

Heart Rhythm Society Policy Statement Update: Recommendations on the Role of Industry Employed Allied Professionals (IEAPs)

Bruce D. Lindsay, MD, FHRS,* N. A. Mark Estes III, MD, FHRS,[†] James D. Maloney, MD, FHRS,[‡]
Dwight W. Reynolds, MD, FHRS[§]

From *Cleveland Clinic, Cleveland, OH, [†]Tufts University School of Medicine, Boston, MA, [‡]University of Toledo, Health Science, Toledo, OH, [§]University of Oklahoma, College of Medicine, Oklahoma City, OK.

Introduction

In 2001, the North American Society of Pacing and Electrophysiology (Heart Rhythm Society) published a policy statement to provide guidance for industry employed allied professionals (IEAPs) who render technical assistance during pacemaker/Implantable Cardioverter Defibrillator (ICD) implantations, programming, analysis of malfunctions, and follow-up.¹ These principles were incorporated in a recent consensus document on the monitoring of implanted cardiovascular electronic devices.² The term IEAP is applied to persons who are employed or contracted manufacturer representatives, field clinical engineers, and industry employed technical specialists. These individuals often have expertise about specific features of pacemakers or ICDs that is unique to the manufacturer's product. This expertise may be extremely valuable to physicians and the clinical allied professionals (CAPs) they employ. In some instances, CAPs may be employed by the institution incident to the practice of the responsible physician. The physician bears the responsibility for assessing effectiveness of device programming and any device malfunctions and recommending specific courses of action.

The Heart Rhythm Society sponsored an Industry Forum in July 2007 to discuss the role of industry in the care of patients with heart rhythm disorders. One topic of discussion was the role of IEAPs and the need to update the guidelines published in 2001. The meeting was attended by senior Heart Rhythm Society (HRS) staff, officers of HRS, and executives representing several leading manufacturers of technology used in the care of heart rhythm disorders. A broader scope of devices is in widespread use today. Although pacemakers and ICDs remain central to this discussion, the guidelines must also account for technical assistance supporting intra-cardiac echocardiography, electro-anatomic mapping systems, remote navigation, and other technologies that are evolving to assist complex procedures

performed in the electrophysiology laboratory or management of patients in the hospital or outpatient setting.

The consensus of those attending the Industry Forum was that the guidelines pertaining to IEAPs have been extremely valuable, but the group was unanimous in recommending that HRS update the guidelines. The following revisions were developed by officers of HRS in collaboration with representatives from industry.

Recommendations

- 1. The IEAP's role in the clinical environment is to provide technical expertise on the implant, use, and operation of their proprietary equipment specific to their company** (including operation of programmers, analyzers, catheters, remote monitoring systems, mapping systems, and other support equipment). Because IEAPs are not licensed or authorized to practice medicine, these activities must be carried out only at the request and under the direction of a qualified physician.
- 2. An IEAP trained in sterile techniques may participate in the implant procedure, but as a rule the IEAP should not enter the sterile field.** The role of the IEAP during the implant procedure is to operate the programmers, analyzers, and other proprietary equipment under the supervision of the physician. The IEAP may also provide education and training to CAPs and physicians. In the rare circumstance where the physician feels it is necessary for the IEAP to enter the sterile field, a specific written request is required to outline the reasons justifying this action. An IEAP may enter the operative field only after receiving specific written approval from the institutional representative who is responsible for granting clinical privileges.
- 3. IEAPs should perform technical support tasks in the office only under direct supervision by the physician.** Direct supervision means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the

Endorsed by the Heart Rhythm Society Board of Trustees on September 10, 2008. **Address reprint requests and correspondence:** Ms. Donna M. Cohen, Heart Rhythm Society, 1400 K Street NW, Suite 500, Washington, DC 20005. E-mail address: dcohen@HRSONline.org.

physician must be present in the room when the procedure is performed.

4. **If an IEAP is requested to evaluate a pacemaker or ICD in the hospital, the physician who made the request should be immediately available by phone if he or she cannot provide direct supervision.** It is the physician's responsibility to interpret the recordings and make any related clinical decisions.
5. **IEAPs may provide technical support/expertise to CAPs (clinical allied professionals, e.g., nurses, technicians . . .) rendering patient care under the supervision of a physician.** The presence of the IEAP does not change the level of supervision the physician must provide for the CAP. That level of supervision is still subject to the relevant regulations applicable to physician and allied provider's scope of practice.
6. **Although IEAPs provide expertise and may train and answer questions on their systems and equipment, they should not be used as unpaid employees of a physician's practice or routinely assume administrative functions, such as routine retrieval of patient information or enrolling patients in remote monitoring systems.**
7. **IEAPs should not provide clinical assistance in the clinical environment when they are alone and/or unsupervised by an appropriately trained or experienced physician. IEAPs should not provide technical assistance in a patient's home in the absence of a responsible physician.** If a patient is in a life-threatening situation, a call to an emergency response unit should be placed to transfer the patient to the emergency department of a hospital. Only under rare and urgent circumstances should an IEAP provide technical assistance remote from supervision (i.e., in a nursing home facility). This should occur only in situations where the patient's condition and/or distance from the medical facility are such that the patient's health could be significantly impacted if the technical assistance were delayed. The patient's comfort is a legitimate consideration when ICDs are reprogrammed not to shock a terminally ill patient who is at home or in a hospice. If deemed necessary, the IEAP should only provide service remotely under written and direct order by the physician. The actions performed by the IEAP should be limited to what is specified in the order. To facilitate prompt action, the order may be given verbally, but subsequently the physician is responsible for a written order and documentation of the episode in the patient's medical record.
8. **IEAPs should not provide technical assistance for a competitive manufacturer's device(s) unless the patient is in an immediately life-threatening condition or when a physician replaces an implanted device with another manufacturer's product.** In that instance, the IEAP from the company of the device to be implanted, under the direct supervision of the implant-

ing physician, may be asked to assist in performing "routine" actions for the previously implanted device (interrogation, current parameter documentation and printing, turning off the current device, etc.). In this situation, and under the direct supervision of the implanting physician, the IEAP may assist in performing these actions in support of the intra-operative device change.

9. **The support services of the IEAP are provided by the manufacturer to enhance the benefit of its product. Physicians bear final responsibility for both clinical oversight of the IEAP and appropriate billing in accordance with all local, state, and federal laws and regulation.** Medicare guidelines prohibit a physician from reporting the technical component of services performed primarily by an IEAP who is not employed by the physician. Billing services "incident-to" a physician's professional service must meet the criteria defined by 42 CFR § 410.26. The incident-to rules pertain exclusively to Medicare reimbursement. Other third-party payers may reimburse services differently.
10. **When working within a hospital, IEAPs must abide by any specific hospital policies that may pertain to their presence and clinical activity.** Some hospitals may have policies that preclude IEAPs from some or all clinical activities.
11. **In the event of any conflict between these guidelines and an applicable state, provincial or federal law or regulation, such law or regulation shall take precedence and control.** This position statement clarifies the role IEAPs play in providing technical assistance and expertise to the heart rhythm team and patients with implantable cardiac rhythm devices. In addition, it sets forth the premise that the physician has overall responsibility for the patient being treated and for the pacemaker/ICD function and programming. The IEAP is an invaluable technical resource for physicians and their allied health care providers attempting to deliver high quality health care in the most cost-effective manner to patients with electronically complex arrhythmia management devices.

The preceding statements serve as guidelines to physicians and allied professionals, but they should not be interpreted as an all inclusive set of regulations. Conduct by physicians and allied professionals should be consistent with ethical standards endorsed by professional societies³ and the Advanced Medical Technology Association.⁴

References

1. Hayes JJ, Juknavorian R, Maloney JD. NASPE policy statement. The role(s) of the industry employed allied professional. *Pacing Clin Electrophysiol* 2001;24: 398-399.
2. Wilkoff BL, Auricchio A, Brugada J, Cowie M, Ellenbogen KA, Gillis AM, Hayes DL, Howlett JG, Kautzner J, Love CK, Morgan JM, Priori SG, Reynolds DW, Schoenfeld MH, Varda PE. HRS/EHRA Expert Consensus on the moni-

toring of cardiovascular implantable electronic devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations. *Heart Rhythm* 2008;5:e1–e62.

3. Popp RJ, Smith SC Jr, Adams RJ, Antman EM, Kavey RE, DeMaria AN, Ohman EM, Pitt B, Willerson JT, Bellande BJ, Fonarow GC, Nishimura RA, Shah PM, Hirshfeld JW Jr, Messer JV, Peterson ED, Prystowsky EN, Anderson

JL, Cheitlin MD, Goldstein LB, Grant AO, Beller GA, Hines EF Jr, Livingston DW, McEntree CW, American College of Cardiology Foundation, American Heart Association. ACCF/AHA consensus conference report on professionalism and ethics. *Circulation* 2004;110:2506–2549.

4. Code of ethics for interactions with health care professionals. Available from <http://www.advamed.org>.

Author Relationships with Industry

Author	Consulting fees/Honoraria and Research Grants	Speaker’s Bureau	Ownership/Partnership/Principal	Institutional or other Financial Benefit
Bruce D. Lindsay, MD	None	None	None	None
N.A. Mark Estes III, MD	None	None	None	None
James D. Maloney, MD	None	None	None	None
Dwight W. Reynolds, MD	Biotronik Boston Scientific Medtronic, Inc. Sorin	Medtronic, Inc.	Medtronic, Inc.*	Medtronic, Inc. (Fellowship Support)

*Indicates Significant Level Relationship (More than \$10,000).

Industry Forum Participants (July 2007)

1. Joel Becker, St. Jude Medical VP-Business Development, Atrial Fibrillation Division
2. Mark Carlson, MD, St. Jude Medical CMO/SVP-Clinical Affairs
3. N.A. Mark Estes, MD, Tufts University School of Medicine, President-Elect HRS
4. Jake Langer, Biotronik President
5. Bruce Lindsay, MD, Cleveland Clinic (formerly from the Washington University School of Medicine), President HRS
6. Daniel Lippis, Biosense Webster Director-Global Marketing
7. Pat Mackin, Medtronic VP-CRDM Commercial Operations
8. William McConnell, Boston Scientific Senior VP-Sales, Marketing & Administration
9. Dwight Reynolds, MD, University of Oklahoma College of Medicine, Immediate Past-President of HRS
10. Ruchir Sehra, Stereotaxis, Inc., Chief Medical Officer
11. David Steinhaus, MD, Medtronic VP-Medical Director, CRDM