Procirca

Intraoperative Neurophysiological Monitoring Standards of Practice

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Introduction

Intraoperative neurophysiologic monitoring (IOM) has established standards governing "best practice." These form the core of Procirca's approach to IOM. The Procirca Center for Clinical Neurophysiology (CCN) continuously reviews and updates these standards in concert with changes in our knowledge of IOM. Procirca's model and approach is based on decades of experience, peer reviewed literature, guidelines established by governing societies, and best medical practice.

Components of IOM

Procirca recognizes that the following components are critical for quality IOM service delivery:

- I. Staffing Model
- II. IOM Service Delivery Standards
- III. Continuing Education
- IV. Quality Assurance/Quality Control/Performance Improvement Metrics
- V. Policies and Procedures
- VI. IT and HIPAA Compliance

I. Procirca Staffing Model

Organization

The following outlines the fundamental and essential model for the establishment, execution and maintenance of IOM services by Procirca. IOM has both professional (interpretive) and technical components. To that end, Procirca has physician and doctoral level personnel providing the professional component as well as bachelor's and master's level personnel providing the technical and managerial components.

Procirca Medical Director

Procirca's Medical Director ensures that IOM delivery is consistent with current medical practices and guidelines. In addition to providing supervision on individual procedures, Procirca's Medical Director is prominently involved in the day-to-day operations of IOM.

Procirca's Medical Director is a board-certified neurologist with fellowship training in clinical neurophysiology and IOM. Furthermore, our Medical Director is licensed to practice medicine in each state where Procirca delivers IOM services and is on staff with privileges to perform IOM at the hospitals where Procirca provides all IOM services.

Procirca Clinical Neurophysiologists

Procirca's Clinical Neurophysiologists supervise, interpret and/or perform IOM in every case. Clinical Neurophysiologists are assigned to a case(s) and are responsible for ensuring that IOM is performed according to Procirca's standards. Specifically, Procirca's Clinical Neurophysiologists are responsible for providing interpretations regarding the meaning of all significant changes in the IOM. Whether interpretations are provided in-person or by real-time remote monitoring, it is imperative that the Neurophysiologist provide an interpretation in a clinically meaningful time frame after the onset of a significant change.

Procirca's Clinical Neurophysiologists are board-certified (IOM) physicians or non-physician doctoral level individuals who have demonstrated skill and expertise in the field of IOM, as well as continuing clinical experience in the field of IOM. All Clinical Neurophysiologists work with and under the general supervision of the Medical Director. Every case, regardless of day or time, is overseen contemporaneously by a Procirca Clinical Neurophysiologist. All Clinical Neurophysiologists are credentialed and privileged to provide supervision and interpretation of IOM data at every institution where they provide IOM services.

Procirca Technologists

The technical component of IOM is performed by a certified, experienced, and qualified Procirca technologist.

The general responsibilities of our technologists have been described by the American Society of Electroneurodiagnostic Technologists (ASET) and are outlined in Procirca's Policy & Procedure manual. Procirca's technologists prepare the patient for IOM, operate the IOM equipment, record data, recognize quality data and changes in data, and communicate with the Clinical Neurophysiologist in real-time during all procedures utilizing IOM.

In order to provide high quality care, Procirca ensures that technologists are appropriately trained and qualified before providing IOM services. Moreover, Procirca's technologists do not independently perform IOM (without on-site supervision of another certified technologist and Clinical Neurophysiologist oversight) until they successfully complete our comprehensive in-house training program, demonstrate competence via internal standards, successfully pass the CNIM examination (abret.org) and become certified.

Procirca technologists are never asked to independently provide interpretation of IOM to the surgical team. As such, a Procirca board-certified Clinical Neurophysiologist is always (24 hours a day, seven days a week, 365 days a year) available either physically or by real-time remote connection, to contemporaneously review the recordings, provide an interpretation, and develop a differential diagnosis.

Procirca never provides IOM services without a technologist in personal attendance in the OR during the entire course of the surgical procedure. This includes a policy that two procedures are never monitored simultaneously by one technologist. As per each institution's guidelines, all Procirca technologists are credentialed at every facility where IOM services are provided.



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II. Procirca IOM Service Delivery Standards

Prior to Surgery

The IOM approach and planning for each case is discussed prior to the commencement of surgery. This includes a review of the patient's history and physical, a review of relevant diagnostic testing (if possible), and a discussion with the neurophysiologist, technologist, and the anesthesia and surgical teams concerning the optimal IOM approach for that specific procedure. Procirca also relies on a detailed, reference and guideline-driven Policy & Procedure manual as a standard for IOM protocols as they relate to a specific procedure.

Baseline IOM Recording

Procirca technologists obtain baseline recordings as soon as possible but at least prior to skin incision. It is our policy to obtain baselines prior to patient positioning in order to determine if there are any position related changes in the monitoring. All baseline recordings are interpreted for suitability of recording and normalcy based on the patient's preexisting neurological status and normative data. This interpretation is performed by the Clinical Neurophysiologists and conveyed to the surgical team prior to skin incision so that decisions concerning proceeding with the procedure can be made.

Perioperative IOM Recording

During the procedure, all IOM data is continuously collected, reviewed and archived by a Procirca technologist. All data is viewable, from virtually any location, in real-time by the Clinical Neurophysiologist. An open line of communication between the technologist and Clinical Neurophysiologist occurs in every case for its entirety. Significant changes in data are identified based on pre-established standards outlined in Procirca's Policy & Procedure manual. The standards in the Policy & Procedure manual are based on peer-reviewed literature and societal guidelines. Once significant change is identified and established, the Clinical Neurophysiologist interprets the change, develops a differential diagnosis, and makes timely recommendations to the surgical team with regards to addressing/reversing the change in IOM data.

IOM Documentation

Procirca technologists maintain detailed documentation during every procedure. Documentation includes patient demographic information, details of monitoring, patient H&P, a narrative of surgical events, physiologic parameters which include blood pressure, temperature and the rate of administration (or concentration) of various anesthetics, and all communications between the technologist, Clinical Neurophysiologist, and the surgical or anesthesia teams.

Procirca Interpretive Reports

Procirca generates a professional report for every monitored procedure. The report contains the monitoring approach, including the monitoring modalities, interpretation of IOM baselines, interpretation of any significant changes in the IOM data, and any and all communications made with the surgical team during the procedure. Procirca always provides a professional report for each procedure monitored. A copy of the report is sent to the surgeon of record, and a copy is placed in the patient's electronic medical record.

III. Procirca Continuing Education

 $Procirca\ requires\ and\ provides\ for\ ongoing\ continuing\ education\ for\ both\ the\ technical\ and\ professional\ staff.$

Upon request, Procirca provides all documentation of continuing educational programs for all staff. Continuing education for technologists is mandatory and provided internally via Procirca's ASET certified education program as well as external credits acquired from attending local and national IOM meetings. Procirca provides educational opportunities to all staff at least once every month. Every Procirca technologist has all of their educational activities and credit logged and documented. All Procirca technologists are members of ASET and receive the quarterly journal of the Neurodiagnostic Society. Once CNIM certified, Procirca technologists must obtain 50 CEUs every five years for recertification.



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IV. Quality Assurance/Quality Control/Performance Improvement

Quality Assurance/ Quality Control

Procirca tracks numerous technologist quality assurance metrics and conducts serial reviews of documentation for adherence to policy and procedure. Moreover, patient clinical outcomes are regularly reviewed and documented. This data is compared to IOM data for sensitivity and specificity measures. Unanticipated neurological deficits are discussed and presented for discussion and explanation with all staff.

Performance Improvement

Procirca actively reviews and proactively improves the quality of their IOM services. We use a formal approach to the analysis of performance metrics and employ systematic approaches to improve it. Specific metrics addressing the delivery of all aspects of the IOM service and adherence to policy and procedure are recorded for every IOM procedure performed. These activities are all documented and reviewed on a regular basis.

V. Policies and Procedures

Procirca authors and maintains a clear, detailed and up-to-date IOM Policy & Procedure manual. Procirca's clinical policies and procedures are dated and signed off on by the Medical Director. A copy of the Procirca Policy & Procedure manual is available on-line for review and can be accessed from any location where Procirca performs IOM services. A copy of our Policy & Procedure manual is available upon request of the institution where IOM services are being provided.

Procirca's Policy & Procedure manual is reviewed and updated at least yearly. This review is documented by Procirca's Medical Director.

VI. IT and HIPAA Compliance

Data Storage and Archiving

All data (all modalities) collected by Procirca technologists is saved, stored and backed-up for a pre-determined period of time, as dictated by state laws concerning the retention of medical records. All data is stored on secure servers, partitioned and available for review at all times. Access to archived data is available to both the Procirca IOM team and the hospital at which the data was collected. At the end of each procedure, options include storage of data at the site where it is collected or archiving off-site on a secure Procirca server.

Protected Health Information (PHI) and Networking

Secure (encrypted, authenticated, authorized) connections between the Procirca technologists and neurophysiologists are established in each case in order to comply with the contemporaneous oversight stipulations outlined above.

PHI is never transported on mobile devices (laptops) after cases are completed. Any and all patient data and identifiers are uploaded and archived to a secure server and then securely erased after each procedure. In order to prevent breaches of PHI, this process occurs while the equipment is on site.

For each hospital or facility, Procirca establishes a mutually agreed upon security plan for data transfer between the site where IOM data is being collected (i.e., the operating room) and the routing of data off-site for interpretation and/or archiving.

