

POLICY STATEMENT

North American Society of Pacing and Electrophysiology Standards of Professional Practice for the Allied Professional in Pacing and Electrophysiology

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Background and Significance

The North American Society of Pacing and Electrophysiology (NASPE) was established in recognition of the unique challenges that the management of patients with cardiac rhythm disorders present. As with other subspecialty fields within cardiology, the genesis of this specialty evolved from technological innovations and ensuing biomedical applications, which fueled the development of electrophysiological related interventions. The provision of services accompanying these technology-based interventions created an opportunity for health care professionals to specialize in the field of cardiac rhythm management. Known as Allied Professionals (APs), this diverse group of nurses, physician assistants, technologists, technicians, and engineers is dedicated to promoting excellence in the care of patients with cardiac rhythm disorders.

The provision of safe, optimal care is contingent on the coordinated efforts of multiple disciplines, the acquisition of a defined specialized knowledge base, and the application of knowledge and skills in rendering patient care and technical support services. The Standards of Professional Practice for the Allied Professional in Pacing and Electrophysiology have been developed to articulate the scientific foundation, clinical skills, and technical knowledge requisite to provide and facilitate the provision of safe quality patient care.

The Standards of Professional Practice address the scope of activities of the AP employed in the field of cardiac rhythm management. The first section, Core Knowledge and Skills, addresses essential areas of practice germane to the specialty to provide professional care and technical support services. Subsequent sections address knowledge requirements for specific technology-based interventions and therapies to patients undergoing invasive and noninvasive diagnostic, therapeutic,

and surgical procedures in cardiac pacing, defibrillation, and electrophysiology. It is recognized that these subsequent sections are not applicable to all APs.

The AP provides and facilitates the provision of technology-based interventions and therapies to patients undergoing invasive and noninvasive diagnostic, therapeutic, and surgical procedures in cardiac pacing, defibrillation, and electrophysiology. Guidelines addressing the roles of the individual professions in providing care and performing technical support services have been addressed in policy and position statements issued by the NASPE.

The distinction between the regulatory requirements governing the rendering of professional direct patient care and technical support services and their relationship to specific areas of employment is acknowledged. NASPE affirms that the AP must comply with and practice according to state, province, and country statutes. As directed by these regulations, patient care and technical support services are rendered in collaboration with and/or under the direct or indirect supervision of the physician.

Section I: Core Knowledge and Skills – Cardiac Rhythm Management

Overview

The goal of the core knowledge and skills standard is to establish that the AP acquires, maintains, and integrates knowledge of scientific principles, and derived technology-based interventions and therapies in cardiac pacing, defibrillation, and electrophysiology to provide and facilitate the provision of safe, optimal patient care. The AP in collaboration with and/or under the direct or indirect supervision of the physician:

1. Acquires, maintains, and integrates a knowledge base from the biomedical and physical sciences including physiology, pathophysiology, and the fundamentals of electronics.

2. Acquires and demonstrates the technical knowledge and clinical skills to assist in the care of

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patients who will undergo, are undergoing, or have undergone diagnostic, interventional, and therapeutic procedures.

3. Adheres to established standards to ensure a safe environment and promotes the delivery of optimal health care.

4. Serves as a patient advocate by adhering to ethical tenets and principles in clinical practice, and in the conduct of clinical trials.

5. Acquires and integrates principles from the social sciences to evaluate and provide psychosocial support to the patient and family.

6. Participates in patient and family education.

Core Standards and Required Elements

1. The AP acquires, maintains, and integrates a knowledge base from the biomedical and physical sciences including physiology, pathophysiology, and the fundamentals of electronics.

Required elements:

- Uses knowledge of pathophysiology and cardiovascular anatomy and physiology, including the electrical conduction system and cardiovascular hemodynamic principles.

- Applies scientific principles from the physical sciences to cardiac rhythm management.

- Demonstrates basic knowledge of human genetics and its relevance to the management of cardiac rhythm disorders.

- Identifies indications for technology-based evaluations, interventions, and therapies.

- Applies knowledge of surface and intracardiac electrocardiography.

- Integrates knowledge of pharmacology and physiology to anticipate and recognize effects of pharmacologic agents on the electrical conduction system, and contractility properties of the heart.

2. The AP acquires and demonstrates technical knowledge and clinical skills to assist in the care of patients who will undergo, are undergoing, or have undergone diagnostic, interventional, and therapeutic procedures.

Required elements:

- Applies scientific principles in the operation and evaluation of laboratory equipment and implanted cardiac rhythm management devices.

- Demonstrates technical knowledge to operate and troubleshoot equipment used for diagnostic, interventional, and therapeutic testing and evaluation of patients.

- Assists with obtaining measurements and monitoring of the patient's hemodynamic parameters.

- Participates in or conducts a health history and physical assessment of the patient.

- Uses data from laboratory tests, chest radiography, and diagnostics procedures.

- Formulates the patient's plan of care from assessment, procedures, and test data.

- Documents observations and communicates relevant information to the health care team.

3. The AP adheres to established standards to ensure a safe environment and promotes the delivery of optimal health care for the patient.

Required elements:

- Applies principles of aseptic and sterile techniques as appropriate.

- Uses and ensures use by others of body substance precautions.

- Minimizes radiation exposure to the patient and the health care team.

- Applies principles for maintaining an electrically safe environment for the patient and the health care team.

- Evaluates equipment for functionality and safety prior to use; troubleshoots malfunctions.

- Ensures that emergency equipment, supplies, and pharmacologic agents are available at all times.

- Ensures that an adequate number of qualified personnel are present to assist the physician during procedures.

- Anticipates potential responses to intervention and responds appropriately to provide patient care and technical support services in a timely manner.

- Intervenes to minimize procedural/device related symptomatology and potential complications.

4. The AP serves as a patient advocate by adhering to ethical tenets and principles in clinical practice and in the conduct of clinical trials.

Required elements:

- Practices within the legal scope of practice as defined by the appropriate licensing or regulatory authority.

- Applies ethical principles in clinical practice and in professional relationships.

- Complies fully with the patient's right to self-determination, including participating in the informed consent process for diagnostic and therapeutic procedures, clinical trials and investigational devices, advanced directives, the living will, and durable power of attorney for health care.

- Complies with guidelines addressing the ethical conduct in clinical trials like the International Conference on Harmonisation-Good

Clinical Practice Guidelines and The Belmont Report.

- Ensures individual patient rights including the rights to confidentiality, privacy, dignity, safety, comfort, and self-determination.
- Assumes appropriate responsibility and liability when caring for patients.

5. The AP acquires and integrates principles from the social sciences to provide psychosocial support to the patient and family.

Required elements:

- Assesses the anxiety level of the patient and family and anxiety reduction needs.
- Evaluates and determines psychosocial support system needs of the patient and family.
- Identifies potential barriers to compliance with medical plan of care for optimal clinical outcomes.
- Anticipates and verifies comfort and therapeutic measures.
- Communicates relevant information to the health care team.

6. The AP participates in, and conducts, when appropriate, patient and family education.

Required elements:

- Identifies learning needs and potential barriers to learning of the patient and family.
- Assesses learning level and readiness to learn.
- Provides education based on identified needs of the patient and family.
- Evaluates effectiveness of learning and accomplishment of learning objectives.
- Documents teaching/learning and communicates relevant information to the health care team.

Section II: Rhythm Management

A. Device Implantation

Overview

The goal of the device implantation standard is to establish that the AP will apply the knowledge and skills described in the core section to provide and facilitate the provision of safe, optimal patient care to patients who will undergo, are undergoing, or have undergone implantation of a cardiac rhythm management device. The AP in collaboration with and/or under the direct or indirect supervision of the physician:

1. Applies knowledge of cardiovascular physiology, pathophysiology, and pharmacology to assess the patient prior to the procedure and

when monitoring the patient for potential and actual physiological and behavioral changes intraprocedure and postprocedure.

2. Applies scientific principles and technical knowledge in the operation and evaluation of laboratory equipment and in the testing and evaluation of the implanted device.

3. Complies with regulatory guidelines addressing registration of implanted devices.

Standards and Required Elements

The AP applies knowledge of cardiovascular physiology, pathophysiology, and pharmacology to assess the patient prior to procedure and when monitoring for potential and actual physiological and behavioral changes intraprocedure and postprocedure.

Required elements:

- Identifies the significance of the underlying pathophysiological indications for device implantation.

- Observes and assesses the patient for potential and actual physiological and behavioral changes.

- Anticipates potential adverse responses, recognizes complications, and intervenes appropriately.

- Documents observations, perioperative complications, and communicates relevant information to the health care team.

2. The AP applies scientific principles and technical knowledge in the operation of laboratory equipment and in the testing and evaluation of the implanted device.

Required elements:

- Operates fluoroscopic table and recognizes anatomic landmarks and lead position of the implanted device.

- Performs measurement of cardiac stimulation, sensing, and defibrillation thresholds.

- Uses noninvasive programmable options to make patient-specific appropriate device system adjustments.

- Intervenes to minimize procedural/device related symptomatology and potential complications.

3. The AP complies with regulatory guidelines addressing registration of implanted devices.

Required elements:

- Documents lead and device performance.

- Documents and records registration of device with manufacturer in accordance with

regulatory guidelines, like The Safe Medical Devices Act.

B. Device Follow-Up

Overview

The goal of the cardiac rhythm management device follow-up standard is that the AP will apply the knowledge and skills described in the core section to provide and facilitate the provision of safe optimal patient care for the patient with an implanted device. The AP in collaboration with and/or under the direct or indirect supervision of the physician:

1. Facilitates optimal clinical effectiveness of the device through the application of technical knowledge and skills to evaluate device function.
2. Applies technical knowledge and clinical skills to minimize device related symptomatology and potential device related complications.
3. Participates in the monitoring of patients with implanted cardiac rhythm management devices under advisory or recall.

Standards and Required Elements

1. The AP facilitates optimal clinical effectiveness of the device through the application of technical knowledge and skills to evaluate device function.

Required elements:

- Performs or assists with cardiac rhythm management device evaluation via device interrogation and analysis of data.
- Determines stimulation and sensing thresholds, assesses intrinsic rhythm and pacemaker dependency.
- Conducts evaluation for ventriculoatrial conduction and for pacemaker mediated tachycardia (Endless Loop Tachycardia) when appropriate.
- Evaluates appropriateness of antitachycardia pacing, cardioversion, and defibrillation therapies.
- Determines appropriateness of rate-modulated (adaptive) pacing.
- Programs device parameters, controlling for optimal safety, longevity, and therapeutic needs of the patient.
- Anticipates and recommends elective device and/or lead replacement based on patient requirements and manufacturer guidelines.
- Plans and implements appropriate device surveillance at intervals based on individual patient requirements and recommended guidelines.
- Documents findings and parameters and communicates relevant information to the health care team.

2. The Allied Professional applies technical knowledge and clinical skills to minimize device related symptomatology, and potential device related complications.

Required elements:

- Identifies causes of failure to output, failure to capture, and sensing abnormalities.
- Recognizes patient symptoms and physiological signs of inappropriate or potential device system malfunction.
- Identifies appropriate measures and interventions to correct device malfunction.
- Identifies and intervenes appropriately for complications of device therapy.
- Documents lead and device performance, including anomalous behavior and/or malfunction of device system components.

3. The AP participates in the monitoring of patients with implanted cardiac rhythm management devices under advisory or recall.

Required elements:

- Participates in the assessment of the severity of a device recall/advisory, the degree of risk to the patient, and identifies appropriate actions to be taken.
- Implements appropriate/recommended recall, and advisory strategies.
- Participates in the education of the patient and family regarding a device recall or advisory.
- Documents advisories/recalls, patient response, and programming changes.
- Communicates relevant information to the health care team, manufacturers, distributors, and Regulatory Agencies in accordance with The Safe Medical Devices Act and Medical Device Amendment.

Section III: Electrophysiological Procedures

Overview

The goal of the electrophysiological procedures standard is that the AP will apply the knowledge and skills described in the core section to provide and facilitate the provision of safe, optimal care to patients who will undergo, are undergoing, or have undergone diagnostic, therapeutic, and interventional electrophysiological-based procedures. These procedures include arrhythmia provocation, arrhythmia mapping, transseptal puncture, catheter ablation, and external or internal cardioversion and defibrillation. The AP in collaboration with and/or under the direct or indirect supervision of the physician:

1. Applies scientific principles related to clinical electrophysiology to provide technical support and patient care services.

2. Acquires and demonstrates technical knowledge and clinical skills to operate laboratory equipment and troubleshoot equipment malfunction.

3. Integrates knowledge of cardiovascular physiology, pathophysiology, pharmacology, and electrical techniques and interventions being performed to monitor the patient for potential and actual physiological and behavioral changes intraprocedure and postprocedure and intervenes appropriately.

Standards and Required Elements

1. The AP applies scientific principles related to clinical electrophysiology to provide technical support and patient care services.

Required elements:

- Describes the principles of electrophysiological testing.
- Demonstrates knowledge of the clinical indications for electrophysiological studies.
- Implements programmed electrical stimulation protocols and measurements related to the functional properties of the conduction system and induced arrhythmias.
- Differentiates the origin and route of conduction of tachycardia-related and bradycardia-related arrhythmias based on interpretation of intracardiac and surface electrocardiograms.
- Identifies the clinical significance of induced tachyarrhythmias and bradyarrhythmias.
- Documents indications and relevant findings for electrophysiologically guided procedures.

2. The AP acquires and demonstrates technical knowledge and clinical skills to operate laboratory equipment and troubleshoot equipment malfunction.

Required elements:

- Operates physiological recording system and computerized mapping systems.
- Operates stimulator to deliver programmed electrical stimulation to induce arrhythmia

and evaluate properties of the conduction system upon physician direction.

- Operates fluoroscopic table and recognizes anatomic landmarks and location of catheter position.

- Operates ablation generator systems.
- Operates emergency equipment.
- Participates in head-up tilt table testing.

3. The AP integrates knowledge of cardiovascular physiology, pathophysiology, pharmacology, and electrical techniques and interventions being performed to monitor the patient for potential and actual physiological and behavioral changes intraprocedure and postprocedure.

Required elements:

- Assesses intracardiac and surface electrocardiography.
- Observes and assesses the patient for potential and actual physiological and behavioral (physical and psychosocial) changes preprocedure, intraprocedure, and postprocedure.
- Anticipates potential adverse response, recognizes complications, and intervenes appropriately.
- Administers anticoagulation agents and monitors activated clotting time (ACT) under the direction of a physician and institutional policy.
- Administers pharmacologic agents including IV sedation/analgesia.
- Evaluates appropriate implanted device function prior to and following therapeutic intervention.
- Determines atrial and/or ventricular stimulation and sensing thresholds.
- Documents physiological findings, interventions, and device evaluation and communicates relevant information to the health care team.

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