



# North American Neuromodulation Society NEWSLETTER

## President's Message

### Reflections on a Presidency



I very much appreciate the opportunity to have served the North American Neuromodulation Society (NANS) as president for the last 2 years. During the last 6 years, as vice

president, president elect, and president, I was fortunate to meet many greatly motivated people in the field of neuromodulation and hear many extraordinary presentations related to our field. It is amazing to observe the rapid progress that has occurred during this interval. In the field of neurostimulation (in addition to the multitude of new applications now being treated), we have seen the development and release of rechargeable systems that make our capabilities so much more robust. In terms of neuraxial drug delivery, we received the U.S. Food and Drug Administration's approval of one new medication, ziconotide, as well as the convening of two additional consensus conferences related to intrathecal medications. Our knowledge and sophistication with regard to mixing medications and avoiding complications continue to progress.

Both NANS and its parent organization, the International Neuromodulation Society,

have increased their membership numbers dramatically, and our scientific meetings have increased in size, quality, and diversity. We now see the attendance of basic scientists, researchers, and a large number of Wall Street analysts in addition to clinicians. Modalities that were barely on the radar screen a decade ago are more commonly known and used today. As we better understand the nervous system through more sophisticated imaging techniques, we also appreciate the effects of our interventions.

I am proud to be able to pass the presidency to the leadership of Jaimie M. Henderson, MD, a most accomplished neurosurgeon and leader in our field. I wish to thank the members of the board who have served with me, as well as the executive director, Vanessa Mobley, CMP, who has supported our endeavors. Special thanks go to our four major corporate sponsors, Boston Scientific, Elan Pharmaceuticals, Medtronic, and St. Jude Medical. Without their continued support, our society would not be able to flourish.

I wish to provide a special thanks to Richard B. North, MD, the immediate past president, who, as president, provided leadership and generosity of time and spirit to foster the development of the

organization. His continued activity during his immediate past-presidency has been invaluable.

Our field would not move forward the way it has without an extraordinary journal to document the achievements in neuromodulation, and for this publication, the work of Elliot S. Krames, MD, editor of *Neuromodulation*, has been extraordinary.

I look forward to seeing members and supporters of NANS at our upcoming meeting at the Fairmont Acapulco Princess Hotel in Mexico.

Sincerely,

Joshua P. Prager, MD MS  
President

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**T**he Lifetime Achievement Award will be presented at the NANS

Annual Meeting to C. Norman Shealy,

MD PhD, to commemorate the 40th Anniversary

of his implantation of the first spinal cord stimulator

(see page 7).





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Classified and display rates are available. Please contact NANS Senior Manager, Professional Relations Sheila Lee at 847/375-4760, fax 877/594-6704.

# Behavioural Improvements with Thalamic Stimulation After Severe Traumatic Brain Injury

**Abstract:** Widespread loss of cerebral connectivity is assumed to underlie the failure of brain mechanisms that support communication and goal-directed behaviour following severe traumatic brain injury. Disorders of consciousness that persist for longer than 12 months after severe traumatic brain injury are generally considered to be immutable; no treatment has been shown to accelerate recovery or improve functional outcome in such cases. Recent studies have shown unexpected preservation of large-scale cerebral networks in patients in the minimally conscious state (MCS), a condition that is characterized by intermittent evidence of awareness of self or the environment. These findings indicate that there might be residual functional capacity in some patients that could be supported by therapeutic interventions. We hypothesize that further recovery in some patients in the MCS is limited by chronic underactivation of potentially recruitable large-scale networks. Here, in a 6-month double-blind alternating crossover study, we show that bilateral deep brain electrical stimulation (DBS) of the central thalamus modulates behavioural responsiveness in a patient who remained in MCS for 6 yr following traumatic brain injury

before the intervention. The frequency of specific cognitively mediated behaviours (primary outcome measures) and functional limb control and oral feeding (secondary outcome measures) increased during periods in which DBS was on as compared with periods in which it was off. Logistic regression modelling shows a statistical linkage between the observed functional improvements and recent stimulation history. We interpret the DBS effects as compensating for a loss of arousal regulation that is normally controlled by the frontal lobe in the intact brain. These findings provide evidence that DBS can promote significant late functional recovery from severe traumatic brain injury. Our observations, years after the injury occurred, challenge the existing practice of early treatment discontinuation for patients with only inconsistent interactive behaviours and motivate further research to develop therapeutic interventions. **N**

Source. Schiff, N. D., Giacino, J. T., Kalmar, K., Victor, J. D., Baker, K., Gerber, M., et al. (2007). Behavioural improvements with thalamic stimulation after severe traumatic brain injury. *Nature*, 448, 600. Reprinted with permission from Macmillan Publishers, Ltd.

# How to Turn Personal Attacks into Patient Satisfaction

Tim Dawes, President of Interplay, Inc.

**P**atients are more than healthcare consumers. Unlike mere consumers, our customers are often frightened and in pain. If you are a caregiver working with people in fear and pain, you can count on hearing accusations—"You don't care!" "You're incompetent!" "You're a racist!"

When responding to accusations like these, the words you say are critical. They can spell the difference between creating a deeper level of respect with your patient and opening the door to a law suit. (Always consult your risk management department first when considering how to handle an interaction that could have an impact on your medical group's liability.) The eventual outcome hinges on a critical choice you'll make: the way you choose to hear the negative comment.

There are two ways to hear an accusation. You can play "The Blame Game" or become a "Needs Detective."

For example, suppose your patient says, "You're not listening to me, but you're gonna!" Let's examine how your choice of context determines your response.

### The Blame Game

You can choose to take the comment personally and attack or defend. If you blame yourself, you accept the criticism and apologize by saying "I'm sorry. I didn't mean to disturb you. Maybe I can come back later." If you blame your patient, you find fault with him or her. You might say, "I assure you that your care is my highest concern," while thinking to yourself, "and right now, your attitude is an obstacle to that care."

When you blame yourself, you feel guilt or shame. When you blame your patient, you become angry. All those emotions are likely to come between you and the quality of experience you want to create.

*continued on page 6*

# Update from *NTAC Monthly*

## What and Who is NTAC?

The Neuromodulation Therapy Access Coalition (NTAC) is a newly formed, national coalition of professional medical societies, industry partners, and patient advocates dedicated to ensuring appropriate patient access to neuromodulation therapies. The coalition, spearheaded by the North American Neuromodulation Society (NANS), is partnering with other interventional physician societies that have a strong interest in neuromodulation therapies.

## Why is the Coalition Necessary?

Neuromodulation therapies hold great promise for certain complex, chronic conditions including intractable pain. However, patient access is at risk when private and public payers (e.g., state workers compensation programs, Medicaid, and Medicare) won't cover or appropriately reimburse for the devices. Professional societies and patients must work to educate policymakers and advocate for coverage and payment to ensure that patients get the treatments they need—when they need them—to manage their conditions.

A coalition like NTAC brings together multiple stakeholders (physicians, patient advocates, and medical device manufacturers), creating the strength in numbers to truly make a difference.

## What Advocacy Activities will NTAC Pursue?

Our fundamental goal is to maintain appropriate access to neuromodulation therapies. To fulfill this mission, we will:

- educate policymakers on the essential role of neuromodulation therapies in treating certain chronic conditions
- lobby regulators and legislators to ensure that their policies are supportive of therapy access
- advocate to private health plans for appropriate coverage of neuromodulation therapies
- promote evidence-based practice parameters on neuromodulation
- assist physician and patient advocates to effectively engage in the political process
- improve public awareness and understanding about these important medical technologies.

## Will NTAC Support or Endorse Candidates for Public Office?

No. NTAC is not structured to support political candidates, which requires the formation of a registered political action committee.

## What Does it Cost My Organization to Join?

At this stage, nothing more than a commitment of time and energy. Also, joining NTAC gives you a seat at the table to help develop its advocacy agenda and help build public awareness about neuromodulation therapies.

## What is the Value to My Organization in Joining NTAC?

NTAC allows you to take advantage of an existing and highly focused advocacy infrastructure that can help you achieve your organizational mission and promote the interests of members involved in neuromodulation therapies at no cost except your commitment of time and energy.

## Will Joining NTAC Impact Our 501(c)(3) Tax-Exempt Status?

No. It is a common misperception that the IRS does not permit 501(c)(3) organizations to engage in advocacy and lobbying. In fact, 501(c)(3) organizations can, and arguably should, engage in advocacy to ensure that the interests of their members are represented in policy decisions that affect them.

Even if NTAC charged dues to non-industry members (which it does not), a contribution would only count towards the advocacy spending threshold for 501(c)(3)s imposed by the IRS. Simply put, such spending imposes only a minor filing requirement to the IRS. Again, this is not an issue for any 501(c)(3) interested in joining NTAC.

## As a Member of NTAC, What is Required of My Organization?

We ask every member to designate at least one representative to the coalition to participate in regular strategic planning conference calls. We will also strongly encourage each member to identify neuromodulation advocates within their organization—individuals with the interest and commitment to help NTAC achieve its goals. Finally, each member

is allowed to appoint one representative to serve on the Policy & Advocacy Committee, which will drive the policy priorities and advocacy initiatives of NTAC.

## Federal Pain Legislation Introduced

On July 11, Congresswoman Lois Capps (D-CA) and Congressman Mike Rogers (R-MI) introduced the National Pain Care Policy Act of 2007, legislation to improve pain care research, education, training, access, outreach, and care.

There are four main components of the bill:

1. the authorization of an Institute of Medicine Conference on Pain Care
2. permanent authorization of the trans-institute Pain Consortium at the National Institutes of Health, including an advisory committee on pain research
3. the creation of grant programs to improve health care professionals' understanding of pain management, including the ability to assess and appropriately treat or manage pain
4. the creation of a national public awareness campaign about pain management, conducted by the Department of Health and Human Services, with particular attention to improving access to appropriate pain treatment among underserved populations.

Importantly, the legislation has garnered support from a number of NTAC partners and potential allies in our efforts to advance patient to neuromodulation therapies in the treatment of chronic pain. NTAC is evaluating the legislation and is considering adding the coalition name to the list of endorsing organizations. **N**

## Questions or Comments?

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Source: Hauth, E. (2007). Executive director's report. *NTAC Monthly*, 2, 3–4. Reprinted with permission.

# 2007 INS-NANS

December 7–12, 2007 • Fairmont Acapulco



## Dear Colleagues,

We have titled this event *Neuromodulation: Technology at the Neural Interface* because it defines our field of medical, bioengineering, and manufacturing as the fastest growing field in medicine today. *Neuromodulation* is defined as technology that modulates the nervous system for the improvement of humankind. Today, medical devices have been engineered and used to improve psychiatric function; movement disorders; epilepsy; chronic pain; and cardiac, bowel, and bladder function; and to improve abilities of patients who have lost these abilities because of various illnesses and traumas. Our combined event will focus on all aspects of neuromodulation during 5 days, and we sincerely hope to see you there for the entire event. Our meeting is designed as a learning tool for physicians, nurses, bioengineers, members of industry, and others interested in investing in the growth of the field.

Our conference will start on December 7 with a full-day seminar titled “Fundamentals of Neuromodulation,” chaired by Joseph Pancrazio, project director for the National Institute of Neurologic Disorders and Stroke (NINDS) of the National Institutes of Health (NIH). Dr. Pancrazio has brought together some of the leading experts in the field of the science that is fundamental to neuromodulation. On December 8, two half-day seminars will continue the theme of fundamentals. Professor Dominique Durand of Case Western University, editor-in-chief of *Neural-Engineering*, will present “Neural Engineering for Non-Engineers,” and Christopher Coburn, executive director of innovations for the Cleveland Clinic, will chair a half-day seminar, “Creating a Neuromodulation Startup Company,” a course on how to bring a neurotech idea to completion. Mr. Coburn has many years of experience in creating businesses from innovations and will bring representatives of neuromodulation start-up companies to discuss the process.

The conference scientific sessions will begin December 9 and will end December 12. Our scientific program will include CME-supported plenary sessions from leading experts in their fields, open paper presentations, and CME-supported break-out sessions. There will be industry-sponsored luncheons and industry-sponsored, non-CME symposia. The exhibit hall will



# Joint Meeting Invitation

ulco Princess Hotel • Acapulco, Mexico

be a place to network with industry members and colleagues. The exhibit hall will be open before and after our scientific sessions and will be open during breakfast and coffee breaks. December 9 will offer an entire day of scientific sessions focused on neuromodulation for the brain with discussions on deep brain stimulation for psychiatric disorders, movement disorders, epilepsy, and pain and motor cortex stimulation for pain and rehabilitation. Dr. Ali Rezai, chairman of functional neurosurgery at the Cleveland Clinic, and Bart Nuttin, professor at the University of Leuven in Belgium, will chair these sessions. Dr. Joshua P. Prager, president of the North American Neuromodulation Society (NANS), will chair the sessions dedicated to pain and neuromodulation on December 10. Paul Meadows, president of the International Functional Electrical Society, will chair the sessions on functional electrical stimulation on December 11. Dr. Marc Penn of the Cleveland Clinic and Dr. Magdi Hassouna of Toronto will chair the sessions for the heart, gut, and bladder on December 12.

We are proud to bring this exciting event to you. We hope to see you in Acapulco!

*Elliot S. Krames, MD, Conference Cochair and President of the International Neuromodulation Society (INS)*

*Joshua P. Prager, MD, Conference Cochair and President of the North American Neuromodulation Society (NANS)*

## Register Now!

We encourage you to register for the conference and make your hotel reservations as soon as possible because our room block is selling out quickly.

### **Cartan Tours, Inc.**

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International: 001-310-546-9662, ext. 0

[chenoas@cartan.com](mailto:chenoas@cartan.com)

For the latest information on the 2007 INS-NANS Joint Meeting, please visit our conference Web site at [www.neuromodulation.com/2007-ins-nans-neuromodulation-conference-in-acapulco.htm](http://www.neuromodulation.com/2007-ins-nans-neuromodulation-conference-in-acapulco.htm)



# Neurostimulation Therapy Improves Chronic Neuropathic Leg and Back Pain



**N**ANS Director at Large Krishna Kumar, MD, clinical professor and chairman of the neurosurgery department at the University of Saskatchewan's Regina General Hospital in

Canada, recently published a major study in *PAIN: The Journal of the International Association for the Study of Pain* that found that people with chronic neuropathic leg and back pain benefited more significantly from neurostimulation therapy and conventional medical management than from conventional medical management alone. The study was supported by NANS corporate sponsor Medtronic, Inc.

Associated with nerve damage or nervous system disease, neuropathic pain affects up to 8% of the population but is often underdiagnosed and undertreated. Of all pain types, it is among the most severe, chronic, disabling, costly, and difficult to treat. Neuropathic pain most commonly affects the back and legs.

The study, known as PROCESS (for PROspective randomized Controlled trial of the Effectiveness of Spinal cord Stimulation), showed that Medtronic neurostimulation therapy in addition to conventional medical management provided patients with greater pain relief, quality of life, functional capacity, and treatment satisfaction than conventional medical management alone after 6 months. In fact, 48% of the patients assigned to receive neurostimulation and conventional treatments experienced a 50% or greater

## Spinal Cord Stimulation Versus Conventional Medical Management for Neuropathic Pain: A Multicentre Randomised Controlled Trial in Patients with Failed Back Surgery Syndrome

**Abstract:** Patients with neuropathic pain secondary to failed back surgery syndrome (FBSS) typically experience persistent pain, disability, and reduced quality of life. We hypothesised that spinal cord stimulation (SCS) is an effective therapy in addition to conventional medical management (CMM) in this patient population. We randomised 100 FBSS patients with predominant leg pain of neuropathic radicular origin to receive spinal cord stimulation plus conventional medical management (SCS group) or conventional medical management alone (CMM group) for at least 6 months. The primary outcome was the proportion of patients achieving 50% or more pain relief in the legs. Secondary outcomes were improvement in back and leg pain, health-related quality of life, functional capacity, use of pain medication and non-drug pain treatment, level of patient satisfaction, and incidence of complications and adverse effects. Crossover after the 6-months visit was permitted, and all patients were followed up to 1 year. In the intention-to-treat analysis at 6 months, 24 SCS patients (48%) and 4 CMM patients (9%) ( $p < 0.001$ ) achieved the primary outcome. Compared with the CMM group, the SCS group experienced improved leg and back pain relief, quality of life, and functional capacity, as well as greater treatment satisfaction ( $p \leq 0.05$  for all comparisons). Between 6 and 12 months, 5 SCS patients crossed to CMM, and 32 CMM patients crossed to SCS. At 12 months, 27 SCS patients (32%) had experienced device related complications. In selected patients with FBSS, SCS provides better pain relief and improves health-related quality of life and functional capacity compared with CMM alone.

Source: Kumar, K., Taylor, R. S., Jacques, L., Eldabe, S., Meglio, M., Molet, J., et al. (2007). Spinal cord stimulation versus conventional medical management for neuropathic pain: A multicentre randomised controlled trial in patients with failed back surgery syndrome. *PAIN: The Journal of the International Association for the Study of Pain*, 132, 179–188. Copyright by the International Association for the Study of Pain. Reprinted with permission.

improvement in leg pain compared to 9% of patients assigned to receive only conventional treatments ( $p < .001$ ).

“Patients with persistently disabling neuropathic pain in the back and legs represent one of the most difficult treatment problems in clinical practice, the real-world setting of our trial,” said Dr. Kumar. “Our findings show that neurostimulation offers patients

in this situation a treatment option that can relieve their pain to a significantly greater degree than conventional medical management alone, and as a result, helps restore quality of life and functional capacity as well. Neurostimulation therapy should, therefore, be added to the list of conventional treatments and routinely considered for appropriate patients.” **N**

## How to Turn Personal Attacks into Patient Satisfaction *continued from page 2*

### The Needs Detective

Alternatively, you can tune into your needs and the patient's needs that are going unmet. When you turn your attention to your own needs, you reveal your humanity. You might say, “When I hear you talk that way, I'm frustrated that I'm working hard and not getting the results I'd hoped for.” When you turn your attention to your patient's needs, you demonstrate your empathy. You might say, “Are you anxious about getting the support you need?”

You might think it would be tough for your patients to listen to your needs and feelings, and much of the time, I'd agree with you. If the patient is making judgments and accusations, your patient likely has important needs to satisfy before he or she will be a good audience for you. Surprisingly, though, many patients are aching to hear what's alive in you, especially if it's a reaction to them. It reminds them that you're human and lets them know they're having an effect on you.

A supervising nurse I worked with recently told me, “I'm not a racist, but there's nothing I can say to change this patient's mind.” That's the core. If you hear a judgment about you, you'll try to defend yourself, but nothing you can say will be enough for that patient.

Shift your perspective. See your patient as suffering and identify his or her call for help. You'll open up a whole new line of responses and possibly a whole new relationship. **N**



# 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.

## November

### Clinical Imaging Course

International Spine Intervention Society  
November 3–4, New Orleans, LA  
www.spinalinjection.com

### AANS Web Conference 3: Managing and Controlling Practice Overhead Cost

American Association of Neurological Surgeons  
November 7  
www.aans.org

### Cornell Pain Medicine Symposium: Evidence Based Practice and Updates in Pain Medicine

American Pain Society  
November 10, Weill Cornell Medical College, New York, NY  
www.ampainsoc.org

### Workshop on Transesophageal Echocardiography

American Society of Anesthesiologists  
November 10–11, Phoenix, AZ  
www.asahq.org

### 2007 Annual Pain Medicine Meeting and Workshops

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

### AANS/CNS Section on Pediatric Neurological Surgery Annual Meeting

American Association of Neurological Surgeons  
November 26–December 1, Miami Beach, FL

### Comprehensive Spinal Cord Stimulation Review Course and Interventional Cadaver Workshop

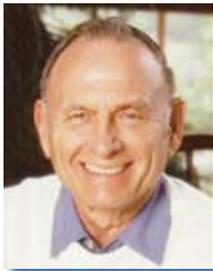
American Society of Interventional Pain Physicians  
November 30–December 2, Memphis, TN  
www.asipp.org

## December

### NANS 11th Annual Meeting Neuromodulation: Technology at the Neural Interface

December 7–12, Acapulco, Mexico  
www.neuromodulation.org

# NANS 2007 Lifetime Achievement Award Winner



**N**ANS is pleased to announce that the 2007 Lifetime Achievement Award will be presented to neurosurgeon C. Norman Shealy, MD PhD, at the NANS 11th Annual Meeting in December. Dr. Shealy attended medical school at Duke University and trained at Massachusetts General Hospital. He has taught at Harvard, Western Reserve, University of Wisconsin, University of Minnesota, and Forest Institute of Professional Psychology. He is currently president

of Holos University Seminary (www.holosuniversity.org) and president of the International Society for the Study of Subtle Energy and Energy Medicine (www.issseem.org).

Dr. Shealy introduced the concepts of Dorsal Column Stimulation and Transcutaneous Electrical Nerve Stimulation (TENS), both now used worldwide. In 1971 he founded the first comprehensive, holistic clinic for management of pain and stress management. The Shealy Institute became the most successful and most cost-effective pain clinic in the United States, with 85% success for more than 30,000 patients. The Shealy protocols for management of depression, migraine, fibromyalgia, and back

pain are increasingly being integrated into hospitals and individual practices. In 1973, after recognizing the need to incorporate spirituality into medical practice, he founded, with Reverend Henry Rucker, the Science of Mind Church of Chicago (now the International Science of Mind Church for Spiritual Healing) and created Holos University Graduate Seminary, which offers masters and doctoral programs in spiritual healing and energy medicine. Dr. Shealy was instrumental in creating the American Holistic Medical Association in 1978 and was the founding president for its first 2 years. His current research emphasizes the potential for using spiritual energetics in rejuvenating the body's production of DHEA and calcitonin, in reducing free radicals, and in reversing DNA damage to enhance health and longevity. Dr. Shealy holds 10 patents for innovative discoveries and has published more than 300 articles and 24 books (the latest of which are *Life Beyond 100—Secrets of the Fountain of Youth* and *Soul Medicine*). In 2008, he will release a new book, *Pony Wisdom for the Soul*, and a movie, *The Secret Code*, on the benefits of complementary and integrative medicine. His free e-newsletter is available at [www.normshealy.com](http://www.normshealy.com). **N**

Dr. Shealy holds 10 patents for innovative discoveries and has published more than 300 articles and 24 books (the latest of which are *Life Beyond 100—Secrets of the Fountain of Youth* and *Soul Medicine*). In 2008, he will release a new book, *Pony Wisdom for the Soul*, and a movie, *The Secret Code*, on the benefits of complementary and integrative medicine. His free e-newsletter is available at [www.normshealy.com](http://www.normshealy.com). **N**

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## Call for Article Submissions

The North American Neuromodulation Society is seeking experts to submit articles for the 2008 newsletters.

Suggested article topics:

- local and regional challenges
- new technology
- treatments, surgery, and therapy options for various disorders
- clinical trials
- ethical dilemmas and controversy
- 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 M. Henderson, MD, at [henderj@stanford.edu](mailto:henderj@stanford.edu).

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](http://www.neuromodulation.org/publications.htm) to read current and past issues.



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