

Testimony of Daniel M. Schwartz, Ph.D. on the Historical Role of the Audiologist in Intraoperative Neurophysiological Monitoring in the State of Pennsylvania and the United States of America

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The genesis of intraoperative neurophysiological monitoring (IONM) in the United States came in 1977 from the seminal work of Richard Brown, Ph.D. a biomedical engineer from Cleveland, OH, and Clyde Nash, MD, a pediatric orthopaedic surgeon, who were the first to describe the application of monitoring spinal cord function continuously using cortical somatosensory evoked potentials during surgical correction of scoliosis in children. Shortly thereafter, in 1979, Aage Moller, Ph.D., an auditory physiologist working with Peter Jennetta, MD, then Chairman of Neurosurgery at the University of Pittsburg Medical Center (UPMC) described methodology to monitor the functional status of the auditory and facial nerves during operations in the brainstem for tumor removal. In 1981, Daniel M. Schwartz, Ph.D., Director of Audiology at the Hospital of the University of Pennsylvania (HUP) introduced intraoperative neuromonitoring as an independent clinical service for neurosurgery, vascular surgery, ear nose and throat surgery and orthopaedic surgery in Philadelphia.

A review of the limited landscape of IONM during the pioneering 1980s shows that the vast majority of professionals actually providing such a clinical service were Audiologists like Dr. Schwartz, not physicians. For example, Paul Kileny, Ph.D, Director of Audiology at the University of Michigan Medical Center, Gary Jacobson, Ph.D. Director of Audiology at the University of Cincinnati Medical Center, J. Michael Dennis, Ph.D., Director of Audiology at the University of Oklahoma Medical Center, Gayle Hick, Ph.D., Director of Audiology at the Children's Hospital of San Diego, Jeffrey Owen, Ph.D. Audiologist, Director of Intraoperative Neurophysiological Monitoring, Barnes Hospital, St. Louis, Mo., William Martin, Director of Audiology, Temple University Hospital, Joseph Danto, Ph.D. Director of Audiology, Kingsbrook Hospital, Brooklyn, NY, all were among the foremost pioneers working to advance the scope of knowledge in this infant clinical neurophysiology specialty field. In fact, with the exception of less than a handful of neurologists and just a few anesthesiologists, audiologists performed the vast majority of intraoperative monitoring during the 1980s and early 1990s in the USA. This was particularly true in Pennsylvania. For example, in addition to Dr. Schwartz, there were four other audiologists involved in the delivery of IONM at the HUP in the 1980s and well as William Martin, Ph.D., Director of Audiology, Temple University Hospital, Philadelphia, PA.

Further evidence as to the significant role Audiologists played in the development of the field of IONM comes from the formation of the American Society of Evoked Potential Monitoring in 1985 (renamed the American Society of Neurophysiological Monitoring, 1990). Of the 11 professionals who met in Detroit, MI in November

1984 to discuss the formation of a society dedicated to the advancement of knowledge and the education in this nascent discipline, only four were physicians; two surgeons, and two anesthesiologists. The remaining seven consisted of six Audiologists and one auditory physiologist (Dr. Moller). Absent was a neurologist.

Perhaps the most indisputable confirmation as to the primacy of Audiologist involvement in IONM came as early as 1992 when the first professional level scope of practice statement dedicated to the clinical practice of intraoperative monitoring was published by the American Speech, Language and Hearing Association as a subspecialty of Audiology. In fact, it still remains the only licensed health-care profession to have a dedicated scope of practice in IONM and now is the only one to have a dedicated Specialty Board Certification specifically for IONM.

It is interesting on an historical note that throughout the 1980s and early 1990s, physicians were entirely disinterested in involving themselves with IONM owing to the demand for long hours working in the operating, night and weekend on-call responsibilities and inability to obtain reimbursement from third-party insurance carriers since so few recognized IONM as a formal clinical entity.

In 1987, Denis Drummond, a world renowned pediatric spine surgeon and new Chief of Pediatric Orthopaedic Surgery at the Children's Hospital of Philadelphia (CHOP) approached Dr. Schwartz and asked if he would be willing to develop a spinal cord monitoring program at CHOP for children undergoing surgical correction of scoliosis. Dr. Drummond indicated that he had spoken to the neurology service and asked them to initiate such a program; however, it was a total failure since all they did was send in an EEG technician who was completely unskilled and uneducated in the field and the MD also was unknowledgeable as to the vast differences between intraoperative neurophysiological monitoring and diagnostic neurophysiologic testing. In his peer reviewed publication entitled "Four Decades of Advancement for the Surgical Treatment of Spinal Deformity" (University of Pennsylvania Orthopaedic Journal, 19: 2008-2009) Dr. Drummond wrote the following:

"Daniel M. Schwartz, Ph.D. a long time colleague of mine, has clearly been the leader in this field and has been at the forefront of multimodality spinal cord monitoring. Also, he has published the seminal studies in this discipline."

In July 1990, Dr Schwartz left the HUP and formed the first private IONM practice in Philadelphia, Surgical Monitoring Associates, and one of only two such practices in the state of Pennsylvania. Moreover, of the 10 IONM private practices in the USA in the 1990's, all but two were owned by Audiologists; the others by two Ph.D. Biomedical Engineers. No physician was involved in providing IONM services outside a small minority of large academic medical centers. Moreover, there remained less than 8-10 neurologists involved in any aspect of IONM in the entire USA, none of whom were dedicated solely to this practice.

Ironically, following Dr. Schwartz's departure from the HUP in 1990, the opportunity existed for the Department of Neurology to assume the responsibility for providing the IONM services to the ever-growing list of neurosurgeons, otolaryngology, head and neck surgeons, vascular surgeons, and orthopaedic surgeons. Instead, however, following consultation with the chiefs of the various surgical specialties, the hospital administration elected to ask William Martin, Ph.D., Director of Audiology and Neuromonitoring at Temple University Hospital to assume Dr. Schwartz's responsibilities.

Dr. Schwartz went on to build one of the largest and most clinically advanced IONM private practices in the USA, delivering IONM services to virtually every hospital in the Philadelphia and surrounding area including such notable hospitals as the Children's Hospital of Philadelphia, St. Christopher's Hospital for Children, Hahnemann Hospital, Thomas Jefferson University Hospital, Presbyterian Hospital of the University of Pennsylvania, Pennsylvania Hospital, Lehigh Valley Hospital, as well as most community hospitals in eastern Pennsylvania.

A review of the surgical literature as well as authored book chapters related to IONM published in surgical journals serves as further testimony of Audiologist expertise and involvement in all phases of IONM. Further validation as to Audiologist expertise in IONM in general and spinal cord and nerve root monitoring in particular, comes from the Society for Research In Scoliosis (SRS), the largest spine surgery society in the world. In 2009 the SRS published an Information Statement entitled "Neurophysiological Monitoring of Spinal Cord Function During Spinal Deformity Surgery" which stated "...Also, the American Academy of Audiology and the American Speech, Language and Hearing Association have scope of practice statements indicating that licensed audiologists with specialty training in intraoperative neurophysiological monitoring are among those professionals capable of rendering an interpretation of the intraoperative monitoring data."

In reality, physician interest in IONM throughout the USA in general and in Pennsylvania, in particular, did not appear in earnest until third-party insurance carriers began reimbursing for the service beginning in around the late 1990s into the early 2000s. Then, and only then did they decide not only that perhaps this was a worthwhile endeavor, but also that they should be the only professionals responsible to provide the service.

Yet, physicians themselves did not want to be burdened with spending exceedingly long hours in an operating room. Rather, they thought it sufficient to send a technician with no formal education or training to provide direct patient care and simply to report back to the physician should they note a problem. Quite simply, neither the EEG technicians nor the neurologist or other physician had any expertise in IONM, thereby raising significant question as to patient safety.

The unfortunate mistake that has been made both by insurance companies and politicians is that a license to practice medicine in general and neurology in particular, equates to the physician having specialized training, knowledge and expertise in intraoperative neurophysiological monitoring.

More than three decades since the pioneering efforts of the real pathfinders of this now burgeoning health-care specialty, there has yet to be a formal dedicated board certification process to ensure at least minimal level competency for physicians, including neurologists. For neurologists who have completed a specialty fellowship in clinical neurophysiology, usually diagnostic electroencephalography or electromyography, there is a subset of questions on the board exam related to IONM, but no dedicated exam solely for IONM.

Conversely, there has been in existence since 1999 the Diplomate of the American Board of Neurophysiological Monitoring (DABNM), a professional board examination-verifying competency in both the interpretative and technical aspects of IONM. The DABNM is open both to non-physician and physician providers who hold graduate academic degree in the health or biological sciences, demonstration of 300 hours of clinical practice under supervised direction of an existing DABNM, and successful completion of a written and oral exam. Yet, few physicians across America hold such certification attesting to competency. Moreover, there now exists a Specialty Recognition Board for IONM solely for Audiologists (American Audiology Board of Intraoperative Neurophysiological Monitoring, 2012). No such board exists for physicians. Hence, there is nothing to verify competency outside of a generic license to practice medicine.

The challenge by the Pennsylvania Medical Society (PMS) against audiologists being recognized as licensed providers of IONM services without physician oversight not only is unsubstantiated on the basis of the plethora of historical, publication and clinical practice evidence, but is apparently driven solely by reasons of medical economics rather than actual concern for patient safety. The fact is that there simply is not enough qualified and specialty trained physician resources throughout the United States, let alone in Pennsylvania, to meet the ever-growing demand for IONM across the myriad surgical specialties. To equate an MD or DO with competency in this highly specialized field, with no specific training or experience, is antithetical to the heightened concerns for patient safety that surround health care delivery today.

The PMS's challenge is not even supported by the American Medical Association language as to who is a "qualified health-care provider" as per "Current Procedural Terminology" definitions for third-party billing for professional health-care services which states:

“A physician or other qualified health-care provider” is an individual who is qualified by education, training, licensure regulation (when applicable) and facility privileging (when applicable), who performs a professional service within his/her scope of practice and independently reports that professional service. These professionals are distinct from “clinical staff”. A clinical staff member is a person who works under the supervision of a physician or other qualified professional and who is allowed by law, regulation and facility policy to perform or assist in the performance of a specified professional service, but who does not individually report professional service. Other policies may also affect who may report a specific service.”

To be sure, by nature of a published scope of Audiology Practice dedicated to IONM since 1992, an independent specialty board certification in IONM and a long history of pioneering clinical activity in IONM, Audiologists actually are more or equally qualified as a physician to engage in the total practice of intraoperative neurophysiological monitoring. Failure of the State of Pennsylvania to recognize this Audiology licensure component would limit patient access to the most qualified professionals for performing IONM and interpreting the pertinent data and would restrict the available manpower resources necessary for providing this important patient safety clinical service.

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Position Statement

Neurophysiologic Intraoperative Monitoring

Ad Hoc Committee on Advances in Clinical Practice

About this Document

This was prepared by the American Speech-Language-Hearing Association (ASHA) Ad Hoc Committee on Advances in Clinical Practice: Donald E. Morgan, chair; Carol M. Frattali, ex officio; Zilpha T. Bosone; David G. Cyr; Deborah Hayes; Krzysztof Izdebski; Paul Kileny; Neil T. Shepard; Barbara C. Sonies; Jaclyn B. Spitzer; and Frank B. Wilson. Diane L. Eger, 1991–1993 vice president for professional practices, and Teris K. Schery, 1988–1990 vice president for clinical affairs, served as monitoring vice presidents. The contributions of the Executive Board, and select and widespread peer reviewers are gratefully acknowledged. The Legislative Council approved the document as official policy of the Association at its November 1991 meeting (LC 51F-91).

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I. Introduction

Speech-language pathology and audiology are dynamic and expanding professions with constantly developing technological and clinical advances. Before conducting procedures involving such advances,

practitioners must have acquired the knowledge, skills, education, and experience necessary to perform them competently. This policy statement is one of seven documents¹¹¹ developed by the Ad Hoc Committee on Advances in Clinical Practice. Each statement expresses the position of the American Speech-Language-Hearing Association (ASHA) concerning specific clinical procedures within the scope of practice of speech-language pathology or audiology, most of which have developed only within the last few years. Each statement further provides guidelines for practitioners performing these procedures. The guidelines consider the knowledge and skills normally associated with the required competencies, the clinical settings recommended for the procedure, and the appropriate involvement of personnel from other disciplines.

Clinical certification by ASHA ensures that practitioners have met the education, knowledge, and experience requirements established by the Association for providing basic clinical services in the professions of speech-language pathology or audiology. Certification in the appropriate profession is necessary, but not sufficient to perform the specific clinical procedure(s) discussed in this statement. The procedure(s) addressed in this document requires the practitioner to obtain education and training beyond that necessary for ASHA certification. Practitioners are bound by the ASHA Code of Ethics to maintain high standards of professional competence. Therefore, practitioners should engage only in those aspects of the professions that are within the scope of their competence, considering their level of education, training, and experience.

In promulgating this policy statement, there is no intention to imply that the practitioner holding ASHA Certification is prepared to conduct the procedure(s); nor is it incumbent on any certified professional to provide the procedure(s) merely because the practitioner holds certification.

The following document is intended as guidelines for the practitioner to ensure the quality of care, welfare, safety, and comfort of those served by our professions.

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II. Background

Neurophysiologic intraoperative monitoring involves continuous direct or indirect electrophysiologic measurement and interpretation of myogenic and neural responses to intraoperative events or modality-specific, controlled stimulation in the course of surgery on or in the vicinity of those structures. An important aspect of intraoperative monitoring is the on-line, moment-to-moment correlation between changes in neurophysiologic responses and intraoperative events. The purpose of intraoperative monitoring is to facilitate the maintenance of the functional and structural integrity of neural structures, at risk for iatrogenic injury.

The principal objectives of neurophysiologic intraoperative monitoring are: (a) to avoid intraoperative injury to neural structures; (b) to facilitate specific stages of the surgical procedure; (c) to reduce the risk of

permanent postoperative neurological injury; and (d) to assist the surgeon in identifying specific neural structures.

As this clinical procedure has developed over the past several years, a variety of disciplines have been involved in its development and practice. Prominently figuring among such disciplines as neurology, neurophysiology, anesthesiology, and others is the profession of audiology. Therefore, in many clinical settings, audiologists deliver or are expected to deliver this clinical service.

It is important to note that neurophysiologic intraoperative monitoring is an interactive process involving close collaboration and interaction between the surgical and the monitoring team. Therefore, it is only effective if both parties are knowledgeable and in agreement about the limitations and goals of intraoperative monitoring.

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III. Purpose

The purpose of this position statement is to assist audiologists who are involved in, and those who plan to be involved in, intraoperative monitoring. Specifically, the purposes are: (a) to inform audiologists that performing neurophysiologic intraoperative monitoring is within the scope of practice of audiology; (b) to define the procedure known as neurophysiologic intraoperative monitoring; (c) to advise audiologists of the education, training, circumstances, and precautions that should be considered prior to undertaking this clinical activity; (d) to provide guidance for audiologists as to the knowledge and skills required to perform neurophysiologic intraoperative monitoring; and (e) to educate health care professionals, consumers, and the general public of the services offered by audiologists as qualified health care providers.

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IV. Scope of Practice

It is the position of the American Speech-Language-Hearing Association (ASHA) that neurophysiologic intraoperative monitoring is within the scope of practice of audiologists with the appropriate knowledge base and skills. The purpose of neurophysiologic intraoperative monitoring is to assist surgeons to minimize or avoid altogether the occurrence of intraoperative injury to neural structures at risk due to the nature of the pathology and their proximity to the surgical field. The practice of neurophysiologic intraoperative monitoring by an audiologist requires knowledge in neuroanatomy and neurophysiology, with special emphasis in neurodiagnostic techniques and their intraoperative applications. In addition, familiarity with the surgical procedure, effects of surgical manipulations and pharmacologic agents on neurophysiologic events, and the ability to recognize those events also is required.

If practitioners choose to perform these procedures, indicators should be developed, as part of a continuous quality improvement process, to monitor and evaluate the appropriateness, efficacy, and safety of the procedure conducted.

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V. Education and Training

Appropriate education and training are the cornerstones of involvement in intraoperative monitoring by audiologists. These should include relevant and appropriate academic training, followed by extensive clinical training in a setting providing the opportunity to be involved in a sufficient number of cases, under the supervision of experienced and competent professionals. It is the practitioner's responsibility to determine whether he/she has obtained the appropriate type and sufficient degree of education and training to be competent in the performance of neurophysiologic intraoperative monitoring. The specific education and training may vary for each type and modality of intraoperative monitoring. For instance, appropriate background and experience in monitoring posterior cranial fossa surgical procedures does not automatically ensure competence in the monitoring of somatosensory evoked potentials during spinal-cord surgery.

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VI. Precautions

Each practitioner should consider the following precautions or circumstances prior to undertaking intraoperative monitoring:

1. Inform institutional and/or regulatory bodies, such as state licensure boards, about these procedures as within the scope of practice;
2. Check with appropriate state licensure boards to ensure that there is no limitation imposed on the scope of audiology practice that restricts the performance of neurophysiologic intraoperative monitoring;
3. Check professional liability insurance to ensure that there is no exclusion applicable to this procedure;
4. Follow the universal precautions to prevent the risk of disease from blood-borne pathogens contained in the Centers for Disease Control *Morbidity and Mortality Weekly Report* (June 24, 1988, *Perspective in Disease Prevention and Health Promotion*, 37 (24), 377-388 or ASHA's AIDS/HIV Update (*Asha*, 1990);
5. Know whom to contact in the event of a medical emergency;

6. Obtain the informed consent of the patient/client, and maintain complete, and adequate documentation.

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VII. Roles and Definitions

The audiologist has the responsibility of preoperative patient preparation, including placement and securing recording electrodes and stimulators or transducers to avoid interfering with or being dislodged during the surgical procedure. If subdermal needle electrodes are used for recording or stimulus purposes, their placement may be the responsibility of the audiologist or of a surgeon, as dictated by each institution's policies and procedures. The audiologist is responsible for determining, prior to sterile draping, that the recording electrodes have adequate low impedances and that the stimulators or transducers are delivering the appropriate stimuli in an undisturbed fashion.

The audiologist is also responsible for operating the electrophysiological equipment used in intraoperative monitoring, including its proper maintenance, function, and calibration. The selection of appropriate recording and stimulus parameters is also the responsibility of the audiologist, including safe stimulation, whether or not stimulus modality is acoustic or electric. The audiologist is also responsible for providing safe, effective, high-quality, artifact-free, interpretable recordings.

The on-line intraoperative interpretation of the recorded neurophysiologic responses or events and their correlation with relevant intraoperative surgical events is also the responsibility of the audiologist. This needs to be carried out by means of close interaction and collaboration with the surgical and anesthesia team. The audiologist must apply knowledge of the effects of anesthetics and other intraoperatively administered pharmacologic agents and the knowledge of the surgical procedure to carry out this responsibility, which involves the capability of making on-line distinctions between relevant and irrelevant neurophysiologic changes and, with a good understanding of the limitations imposed by the surgical procedure, to communicate this information to the surgical team in anticipation of steps taken by the surgeon to correct the problem. The audiologist also needs to communicate to the surgical team when a potential problem has been corrected so that surgery may proceed at an optimal pace.

At times, neurophysiologic monitoring involves direct electrical stimulation of the neural or surrounding tissue for the purposes of identification and the determination of morphology, topography, and functional status. The electrical current stimulus may be delivered by means of a hand-held probe by the surgeon or by previously attached surface electrodes. It is the audiologist's responsibility to ascertain that appropriate, safe current levels are being delivered. This implies that the level has to be adjusted to be effective but not potentially damaging.

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VIII. Knowledge and Skills

In order to be effective in the performance of intraoperative monitoring, audiologists should have the following knowledge base and skills:

1. Fundamental knowledge in basic and applied neuroanatomy and neurophysiology;
2. Fundamental and applied knowledge in the measurement of bioelectric signals;
3. Fundamental and practical knowledge in electronic instrumentation used in clinical neurophysiology applications;
4. A practical working knowledge of clinical neurophysiology/neurodiagnostic procedures, including technical and interpretive/diagnostic aspects, particularly those related to the neural systems to be monitored in the operating room;
5. A basic knowledge of medical and surgical considerations as they pertain to the procedures to be monitored. The audiologist needs to have a good theoretical knowledge of the specific surgical procedure, anatomical structures encountered, and risk factors specified to the particular surgical procedures;
6. A fundamental understanding of anesthesia and the effects of pharmacological agents used in the operating room on the electrophysiologic events and responses monitored during surgery;
7. A solid understanding of the biological mechanism involved in the electrical stimulation of neural tissue, safe limits of stimulation, and the identification of false-positive and false-negative outcome resulting from electrical stimulation. When the electric stimulus is applied manually by the surgeon by means of a handheld monopolar or bipolar probe, it is the audiologist's responsibility to control the stimulus delivery, including rate and intensity.
8. Direct supervised experience in neurophysiologic intraoperative monitoring, prior to independently monitoring surgical procedures, is necessary. The audiologist should also have a thorough understanding of operating room conditions, sterile fields, and general operating room etiquette.

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References

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Centers for Disease Control. (1988). *Morbidity and mortality weekly report: Perspectives in disease prevention and health promotion*, 37, 377–388.

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Notes

[1] The documents include position statements and guidelines for balance system assessment, electrical stimulation for cochlear implant selection and rehabilitation, evaluation and treatment for tracheoesophageal fistulization/puncture, external auditory canal examination and cerumen management, instrumental diagnostic procedures for swallowing, neurophysiologic intraoperative monitoring, vocal tract visualization and imaging.

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Index terms: monitoring, assessment

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