Heart Rhythm Society Policy Statement Update: Recommendations on the role of industry-employed allied professionals

David E. Haines, MD, FHRS,* Christopher Austin, MD,† Fred M. Kusumoto, MD, FHRS,‡ Christopher H. Liu, MD, FHRS,§ J. Paul Mounsey, MD, PhD,¶ Kimberly Proto-Conroy, MSN, APRN,‡ Kimberly A. Selzman, MD, MPH, FHRS‖

*From the *Oakland University William Beaumont School of Medicine and Beaumont Hospital, Royal Oak, Michigan, †Baptist Health, Jacksonville, Florida, ‡Mayo Clinic, Jacksonville, Florida, §New York-Presbyterian Hospital/Weill Cornell Medical Center, New York, New York, ¶University of Arkansas Medical Center, Little Rock, Arkansas, and ‖University of Utah, Salt Lake City, Utah.*

Introduction

In 2001, the North American Society of Pacing and Electrophysiology (now the Heart Rhythm Society) published a policy statement to provide guidance for industry-employed allied professionals (IEAPs) who provide technical assistance during pacemaker/implantable cardioverter defibrillator (ICD) implantations, programming, analysis of malfunctions, and follow-up[1]; the policy was updated in 2008 (Table 1).[2] Since those publications, their principles have been incorporated in the other Heart Rhythm Society expert consensus statements that look at the role of the cardiac implantable electronic device (CIED) team and IEAPs in patient care delivery in our profession.[3–5] The term IEAP is applied to individuals who are employed or contracted manufacturer representatives, field clinical engineers, and industry-employed technical specialists. These individuals often have expertise about specific features of CIEDs, electroanatomical mapping systems, left atrial appendage occlusion devices, ambulatory electrocardiography recording devices, or other heart rhythm–related technologies that are unique to the manufacturer's product. This expertise is often extremely valuable to physicians and allied professionals.

A common topic of discussion among heart rhythm physicians, allied health professionals, industry supervisors, and IEAPs is the delineation of the roles, responsibilities, and limits of IEAP participation in direct patient care. Physicians and allied health professionals appreciate the work performed by the IEAPs, and IEAPs benefit from the close working relationship with the health care providers. Nevertheless, in all settings, the primary health care provider has responsibility for all care delivery to their patients. This document represents a consensus among clinician experts and industry representatives to establish guidelines and expectations regarding the roles of IEAPs in the patient care setting, with the goal of delivering the highest level of care possible to all our patients.

Address reprint requests and correspondence: Dr David E. Haines, Department of Cardiovascular Medicine, Beaumont Hospital, 3601 West 13 Mile Rd, Royal Oak, MI 48073. E-mail address: dhaines@beaumont.edu.

Role delineation

There are multiple professionals who are involved in the delivery of care for a patient with a CIED or arrhythmia that can vary depending on the clinical setting and the needs of a specific patient.

Physicians

Physicians are defined in this document as those with the appropriate credentials, licensing, and privileges to act as a medical doctor in the health care environment. This may include those with specific expertise in clinical cardiac electrophysiology (EP) as well as any physician who has responsibility for the care of the patient in any setting. It is the expectation that all physicians will adhere to the tenets of medical ethics and the principles of professionalism.[6] Allied professionals (industry employed or non–industry employed) who have specialized training in technical aspects of arrhythmia care may provide expertise for the operation of specific equipment. For example, anesthesiologists and surgeons may provide direct supervision of an allied professional in the perioperative setting. Similarly, specialists in palliative care who manage patients with CIEDs may oversee IEAP personnel or provide direction to the appropriately trained non–industry allied professional for a patient in a long-term care facility or at the home of a patient who is under hospice care. A physician who is directly supervising the care of the patient is defined as the primary health care provider.

1547-5271/$-see front matter https://doi.org/10.1016/j.hrthm.2022.08.029

Allied health professionals

For this document, the term allied health professional encompasses individuals with specific training and expertise in arrhythmia management who work under the direction of a cardiac electrophysiologist, cardiologist, or other physician with device and arrhythmia expertise. Allied health professionals are a diverse group with different experience, education, training, licensing, and certification and include nurse practitioners, physician assistants, registered nurses, and cardiovascular technicians. They have been trained in the care and management of arrhythmia patients. In many cases they also have proficiency in outpatient arrhythmia monitoring, CIED management (including interrogation, programming, and technical troubleshooting), and running and troubleshooting EP laboratory equipment (including imaging systems, EP systems, mapping systems, and ablation systems). The allied health professionals may consult an IEAP for their manufacturer-specific knowledge and expertise. Nurse practitioners and physician assistants are also grouped together as advanced practice providers and may serve as the primary health care provider for arrhythmia patients. It is important that the IEAP is aware of the identity and role of care delivery of the advanced practice providers that they are assisting.

Industry-employed allied professionals

The term industry-employed allied professional is applied to individuals who are employed by industry as contracted manufacturer representatives, field clinical engineers, or expert technical specialists. These individuals often have expertise about specific features of EP equipment, including CIEDs, that are specific to the manufacturer's product. While historically the term IEAP has been used to describe individuals with expertise in CIED management, this term also refers to individuals employed by industry who provide technical assistance supporting a range of procedures (Table 2).

General principles of IEAP scope of activities

The following general principles provide an overview of the IEAP scope of practice. Individual health care facilities may have specific policies for IEAP scope of practice, and those policies would have precedence and jurisdiction over these recommendations, as would any state, provincial, or federal laws or regulations.

1. The IEAP should not provide clinical assistance in the clinical environment when they are alone and not directly or indirectly supervised by an appropriately trained or experienced primary health care provider. The IEAP provides important manufacturer-specific information and expertise that supports patient care, but responsibility for the patient always falls on the primary health care provider. The IEAP provides service under the direct supervision or specific instruction of the primary health care provider for the individual patient, and while the IEAP provides technical assistance, they should not be considered a member of the responsible care team for a patient.

Table 1

What's new

- Discussion of the roles of mapping specialists, imaging specialists, and specialists in left atrial appendage occlusion device implantation
- Definition of the primary health care provider to whom the IEAP must report and respond
- Expansion of the wide variety of settings in which IEAPs perform their activities: the magnetic resonance imaging laboratory, ambulatory surgical centers, rural outpatient clinics, long-term care facilities, and patient homes
- HIPAA-compliant secure data transfer and the electronic medical record

IEAP = industry-employed allied professional.

2. The IEAP should not enter the sterile field. The IEAP can provide advice within the procedure suite or operating room but should not enter the sterile field unless doing so is life-saving, such as when administering cardiopulmonary resuscitation during cardiac arrest.

3. The IEAP should not have direct access to the electronic medical record. While the IEAP can be involved with recording patient information and data on their manufacturer-specific equipment, transfer of this information to the electronic medical record is the responsibility of the staff employed by the health care facility, the primary health care provider, or an employee of the primary health care provider.

4. The IEAP's role in the clinical environment is to provide technical expertise on the implantation, use, and operation of their proprietary equipment specific to their company. In particular circumstances, when the IEAP is knowledgeable about another manufacturer's equipment and is comfortable with its operation, the IEAP can operate equipment from another manufacturer. Examples of such situations include device inactivation during generator change procedures, using a competitor's pacing system analyzer during lead implantation, or device reprogramming in an immediately life-threatening situation or when specifically directed by a primary health care provider. The latter should not be a routine expectation or request.

5. The IEAP is not an unpaid employee of the health care system or health care provider and can refuse tasks that they are asked to perform by the health care provider or health care facility staff without fear of retribution or consequence. The IEAP is not part of the responsible care team for a patient and should not be given any standing or expected responsibilities or duties for patient care other than those that are required to support the optimal operation of their manufacturer-specific equipment.

6. IEAPs should be aware of and abide by institutional policies pertaining to their presence and clinical activity.

Table 2 Procedures and technologies supported by industry-employed allied professionals

Device implantation	**Imaging and navigation**
CIEDs	Electroanatomical mapping
Pacemaker implants	Intracardiac echocardiography
ICD implants	Robotic navigation
S-ICD implants	
CRT device implants	**Ablation**
ILR implants	Radiofrequency catheter ablation
Wireless pacemaker implant	Cryoballoon ablation
CIED interrogation, troubleshooting, and programming	Endoscopic balloon laser ablation
	Pulsed field ablation
CIED lead extraction	
LAA occlusion device implant	
Industry-sponsored research	
Clinical site leads	
Procedure specialists	
Study monitors	

CIED = cardiac implantable electegronic device; CRT = cardiac resynchronization therapy; ICD = implantable cardioverter defibrillator; ILR = implantable loop recorder; LAA = left atrial appendage; S-ICD = subcutaneous cardiac implantable electronic device.

The IEAP in the electrophysiology laboratory environment

IEAPs have traditionally played a significant role in the EP laboratory by collaborating with operators in both CIED implantation and arrhythmia mapping and ablation procedures, and they will continue to do so in the future. IEAPs may provide expertise and training of staff, along with direct physician support on their manufacturer's devices, but they should not exceed their scope of practice or be asked to perform routine administrative functions in the EP laboratory.

CIED specialist

The IEAP's role is to provide technical expertise during implantation related to their manufacturer's propriety equipment under the direct supervision of the implanting physician. This includes operation of programmers and remote monitoring systems and may involve advice in the selection of products from their manufacturer's portfolio to expedite the implant operation.

Mapping and ablation specialist

IEAPs with expertise in 3-dimensional mapping of cardiac chambers and electroanatomic mapping of arrhythmias will continue to have a major role in cardiac ablation procedures. As the complexity of the arrhythmia substrates encountered in the EP laboratory increases, it is anticipated that the role of the mapping specialist will also increase. Mapping and ablation IEAPs should confine themselves to operation of their manufacturer's systems, and the procedure should at all times be under the direct control of an experienced supervising physician.

Imaging specialist

The expanding role of advanced imaging technologies such as intracardiac echocardiography in the management of complex arrhythmias has led to the increased deployment of IEAPs skilled in imaging technologies to EP laboratories. Their role is to guide the physician in optimal imaging catheter placement and to assist in image acquisition and interpretation. The final interpretation of the image is the responsibility of the physician.

Structural device specialist

Insertion of left atrial appendage occlusion devices for the prevention of stroke in patients with atrial fibrillation is a procedure performed by interventional cardiac electrophysiologists and structural heart disease interventional cardiologists. IEAPs provide technical expertise in assessment of the ultrasound and radiographic imagery, employ computer modeling, and advise implanters on optimal catheter/device selection and trajectory of device deployment.

The IEAP in non-electrophysiology procedure areas

The IEAP's role in non-EP procedural areas is to provide technical expertise with regard to the safety, use, and operation of their proprietary CIED and to perform device interrogation and reprogramming as specified by a primary health care provider. IEAPs can provide technical clarifications to device evaluations, but they should not be expected to perform routine device transmission review. In many cases, the physical presence of the IEAP is not required, as newer CIEDs may be interrogated with appropriately enabled cell phones and the data may be rapidly transmitted electronically to the IEAP at a remote location. Often the device issue can be managed with magnet application without the need for device reprogramming. These activities must be carried out only at the request and under the direction of a qualified primary health care provider, or as delineated in an approved procedural area patient care protocol. The supervising clinician should be available to provide guidance, either directly or remotely, to the IEAP throughout the duration of the procedure. The primary health care provider should abide by hospital or facility policies with regard to the direction of IEAPs.

Operating room

IEAPs may be asked to provide technical assistance in non-EP surgical and procedural areas with regard to CIED interrogation and reprogramming, typically in the perioperative setting (pre- and post-procedure). In this setting, the primary health care provider is often an anesthesiologist or surgeon. The IEAP should identify and communicate with this individual. In many cases, device inhibition for prevention of inappropriate therapies during electrocautery can be simply achieved with magnet application over the device without direct participation of the IEAP. While the IEAP may provide technical assistance regarding device function and programming changes, it is the primary health care provider's responsibility to finalize clinical interpretations of arrhythmia

recordings and make decisions regarding temporary and permanent programming changes. If permanent programming changes are made by a provider who is not the managing heart rhythm specialist, it is necessary that the heart rhythm specialist is informed of that change. The IEAP should not make any programming changes unless the primary health care provider is immediately available directly or remotely and has requested those specific changes, after which the IEAP should communicate the final device settings directly to them (eg, pacing mode off or asynchronous, ICD tachycardia detection/therapy off). The IEAP should be familiar with any hospital-specific protocols that delineate device programming specifics. It is the primary health care provider's responsibility to document in the medical record and to ensure that appropriate rhythm monitoring and care is provided for the patient.

Magnetic resonance imaging laboratory

The IEAP's role in the magnetic resonance imaging environment is to provide technical information regarding the safety, use, and operation of their proprietary CIED and to directly or remotely support device interrogation and reprogramming as specified by the primary health care provider in conjunction with specific hospital-approved protocols. These activities must be carried out only at the request and under the direction of the primary health care provider, who should be available to supervise the IEAP directly or remotely throughout the duration of the procedure. IEAPs cannot be responsible for patient monitoring and do not provide any other type of emergency backup during the scan, nor are they expected to remain present during the image acquisition.

In hospital and emergency department

IEAPs may be called upon to assist in device evaluation in hospital and emergency department settings. In many cases, the necessary information can be accessed using remote interrogation without requiring the IEAP to be physically present. IEAPs should not provide routine technical assistance in the clinical environment when they are alone or unsupervised by an appropriately trained or experienced clinician. 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 remotely without supervision. This should occur only in situations where failure to act immediately would result in the patient's death or serious injury.

Ambulatory surgical centers

As the range and extent of procedures (both EP and non-EP) being performed at ambulatory surgical centers (ASCs) continue to expand, there will be increasing demand for support from IEAPs in these settings. Procedures being performed at ASCs are anticipated to be less complex and involve patients who are at lower risk than those in hospital settings, but the same principles should apply. ASCs may not have the same level of staffing, equipment, and support as hospitals for complex patients or procedures, and there may be greater pressure on the IEAP to exceed their scope of practice and to serve as an unpaid employee. IEAPs should be aware of this distinction. As in other settings, IEAPs should provide only technical assistance that is within the realm of their expertise, under supervision of the primary health care provider.

Outpatient clinics

As is the case with care delivery in all settings, the IEAP should perform technical support tasks in the office or any outpatient environment only under supervision of an appropriately trained or experienced primary health care provider. The supervising provider does not need to be physically present, but a trained health care provider should be present, and the supervising provider should be readily available for communication with the IEAP if necessary. IEAPs should not assist in the clinic when they are alone or unsupervised. Some rural device clinics may not have access to CIED specialists, but a trained or experienced primary health care provider should still be responsible for overseeing the clinic and available during clinic hours. The CIED specialists will provide technical support but must not be the sole provider of care during the patient visit.

In-home and nursing home care

Patients with CIEDs residing in long-term care facilities have primary health care providers who are responsible for their medical care while in the facility. They may also receive support from an interdisciplinary team including nursing, physical, occupational, and spiritual care providers. Any member of this team should be able to consult IEAPs for technical assistance and information regarding device operation and remote CIED follow-up. IEAPs should provide technical assistance in a patient's residence only with the direct involvement of a responsible primary health care provider familiar with the patient and CIEDs. It is appropriate on occasion for IEAPs to travel to a patient's home or a nursing home facility to assist with device management (eg, to inactivate ICD tachycardia therapies in a terminally ill patient). In rare, life-threatening situations at a residence, an IEAP may be asked to provide emergent device interrogation/reprogramming services prior to arrival at a medical facility. To facilitate prompt action, the order may be given verbally, but subsequently the primary health care provider must generate written documentation of any device reprogramming and rationale for doing so in the medical record. Each manufacturer has policies that apply to their personnel entering a patient home (if that is the setting in which this activity is required) to which the IEAP should adhere. In extraordinary circumstances, the IEAP cannot be compelled to inactivate device therapies if it is against their best judgment.

Data management

IEAPs working with protected personal and health information should follow local and national policies on patient privacy and data protection. When obtaining or reviewing data and relaying the information to the patient's clinical care team or other health care providers, the IEAP should follow guidelines and protocols and use secure means of communicating any patient data in order to be HIPAA compliant. Any third-party vendor that manages or reviews patient data must comply.[7]

Summary

The present consensus document represents the perspectives from clinician experts and industry representatives and is intended to provide a framework for expectations and scope of practice for IEAPs in the patient care setting. These statements should serve as guidelines for physicians, allied professionals, and IEAPs but should not be interpreted as all inclusive. Conduct by all health care professionals should be consistent with ethical standards endorsed by professional societies.[6,8]

Acknowledgments

We would like to thank the following representatives from industry for their guidance and critical review of the manuscript: Julia R. Bucheger, Vice President, US CRM Service and Service Transformation, Medtronic, Inc; Kenneth M. Stein, MD, FHRS, Senior Vice President & Chief Medical Officer, Rhythm Management & Global Health Policy, Boston Scientific Corporation, Inc; Leonard I. Ganz, MD, FHRS, Divisional Vice President, Medical Affairs and Chief Medical Officer, Cardiac Rhythm Management, Abbott Laboratories; Tushar Sharma, MD, MPH, Director & Head, Medical Affairs & Preclinical Research, Biosense Webster, Inc.

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. Lindsay BD, Estes NAM, Maloney JD, Reynolds DW, Heart Rhythm Society. Heart Rhythm Society policy statement update: Recommendations on the role of industry employed allied professionals (IEAPs). Heart Rhythm 2008;5. e8–e10.
3. Slotwiner D, Varma N, Akar JG, et al. HRS expert consensus statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. Heart Rhythm 2015;12:e69–e100.
4. Crossley GH, Poole JE, Rozner MA, et al. The Heart Rhythm Society (HRS)/American Society of Anesthesiologists (ASA) expert consensus statement on the perioperative management of patients with implantable defibrillators, pacemakers and arrhythmia monitors: Facilities and patient management. This document was developed as a joint project with the American Society of Anesthesiologists (ASA), and in collaboration with the American Heart Association (AHA), and the Society of Thoracic Surgeons (STS). Heart Rhythm 2011; 8:1114–2254.
5. Lampert R, Hayes DL, Annas GJ, et al. American College of Cardiology; American Geriatrics Society; American Academy of Hospice and Palliative Medicine; American Heart Association; European Heart Rhythm Association; Hospice and Palliative Nurses Association. HRS Expert consensus statement on the management of cardiovascular implantable electronic devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy. Heart Rhythm 2010; 7:1008–1026.
6. Benjamin IJ, Valentine CM, Oetgen WJ, et al. 2020 American Heart Association and American College of Cardiology consensus conference on professionalism and ethics: A consensus conference report. J Am Coll Cardiol 2021;77:3079–3133.
7. Varma N, Cygankiewicz I, Turakhia MP, et al. 2021 ISHNE/HRS/EHRA/APHRS expert collaborative statement on mHealth in arrhythmia management: Digital medical tools for heart rhythm professionals: From the International Society for Holter and Noninvasive Electrocardiology/Heart Rhythm Society/European Heart Rhythm Association/Asia-Pacific Heart Rhythm Society. Circ Arrhythm Electrophysiol 2021;14:e009204.
8. Advanced Medical Technology Association. AdvaMed code of ethics. Accessed August 10, 2022. Available from: https://www.advamed.org/wp-content/uploads/2022/03/2022-AdvaMed-Code-of-Ethics-Digital.pdf.

Appendix 1 Author Disclosures

Name	Employment	Honoraria/Speaking/ Consulting	Speakers' bureau	Research*	Fellowship support*	Ownership/Partnership/ Principal/Majority stockholder	Stock or stock options	Intellectual property/ Royalties	Other
David E. Haines, MD, FHRS	Oakland University William Beaumont School of Medicine and Beaumont Hospital, Royal Oak, Michigan	1: Biosense Webster, Inc; 1: Boston Scientific; 1: Integer–Greatbatch Medical; 1: Medtronic, Inc; 1: Philips					0: Ablacon; 1: Affera, Inc		
Christopher Austin, MD	Baptist Health, Jacksonville, Florida	None	None	None	None	None	None	None	None
Fred M. Kusumoto, MD, FHRS	Mayo Clinic, Jacksonville, Florida	None	None	None	None	None	None	None	None
Christopher H. Liu, MD, FHRS	New York-Presbyterian Hospital/Weill Cornell Medical Center, New York, New York	None	None	None	None	None	None	None	None
J. Paul Mounsey, MD, PhD	University of Arkansas Medical Center, Little Rock, Arkansas	1: Boston Scientific; 1: Medtronic; 1: Portola Pharmaceuticals							
Kimberly Proto-Conroy, MSN, APRN	Mayo Clinic, Jacksonville, Florida	None	None	None	None	None	None	None	None
Kimberly A. Selzman, MD, MPH, FHRS	University of Utah, Salt Lake City, Utah	None	None	None	None	None	None	None	None

Number value: **0** = $0; **1** = ≤$10,000; **2** = >$10,000 to ≤$25,000; **3** = >$25,000 to ≤$50,000; **4** = >$50,000 to ≤$100,000; **5** = >$100,000.

*Research and fellowship support are classed as programmatic support. Sources of programmatic support are disclosed but are not regarded as a relevant relationship with industry for writing group members or reviewers.