> (e.g. current SHEA and/or partnering organizations' recommendations, including IDSA, APIC, PIDS, AORN, and others; SHEA or external <b>guidelines/guidance</b> being updated or in development)	
<b>Is there perceived or documented variation in practice management of practice/intervention?</b>	
<b>Current level of evidence available?</b>	
<b>Objectives:</b>	
<b>If this document were developed, would it make a significant impact on clinical decision-making/clinical outcomes/reduction in practice variation?</b>	
<b>Estimated page count including tables</b> (Arial, 11 pt, double spaced):	
<b>Estimated month of submission:</b>	

<b>Reviewers in addition to SHEA:</b>	
<b>Intended endorser invitations:</b>	
<b>Derivative Products (e.g. patient, pocket guides, Medscape slides):</b>	

## Appendix 3: Topic Review and Approval for 15-Month Development; 18-24 Month Publication

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



## Appendix 4: SHEA Guidelines and EG Review and Comment Period

Applies to:	Action	Participants
EGs, compendium format, guidelines	Draft finalized by writing group	Writing panel
Guidelines only	Draft posted for comment to hidden page on SHEA website that includes online review form  Draft posted to SHEA News	<ul style="list-style-type: none"> <li>External Reviewing Organizations (beyond representatives on writing panel)</li> <li>SHEA members via SHEA News</li> </ul>
EG, compendium format, guideline	Invitation to review emailed to coauthoring organizations	<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>
EG, compendium format, guideline	Decision regarding endorsement due by external organizations, SHEA committees	External organizations
EG, compendium format, guideline	Comments provided to authors for response and incorporation into document	Writing panel
EG, compendium format, guideline	Finalized document and responses to comments sent to SHEA and co-authoring organizations for consideration for final approval (the full writing panel should approve of the final version)	<ul style="list-style-type: none"> <li>Writing panel</li> <li>Staff</li> <li>GLC</li> <li>SHEA Board</li> <li>SHEA Publications Committee (feedback only; formal approval not requested)</li> <li>Coauthoring organizations</li> </ul>
Compendium format, guidelines	If applicable, document submitted for CDC clearance at the same time as final approval by authoring organizations	CDC
EG, compendium format, guideline	Document submitted for publication with endorsing organizations acknowledged	Staff, ICHE

1. The decision to endorse a guideline is the decision of the organization.
2. Draft for public comment includes "DRAFT" watermark, header that draft is not for distribution, page numbers, line numbers, staff contact.
3. External organizations who submit comments will be notified that if the organization has concerns or considerations that affect the potential for endorsement, these should be expressed before the end of the comment period.
4. Standard online comment form:

- a. Official name (if organization)
- b. Reviewer's contact name or organization's contact
- c. Individual's institution, if applicable
- d. Contact's email
- e. Open field for submission of: page number, line number, comment, proposed resolution
- f. Option for organization to submit endorsement

## Appendix 5: Literature Review Checklist

This form is included as a suggestion for how reviewers may evaluate or adjudicate articles in question after the primary or secondary review. Completion of this form is not a requirement for the literature review process.

Study identification <i>(Include author, title, year of publication, journal title, pages)</i>		
Document topic:	Key Question No:	Reviewer:
Study design:		
<p><b>Before</b> completing this checklist, consider:</p> <p>1. Is the paper relevant to key question? Analyze using PICO (Patient or Population, Intervention, Comparison, Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.</p>		
Reason for rejection: Reason for rejection: 1. Paper not relevant to key question <input type="checkbox"/>		
2. Other reason <input type="checkbox"/> (please specify):		
<b>SECTION 1: OVERALL ASSESSMENT OF THE STUDY</b>		
1	The study addresses an appropriate, focused question.	Yes <input type="checkbox"/> No <input type="checkbox"/> Can't say <input type="checkbox"/>
2	Relevant data is presented in a in a standard, valid and interpretable way.	Yes <input type="checkbox"/> No <input type="checkbox"/> Can't say <input type="checkbox"/>
3	Attempts are made to reduce bias and there is no apparent external influence on the results	Yes <input type="checkbox"/> No <input type="checkbox"/> Can't say <input type="checkbox"/>

4	Overall assessment of the study.	High quality (++) <input type="checkbox"/> Acceptable (+) <input type="checkbox"/> Unacceptable <input type="checkbox"/>
6	Brief conclusion(s)	
<b>SECTION 2: LIMITATIONS/COMMENTS</b>		
7	Are there significant limitations to the study?	Yes <input type="checkbox"/> No <input type="checkbox"/> Can't say <input type="checkbox"/>
8	Important limitations to the study	

## Appendix 6: Conflict of Interest and Management Plan Forms

### Introduction

SHEA Board and Committee volunteers provide invaluable service and expertise to the business and content of the society. Each year, all Board and Committee members and staff disclose all financial relationships that may pose a conflict of interest to the work and activities of SHEA, and the Conflict of Interest Review Committee reviews such disclosures to determine whether actual conflicts exist and identify opportunities for management that will mitigate any real or perceived “undue influence” caused by such financial relationships. 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.

### Name and Office/Role

**Section 1: For any disclosed relationships relevant to SHEA role/work, please complete the following:**

#### Disclosure

Please write one to two sentences outlining the financial relationships you have related to your role/work with SHEA.

For example:

- *I have received honoraria for serving on an advisory board to Sanofi Pasteur and I have been a clinical investigator on vaccine clinical trials for GlaxoSmithKline. Both of these companies manufacture influenza vaccine.*

#### Rationale for Disclosure

Please write one to two sentences outlining the nature of how these financial disclosures relate to and might influence the topic area of your section.

For example:

*I disclose these relationships as potential conflicts of interest as I serve as a member of the writing group drafting a paper addressing the prevention of viral respiratory tract infections in hospital and recommendations regarding influenza vaccination will likely be a part of this document.*

### **Management Strategy**

Please outline your proposed management strategy to minimize the influence of the financial relationships you have related to your role/work with SHEA.

For example:

*(To manage this potential conflict, I propose ....*

Each of the following might be potential solutions but this is not a comprehensive list. Please add details to your particular situation)

- I will recuse myself from voting on/acting on XXX issue and disclose the reason for recusal to the Board or relevant committee.
- I will not write a guideline/policy statement related to XXX and I will not vote on recommendations related to XXX.
- I will write the section related to XXX but the recommendations in this section will reflect the recommendations of the XXX.
- A panel of experts with no relevant conflicts of interest will review the sections I write to confirm that the recommendations therein are consistent with national recommendations and evidence-based practice.
- Other [Please describe below]:

### **Section 2: If your disclosed financial relationships are not relevant at all to SHEA role/work, please complete the following attestation:**

- None of the financial relationships disclosed require management as they are unrelated to SHEA activities.

### **Signature and Date**

For official use only:

- This plan has been reviewed and accepted by <NAME>, <ROLE/TITLE for SHEA as a reasonable method to ensure that financial relationships disclosed herein do not pose a conflict of interest related to SHEA activities.

## Appendix 7: Evidence Table for National Guidelines Clearing House

If submission to National Guidelines Clearinghouse will occur, the following format may be used to document studies that were included in the final version of the manuscript. This table does not need to be published with the manuscript.

Author, Year, Country	Participants, Behaviors, Setting	Criteria	Results	Comments	Quality Rating (see Grading of Quality of Evidence)

### Grading of the Quality of Evidence

I = High	Highly confident that the true effect lies close to that of the estimated size and direction of the effect. Evidence is rated as “High” quality when there no major limitations, little variation, and the summary estimate has a narrow confidence interval.
II = Moderate	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. Evidence is rated as “Moderate” quality when there are limitations but no major flaws, or the confidence interval of the summary estimate is wide.
III = Low	The true effect may be substantially different from the estimated size and direction of the effect. Evidence is rated as “Low” quality when there is important variation the confidence interval of the summary estimate is very wide, or when based on expert consensus.

*Based on Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) and the Canadian Task Force on Preventive Health Care*