The theme of the 10th Annual Meeting of the North American Neuromodulation Society (NANS) was “Neuromodulation: Coming of Age.” Held at the Wynn Hotel in Las Vegas, this exciting conference was attended by 447 neuromodulators, in addition to more than 200 industry representatives. This meeting demonstrated that, in fact, neuromodulation has come of age. All sessions were well attended; many of them had standing room only. The level of enthusiasm was perceptible.

Congratulations to Ali Rezai, MD, Program Chairman, on an extraordinary job of putting this meeting together. NANS was formed more than a decade ago by a handful of physicians sitting around a table with two industry representatives. In the last year our membership has grown to more than 500 individuals. There are now three major medical companies that manufacture devices that are implanted for the control of pain, movement disorders, and an ever-growing list of applications. Estimates vary on the penetration of these modalities in the patient population that could potentially benefit from them. These estimates are consistently small—less than 10%. Thus, 10 times the number of patients who are being considered for neuromodulation could potentially benefit from these modalities.

The two largest impediments to greater adoption of these technologies are ignorance and lack of insurance coverage. Ignorance can be overcome by creating greater awareness through a variety of means. Coverage obstacles present a greater challenge. The ever-expanding use of evidence-based medicine has created greater difficulties for authorization of neuromodulation because of the lack of class 1 data.

Smith and Pell (2003) wrote an article in the British Medical Journal titled “Parachute Use to Prevent Death and Major Trauma Related to Gravitational Challenge: Systematic Review of Randomised Controlled Trials” (see abstract above). The article concludes that “as with many interventions intended to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised control trials. Advocates of evidence based medicine have criticised the adoption of interventions evaluated by using only observational data. We think that everyone might benefit if the most radical protagonists of evidence based medicine organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute.”

This is more than black humor. The reality is that it is nearly impossible, both ethically and methodologically, to perform a randomized, placebo-controlled crossover trial of an implantable device. One cannot subject patients to either sham implantations or implantations of placebo devices. Thus, the literature supporting the use of neuromodulatory procedures does not predominantly stand up to Cochrane criteria. Insurers are using this phenomenon to deny coverage using evidence-based criteria alone.

Parachute Use to Prevent Death and Major Trauma Related to Gravitational Challenge: Systematic Review of Randomised Controlled Trials

Objectives: To determine whether parachutes are effective in preventing major trauma related to gravitational challenge.

Design: Systematic review of randomised controlled trials.

Data Sources: Medline, Web of Science, Embase, and the Cochrane Library databases; appropriate internet sites and citation lists.

Study Selection: Studies showing the effects of using a parachute during free fall.

Main Outcome Measure: Death or major trauma, defined as an injury severity score >15.

Results: We were unable to identify any randomised controlled trials of parachute intervention.

Conclusions: As with many interventions intended to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised controlled trials. Advocates of evidence based medicine have criticised the adoption of interventions evaluated by using only observational data. We think that everyone might benefit if the most radical protagonists of evidence based medicine organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute.


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NANS Member Receives Founders Award

NANS is pleased to announce that Richard B. North, MD, one of our members and the Immediate Past President, received the prestigious Founders Award at the American Academy of Pain Medicine’s 23rd Annual Meeting in February. The Founders Award is presented to an individual for outstanding contributions to the science or practice of pain medicine. The award is given for continued contributions to the basic or clinical science of pain medicine or for demonstration of clinical excellence or innovation in the practice of pain medicine.

In 1977, 10 years after the first report on the use of spinal cord stimulation (SCS) to control pain, Dr. North, who was then a biomedical engineer fellow at Johns Hopkins University (JHU), published his first report on SCS. As a consultant to the JHU Space Development program, Dr. North helped apply satellite technology to implanted electronic devices. Dr. North’s interests and abilities came together in his work with SCS—its optimization demands expertise in diverse fields.

In the ensuing 30 years, Dr. North has addressed many of SCS’s challenges, confirming the advantages of multicontact, programmable systems and inventing a patient-interactive computerized system to optimize stimulator adjustment and extend battery life. His work has facilitated technical studies of SCS, including comparisons of electrode types and configurations and of pulse-delivery methods.

After documenting the positive outcome of SCS in a series of patients with failed back surgery syndrome (FBSS), Dr. North reported in his seminal crossover randomized controlled trial (RCT) that SCS is more effective than reoperation in patients with primary radicular pain. His conclusion that an SCS trial should precede reoperation in selected FBSS patients and his documentation of the cost-effectiveness of SCS have widened the applicability and availability of the treatment.

Dr. North has conducted RCTs to compare the technical and clinical results of SCS treatment choices for primary radicular pain and for primary axial low back pain. He also devised a simple method that eliminated the persistent and costly problem of longitudinal electrode migration. His work on other surgical procedures for chronic pain, including the specificity of diagnostic nerve blocks, has been widely published.

As professor of neurosurgery, anesthesiology, and critical-care medicine at the Johns Hopkins University School of Medicine, Dr. North generously shares his experience and expertise by training physicians in multiple specialties. In the mid-1990s, he coordinated expertise by training physicians in multiple specialties. In the mid-1990s, he coordinated an important consensus conference on the neurosurgical management of pain, and he is preparing to publish practice parameters for the use of SCS to treat neuropathic pain.

AAPM Immediate Past President Frederick Burgess, MD PhD, presented Dr. North with the AAPM Founders Award.

Richard B. North, MD, spoke at the AAPM Annual Meeting about his 30 years of experience in spinal cord stimulation.

AAPM Immediate Past President Frederick Burgess, MD PhD, presented Dr. North with the AAPM Founders Award.

NANS President Joshua Prager, MD MS, presented the Decade of Pain Lecture titled “Four Decades of Neuromodulation” at the AAPM Annual Meeting.
The 10th Annual Meeting of the North American Neuromodulation Society was held December 2006 at the spectacular Wynn Hotel on the Strip in Las Vegas. The theme of the meeting was “Neuromodulation: Coming of Age,” and this conference truly celebrated the remarkable achievements and continued growth in the field of neuromodulation.
2007 INS-NANS Joint Meeting

Elliot S. Krames, MD, INS President and Editor-in-Chief of Neuromodulation

It is with great pleasure that I offer this update on the progress of the 8th World Congress of the International Neuromodulation Society (INS) and the 11th Annual Meeting of the North American Neuromodulation Society (NANS) in Acapulco, Mexico, December 7–12, 2007. The theme is “Neuromodulation: Technology at the Neural Interface.” This exciting meeting will be held at the breathtaking Fairmont Acapulco Princess hotel with its own private beach and two golf courses. There will be full- and half-day seminars, plenary sessions, presentations of papers, poster sessions, breakout sessions, and industry-sponsored seminars.

The following leaders in neuromodulation will serve as meeting chairs:

- Joe Pancrazio, PhD, National Institutes of Neurologic Diseases and Stroke (NINDS) of the National Institutes of Health (NIH), Bethesda, MD
- Dominique Durand, PhD, Neural Engineering Center, Case Western Reserve University, Cleveland, OH
- Christopher Colburn, Cleveland Clinic Foundation, Cleveland, OH
- Ali Rezai, MD, Cleveland Clinic Foundation, Cleveland, OH
- Bart Nuttin, MD PhD, Benelux Neuromodulation Society, University of Leuven, Belgium
- Joshua Prager, MD MS, NANS President
- Paul Meadows, PhD, International Functional Stimulation Society, Glendale, CA
- Timothy Deer, MD, Center for Pain Relief, Charleston, WV
- Leo Kapural, MD, Cleveland Clinic Foundation, Cleveland, OH
- Robert Foreman, PhD, University of Oklahoma Health Science Center, Oklahoma City, OK

This exciting event begins on Friday, December 7, with a full-day seminar covering various topics including:

- Bioelectrical Basis for Neuromodulation (Warren Grill, PhD, Duke University)
- Design and Implementation of Interfaces for Neuromodulation (Dominique Durand, PhD, Case Western Reserve University)
- Modeling Neural Networks and Fields: Implications for Neuromodulation (Cameron McIntyre, PhD, Cleveland Clinic Foundation)
- Assessing Safety of Electrical Stimulation for Neuromodulation (Douglas McCreery, PhD, Huntington Medical Research Institutes)
- Material Biocompatibility for Implanted Devices (Ravi Bellamkonda, PhD, Georgia Tech)
- Applied Science of Biomaterial Coatings (speaker to be determined)
- Regulatory Issues for Neuromodulation Devices (speaker to be determined)
- Working Lunch—Neural Engineering Partnerships: Bridging the Clinical and Engineering Divide (Ali Rezai, MD, Cleveland Clinic Foundation; Hunter Peckham, Case Western Reserve University)
- Principles of Drug Delivery in the Nervous System (Charles Nicholson, PhD, New York University)
- Convective Drug Delivery in the Spinal Cord: Implications for Neuromodulation (Malisa Sarntinorarom, PhD, University of Florida)
- Research and Funding Opportunities for Neuromodulation (Joseph J. Pancrazio, PhD, National Institutes of Health).

On Saturday, December 8, there will be two half-day seminars chaired by Dominique Durand, editor-in-chief of the Journal of Neural Engineering, and Christopher Colburn of the Cleveland Clinic Foundation. Professor Durand will chair the first half-day session, “Neural Engineering for Non-Engineers,” and Christopher Colburn will chair the second half-day session, “Turning Neuromodulation Innovations into Effective Medical Products.”

The regular sessions will begin on Sunday and continue through Wednesday, December 12. These all-day sessions will include morning plenary sessions and presentations of papers followed by an afternoon of choice of three breakout sessions. There is something for everyone—neuromodulation for the brain, pain, functional electrical stimulation, intrathecal therapies, and much more.

We expect approximately 1,000 attendees from Asia, Australia, Europe, the Middle East, North America, and South America, for this exciting meeting. The days are full, and the evenings will be enchanting and exciting. There will be time for intimate dinners and networking with friends and colleagues from the four corners of the world. We will highlight all the newest innovations in our field. Our sponsors include Advanced Bionics (Boston Scientific), Advanced Neuromodulation Systems, and Medtronic, and each sponsor has planned major events for our attendees and their families.

Don’t miss this stimulating meeting. You are invited to submit abstracts for paper presentations or posters. Visit www.neuromodulation.com for more information and to register or e-mail INS@neuromodulation.

Call for Article Submissions

The North American Neuromodulation Society is seeking experts to submit articles for the 2007 newsletters. Suggested article topics:

- local and regional challenges
- new technology
- treatments, surgery, and therapy options for various disorders
- clinical trials
- ethical dilemmas and controversy in the field
- members in the news
- tips and strategies
- case studies
- informed consent
- determining risks and benefits
- conflicts of interest
- best practices in neuromodulation
- respecting the rights of patients and families

Suggested length for newsletter articles is 500–1,500 words. To submit an article or suggest topics for upcoming issues, please contact Jaimie Henderson, MD, at henderj@stanford.edu.
Implantable Therapies and Reimbursement Woes

David S. Kloth, MD, Founder and Medical Director, Connecticut Pain Care, Danbury, CT

Reimbursement issues continue to plague physicians in all areas of medicine, but especially in the area of implantable technologies. Reimbursement difficulties most significantly affect the use of implanted spinal drug delivery systems, and many physicians have abandoned this therapeutic modality in favor of other techniques. Some physicians do not offer implanted spinal drug delivery systems as a treatment for their patients, choosing to use alternative methods such as high-dose medications or to not treat the patient when implanted spinal drug delivery systems become the only remaining option. In some areas of the United States almost no physicians will implant spinal drug delivery systems. Every week I speak to another physician who has stopped implanting pumps or will no longer manage existing pumps. Certain crisis areas have developed, and in the state of Washington, physicians have discharged their patients and referred them to a tertiary teaching center for long-term management. This situation has placed a tremendous burden on teaching centers to manage these intrathecal drug delivery systems, often at a reimbursement loss with each refill.

No universal policy for reimbursement of pump refills exists. Local Medicare carriers have the power to choose how they want to reimburse organizations for these procedures. Although there is consistency in the actual reimbursement for the technical component (Current Procedural Terminology® [CPT] 95990 and 95991), there is no uniformity in how associated evaluation and management (E/M) visits are handled or, more important, in how the medications are reimbursed. This latter problem has significantly affected physicians. In some states the Medicare intermediary has decided to reimburse physicians only for the cost of the powdered medication and not for the actual act of compounding. This decision makes the physicians responsible not only for the cost of compounding the medication but for the shipping cost to obtain the medications. Because of this significant loss of revenue to the physician—combined with the severe reductions in the reimbursement for the refill and reprogramming—many physicians have abandoned this therapeutic modality. This situation is obviously problematic for patients in need of this service. The loss of implantable therapies affects many types of patients including, sadly, the cancer patient population.

In July 2006, the American Medical Association (AMA) released vignettes describing the appropriate use of E/M services with pump refills. The use of E/M codes is appropriate when a separate and identifiable service is performed at the time of a pump refill. If the patient is seen only for back pain, no change of medications or dosages is needed, and if the patient's pain level is stable, an E/M service cannot be billed. However, if a patient is seen with a coexisting disease in other areas (e.g., arthritis of the shoulder in addition to a failed back syndrome or chronic headaches), the patient can be billed for an E/M service, provided that a separate and identifiable service is performed. In addition, the chronic management of medications and the requirement of the physician to deal with side effects from the intrathecal medications are billable E/M services (e.g., if a patient has hypogonadism from intrathecal narcotics or urinary retention from intrathecal narcotics and this condition must be managed, then an E/M service can be billed). These E/Ms that I provided to the AMA CPT panel for review and publication have been carefully edited and should, I hope, help physicians with denials for concurrent E/M services.

I have spent the last 3–4 years working with the Centers for Medicare & Medicaid Services (CMS) to handle the global reimbursement for pump refills. One of the glaring problems that we discovered was that CPT 95991 did not include the cost of the refill kit. After lengthy discussions with CMS we were able to get this cost added to the relative value units (RVUs) for this CPT code; however, this addition resulted in minimal change because of offsets from practice expense and other complicated Medicare formulas. During the next several years we will see that money put back into this code; however, it will take a number of years, and we will see this money only as long as Medicare reimbursement does not continue to decrease.

The AMA also stated that there is a need to reprogram the pump every time the pump is refilled. Because reprogramming of the pump requires the pump to be reset with a new volume, this step indeed correlates with reprogramming of an implanted intrathecal delivery system. However, if a pump is interrogated following a magnetic resonance imaging (MRI) scan and no changes are made to the pump, then this procedure is billed with CPT code 62367 rather than the reprogramming code 62368.

A committee of physicians representing multiple professional societies including NANS, the American Society of Interventional Pain Physicians, the International Spine Intervention Society, the American Pain Society, the American Academy of Pain Management, and the American Society of Anesthesiologists has been working with CMS to correct some of the glaring inadequacies in pump refill reimbursement. These inadequacies have led to an access problem for this treatment modality across the country, affecting certain regions more significantly where the reimbursement is lower than other areas. In certain states the reimbursement continues to be good. For example, physicians in Texas and California have worked closely with their Medicare intermediaries to achieve a better policy. Unfortunately, most of the policies have been instituted unilaterally without input from physicians. At this juncture our committee is working with CMS to discuss a national Medicare reimbursement policy for these devices.

In regard to spinal cord stimulation, many problems are occurring with this treatment modality as it relates to reimbursement. Perhaps one of the most significant problems today is with Aetna, which has recently released a policy precluding reimbursement for spinal cord stimulation in the cervical region. Their rationale is that these devices are not FDA approved for the cervical region. A committee of physicians is planning to meet with Aetna in the near future to discuss this policy.

Members of the leadership committee continue to work very hard for members of their organizations to ensure appropriate reimbursement for these treatment modalities. It is incumbent upon our physician members to support their leaders and keep them informed when these reimbursement issues arise.
Meetings of Interest

NANS members are encouraged to attend these meetings of interest presented by other pain, spine, and neurological associations. Please visit their Web sites for more information.

**June**

Radiofrequency Workshop  
International Spine Intervention Society  
June 2–3, Pittsburgh, PA  
www.spinalinjection.com

ASIPP 9th Annual Meeting and Legislative Session  
American Society of Interventional Pain Physicians  
June 23–27, Washington, DC  
www.asipp.org

**July**

AANS Practice Management Workshop  
American Association of Neurological Surgeons  
July 1, Chicago, IL  
www.aans.org

Comprehensive Imaging Review in Interventional Pain Management and Competency Certification in Fluoroscopic Interpretation and Radiation Safety  
American Society of Interventional Pain Physicians  
July 13–16, Las Vegas, NV

Training Examination  
American Society of Anesthesiologists  
July 14, various locations  
www.asahq.org

ISIS 15th Annual Meeting  
International Spine Intervention Society  
July 15–21, Baltimore, MD

**August**

Phase 3 Cervical Workshop  
International Spine Intervention Society  
August 4–5, Charlotte, NC

Comprehensive Pain Medicine Board Review Course and ASIPP Part 1 Examination  
American Society of Interventional Pain Physicians  
August 5–11, Nashville, TN

5th Annual Comprehensive Pain Board Review Symposium  
American Pain Society  
August 7–11, Middleton, WI  
www.ampainsoc.org

Practice Management  
International Spine Intervention Society  
August 18–19, San Diego, CA

**September**

PAIN Week 2007  
American Pain Society  
September 6–9, Las Vegas, NV

Phase 1 Lumbar Workshop and Fri Fluoroscopy  
International Spine Intervention Society  
September 7–9, Memphis, TN

XXVI Annual Congress on the European Society of Regional Anaesthesia and Pain Therapy  
American Pain Society  
September 12–15, Valencia, Spain

**October**

Radiofrequency Workshop  
International Spine Intervention Society  
October 13–14, Phoenix, AZ

ASA Annual Meeting  
American Society of Anesthesiologists  
October 13–17, New Orleans, LA

NASS 22nd Annual Meeting  
North American Spine Society  
October 23–27, Austin, TX  
www.spine.org

**November**

Clinical Imaging Course  
International Spine Intervention Society  
November 3–4, New Orleans, LA

2007 Annual Pain Medicine Meeting and Workshops  
American Society of Regional Anesthesia and Pain Medicine  
November 15–18, Boca Raton, FL  
www.asra.com

**December**

11th NANS Annual Meeting  
Neuromodulation: Technology at the Neural Interface  
December 7–12, Acapulco, Mexico  
www.neuromodulation.org

President’s Message continued from page 1

and weaknesses of a large body of literature that is convincing in its entirety despite the fact that there is a paucity of class 1 data. This study is being disseminated and reviewed by a variety of medical organizations for publication in a major medical journal. We congratulate Dr. North and Ms. Shipley on a job well done. (For more information about Dr. North’s work with spinal cord stimulation, see the “Members in the News” section on page 2.)

The next NANS annual meeting, a joint meeting with the International Neuromodulation Society, will be held December 7–12, 2007, in Acapulco, Mexico. We are enthusiastic about this upcoming meeting titled “Neuromodulation: Technology at the Neural Interface.” For more information, visit the NANS Web site at www.neuromodulation.org. Because the International Neuromodulation Society continues to grow at a rate similar to that of our society, we expect a large attendance from the entire world. I hope to see you there.

Sincerely,

Joshua P. Prager, MD MS  
President
For the third time in the last decade, an international group of distinguished experts met to address the evolving practice of intrathecal drug delivery. The discussions from the January 2007 meeting held in Miami will result in the publication in peer-reviewed journals of three papers addressing various aspects of nedural spinal medication administration, including an algorithm for polyanalgesia, a discussion of reimbursement issues, and an update on intrathecal granulomas.

In 2000, a group of experts gathered to review the world literature on the use of intrathecal agents for the treatment of pain. This panel, chaired by Dr. Samuel Hassenbusch and Dr. Russell Portenoy, conducted a survey of users of intrathecal agents in the United States, Europe, and Australia. Based on the reported use of medications by those surveyed, an extensive search for published literature was performed. The consensus group ranked the articles according to the quality of data and their clinical importance. Using this information and their own clinical experience, the diverse group of physicians developed an algorithm to guide physicians in the use of intrathecal agents.

This algorithm recommended beginning treatment with an opioid (morphine) and then making changes by substituting other opioids such as hydromorphone. Other recommendations of the algorithm were to add nonopioid agents such as bupivacaine or clonidine to the infusion to overcome side effects and improve efficacy. This algorithm further informed physicians of the possible treatment alterations that could be made on the basis of the scientific criteria until eventually the options included drugs that should be used only in research settings or by physicians in end-of-life clinical situations.

In 2003, Dr. Hassenbusch, Dr. Portenoy, and Dr. Michael Cousins reconvened the group to update the algorithm. The panel surveyed previous information as well as all significant peer-reviewed articles published since the previous meeting and developed several new recommendations. The first line of drug therapy was changed to include both morphine and hydromorphone. Second-line therapies continued to include substitution of opioids or the addition of nonopioid adjuvants. The other major change from the previous algorithm was the addition of recommended doses and concentrations for opioids. These numbers added to the increasing awareness of the risk of granuloma with high concentrations of opioid. The group also made recommendations regarding safety and compounding.

In 2007, Dr. Hassenbusch and Dr. Timothy Deer reconvened another group to update the algorithm. This panel included a diverse group of anesthesiologists, neurosurgeons, and physiatrists from academic and private clinical settings. The group updated the literature search and reviewed new clinical issues that had developed during the past 4 years. The proceedings and conclusions of that meeting are now being submitted for publication in the journals *Neuromodulation* and *Pain Medicine*.

The highlights of the new consensus statement include a change in the first line of therapy to include morphine, hydromorphone, and ziconotide. The second line of therapy recommendations will also include ziconotide as an adjuvant option along with clonidine and bupivacaine. The group also ranked other drugs in order of scientific support and clinical utility. An important new component including special recommendations for end-of-life care was also developed for the 2007 version of the consensus statement.

The group created a separate document to give a consensus on the prevention, diagnosis, and treatment of inflammatory masses at the catheter tip. This document represents the first major consensus on this issue since 2002, and this consensus is greatly needed to improve clinical care and patient safety. Included in the statement are the recommended drug concentrations for opioids, recommended screening techniques, and recommended algorithms for treatment of this problem. The panel also made recommendations for the priorities for future intrathecal drug research and development.

The other critical issue that the 2007 group reviewed and made recommendations on was patient access to intrathecal therapies.

Dr. Deer, Dr. Hassenbusch, Dr. Robert Levy, and Dr. Elliot Krames developed a new survey to analyze the issues that limit patient access to intrathecal drug infusion systems. The factors that were felt to have an impact on this major public health problem included education of the public and the physician referral group, physician education on implanting and managing pumps, physician reimbursement for implanting and managing intrathecal drug delivery systems, facility reimbursement for devices and infusion drugs, and insurance coverage for patients who see pain physicians. The group made recommendations to address these issues and help patients receive proper care.

The complete proceedings of the 2007 consensus group will be published during the next several months, and the important components of this work will be presented at the December 2007 joint meeting of the International Neuromodulation Society and NANS in Acapulco, Mexico. See page 4 for more information about the joint meeting.

**Suggested Reading**


Save the date!

Neuromodulation:
Technology at the Neural Interface

The 8th World Congress of the
International Neuromodulation Society
The 11th Annual Meeting of the
North American Neuromodulation Society

- Pre-conference on The Fundamentals of Neuromodulation
  Faculty: Joseph J. Pancrazio PhD - Program Director, Extramural Research, NIH
- Implantable Technology for Pain
- Functional Electrical Stimulation
- Deep Brain Stimulation for Movement and Psychiatric Disorders
- Emerging Indications for Neuromodulation

Something for the Clinician
Something for the Engineer
Something for the Scientist

December 7 - 12, 2007
We invite you and your family to
Acapulco, Mexico

NANS Newsletter Available Online
Visit www.neuromodulation.org/publications.htm to read current and past issues.

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