

NASPE POLICY STATEMENT

The Role(s) of the Industry Employed Allied Professional

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Introduction

Industry employed allied professionals (IEAPs) have traditionally played an important role providing technical assistance to physicians and their clinically employed allied professionals (CEAPs) during pacemaker/ICD implantation, programming, troubleshooting, and follow-up. The IEAPs include directly employed or contracted manufacturer representatives, field clinical engineers, and industry employed technical specialists. Given the increased complexity of technology, the rapidly expanding number of patients being treated with implantable cardiac arrhythmia management devices, and accelerated pace of advancements in these devices, the IEAPs have become even more valuable to clinicians and their patients. Increased utilization of the IEAPs have raised questions regarding what is an appropriate or inappropriate activity for the IEAPs in regard to medical, legal, and economic issues. In the interest of continuing to deliver high quality medical care to patients with implantable cardiac rhythm devices, the Ad Hoc NASPE/Industry Task Force* was assembled by the president of the NASPE Board of Trustees to address the role(s) of IEAPs in the clinical environment. Members of the task force included NASPE physicians, members of NASPE/CAP, and representatives from industry.

The task force had initial discussions addressing the current role(s) of IEAPs in the clinical environment, identifying areas where the role of the IEAP was clinically appropriate, questionable, or inappropriate. The committee sought input from U.S. and Canadian implanting physicians, pacemaker /ICD clinic nurses, industry field representatives, their supervisors, and legal counsel. The committee noted that a few clinicians and industry leaders had requested that NASPE address these concerns. After reviewing the extent and va-

riety of interactions the industry representatives have been asked to participate in, there was consensus by this ad hoc task force that the boundaries of what constitute appropriate activities for IEAPs required a clearer definition. Lack of guidelines regarding this issue has led to rising concerns regarding medical, legal, reimbursement, economic, and ethical issues. The task force concurred that further clarification of the IEAP's role would be beneficial.

The ad hoc committee recognizes that the continued support by IEAPs is important and that their participation improves the quality and efficiency of cardiac arrhythmia management device care. It was also recognized that most physicians and their allied professionals (CEAPs) cannot be completely familiar with every aspect of each manufacturer's products. Therefore, this task force developed the following position statement to clarify the role IEAPs should play in the clinical environment. The objective of these position statements are to maintain and improve high quality and cost-effective care to patients with implanted cardiac rhythm devices, while further defining appropriate roles for IEAPs.

Position

1. The IEAP's role in the clinical environment is to provide technical expertise on the implant, use, and operation of their companies' equipment (including operation of programmers, analyzers, catheters, mapping systems, and other support equipment). Since IEAPs are not licensed or authorized to practice medicine, these activities are carried out at the request and direction of a physician. An IEAP trained in sterile techniques may participate in the implantation procedure, but as a rule should not enter the sterile field. The role of the IEAP during the procedure is to operate the programmers, analyzers, and other support equipment under the supervision of the physician; while also providing education and training to CEAPs. In the rare circumstance where the physician feels it is necessary for the IEAP to enter the sterile field, specific written request must be made, outlining the reasons. An IEAP may en-

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ter the operative field only after specific written approval from the institution's representative responsible for granting clinical privileges.

2. IEAPs should generally perform technical support tasks with the physician in close proximity. Close proximity is defined as the physician either in the same room or close enough within the facility and accessible to attend to the patient within a few minutes.

3. IEAPs may provide technical support/expertise to CEAPs (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 clinically employed allied professional. That level of supervision is still subject to the relevant regulations applicable to physician and allied provider practices.

4. IEAPs should not provide technical assistance in the clinical environment when they are alone and/or unsupervised by an appropriately trained or experienced physician.

5. IEAPs should not provide technical assistance in a patient's home in the absence of a responsible physician or his/her CEAP. 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. IEAPs should only provide technical assistance remote from supervision (i.e., in a nursing home facility) under rare and emergent circumstances. This should only occur in situations where the patient's condition and/or distance from the medical facility is such that it would be more detrimental to transfer the patient rather than provide the service remotely. The IEAP should only provide service remotely under written and direct order of 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 orally, but subsequently the physician is responsible for a written order and documentation of the episode in the patient's medical record.

6. IEAPs are not to provide technical assistance for a competitive manufacturer's device(s) unless the patient is in an immediately life-threatening condition. It is preferred that technical assistance by

IEAPs be limited to those devices manufactured by their own employers and/or contractors.

7. The support services of the IEAP are provided by the manufacturer to enhance the benefit of their product. A physician or CEAP is not prohibited from billing for services they deliver while an IEAP is assisting them. The patient or their health insurance provider should not be billed for services rendered solely by the IEAP. In some instances billing for these services may be considered fraudulent.

8. 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.

9. 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 physician 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.

*Ad Hoc NASPE/Industry Task Force: Participants representing NASPE included: James D. Maloney, M.D. (Co-Chair); John J. Hayes, M.D. (Co-Chair); Richard A. Juknavorian, M.Sc. (NASPE Staff); Daniel Kincaid, M.D.; Helen Barold, M.D.; Sandra Nishimura, RN, B.Sc.; and Mary Jane Rasmussen, RN.

Participants representing industry included: Bruce Johnson (Medtronic, retired); Neal Pfeifer (Medtronic); Jim Garrity (ELA Medical); Rich Sanders (Guidant); Joe Janda (Guidant); and Mark Bartell (Guidant). **Other contributing members:** Representing NASPE/CAP: Rosemary Bubien, R.N., M.S.N.; Melanie Gura, R.N., M.S.N. Representing NASPE Committee on the Development of Position Statements (CDPS): Blair Grubb, M.D.