**Appendix 1. GUIDELINE DEVELOPMENT PROCESS & METHODS**

The overall guideline-development process, including funding of the work, panel formation, management of competing interests, guideline peer review, and organizational approval, was guided by SAGES policies and procedures for guideline development to meet recommendations for trustworthy guidelines by the Institute of Medicine (now *The National Academy of Medicine*) and the Guidelines International Network.1-4

## 1.1 Guideline Steering Group

A Steering Group (SG) provided broad oversight of the entire guideline development process. The SG included the guideline development group (GDG) Chair (L. Michael Brunt), the Chair of the SAGES guidelines committee (Dimitrios Stefanidis), three international experts on cholecystectomy/bile duct injury (Steven Strasberg, Daniel Deziel, and Dana Telem) and a methodologist with experience in guideline development (Mohammed Ansari). The GDG chair worked with leaders of the five participating societies (Horacio Asbun [SAGES], Rebecca Minter [AHPBA], Charles Vollmer [AHPBA], Gazi Zibar [IHPBA], Oscar Imventarza [IHPBA], Nat Soper [SSAT], and Jaap Bonjer [EAES] to identify the GDG members that participated in the systematic reviews of the evidence and guideline formulation. All GDG members were chosen based on their expertise with the topic and after their disclosures of competing interests had been evaluated and cleared by the SAGES Conflict of Interest Task Force. The SG held frequent conference calls throughout the development process, organized in-person meetings when necessary including the consensus conference, drafted the guideline document, and planned guideline publication and dissemination. The SG further ensured the implementation of explicit processes and procedures for guideline development as laid out by SAGES.

## 1.2 Guideline Funding and Management of Competing Interests

The consensus conference and guideline development were supported by funds from each of the participating societies, a grant from the SAGES Education and Research Foundation, and an R-13 conference grant from the NIDDK (NIDDK1 R13 DK 120271-01). The conference meeting was also supported by unrestricted education grants from industry. Members of the GDG received travel reimbursement for attendance at one in-person meeting retreat to prepare for the consensus meeting but no other payments were made. The evidence review and guideline development methodologists received monetary compensation for their time and travel by SAGES.

All commercial relationships and potential conflicts were disclosed by the GDG members and were reviewed and managed by the SAGES *Conflict of Interest Task Force* according to SAGES policies ([www.sages.org/accme/policy-commercial-support-conflict-interest/](http://www.sages.org/accme/policy-commercial-support-conflict-interest/)).  At the time of their appointment, all SG and the GDG members had no competing interests that might impact the rigor of the guideline development process and judiciousness of the guideline recommendations. Appendix 2 provides the complete “Disclosure of Interests” of all panel members.

## 1.3 The Guideline Panel

The GDG consisted of the group leads and co-leads for the evidence review and the SAGES Guidelines committee chair (Table 2). Members of the GDG participated as individuals and did not officially represent the institutions or organizations with which they were affiliated. The Chair of the GDG initiated and has led the SAGES Safe Cholecystectomy Task Force. One of the panel members (MA) was a methodologist with expertise in the *Grading of Recommendations Assessment, Development and Evaluation* (GRADE) approach of rating the certainty of evidence, going from evidence to recommendations, and grading the strength of recommendations. The GRADE methodologist was a non-voting panel member. Panel members represented North and South America, Europe, and Australasia.

## 1.4 Wider Stakeholder Participation

The GDG formulated provisional recommendations which were presented and finalized in the consensus conference meeting for wider stakeholder input. At the consensus meeting, evidence for each guideline key question and the corresponding provisional recommendation were presented followed by discussion, voting on the recommendation, rewording of the recommendation when required, and re-voting on the final recommendation. A panel of 25 experts was selected based on their expertise in the field and their representation of the five participating societies. In addition, there were invited representatives from other stakeholder groups: the American Association for the Surgery of Trauma (AAST), the Endoscopic and Laparoscopic Society of Asia (ELSA), the American College of Surgeons Rural/Community Surgeons, and an at-large expert. A full list of the voting expert panel is provided in Appendix 3. The consensus meeting was open to the public and included separate audience voting and comment by participating surgeons.

## 1.5 Evidence Review Team

Six groups were assigned a lead, co-lead(s) and review team members that consisted of HPB and general surgery attending surgeons, fellows and residents (Table 2). The groups were created based on the theme of the key questions listed in Section 2. The SAGES guidelines chair along with a methodologist (Valerie Rofeberg, Brown University) provided training to the groups on evidence review methodology and guided them throughout the review process.

## 1.6 Guideline Peer Reviewers

Sixteen experts from five organizations were asked to review the final draft guideline (see Acknowledgements section). Reviewers were asked to comment on the guideline document and recommendations without changing their strength and direction. Reviewers examined the guideline draft for technical and factual errors, inaccuracies or missing data, and commented on clarity, setting-specific issues, and implications for implementation.

## 1.7 Guideline Key Questions

Previously, a Delphi consensus process was used to identify key factors in safety in cholecystectomy and prevention of biliary injury.5 Taking these factors into consideration, the SG in consultation with the GDG created 18 key questions that were considered important for this guideline using the PICO (**P**opulation, **I**ntervention, **C**omparison, **O**utcome) question model (Table 3). An iterative process was used to refine these questions under the guidance of a methodologist (MA). The GDG felt that these questions addressed all relevant clinical questions to BDI prevention. The GDG took a patient perspective to pre-specify the critical and important decision-making outcomes for each question. Should evidence be lacking for the main outcomes, the GDG pre-specified relevant proxy outcomes as indirect evidence for the main outcomes (Appendix 4). When proxy outcomes were used, certainty was downgraded for indirectness.

**1.8 Evidence Review Process**

A systematic literature search was conducted by the SAGES librarian in August 2017. Databases searched were the Cochrane library, CRD, ​PROSPERO, CenterWatch, Clinicaltrials.gov, ICTRP, LILACS, and MEDLINE/PubMed. Retrieved records were imported into a web-based program ([www.covidence.com](http://www.covidence.com), Melbourne, Australia) and were screened by two reviewers independently at two levels – title and abstract screen, and a full text screen. Group leads resolved any disagreements. Prior to screening, reviewers underwent a calibration session using the same 100 abstracts imported into Abstrackr (<http://abstrackr.cebm.brown.edu/account/login>). Bibliography of included records was also screened by reviewers to identify any missing studies in the literature search.

Relevant systematic reviews (SRs) and meta-analyses were reviewed first and their quality assessed using the R-AMSTAR assessment tool.6 When SRs were deemed to be of good quality (ie high R-AMSTAR rating), up-to-date, and directly addressing the guideline question, the relevant findings were graded to inform guideline recommendations. Alternatively, study-level data were extracted, generically assessed for risk of bias, and evidence synthesized narratively or quantitatively. Meta-analyses were performed in metaphor: Meta-Analysis Package for R7 or the *Review Manager* 5 as per *Cochrane* guidance.8, 9 Full text references extracted but not included in the evidence synthesis are listed in Appendix 5.

To judge reviewer certainty in estimate of effects, the GRADE approach was employed.10, 11 As per the GRADE approach, certainty of evidence is downgraded from high to moderate, low, or very low depending upon the limitations in the design or conduct of studies, inconsistency in findings, imprecision in estimates of effect due to lack of statistical power of the body of evidence, concerns that results may not be applicable to the population and settings of interest, or concerns that some existing outcome data might be missing from the review. Occasionally, certainty in findings may be upgraded from moderate, low, or very low to higher levels. Identification of dose-response relationship, large magnitude of effect, or biases that would have reduced a demonstrated effect or increased the effect when no effect was observed are reasons for upgrading the certainty to higher levels.

## 1.9 Formulating Recommendations

GRADE Evidence-to-Decisions (EtD) framework was used to formulate question specific recommendations using the online GRADEPro Tool.12-14 The GRADE guideline methodologist provided the methodological oversight. The EtD framework is a systematic, structured and transparent approach to decision making. The framework comprises explicit criteria for deciding between alternative management options in light of current best evidence. The criteria elicit judgments about the balance between the observed evidence of desirable and undesirable outcomes, overall certainty of evidence, relative values of patients for desirable and undesirable outcomes, concerns about the potential for inequities in health, and acceptability and feasibility of recommendations. Based on their experience with patients, the GDG represented patient voice as it valued relative importance of outcomes against each other when judging the balance of desirable and undesirable effects of interventions.

When the GDG is certain that EtD criteria judgments lead to one course of action, then recommendations are strong and worded accordingly. Conditional (ie, discretionary) recommendations are issued when the GDG thinks that while most panels or surgeons would make a similar choice, not all would. Conditional recommendations are made when the balance of benefit and harm is close, certainty of evidence is low or very low, there is substantial variability in anticipated patient values and preferences for outcomes, there are some concerns about increase in health inequities given the recommendation, or there are concerns about the acceptability or feasibility of the recommendations. Conditional recommendations can only be a general guide, and surgeons’ discretionary case-by-case choices may drive surgical decision-making. In select instances, the GDG made strong recommendations by invoking one of the five GRADE paradigmatic situations for making a strong recommendation despite low or very low certainty of evidence.15

When empiric research evidence was not found or was deemed too insufficient or methodologically questionable to generate evidence-based recommendations, the GDG made recommendations labelled as “expert opinion” in light of their collective experience-based judgments. Development of EtD tables for each key question followed the GRADE approach.

## 1.10 Group Consensus Approach

As described under 1.4, a consensus conference was organized to obtain broad consensus and vet the recommendations of the GDG. Each recommendation was voted on by the participating experts. Consensus was considered >80% agreement or >80% disagreement. To achieve consensus, participants had to agree on both the strength and direction of the recommendation. Methodologists did not contribute to, or influence the GDG’s judgments. Results of formal voting were documented. Consistently, the full voting quorum comprised 16 GDG members and 26 expert panelists. Recommendations that did not achieve consensus after initial voting were opened for discussion by the expert panel and modified as necessary. A second vote followed and the results were noted. Recommendations were then posted online (www.preventbdi.org) for public comment for two months after the conference.

## 1.11 Guideline Presentation

Owing to the readability considerations for a surgical audience, the style of this guideline follows a narrative approach to summarize the supporting evidence and justification for recommendations. The GRADE methodological approach to formulating recommendations is presented in guideline question specific grade EtDs which were adapted for presentation and are appended to this document (Appendix 6) and on line at www.preventbdi.org.

1. Schunemann HJ, Wiercioch W, Etxeandia I, et al. Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise. *CMAJ* 2014; 186(3):E123-42.

2. Committee on Standards for Developing Trustworthy Clinical Practice Guidelines BoHCS. In: Graham R MM, Wolman DM, Greenfield S, Steinberg E, ed. Clinical Practice Guidelines We Can Trust: National Academies Press; 2011.

3. Qaseem A, Forland F, Macbeth F, et al. Guidelines International Network: toward international standards for clinical practice guidelines. *Ann Intern Med* 2012; 156(7):525-31.

4. Schunemann HJ, Al-Ansary LA, Forland F, et al. Guidelines International Network: Principles for Disclosure of Interests and Management of Conflicts in Guidelines. *Ann Intern Med* 2015; 163(7):548-53.

5. Pucher PH, Brunt LM, Fanelli RD, et al. SAGES expert Delphi consensus: critical factors for safe surgical practice in laparoscopic cholecystectomy. *Surg Endosc* 2015; 29(11):3074-85.

6. Kung J, Chiappelli F, Cajulis OO, et al. From systematic reviews to clinical recommendations for evidence-based health care: Validation of revised assessment of multiple systematic reviews (R-AMSTAR) for grading of clinical relevance. *Open Dent J* 2010; 4:84-91.

7. Viechtbauer W. Conducting meta-analyses in R with the metafor package. *J Statistical Software* 2010; 36:1-48.

8. Review Manager (RevMan) [Computer program]. Version 5.3. [computer program]. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration; 2014.

9. Higgins JG. Cochrane Handbook for Systematic Reviews of Interventions [Internet]. 5.1.0. Available from: <http://handbook-5-1.cochrane.org/>: The Cochrane Collaboration; 2011.

10. Schünemann H, Brożek J, Guyatt G, et al. Handbook for grading the quality of evidence and the strength of recommendations using the GRADE approach [Internet} 2013. Avalable from <https://gdt.gradepro.org/app/handbook/handbook.html>, 2013.

11. Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol* 2011; 64(4):401-6.

12. Alonso-Coello P, Schunemann HJ, Moberg J, et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: Introduction. *BMJ* 2016; 353:i2016.

13. Alonso-Coello P, Oxman AD, Moberg J, et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 2: Clinical practice guidelines. *BMJ* 2016; 353:i2089.

14. GRADEpro Guideline Development Tool [Software] [computer program]. developed by Evidence Prime, Inc.): McMaster University 2015.

15. Neumann I, Santesso N, Akl EA, et al. A guide for health professionals to interpret and use recommendations in guidelines developed with the GRADE approach. *J Clin Epidemiol* 2016; 72:45-55.