

<u>07 September 2023</u>

07:30 - 10:30 Pavilion 5A-C

Comprehensive Assessment of Neuropathic Pain: Neurological Exam and Quantitative Sensory Testing Hands-on-Workshop

The diagnosis of neuropathic pain requires abnormal somatosensory findings that are logically related to the neuroanatomy and are consistent with a specific lesion or disease of the somatosensory nervous system. In addition to obtaining pain history, as well as information on its quality, severity, and interference, the assessment of somatosensory function should comprehensive, to determine the presence of any negative neurological signs (sensory loss) or positive neurological signs (sensory gain).

This hands-on workshop will focus on the key approaches for comprehensive assessment of somatosensory function — which are a) neurological examination, as the gold standard for clinical practice, and b) quantitative sensory testing, which depending on the particular approach, can be performed in the research or clinical settings.

Specifically, one of the workshop stations will be dedicated to neurological examination by an experienced neurologist, two stations will focus on mechanical and thermal aspects of classic quantitative sensory testing, respectively, and another station will specifically focus on bedside QST approaches for more rapid quantitative assessment of somatosensory function.

Attendees will rotate between all four stations.

Station I – Neurological Exam Andrea Truini, Daniel Ciampi de Andrade

Station II – Thermal QST Jan Vollert

Station III - Quantitative Sensory Testing for Everyone: Bedside Protocols Bridging the Gap Between Research and Clinic and Mechanical QST

Jan Vollert, Manon, Roy Freeman, Harriet Kemp, Roy Freeman, Harriet Kemp

10:45 - 12:15 Auditorium IV

New Approaches to Advance Studies in Pain Pathophysiology and Pharmacology

The pain experience reflects the interaction of diverse genetic and epigenetic factors, and environmental factors. This complexity necessitates the need to establish more relevant pre-clinical models to investigate sensory neuron physiology and disease pathophysiology, with the intention to inform the development of more effective treatment for pain disorders.



This workshop will cover examples of how cell-based experiments are being conducted to understand changes in excitability of sensory neurons are heavily linked to the onset and maintenance of pain. To understand how these changes occur after disease or injury, this workshop will discuss dynamic regulation of axonal trafficking of ion channels that are implicated in nociception.

Detailed assessments of human sensory neurons derived from iPSCs are leading to the identification not only of causative mutations, but also being used as pain-in-a-dish cellular models to fill gaps in our understanding of clinical phenotypes, and as cellular models to test effective treatment options. Finally, natural pain-inducing toxins are leading to new discoveries including deorphanizing members of the dispanin family as the first NaV channel-interacting proteins that are indispensable for toxin-mediated effects on NaV channel gating, providing insights into the function of these channels in sensory neurons.

10:45

Dynamic Regulation of Axonal Trafficking of Ion Channels in Sensory Neurons Sulayman Dib-Hajj

11:15

Enhanced Sensory Neuron Excitability Through Pharmacological Modulation of Sodium Channel Interacting Proteins

Irina Vetter

11:45

Inhibition of Sensory Neuron Driven Acute, Inflammatory, and Neuropathic Pain Using a Humanised Chemogenetic System

Steve Middleton

10:45 - 12:15 Auditorium III

Patient Lived Experience: Adding Value to Neuropathic Pain Research

Involving people with lived experience of pain at all stages of research is increasingly recognized by funders, researchers, and the public as necessary for relevant, robust, and impactful research. Successful (reverse) translation depends not just on using relevant preclinical models but using robust patient and public involvement (PPI) to ensure relevant research questions are asked and tested in appropriate populations.

PAINSTORM is a UK-wide research consortium focusing on neuropathic pain, funded (£3M) through the Advanced Pain Discovery Platform. People with lived experience of neuropathic pain have been centrally involved with PAINSTORM since its inception, including shaping the study design in the pre-funding phase. Based on this and related experience/evidence, speakers will provide an interactive session focused on three areas of PPI in pain research:

- 1. What PPI is, what it is not, why it is essential, and how to build PPI confidence and capacity.
- 2. A case study of the importance and impact of PPI in the PAINSTORM consortium including practical tips and resources to support PPI and its evaluation.



3. The lived experience perspective of being involved in pain research, education, publishing, and pushing forward ground-breaking initiatives through IASP's Global Alliance of Partners for Pain Advocacy (GAPPA).

10:45

Patient and Public Involvement (PPI) in Neuropathic Pain Research: What It is (and is Not), Why It Matters, and How to Build Confidence and Capacity

Kathryn Martin

11:15

How to Ensure Meaningful Patient and Public Involvement (PPI): Learnings and Impact from the UK-wide Advanced Pain Discovery Platform's PAINSTORM Consortium

Gillian Martin

11:45

Lessons Learned from Lived Experience of Pain: The Patient and Public Partner Perspective Joletta Belton

10:45 - 12:15 Auditorium II

Spontaneous Activity in Nociceptors: Innovative Investigative Approaches from Human Cellular Models and Engineering

Neuropathic pain is linked to ongoing activity of peripheral nerve fibers. Although we have some ideas on which components may contribute to this phenomenon, we are still in the dark on its underlying mechanism in human nociceptors and sensory neurons. New, innovative approaches are needed to improve our capability to investigate nociceptor's spontaneous activity.

In this symposium we aim to discuss cutting-edge tools that are providing new mechanistic information on the origin of spontaneous activity of peripheral nerve fibers at the cellular and molecular level. We will present new multi-electrode-array (MEA) recording tools (Aguiar) for assessing neuronal excitability in cell cultures. These tools can be used to their full translational potential by using induced pluripotent stem cell (iPSC) derived nociceptors, for which we present differentiation approaches (Röderer) and biophysical analysis of pain linked spontaneous activity and hyperexcitability (Eberhardt). In an attempt to recreate a nerve in a dish, we will present results of the combination of MEAs with microfluidics and their use with iPSC derived neurons. Experimental findings are integrated into an *in silico* simulation of a peripheral nerve ending (Tigerholm), linking wet lab results with observations during microneurography recordings in humans.

10:45

Introduction

Angelika Lampert

10:50

Advanced Electric Recordings of Cultured Sensory Neurons

Paulo Aguiar



Programming iPSCs Towards Authentic Human Sensory NeuronsPascal Röderer

11:20

Spontaneous Activity of IPSC-derived Sensory Neurons for Modelling Chronic Pain Disorders Esther Eberhardt

11:35

Multicompartment Nerve-on-a-chip Model Towards Personalizing Pain Research and Therapy Janos Vörös

11:50

The Usability of In Silico Modeling to Understand Pathological Alterations in Small Fiber Neuropathy Jenny Tigerholm

10:45 - 12:15 Auditorium I

Treatment Guidelines for Neuropathic Pain: Pharmacotherapy and Neuromodulation

Neuropathic pain is responsible for a major socio-economic burden and is considered highly difficult to treat. Evidence based guidelines are mandatory to guide the appropriate use of therapies in clinical practice. In 2015 the NeuPSIG published the first international recommendations based on a large systematic review and meta-analysis for the pharmacotherapy of neuropathic pain (Finnerup et al 2015). Since these recommendations, newer therapies for neuropathic pain have emerged including drug treatments but also neurostimulation techniques, for which randomized placebo-controlled trials have also been conducted.

To encompass these newer therapeutic strategies, the NeuPSIG has committed a large international group of experts of over 30 researchers, from over 10 countries, aiming to revise prior guidelines which were focused on pharmacotherapy and expand the search to neurostimulation techniques. The workshop will present the systematic review and meta-analytical methods and summarize the main results which will be used to inform the revised NeuPSIG evidence-based guidelines.

10:45

Pharmacotherapy and Neuromodulation for Neuropathic Pain

Simon Haroutounian

11:07

Pharmacotherapy and Neuromodulation for Neuropathic Pain - A Systematic Review and Meta-analysis Nadia Soliman

11:29

The Revised NeuPSIG Guidelines for Neuropathic Pain: Neurostimulation Nadine Attal



Neuropathic Pain Treatment Recommendations

Nanna Finnerup

12:30 - 13:45 Pavilion 5A-C

HALEON Symposium - Gaining Insight into Pain's Real Impact: Recent Findings from the HALEON Pain Index's Longitudinal Global Study

Lunch Provided

14:00 - 15:00 Auditorium I

Welcome Remarks & the J. Edmond Charlton Lecture

The J. Edmond Charlton Lecture: Peripheral Nervous System Targets for Treating Neuropathic Pain
Professor Srinivasa Raja - Professor of Anesthesiology & Critical Care Medicine, Director of Pain Research - Johns Hopkins University

15:00 - 16:00 Pavilion 4

Poster Session - All Numbers

16:00 - 17:30 Auditorium I TRAINEE DATA BLITZ

17:45 - 20:00 Pavilion 4 and 5 Welcome Reception



<u>08 September 2023</u>

08:45 - 09:45 Auditorium I

Friday Morning Plenary Session

08:45

Mapping and Addressing the Biopsychosocial Complexity of Neuropathic Pain: Let's Do Better Dr Whitney Scott - Senior Lecturer and Clinical Psychologist - King's College London

09:15

The Molecular Basis of Neuropathic Pain

Theodore "Ted" Price - Professor of Neuroscience, Founding Director of the Center for Advanced Pain Studies, Ashbel Smith Professor - The University of Texas at Dallas

09:45 - 10:45 Pavilion 4

Poster Session - Odd Numbers

10:45 - 12:15 Pavilion 4, 1.04

A Practical Approach to Skin Biopsy - From Acquisition to Analysis

One histological hallmark of neuropathies is loss of intraepidermal nerve fibers, as shown by skin punch biopsy from the distal and proximal leg. While the procedure is fast and simple, even small missteps may lead to clinically relevant misinterpretations. Following standardized guidelines for processing and analyzing skin samples should be mandatory to ensure accurate data. Even so, the literature is filled with heterogeneous and erroneous methodology, making comparison between studies difficult and, in worst cases, leading to inaccurate findings. Advance in methodology has carried skin biopsies far beyond the mere determination of nerve fiber density. It is, for example, possible to distinguish between somatosensory and autonomic nerve fibers, assess sweat gland innervation, quantify morphological abnormalities of the nerve fibers such as axonal swellings, and identify nerve fiber subtypes. Skin punch biopsy also allows the investigation of other cells such as keratinocytes, Langerhans cells, inflammatory cells, glia cells and many more.

This interactive workshop will teach the audience how to accurately obtain, process, and analyze skin punch biopsies for clinical and research purposes using short presentations, live demonstrations, pre-recorded videos, and on-stage microscopy. **Attendance at this workshop requires registration. Fee: \$99 USD**

10:45

How to Take and Process a Skin Biopsy Following Published Guidelines

Pall Karlsson - Associate Professor - Aarhus University, Danish Pain Research Center



Skin Punch Biopsies - Why, When, Where, How, What, and What Not? A Quick Guide Roy Freeman

11:45

How to Stain and Analyze Skin Biopsies with Traditional and Unconventional Biomarkers Eleonora Galosi

10:45 - 12:15 Auditorium I

Chemotherapy-induced Polyneuropathy: Excitability, Non-neuronal Cells, and Patients

Patients with cancer are nowadays better treated than before. However, cancer survivors often suffer from neurological complications after exposure to anticancer therapy. Chemotherapy-induced peripheral neurotoxicity (CIPN) with sensory loss and neuropathic pain in the extremities is most encountered. In this workshop the three speakers will cover new advances in the pathophysiology of CIPN and transfer preclinical pathways in the clinic. Dr. Dib-Hajj will explore excitability of axons and the contribution of voltage gated sodium channel to the pathophysiology of allodynia in vincristine-induced polyneuropathy. Different channels govern the development and maintenance of CIPN – some of which could be targeted by existing drugs or useful for development. Dr. Rittner will focus on non-neuronal cells controlling bortezomib-induced polyneuropathy. Nerve barriers and their preservation with growth factors are important axonal protectors. Preventing their damage, e.g., by enforcing neuronal barriers could help to shield the nerve. Dr. Alberti will address the clinical phenotype of CIPN and two types of oxaliplatin-induced polyneuropathy, early and delayed. She will especially enlighten the challenges or translating diseases into preclinical models applying translational outcome measures as the basis for phase I clinical trials. Finally, all speakers will discuss the next steps to implement their findings into the clinic.

10:45

Local Mechanisms of Bortezomib-induced Polyneuropathy and Its RecoveryHeike Rittner

11:15

Contribution of Nav1.8 Channels to Chemotherapy-Induced Polyneuropathy in Rodents Sulayman Dib-Hajj

11:45

Oxaliplatin Induced Peripheral Neurotoxicity: From Bed to Bench Side and Vice Versa Paola Alberti

10:45 - 12:15 Auditorium III

Harnessing the Power of the Brain to Treat Neuropathic Pain



It is well established that neuropathic pain is associated with maladaptive changes in neural tissue and circuitry. Current advances in adaptive neurotechnologies have enabled critical insights into understanding and

treating neuropathic pain. These novel technologies have gained recent popularity for elucidating mechanisms of neuropathology and providing a means to modulate aberrant neural activity patterns. By extracting distinct electrophysiological patterns related directly to pain perception,

it is possible to develop safe and novel approaches to treating a wide range of neuropathic pain symptoms. This session will focus on novel ways to leverage physiological markers of pain perception to improve the current repertoire of pain therapies. We will describe new electrophysiological patterns associated with pain relief, nociceptive processing, and post-operative pain severity. We will then describe how these mechanisms can be harnessed to create new devices and treatments for neuropathic pain.

10:45

Brain Computer Interface Mediated Frontal Theta Modulation for Treating Chronic Posttraumatic Neuropathic Pain

Eric Leuthardt

11:15

Leveraging the Use of Peripheral Nerve Stimulation to Decrease Neuropathic Pain and Its Implementation in a Closed-loop Brain Computer Interface

Greta Preatoni

11:45

The Potential of Brain Rhythms in Predicting the Severity of Post-operative Pain Ali Mazaheri

10:45 - 12:15

Auditorium II

Pre-Clinical Models of Nerve Injury - Recent Developments & Lessons on Immune Dysregulation and Pain

This workshop will give an overview of recent developments in pre-clinical models of nerve injury and neuropathic pain. We will highlight the latest mechanistic findings obtained with cutting-edge technologies, improved animal models and interdisciplinary know-how. Specifically, we show evidence from 2-photon imaging that abnormal re-innervation patterns could contribute to the emergence of neuropathic pain. We will present findings on innate and adaptive immune cell dysregulation locally, within nerves, some of which persist over very long periods of time. And finally, we will present a novel translational model for pain after nerve crush.

By the end, attendees will have gained an idea of what we have learned in the past few years about persistent local inflammation and neuron dysfunction in animal models of neuropathic pain.

10:45

Differences in Myeloid Cell Abnormalities in Different Models of Traumatic Neuropathic Pain Franziska Denk



A Reproducible Partial Crush Nerve Injury Model for the Study of Clinically-Relevant Neuropathic Pain Alexander J. Davies

11:29

Chronic Neuropathic Pain Via Aberrant Regenerative Plasticity Vijayan Gangadharan

11:52

A Role of IL-17 Producing Gamma Delta T cells in Sciatic Nerve Regeneration
André Luís Bombeiro

10:45 - 12:15 Auditorium IV

What's New in Combination Pharmacotherapy for Neuropathic Pain? From Bench to Bedside

Laura Stone will illustrate the therapeutic potential of combination pharmacotherapy by highlighting — with recent examples — additive and synergistic analgesic interactions using preclinical investigative techniques. The rationale for picking certain targets for combinations will be presented as will issues of adverse drug interactions.

Ian Gilron will provide a recently updated evidence-based review of combination pharmacotherapy for neuropathic pain in order to highlight critical issues surrounding optimal combinations and necessary improvements for future combination trials. Key issues relating to combination therapy will be discussed including: safety, simultaneous versus sequential "add-on" therapy, and optimal use of fixed dose combinations.

Flemming Bach will discuss combination pharmacotherapy in the context of real-world neuropathic pain. This will include a review of safe and effective evidence-based pain management practices by discussing known adverse drug interactions. The challenges and limitations of combination therapy with currently available drugs will also be presented. In particular consideration of the narrow therapeutic window due to cognitive side effects represents an obstacle and calls for consideration of alternative combination approaches.

10:45

Clinical Research and Evidence Surrounding Combination Pharmacotherapy for Neuropathic Pain lan Gilron

11:15

Preclinical Approaches to the Understanding and Development of Analgesic Combination TherapyChristina Peterson

11:45

Combination Pharmacotherapy in Real-world Management of Neuropathic Pain Flemming Bach



12:30 - 13:45 Pavilion 5A-C

Cancer Pain

This session will focus on cancer pain states across the cancer cycle from diagnosis, pre, post-surgical and chemotherapy states, and the encompassing management of pain. Cancer pain has been identified as having significant prevalence across the globe.

This session has been independently planned and developed to be delivered by IASP/NeuPSIG. Grünenthal has provided a donation for the independent development of this session.

12:30

Diagnosis and Management of Neuropathic Cancer Pain Lesley Colvin

13:05

Research Advances in Understanding Cancer Pain

Patrick Dougherty

14:00 - 15:00 Auditorium I

Plenary Debate: Translational Traps: Are Mouse Models Relevant for Understanding Painful Diabetic Neuropathy?

Daniela Maria Menichella - Northwestern University

Pall Karlsson - Associate Professor - Aarhus University, Danish Pain Research Center, David Bennett

15:00 - 16:00 Pavilion 4

Poster Session- Even Numbers

16:00 - 17:30 Auditorium III

Chemotherapy-induced Peripheral Neuropathy: Improving Translation from Lab to Lived Experience

This workshop will provide new insights into the basic, translational, and clinical aspects of chemotherapy-induced peripheral neuropathy (CIPN) and explore translation and failures. Recognizing the importance of people living with CIPN, Fiona Talkington, BBC broadcaster, will co-chair the session and give the view of someone with lived experience.



Dr. Lesley Colvin will discuss the current clinical state of CIPN; the clinical and research challenges the field faces, and the emerging scientific opportunities to find effective therapeutics for CIPN. Second, Dr. Peter Grace will describe how histone deacetylase 6 (HDAC6) inhibitors have therapeutic potential to reverse cisplatin-induced neuropathic pain via enkephalin-delta opioid receptor signaling in peripheral sensory neurons in a rodent model. And third, co-chair Dr. Alfonso Romero-Sandoval will provide translational evidence on how an endoplasmic reticulum stress sensor (IRE1a/XBP1) in circulating immune cells, correlates with neuropathy severity in cancer patients with CIPN, as predicted by preclinical studies.

16:00

IRE1/XBP1 as a Potential Biomarker for Chemotherapy-induced Peripheral Neuropathy Alfonso Romero-Sandoval

16:23

Chemotherapy-induced Peripheral Neuropathy: Improving Translation from Lab to Lived Experience Fiona Talkington

16:46

Chemotherapy Induced Peripheral Neuropathy: Challenges and ProgressLesley Colvin

17:08

HDAC6 Inhibitors as Novel Drug Candidates to Reverse Chemotherapy-induced Mechanical PainPeter Grace

16:00 - 17:30 Auditorium IV

Cortical Neuromodulation for Pain Relief: New Evidence from Large Trials, and Translational Efforts to Personalize Treatment

In this TW DB will initially review the up-to-date evidence supporting the use of non-invasive motor cortex stimulation for neuropathic pain management. He will provide a critical appraisal of the rationale, utility and limitations of a treatment approach that is currently entering guidelines for pain management of refractory to pharmacological approaches.

This presentation will be followed by Zheng Gan, who will review the known mechanistic framework for M1 stimulation for analgesic purposes. He will then present new groundbreaking data indicating that stimulation of different cortical layers of the precentral gyrus can lead to different outcomes in experimental animals. Based on a comprehensive use of viral tracing and mouse genetics, combined with chemo- and optogenetic approaches, he will show how steering of stimulation within M1 cortical layers can improve pain-related symptoms and improve outcomes. These presentations will be followed by DCA, who will present new strategies to personalize non-invasive neuromodulation such as the use of connectivity measurements by EEG coupled with TMS and the possibility to use the individual's own brain oscillatory activity to guide stimulation, om another attempt to individualize and personalize analgesic approaches to neuropathic pain by non-invasive neuromodulation.



Introduction to the Topical Workshop

Daniel Ciampi de Andrade

16:05

Noninvasive Brain Stimulation for Neuropathic Pain: Where Do We Stand? Didier Bouhassira

16:34

Layer-specific Motor Cortex Circuits Modulating Neuropathic Pain on Sensory and Emotional Components Zheng Gan

17:02

Use of Personal Brain Connectivity and Cortical Oscillatory Patterns as a Way to Personalize Treatment: Rationale and New Perspectives

Daniel Ciampi de Andrade

16:00 - 17:30 Auditorium I

Noncoding RNAs: Potential Biomarkers and Targets for Neuropathic Pain

Dysregulation of pain-associated genes in sensory nerve system is considered to be a molecular basis of chronic neuropathic pain genesis. Non-coding RNAs including miRNAs and long non-coding RNAs govern gene expression. In this workshop, we will discuss the updated evidence that non-coding RNAs contribute to chronic neuropathic pain and are potential biomarkers and/or targets for this disorder. Dr. Malcangio will discuss how miRNAs regulate neuron-immune communication in the dorsal root ganglia (DRG) under neuropathic pain conditions. Dr. Sakai will present a potential of non-coding RNAs, especially lncRNAs, as therapeutic targets and biomarkers in neuropathic pain. Dr. Tao will discuss how a newly identified nerve injury-specific long lncRNA expressed in rodent and human DRG participates in neuropathic pain and provide novel evidence that it could be a potential target for this disorder.

16:00

Identification of a Nerve Injury-specific Long Non-coding RNA (NIS-IncRNA) and Its Role in Neuropathic Pain Yuan-Xiang Tao

16:30

Sensory Neuron-macrophage Communication by Extracellular Vesicles in Neuropathic Pain Mechanisms Marzia Malcangio

17:00

Long Non-coding RNAs in Primary Sensory Neurons as Potential Biomarkers and Pain Modulators in Neuropathic Pain

Atsushi Sakai



16:00 - 17:30

Sciatica: Neuropathic or Not and Does It Matter? Outcomes from a NeuPSIG Working Group

Pain radiating from the spine into the leg is commonly referred to as 'sciatica'. 'Sciatica' is associated with reduced quality of life, significant suffering and socio-economic burden. Two of the main challenges associated with a diagnosis of 'sciatica' relate to the inconsistent use of terminology for the diagnostic labels 'sciatica'/radicular pain/painful radiculopathy, and the identification of neuropathic pain. These challenges hinder collective clinical and scientific understanding and clarity regarding these conditions, impact effective clinical communication and care planning, prevent clear interpretation of the scientific literature related to the

condition, and ultimately may contribute to the limited efficacy and personalization of care for people living with 'sciatica'.

In this workshop, we will highlight these challenges from a clinical, research and lived experience perspective. We will summarize the outcome of a working group commissioned by the Neuropathic Pain Special Interest Group (NeuPSIG) of the International Association for the Study of Pain which includes recommendations on the terminology as well as an adaptation of the neuropathic pain grading system in the context of spine-related leg pain. These recommendations will facilitate common language in clinical practice and research and assist the initiation of more specific management for this patient population.

16:00

Research and Clinical Practice in 'Sciatica': Time to Shift Gears?

Annina Schmid

16:22

Sciatica: What's in a Name?

Christine Price

16:44

Working in Genuine Partnership to Codevelop Key Recommendations that Can Advance Our Shared Understanding and Improve the Care of People with Spine-related Leg Pain Helen Slater

17:07

Identification of Neuropathic Pain in Spine-related Leg Pain - Application of the Adapted Neuropathic Pain Grading System

Brigitte Tampin



<u>09 September 2023</u>

08:45 - 09:45 Auditorium I

Saturday Morning Plenary Session

08:45

Novel Insights on Basic Neuropathic Pain Mechanisms

Professor Gary Lewin - Professor and Group Leader - Max-Delbrück Center for Molecular Medicine

09:15

Novel Insights from Clinical Neuropathic Pain Studies

Prof. Dr. Catharina Faber - Neurologist - Maastricht University Medical Centre

09:45 - 10:45 Pavilion 4

Poster Session – All Numbers

10:45 - 12:15 Auditorium I

How Studying C Fibres Activity in Health and Disease Improves Our Understanding of Neuropathic Pain Pathophysiology

Microneurography is the only neurophysiological technique that records neuronal activity directly from nerves in awake patients. Recording from nociceptive fibres provides unrivalled insight into peripheral neuronal activity and how it can relate to chronic neuropathic pain. The unmyelinated nociceptive fibres, tested by microneurography, are not assessed by conventional nerve conduction studies and are important for sensing pain. Nociceptive fibres are heterogenous, they show different stimulus-response functions, and some are mechanically insensitive in the naive state. We still have an incomplete understanding of which nociceptive afferent population and which activity is the key driver of neuropathic pain. Microneurography has the potential to answer these fundamental questions. The application of microneurography to the study of neuropathic pain is under-utilized. We believe that these techniques should be adopted more widely by the neuropathic pain field.

In our workshop we will provide an introduction to microneurography and show how this technique can provide new insights into our understanding of neuropathic pain and sensory nerve function.

10:45
Introduction to Microneurogrpahy
Jordi Serra

11:07

Action Potential Morphology Analysis in Health and Neuropathic Pain



Andreas Themistocleous

11:29

Clinical Application of Microneurography in Assessing Small Nerve Fibre Dysfunction in Postural Orthostatic Tachycardia Syndrome

Ana Ribeiro

11:52 Small Fibre Neuropathy Barbara Namer

10:45 - 12:15 Auditorium IV

Multimodal Assessments for Neuropathic Pain: A Critical Appraisal of Classical and Emerging Techniques

Despite major advances in our understanding of the pathophysiology of neuropathic pain, progress in mechanism-based therapies has lagged behind. While several different neurophysiological techniques have proven useful to diagnose lesions of the somatosensory system – a prerequisite for the neuropathic pain diagnosis – objective measures of sensitization or spontaneous neural activity are less established. This workshop will focus on the use of pain-related evoked potential, quantitative sensory testing, advanced paradigms of thermosensory integration (thermal grill illusion) and microneurography to close important gaps in our understanding of neuropathic pain mechanisms. In addition to classical applications of diagnosing sensory loss, novel paradigms to reveal sensitization processes will be highlighted. The methods will be presented and critically appraised with regard to research and clinical applications. To this end, "bedside" protocols, which can be integrated into the diagnostic routine in dedicated outpatient clinics will be presented.

10:45

Pain-related Evoked Potentials - Moving Beyond Diagnosis of DamageJan Rosner

11:07

Quantitative Sensory Testing - Time for Change?

Julia Forstenpointner

11:29

Thermal Grill Illusion of Pain in Patients with Chronic Pain: A Clinical Marker of Central Sensitization? Didier Bouhassira

11:52

Microneurography: Current Uses and Future Perspectives in the Examination of Neuropathic Pain Alexander Gramm Kristensen



10:45 - 12:15 Auditorium II

Solving the Puzzle of Trigeminal Neuralgia Using a Multimodal Approach

Chronic pain affects a significant portion of the global population and poses a major socioeconomic burden. Recent research has shown the importance of data-driven approaches in understanding and treating chronic

pain. This workshop will focus on the latest developments and applications of brain imaging and data analysis techniques in the study of Trigeminal Neuralgia (TN). Topics will include the genetics of TN, potential risk factors, comorbidities, new imaging techniques, and how these novel methods can be used in the assessment, diagnosis, and management of TN, including prognosis and outcome prediction. The goal of this workshop is to share and integrate new insights in this field to expedite research and improve pain care.

10:45

Advanced Brain Imaging Helps Guide Surgical Treatment for Trigeminal Neuralgia Mojgan Hodaie

11:15

Phenotyping a Screening Tool for Trigeminal Neuralgia Joanna Zakrzewska

11:45

Disease Trajectories in Trigeminal Neuralgia: Potential Risk Factors and Co-morbiditiesStine Maarbjerg

10:45 - 12:15 Auditorium III

We Can Do Better: Improving Reproducibility and Translatability in Pre-clinical Pain Research

The reproducibility and translatability of pre-clinical studies remains a challenge as we seek to better understand and treat chronic neuropathic pain. In this session, we will offer positive and practical solutions to improve the impact of pre-clinical experiments on the pain field. Dr. Laura Stone will reflect on her recent efforts to conduct multi-center rodent behavioral experiments. She will consider the lessons we can take from the results and how they might help us further improve how we standardize and validate in vivo outcome measures in pain research. Andrew Rice will discuss the utility of ethologically relevant behavioral measures in animal models; he will focus on diverse tactics for cross laboratory validation of such measures using the innate rodent behaviors of burrowing and predator avoidance as examples. Finally, Dr. Duncan Lascelles will discuss the measurement of pain and the role of clinical studies in non-rodent models, including the potential utility of using owned pet animals with naturally occurring pain conditions.

10:45

Reproducibility in pre-clinical drug efficacy studies: results of an ACTTION-funded multi-site comparative study.

Alfonso Romero-Sandoval



Measuring ethologically- relevant complex behaviors in animal models - approaches to staged validation and contextualization to pain.

Andrew Rice

11:45

Improving the success of translational research by enriching the paradigm through the use of naturally occurring large animal models of pain.

Duncan Lascelles

12:30 - 13:45 Pavilion 5A-C

Painful Diabetic Neuropathy

This session will focus on the diagnosis of and treatment options for pDPN, and the management of pain. Diabetic neuropathy is a serious diabetes complication that affects many people with diabetes.

*This session has been independently planned and developed to be delivered by IASP/NeuPSIG. Grünenthal has provided a donation for the independent development of this session.

12:30

A stratified approach to painful diabetic neuropathy to understand pain mechanisms, improve diagnosis and management

David Bennett

13:05

Management of painful diabetic neuropathy

Nadine Attal

14:00 - 15:15 Auditorium I

Plenary Session, Poster Awards & Conference Close

14:00 pm

Final plenary session and closing remarks

14:15 pm

The Brain in Pain - Placebo/Nocebo

Ulrike Bingel - Professor of Clinical Neuroscience, University Medicine Essen

14:45 pm

Neuromodulation to Treat Pain: Novel Frontiers

Scott Lempka - Assistant Professor - University of Michigan



15:30 - 17:00 Auditorium I

Emerging Role of Peripheral Neuronal and Non-Neuronal Cells in Neuropathic Pain

The primary reason for inadequate analgesic effects of current pharmaceuticals for neuropathic pain is that we do not fully understand the pathophysiological mechanisms that underlie its development. We will discuss the concept that non-neuronal cells residing in the skin (e.g. glia, inflammatory cells) and peripheral mediators (e.g. axon guides) may play a key role in nociceptive signal transduction. This shift in paradigm has opened an exciting field of studies regarding pain mechanisms. We will present potential implications on clinical practice. Data from preclinical and clinical studies will be discussed critically focusing on Schwann cells and other glia cells, keratinocytes, fibroblasts, mechanoreceptors, ion channels, and axon guidance mechanisms. Lastly, we will present new data on changes in cutaneous sensory and sympathetic vaso- and sudomotor innervation in peripheral and central neuropathic pain conditions. Experimentally- and pathology-induced changes using 8% capsaicin will be related to the clinical (pain) phenotype, and novel insights into potential therapeutic targets showcased.

15:30

Histopathological Signature of Painful and Non-Painful DPN

Pall Karlsson - Associate Professor - Aarhus University, Danish Pain Research Center

15:52

Cutaneous Autonomic Innervation and Neuropathic Pain - Old Wine in a New Bottle?Jan Rosner

16:14

Neuropathic Pain - Fully Human and In Vitro Nurcan Üçeyler

16:37

Keratinocytes and Their Role in Aiding Intraepidermal Nerve Fibre Regeneration Margarita Calvo

15:30 - 17:00

Auditorium III

Exploring the Role of Autoantibodies in Pain Conditions: Clinical and Preclinical Findings

This workshop will update clinicians and basic researchers about emerging neuroimmunology research to highlight new clinical and research opportunities. Basic research approaches using patient specimens have already proven that specific neuropathies are maintained by pathological antibodies targeting cells in symptom-associated pathways. Rapid, accurate diagnosis enables consideration of targeted mechanism-based therapies available today with clinical-trial efficacy data. We will mention the classic dysimmune neuropathies but focus on the more recent evidence in painful disorders including peripheral neuropathies and fibromyalgia. We will review the methods and conclusions from experiments analyzing samples from patients that demonstrate causality and elucidate pathological mechanisms. These include *in vitro* studies and passive-



transfer models *in vivo*, where antibodies from patients are administered to mice that develop behavioral, anatomical, and physiological correlates of human pain syndromes. *In vitro* assays effectively identify putative pathogenic antibodies and targets, and passive-transfer approaches are the gold-standard for proving autoimmune causality. Both have yielded mechanistic advances with high degrees of predictive validity. We will end by discussing less-certain topics including which other chronic pain conditions have lesser evidence of dysimmune contributions, steps in clinical diagnostic pathways, the best-established immunotherapies, when immunotherapy is not appropriate to consider. Emerging research opportunities will be highlighted.

15:30

Assessing the Pathogenicity of Autoantibodies from Pain Patients Using Live Sensory Neurons John Dawes

15:52

Fibromyalgia is an Autoantibody Mediated Disorder David Andersson

16:14

Immune Contribution to Pathological Pain Mechanisms in FibromyalgiaMargot Maurer

16:37

Dysimmune Neuropathies: Evidence-based Diagnostic and Treatment FrameworkAnne Louise Oaklander

15:30 - 17:00

Auditorium II

Shall We Include Fibromyalgia Syndrome in the Spectrum of Small-fibre Neuropathy? A Pros and Cons Discussion.

Fibromyalgia syndrome is a chronic pain condition associated with autonomic symptoms, fatigue and cognitive disturbances. Despite the large body of studies on the topic, the mechanisms underlying this common chronic pain condition are still a matter of debate. However, recent preclinical investigations have indicated that dorsal root ganglia damage, due to circulating autoantibodies, may play a role in fibromyalgia. Accordingly, approximately 50% of patients with fibromyalgia have a reduced intraepidermal nerve fibre density as assessed with skin biopsy. This small nerve fibre loss, commonly defined as small-fibre pathology, may also underlie the multiple symptoms that patients with fibromyalgia experience, such as ongoing burning extremity pain, bladder and bowel disturbances.

However, the relationship between small-fibre pathology and the symptoms and signs that patients with fibromyalgia experience is still an issue of controversy. Whereas several studies have reported that patients with fibromyalgia have impaired sensory profiles at the quantitative sensory testing and abnormal nociceptive evoked potentials, other studies showed that small-fibre pathology is not associated with clinically meaningful abnormalities of the somatosensory nervous system.



This workshop addresses the two opposite views on fibromyalgia. The first speaker, Jordi Serra, will detail all the evidence supporting the specific role of small-fibre pathology in patients with fibromyalgia. The second speaker, Andrea Truini, will provide evidence that the small-fibre pathology may have a negligible impact on symptoms that patients with fibromyalgia experience.

The discussion will be led by the chair, Claudia Sommer.

15:30

How Small-fibre Damage is Relevant to Symptoms That Patients with Fibromyalgia Experience Claudia Sommer

16:00

Abnormal C-nociceptor Function Underlies Pain in Fibromyalgia
Jordi Serra

16:30

Small-fibre Pathology has a Negligible Impact on Somatosensory and Autonomic System Function in Fibromyalgia

Andrea Truini

15:30 - 17:00 Auditorium IV

Translational Implications of Novel Mechanisms of Spontaneous Activity in Nociceptors that Drive Non-Evoked Pain

A key question in this topical workshop is whether basic mechanisms being defined for spontaneous activity in nociceptors have useful clinical implications. Spontaneous activity in primary somatosensory neurons has long been associated with non-evoked pain, but the underlying mechanisms have been slow to emerge. However, recent advances have identified electrophysiological and cellular mechanisms of spontaneous activity in rodent and human nociceptors that make therapeutically promising predictions that can be tested in human patients. Dr. Carolina Roza will summarize aberrant electrophysiological behavior of peripheral nerve fibers observed in experimental models, the associated pathophysiological mechanisms, and their relationship to symptoms reported by patients. Dr. Edgar Walters will describe newly characterized irregular depolarizing spontaneous fluctuations of membrane potential in dissociated rodent and human nociceptors that drive spontaneous activity, how these synergize with other electrophysiological alterations that promote ongoing discharge, and the identification of prominent underlying biophysical and cell signaling alterations. Dr. Martin Schmelz will show microneurographic evidence for depolarization of spontaneously active nociceptors in patients and describe how the effects of slow depolarizing electrical stimuli applied to human and pig nociceptors are consistent with new findings from rodent nociceptors, potentially providing improved translational tools to assess alterations of nociceptor excitability in patients.

15:30

Novel Electrophysiological and Cell-signaling Mechanisms Driving Spontaneous Activity in Nociceptors Edgar Walters



Mechanisms of Ectopic Spontaneous Discharge in Damaged and Intact Nociceptors after Nerve Injury Carolina Roza

16:30

Translating Mechanistic Insights about Spontaneous Activity in Nociceptors into Optimized Assessment of Nociceptor Excitability in Patients

Martin Schmelz

17:00

Close of NeuPSIG 2023



Accreditation, Support and Credit



In support of improving patient care, this activity has been planned and implemented by Medical Learning Institute, Inc., and International Association for the Study of Pain. Medical Learning Institute, Inc. is jointly accredited by the Accreditation Council for



Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

Target Audience

This CE activity is intended for physicians, pharmacists, and other health professionals who treat patients with pain.

Scientific Program

Live On-site 7-9 September 2023

Educational Objectives

After completing this CE activity, the participant should be better able to:

- Review the latest basic science, clinical, and translational research regarding its applicability to current practice
- Describe research investigations that study the mechanisms underlying neuropathic pain.
- Discuss the assessment, prevention, and treatment of neuropathic pain.
- Demonstrate through practical training sessions the assessment and treatment of neuropathic pain.
- Identify programs that prevent the development of neuropathic pain.

Physician Continuing Medical Education

Medical Learning Institute, Inc. (MLI) designates this live activity for a maximum of 14.0 AMA PRA Category 1 $Credits^{TM}$. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

ECMEC® Credit



The International Congress on Neuropathic Pain NeuPSIG 2023, Lisbon, Portugal, 07/09/2023-09/09/2023 has been accredited by the European Accreditation Council for Continuing Medical Education (EACCME®) with 14 European CME credits (ECMEC®s). Each medical specialist should claim only those hours of credit that he/she actually spent in the educational activity.

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Live educational activities, occurring outside of Canada, recognised by the UEMS-EACCME® for ECMEC®s are deemed to be Accredited Group Learning Activities (Section 1) as defined by the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

Continuing Pharmacy Education

Medical Learning Institute, Inc. designates this continuing education activity for 14.0 contact hours (1.4 CEUs) of the Accreditation Council for Pharmacy Education.

Universal Activity Number: UAN# JA0007322-9999-23-061-L01-P

Type of Activity: Knowledge

Acknowledgement of Support Statement

IASP gratefully acknowledges support for NeuPSIG from the following:

- Biohaven Mobile App and Meter Board in Exhibit Floor
- Medoc Exhibit Booth
- MRC Exhibit Booth
- Somedic Exhibit Booth

Comprehensive Assessment of Neuropathic Pain: Neurological exam and Quantitative Sensory Testing (laboratory-based and bedside) Hands-on-Workshop

Hands-on Workshop 7 September 2023 (separate registration required) 7:30 - 10:30am

Educational Objectives

After completing this CE activity, the participant should be better able to:

Station I:

- Differentiate between spontaneous and provoked neuropathic pain, recognizing the characteristic
 features, such as constant burning sensation, intermittent or paroxysmal nature, and the presence of
 dysesthesias and paresthesia's.
- Perform a comprehensive neurological examination in patients with suspected neuropathic pain, including the assessment of motor, sensory, and autonomic phenomena.
- Identify signs of neurological dysfunction and accurately diagnose and localize the lesion site.

Station II:

- Describe the subtypes of nerve fibers that can be assessed with thermal QST approaches.
- Outline common protocols for assessing warmth and cold detection thresholds, as well as heat and cold pain thresholds in patients with neuropathic pain.



Experience, hands-on, the measurements of thermal thresholds as a participant, and as a tester;
 compare and contrast the anticipated vs real sense of participating in a sensory testing session as a subject.

Station III:

- Describe the subtypes of nerve fibers that can be assessed with mechanical QST approaches i.e. Von Frey monofilaments, Pinprick, and pressure algometer
- Outline common protocols for assessing mechanical detection threshold, mechanical pain threshold, dynamic mechanical allodynia, pressure pain thresholds, and temporal summation.
- Experience, hands-on, the measurements of mechanical sensation and pain thresholds as a participant, and as a tester
- Compare and contrast the anticipated vs real sense of participating in a sensory testing session as a subject.

Station IV:

- Describe the value of QST for assessing nerve fibre function comprehensively.
- Explain the challenges of translating laboratory QST to point-of-care and bedside settings.
- Apply two common bedside QST protocols in their research and practice.

Physician Continuing Medical Education

Medical Learning Institute, Inc. (MLI) designates this live activity for a maximum of 3.0 AMA PRA Category 1 $Credits^{TM}$. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

ECMEC® Credit



The Comprehensive assessment of Neuropathic Pain: Neurological exam and quantitative sensory testing (laboratory-based and bedside) Hands-on- Workshop, Lisbon, Portugal, 07/09/2023-07/09/2023 has been accredited by the European Accreditation Council for Continuing Medical Education (EACCME®) with 3 European CME credits (ECMEC®s). Each medical specialist should claim only those hours of credit that he/she actually spent in the educational activity.

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Live educational activities, occurring outside of Canada, recognised by the UEMS-EACCME® for ECMEC®s are deemed to be Accredited Group Learning Activities (Section 1) as defined by the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

Continuing Pharmacy Education



Medical Learning Institute, Inc. designates this continuing education activity for 3.0 contact hours (0.3 CEUs) of the Accreditation Council for Pharmacy Education.

UAN ID: JA0007322-9999-23-064-L01-P

Type of Activity: Application

Support Statement

In-Kind equipment support provided by BIOSEB, MEDOC, MRC Systems and Somedic.

A Practical Approach to Skin Biopsy – From Acquisition to Analysis

Hands-on Workshop 8 September 2023 (separate registration required) 10:45am - 12:15pm

Educational Objectives

After completing this CE activity, the participant should be better able to:

- Describe the theoretical and practical aspects on how to take, process, and analyse skin punch biopsies.
- Discuss other structures and analyses that can be performed on the skin biopsies other than quantification of intraepidermal nerve fibers.
- Discuss the strengths and limitations of skin punch biopsies.

Physician Continuing Medical Education

Medical Learning Institute, Inc. (MLI) designates this live activity for a maximum of 1.5 AMA PRA Category 1 $Credits^{TM}$. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

ECMEC® Credit



The A Practical Approach to Skin Biopsy – From Acquisition to Analysis (Hands On Workshop), Lisbon, Portugal, 08/09/2023-08/09/2023 has been accredited by the European Accreditation Council for Continuing Medical Education (EACCME®) with 1 European CME credits (ECMEC®s). Each medical specialist should claim only those hours of credit that he/she actually spent in the educational activity.

Through an agreement between the Union Européenne des Médecins Spécialistes and the American Medical Association, physicians may convert EACCME® credits to an equivalent number of *AMA PRA Category 1 CreditsTM*. Information on the

process to convert EACCME® credit to AMA credit can be found at www.ama-assn.org/education/earn-credit-participation-international-activities.

Live educational activities, occurring outside of Canada, recognised by the UEMS-EACCME® for ECMEC®s are deemed to be Accredited Group Learning Activities (Section 1) as defined by the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.



Continuing Pharmacy Education

Medical Learning Institute, Inc. designates this continuing education activity for 1.5 contact hours (0.15 CEUs) of the Accreditation Council for Pharmacy Education.

UAN ID: JA0007322-9999-23-065-L01-P

Type of Activity: Application

Support Statement

In Kind equipment support has been provided by Carl Zeiss Iberia S.L.

Cancer Pain

Lunch Symposium 8 September 2023 12:30 – 1:45pm

Educational Objectives

After completing this CE activity, the participant should be better able to:

- Recognize the types of neuropathic pain that cancer patients may experience.
- Describe appropriate diagnosis in the outcome of patient treatment.
- Discuss the range of treatment options available to patients.

Physician Continuing Medical Education

Medical Learning Institute, Inc. (MLI) designates this live activity for a maximum of 1.25 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

ECMEC® Credit

The Cancer Pain, Lisbon, Portugal, 08/09/2023-08/09/2023 has been accredited by the European Accreditation Council for Continuing Medical Education (EACCME®) with 1 European CME credits (ECMEC®s). Each medical specialist should claim only those hours of credit that he/she actually spent in the educational activity."

Through an agreement between the Union Européenne des Médecins Spécialistes and the American Medical Association, physicians may convert EACCME® credits to an equivalent number of *AMA PRA Category 1 CreditsTM*. Information on the process to convert EACCME® credit to AMA credit can be found at www.ama-assn.org/education/earn-credit-participation-international-activities.

Live educational activities, occurring outside of Canada, recognised by the UEMS-EACCME® for ECMEC®s are deemed to be Accredited Group Learning Activities (Section 1) as defined by the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.



Continuing Pharmacy Education

Medical Learning Institute, Inc. designates this continuing education activity for 1.25 contact hours (0.125 CEUs) of the Accreditation Council for Pharmacy Education.

UAN ID: JA0007322-9999-23-062-L01-P

Type of Activity: Knowledge

Support Statement

This session has been independently planned and developed to be delivered by IASP/NeuPSIG. Grunenthal has provided a donation for the independent development of this session.

Painful Diabetic Neuropathy

Lunch Symposium 9 September 2023 12:30 – 1:45pm

Educational Objectives

After completing this CE activity, the participant should be better able to:

- Articulate the importance of early diagnosis of pDPN.
- Determine the appropriate tools that can facilitate early diagnosis of pDPN.
- Summarize the range of treatment options available for pDPN.

Physician Continuing Medical Education

Medical Learning Institute, Inc. (MLI) designates this live activity for a maximum of 1.25 AMA PRA Category 1 $Credits^{TM}$. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

ECMEC® Credit

The Painful Diabetic Neuropathy, Lisbon, Portugal, 09/09/2023-09/09/2023 has been accredited by the European Accreditation Council for Continuing Medical Education (EACCME®) with 1 European CME credits (ECMEC®s). Each medical specialist should claim only those hours of credit that he/she actually spent in the educational activity.

Through an agreement between the Union Européenne des Médecins Spécialistes and the American Medical Association, physicians may convert EACCME® credits to an equivalent number of *AMA PRA Category 1 CreditsTM*. Information on the process to convert EACCME® credit to AMA credit can be found at www.ama-assn.org/education/earn-credit-participation-international-activities.

Live educational activities, occurring outside of Canada, recognised by the UEMS-EACCME® for ECMEC®s are



deemed to be Accredited Group Learning Activities (Section 1) as defined by the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

Continuing Pharmacy Education

Medical Learning Institute, Inc. designates this continuing education activity for 1.25 contact hours (0.125 CEUs) of the Accreditation Council for Pharmacy Education.

UAN ID: JA0007322-9999-23-063-L01-P

Type of Activity: Knowledge

Support Statement

This session has been independently planned, and developed to be delivered by IASP/NeuPSIG, Grunenthal has provided a donation for the independent development of this session.

Requirements for Successful Completion

There is a fee for participating in or receiving credit for this CE activity; and you must be registered for the NeuPSIG 2023 International Congress on Neuropathic Pain. In order to receive credit, learners must participate in the CE activity and complete an evaluation. A statement of credit will be issued only upon receipt of a completed activity evaluation. You will receive your certificate from Medical Learning Institute, Inc. If you have any questions regarding the receipt of your certificate, please contact via email at mvu@mlieducation.org.

For Pharmacists, Medical Learning Institute, Inc. will accept your completed evaluation form for up to 30 days post-activity and will report your participation to the NABP only if you provide your NABP e-Profile number and DOB (MM/DD). Within 6 weeks, you can view your participation record at the NABP website.

For **ECMEC®** credits, each participant can only receive the number of credits he/she is entitled to according to his/her actual participation at the event once he/she has completed the feedback form. Cf. criteria 9 and 23 of UEMS 2016.20.

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Disclaimer

Participants have an implied responsibility to use the newly acquired information to enhance patient outcomes and their own professional development. The information presented in this CE activity is not meant to serve as a guideline for patient management. Any procedures, medications, or other courses of diagnosis or treatment discussed or suggested in this CE activity should not be used by clinicians without evaluation of their patient's conditions and possible contraindications and/or dangers in use, review of any applicable manufacturer's product information, and comparison with recommendations of other authorities.

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