

## **ICSI Guideline and Protocol Program**

ICSI began developing guidelines in 1993 and has developed over 60 guidelines and protocols.

**A health care guideline** is an evidence-based statement of best practice in the prevention, diagnosis, or management of a given symptom, disease, or condition for individual patients under normal circumstances.

**A health care protocol** is a step-by-step statement of a procedure routinely used in the care of individual patients to assure that the intended effect is reliably achieved.

### **Conflict of Interest**

ICSI has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report, *Clinical Practice Guidelines We Can Trust* (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI Policy regarding Conflicts of Interest is available at

[https://www.icsi.org/asset/fwsfmi/coi\\_policyletter.pdf](https://www.icsi.org/asset/fwsfmi/coi_policyletter.pdf)

### **Funding Source**

The Institute for Clinical Systems Improvement provides the funding for guideline work. ICSI is a not for profit, quality improvement organization based in Bloomington, Minnesota. The annual dues of the member medical groups and health plans fund ICSI's work. Individuals on the work group are not paid by ICSI, but are supported by their medical group for this work.

ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups and health plans review and provide feedback, but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

## **Document Topic Selection**

The following are considered when selecting document topics:

- Frequency of the topic in health care provided by our members
- Probability of achieving change, including the likelihood of reaching agreement on the recommendations and the likelihood of implementing the provisions of the document
- Anticipated improvements, including improvements in outcomes and in waste reduction
- Health care environment, regulatory requirements, and other initiatives

Topic ideas are solicited from all member groups and guideline work groups.

## **Document Development**

A work group consisting of 8-12 members that includes physicians, nurses, pharmacists, other health care professionals relevant to the topic, and an ICSI staff facilitator, develops each document. One or two of the work group members serve as leaders. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, one or two work group members may be recruited from medical groups, hospitals or other organizations that are not members of ICSI. Patients are occasionally invited to serve on work groups.

## **Development or Revision of a Guideline/Protocol**

The work group will meet for at least six three-hour meetings to develop or revise a document. Under the coordination of the ICSI staff facilitator, the work group develops the algorithm and writes the annotations, citing literature where appropriate.

## **Literature Search**

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. The literature search includes systematic review/meta-analysis and where appropriate, randomized controlled trials and observational studies.

In addition, other professional guidelines on the topic are reviewed.

## **Evidence Review for Guidelines**

Evidence is reviewed using GRADE methodology. Evidence is reviewed for quality utilizing explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings. Recommendations are then made providing a clear, pragmatic interpretation of strong versus weak recommendations. Explicit acknowledgement of values and preferences and evaluation of the importance of outcomes of alternative management strategies are revealed during evidence review.

## **Public Comment**

The purpose of public comment is to provide an opportunity for clinicians in the member groups and the community to review the draft guideline and provide feedback, prior to finalization of the guideline.

After the public comment period, the guideline work group reconvenes to review the comments and make changes as appropriate.

## **Document Approval**

The Committee for Evidence-Based Practice (CEBP) approves each document. The committee will review and approve each document, based on the following criteria:

- The aim(s) of the document is clearly and specifically described.
- The need for and importance of the document is clearly stated.
- The work group included individuals from all relevant professional groups and had the needed expertise.
- Patient views and preferences were sought and included when possible. The work group has responded to all feedback and criticisms reasonably.
- Potential conflicts of interest were disclosed and do not detract from the quality of the document.
- Systematic methods were used to search for the evidence to assure completeness and currency.
- Health benefits, side effects, risks and patient preferences have been considered in formulating recommendations.
- The link between the recommendations and supporting evidence is clear.
- Where the evidence has not been well established, recommendations based on community practice or expert opinion are clearly identified.
- Recommendations are specific and unambiguous.
- Different options for clinical management are clearly presented.
- Clinical highlights and recommendations are easily identifiable.
- Implementation recommendations identify key strategies for *health care systems* to support implementation of the document.

- The document is supported with practical and useful tools to ease *clinician* implementation.
- Suggested measures are clear and useful for quality/process improvement efforts.

Once the document has been approved, it is posted on the ICSI website and released to members for use.

### **Document Revision Cycle**

Scientific documents are revised every two to five years as indicated by changes in clinical practice and literature. ICSI checks with the work group as needed to determine if there have been changes in the literature significant enough to cause the document to be revised earlier or later than scheduled.

### **More Information**

If you have questions about our programs, please contact Jodie Dvorkin, MD, Associate Medical Director, at [dvorkin@icsi.org](mailto:dvorkin@icsi.org) or Lisa Carlson, Team Director, at [lcarlson@icsi.org](mailto:lcarlson@icsi.org).