Part 2: Evidence Evaluation and Management of Potential or Perceived Conflicts of Interest: 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care


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Part 2: Evidence Evaluation and Management of Potential or Perceived Conflicts of Interest

2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care

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Evidence-based medicine integrates the best available evidence and clinical expertise to deliver the finest possible patient care.1 The victim of cardiac arrest requires immediate action, and potential rescuers must be ready to respond. Evidence must be compiled, analyzed, and discussed; clear recommendations must be established prior to the patient encounter. The 2010 American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC) (2010 AHA Guidelines for CPR and ECC) are based on a transparent, expert review of scientific evidence, informed by the clinical expertise of the writing teams. These guidelines are designed to provide rescuers and clinicians with a strategy for action that can save lives from cardiac arrest. Clinicians should always apply these evidence-based guidelines in combination with clinical judgment.

The International Liaison Committee on Resuscitation (ILCOR), an international consortium of many of the world’s resuscitation councils, was formed in 1992, in part to collect, discuss, and debate scientific data on resuscitation. The majority of ILCOR’s work focuses on reviewing published, peer-reviewed evidence on resuscitation to produce science-based consensus summaries.2 As one of ILCOR’s member councils, the AHA transforms international scientific consensus statements into periodic revisions of the AHA Guidelines for CPR and ECC.

During production of the 1992 AHA Guidelines for CPR and ECC, an evidence evaluation process was developed to guide topic experts in conducting a thorough evidence review, distilling the evidence, and producing treatment recommendations. This evidence evaluation process was revised in 2000, when an international set of CPR and ECC guidelines was developed. The evidence evaluation process was refined for the creation of the 2005 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations (ILCOR 2005 CPR Consensus).3 For the 2010 AHA Guidelines for CPR and ECC, the process was further refined, and a comprehensive description of the 2010 process has been published.4 The purpose of this chapter is to briefly describe this evidence evaluation process and its translation to the 2010 AHA Guidelines for CPR and ECC.

Evidence Evaluation Process

To begin the 2010 review process, ILCOR representatives established six task forces: basic life support; advanced life support; acute coronary syndromes; pediatric life support; neonatal life support; and a task force for education, implementation, and teams. The AHA established two additional task forces that were not part of the ILCOR process, one for stroke and one for first aid. Two co-chairs were recruited for each task force to oversee the processes of evidence evaluation and consensus development. For most task forces, one co-chair was recruited from the AHA and the other from the international resuscitation councils. Within the advanced life support (ALS) task force, five domain subgroups were created: electrical therapy, CPR and airway devices, drugs, special situations, and post–cardiac arrest care. The ALS co-chairs designated leaders for these domains to direct completion of the evidence reviews. Three worksheet experts (Atkins, Callaway, and Jacobs) and one evidence evaluation expert (Morley) were recruited to oversee the evidence evaluation worksheets, review the search strategies, ensure correct assignment of levels of evidence (LOE), and verify completeness. The lead evidence evaluation expert, trained in the Cochrane methodology and experienced in the CPR and ECC evidence evaluation process, and the three similarly trained worksheet experts shepherded individual evidence evaluation worksheet authors through the established ILCOR process.

The process included the appointment of two co-chairs (Billi and Shuster) to review conflict of interest (COI)
Prognosis In adult cardiac arrest (prehospital or in-hospital) (P), authors were invited to complete independent reviews of each assigned worksheet. If a COI was identified, the topic was not have any significant COI issues pertaining to their conflicts of interest were disclosed and evaluated by the task sheet author were reviewed by the task force, and potential authors. Specialty organizations were also solicited to suggest around the world to serve as evidence evaluation worksheet selected based on controversy, new information, and previous list of questions for evidence evaluation. Questions were published, the task forces generated a comprehensive 2010 AHA Guidelines for CPR and ECC Shortly after the 2005 process. The template was designed to facilitate the structured evidence reviews for the production of the final consensus on science and treatment recommendation documents. Successful completion of the evidence evaluation worksheet was required to ensure consistent application of the process by many different worksheet authors from around the world.

Use of PICO Format
Shortly after the 2005 AHA Guidelines for CPR and ECC were published, the task forces generated a comprehensive list of questions for evidence evaluation. Questions were selected based on controversy, new information, and previously identified knowledge gaps. The clinical questions posed during the 2005 guidelines process and the knowledge gaps identified during the 2005 Consensus on Science process provided the initial basis for this list, which was supplemented during in-person meetings and conference calls among the task forces. Questions were then refined to fit the Population Intervention Comparator Outcome (PICO) format (see Table 1 for examples). The task forces selected and invited topic experts from around the world to serve as evidence evaluation worksheet authors. Specialty organizations were also solicited to suggest potential worksheet authors. The qualifications of each worksheet author were reviewed by the task force, and potential conflicts of interest were disclosed and evaluated by the task force co-chairs and COI co-chairs. Worksheet authors could not have any significant COI issues pertaining to their assigned worksheet. If a COI was identified, the topic was assigned to a different worksheet author. Generally two authors were invited to complete independent reviews of each PICO question. A total of 356 worksheet authors from 29 countries completed 411 evidence reviews on 277 topics. After generating formal search strategies directly from the PICO questions, the worksheet authors searched, at a minimum, four databases: the Cochrane Library (The Cochrane Collaboration, Oxford, England), PubMed (National Library of Medicine, Washington, DC), Embase (Elsevier B.V., Amsterdam, Netherlands), and an internal database of articles constructed from previous ILCOR and ILCOR council CPR guidelines development cycles. Worksheet authors were asked to review the references cited in key articles to identify other relevant articles, and authors were encouraged to review any articles that cited the key studies found. Worksheet authors then submitted their search strategies, criteria for inclusion and exclusion of articles, and initial search results for review by the task force co-chairs, worksheet experts, and an evidence evaluation expert before initiating their literature review. If necessary, the search strategy was modified and repeated based on feedback from the reviewers. The complete search strategy was documented in the evidence evaluation worksheet; this process provided transparency and enabled the worksheet authors to use the same strategy to update the literature search just prior to the 2010 Consensus Conference. Articles could be included in the evidence review only if the full manuscript was published or accepted for publication in a peer-reviewed journal. Abstracts and unpublished data were excluded.

Classification of Evidence
After a search strategy was approved, worksheet authors identified and reviewed each relevant study. Each relevant study was assigned both a numeric level of evidence (LOE) and a quality of evidence. The numeric LOE classification system was updated from the system used for the 2005 process based on a review of available classification schemes (see Table 2). The levels of evidence were reduced from seven categories in 2005 to five in 2010 (see Table 3). The LOEs were subdivided into three major categories, depending on the type of question being asked: intervention, diagnosis, or prognosis. The quality of evidence categories were reduced from five categories in 2005 to three (good, fair, poor) in 2010.

Several characteristics within each LOE were defined to guide the worksheet authors. Examples included methods of randomization, blinding, similarity of groups, and equal treatment of all groups. Complete instructions for both LOE and quality of evidence were provided to the worksheet authors. Worksheet authors also created a short summary of each article including the LOE, quality of evidence, direction of outcome effect for the question asked (supporting, neutral, or opposing), and outcome measured. Worksheet authors also noted industry support for the study and wrote a one- or two-sentence synopsis.

Worksheet Author Summary
The worksheet authors summarized the evidence in a form similar to that typically used in published systematic reviews, using the evidence evaluation worksheet “grid” to position relevant studies in three dimensions: LOE, Quality, and

Table 1. Population, Intervention, Control, Outcome (PICO) Question Examples

<table>
<thead>
<tr>
<th>Type of Question</th>
<th>Example Question in PICO Format</th>
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</thead>
<tbody>
<tr>
<td>Outcome</td>
<td>In adult patients in cardiac arrest (asystole, pulseless electrical activity, pulseless VT and VF) (P), does the use of vasopressors (epinephrine, norepinephrine, others) or combination of vasopressors (I) compared with not using drugs (or a standard drug regimen) (C), improve outcomes (e.g. ROSC, survival) (O)?</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>In adult and pediatric patients with presumed cardiac arrest (prehospital or in-hospital) (P), are there any factors (eg, on clinical exam) (I), as opposed to standard care (C), that increase the likelihood of diagnosing cardiac arrest (as opposed to nonarrest conditions, eg, post-seizure, hypoglycemia, intoxication) (O)?</td>
</tr>
<tr>
<td>Prognosis</td>
<td>In adult cardiac arrest (prehospital or in-hospital) (P), does the use of end-tidal CO₂ (eg, absolute CO₂ values or changes in waveform) (I), compared with not using end-tidal CO₂ (C), accurately predict outcomes (e.g. ROSC, survival) (O)?</td>
</tr>
</tbody>
</table>
Direction of Effect. In the later section of the worksheet template, authors summarized the evidence, noting merits and shortcomings of the published literature. Finally the worksheet authors proposed draft Consensus on Science statements and draft Treatment Recommendations.

Evidence Evaluation Expert and Task Force Reviews

Several iterative reviews were completed for each worksheet. As noted above, the search strategies were first reviewed by the task force co-chairs and worksheet experts to confirm accuracy and completeness. Once the search strategy was approved, the worksheet authors independently performed the evidence evaluation. The evidence evaluation was again reviewed by the task force co-chairs and the worksheet experts, and the authors were asked to offer revisions when necessary. The evidence evaluation expert approved each final worksheet. For evidence reviews completed earlier than August 2009, the literature search was repeated just prior to the February 2010 ILCOR International Consensus on CPR and ECC Science With Treatment Recommendations Conference so that any new publications could be identified and then incorporated into the final worksheet.

From 2007 to 2010, the worksheet authors summarized their evidence evaluation for the task force using a standardized presentation format, either during one of six international face-to-face meetings or during Web conferences using Microsoft Live Meeting collaboration software. Task force co-chairs occasionally asked worksheet authors who reviewed the same question to work together after their initial review, either to reconcile different interpretations of the scientific evidence or to consider studies identified by only one author. During those meetings and Web conferences, the task forces debated and discussed the evidence presented by the worksheet authors and developed final Task Force Consensus on Science and Treatment Recommendations statements. Starting in May 2009, worksheets approved by the task forces were posted on the Internet for external review and comments from the broader resuscitation community. Authors of comments disclosed conflicts of interest, if any, and the task forces and worksheet authors carefully considered those comments.

2010 International Consensus on Science Conference

Reviews culminated in the 2010 Consensus Conference held in Dallas, TX, in February 2010. A total of 313 international experts from 30 countries attended the conference to discuss and debate the evidence evaluation reviews presented by invited worksheet authors and experts. The program provided ample time for open discussion of each topic with the audience. Prior to the meeting, each participant completed an AHA Conflict of Interest (COI) Form. Whoever anyone spoke, whether that person was speaking as a scheduled presenter, panelist, or moderator or was asking questions or making comments from the floor, the speaker’s COI disclosure was projected on a screen separate from the screen used to display presentation slides.

Immediately following the conference, ILCOR Consensus on Science writing groups compiled, discussed, reviewed, and edited the draft Consensus on Science and Treatment Recommendations statements of the task forces to create the 2010 ILCOR International Consensus on CPR and ECC Science With Treatment Recommendations, published simultaneously in Circulation® and Resuscitation.® If the writing groups

Table 2. ILCOR Levels of Evidence

<table>
<thead>
<tr>
<th>Studies of Interventions</th>
<th>Studies of Prognostic Tests</th>
<th>Studies of Diagnostic Tests</th>
<th>Level of AHA Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOE 1: Randomized controlled trials (RCTs) or meta-analyses of RCTs</td>
<td>LOE P1: Inception (prospective) cohort studies (or meta-analyses of inception cohort studies), or validation of Clinical Decision Rule (CDR)</td>
<td>LOE D1: Validating cohort studies (or meta-analyses of validating cohort studies), or validation of Clinical Decision Rule (CDR)</td>
<td>Level A</td>
</tr>
<tr>
<td>LOE 2: Studies using concurrent controls without true randomization (e.g., “pseudo”-randomized)</td>
<td>LOE P2: Follow-up of untreated control groups in RCTs (or meta-analyses of follow-up studies), or derivation of CDR, or validated on split-sample only</td>
<td>LOE D2: Exploratory cohort study (or meta-analyses of follow-up studies), or derivation of CDR, or a CDR validated on a split-sample only</td>
<td>Level B</td>
</tr>
<tr>
<td>LOE 3: Studies using retrospective controls (eg, case series)</td>
<td>LOE P3: Retrospective cohort studies</td>
<td>LOE D3: Diagnostic case control study</td>
<td>Level B</td>
</tr>
<tr>
<td>LOE 4: Studies without a control group (eg, case series)</td>
<td>LOE P4: Case series</td>
<td>LOE D4: Study of diagnostic yield (no reference standard)</td>
<td>Level C</td>
</tr>
<tr>
<td>LOE 5: Studies not directly related to the specific patient/population (eg, different patient/population, animal models, mechanical models etc.)</td>
<td>LOE P5: Studies not directly related to the specific patient/population (eg, different patient/population, animal models, mechanical models etc.)</td>
<td>LOE D5: Studies not directly related to the specific patient/population (eg, different patient/population, animal models, mechanical models etc.)</td>
<td>Level C</td>
</tr>
<tr>
<td>Expert Opinion</td>
<td>Expert Opinion</td>
<td>Expert Opinion</td>
<td>Level C</td>
</tr>
</tbody>
</table>

Table 3. Comparison of ILCOR Levels of Evidence for 2005 and 2010

<table>
<thead>
<tr>
<th>Type of Evidence</th>
<th>2005 Level</th>
<th>2010 Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized clinical trials</td>
<td>1 or 2</td>
<td>1</td>
</tr>
<tr>
<td>Meta-analyses</td>
<td>1</td>
<td>1 or 2</td>
</tr>
<tr>
<td>Concurrent controls</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Retrospective controls</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Case series without controls</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Animal/mechanical/model</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Extrapolations from data collected for other purposes; theoretical analyses</td>
<td>7</td>
<td>5</td>
</tr>
</tbody>
</table>
agreed on common treatment recommendations, those recommendations were included with the Consensus on Science statements.

**Development of the AHA Guidelines**

**AHA Writing Groups**

In 2009 the chairs and writing group members for each chapter of the 2010 AHA Guidelines for CPR and ECC were nominated and required to complete an AHA conflict of interest disclosure that was reviewed by AHA staff and the AHA officers. Writing group chairs and most of the writing group members were required to be free of relevant conflicts of interest.

After the 2010 Consensus Conference, seventeen AHA writing groups developed the 2010 AHA Guidelines for CPR and ECC based on the ILCOR Consensus on Science statements, citations, and treatment recommendations. In essence, the 2010 ILCOR International Consensus on CPR and ECC - Science With Treatment Recommendations summarizes what is known in each subject area. The ILCOR Treatment Recommendations present the evidence-supported treatment approach for each problem. The 2010 AHA Guidelines for CPR and ECC expand on the details of how and when to provide treatment, and they address the training requirements for treatment providers. Other resuscitation councils around the world performed a similar process to develop their versions of the 2010 guidelines.

In developing these guidelines, the writing groups used a recommendation system consistent with that used by the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) collaboration on evidence-based guidelines (see Table 4). These classes represent the inter-
AHA Classes of Recommendations and Levels of Evidence

Generally for Class I recommendations, high-level prospective studies support the action or therapy, and the benefit substantially outweighs the potential for harm. An exception is possible for actions or therapies with extraordinarily large treatment effects for which expert consensus alone may suffice. Under ideal conditions all CPR and ECC recommendations should be based on large, prospective, randomized, controlled clinical trials that find substantial treatment effects on long-term survival and carry a Class I label. In reality, more questions exist than there are studies attempting to answer them; and when studies have been done, they are not typically large, randomized trials on human subjects. As a result, the writing groups were often confronted with the need to make recommendations based on results from human trials that reported only intermediate outcomes, nonrandomized or retrospective observational studies, animal models, or extrapolations from studies of human subjects who were not in cardiac arrest.

For Class IIa recommendations, the weight of available evidence supports the action or therapy, and the therapy is considered reasonable and generally useful. Recommendations were generally labeled Class IIb when the evidence documented only short-term benefits from the therapy or weakly positive or mixed results. Class IIb recommendations are identified by terms such as “can be considered” or “may be useful” or “usefulness/effectiveness is unknown or unclear or not well established.”

Class III recommendations were reserved for interventions for which the available evidence suggests more harm than good, and experts agreed that the intervention should be avoided.

“Class Indeterminate” recommendations, which were used in 2005, are not included in the 2010 AHA Guidelines for CPR and ECC. The elimination of the term “Class Indeterminate” is consistent with the ACCF–AHA Classes of Recommendation. When the AHA writing groups felt that the evidence was insufficient to offer a recommendation either for or against the use of a drug or intervention, no recommendation was given.

The Levels of Evidence used by the ACCF/AHA Task Force on Practice Guidelines employs an alphabetic system (LOE A, B, or C) to describe the body of evidence supporting a given recommendation, in comparison to the numeric system used for the ILCOR evidence evaluation. Generally a level-A body of evidence means there are 2 or more ILCOR LOE 1 studies in support of the recommendation: multiple populations have been evaluated, or data are derived from multiple randomized clinical trials or meta-analyses. A level-B body of evidence indicates that most studies supporting the recommendation are ILCOR LOE 2 or 3 studies: limited populations have been evaluated, or data are derived from a single randomized trial or nonrandomized trial. A level-C body of evidence means that very limited populations have been evaluated or that only the consensus opinions of experts, case studies, or standards of care support the recommendation.

Management of Potential Conflicts of Interest

Rescuers rely on the AHA ECC Guidelines development process to distill the extensive and diverse scientific evidence into straightforward recommendations on how to manage critical emergencies. They trust that the 2010 AHA Guidelines for CPR and ECC will be evidence based and free of commercial bias. For creation of the 2005 AHA Guidelines for CPR and ECC, the AHA and ILCOR adopted extensive conflict of interest (COI) management principles. For 2010 those principles were revised to incorporate what was learned from the 2005 COI process and to incorporate new COI guidelines developed by the AHA.

The revised COI policy governed the entire development process for the 2010 ILCOR International Consensus on CPR and ECC Science With Treatment Recommendations and 2010 AHA Guidelines for CPR and ECC, including selection of ILCOR task force and writing group leaders and members, selection of questions for review, selection of worksheet authors, creation of worksheets, presentation and discussion of worksheets, distillation into the 2010 ILCOR International Consensus on CPR and ECC Science With Treatment Recommendations, and development of the 2010 AHA Guidelines for CPR and ECC. All participants completed the detailed AHA online COI disclosure form and updated it annually and when changes occurred. Relationships were considered inactive if they terminated over 12 months prior to the AHA activity, consistent with AHA policy. The policy requires all participants to disclose all commercial relationships, including consulting agreements; speakers’ bureau memberships; membership in advisory boards; equity or stock ownership; patents or intellectual property; grant funding from industry or foundations; roles on industry-sponsored, data–safety monitoring boards; and any other commercial relationship. Individuals with a commercial relationship were not selected to serve in roles for which they had a possible conflict.

Because of their greater potential to influence discussion and outcomes, those in leadership positions (task force or writing group leaders) were held to a higher standard, having no commercial relationships with the issues or industries under discussion and review by their group. Consistent with new AHA guidelines for manuscript authorship, the writing group chairs had no relevant industry relationships, the majority of the members of each writing group had no significant commercial relationships, and no two individuals with relationships with the same industry entity were permitted to serve on the same writing group (ILCOR COI policy can be found at http://ecccanadaheart.com/presenter.jshtml?identifier=3033464). Participants with limited relationships (eg, industry-funded research) were permitted to comment during discussions, with full concurrent disclosure of their relationships, but they were required to recuse themselves from voting and writing about issues related to that relationship for the 2010 ILCOR International Consensus on CPR and ECC Science With Treatment Recommendations and the 2010 AHA Guidelines for CPR and ECC. Participants...
with more direct commercial relationships (eg, consultant, equity ownership) were precluded from participation in decisions, votes, or writing for any topic directly relating to the company’s business (Please see 2010 ILCOR International Consensus on CPR and ECC Science With Treatment Recommendations for details of the worksheet author selection process and the management of COI during the 2010 Consensus Conference.)

The AHA is committed to the most transparent and influence-free evidence-based guidelines process possible. To help improve the process for the future, readers are encouraged to send their questions, suggestions, or comments to one of the authors who oversaw the COI effort (jbilli@umich.edu).

Writing Group Voting Procedures
Writing group members voted on every recommendation contained in these guidelines, unless they had a conflict of interest related to the topic. In the case of a conflict, the writing group member abstained from the vote and that abstention was recorded.

Integration of Science Into Practice Guidelines
The final 2010 AHA Guidelines for CPR and ECC are not intended to repeat verbatim the International Consensus on Science because that document is available online and because it contains a more extensive review of the literature than is needed for a guidelines document. Instead these 2010 AHA Guidelines for CPR and ECC are intended to reflect the interpretation of the Consensus on Science by the AHA writing groups and members of the ECC Committee and its subcommittees. Whenever possible, the AHA Guidelines for CPR and ECC are consistent with the 2010 ILCOR International Consensus on CPR and ECC Science With Treatment Recommendations statements, and they reference the supporting science publications. However, the 2010 AHA Guidelines for CPR and ECC also take into consideration local resources, training and education issues, available healthcare systems, and cost-effectiveness. That translation often must balance an acknowledgment of the limitations of systems with an effort to advocate for the care most likely to improve survival from cardiac arrest.

Summary
In summary, the evidence review process has attempted to provide a systematic review of the scientific literature using a priori defined methods. The details and steps of the literature review are transparent and replicable. External opinions and community critique are highly valued, and the final products represent the combined labor of hundreds of participants.

Disclosures

<table>
<thead>
<tr>
<th>Writing Group Member</th>
<th>Employment</th>
<th>Research Grant</th>
<th>Other Research Support</th>
<th>Speakers’ Bureau/ Honoraria</th>
<th>Ownership Interest</th>
<th>Consultant/ Advisory Board</th>
<th>Other</th>
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### References


15. ILCOR/AHA COI. Available at: http://www.americanheart.org/presenter.jhtml?identifier=3049576.

KEY WORDS: resuscitation