Part 4: Conflict of Interest Management Before, During, and After the 2010 International Consensus Conference on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations

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The International Liaison Committee on Resuscitation (ILCOR, www.ILCOR.org) established a conflict of interest (COI) policy in 2004 to manage actual or potential conflicts of interest in an open and effective manner.[1] This article describes the current ILCOR and American Heart Association (AHA) COI policies and their application throughout the 2010 evidence evaluation process. The purpose of the COI policies and procedures is to protect the integrity of the decision-making processes and ILCOR's Consensus on CPR and ECC Science and Treatment Recommendations, as well as the integrity of the *2010 AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.* ILCOR and the AHA welcome readers' questions and feedback on this process.

The validity of the ILCOR evidence evaluation process depends on rigorous and objective expert review of published science. Therefore, it is essential that any potential professional conflict of interest be fully disclosed and managed transparently and effectively during the planning and conduct of the evidence evaluation process, especially when concerns are expressed or when issues arise. Many of the world's most qualified scientific experts have professional relationships that could pose a real or perceived conflict of interest. In order to benefit from their knowledge and expertise, it is necessary to manage the way these experts are involved in discussions of topics of potential conflict, and especially to minimize their influence over consensus statements or recommendations in such areas.

ILCOR COI procedures apply to all volunteers and staff working on any aspect of the evidence evaluation process. As host of the 2010 CPR Consensus Conference (C2010), the AHA required all participants to complete an AHA COI disclosure questionnaire and to comply with all current AHA COI policies, including new writing group authorship requirements noted below. Relationships that ended more than 12 months prior to COI submission were considered no longer relevant by current AHA policy.

Summary of COI Procedures

Because the 2010 Evidence Evaluation process has taken place over the past 5 years, COI management for C2010 has been an ongoing, dynamic process; it was modeled on the COI model used successfully in the 2005 CPR Consensus Conference.[2–4] COI for the evidence evaluation process was overseen by co-chairs, who were appointed by the ILCOR Executive Committee in 2007. One of the identified co-chairs served that role for the C2005 process and provided continuity. Improvements in the COI process for C2010 (such as earlier identification of commercial relationships) were based on lessons learned from the C2005 process and were formally adopted by the ILCOR Steering Committee in March 2007 (see Table).

From 2005 onward, every participant joining the 2010 evidence evaluation process has completed and submitted an AHA COI disclosure form. Participants are required to update their disclosure form annually or whenever there is a substantive change from prior disclosure. AHA staff verified that a disclosure form was completed by each participant, C2010 attendee, and systematic review (worksheet) author, and they reviewed the disclosures.

ILCOR formed 6 task forces to review the evidence in key resuscitation areas: basic life support; advanced life support;

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*Co-chairs and equal first co-authors.

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Table. ILCOR Conflict of Interest Policy and Procedures, Including Procedures for the 2005 Consensus Conference and Evidence Evaluation Process

This policy will ensure that ILCOR manages real and potential conflicts of interest in an open and effective manner in order to preserve public trust in the integrity of ILCOR's process and products. It is not always possible or prudent to avoid such situations, because experts in a clinical area often have relationships that could pose a real or potential conflict of interest in that area. It is essential that these potential conflicts be disclosed and managed effectively. Disclosure is the mainstay of effective management of potential conflicts of interest. COI procedures apply to all ILCOR delegates, C2005 participants, observers, editors, worksheet experts, worksheet authors, and others working on ILCOR projects.

Each ILCOR participant should follow the procedures listed below:

1. At each meeting in which resuscitation science is discussed, each ILCOR participant must disclose all relationships that could pose a direct or indirect conflict of interest. For most meetings this can be done at the time of introductions. ILCOR will keep written records of these disclosures through the minutes of the meeting. At large meetings speakers will also provide meeting organizers with a COI disclosure form before the meeting. A list of participants and their commercial relationships (commercial entity and type of relationship) will appear in the agenda/program for the meeting.
2. Each ILCOR participant will abstain from any vote in which he/she has a relationship that could pose a direct or indirect conflict of interest. The individual abstaining must leave the room during the vote. Abstentions will be recorded in the minutes.
3. Each ILCOR participant will bring COI concerns or issues to the ILCOR cochairs for investigation and resolution. If the issue involves a cochair, the issue will be raised with the other cochair.
4. Whenever possible, an individual with a substantial relationship to a particular topic or area should not be selected to lead a group or serve as a reviewer (worksheet author) for that topic. ILCOR cochairs will review disclosures by topic moderators and leaders of any subgroup to ensure that any commercial relationships are understood and that potential conflicts are limited and manageable. This shall not prevent an individual with a substantial relationship regarding a topic from contributing to discussions and deliberations on that topic, provided the individual has disclosed those relationships during that meeting.
5. At least annually each ILCOR participant must complete the COI disclosure form and update it if substantive changes occur. The ILCOR cochairs will review the forms. Each cochair will review the other cochair's form. Difficult issues that cannot be resolved by the cochairs will be brought to the entire group for discussion and resolution.

Special Conflict of Interest Procedures for 2005 International Consensus Conference on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations (C2005).

1. The formal conference invitation packet for such conferences will include the following COI-related materials:
   a. AHA COI Annual Disclosure Form
   b. AHA ECC COI Policy and Procedures
   c. ILCOR COI Policy and Procedures
   d. ILCOR COI Annual Disclosure Form
2. When returning conference registration forms, worksheet authors, participants, speakers, moderators, and attendees will also submit to the AHA both the ILCOR COI Disclosure Form and the AHA ECC COI Disclosure Form. AHA staff will collate the forms and pursue any missing forms well before the conference. Task Force chairs (BLS, ACLS, and Pediatric Resuscitation) will review forms submitted by their speakers and Task Force members for potential conflicts. Questions or problems will be brought to the ILCOR COI cochairs for resolution (David Zideman of the European Resuscitation Council and John Billi of the AHA). The AHA and ILCOR will keep written records of all disclosure forms and any actions taken. Failure to provide the disclosure form before the conference will result in the participant not being permitted to register for the conference and being removed from the program.
3. In those instances in which a worksheet author has substantive, relevant conflicts of interest, the Task Force chairs will name another reviewer to review the worksheet, including the draft scientific conclusion. In addition, a Task Force chair or designee without a conflict of interest will write the final summary statement, with attribution.
4. When worksheets are posted on the Internet before the conference, the author's conflict of interest will be listed even if the author's name is not. The website will have a hyperlink from each worksheet to this policy. Those who wish to comment on the worksheets must complete the same COI form so that the worksheet authors will have that information as context for the comment.
5. For the conference, the AHA will print a COI disclosure booklet that contains participants' names, institutions, assigned participant numbers, and the basic details of any relationship that might pose a conflict (name of company and nature of relationship). This booklet will be distributed at the conference, either as a separate booklet, part of the syllabus, or both. The disclosures will also be included on the conference website.
6. During presentations moderators will introduce themselves, state their participant numbers, and disclose potential conflicts of interest. Each presenter will use the standard slide listing his/her potential conflicts of interest at the beginning of the presentation. This procedure will be enforced by the moderators. Presenters will not orally state the relationships listed on the slide but must state their participant numbers so that the audience can refer to the disclosure list. If the presentation does not contain such a slide, the moderator will ask the presenter to state his/her disclosures at the beginning of the presentation (not optimal but necessary).
7. During discussions each moderator will ask the floor speakers to identify themselves, state their participant numbers and institutions/companies, and declare any potential conflicts. Each floor speaker must make this verbal disclosure once during each worksheet topic session.
8. If COI problems arise during the conference, moderators will handle them if possible. If necessary, moderators will refer any problems to the 2 ILCOR COI cochairs for resolution. Either may call together the Ad Hoc COI Committee should it be needed. The Ad Hoc COI Committee will be composed of representatives from different councils and areas (pediatric, adult, basic, etc) and outside experts in COI. If the session moderator believes the session should not continue until the COI issue is resolved, then the moderator should move to the next presentation to allow the ILCOR COI cochairs to resolve the issue rapidly. After resolution, the topic discussion can resume.
9. A poster at the conference will display the ILCOR and AHA COI policies, including a copy of the booklet listing the disclosures of each conference participant by participant number. This will inform participants about the ILCOR and AHA COI process and allow the opportunity for questions and feedback. The poster will also include the multiple steps taken to manage potential conflicts, including policies, COI review steps, use of 2 independent worksheet reviewers, the disclosure process before and during the conference, and the Ad Hoc COI Committee.

Endorsed ILCOR Business Meeting September 13, 2004; modified 2007 (See footnotes 1 and 2 later in document).

pediatric life support; neonatal life support; acute coronary syndromes; and education, implementation, and teams. The ILCOR Executive Committee chose task force co-chairs to avoid any potential conflict of interest in the topics addressed by the task force. For 1 task force, both co-chairs had commercial conflicts in the same area relevant to the task force. ILCOR then created a separate "overlap" task force to handle the areas of conflict and appointed additional co-chairs who had no conflicts in the area of overlap.

Before assigning systematic review topics, ILCOR task force co-chairs reviewed the completed disclosure forms of proposed worksheet authors and avoided assigning worksheets to authors with potential conflicts. Although the COI process focused primarily on avoiding financial and commercial conflicts, worksheet topics were also assigned to minimize intellectual conflicts such as authorship of key studies relevant to the worksheet topic under review. As a second check, each evidence evaluation worksheet included a space for the author to disclose potential conflicts of interest relevant to that worksheet. Worksheets were not accepted unless the COI section was complete. The COI information submitted for each worksheet was reviewed by the task force co-chairs and by the evidence evaluation expert, and potential conflicts that had not been identified based on the pre–worksheet assignment COI disclosure were identified. When potential conflicts were discovered after initial assignment, the worksheet was reassigned to a nonconflicted author. In 1 case, a worksheet author was discovered to have a potential conflict of interest after completion of the worksheet first draft. A second worksheet author without any potential COI assumed responsibility for completing the worksheet, performed another literature search, and revised the consensus on science and the treatment recommendation sections.

If task force members or assigned worksheet authors received grants from industry within the past 12 months, the task force co-chairs attempted to reassign the author to avoid the conflict. In rare instances it was not feasible to replace a worksheet author who had industry grants. In these situations we investigated the conditions of the grant for details including investigator control of study design, control of data/analysis, lack of publication restrictions, and salary support. We initially planned not to scrutinize grants from nonprofit foundations, but in view of the heavy support some foundations receive from industry, we applied these rules to foundation funding as well.

Completed worksheets were electronically posted for public comment from October 2009. Representatives of industry and industry employees were not permitted to participate in the evidence evaluation process. However, to be able to benefit from the expertise of industry representatives who had valuable input to contribute, ILCOR did permit them to provide "public" comment to the posted worksheets. Those who commented were asked to declare potential COIs, but they were not required to identify themselves. Task Forces evaluated all posted comments on their merits, consistent with open peer review.

At all meetings for the 2010 evidence evaluation process, COI disclosure was required either orally or by simultaneous slide projection (described below), and monitors present in each room ensured compliance with COI procedures. Although potential COI was largely self-identified, all participants were encouraged to request clarification about affiliation or involvement during presentations and discussions. In several instances before and during the C2010 Conference, participants raised issues regarding potential conflicts of interest that were clarified by the COI co-chairs, resulting in modification of disclosures and sometimes a change in role. Anyone with a potential conflict of interest was permitted to participate in debate but not in decisions or votes regarding wording of consensus on science and treatment recommendations.

In the 5 years leading up to the conference, COI co-chairs fielded many questions and issues regarding the nature of diverse relationships and whether they posed a potential conflict of interest. The co-chairs maintained written documentation of the issues raised and their resolution, for transparency and to aid consistency. Many participants asked co-chairs for feedback about their personal disclosures. In at least 1 instance, a participant ended his relationship with commercial entities to eliminate potential conflict, in order to participate fully in the process.

Management of Potential COI During the C2010 Conference

All participants who attended the C2010 conference were required to submit a COI disclosure within 12 months of the conference; late registrants and those with outdated or missing disclosures were required to complete the COI disclosure when they arrived on-site. Throughout the conference, participants were afforded the opportunity to revise or update their COI disclosure, as appropriate. Five computers dedicated to COI use allowed rapid completion or updating of the online COI form; COI information was then immediately entered into the COI database.

All C2010 participants were asked to bring a laptop computer and were given complimentary wireless Internet access throughout the conference. All conference materials including COI disclosures were available electronically. Participants were directed to access the C2010 COI website listing each attendee's name and institution and the basic details of any declared professional relationship that could pose a potential conflict of interest, categorized by type of relationship (grant, consultant, speakers bureau, stock ownership, intellectual property, other; see Disclosures at the end of each part of the *2010 ILCOR Consensus for CPR and ECC Science With Treatment Recommendations*). In addition, this information was available in a printed copy present at the moderator's table and the registration desk. As in C2005, each participant was assigned a participant number. Based on pilot testing at the 2009 Orlando ILCOR meeting, we assigned numbers in different ranges based on the participant's COI declaration, so all participants could easily determine whether the participant had declared commercial relationships. Participants were assigned numbers 1 to 399 if they declared no relationships and 400 to 599 if they declared relationships. Participants who had not completed COI disclosure in advance were assigned a temporary number (600–700), were required to complete the online COI form during on-site C2010 registration, and were required to make full oral disclosure prior to each comment until their COI slide was updated, usually within 4 hours. COI information for each participant was listed numerically on the COI website, and the website was updated daily with new or revised COI disclosure information.

As in C2005, continuous COI disclosure for all speakers (scheduled or unscheduled) was provided without interruption or delay in the proceedings throughout C2010. All participants who commented during the conference, whether they were a moderator, presenter, panelist, or conference attendee, were required to state their name and participant number prior to speaking. A slide listing the speaker's institution and COI disclosure information was projected on a designated screen for the duration of the speaker's presentation, question, response, or comment. This provided conference participants with immediate and continuous information about any relationships the speaker had that could pose a COI issue.

Questions from the audience, comments, and statements from all moderated sessions were audio recorded for future reference. Speakers' statement of participant number at the beginning of comments made the task of identifying recorded speakers easier and made it possible to assess the impact of potential conflicts of interest from the recordings.

A COI monitor was assigned to each session to ensure that policies were followed and to manage questions or issues arising during the session. The monitors' COI Attestation Forms were reviewed and retained as part of the AHA ECC COI documentation file. Conference participants were repeatedly reminded to raise COI issues with COI monitors, moderators, or COI co-chairs. COI co-chair mobile telephone numbers were printed at the bottom of all COI Attestation Forms. A confidential COI telephone "hotline" was announced and listed in the conference program to enable participants to report issues anonymously if they did not wish to make their comments in person. During the conference any new COI problems or questions that could not be resolved by the session moderators were referred to the COI co-chairs for rapid resolution. If a problem became apparent during a session, moderators were instructed to stop discussion if they could not resolve the problem immediately to enable the COI co-chairs time to resolve the issue. When the problem was resolved, the panel was then permitted to resume the earlier presentation and discussion. An Ad Hoc COI Committee composed of the 2010 Consensus Conference coordinator (William H. Montgomery), conference co-chairs (Robert W. Hickey and David Zideman), and COI co-chairs (John E. Billi and Michael Shuster) was available to deal with any issue the COI co-chairs deemed sufficiently challenging.

Potential COI Management Issues Arising During the C2010 Conference

COI co-chairs investigated and recommended resolution for a number of issues that arose during the conference. None of the COI issues required interruption of discussion or convening of the Ad Hoc COI Committee (each of these events did occur once in C2005).[3,4] No anonymous calls were received on the COI hotline. Six participants voluntarily revised their COI disclosure forms once they observed the comprehensive level of disclosure of their peers or were reminded of relationships that might pose a potential conflict. In 1 instance, 2 participants provided information regarding a potentially conflicting, undisclosed relationship of another participant. A COI co-chair investigated each issue, and in both cases, the participant's disclosure form, online list, and slide were updated.

Minor difficulties with the planned COI procedures included difficulty experienced by the projectionist in hearing or understanding the speaker's number, the speaker forgetting to provide the number at the beginning of comments (this occurred less frequently as the conference progressed), occasional slow slide projection, the COI slide not yet being updated, or the speaker failing to highlight an intellectual or commercial relationship directly related to the issue under discussion. All of these minor difficulties occurred infrequently and were handled locally by the moderators or the COI monitor assigned to the session; no breaches of COI policy were observed or reported. One unintended benefit of the simultaneous projection of the COI slide was that the audience always knew who was speaking, something that can be difficult to discern in a large meeting room with floor microphones and a wide variety of native languages among participants.

Management of Potential COI Issues After the C2010 Conference

Writing groups were formed to write the *2010 Consensus on CPR and ECC Science and Treatment Recommendations*. All writing group co-chairs and writing group members' COI forms were reviewed by AHA officers to ensure compliance with current AHA writing group COI policies. The chair of each writing group and more than 50% of the members of each writing group were required to be free of any relevant relationship with industry and of any significant intellectual bias or competing organizational relationship. Any chair of a writing group with any relevant COI was asked to step down as a chair.

Overall, the C2010 COI management process worked well. Nonetheless, ILCOR and the AHA continue to revise policies and procedures to enhance transparency and ensure scientific integrity throughout the evaluation of the evidence and development of consensus statements and treatment recommendations. Readers are welcome to provide feedback on any aspect of the ILCOR or AHA COI policies and implementation. Please contact the lead author.

1. ILCOR should be especially sensitive to potential COI issues among persons selected for a leadership role with oversight or responsibility for science review of a particular area or topic. These situations must be reviewed on a case-by-case basis. ILCOR may decide that the risk to the integrity of the process from the individual's relationship is not significant and that the individual still represents the best choice for ILCOR, taking into account the risks and benefits. If a person already playing a leadership role develops or is discovered to have a conflict that poses a significant risk to the integrity or credibility of the ILCOR process, another qualified individual without such a potential conflict should replace the first person. Such a substitution shall not imply any impropriety on the part of anyone but rather indicate a preventive step taken to avoid any perceived or real conflict from endangering the integrity of the process. A position of leadership can include the chair or vice chair of any committee, subcommittee, task force, working group, ad hoc group assigned to work on an issue, evidence panel, or evidence collection process. The fact that such perceived conflicts are usually without any improper intent does not protect the individual, ILCOR, or its work from the potential consequences of inadequate management of such a situation.

2. In addition to financial relationships, other bases of potential conflicts of interest must be considered, such as in-kind support, intellectual collaboration or intellectual investment in one's own ideas, or a long-term research agenda in which an investigator has invested substantial time. Although these situations will be considered on an ad hoc basis, financial relationships are more likely to adversely affect the credibility of ILCOR and the integrity of its process and products.

Disclosures

CoSTR Part 4: Writing Group Disclosures

Writing Group Member	Employ-Ment	Research Grant	Other Research Support	Speakers Bureau/Honoraria	Ownership Interest	Consultant/Advisory Board	Other
John E. Billi	University of Michigan: Medical School–Professor	None	None	None	None	None	None
Michael Shuster	Self-employed: emergency physician	None	None	None	None	None	None
Leo Bossaert	University of Antwerp; Professor	None	None	None	None	None	None
Allan R. de Caen	Self employed	None	None	None	None	None	*Canadian Medical Protective Association-medical expert
Charles D. Deakin	South Hampton University Hospital	None	None	None	None	None	None
Brian Eigel	American Heart Association–Director of Science, ECC Programs	None	None	None	None	None	None
Mary Fran Hazinski	Vanderbilt University School of Nursing. Professor. †Compensated consultant to the AHA. I am compensated to co-edit the international consensus on CPR and ECC Science with Treatment and to co-edit the AHA Guidelines on CPR and ECC	None	None	None	None	None	None
Robert W. Hickey	CHP–Attending Physician	*NIH-funded study investigating the role of cyclopentenone prostaglandins on hypoxic ischemic brain injury.	None	None	None	None	*1–2 cases/yr expert witness
Ian Jacobs	†Funds are received into the Discipline of Emergency Medicine-University of Western Australia from the Ambulance Service-Western Australia and Laerdal (Australia) to maintain the Cardiac Arrest Registry for Western Australia. Our role is to independently maintain, analyze and report outcomes of cardiac arrest in Western Australia. I oversee the operation of the registry and reporting of outcomes. These funds are not used in any way to provide any direct or indirect salary or other financial support	†Chief investigator on numerous grants awarded by: a) National Health and Medical Research Council b) The Department of Health-Western Australia c) The National Heart Foundation of Australia These funds are awarded to the University of Western Australia and none are used to provide any direct or indirect salary or other financial support.	None	None	None	None	None
Monica E. Kleinman	Children's Hospital Anesthesia Foundation, Sr Associate in Critical Care Medicine	None	None	None	None	None	None
Rudolph W. Koster	Academic Medical Center; cardiologist, researcher	None	None	None	None	None	None
Mary E. Mancini	University of Texas at Arlington, Professor	None	None	None	None	None	None
William H. Montgomery	self employed anesthesiologist: staff anesthesiologist; AHA consultant-Conference: C2010 Conference Coordinator	None	None	None	None	None	None
Peter T. Morley	Royal Melbourne Hospital: Director of Medical Education; University of Melbourne: Clinical Dean, Royal Melbourne Hospital; AHA–Evidence Evaluation Expert	None	None	None	None	None	None

(Continued)

CoSTR Part 4: Writing Group Disclosures, *Continued*

Writing Group Member	Employ-Ment	Research Grant	Other Research Support	Speakers Bureau/Honoraria	Ownership Interest	Consultant/Advisory Board	Other
Laurie J. Morrison	St. Michaels; clinician scientist	*Laerdal Foundation Centre Grant-infrastructure support without salary support	None	None	None	None	None
Henrietta Munoz	American Heart Association, Inc.–ECC Attorney	None	None	None	None	None	None
Vinay M. Nadkarni	University of Pennsylvania School of Medicine; attending physician	†Laerdal Foundation for Acute Care Medicine: Pediatric Cardiac Arrest Learning Laboratory PI *NIH: THAPCA (Therapeutic Hypothermia After Pediatric Cardiac Arrest) *NIH: NHTSA: Thoracic Compliance in Pediatric Cardiac Arrest and Car Crashes	None	None	None	None	†Cardiac Arrest Facts
Jerry P. Nolan	Royal United Hospital NHS Trust: Consultant in Anaesthesia and Critical Care	None	None	None	None	None	None
Robert E. O'Connor	University of Virginia Health System: Professor and Chair of Emergency Medicine	None	None	None	None	None	None
Jeffrey M. Perlman	Weill Cornell, Professor	NIH-Improving antimicrobial prescribing practices in the NICU	None	None	None	None	None
Sam Richmond	City Hospital Sunderland	None	None	None	None	None	None
Michael R. Sayre	Self employed, physician	None	None	None	None	None	None
Jasmeet Soar	North Bristol NHS Trust: Government Hospital in UK–Consultant in Anaesthetics & Intensive Care Medicine	None	None	None	None	None	None
Jonathan Wyllie	South Tees NHS Foundation Trust-Clinical Director of Neonatology, Consultant Neonatologist	None	None	*Spoke for "Trouble Up North" sponsored by Chiesi. Other invited lectures for no cost. *Will receive small honorarium for speaking at the Middlesbrough Neonatal meeting Honorarium as above from Chiesi.	None	*European Resuscitation Council Board Member and ICC co-chair. Voluntary expenses only *Resuscitation Council (UK) Executive member and Chair of Newborn Life Support Working group. Voluntary expenses only *HEMS Clinical Governance Group. Voluntary expenses only *North east Ambulance Clinical Governance Group. Voluntary expenses only	*Expert Witness-Occasional Case. Nothing recent but one pending report in the UK now.
David Zideman	Imperial College NHS Trust: United Kingdom Healthcare provider–Consultant Anaesthetist; London Organising Committee of the Olympic Games: Lead Clinician for EMS	None	None	None	None	None	*Expert witness reviews for Her Majesty's Coroner for Surrey

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives $10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns $10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Significant.

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KEY WORDS: arrhythmia ■ cardiac arrest ■ cardiopulmonary resuscitation ■ emergency department ■ resuscitation

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